System Manual

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Table of Contents

Document / Revision List		
Section—Title	Document Number	Revision
Cover Page	51000623	06
Table of Contents	51000624	13
01 - Introduction	51000625	05
02 - epoc Blood Analysis System	51000627	05
03 - epoc System Operation	51000635	08
04 - epoc Test Cards	51000629	07
05 - epoc Reader	51000631	04
06 - epoc Host	51000632	08
07 - epoc Host Administration	51000634	08
08 - epoc Data Manager	51001364	04
09 - Quality Assurance	51000636	09
10 - Care and Maintenance of the epoc System	51000639	07
11 - Theory of Operation	51000628	05
12 - BGEM Test Card Specifications	51000630	09
13 - epoc Reader and Host Specifications	51000633	07
14 - Troubleshooting and Error Messages	51000638	07
15 - Glossary	51000626	07

01 Introduction

1.1 epoc System Manual

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 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.

Organization of System Manual

The System Manual is organized into sections corresponding with the Table of Contents at the front of the manual. Each section is controlled and maintained separately by the document and revision number at the bottom of each page.

Section 2 "epoc Blood Analysis System" provides a brief description of the epoc System and its major components.

Section 3 "epoc System Operation" describes the steps and necessary information for performing a test, including sample collection and interpretation of test results.

Sections 4, 5 and 6 "epoc Test Cards", "epoc Reader" and "epoc Host" describe the function and construction details of the major system components.

Section 7 "epoc System Administration" describes to the system administrator how to set up and maintain key settings in the epoc Host application prior to releasing the system for patient use. Requirements for ongoing administrative maintenance are also described.

Section 8 "epoc Data Manager" describes how to set up and operate the optional "epoc Data Manager".

Section 9 "Quality Assurance" describes recommended and additional Quality Control and Calibration Verification procedures used to verify the performance of the epoc System. These procedures include internal, liquid, whole blood, calibration verification, and proficiency testing quality control procedures. The rationale for the epoc System quality control is described in the "Theory of Operation" section of this manual

Section 10 "Care and Maintenance of the epoc System" section describes the cleaning and maintenance procedures.

Section 11 "Theory of Operation" contains the methodology, principles of operation and the special merits and limitations of the epoc System.

Section 12 "BGEM Test Card Specifications" contains performance characteristics and specifications for the test cards, including measurement ranges, limitations and interferences for each analyte.

Sections 13 "epoc Reader and Host Specifications" provides specifications for the entire system and each of the major components as well as compliance information.

Section 14 "Troubleshooting and Error Messages" should be referenced if problems arise during the use of the epoc System.

Section 15 "Glossary" defines terms and acronyms used in the system manual.

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 Operator’s Manual. The correct interpretation of these symbols is located in the Glossary Section.

1.3 Warranty

Epocal Inc. **(“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 Inc. 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.

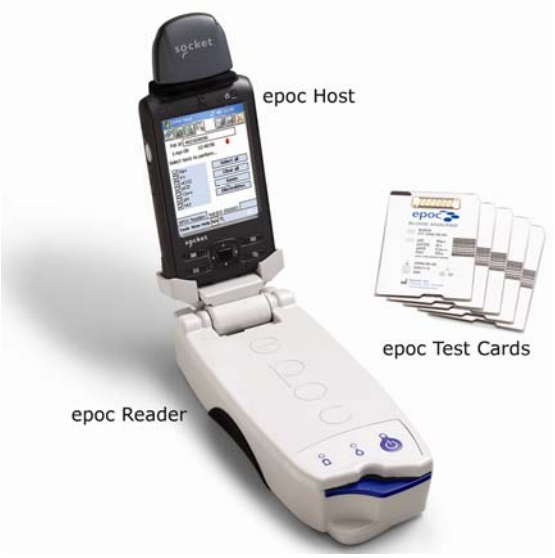
Customers should contact their epoc distributer or Epocal Inc., the manufactuer, to arrange for disposal of their epoc electrical and electronic hardware at the end of product life. Contact information is provided on the cover page of this instruction manual.

02 epoc Blood Analysis System

2.1 System Overview

The epoc Blood Analysis System

- Is a Portable Blood Analyzer comprised of 3 components:
  - epoc Reader
  - epoc Host
  - epoc Test Card



epoc Reader

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

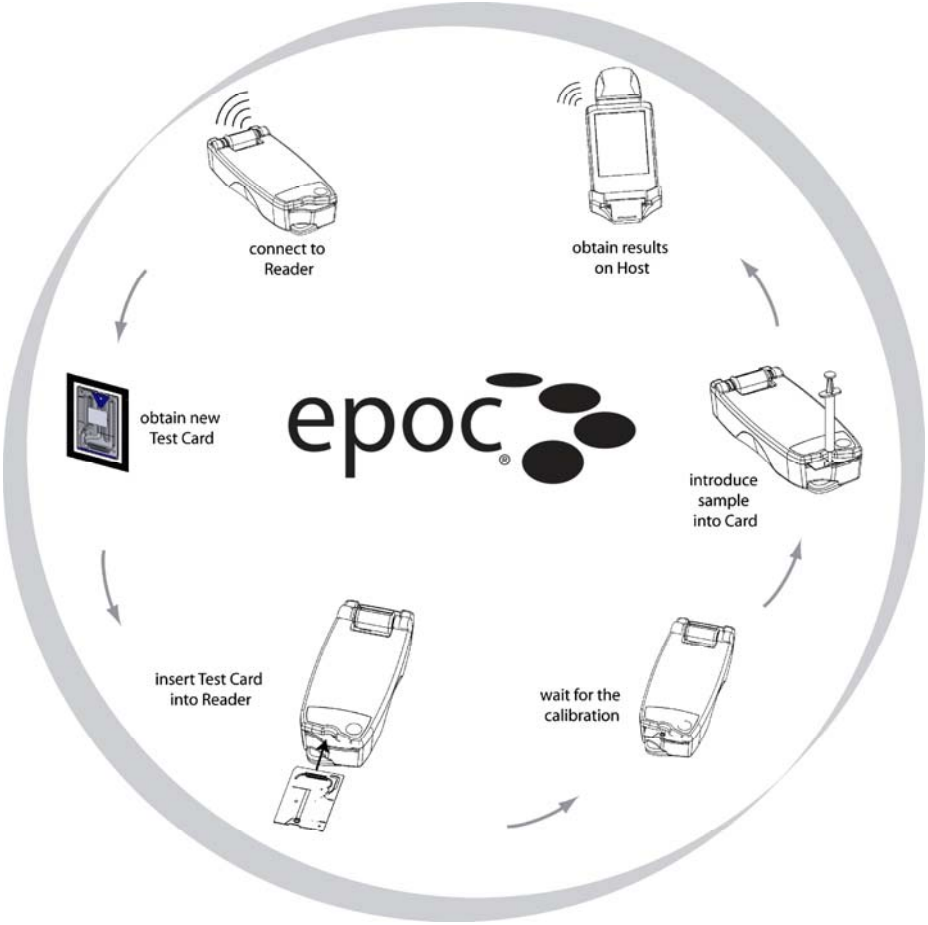
epoc Host

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

epoc Test Card

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

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 serial 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 results 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 Test Cards that have been properly stored.

To complete a test the following steps are required:

1. Turn ‘ON’ epoc Reader and epoc Host.
2. Log in to epoc Host software application.
3. Discover epoc Reader by connecting wirelessly from epoc Host.
4. Begin test sequence.
5. Insert new test card into epoc Reader.
6. Enter patient information, select tests and sample type (if applicable).
7. Introduce blood sample into test card.
8. Observe results and possibly print test results.
9. Remove card and discard.

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

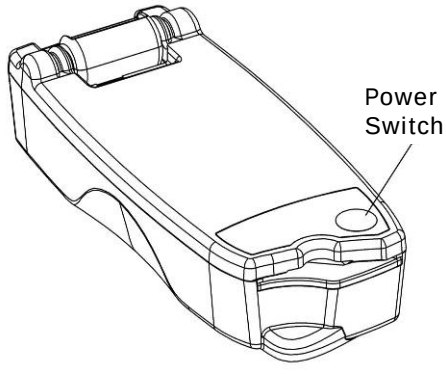
3.2 System Operating Instructions

3.2.1 Turn ‘ON’ epoc Reader

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

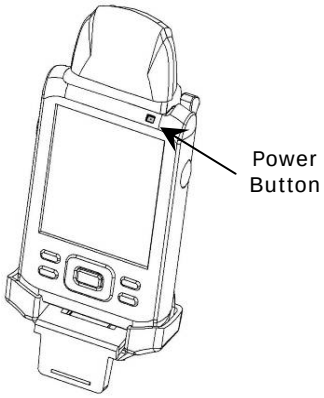
Only epoc Readers that are switched ‘ON’ will be located by the epoc Host.

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

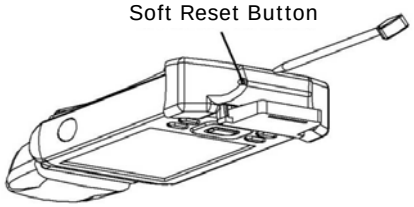


3.2.2 Turn 'ON' epoc Host

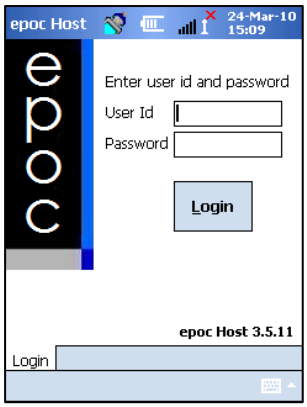
Press the Power Switch (upper right) to wake up the epoc Host if the screen is blank. The epoc Host Power Button starts and stops the device.



Note: The Soft Reset Button always re-boots the epoc Host application and displays the Login page.



3.2.3 Login to epoc Host Software Application



After a soft reset or logging out, the epoc Host software application displays the Login Page.

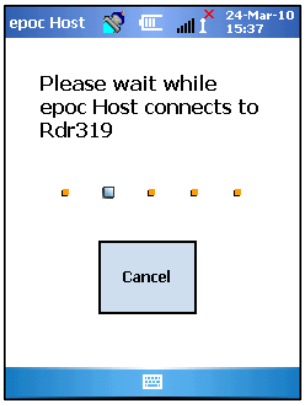
Enter a valid **User ID** and **Password** and press the Login button.

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

3.2.4 Run a Test

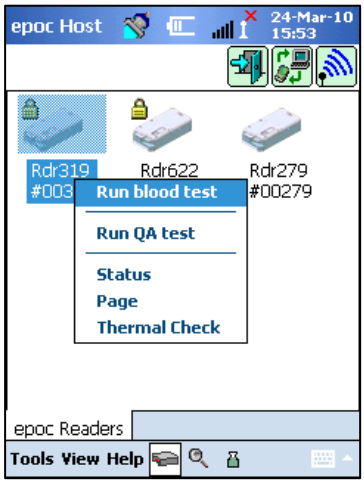
Begin a test process by connecting epoc Host to an epoc Reader. If epoc Host is already configured to connect with a single dedicated epoc Reader, the epoc Host will automatically connect to that epoc Reader to run a **blood test** and begin the Electronic QC Test.

A connection is cancelled by tapping the **Cancel** button.



3.2.5 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 Alias 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 drop down menu is displayed. For a blood test, select **"Run blood test"**. For a QA test (if authorized), select **"Run QA test"**.

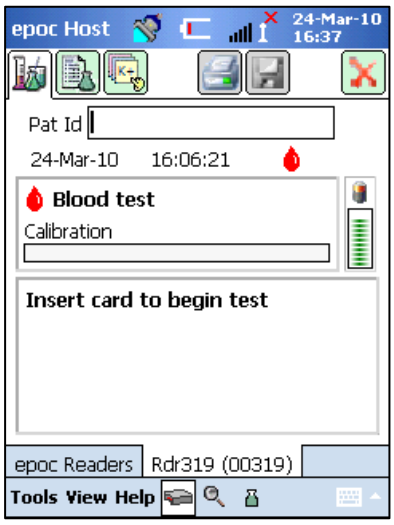
3.2.6 Reader Electronic Internal QC Test

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

Every time a Host and Reader connect, the Reader begins a 2 level Electronic QC Test. Configuration data is sent by the Host to the Reader and preparations begin for a test. The motorized mechanism inside the Reader can be heard as it resets. 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 the epoc Host has been connected to the reader continuously for 8 hours or more, when a new card inserted the Host will disconnect from the Reader and inform the user they must reconnect to the Host to run another Electronic QC Test.

3.2.7 Reader Screen



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

The Reader Screen displays:

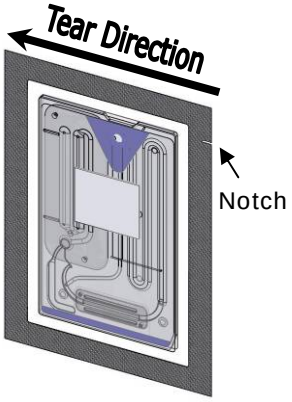
1. Type of test: Blood test or QA test.
2. Battery charge level of the Reader .
3. Current Date and Time.
4. Patient ID or Lot Number field.
5. Additional tabs for accessing other test information entries that may be used to ensure a complete test record. Requirements may vary according to the policy 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, allow sufficient time to complete the test before midnight. Test results do not display after midnight of the “Use By” date.

3.2.8 Obtain Test Card



1. Select a properly stored Test Card.
2. Starting at Notch, tear open the Card Pouch as shown.
3. Carefully (read cautions below) remove the Test Card from the card pouch.
4. Place the test card directly into the epoc Reader’s Card Insertion Slot.
5. Discard the empty pouch.

Never touch Sensor Module’s contact surface, or Blood Sample Entry Port.

Never place Test Card on any surface before running a test

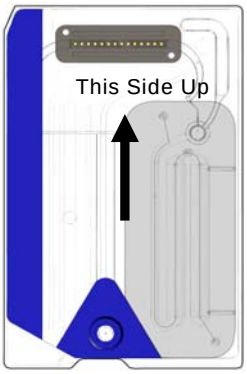
Always take the Test Card directly from the Pouch before inserting into the Reader.

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

3.2.9 Insert Test Card

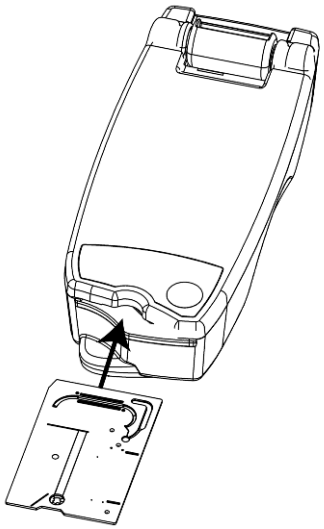
The epoc Reader must be placed on a stable horizontal surface, such as a tabletop, prior to inserting the Test Card.

Never insert anything except a Test Card into the Reader's Card Insertion Slot.



Position Test Card with 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 Test Card into the Reader's Card Insertion Slot at front of Reader with a smooth single motion to enable the Barcode on the Card Label to be correctly read by the Reader during insertion.



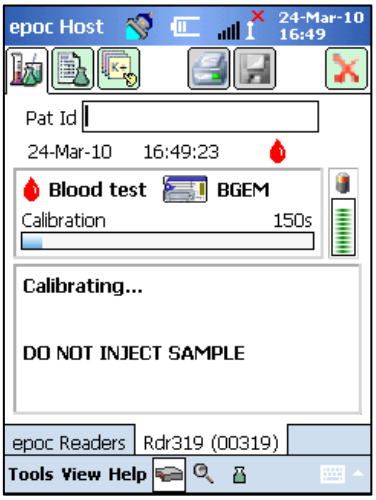
Continue inserting the Test Card until the slight resistance is felt. Push the Test Card past this point to "lock" it into place. This is the final Test Card position. Avoid abrupt stops or unevenness in speed during Test Card insertion.

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 will turn 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. Re-insert the card for a successful insertion and a solid green test status indicator.

3.2.10 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 calibration mode and displays 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.

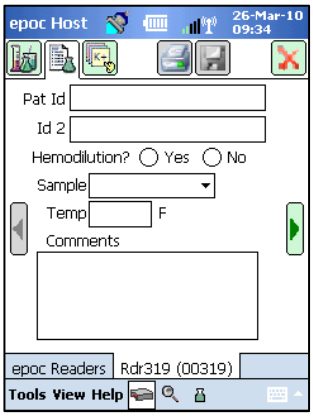
The Reader must rest on a flat horizontal surface without movement for the duration of the test.

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

The Patient ID and related information can be entered at any time during the test.

For a **Blood Test**, Patient ID number is entered to identify the test results for the card under test.

For a **QA Test** (not shown), the QA fluid Lot Number is entered instead of Patient ID.



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

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

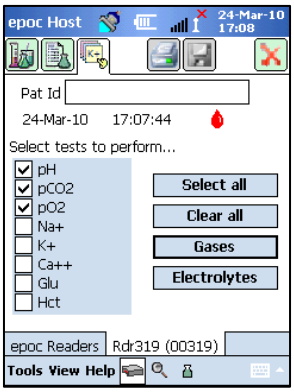
Patient information entered prior to completion of the test is saved automatically with the test results when the test is complete.

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's and other information. Ensure the correct reader is selected by verifying that the Reader Alias corresponds with the reader used to conduct the test.



Select the Test Selection Tab on the Reader Screen to select or de-select 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.

3.2.12 Using Bar Code Scanner to Enter Patient Id

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

Activate Barcode Scanner by pressing the Read Barcode Button at the left or right side of the epoc Host. The Barcode Icon at the top of the screen indicates when the barcode scanner is ready to scan. Point the light coming from the top of the 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: Do not look directly at the laser light. Point the laser at a barcode and away from the eyes at all times.

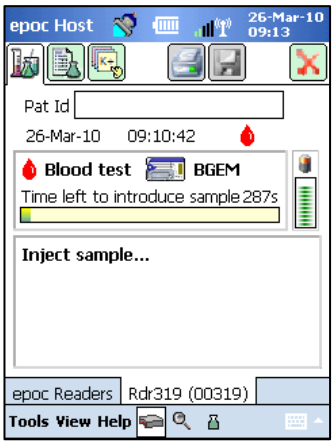
The Patient ID may also be entered using the stylus and Text input display accessible from bottom of screen.

3.2.13 Collect Blood Sample

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

3.2.14 Timing of Sample Introduction

After about 165 seconds of calibration the test status indicator starts flashing green indicating that the 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 card during this five (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.

3.2.15 Sample Introduction

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


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 syringe up to 1/4 turn to ensure a good seal (as shown in Figure 2).**


Figure 2

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

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


Figure 3

Reader provides Audible Beep and 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.

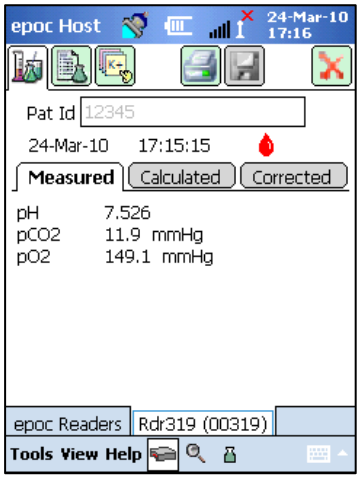
Avoid rapid sample introduction because it can cause fluid segmentation. This condition is detected by the system. The test is aborted and the Host displays an error message.

3.2.16 Sample Analysis

The Reader automatically analyzes the test sample.

The analysis process takes about half a minute.

3.2.17 Test Completion



Once the analysis is complete, the epoc Host displays the Test Results from the Reader Screen (tab on left).

Patient ID must be entered before test results are displayed. Once saved, the Patient Id textbox and Save button are disabled again.

Test results can be viewed in three (3) sub-tabs “Measured”, “Calculated” and “Corrected”.

When the Reader has completed a test, the Test Status Indicator on Reader will flash green, indicating the Test Card can be removed. 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 Test Card from Reader.

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

3.2.18 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 same procedure to complete another test.

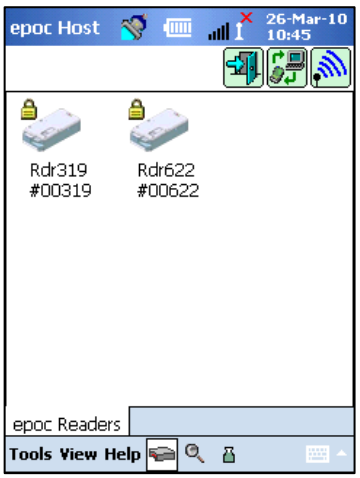
Starting a new test permanently saves the previous test record. Changes to that test are no longer possible.

3.2.19 Close Test and Disconnect Reader

When all testing with a Reader is complete and all data entries are made, the test is closed by tapping on the red X in the top right to close the Reader Screen for that Reader. Disconnecting a Reader does not affect the connection or test status of other Readers already discovered or connected.

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

3.2.20 EDM Synchronization



For epoc Data Manager (EDM) users only:

After disconnecting all readers from running tests, results can be sent to the EDM by pressing the EDM synchronization button  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 System Administrator may configure the epoc Host to synchronize upon closing a test. In this configuration, the EDM synchronization procedure occurs immediately after the Reader Screen is closed at the end of a test.

3.2.21 Log Out and Turn 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  . Use the Power Button on the Host to turn the device 'OFF'.

3.2.22 Reader Auto Power Off

The Reader automatically powers 'OFF' after 20 minutes idle time to conserve battery power, but only if:

a) Reader is NOT plugged in, and

b) Reader is NOT connected to a Host.

3.2.23 Multiple Reader Testing

The epoc System allows multiple Readers to connect to, and run tests using a single Host. 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.

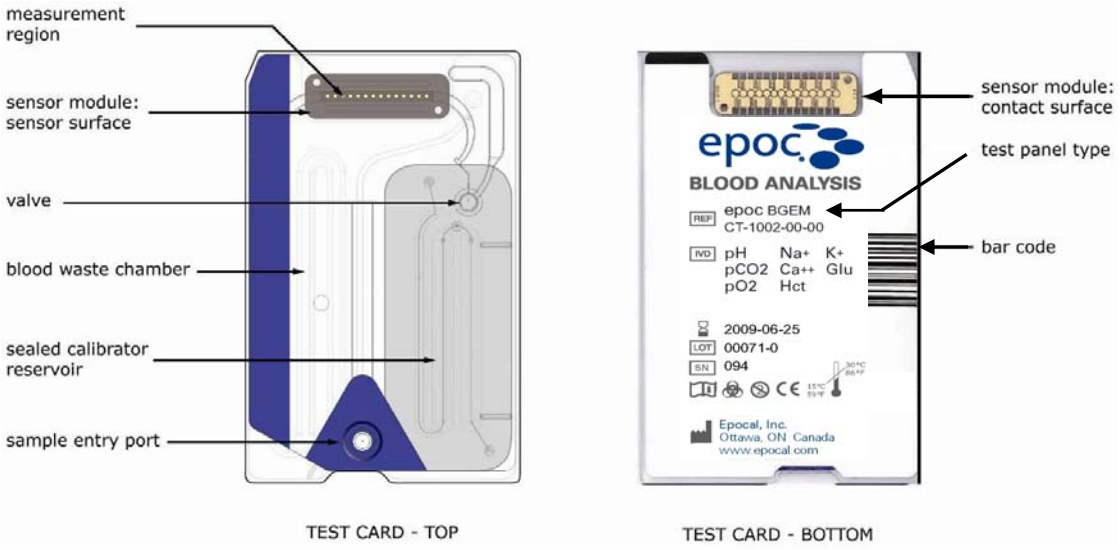
Discover all required Readers using the Host before running multiple tests. Discovery is not permitted while the Host is connected to one or more Readers. Disconnect all connected Readers before attempting to discover additional Readers.

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 same instructions for running a test 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.



The epoc Test Card is available in two (2) different test configurations: 1) Blood Gas and Electrolyte (BGE) Test Card and 2) Blood Gas Electrolyte and Metabolytes (BGEM) Test Card. Refer to BGEM Test Card Specifications Section of this Manual for more information.

4.2 Test Card Packaging, Storage and Shelf Life

4.2.1 Packaging

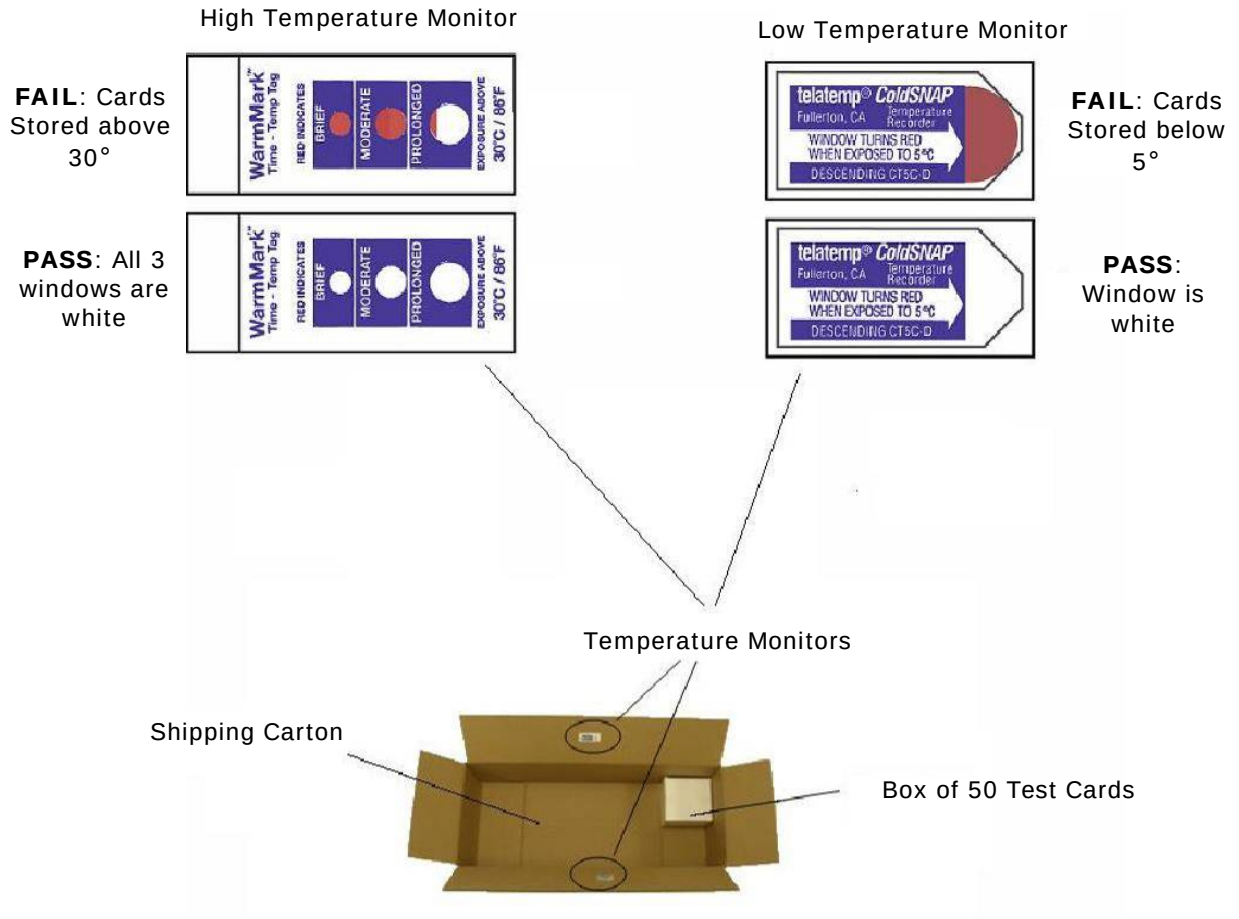
Each single use Test Card is packaged by the manufacturer into a card pouch, which also contains one (1) strip of desiccant. Fifty (50) card pouches are packed into boxes of 50 cards. Quantities of 50 Card Boxes are packed into larger shipping cartons.

4.2.2 Shipping Controls

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 5° C. A High Temperature Monitor turns red above 30° C.

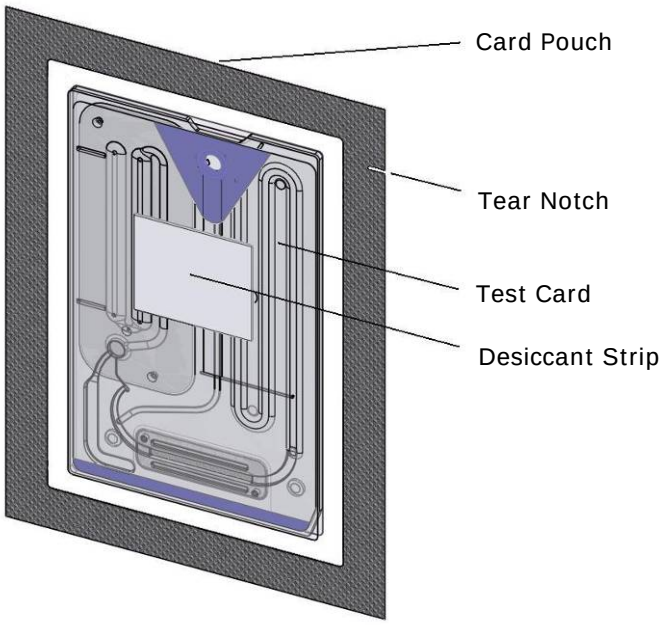
Temperature monitors must be checked when Test Cards are received to verify that the temperature limits were not exceeded during shipment. If one or both of the temperature monitors indicate any RED then the Test Cards were stored outside of the allowable temperature limits. Place the card shipment on “Hold” and isolate from possible use. Contact Epocal Inc. immediately to arrange for exchange of the Test Cards.

Never use Test Cards shipped outside the specified temperature limits (5°-30° C).



4.2.3 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.



4.2.4 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.

4.2.5 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.

4.2.6 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.

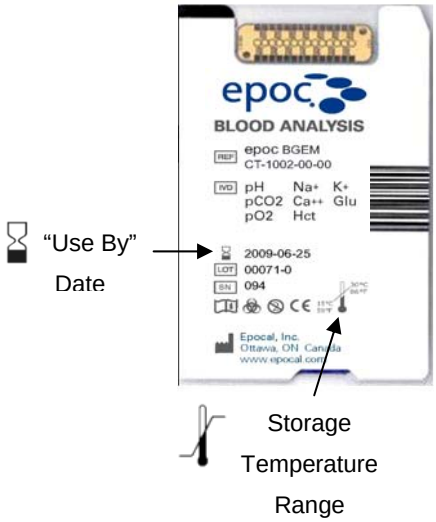
Strong mechanical shocks to the card container may induce bubbles in the Test Cards. Never drop or otherwise mechanically stress the Test Cards or pouches.

4.2.7 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.



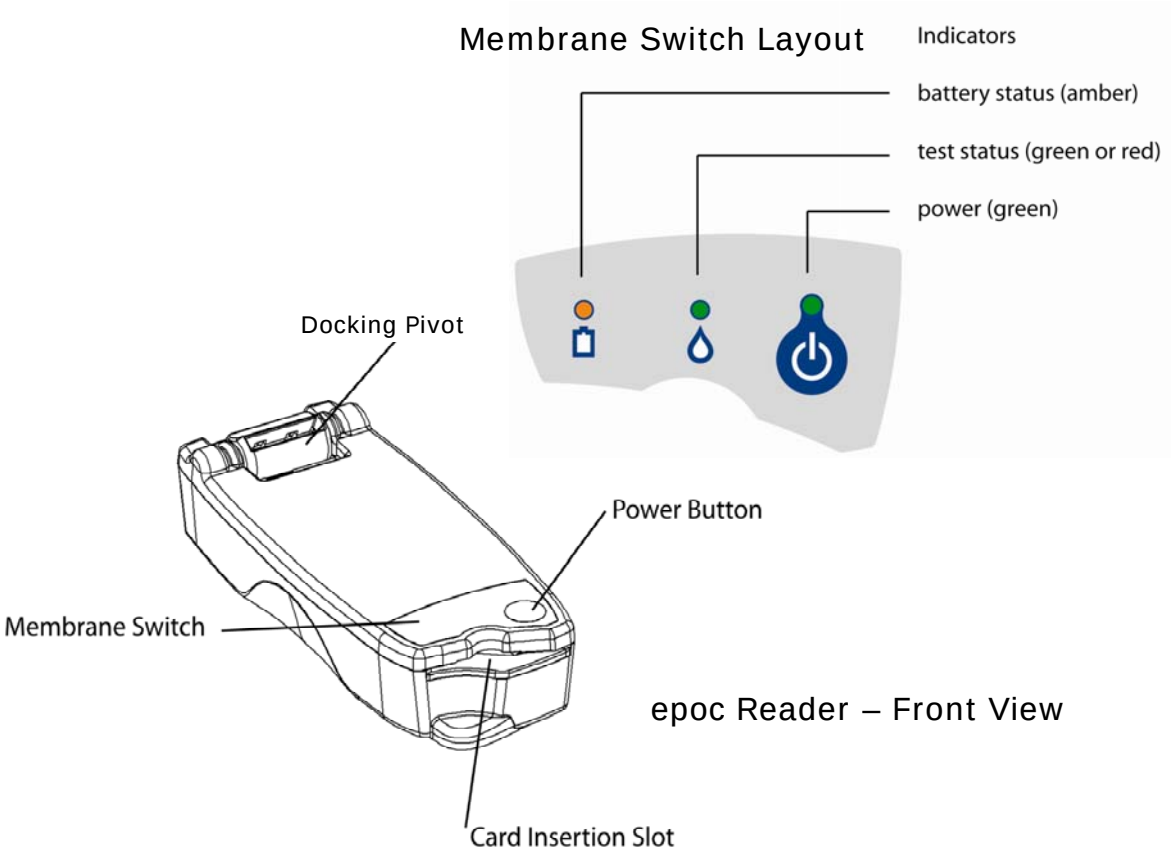
05 epoc Reader

5.1 Overview

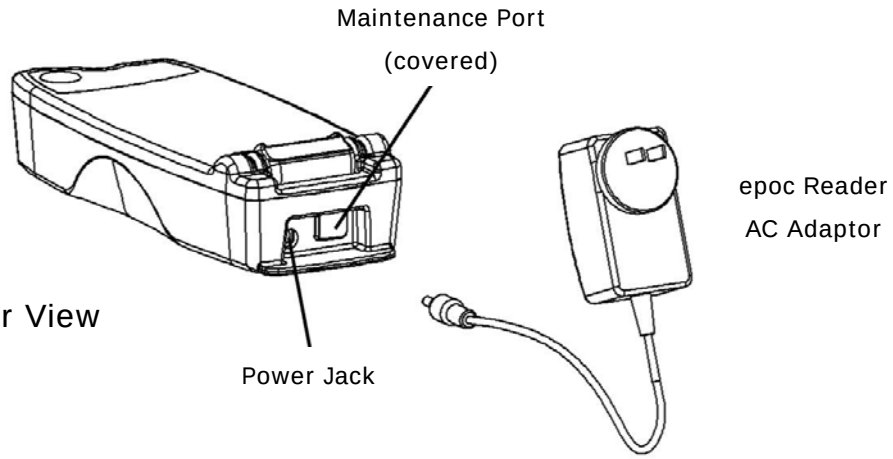
The epoc Reader is a simple-to-use raw-signal acquisition peripheral. The Reader and Host mobile computer together comprise all of the subsystems generally found in a traditional blood analyzer that operates on single use sensors and reagents.

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. Never disassemble the Reader or place any foreign objects into the Card Insertion Slot or the Docking Pivot.



epoc Reader – Front View



epoc Reader – Rear View

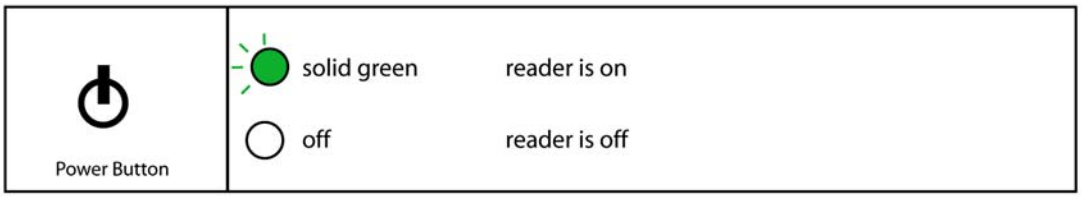
5.2 Power Requirements

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 by the label on the bottom of the Reader.

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.



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.

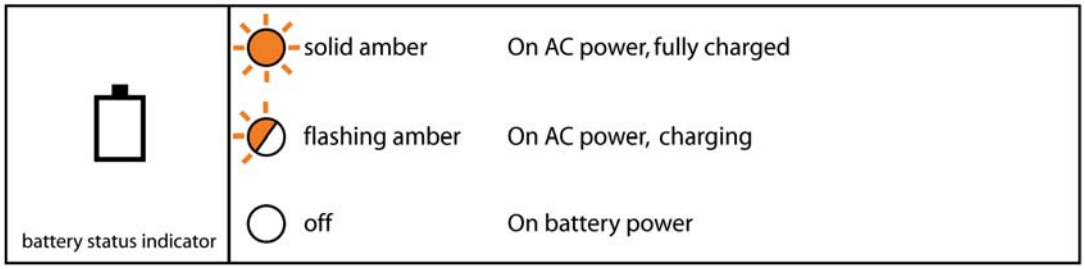
The AC Adapter recharges the Reader when the Reader is either 'ON' or 'OFF'.

5.3 Rechargeable Battery

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

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

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**.

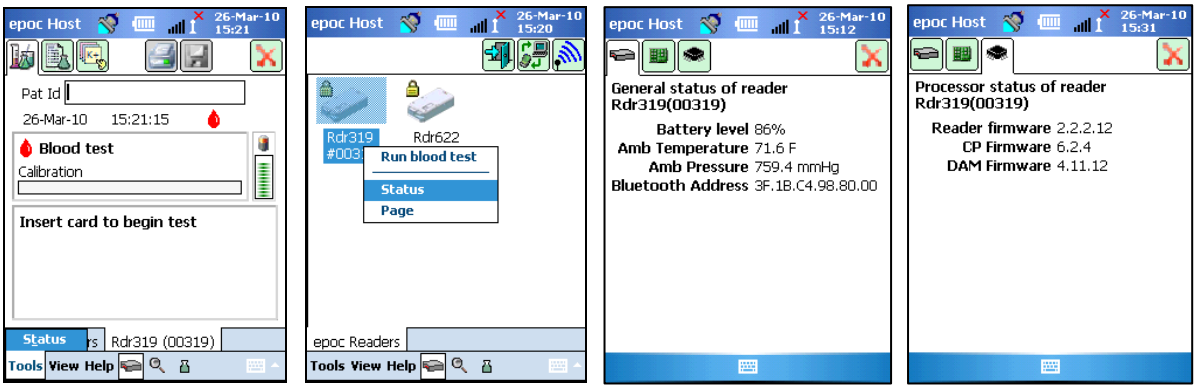
When the indicator is off, it indicates that the AC Adaptor is not connected and the Reader is operating on battery power.

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

5.4 Reader Status and Firmware Version

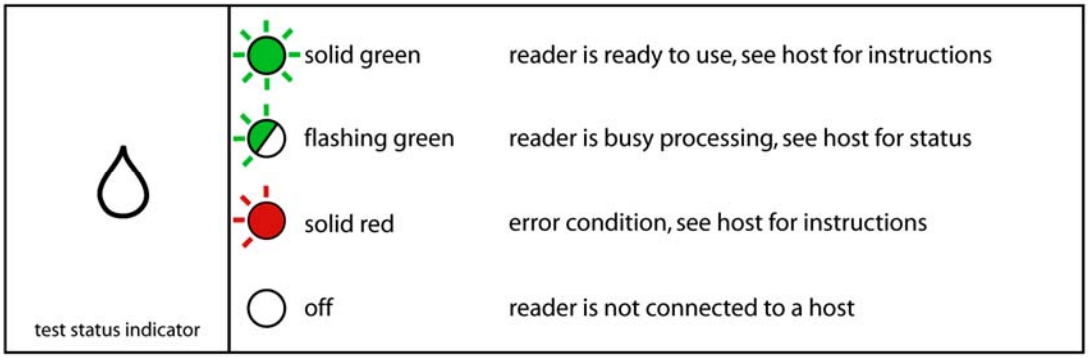
Use the epoc Host to obtain the Reader status. Use "Tools" "Status" when connected to the Reader or press on a Reader icon from the Main Reader Screen and tap "Status" on menu that appears. The epoc Reader Status is displayed.

The third tab  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.



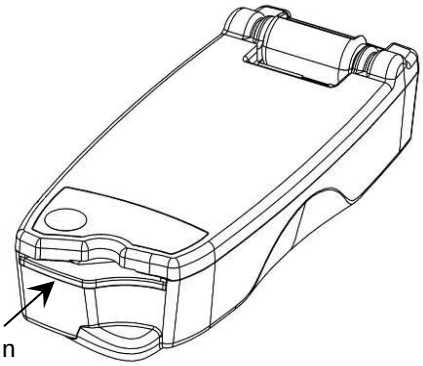
Solid Green when:	**Required User Action**
Test card is first inserted	Fully insert card
Calibration is complete	Inject sample
Test is complete. Results are available	Remove card
Reader is being paged (slow flash with beeps)	No action required
Solid Red when:	
Error has occurred	Check the Host for further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

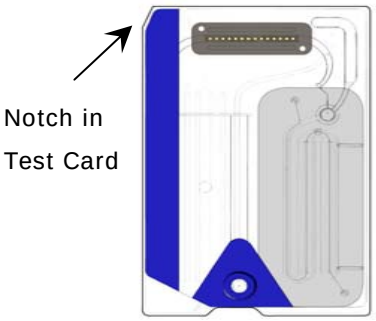
The Test Card has a Notch, allowing only a correctly orientated Test Card insertion into the Card Slot. A properly oriented card requires minimal force for insertion, and encounters minimal resistance up to full insertion.

⚠ 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).

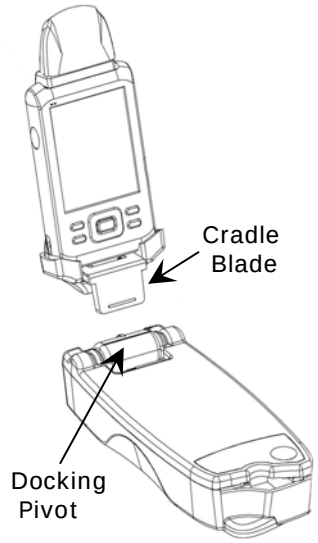
⚠ Avoid placing the Test Card on any surface prior to test. Insert Test Card directly from the Test Card Pouch and insert into the Card Slot.



5.8 Docking Pivot

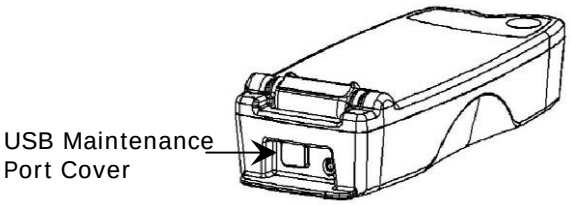
The Docking Pivot provides a physical link between the epoc Reader and epoc Host. A pocket in the Docking Pivot accepts the blade section of the Host Cradle. When docked in the open position, the Host sits with its Screen at 15 degrees from vertical. When in the closed position, the Host is rotated flat 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.



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.



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 three (3) different times:

1. After a short delay when the Host first connects to a Reader for a test.
2. When a new Test Card is completely inserted into the Reader
3. 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 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

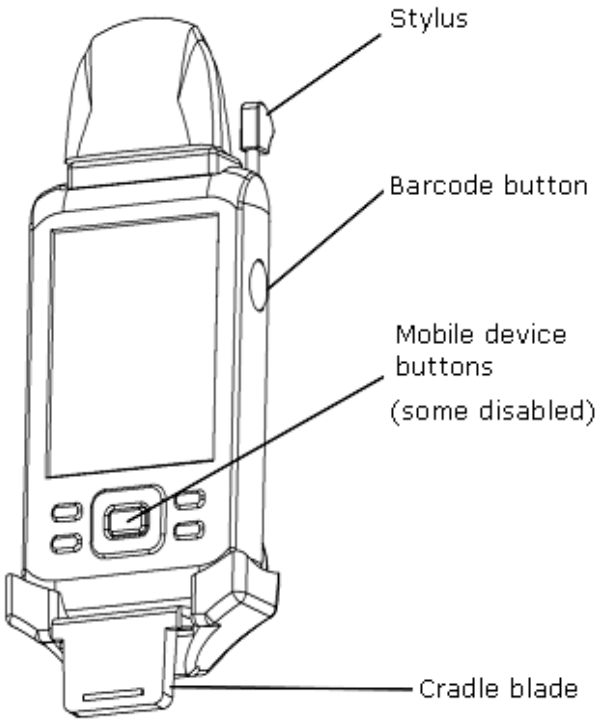
Always keep the epoc Reader in a dry location. Immediately wipe away any liquids on the outside Reader surfaces (using appropriate Biohazard protection). Always follow the recommended cleaning procedure.

06 epoc Host

6.1 Overview

The epoc Host is a dedicated use mobile computer. The SoMo650 from Socket Communications Inc. uses Windows™ Mobile (Version 5.0) operating system and hardware featuring Microsoft Bluetooth™ drivers. 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.

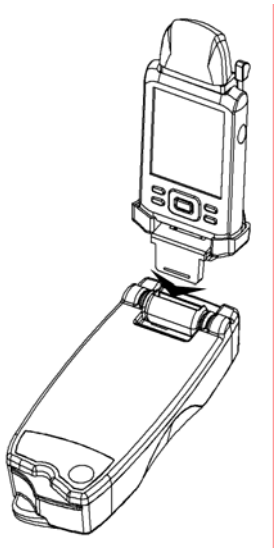
The epoc Host is intended for use as part of the epoc Blood Analysis System and not as a general purpose computing device. Some hardware and software functions have been disabled in the device including several buttons on the front of the device. The Host runs only the epoc Host Application Software 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 Adaptor is to the Power Jack at the rear of the Reader and also into the wall receptacle.

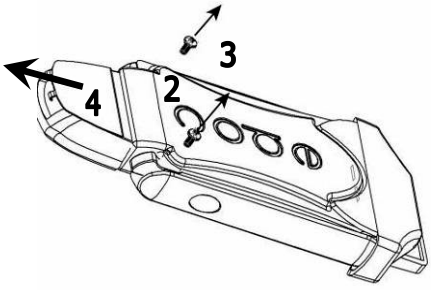
The **red** charging indicator turns 'ON' indicating that the battery is charging. The indicator turns solid **green** when charging is complete.

Up to four (4) hours may be required to fully recharge the battery. The Host can be operated normally while it is being charged.

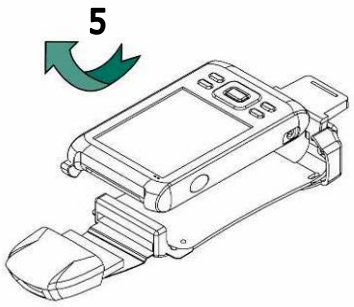
6.3 Host Cradle Removal Instructions

(to access SD Slot and / or replace Battery)

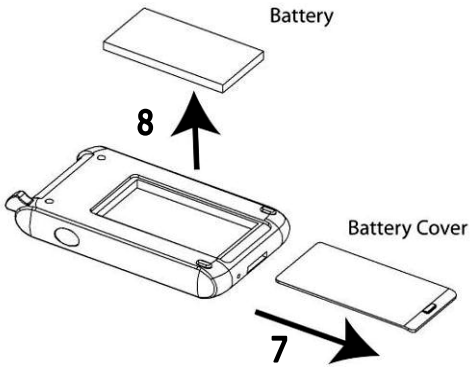
To remove the cradle for **epoc Host Version A (with black Rubber Back)**:



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.

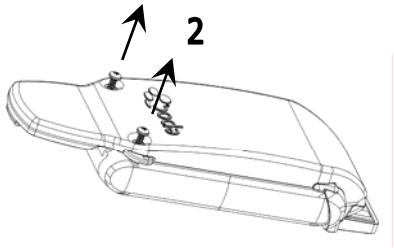


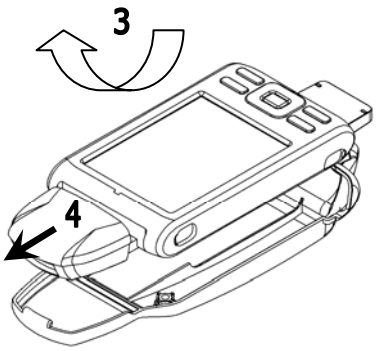
6. SD slot is beneath the Barcode Scanner. If needed, carefully pull Barcode Scanner from its slot to gain access.
7. Use the Stylus to release Battery Cover.
8. Remove Battery Cover from back of Host.
9. Remove Battery.
10. Replacement Battery information is found in Section 13 of this manual.
11. Replace 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.

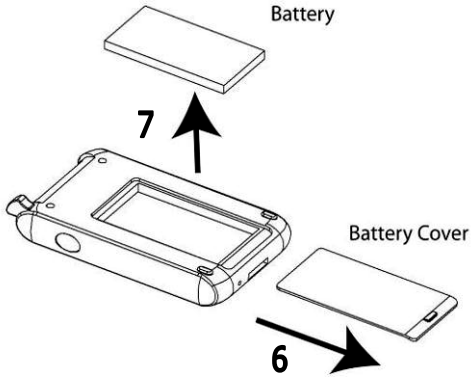


To remove the cradle for **epoc Host Version B (Plastic Back, one piece)**:

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 this 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.







When replacing the battery (with either cradle):

Only replace with Battery designated for use.

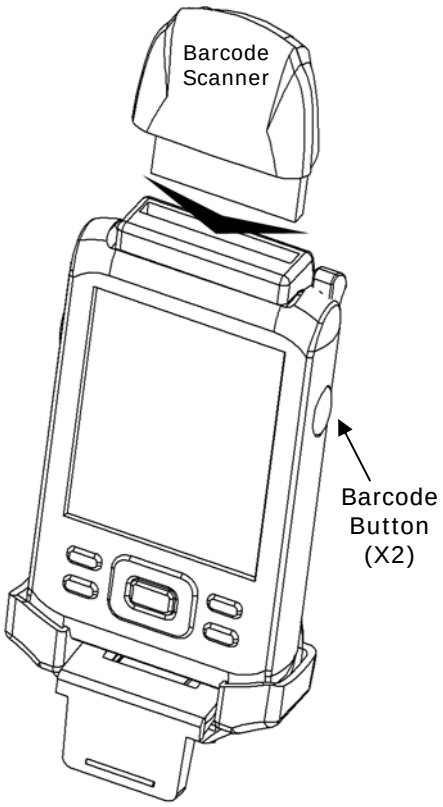
Always dispose of Battery in accordance with local regulations. Never place Battery in municipal waste.

6.4 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.

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

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



To use Barcode Scanner:

1. Place software cursor into field where the scanned text is to be entered.
2. Press Barcode Button at either side of epoc Host to turn 'ON'.
3. Direct red light coming from the top of the scanner towards desired barcode until beep is heard.

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

6.5 Optional AC Adaptor for Host

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

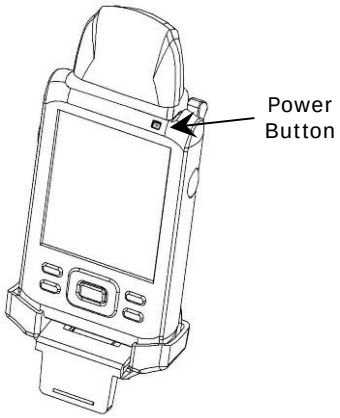
The separate epoc Host AC Adaptor is not approved for medical use. Never use the AC Charger within patient vicinity.

The 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.

6.6 Power Button

The **Power Button** is located on the upper front of the epoc Host.

Pressing this button shuts off the Touch Screen and puts the epoc Host to sleep while keeping the software loaded.



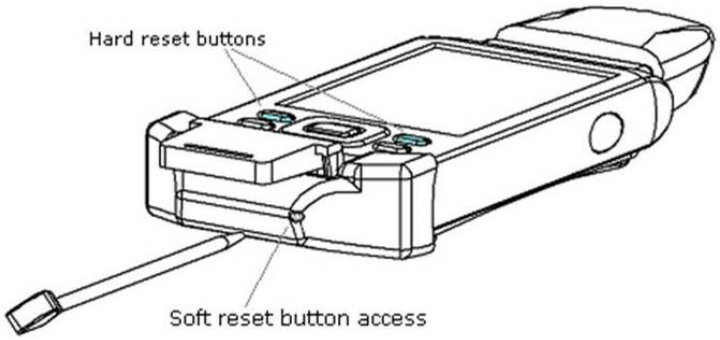
6.7 Soft and Hard Reset

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.

A Soft Reset acts like rebooting a desktop computer. The software stops running and is reloaded. All saved data is safe and is not erased by a Soft Reset.

Pressing the Soft Reset Button initiates a boot-up sequence and loads the epoc Host Application software automatically. 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 below) to perform a **Hard Reset**.



Never press Soft Reset Button during a test. This ends the test immediately.

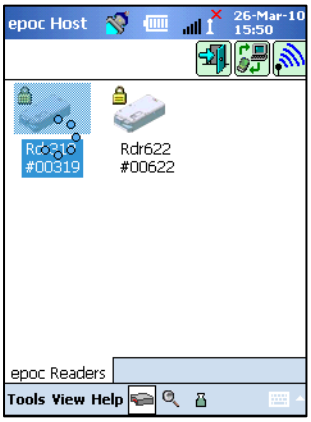
Always verify that date and time are correct after performing Hard Reset.

6.8 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.

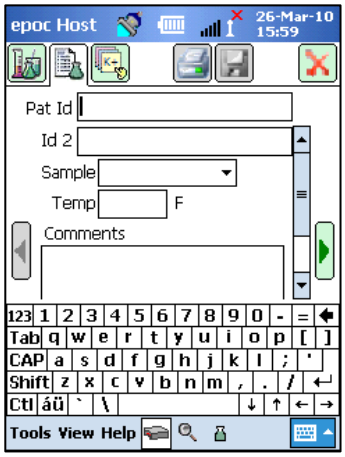
Press and hold an item: A pattern of dots will encircle the Stylus and a menu appears, if available. Similar to right-clicking a computer mouse.



6.9 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. Three (3) methods use recognition technology to convert the letters and symbols written on the screen to computer text. These methods may lead to incorrect text input. Only the **Keyboard Method** should be used.




Keyboard - RECOMMENDED 


Block recognizer – NOT RECOMMENDED 


Letter recognizer – NOT RECOMMENDED 


Transcriber – NOT RECOMMENDED 

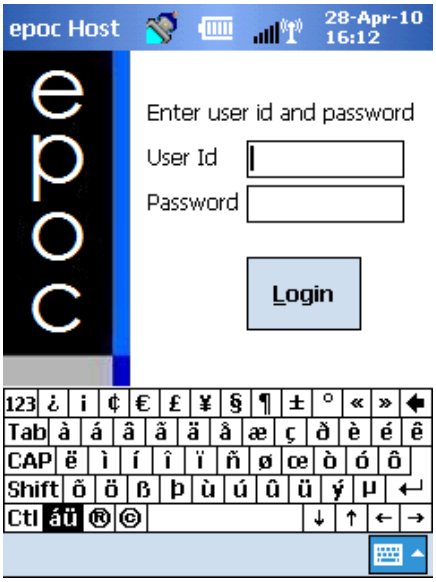
1. Tap the Stylus to locate the cursor into the desired field.
2. The Onscreen Keyboard is normally hidden. Tap the Text Input Button  at the bottom right hand corner of the screen to enable text input functionality.
3. If the Onscreen Keyboard does not appear, then tap the triangle at the right side 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, on right.



6.10 Date / Time Clock

The current Date and Time is 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 epoc Data Manager (EDM) to update Date and Time. Otherwise contact System Administrator to set correct Date and Time before proceeding with a test.

6.11 Status Indicators

A line of Status Indicators appear 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).
	Current Date and time (as set by administrator).

6.12 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.

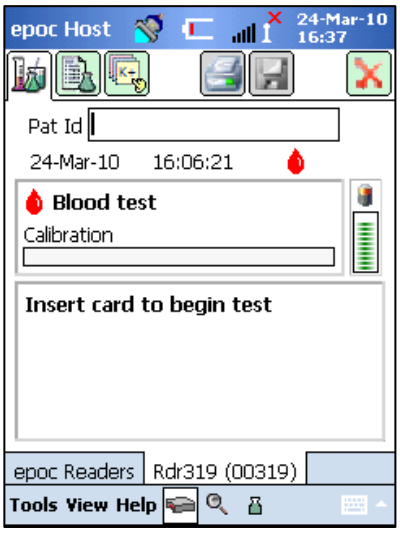
6.13 epoc Host Application User Interface

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.

Example Screenshot shows the basic elements of the user interface.



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

There is always a **Toolbar** 

at the bottom of the Screen that contains Menu Items and Toolbar Buttons. The Text Input Button is located 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 coloured 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 the section on epoc Host Administration.

6.14 User Interface Menu Trees

Toolbar Menu	Tools	[Personal options] [Sync with EDM] Logout
	View	Ranges
		Icons List
	Help	About

Toolbar Buttons	 Testing Mode Button	
	 Viewing Tests Mode Button	View Tests Test Results Filter
	 Viewing Electronic QC Mode Button	 Refresh Button

Testing Mode

Main Reader Screen	 Reader Discovery Button	
	 EDM Synchronization Button	
	 Logout Button	
	 Discovered Reader Icon (one for each Reader)	Run blood test [Run QA test] Status Page [Run Thermal QA]
Reader Screen	 Test Results Page	Measured Results Tab Calculated Results Tab Corrected Results Tab
	 Test Information Page	
	 Test Selection Page	Select all Clear all Gases only Electrolytes only
	 Printer Button	
	 Save Button	
	 Disconnect Reader Button	
	 Reconnect to Reader Button	

Viewing Tests Mode – List

Toolbar Menu **Tools View Help**	Tools	[Personal options] [Sync with EDM] Logout	
	View	Ranges Pat ID/Lot # Test Time Operator Card lot Reader Test Mode	
	Help	About	
Main Test Tab Tests	 Test Results List Page	Patient ID (Default) Date & Time (Default) Operator (Default)	
		View this test Print this test (Press and hold stylus on test row)	
	 Tests Results Filtering Page	Simple << Simple	Clear Apply
		Advanced >> Advanced	Clear All Apply

View this test Viewing Tests Mode - Test Result

Test Tab	Test Results Page	Measured Results Tab	Measured
		Calculated Results Tab	Calculated
		Corrected Results Tab	Corrected
	Test Information Page		
	Reference Ranges Page		
	Critical Ranges Page		

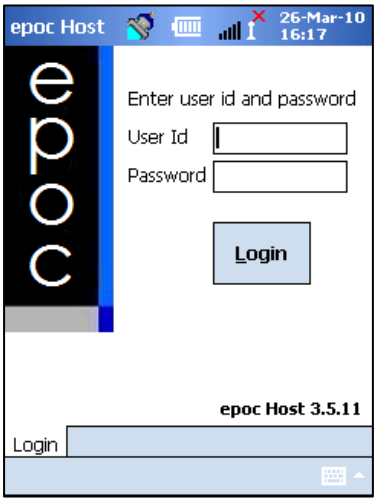
Viewing Electronic QC Mode

List	Refresh Button
Electronic QC Record	Electronic QC Result
	Software and Hardware Versions

6.15 Startup Screen

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

6.16 Login Screen



The Login Screen appears after a Soft or Hard Reset or after the user logs out of the epoc Host Application.

6.17 Operational Modes

The following Operational Modes are available to the Operator:

1. Testing Mode 

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

2. Viewing Tests Mode 

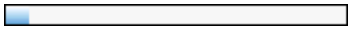
- Review previous Test Results
- View multiple Tests in a List. Select Tests to view on separate screens.

3. Viewing Electronic QC Mode 

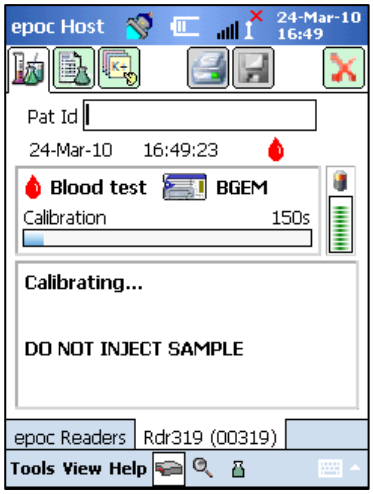
- Review previous Test Results
- View multiple Tests in a List. Select Tests to view on separate screens.

6.18 Testing Mode

The following information is displayed when conducting a Test:

1. **Test Type** ( Blood Test or  QA Test).
2. **Reader Battery Level**  - (Red indicates Low Battery Level).
3. **Progress 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 Test Type performed and stage of testing process.



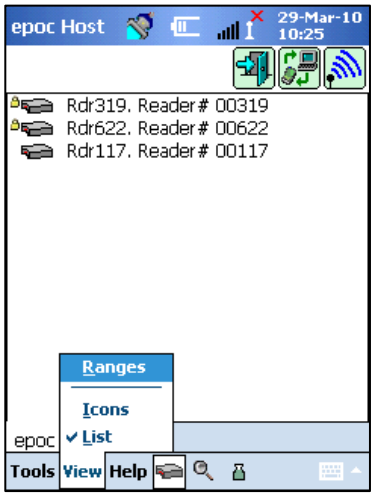
6.19 Main Reader Screen

Access Main Reader Screen by pressing **epoc Readers Tab** epoc Readers . Screen displays all Readers available for use.

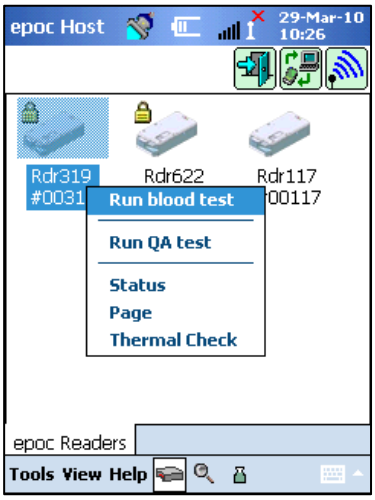
Locate Readers by pressing **Discovery Button** . During Discovery Mode blue radio waves are visible while the Host searches for Readers in the vicinity. Discovery Mode is cancelled by pressing Discovery Button again. Discovery can be performed again to locate additional Readers, but not while a connection already exists between a Host and Reader, such as during a test.

Dedicated Readers are always listed and are indicated by the **Lock Icon** . Available Readers are displayed on Main Reader Screen either as Icons or in a List. The Serial Number and Alias for each Reader is displayed. Select View on Toolbar menu to change how Readers are displayed.

If using an epoc Data Manager (EDM), **EDM Synchronization Button** is used to exchange information (test results, configuration information) between epoc Host and EDM.



Tap the **Logout Button** to logout and display 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 test).

Status – Reader reports to Host with Reader status information.

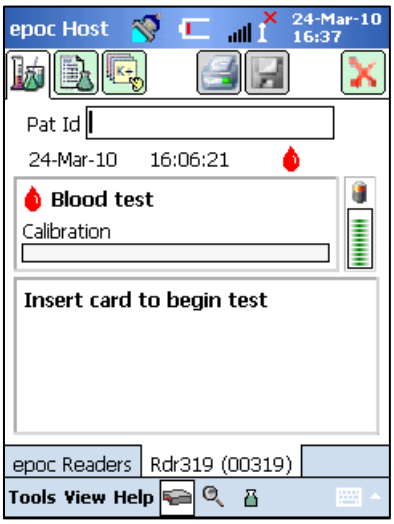
Page – Reader beeps five (5) times. Reader Indicator illuminates to help locate Reader.

Run Thermal QA – available for Operators authorized to run QA test.

6.20 Reader Screen

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

Reader Alias and Serial Number are displayed on **Reader Screen Tab** Rdr319 (00319) at Screen bottom.



Three (3) Buttons appear at the top right corner of a Reader screen:

1. Tap **Print Button** to send test results to a Printer connected to the Host. Print Button is not enabled during a test.
2. **Save Button** is enabled only after test completes. Information entered during a test is automatically saved as test completes. Information entered after test completes must be saved by pressing Save Button.
3. Tap **Close Reader Connection Button** to cancel a test and close Reader connection.

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

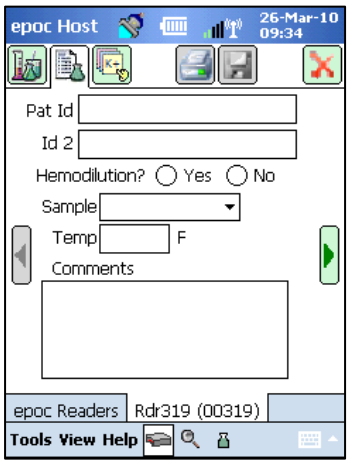
6.21 Reader Screen Pages

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** (shown below) 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.

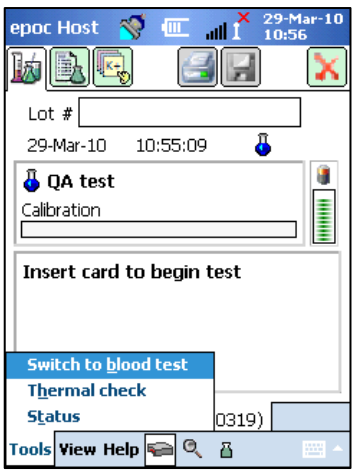


Test Date and Time are displayed on each page, as well as Patient ID (Blood Test) or Lot Number field (QA Test).

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

1. Switch between Blood Test and QA Test.
2. Perform Thermal QA.

Screen shot on right shows Reader Screen on Test Results Page for QA test with Tools menu being accessed.

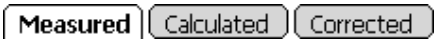


6.22 Test Results Page

While Test Is In Progress:

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

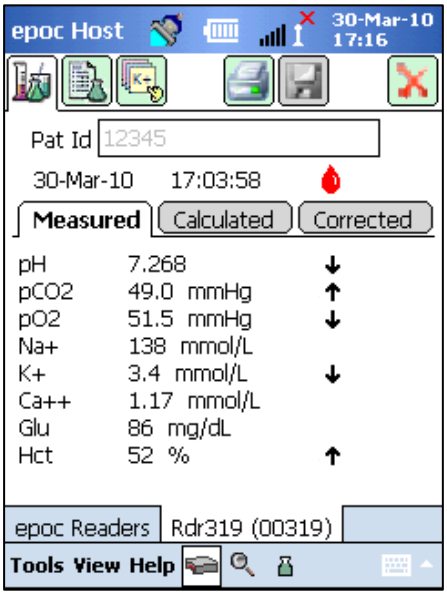
When Is Test Complete:

Three (3) Tabs show 

Measured, Calculated, and Corrected test results. Click on Tabs to display each set of results data. Results displayed depend upon Card Type.

A. Measured Test Results

Measured results are displayed depending on tests selected and those available on the Test Card. The tests available for a Test Card are listed on the Card's label (bottom side of card) and described in Section 12 of this manual.



B. Calculated Test Results

Calculated results (results calculated from measured results) are displayed depending on tests selected and those available on the Test Card. Calculated results are also described in Section 12 of this manual.

C. Corrected Test Results

Temperature-corrected results are computed and displayed for pH(T), pCO_2(T), pO_2(T), but only if the patient temperature is entered on Test Information Page before results are calculated.

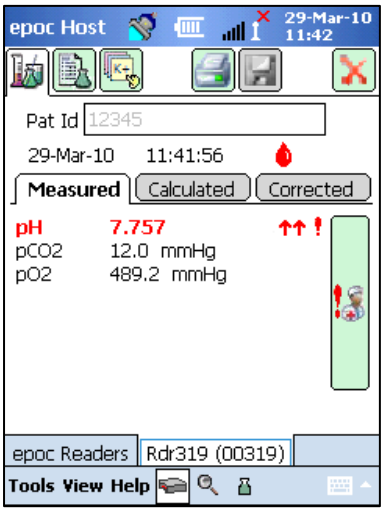
Messages

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.

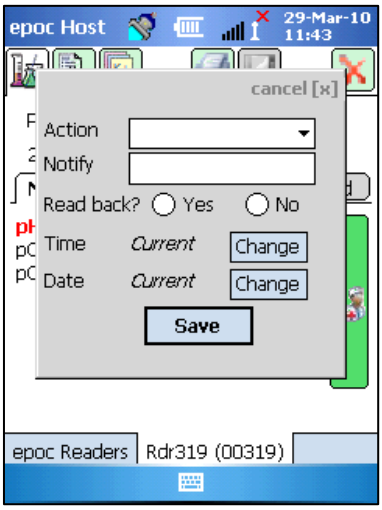
6.23 Critical Values Actions

After completing a test, if one or more of the test results fall outside of its critical range, the result will appear in **bold red** with out-of-critical-range indicator ↑↑ ! and the **Critical Actions Button** is displayed.



Tap **Critical Actions Button**  to open **Critical Actions Window** where actions taken by Operator may be entered.

Critical Actions Window



Action dropdown contains selections for Notify physician, Notify RN, Repeated test, Sent to lab, and Other.

Select **Notify** to enter text information such as name of Physician who was notified. If Action was selected, then 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.

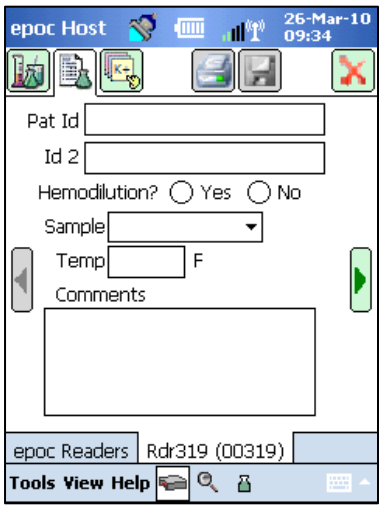
Tap **Save** to keep all text entered. Window closes after save operation.

Tap **cancel [x]**, to close Window. Critical Values Action changes are not saved.

6.24 Test Information Page

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

Enter **Patient information** at any time during 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 **Measurement Method** in Theory of Operation section and **Hematocrit section** of Test Card Specifications for details on Hematocrit measurement.

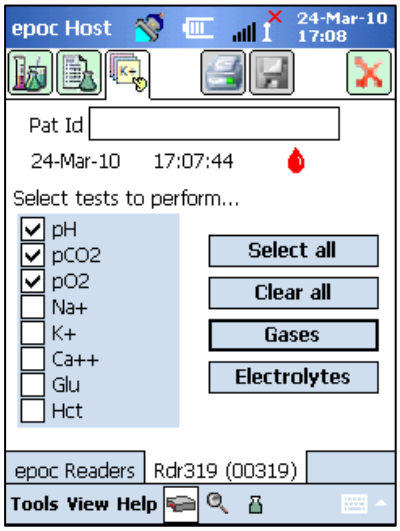
Select **Sample Type** to stamp Test Record for identification purposes. Associated with each sample type are unique reference and critical ranges that are applied to the test results and are configured by the System Administrator.

Sample Types: Unknown, Arterial, Venous, Mixed-Venous, Cord, or Capillary.

Use **Temp** to enter Patient's Body Temperature to obtain temperature corrected values for pH, pCO2 and pO2.

In **Comments Text Box** enter Test related comments to save with Test Record.

6.25 Test Selection Page



Use the **Check Boxes** to select Analytes for testing.

Use four (4) **Quick Buttons** to make multiple selections as described:

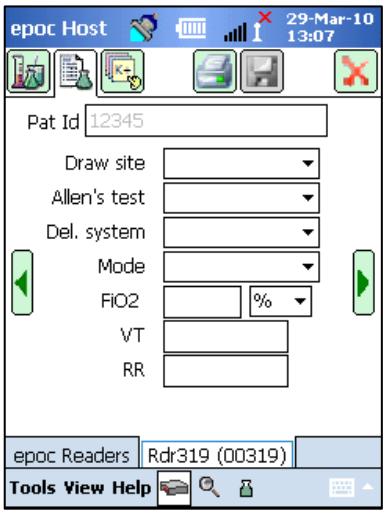
Healthcare Institution policy may require selection of analytes for testing. Policy is set in the Host Application by System Administrator.

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

6.26 Respiratory Therapy Parameters

Use the **Green Arrows** at 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 Onscreen Keyboard. Select Text and tap Backspace Key from 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, L Heel, R Heel, PA, RA, RV, Swan Ganz, UAC and UVC.

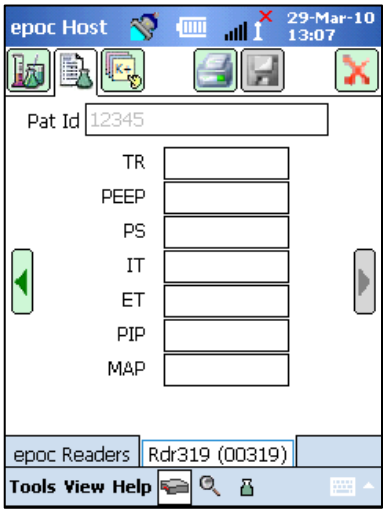
Allen's test: Positive, Negative and N/A.

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

Mode: AC, BiLevel, CPAP/PS, PAV, PC, PRVC, PS, SIMV, SIMV/PC, TC, and VC.

Units: (beside FiO2) % and lpm.

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



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

Always tap Save Button to retain Test Information, additional Test Selections, or Respiratory Therapy Parameters entered after 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
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 O2 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
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
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
PRVC	Pressure Regulated Volume Control
PS	Pressure Support
SIMV	Synchronized Intermittent Mandatory Ventilation
SIMV/PC	Synchronized Intermittent Mandatory Ventilation/Pressure Control
TC	Tracheostomy Collar
VC	Volume Control

Other Parameters:

FiO2	Fraction of inspired oxygen
VT	Tidal Volume
RR	Respiratory Rate
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

6.27 EDM Synchronization

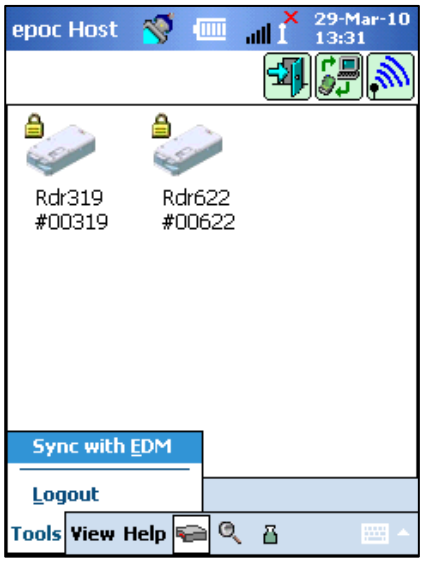
Tap **EDM Synchronization Button**  (or select from Tools menu) to synchronize with epoc Data Manager (EDM).

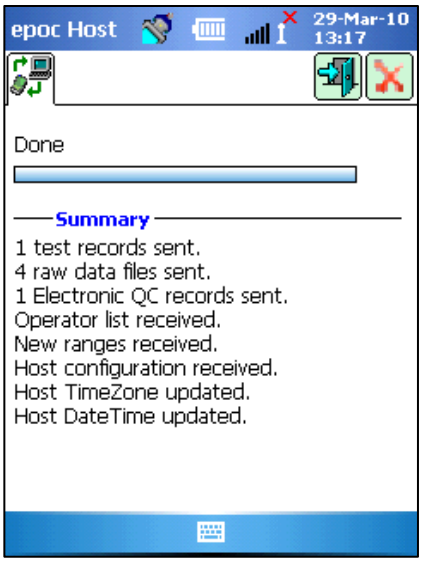
NOTE – the System Administrator may configure the system for automatic EDM Synchronization when closing Test. In this case after a test is completed and the Reader Screen is closed via the Red X  , EDM synchronization proceeds.

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.

Tap Red 'X' to close Screen  or Logout  when Synchronization is complete.



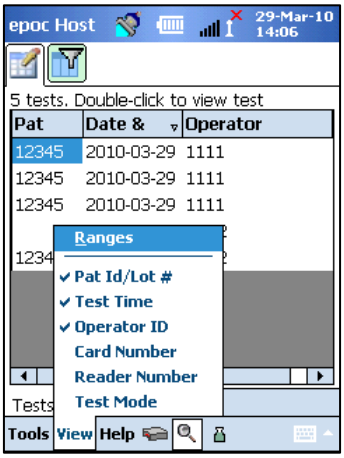


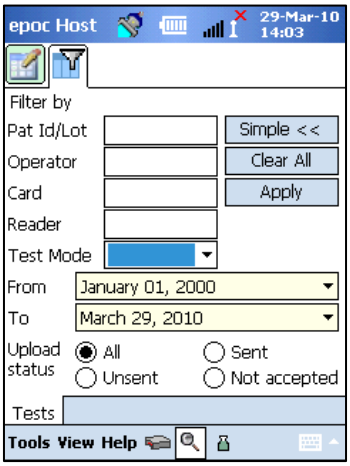
Note: The most recent 2000 Test Records remain on epoc Host for later viewing or printing after each EDM Synchronization.

6.28 Viewing Tests Mode

Tap **Viewing Mode Button** on the Toolbar to display list of Tests Results.

Fields viewed on **List Page** can be selected from View menu on Toolbar. Check or uncheck fields to display on List Page.





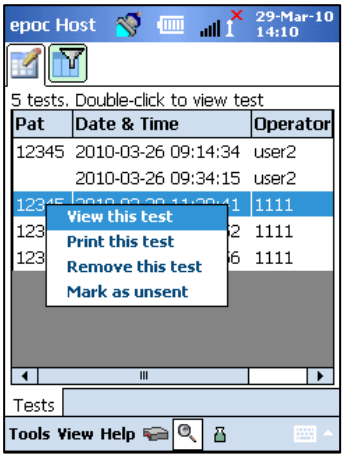
Narrow Test Results by using **Filter Page** . Enter search parameters such as Operator and/or Date Range to limit results.

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 Complete Test Result**:



1. Hold Stylus on the desired Test Result Row momentarily.
   A new Menu Window opens.
2. Select **View this test** from Menu.
   Multiple Tests open on separate Tabs at Screen bottom.
3. Tap Tabs to move between multiple Test Results

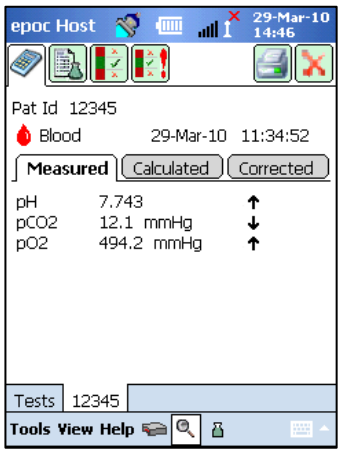
Mark as unsent (used to re-send test to EDM) and **Remove this test** are only available to the System Administrator.

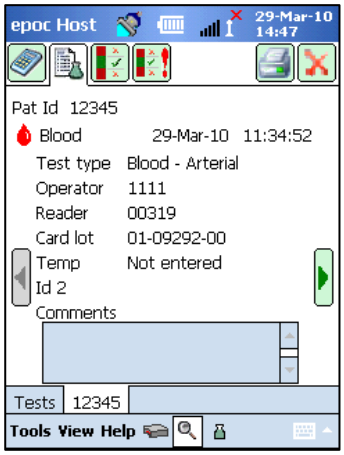
To **Print Complete Test Result**:

1. Hold Stylus on the desired Test Result Row momentarily.
   A new Menu Window opens.
2. Select **Print this test** from Menu.
   (OR **Print Test Result** by tapping Print Icon while on a 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
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





6.29 Viewing Electronic QC Mode

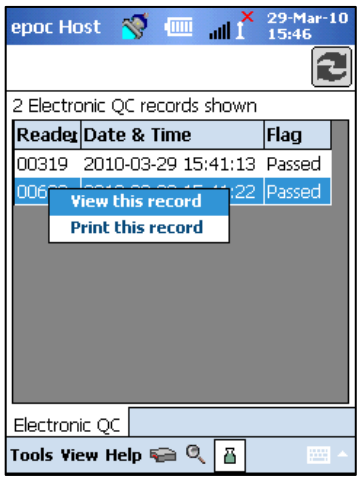
Tap **Viewing Electronic QC Mode Button** on the Toolbar to display list of Electronic QC Records.

To **View Electronic QC Record**:

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

   A new Menu Window opens.
2. Select **View this record** from Menu.

   Multiple Records open on separate Tabs at Screen bottom.
3. Tap Tabs to move between multiple Electronic QC Records



Refresh List by tapping **Refresh Button** if required.

To **Print Electronic QC Record**:

1. Hold Stylus momentarily on Row with desired Record.

   A new Menu Window opens.
2. Select Print this record from Menu.

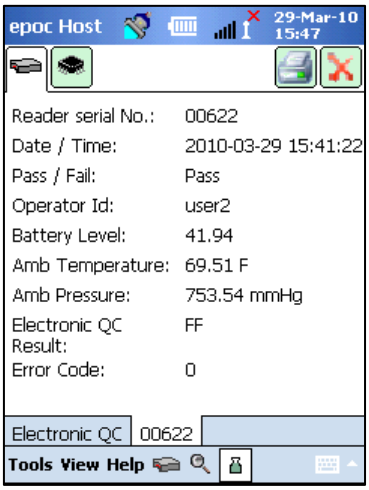
   (OR **Print Electronic QC Record** by tapping Print Icon while on an Electronic QC

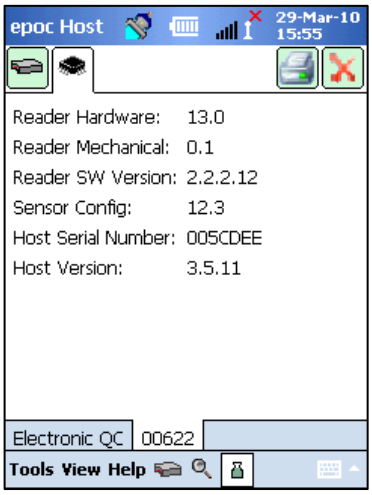
Record Tab).

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.





6.30 Personal Options Page

Use Personal Options Page to **change Password**.

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

Access Personal Options Page from **Tools Menu**. Enter **Old and New Passwords**. Enter new Password again in **Verify field**. Tap **save** Button to retain changes.

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**. System Administrator requires additional training to manage critical settings not available to Operators which that can affect the performance of the epoc System.

7.2 First Time Administrator Log in

System Administrator must login first time using factory defaults for Administrator Account:

User ID: administrator

Password: administrator

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

Contact Epocal for a temporary reset password if 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 mobile computer without written authorization from Epocal Inc. Epocal has no control over use of unauthorized software, which may impact the operation of the epoc System.

The epoc Host is wholly self sufficient. Do not synchronize with other computing devices except epoc Data Manager. Never use epoc Host with any Desktop Cradle that includes Cable for synchronizing with other devices.

Wi-Fi capabilities of epoc Host are factory disabled. Wi-Fi capabilities should be enabled and configured for use only with epoc Data Manager or epoc compatible Printer.

epoc Host supports downloading data to epoc Data Manager only. 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.

7.4 Administrator Access

An 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.

Perform a soft Reset to return to Log In Screen to Log In as Administrator

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

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 necessary for using the mobile computer as an epoc Host. Administrator must review this information and establish appropriate settings in the epoc Host prior to releasing it for patient testing. The Host comes ready to use with Windows Mobile™ Version 5.0 English version 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 log out after inactivity” epoc Host setting. Adjusting these in the operating system has no affect.

7.5.2 Regional Settings

Regional settings are to be set within the epoc Host and are described later in this section under the sub-heading “Identification and Language Page”.

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 epoc Data Manager ("EDM").

If using EDM, 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 institution.

Additional information about Wi-Fi Settings is available in the "SoMo™ 650 Mobile Computer—User's Guide" and other Socket Wi-Fi related user guides, available at www.socketmobile.com.

7.6 Administrator User Interface

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

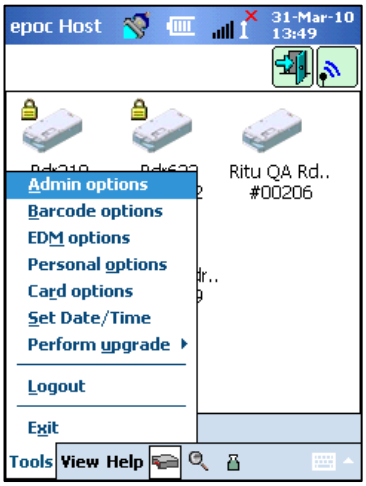
If using epoc Data Manager ("EDM"), epoc Host can be configured for **EDM present** ('Yes' or 'No'). Tap **Tools > EDM Options** from the Toolbar.

If 'Yes', EDM is present, Host Administration is performed using EDM. Refer to Host Configuration sections in EDM Section of this Manual.

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

If 'No', EDM is not present, Host Administration is performed using Host by logging into the epoc Host Application as the Administrator. Use instructions that follow to configure an epoc Host with no EDM present.

7.7 Administrator Options



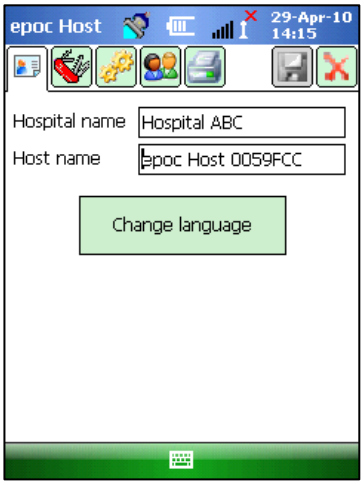
To access Administrator Options, tap **Tools > Admin Options** from the Toolbar.

Five (5) pages of options are available. Navigate using Page Tabs at top of Screen.

Press **Save** Button after making any changes for changes to be effective. **Confirmation Message** appears when changes are successfully saved.

Press **Close** Button to exit Administrator Options. **Warning Box** appears if changes were not already saved.

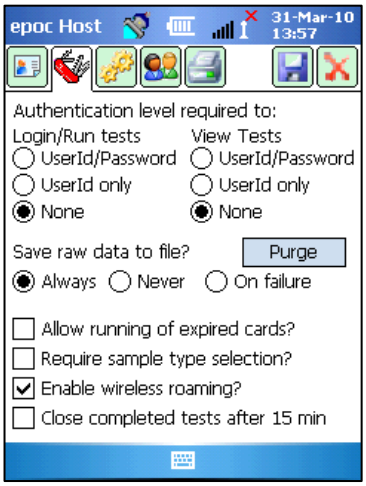
7.7.1 Identification and Language Page



Input the Hospital Name and desired Host Name.

Press **Change language** button to change language for epoc Host. After changing languages and pressing Save , 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 appropriate Radio Button:

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

ID only: All users need only a valid User ID to Login.

None: Any User ID entered into the User ID Login field is accepted. No password is required, but 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 appropriate Radio Button under **View Tests**. Choice must be at least 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 is not available to User or Administrator. It 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 saving of Raw Data when requested to do so by Epocal technical personnel.

Press **Purge Button** to remove all saved Raw Data files.

C. Allow use of Expired Cards?

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

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

Under normal test circumstances following message is displayed:

“Warning! Expired test card. Insert new test card.”

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

When checked, Test runs in normal manner, but Test Results are not displayed, not saved and are not available for viewing later.

The following message is displayed briefly:

"Warning! Expired test card. Results will not be shown"

D. Require Sample Type Selection?

Check option if Healthcare Institution policy requires Sample Type selection for each Test. When selected, option prevents display of Test Results until User selects Sample Type.

E. Enable Wireless Roaming?

Option selection is dependent on Wi-Fi Network infrastructure in installed environment for epoc Host network communications with EDM. Correct option setting is determined during site implementation process.

F. 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 EDM if applicable. For a successful test to be completed all required data entry must be entered.

7.7.3 Patient and Security Page

A. Fixed length patient ID?

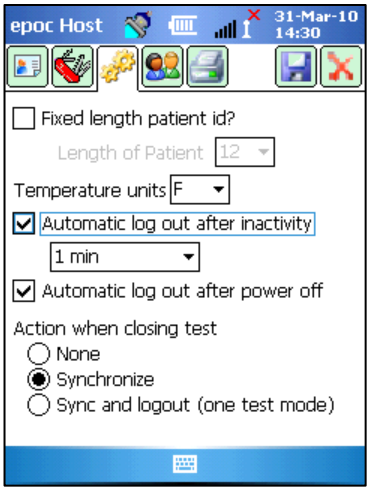
Check option to set fixed length for Patient ID field of Test Record. Select field length of 1 to 23 characters from Drop-down Selector.

B. Temperature units

Set unit of temperature measurement for use in epoc Host Application.

C. Automatic log out after inactivity [1-5 min]

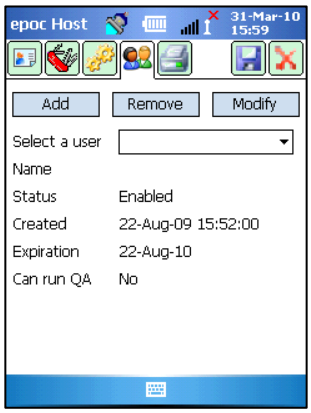
Check option to enable automatic User Log Out after period of no Host activity. Select number of minutes before Log Out from Drop-down Selector. If epoc Host is operating on **battery power** without external power it will **turn off** after logging out. This option should be used to **preserve battery power**.



D. Automatic log out after power off

If selected, Host Application automatically Logs Out User when turning power 'OFF' from Power Button (upper right on epoc Host).

7.7.4 User Accounts Page



Go to User Account Page to **add, remove or modify User Accounts** when not using EDM.

Select a user from Drop-down Selector to **display User Accounts** in epoc Host. Tap on a User Name to view User information including:

Name – User Name

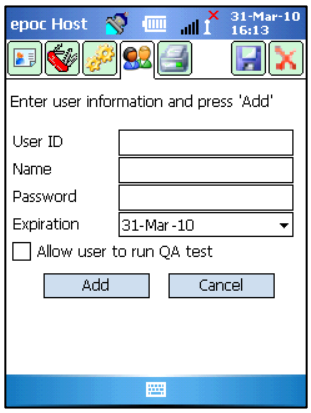
Status - enabled or locked

Created – date User Account created

Expiration – date User Account expires

Can run QA – Yes or No

Administrator account is not shown.



Select a user from Drop-down Selector. Press **Add** Button to **add new User Account**. User 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.

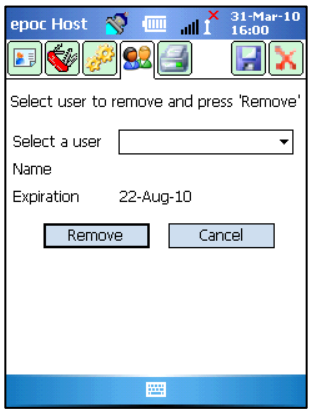
Name – User Name associated with User ID

Password – Log In Password. Password is case sensitive.

Expiration – date User Account expires

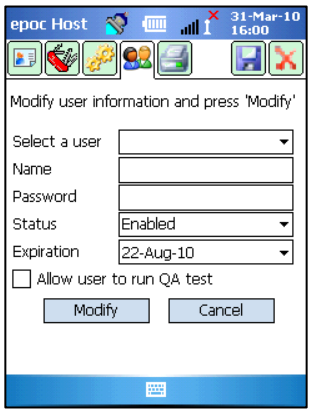
Allow user to run QA test – Select to enable

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



Select a User from Drop-down Selector. Press **Remove** Button and then Press **Remove** Button to **remove User**.

Press **Save** Button after removing one or more Users.

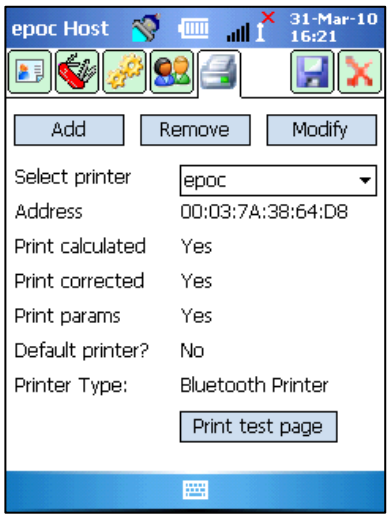


Select a User from Drop-down Selector. Press **Modify** Button to **change User Account**.

Press **Save** Button after completing single or multiple changes.

Press **Close** Button to **exit User Accounts Page**.

7.7.5 Printer Set Up Page



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

To **select Printer**, press Drop-down Selector to list **Printers**. Tap on selected Printer to view current Printer settings.

Press Add Button to **add new Printer**. User is required to provide entries for all information including:

Name - Name associated with Printer

Address – Select **Bluetooth** for Bluetooth Printer or enter **IP Address** for Wi-Fi Printer.

Print calculated results – 'Yes' to enable, and 'No' to disable.

Print corrected results (blood gas results corrected for patient temperature) - 'Yes' to enable, and 'No' to disable.

Print test info (respiratory therapy parameters that were entered) - 'Yes' to enable, and 'No' to disable.

Default printer? – 'Yes' to enable, and 'No' to disable.

Printer Type – 'Bluetooth' or 'Wi-Fi'

Press **Save** Button after adding one or more Printers.

Select Printer from Drop-down Selector. Tap **Remove** Button and then press **Remove** Button to **remove Printer**.

Press **Save** Button after removing one or more Printers.

Select Printer from Drop-down Selector. Press **Modify** Button to **change Printer Settings**.

Press **Save** Button after completing one or more changes.

To **connect to Printer** Bluetooth or IP Address of Printer must be set according to Printer specifications.

Turn 'ON' Printer while holding down Feed Button to locate Bluetooth address of **EPSON TM-P60 Bluetooth Printer**. A **Status Page** prints, providing Bluetooth address.

Factory default IP Address for **Wi-Fi Printers EPSON TM-T88IV** and **TM-P60** is 192.168.192.168.

Use **Print test page** to check Printer connectivity.

Epocal lists all Printers authorized for use with epoc Host in epoc Reader and Host Specifications section of this Manual.

Refer to the Instructions for Use (IFU) included with your Printer for additional information, including information on wireless setup.

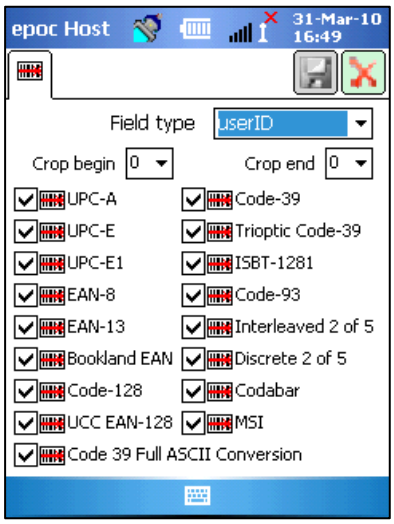
The instructions provided below are not intended to replace or supersede Printer Manufacturer's instructions and/or recommendations.

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 Text Entry Field to which settings are applied. Field choices include:

User ID – User ID

Password – User Password

Pat ID/Lot # - applies to Patient ID ("Pat ID") for blood test or Lot Number ("Lot Num") for QA test.

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

Comment – Comment Field

Other – Use for Barcode Settings for all other possible Text Entry Fields.

Fill **Crop begin** and/or **Crop end** fields with number of digits to remove from Beginning and/or End of **Scanned Barcode**.

Note: For **Patient ID**, Barcodes will be rejected if not the correct length after cropping.

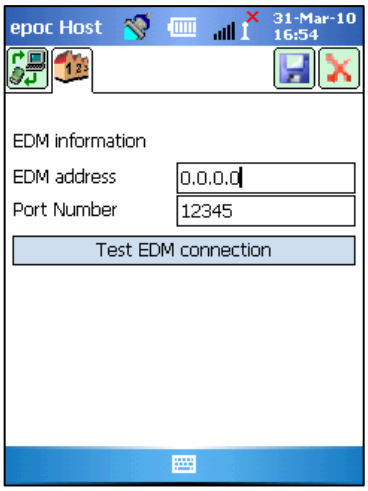
Select **one or more Checkboxes for barcode symbologies** to apply selected symbologies to a particular **Field Type**.

Always press **save** Button  after making any changes for changes to be effective.

7.9 EDM Options Page

Use **EDM options** Page to set up connection to the epoc Data Manager (EDM). Indicate 'Yes' or 'No' as appropriate. If 'Yes', set correct IP Address and Port Number for EDM Server location. IP Address must be set using format XXX.XXX.XXX.XXX and Port Number value must be between 1 and 65535.

Tap **EDM options** Page from **Tools** Menu to begin.



Always press **save** Button after making any changes for changes to be effective.

7.10 Card Options Pages

Use **Card options** Pages 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 corresponding with Reference Ranges in Test Card Specifications. **Default Critical Ranges** are factory set to values outside the reportable ranges. This effectively disables the default critical Ranges.

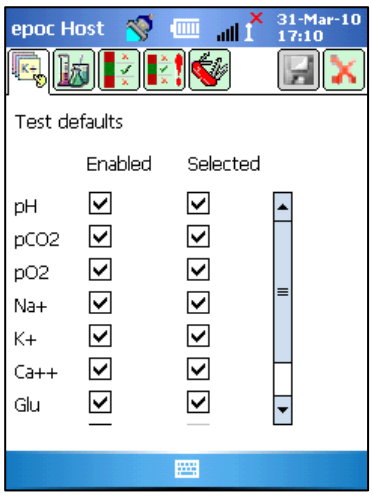
Tap **Card options** Page from **Tools** Menu to start. Press Tabs at top of Screen to navigate between five (5) pages of options available.

Always press **save** Button after making any changes for changes to be effective.

7.10.1 Test Selection Settings Page

Select Test Selection Settings Page Tab to **enable / disable** or **select / deselect Analytes for 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.

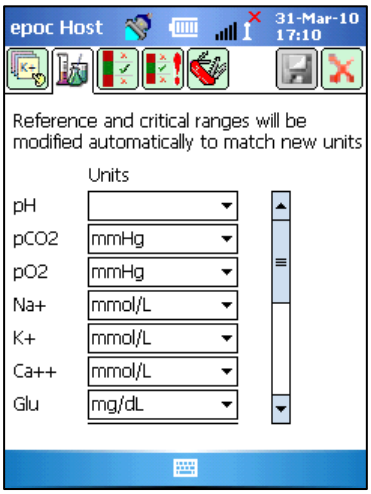
Selected – Choose Analytes to initially default as "Selected" when running a test.

Enabled / Not Selected – Analyte is available, but must be selected during Test to provide Test Result.

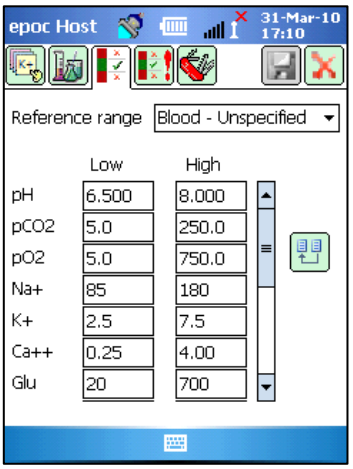
7.10.2 Units Settings Page

Select Units Settings Page Tab to set **Analyte Units of Measurement**.

Select appropriate units from Drop-down Box beside Analyte. Values of Reference Range are automatically converted to correspond with the new Units of Measure.



7.10.3 Reference Ranges Settings Page



Select Reference Ranges Settings Page Tab to set **Reference Ranges**.

Select appropriate **Sample Type** from Reference Range Drop-down Box.

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

To change Low or High Reference Range value, tap **Text Field** where value is displayed. **Highlight and edit values** using Text Input Keyboard.

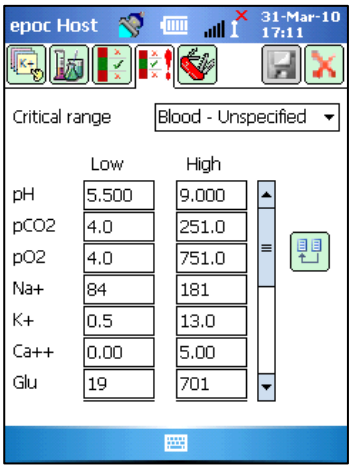
When changes are complete, tap **save** Button to retain changes. If values are outside of allowable Range, a Warning Notice appears with Allowable Range Values.

Transfer values to other Sample Types using Transfer Button . Tap Transfer Button and from Dropdown Box, select range of values to copy. Tap **copy** and **save**.

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

Factory set values for the normal ranges for each Analyte are based on values specified for Arterial Blood Sample in BGEM Test Card Specifications.

7.10.4 Critical Ranges Settings Page



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

Select Critical Ranges Settings Page Tab to set **Critical Ranges**.

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
Ca++	0.00	5.00	mmol/L
Glu	19	701	mg/dL
Lac	0.00	21.00	mmol/L
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	%

Select appropriate **Sample Type** from Critical Range Drop-down Box.

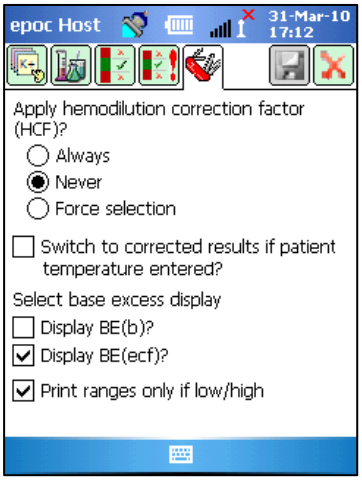
Use the **Scroll Bar** to view information not displayed on Screen.

To change Low or High Critical Range value, tap **Text Field** where value is displayed. **Highlight and edit values** using Text Input Keyboard.

When changes are complete, tap **save** Button to retain changes.

Transfer values to other Sample Types using Transfer Button . Tap Transfer Button and from Dropdown Box, select range of values to copy. Tap **copy** and **save**.

7.10.5 Test Settings Page



Select Test Settings Page Tab  to edit **Test Settings** options.

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

Note: Refer to **Measurement Method** in Theory of Operation section and **Hematocrit section** of Test Card Specifications for details on Hematocrit measurement.

Select **Switch to corrected results if patient temperature entered?** option to display Temperature Corrected Results Tab on **Test Results** Page first. (Measured Results Tab is always available for viewing uncorrected results).

Select **Display BE(b)** and/or **Display BE(ecf)** to determine Base Excess Results to display when running a Test. (At least one must be selected).

Select **Print ranges only if low/high** if, on thermal printer printouts from epoc Host, it is desired to shorten the length of the printout by only displaying ranges where a result has flagged outside of its range.

7.11 Personal Options Page

Use Personal Options Page  to **change Administrator Password**.

Page is not available if using EDM. In this case, Administrator can change password using EDM. Changes are effective with next EDM synchronization.

Access Personal Options Page from **Tools Menu**. Enter **Old and New Passwords**. Enter new Password again in **Verify field**. Press **save** Button to retain changes.

7.12 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 Support 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 epoc Data Manager to automatically send the upgrade to epoc Host when it is synchronized, whereupon epoc Host then upgrades after next logout.

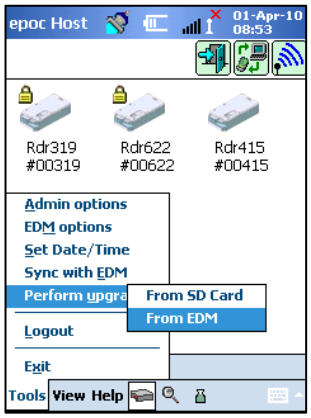
The rest of this sub-section describes Software Upgrades when not using this Automatic Upgrade feature.

The System Administrator 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.

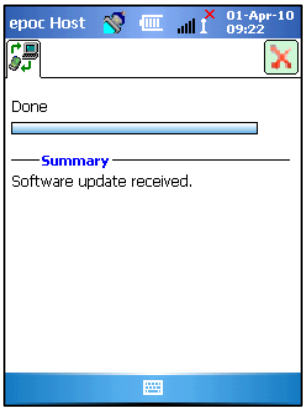
7.12.1 Perform Upgrade from EDM

When using EDM to upgrade, the EDM present setting in the Host must be set to 'Yes' and proper upgrade file must be uploaded to EDM first.

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



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



7.12.2 Perform Upgrade from SD Card

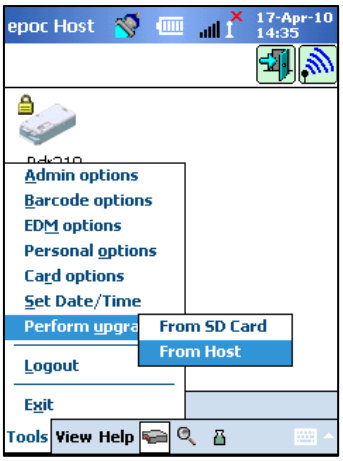
SD Card Slot is located at Top end of epoc Host, in front of Barcode Scanner slot. Carefully remove Barcode Scanner to access SD Card Slot. (See Section 6 for information on removing Host's cradle to gain access to SD slot).

Insert the SD Card (containing the correct upgrade file) into the SD Slot. Then select **Perform Upgrade** and **From SD Card** on **Tools Menu** and follow prompts.

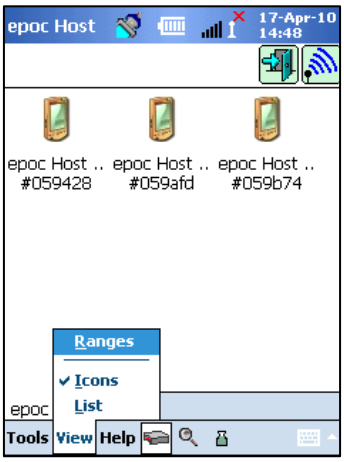
The upgrade process will then proceed (similar to From EDM method).

7.12.3 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.

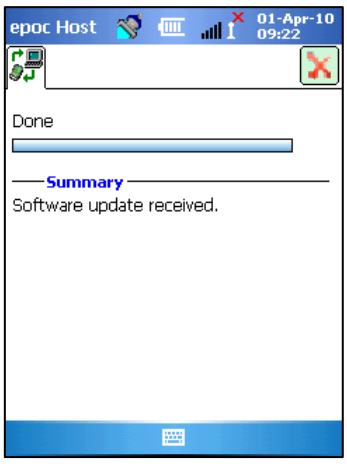


Then select **Perform Upgrade** and **From Host** on **Tools Menu**. The epoc Host will immediately begin to discover other epoc Hosts in the vicinity via Bluetooth. As they are discovered, they will become listed as below. Select **View List** to see full name of Host if required.



Tap and Hold (or double tap) the Host you wish to upgrade from and follow prompts.

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



When the epoc Host upgrade is completed, the version number may be verified from the Login screen (lower right) or from **Help About** menu after logging in.

If Upgrade includes epoc Reader, epoc Host is now able to upgrade Readers using Reader Configuration function described later in this section of the manual.

7.13 Set Date, Time and Time Zone

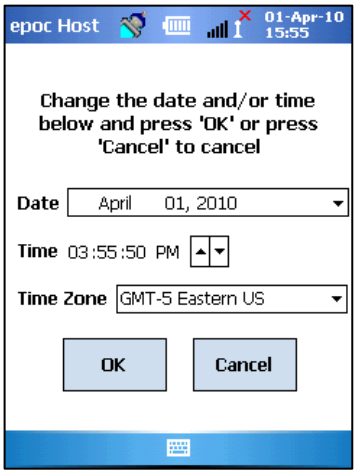
Not applicable when using EDM. EDM updates Date and Time in epoc Host during synchronization. Any changes made on Host will be over-written with during synchronization.

Administrator can change Date and Time settings from Tools Menu by selecting **Set Date/Time**.

Use Drop-down 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 Test is completed.

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

Always verify Host reports correct Time and Date after:

1. Change to/from Daylight Savings Time.
2. Performing a Hard Reset.

7.14 Reader Identifiers

There are three (3) Identifiers for epoc Readers:

1. Serial Number
Serial Number is a fixed, factory set five (5) Digit Number unique to each Reader. Reader Serial Number always displays in epoc Host software Application to identify Reader. Reader Serial Number is permanently labeled on Nameplate on Reader Bottom.

2. Name
Reader Name is a custom Name to identify a Reader. It can be changed by the Administrator. Reader Name is factory set to default one corresponding with Reader Serial Number. Reader Name can be up to 17 Alphanumeric Characters in length, including spaces. Use Reader Name to establish Reader Names meaningful for usage such as selecting a name that describes Reader location, e.g. Department Name, Ward Name, Room Number, etc. After customizing Reader Name, use Reader Name Labels supplied with Reader, to label Reader with new Reader Name to allow for visual Reader identification.

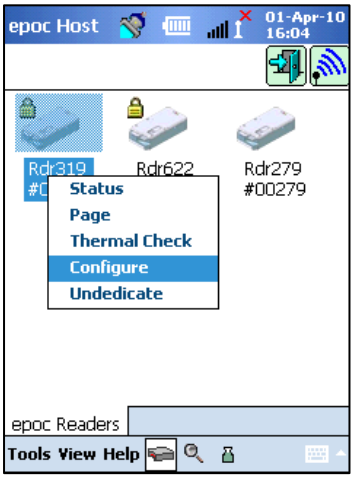
3. PIN (Bluetooth)

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

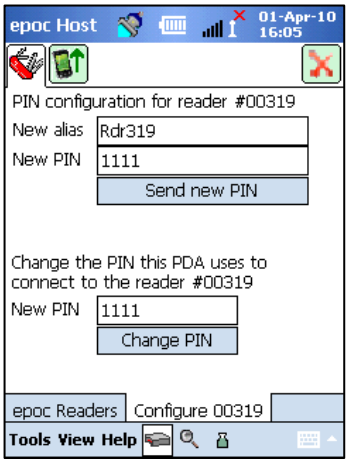
7.15 Reader Configuration and Reader Software Upgrade

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

To access Reader Configuration Pages go to **Main Readers Screen**. Press and Hold a **discovered Reader** with Stylus until **Options Menu** for selected Reader appears. Tap **Configure** from Menu. Reader Configuration Screen for selected Reader appears.



7.15.1 Reader Configuration Page



Use Reader Configuration Page to change **Reader PIN** and **Reader Name**.

Use upper Screen to send Name and PIN data to a Reader.

Use lower Screen to change Reader PIN in Host being used.

To change Reader Name of a Reader, enter the desired name in the **New Name** field and tap **Send new PIN**. The Name will be sent to the Reader.

To **change Reader PIN**, enter new PIN in **New PIN** field **(Upper Screen)** and tap **Send new PIN**. New PIN is sent to Reader. Only Host used to change Reader PIN is updated with new PIN. Update other Hosts using procedure below.

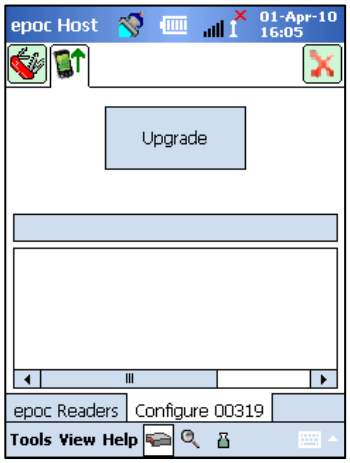
To **change Reader PIN in other Hosts**, use other Host to Discover Reader (with changed PIN). Navigate to Reader Configuration Screen as previously described. Use New PIN field **(Lower Screen)** to **enter new PIN**, and tap **Change PIN**. Repeat this process for all remaining Hosts required to connect to this Reader.

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

If the Reader PIN is changed and new PIN misplaced, it is not possible to retrieve new PIN to communicate with Reader.

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

7.15.2 Reader Software Upgrade Page

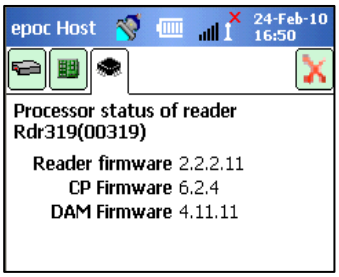


Administrator uses Reader Upgrade Page to update epoc Reader software.

Press **Upgrade** Button.

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

Never interrupt Reader Upgrade process. Do not switch 'OFF' Reader or Host during Upgrade.



Reader version is confirmed by performing Reader Status (third tab):

7.16 Dedicating Readers

Administrator has option of “dedicating” specific Readers to an epoc Host.

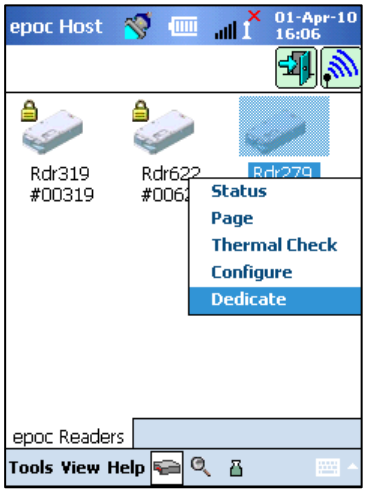
Dedicated Readers always display on Main Readers Screen of epoc Host (regardless of whether or not they are turned on).

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

Press and hold on Reader Icon until new Menu appears.

Tap Dedicate on Menu.

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



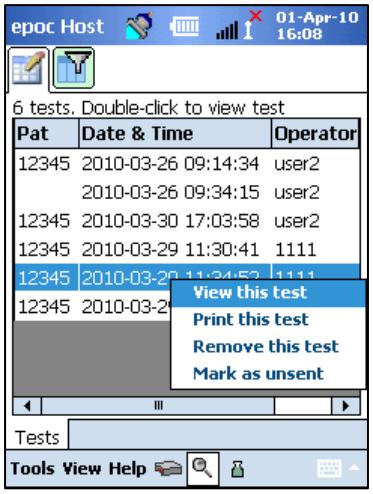
To un-dedicate, follow same steps as above. Tap **Un-dedicate** when new Menu appears**.**

7.17 Test Record Administration

Administrator can permanently **delete a saved Test Result** or **mark a Test Result as unsent** (to re-send to EDM) from epoc Host.

Tap **Viewing Tests Mode** Button from Toolbar. List Page appears showing **Test Results** stored on Host. Use **Filter Page** to narrow results as required.

Press on **Test Result Row** to open Menu. Tap **Remove this test** to **permanently delete Test Result**. Tap **Mark as unsent** to **resend Test Record to EDM** upon next synchronization. Confirmation Window appears. If deleting record, proceed only if sure about record deletion.



Electronic QC records are deleted in similar manner. First navigate to **Viewing Electronic QC Mode** from Toolbar. Remainder of procedure is same as above.

Deleting a saved Test Result or Electronic QC Record is permanent. Deleted records can not be recovered after deletion.

08 epoc Data Manager

8.1 Introduction

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

8.2 Deployment

The computing platform of the epoc Data Manager is an Intel x86 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: Intel-based 2.4 GHz or faster recommended.

Memory: 2 GB or more recommended

Network interfaces: Ethernet 10BASE-T, 100BASE-T or 1000BASE-T network adapter, optionally 802.11 wireless network adapter

Software:

Operating System: Microsoft Windows Server 2003 R2 or Microsoft Windows XP with Service Pack 2 (or later service pack) operating system.

Application Framework: Microsoft .Net Framework 2.0

Database Server: Microsoft SQL Server Standard or Express Edition

Web Server: Microsoft Internet Information Services 6.0 (Server 2003) or 5.1 (XP)

Internet Browser: Microsoft Internet Explorer 6 or newer for Windows XP Service Pack 2 (or later service pack)

8.4 Installation

All hardware and software requirements have to be met prior to installing the epoc 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 2005 Standard or Express Database engine. The relational database solution, along with properly designed data schema offers reliable, high performance data store, regular backups and controlled access.

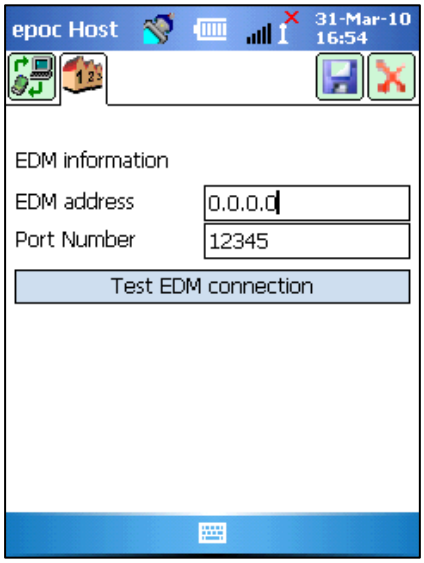
The epoc Database stores test results, Electronic QC statistics, Usage Statistics data and Operators Statistics data. Stored data is accessible for user view via the epoc Manager Web Application.

When EDM is installed in a enterprise networked environment, IT personnel are asked to arrange for adding 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 epoc Data Manager. A single installation of epoc Link supports up to 5 connection points (identified by IP address 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 setup 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 and Port number) of the epoc EDM PC. The Screenshot from the epoc Host illustrates the connection settings for the epoc Data Manager on the epoc Host.

8.7 Using EDM Web Application

Scope

The epoc Data Manager is an ASP .NET 2.0 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 (Internet Explorer 6.0 or higher).

Starting epoc Data Manager

The epoc Data Manager is setup to start automatically on the EDM – PC, along with the start of IIS and the default website.

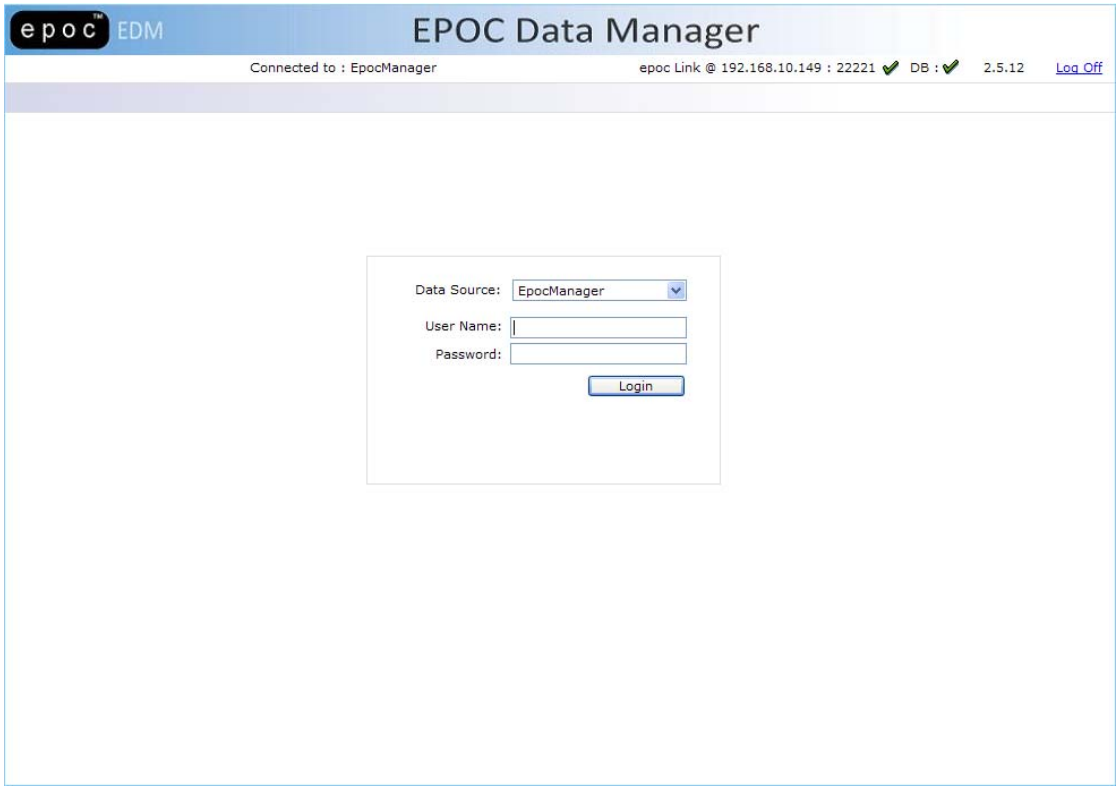
Users can access the EDM Web Application from any computer connected to the LAN, using the EDM's URL.

Notes: 1. Windows XP Professional implements an IIS limitation of maximum 10 simultaneous connections.

2. System Administrator can restrict access to EDM to specific computers.

Login Page

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

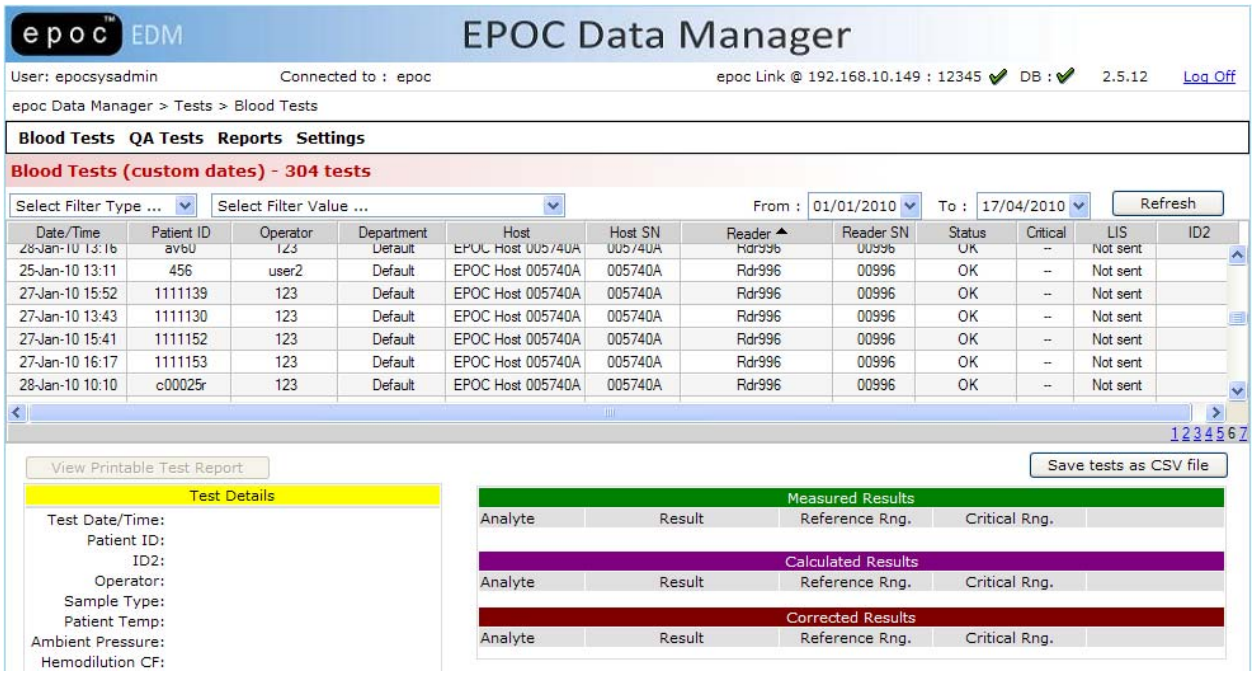


8.8 View / Update Tests Page

After a successful login, EDM displays View Tests Page including:

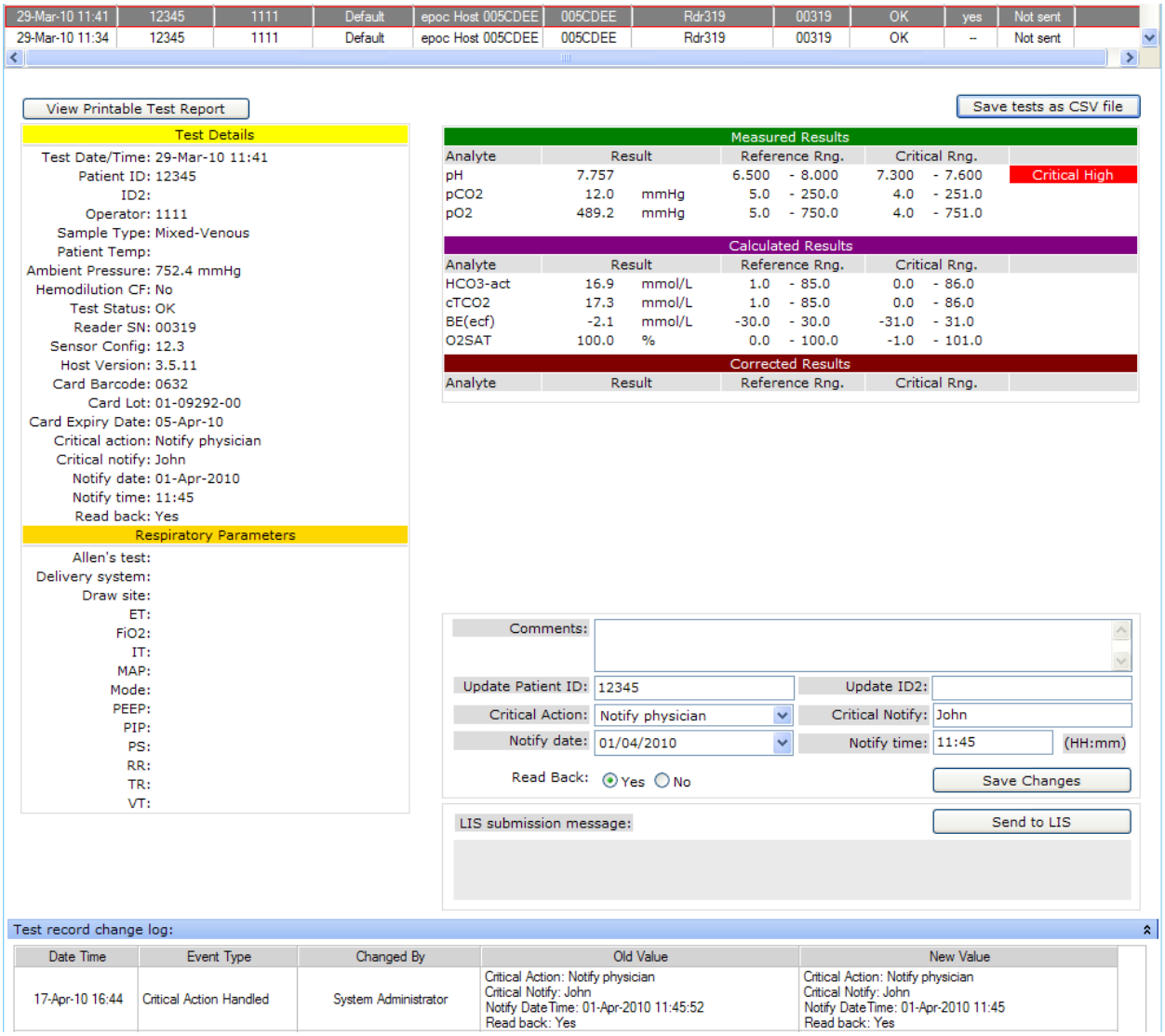
1. Menu Banner near top of Screen.
2. Main Scrollable Table displaying all blood tests and a single test Area with Test Details.
3. Measurement Results, Calculated Results and Temperature Corrected Results.

The Single Test Area is populated with data only if User selects a Test from the Main Table.



To select Single Test Details, click on the row of the desired Test. Test Details are displayed below the table containing Multiple Tests.

Users can **update** Comments, Patient ID, ID2 fields and critical handling by editing fields and pressing **Save Changes** Button. Every change is logged in the **Test record change log** beneath the Test details.



If configured for interface, users may re-send a Test by pressing **Send to LIS Button**. Users must obey all interface rules when doing this.

8.9 Filtering Results In The View Test Page

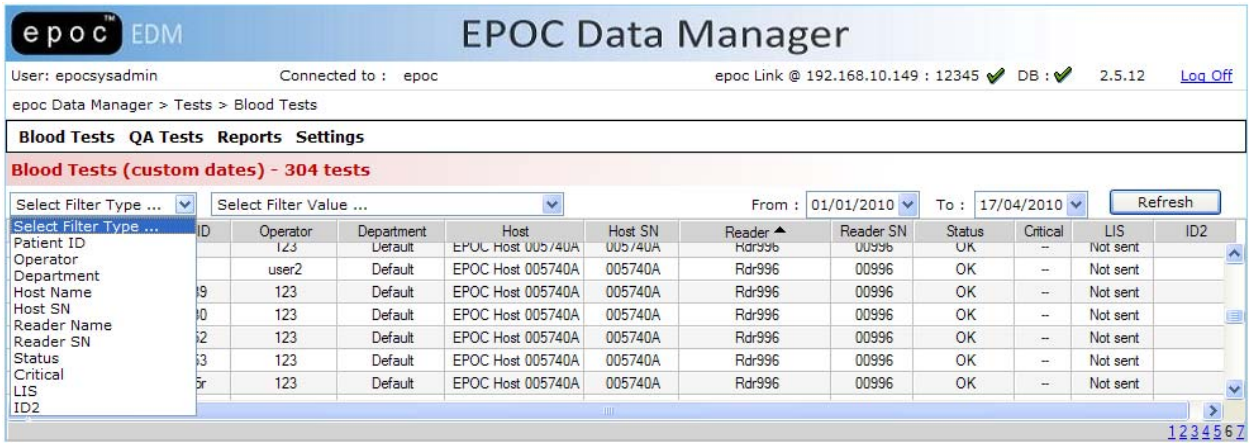
Use one or more of the following methods to filter Test Results in the Main Table:

Click on any of the Column Headers of the Table to order records based on the column content. Click on same Column Header to change order of results to ascending or descending.

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

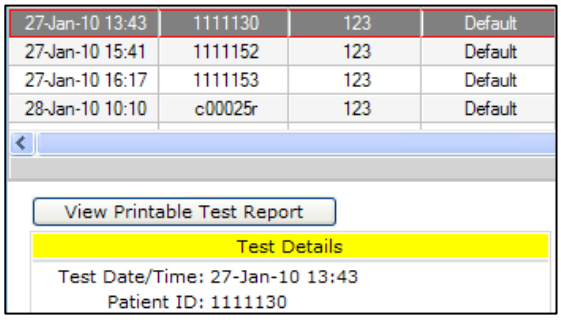
The EDM allows for advanced filtering:

All columns of the Main Tests Table can be used as filters. Users can select a value from the filter type values existing in the database to narrow displayed Test Results to those with only selected attributes.

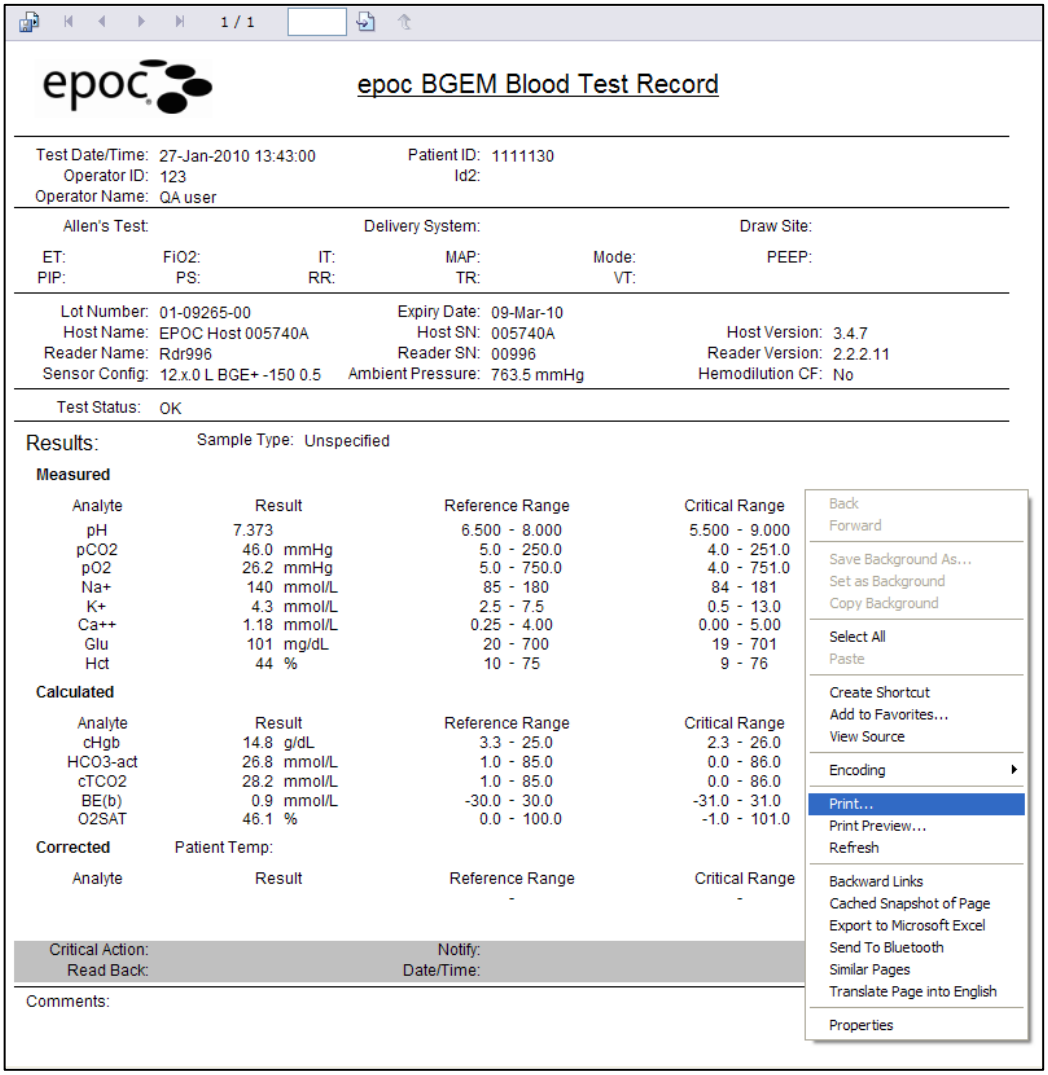


8.10 Printing

Press **View Printable Test Report Button** to display a printable view of a single Test Record.



A new Window opens with a Printable Test Record. Right click over the report and select **Print…** from Context Menu. See sample Test Record below.



epoc BGEM Blood Test Record

Test Date/Time: 27-Jan-2010 13:43:00 Patient ID: 1111130
Operator ID: 123 Id2:
Operator Name: QA user

Allen's Test: Delivery System: Draw Site:

ET: FiO2: IT: MAP: Mode: PEEP:
PIP: PS: RR: TR: VT:

Lot Number: 01-09265-00 Expiry Date: 09-Mar-10
Host Name: EPOC Host 005740A Host SN: 005740A Host Version: 3.4.7
Reader Name: Rdr996 Reader SN: 00996 Reader Version: 2.2.2.11
Sensor Config: 12.x.0 L BGE+ -150 0.5 Ambient Pressure: 763.5 mmHg Hemodilution CF: No

Test Status: OK

Results: Sample Type: Unspecified

Measured

Analyte	Result	Reference Range	Critical Range
pH	7.373	6.500 - 8.000	5.500 - 9.000
pCO2	46.0 mmHg	5.0 - 250.0	4.0 - 251.0
pO2	26.2 mmHg	5.0 - 750.0	4.0 - 751.0
Na+	140 mmol/L	85 - 180	84 - 181
K+	4.3 mmol/L	2.5 - 7.5	0.5 - 13.0
Ca++	1.18 mmol/L	0.25 - 4.00	0.00 - 5.00
Glu	101 mg/dL	20 - 700	19 - 701
Hct	44 %	10 - 75	9 - 76

Calculated

Analyte	Result	Reference Range	Critical Range
cHgb	14.8 g/dL	3.3 - 25.0	2.3 - 26.0
HCO3-act	26.8 mmol/L	1.0 - 85.0	0.0 - 86.0
cTCO2	28.2 mmol/L	1.0 - 85.0	0.0 - 86.0
BE(b)	0.9 mmol/L	-30.0 - 30.0	-31.0 - 31.0
O2SAT	46.1 %	0.0 - 100.0	-1.0 - 101.0

Corrected Patient Temp:

Analyte	Result	Reference Range	Critical Range
		-	-

Critical Action: Notify:
Read Back: Date/Time:

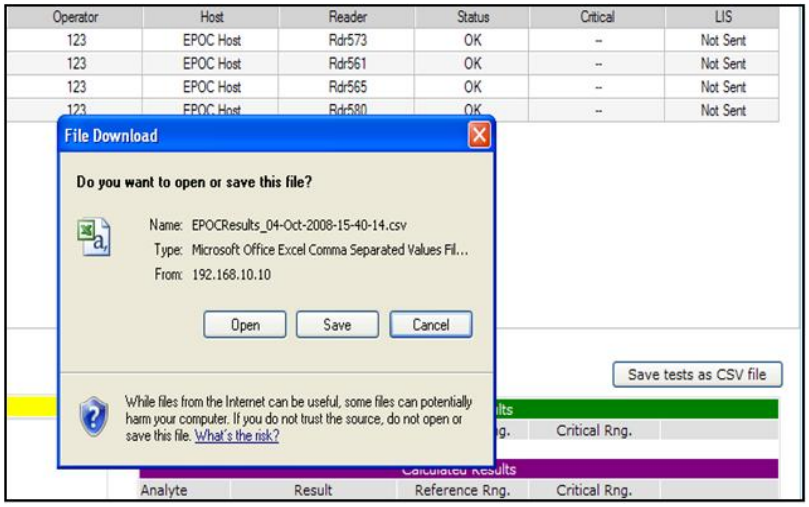
Comments:

8.11 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 **View Tests Page**, through the **Save Tests as CSV file Button**. All Tests from the Main Tests Table are exported to a .csv file.

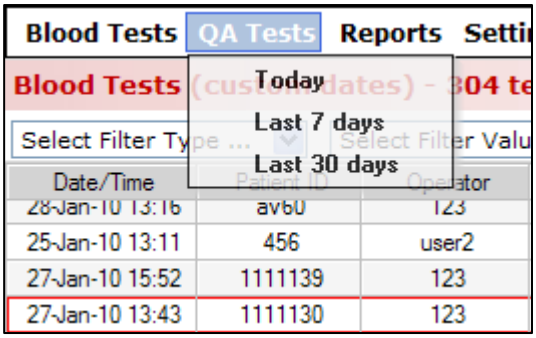
User can Open the file, inspect and print it. The **Save Button** opens a Windows File Save Dialog. User may choose the desired location to save the file on the local hard drive.

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



8.12 QA Tests

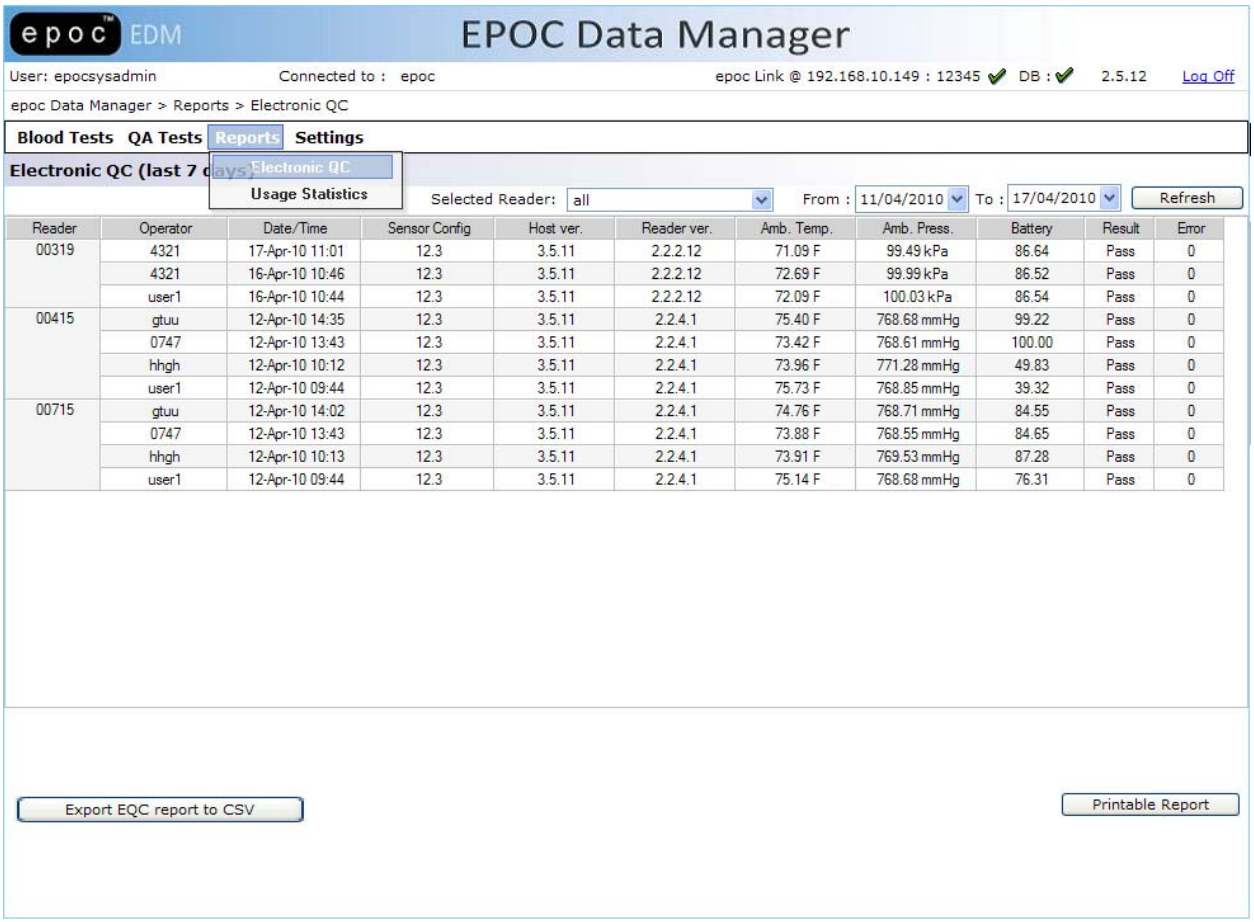
From the **Top Menu**, select **QA Tests** to view. Features for viewing, editing, printing and exporting, function in the same manner as for Blood Tests.



8.13 Electronic QC Page

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 for 3 different Readers: it data can be printed by first generating a **Printable Report** or exported to CSV using the **Export EQC report to CSV button** (same as printing or exporting Blood Test records).

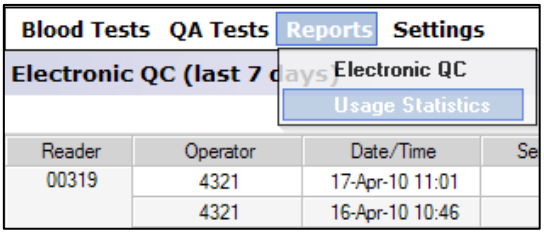


8.14 Usage Statistics Page

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

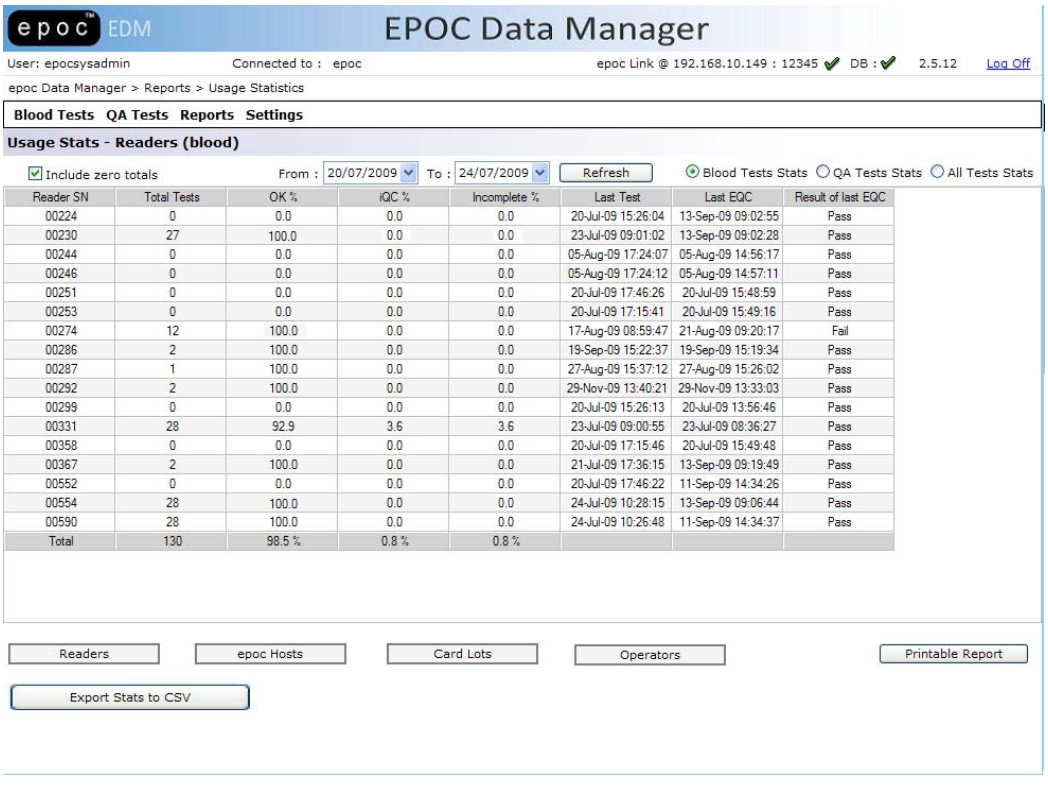
These reports include the following information:

1. 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 last Test performed by Operator.



Data may be filtered by Date, Blood Tests only, QA Tests only, and by All Tests. Reports may generated by selecting **Printable Report Button** or **Export Stats to CSV** at bottom of Page.

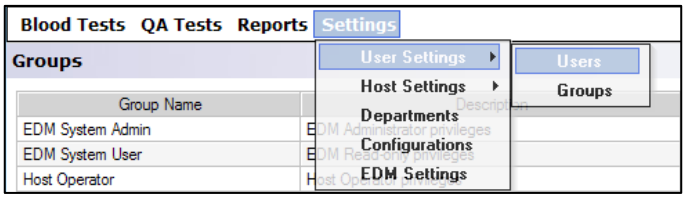
Select appropriate Button at Page bottom to create Views for different System Elements.



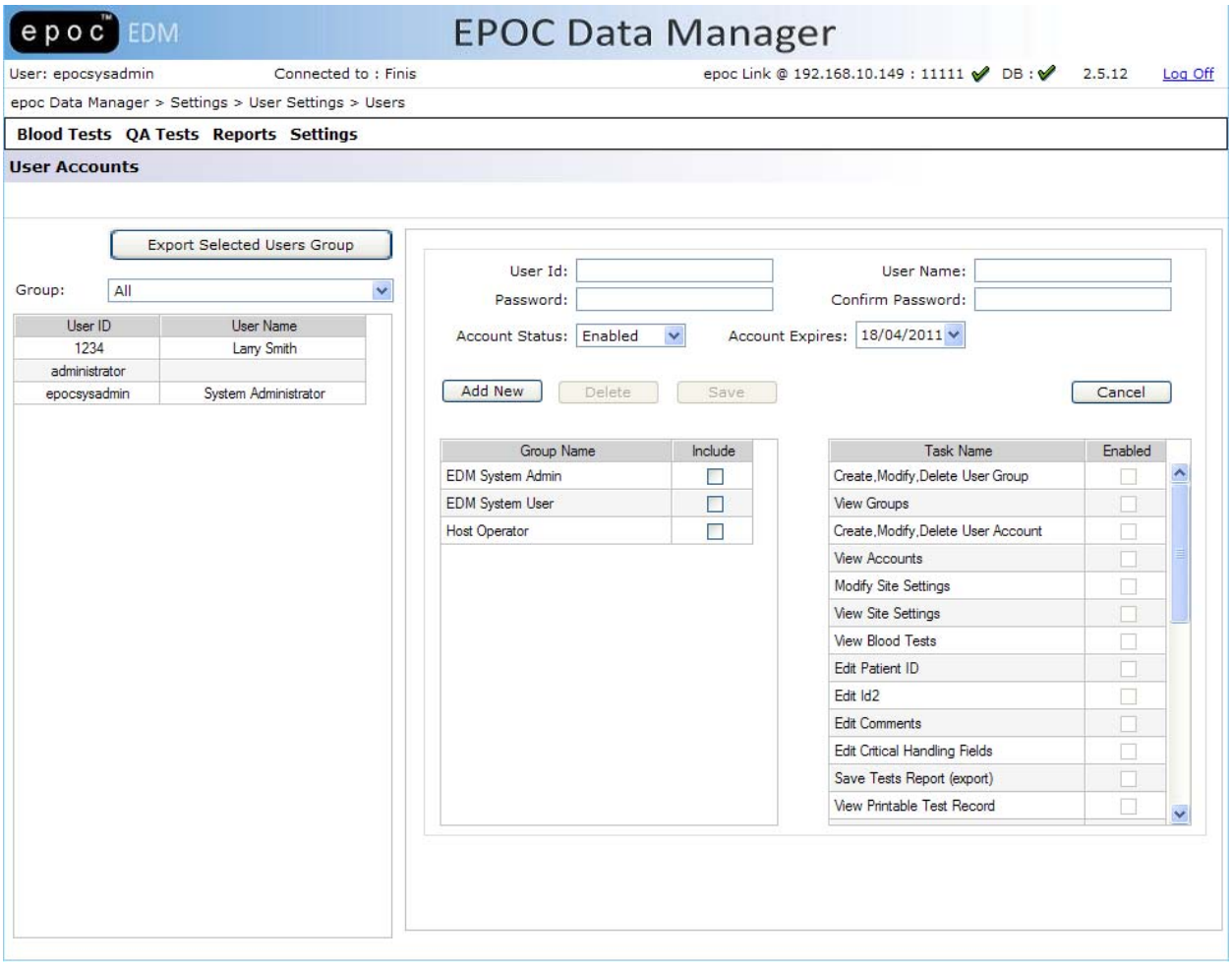
8.15 Users Page

The **Users** page allows making additions and modifications to user accounts for epoc Host and EDM.

The Users page can be accessed from the Top Menu by selecting **Settings** then **User settings** then **Users**.



Users page:



To **add** a new user, type the appropriate information for User Id, Full Name, Password, Confirm Password, Account Status, and Account Expiry. Check appropriate Group Name(s) corresponding to the user's permissions for various tasks. More than one group may be checked. Groups may be customized using the User Settings Groups page (see next section). The User Id will be used for Login for both epoc Host and EDM. When all information is entered, press "Add New". When the new user is created, they appear in the table on the left.

To **delete** or **modify** a user's account, select the user from the table to the left. The user's information will appear in the appropriate locations, the "Delete" and "Save" buttons become enabled, and the "Add New" button becomes disabled.

The user account is deleted by pressing "Delete".

After making changes, a user account is modified by pressing "Save".

Press "Cancel" to exit **delete** or **modify** mode and return to **add** new.

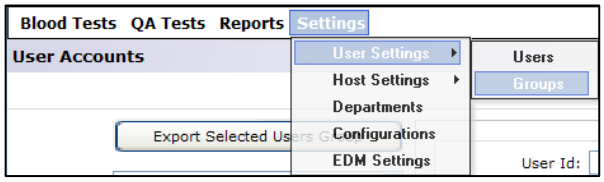
The table on the right, displays a selected user's permissions.

The dropdown labeled "**Group:**" allows the list to be filtering by selected group. The selected group (or All) may be exported to CSV format by pressing the **Export Selected Users Group** button.

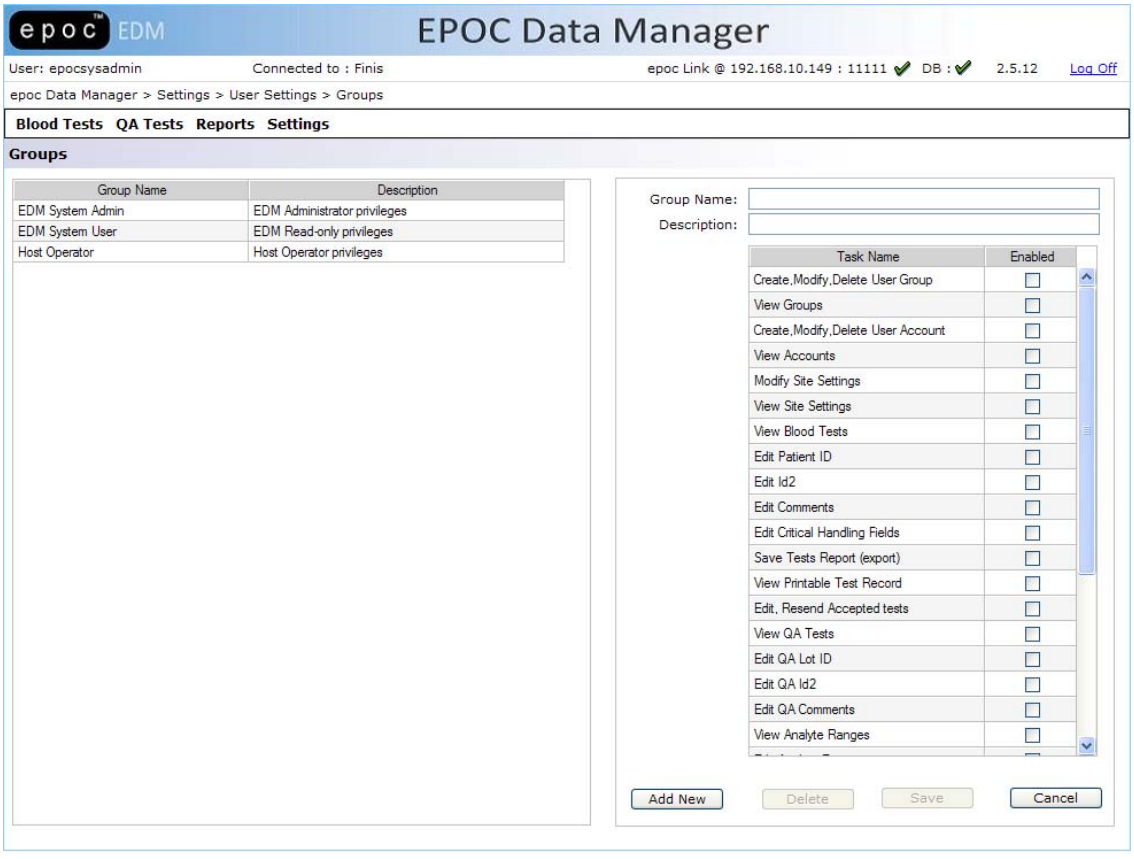
8.16 Groups Page

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 Groups Page from Top Menu. Select **Settings**, then **User settings** and then **Groups**.



Groups page:



Type in Group Name and Description to **Add New Group**. Check applicable Task Names for Group. When finished, press **Add New** Button. Once Group is created, Group Name and Description appear in Table at left side of Page.

Select Group from Table to **Delete** or **Modify** Group. Group Name and Description appear in appropriate locations at right side of Page together with applicable Task Names checked. **Delete** and **Save** Buttons are now enabled. **Add New** Button is now disabled.

Group is deleted by pressing **Delete** Button.

After making changes, press **Save** Button to keep changes.

Press **Cancel** Button to exit **Delete** or **Modify** mode and return to **Add New**.

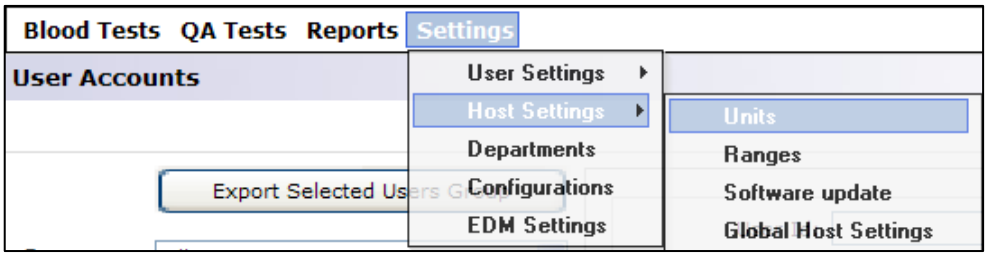
The following EDM Tasks can be enabled to assign specific Permissions:

Create,Modify,Delete User Group	Edit Critical Handling Fields	View Analyte Units
View Groups	Save Tests Report (export)	Edit Analyte Units
Create,Modify,Delete 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 Hosts 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

8.17 Host Settings

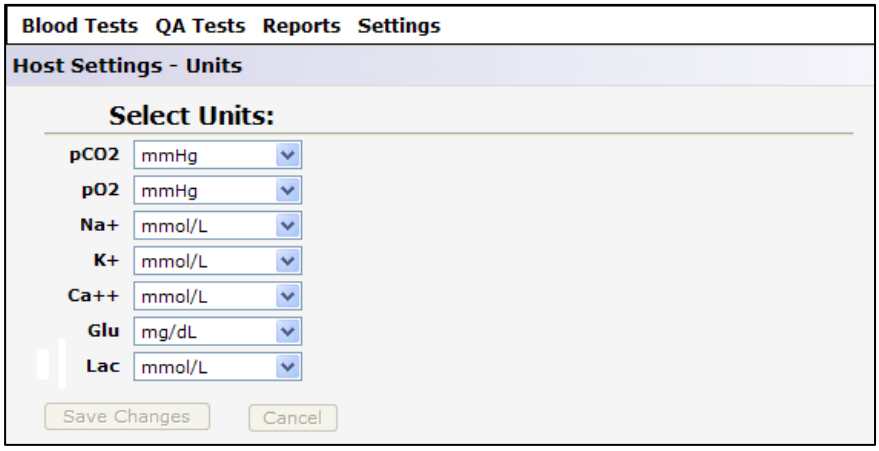
Manage epoc Host configurations on **Host Settings Pages**. There are separate pages for setting Units, Ranges, loading Software updates, and Global Host Settings. Once configured, these settings are automatically sent to epoc Host each time synchronization occurs.

Host Settings Pages are accessed from the Top Menu. Select **Settings**, then **Host Settings**, then **Units**, **Ranges**, **Software update** or **Global Host Settings**.



8.18 Host Settings - Units

To modify **Units of Measure** select required Units from **Dropdown List** and then press **Save Changes** Button. All Range Values are now displayed using new Units.



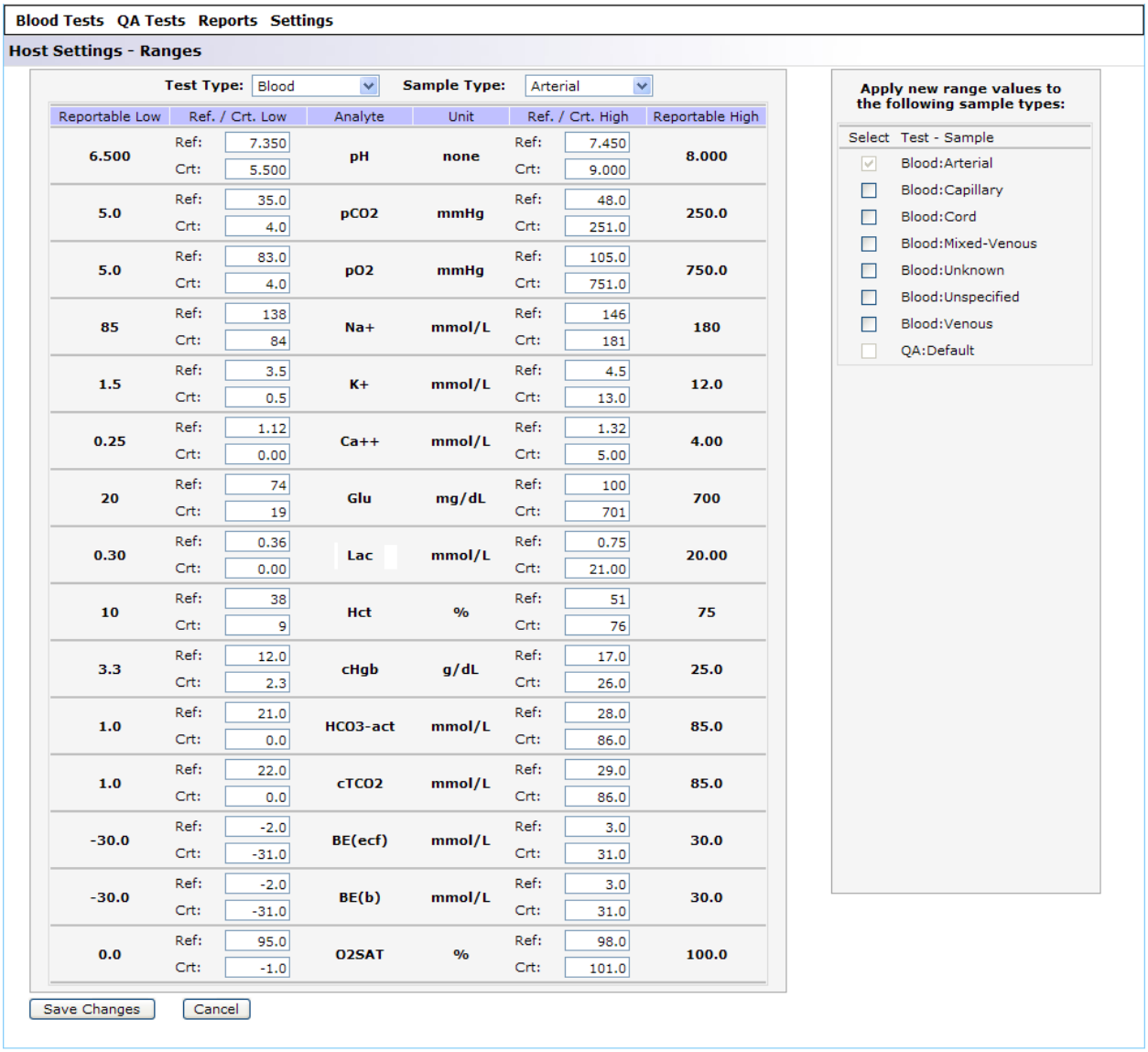
8.19 Host Settings - Ranges

Ranges Page displays Reference and Critical Ranges for all Analytes, for selected Test and Sample Type.

To change Range Values, select 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 at right of Main Range Values Table.

Rules for modifying Range Values:

1. All values must be numerical.
2. Each value must be entered with expected precision (as displayed in the table).
3. Reference Range values must not fall outside of Reportable Range values.



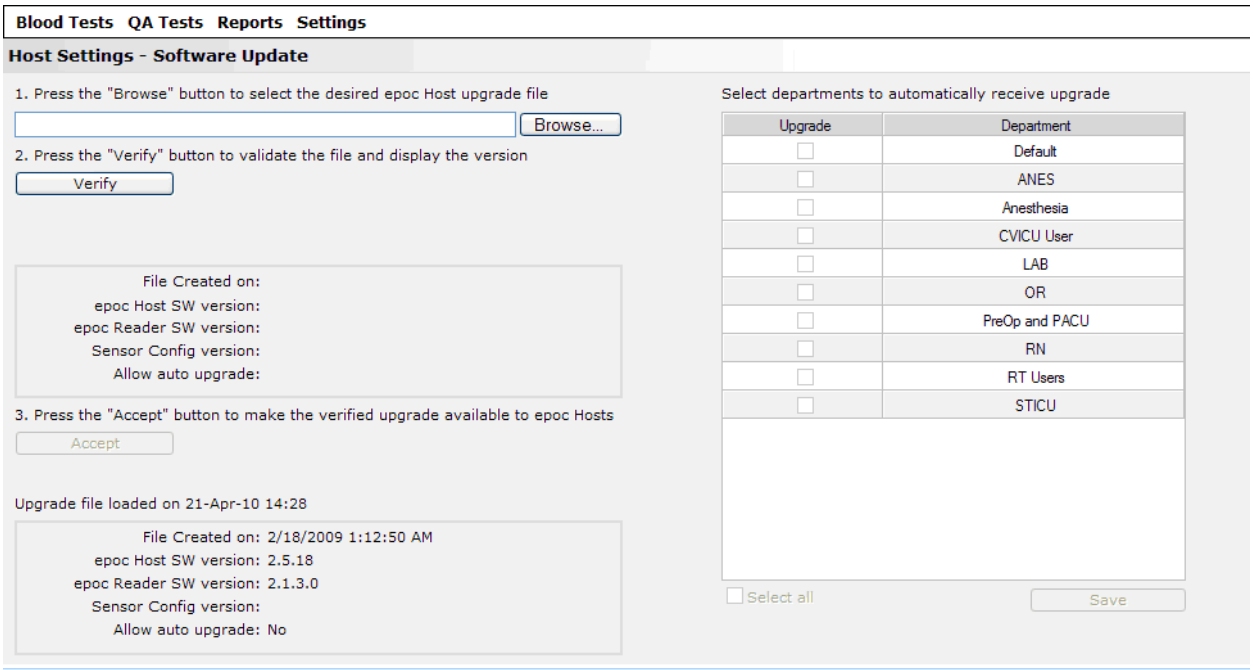
8.20 Host Settings—Software Update

Use **Software Update Page** to upload Software Updates for epoc Host and Reader.

1. Press **Browse** Button to select Upgrade File supplied by Epocal representative. When file is selected, File Path is displayed.
2. Press **Verify** Button to upload File to the server. If file contains valid Software Update, Host and Reader Update Version is displayed below **Verify** Button.
3. Press **Accept** Button to accept File
4. The new Software Update is now available to be uploaded to each epoc Host. See epoc Host Administration Section of this manual for details about performing Software Upgrades on epoc Host.

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

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



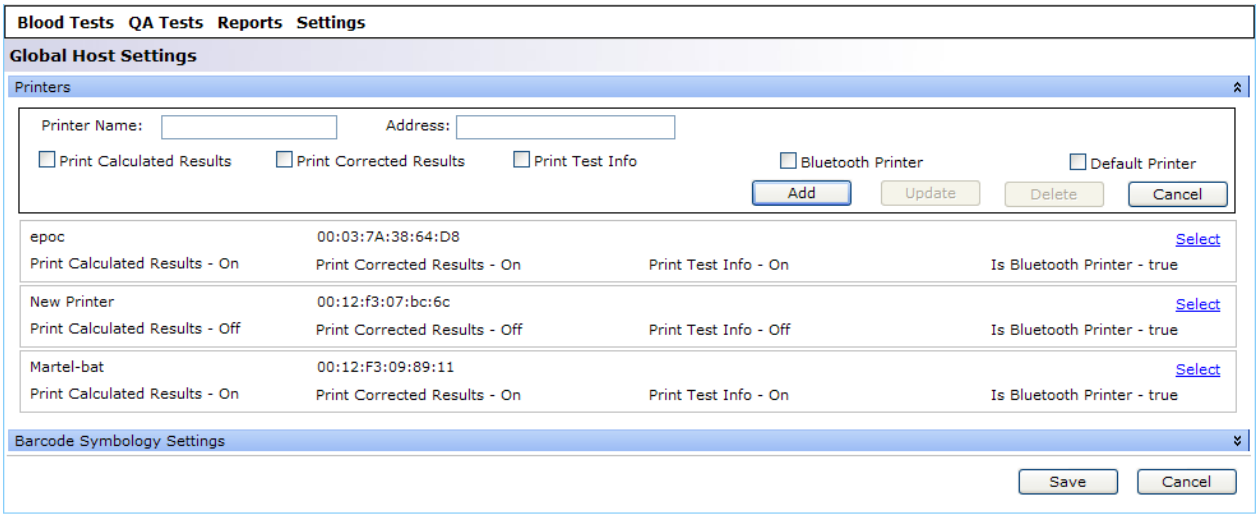
8.21 Host Settings—Global Host Settings

*Note – there are a number of **Host Settings** that may be **configured uniquely** and sent to specific Hosts assigned to specific **Departments**. See subsequent topics for configuring certain Host Settings for specific Departments. The **Global Host Settings** described here (including Units, Ranges, and Software updates described previously) apply globally to all Hosts in all Departments.*

There are two (2) Sections of **Global Host Settings** Page for configuring epoc Host settings: **Printers**, and **Barcode Symbology Settings**.

Each Section is expanded or hidden by pressing Arrows ⌃ ⌄ at right of Section Heading.

Example below shows **Global Host Settings** Page with Printers expanded and Barcode Symbology Settings hidden:



Settings changes are applied by pressing **Save** Button at bottom of Page.

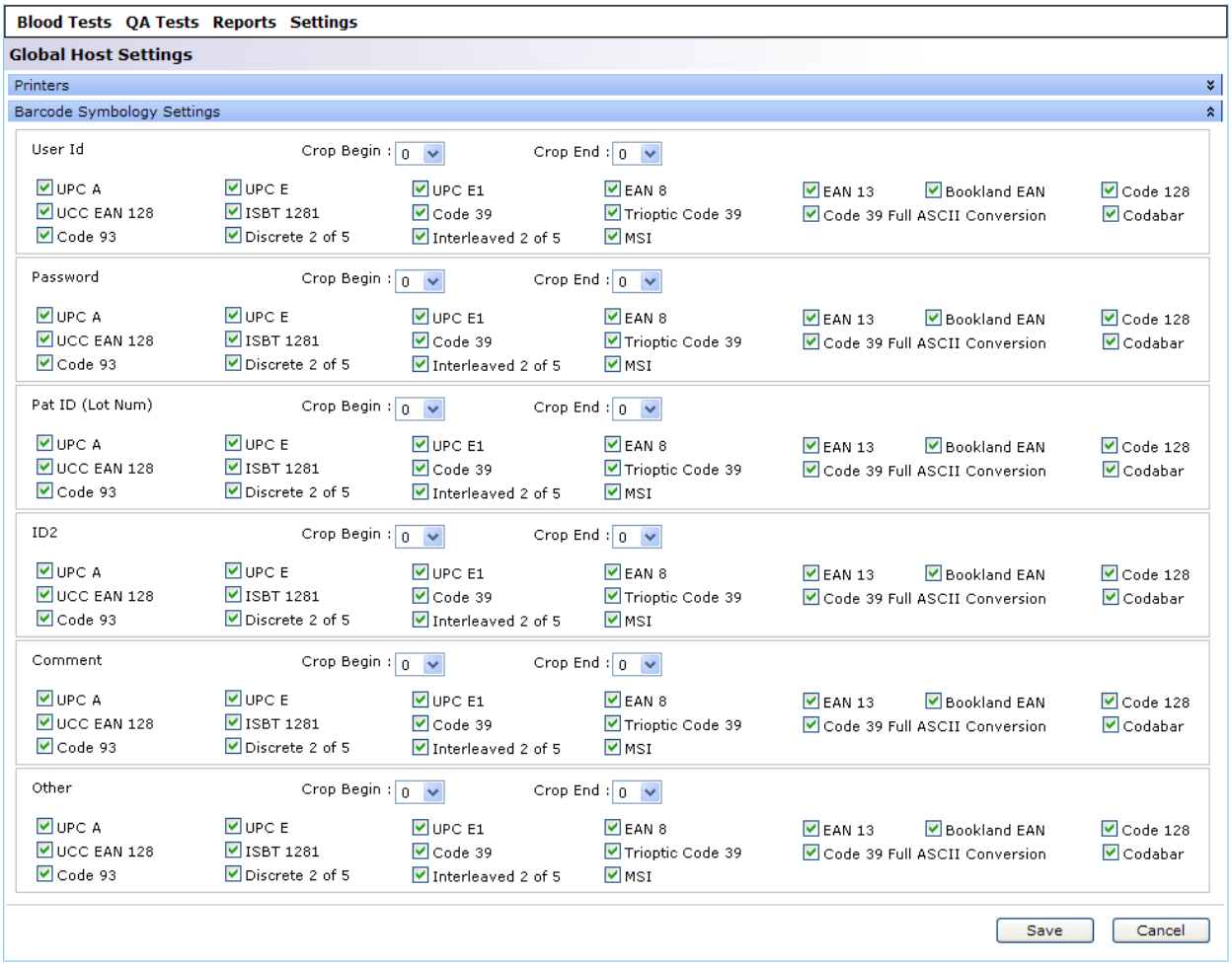
To use Default Tests from EDM, **Send Test selection to Host** Box must be checked. When un-checked, default Tests are set individually on each epoc Host.

To **add** a new Printer, enter Printer Name and Address, select appropriate Check Boxes and press **Add** Button. Printer is added to Printer List below (not shown).

To **Update** or **Delete** a Printer, select Printer from Printer List, make applicable changes, and press **Update** or **Delete** as appropriate. Once all printers are added, updated or deleted, again press **Save** Button to save all changes.

Example below shows **Global Host Settings** with Barcode Symbology Settings expanded.

Barcode Symbology Settings may be entered for five (5) epoc Host data entry fields: (User Id, Password, Pat ID or Lot Num, ID2 and Comment) and for all 'Other' Host fields.

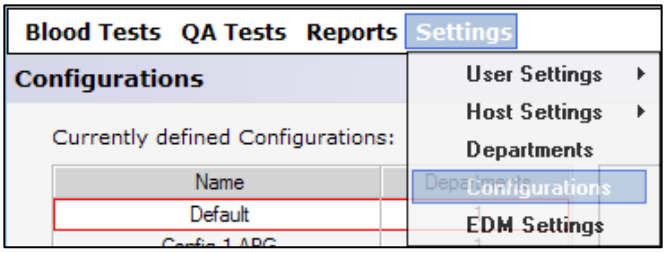


Press **Save** Button after finished making changes.

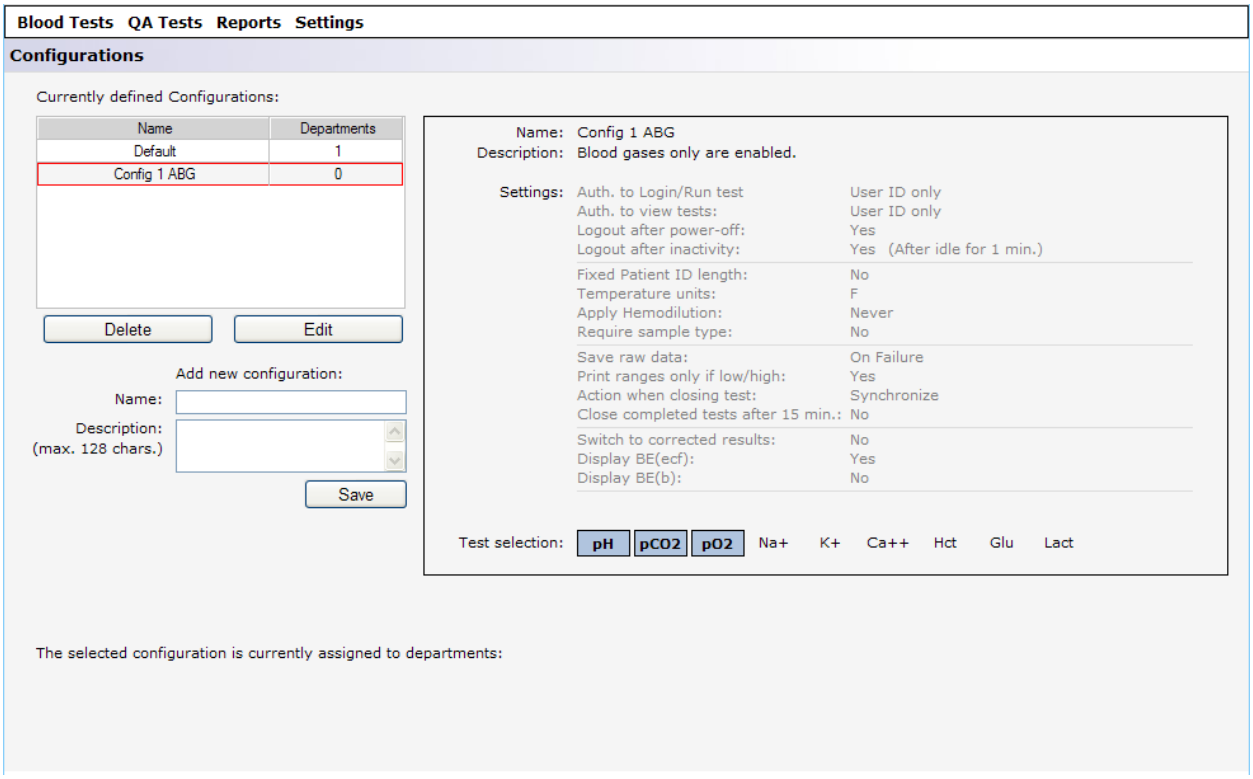
8.22 Configurations

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. The table on the right displays the particular Host Settings which are available to be assigned with **Configurations**:



A new **Configuration** may be created by entering a **Name** and **Description** (optional) under "Add new configuration:" and pressing **Save**.

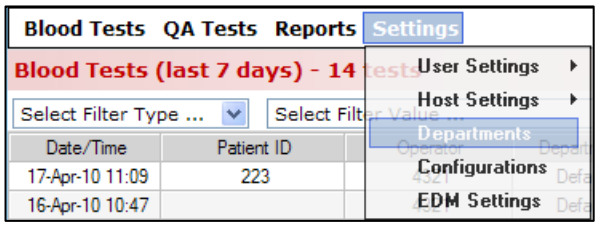
Configurations may then be selected for **Deleting** or **Editing** by clicking on the Configuration's row in the table under "Currently defined Configurations:". The current settings for the selected configuration are displayed to the right of this. Once selected, a Configuration may be removed or modified by pressing its corresponding **Delete** or **Edit** button.

The **Default Configuration** cannot be deleted (only edited). The **Default Configuration** will be sent to Hosts that are not assigned to a **Department**.

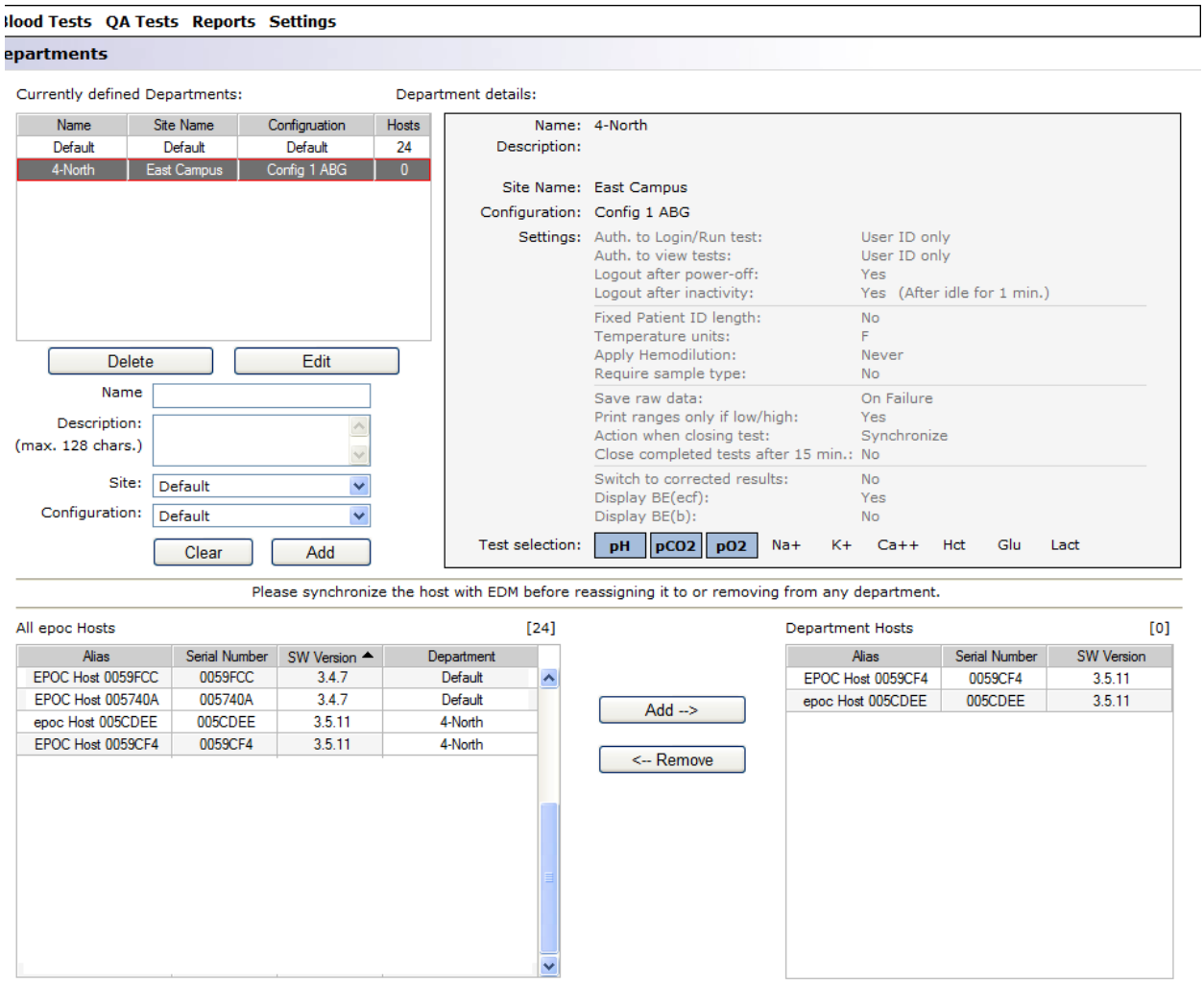
8.23 Departments

Configurations and **epoc Host's** are assigned to **Departments** to allow the unique settings of the Configuration to be used in the 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 Host 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.**



Below is the **Departments** Page:



A new **Department** may be added by entering **Name**, **Description** (optional), assigning **Site** and **Configuration** (by selecting from the dropdown) and then pressing **Add**. Note - the Sites must be previously established on the epoc Manager Settings Page and the Configurations on the Configurations Page.

Departments may then be selected for **Deleting**, **Editing**, **Adding** a Host, or **Removing** a Host by clicking on the Department's row in the table under "Currently defined Departments:". The current settings for the selected Department are displayed to the right of this.

Once selected, a Department may be removed or modified by pressing its corresponding **Delete** or **Edit** button. Note – the **Default Department** can never be deleted or edited and is permanently assigned with the **Default Configuration**.

Also once a Department is selected, an epoc Host may be then be assigned to it by selecting the epoc Host from the list under "All epoc Hosts" (bottom half of page on left) and pressing the **Add** button. An epoc Host may be unassigned from the Department by selecting the epoc Host from the list under "Department Hosts" (bottom half of page on right) and pressing the **Remove** button.

An epoc Host that is not assigned to any Department specifically is automatically assigned to the Default Department.

8.24 Epoc Manager Settings

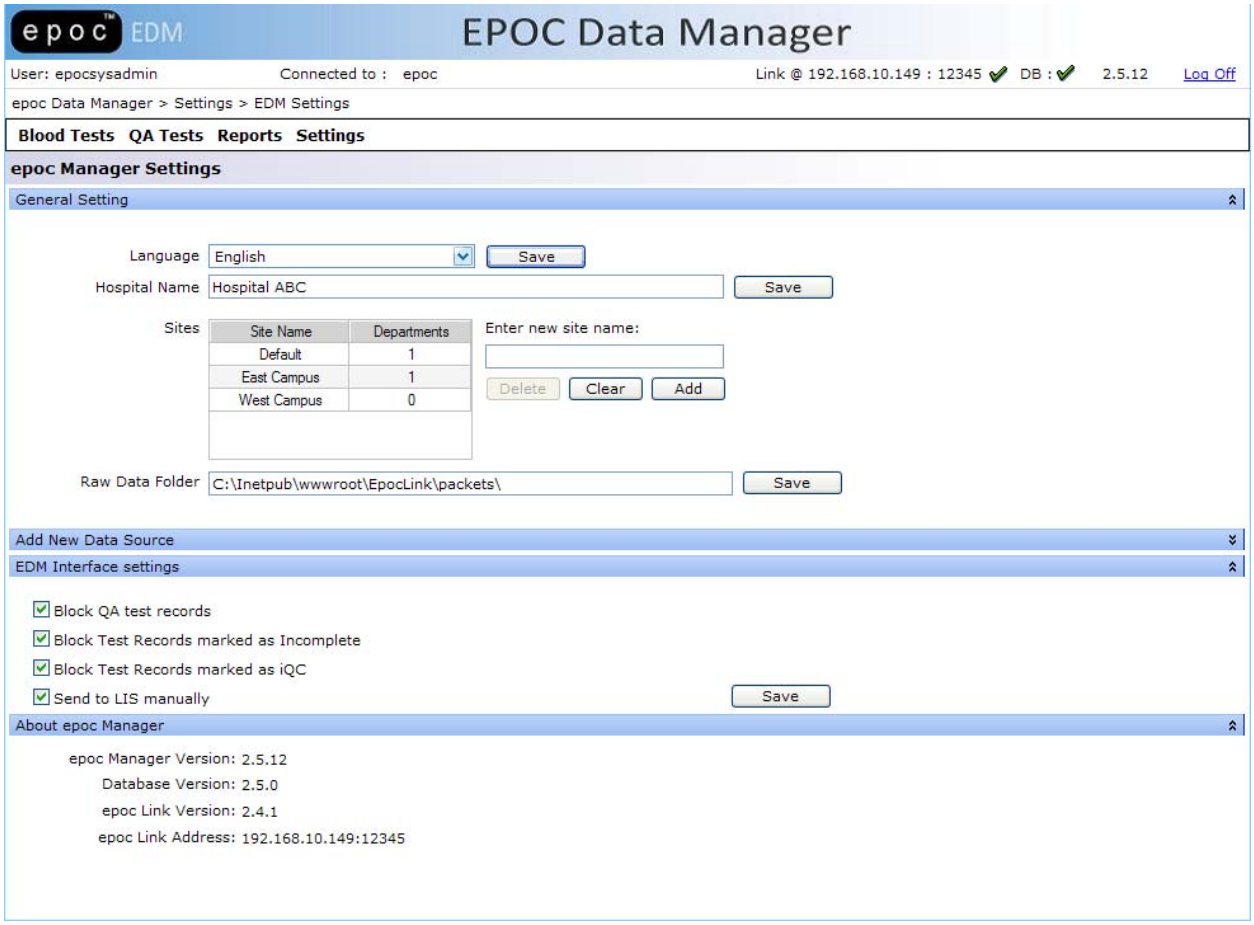
There are four (4) Sections of **epoc Manager Settings** Page: **General Settings**, **Add New Data Source**, **EDM Interface Settings**, and **About epoc Manager** (read-only).

Each Section is expanded or hidden by pressing Arrows at right of Section Heading.

Example below shows EDM Settings page with three (3) Sections expanded.

Language, Hospital Name, different **Sites**, location for **Raw Data Folder**, and various **LIS Test Submission** options may be set or changed, then applied by pressing each "Save" button.

Add New Data Source is for qualified Epocal and facility IT personnel. Type in applicable information and press **Add New Data Source**.



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 Data Manager Sections for setting up an Operator's Account to allow running of QA Tests.

See epoc System Operation and epoc Host Sections 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 shipping carton. Never use Test Cards if Temperature Monitors indicate they were stored outside of specified temperature range (5-30°C). Refer to epoc Test Cards Section of this 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. (For proper fluid handling, see section on Fluid Controls, 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 Test is run. Tests are 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, Heater Block contacts Test Card's sensor region and maintains temperature of the sensors and fluids that come into contact with the sensors

at the required temperature: 37 ^{o} ± 0.15^{o}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) in a room that isn't changing in temperature for at least two (2) hours.

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

Turn Reader 'ON'. Using an epoc Host, **discover**, then **press and hold Reader Icon** for about one (1) second. Select **Run Thermal QA** from the Drop-down 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 use of Eurotrol™ GAS-ISE Metabolite QC fluids are suitable for both epoc BGE and BGEM Test Cards. The use of Bio-Rad Liquicheck^{TM} Blood Gas Plus E Controls is only suitable for epoc BGE Test Cards because it does not contain substances needed to test Metabolite Sensors contained in epoc BGEM Test Card.

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

Manufacturer	Description	REF No.	Usage	Level	Quantity	Volume	Epocal Order No.
Bio-Rad Laboratories, Irvine CA,USA	Bio-Rad Liquicheck Blood Gas Plus EGL	511	BGE & BGEM	1	30 Ampoules	1.7 ml	CC-0001-00-00**
Bio-Rad Laboratories, Irvine CA,USA	Bio-Rad Liquicheck Blood Gas Plus EGL	513	BGE & BGEM	3	30 Ampoules	1.7 ml	CC-0002-00-00**
Eurotrol Inc., Ede, The Netherlands	Eurotrol GAS-ISE-Metabolite QC	179-1-B913	BGE & BGEM	1	12 Ampoules	2.5 ml	CC-0007-00-00
Eurotrol Inc., Ede, The Netherlands	Eurotrol GAS-ISE-Metabolite QC	179-3-B913	BGE & BGEM	3	12 Ampoules	2.5 ml	CC-0009-00-00
Diamond Diagnostics, Holliston, MA, USA	Mission Diagnostics Hematocrit	CD-570405D	Hematocrit	A	30 Ampoules	2.0 ml	CC-0004-00-00
Diamond Diagnostics, Holliston, MA, USA	Mission Diagnostics Hematocrit	CD-570406D	Hematocrit	B	30 Ampoules	2.0 ml	CC-0005-00-00

** Limited availability.

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 later in this Section.

9.3 Additional Quality Control for epoc System

9.3.1 Calibration Verification

Follow Calibration Verification procedure to verify accuracy of Test Results over 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 measurement range can be accomplished using lowest, highest and mid levels.

Commercially available five (5) Level Calibration Verification Sets can be used for the verification of the calibration of epoc Test Cards throughout the reportable ranges. Recommended products are described in Table 9-2 below.

Calibration verification solutions do not contain human serum or serum products, but do contain buffers and preservatives.

Manufacturer	Description	REF No.	Usage	Level	Quantity	Volume	Epocal Order No.
RNA Medical Division of Bionostics Inc.	BGE & Metabolite Linearity Controls	CVC-123	BGE & Metabolite Calibration / Linearity	1-5	4 Ampoules each Level	2.5 ml	CC-0003-00-00
RNA Medical Division of Bionostics Inc.	Hematocrit Calibration Verification	CVC- 9005	Hematocrit Calibration Verification	1-5	4 Ampoules each Level	1.7 ml	CC-0006-00-00

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 later in this Section.

9.3.2 Proficiency Testing

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. Epocal is registered with CAP proficiency testing under Code 2077 (AQ-C, LN13-A and/or XL/XLN-B) and with WSLH proficiency testing under Code 3206. Epocal does not recommend CAP Linearity Studies.

Proficiency Testing samples are run as a QA Test when using epoc System. (Same as Control and Calibration Verification Fluids). Refer to Aqueous Fluid Handling Section later in this Section.

9.3.3 Quality Control Tests Run Using Whole Blood

Quality Control Tests run using whole blood, such as Whole Blood Precision Tests, are run as a **Blood Test** mode when using epoc System. Always use Blood Test (not QA Test) mode when testing blood samples.

9.4 Aqueous Fluid Handling

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

9.4.1 Storage

Always follow Manufacturer's Storage Instructions.

9.4.2 Before Use

If ampoules are taken from cool storage, equilibrate Ampoule to Room Temperature (20-25°C). Equilibration time for blood gas QC Fluids is four (4) hours minimum.

9.4.3 Ampoule Use for Blood Gas QC fluids

Handle Fluid carefully to avoid air contamination. Air contains less than 1mmHg pCO_2 and about 150-180mmHg pO_2. Gas Levels and pH 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 over time after opening the Ampoule. Once 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 last 0.5 mL of Control Fluid in 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 laboratory is 15-17°C and pO2 range is 135 to 155 mmHg, Range can be adjusted by adding 9.5 mmHg to upper and lower limit to obtain Adjusted Range as (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
pCO_2	~70 mmHg	1.6	0.8	0.0	-0.8	-1.5
pO_2	~55 mmHg	4.0	2.0	0.0	-2.0	-3.6
pO_2	~95 mmHg	6.9	3.5	0.0	-3.5	-6.3
pO_2	~145 mmHg	9.5	4.8	0.0	-4.8	-8.7

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

Table 9-3. Temperature Correction for pCO2 and pO2 Targets for Aqueous Control Fluids

9.4.6 Procedure

All Aqueous Control Fluids, including Proficiency Test Samples, must be run as QA Test when using epoc System.

QA Test feature provides following characteristics:

- Ranges are increased so User can test Levels at, or just outside of, Reportable Range
- Hematocrit Result is reported as “uncorrected”, i.e. Result does not take into account Sodium Concentration of Sample. This allows for independent evaluation of Hematocrit Sensor from Sodium Sensor. Note: Sodium Sensor performance is verified separately.
- QA Test Results are stored separately from Blood Test Results in epoc Data Manager.

Immediately before use, shake Ampoule vigorously for 5 to 10 seconds to equilibrate liquid and gas phases. Always hold Ampoule at tip and at bottom with forefinger and thumb to minimize increasing temperature of Fluid. If necessary, tap Ampoule Tip to return Fluid into bottom section of Ampoule. Protect fingers with gauze, tissue or glove, or use Ampoule Breaker to snap off Ampoule Tip at Neck.

Immediately transfer Fluid from Ampoule into a plain Syringe, avoiding fast suction and thin needles in order to preserve gases in Fluid. Transfer Fluid immediately into Test Card.

9.4.7 Transfer with Syringe

Epocal recommends 1 mL or 3 mL plain sterile Syringes with 16-20 gauge blunt needles to transfer Control Fluids from Ampoule to the Test Card. While loading syringe, slowly draw about 1mL of Fluid from bottom of Ampoule. If air is trapped between leading edge of Fluid and Syringe Plunger, never invert Syringe to expel because this will not affect solution near front of Syringe.

If Air Bubbles are continually drawn into Syringe, or if a Bubble is trapped near Syringe Tip, discard Ampoule and Syringe. Begin again with a fresh Ampoule and Syringe.

Before inserting Fluid in Test Card, expel one (1) or two (2) drops from Syringe. Remove blunt needle and apply Syringe Luer in Test Card’s Sample Introduction Port as during normal Blood Test procedure.

9.5 Value Assignment Datasheets

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

Download the current Value Assignment Datasheets at http://www.epocal.com/ or contact your Epocal Distributor.

Never use Target Values or Ranges from Package Insert included with Control Fluids.

Each Value Assignment Datasheet (VAD) is identified by Fluid Name, Level, Lot Number and epoc System Sensor Configuration Version. Assure all information is correct when using VAD to determine acceptability of Results. The epoc System Sensor Configuration version is located in 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 21-23°C Temperature Range. pCO_2 and pO_2 values vary inversely proportional with Temperature by about 1%/°C. Refer to 9.4.5 Temperature Correction for Blood Gas QC Fluids, for information to adjust pO_2 and pCO_2 Ranges outside 21-23°C Temperature Range.

Also to establish Target Values, Samples are analyzed at approximately 760 mmHg Atmospheric Pressure. pCO_2 values decrease by 1% per 100mmHg below 760mmHg. pO_2 values decrease by 2.3% per 100mmHg below 760mmHg.

Target Values are specific to epoc System. Results obtained from Aqueous Fluids may differ using other methods due to Sample Matrix Effects.

9.5.2 Ranges

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

Ranges for **Control Fluids** are determined for individual readings.

Ranges for **Calibration Verification Fluids** are determined for average of 3 readings.

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-born 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 in plastic bag with a Biohazard Label on bag. Contact Epocal distributor to arrange for return of 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 epoc Reader and epoc Host when not in use to conserve battery life.
2. Store Reader and Host in secure location when not in use.
3. Keep 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 epoc System Manual (IFU) available to both the Operator and Administrator.
6. Ensure that epoc System Manual is complete and kept up to date.

10.3 Cleaning

Cleaning procedures should always follow institution's standard practice for cleaning electrical equipment and instruments.

Do not expose any electrical contacts to wash fluids.

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

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

Avoid using excess fluids that may enter epoc Reader or epoc Host and possibly contact electrical components.

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

- Mild detergent or non-abrasive cleaner
- Alcohol
- Soap and water
- 0.4% bleach solution

Decontamination Method

Decontaminate epoc Reader or epoc Host when blood is spilled to prevent exposure to any blood-born pathogens.

Wear appropriate gloves to perform the following procedure:

1. Prepare 0.4% bleach solution (nine (9) parts tap water with one (1) part household 4% bleach). Use same solution for up to one (1) week.
2. Soak several gauze pads in bleach solution. When removing pad from solution, squeeze excess liquid, so that 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.
5. Rinse all surfaces using fresh pads soaked in warm tap water. Allow surfaces to dry before turning 'ON' any of the epoc System components.
6. Dispose of the used gauze pads in 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 Reader battery can only be replaced by Epocal authorized personnel.

The rechargeable Host battery can be replaced by a user. Refer to instructions for removing Host battery in epoc Host Section of this manual.

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

11.2.1 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^{o}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).

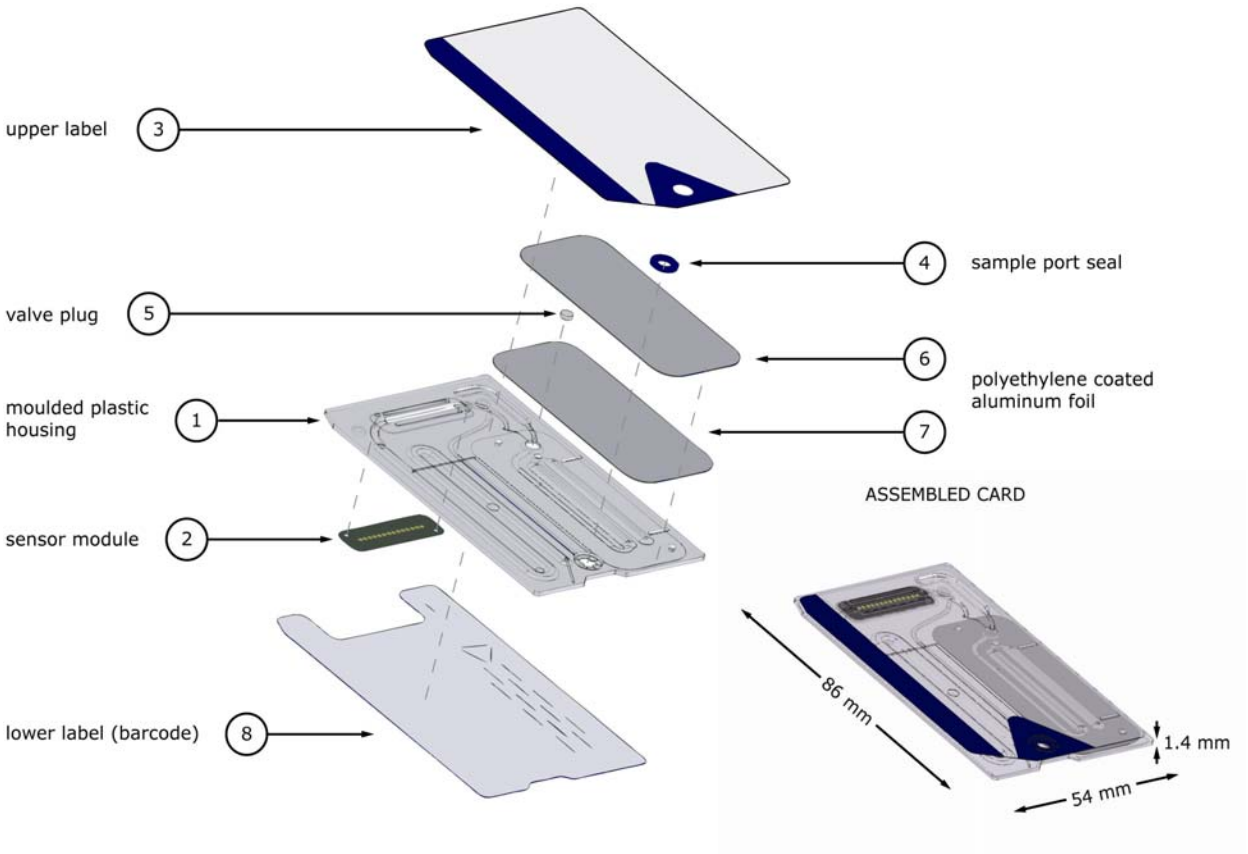
11.2.5 Operator Interface

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:

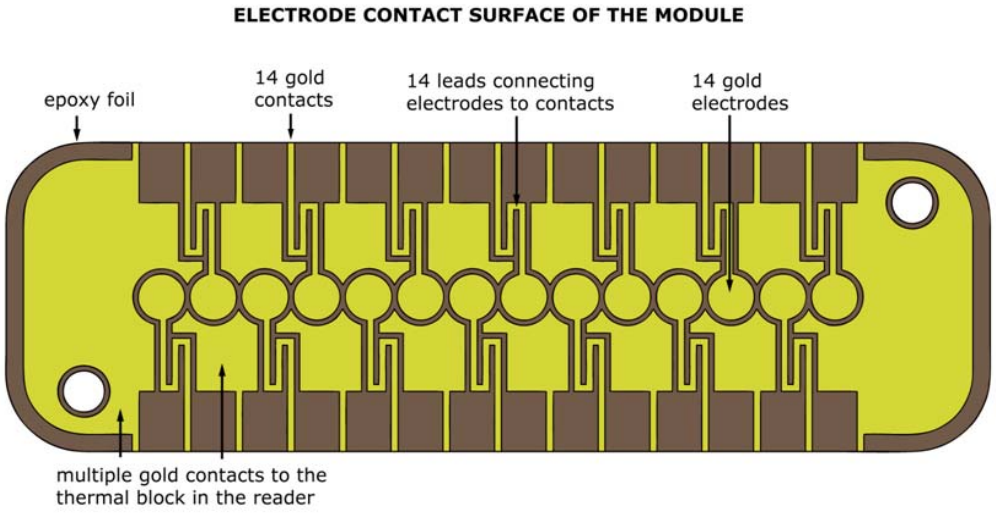
- **Moulded Plastic Housing [1]** with fluid channels, reservoirs, and a recess where **Sensor Module [2]** is mounted so module's outer contact surface is flush with card surface and module's inner sensor surface is facing the card's fluid channels.
- **Sensor Module [2]** is an epoxy foil supporting 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.

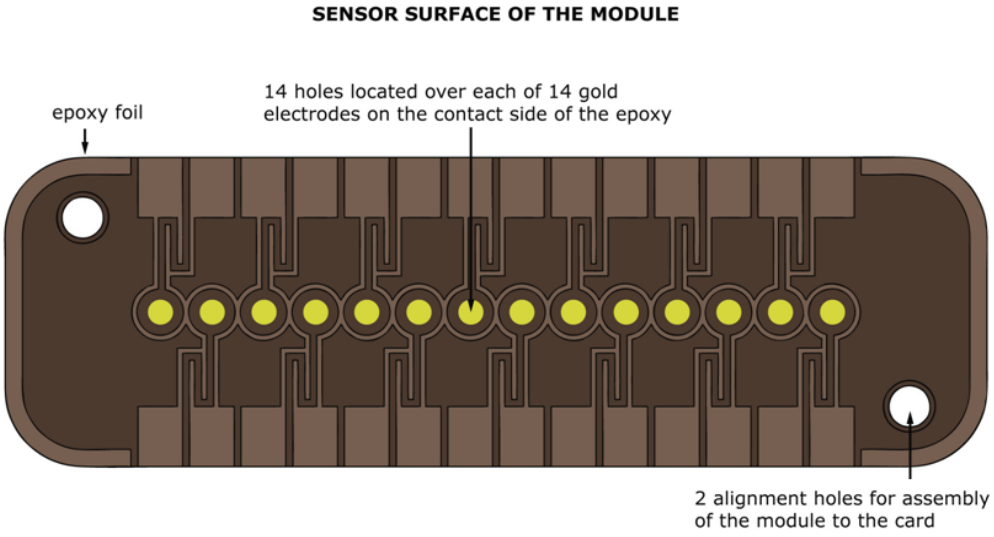


11.4 Sensor Module

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.





- 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

VIEW ALONG MODULE SENSOR CHANNEL ***AFTER*** MEMBRANE PRINTING

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 normal ranges for all instruments are in agreement. In the factory epoc sensors are calibrated so that normal 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 demodulated 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, 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 and Lactate) 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, 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 sensor 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 minimized 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. Hematocrit Electrodes

Two gold electrodes.

2. Sodium Electrode

The sodium sensor is compromised of a plasticized PVC membrane ion selective electrode[4] containing the sodium selective salt sodium methylmonensin.

3. Potassium Electrode

The potassium sensor is compromised of a plasticized PVC membrane ion selective electrode[4] containing the potassium selective ionophore valinomycin.

4. 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.

5. pH Electrode

The pH sensor is comprised of a plasticized PVC membrane ion selective electrode[4] containing the pH selective ionophore tridodecylamine.

6. *p*CO_2 Electrode

The *p*CO_2 sensor is a modified Severighaus 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.

7. *p*O_2 Electrode

The *p*O_2 sensor is a modified Clarke electrode[2.5] comprising a gold cathode surface coated with a heterogeneous oxygen permeable membrane.

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. 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 when it occurs. It is also not effective to use as the primary 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. lf 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, 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.

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

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. Burns eds., Elsevier Saunders, St.Louis, 2006.
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, pp575-587, 1925.
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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 in hospitals, nursing homes or other clinical care institutions.

The **Blood Gas Electrolyte and Metabolite (BGEM) Test Card** panel configuration includes sensors for Sodium, Potassium, ionized Calcium, pH, pCO2, pO2, Hematocrit, Lactate and Glucose.

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.

pH, pCO_2, $p0_2$ (blood gases) measurements from the epoc Blood Analysis System are used in the diagnosis and treatment of life-threatening acid-base disturbances.

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

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).

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.

12.2 Test Card Configuration

The epoc Blood Gas and Electrolyte (BGE) Test Card and Blood Gas Electrolyte and Metabolytes (BGEM) Test Card include the following measured and calculated Test Results. (BGEM Test Card includes all tests on BGE Test Card):

epoc BGE
Sodium Na+
Potassium K+
Ionized Calcium Ca++
pH
pCO_2
pO_2
Hematocrit Hct
*Total carbon dioxide cTCO_2
*Bicarbonate cHCO_3-
*Base excess BE
*Oxygen saturation cSO_2
*Hemoglobin cHgb

* *calculated values*

epoc BGEM
Sodium Na+
Potassium K+
Ionized Calcium Ca++
pH
pCO_2
pO_2
Lactate
Glucose
Hematocrit Hct
*Total carbon dioxide cTCO_2
*Bicarbonate cHCO_3-
*Base excess BE
*Oxygen saturation cSO_2
*Hemoglobin cHgb

* *calculated values*

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 “03 - epoc System Operation” of the epoc System Manual for detailed sample collection and system operating instructions for conducting a blood test.

Refer to section “09 - Quality Assurance” of the epoc System 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 five (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, introduced to the card using a Syringe or epoc Care-Fill™ Blood Collection Tube.

12.2.5 Sample Volume

>92µL, non-volumetric quantity

12.2.6 Sample Collection

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

Samples without anticoagulant can always be used in this circumstance.

*****Always use ISO594-1 compliant Syringe for sample introduction. Verify that syringe to be used for sample collection is evaluated by Epocal prior to use.

The epoc System is intended to be used with fresh whole blood samples only.

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 Method** *(see also references at end of Section)*		
	Syringes*	**Evacuated Tubes**	**Capillary Tubes**
pO_2	• 1 or 3ml plastic, non-iced[1,2] • Test in less than 30 min[1,2]	• Not recommended[1]	• epoc Care-Fill Capillary Tubes
pH/pCO_2	• 1 or 3ml plastic • Test in less than 30 min[1,2]	• Without anticoagulant • With Li or Na heparin	• epoc Care-Fill Capillary Tubes
Ionized Calcium (Ca++)	• 1 or 3ml plastic • Without anticoagulant • With Li or Na heparin only if <10 IU/ml[3] • With balanced heparin only if <70 IU/ml[3]	• Without anticoagulant • With Li or Na heparin only if <10 IU/ml[3]	• epoc Care-Fill Capillary Tubes • Care-Fill capillary tubes contain 70 IU/ml of calcium balanced lithium heparin

Test	Sample Collection Method *(see also references at end of Section)*		
	Syringes*	**Evacuated Tubes**	**Capillary Tubes**
Hematocrit (Hct)	• 1 or 3ml plastic • Immediate testing is recommended in order to avoid RBC settling. (Note: Re-suspension of RBC requires an air bubble of significant volume[4])	• Without anticoagulant • With Li or Na heparin only (do not use EDTA)	• epoc Care-Fill Capillary Tubes • Immediate testing is recommended in order to avoid RBC settling
All other tests	• 1 or 3ml plastic	• Without anticoagulant • With Li or Na heparin	• epoc Care-Fill Capillary Tubes

12.2.7 Analysis Time

Approximately 35 seconds after sample introduction for Blood Sample Tests.
Approximately 44 seconds after sample introduction for Aqueous Control Tests.

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 Range (some values may be rounded)

Measured Parameters				
Test Name	**Acronym**	**Units of Measure**	**Measurement Range**	**Normal Range[7-9]**
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
				42-51 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	0.25–4.0	1.15–1.33
		mg/dL	1.0-16.0	4.6-5.3
		mEq/L	0.5-8.0	2.3-2.7
Lactate	Lac	mmol/L	0.30 - 20.00	0.56 - 1.39
		mg/dL	2.7 – 180.2	5.0 – 12.5
		g/L	0.03 - 0.18	0.05 – 0.12
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
Hematocrit	Hct	% PCV	10–75	38-51
		L/L	0.10-0.75	0.38-0.51

Calculated Parameters				
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
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

12.2.10 References

1. CLSI C46-A2, Vol. 29, No. 8, Blood gas and pH analysis and related measurements- Approved Guideline—second edition, Wayne, Pennsylvania, USA, 2009.
2. CLSI H11-A4, Vol. 24, No. 28, Procedures for the collection of arterial blood specimens- Approved Standard, Wayne, Pennsylvania, USA, 2004.
3. CLSI C31-A2, Vol. 21, No. 10, Ionized Calcium Determinations: recollection variables, specimen, choice, collection and handling, approved guideline-second edition, Wayne, Pennsylvania, USA, 2001.
4. CLSI H7-A3, Vol. 20, No. 18, Procedures for determining packed cell volume by micro-hematocrit method- Approved Standard, Wayne, Pennsylvania, USA, 2000.
5. T.P. Moyer, L.M. Shaw, Chapters 33 of 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.
6. D.S. Young, Effects of Drugs on Clinical Laboratory Tests, 3rd Edition, AACC Press, Washington DC, 1990.
7. N.W. Tietz, Clinical Guide to Laboratory Tests, 3rd Edition, W.B. Saunders Company, 1995.
8. 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. Burns eds., Elsevier Saunders, St. Louis, 2006.
9. B.E. Statland, Clinical Decision Levels for Lab Tests, Medical Economic Books, Oradell, NJ, 1987.

12.3 Sodium (Na+)

12.3.1 General

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]

12.3.2 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 in hospitals, nursing homes or other clinical care institutions.

Measurement of sodium is used in diagnosis and treatment of diseases involving electrolyte imbalance.

12.3.3 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.

12.3.4 Traceability

Values of sodium ion concentration assigned to controls and calibrator fluids are traceable to NIST standards.

12.3.5 Sample Collection

Refer to 12.2.6 Sample Collection

12.3.6 Additional Information

Refer to section “03 - epoc System Operation” of the epoc System Manual for detailed sample collection and system operating instructions for conducting a blood test.

Refer to section “09 - Quality Assurance” of the epoc System Manual for quality control requirements.

12.3.7 Measurement Range

	Measurement Range	Normal Range[2,3]
Na+	85–180 mmol/L	138–146 mmol/L
	85–180 mEq/L	138–146 mEq/L

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 EP9-A2[4] for method comparison studies, CLSI EP7-A2[5] for interference studies and CLSI EP5-A2[12] for precision studies.

A. Precision Data

In the precision data tables below, SD_{WR} denotes within run standard deviation and SD_T denotes total standard deviation.

In-house Precision 1: Commercial aqueous blood gas and electrolyte controls run on 20 sequential manufactured lots using at least 8 different epoc Readers, with 16 replicate measurements per lot per each control fluid level.

	Units	Mean	SD_{WR}	%CV	SD_T	%CV
Level 1	mmol/L	113	0.9	0.8	1.2	1.1
Level 3	mmol/L	153	1.0	0.7	1.6	1.0

In-house Precision 2: Commercial aqueous blood gas and electrolyte controls run in a 20 day precision study[12] with 2 measurements each day per each control level. 4 manufactured lots, 6 different epoc Readers

	Units	Mean	SD_{WR}	%CV	SD_T	%CV
Level 1	mmol/L	115	0.6	0.5	0.8	0.7
Level 3	mmol/L	153	0.7	0.5	1.0	0.6

In-house Precision 3: Whole blood samples run on 20 sequential manufactured lots using at least 8 different epoc Readers, with 12 replicates per each blood sample per lot.

	Units	Mean	mean SD_{WR}	%CV
Blood level 1	mmol/L	147	0.9	0.6
Blood level 2	mmol/L	168	1.4	0.8

Clinical Site Precision 1: 10 replicates of commercial aqueous blood gas controls run by operators of the epoc system at 3 different point-of-care sites. Each precision study employed from 2 to 4 different epoc Readers.

High sodium level commercial aqueous blood gas control

	Units	Mean	SD_{WR}	%CV
Operator 1	mmol/L	158	1.3	0.8
Operator 2	mmol/L	155	0.8	0.5
Operator 3	mmol/L	157	1.3	0.8

Low sodium level commercial aqueous blood gas control

	Units	Mean	SD_{WR}	%CV
Operator 4	mmol/L	109	0.6	0.5
Operator 5	mmol/L	109	1.0	0.9
Operator 6	mmol/L	108	0.8	0.8
Operator 7	mmol/L	109	0.5	0.5

Clinical Site Precision 2: 10 replicates of different whole blood Patient samples run by different operators of the epoc system at different point-of-care sites. Each precision study employed 5 different epoc Readers.

		Units	Mean	SD_{WR}	%CV
Site 1	Operator 1	mmol/L	142	0.5	0.3
	Operator 2	mmol/L	143	1.5	1.0
Site 2	Operator 3	mmol/L	142	1.2	0.8
	Operator 4	mmol/L	143	0.8	0.6
	Operator 5	mmol/L	143	0.7	0.5
Site 3	Operator 6	mmol/L	141	0.7	0.5
	Operator 7	mmol/L	140	1.0	0.7

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^2
Na+	80-190	mmol/L	0.973	3.8	0.999

C. Clinical Sites Method Comparison Data

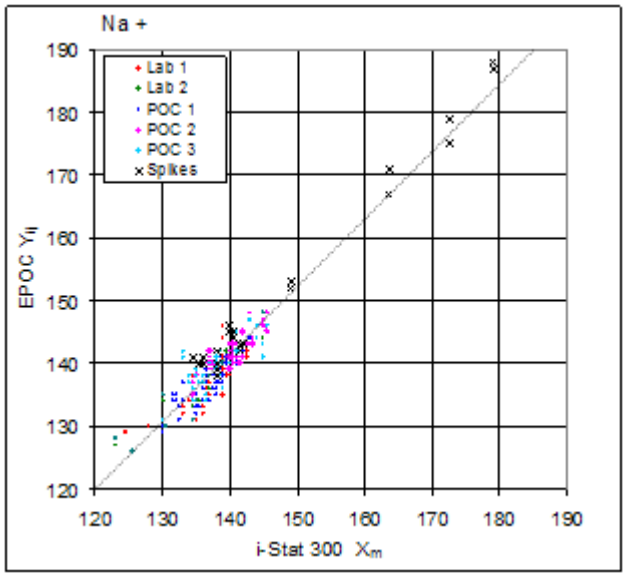
Linear regression analysis was performed on the method comparison data in accordance with CLSI EP9-A2[4]. In the method comparison statistics table, N is the number of Patient specimens in the data set, Sxx and Syy are the pooled pair-wise imprecision of the comparative and epoc test methods respectively, 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 in 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	-9.579
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
X min	125	123	130	135	130	123	123
X max	143	145	143	146	146	146	179
R	0.822	0.914	0.888	0.847	0.813	0.880	0.953

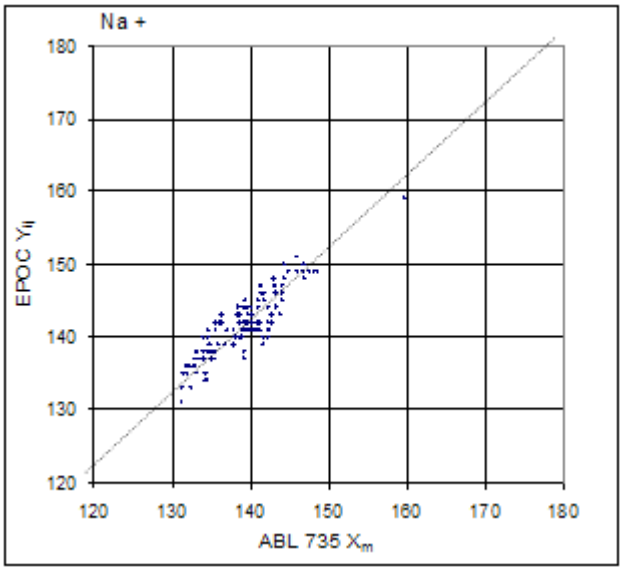
*data set includes Patient samples spiked with NaCl for extended data range



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+	Lab
N	77
Sxx	0.78
Syy	0.79
Intercept	19.1
Slope	0.881
Syx	1.81
X min	131
X max	160
R	0.924



D. Limitations and Interferences

Similar to other dry reagent methods, a decrease (increase) of total protein will increase (decrease) Na+ by 1.3mM/(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[7,8]. 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[4] 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:

- Sodium heparin will give erroneously high Na+ results
- 20 mmol/L β-hydroxybutyrate will decrease Na+ by 3 mmol/L
- 20 mmol/L lactate will decrease Na+ by 4 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 H-11[11].

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 salycilate, 0.4 mmol/L ascorbate, 4.3 mmol/L salycilate, 0.7 mmol/L iodide, 2.2 mmol/L ibuprofen, 1.66 mmol/L acetaminophen, 2 mmol/L ammonium, 4 mmol/L lithium, 10 mmol/L bromide, 3 µmol/l dobutamide, 2.5 mmol/L tolbutamide.

The following levels of endogenous interferences were tested and found to be clinically insignificant: 8 mmol/L KCl, 3mmol/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, 9.1 mmol/L cholesterol, 1 mmol/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. Burns 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. Burns eds., Elsevier Saunders, St. Louis, 2006.
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4. CLSI. Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline-Second Edition, CLSI document EP9-A2 (ISBN 1-56238-472-4), CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2002.
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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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10. CLSI. Blood Gas and pH Analysis and Related Measurements; Approved Guideline, CLSI document C46-A (ISBN 1-56238-444-9), CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2001.
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12.4 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]

12.4.1 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 in hospitals, nursing homes or other clinical care institutions.

Measurement of potassium is used in diagnosis and treatment of diseases involving electrolyte imbalance.

12.4.2 Contents

Each Test Card incorporating a potassium test contains a potassium sensing electrode with a potassium selective membrane, a reference electrode and a calibrator fluid containing a known concentration of potassium salts.

12.4.3 Traceability

Values of potassium ion concentration assigned to controls and calibrator fluids are traceable to NIST standards

12.4.4 Sample Collection

Refer to 12.2.6 Sample Collection

12.4.5 Additional Information

Refer to section “03 - epoc System Operation” of the epoc System Manual for detailed sample collection and system operating instructions for conducting a blood test.

Refer to section “09 - Quality Assurance” of the epoc System Manual for quality control requirements.

12.4.6 Measurement Range

	Measurement Range	Normal Range[2]
K+	1.5 – 12 mmol/L	3.5 – 4.5 mmol/L
	1.5 – 12 mEq/L	3.5 – 4.5 mEq/L

12.4.7 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 EP9-A2[3] for method comparison studies, CLSI EP7-A2[4] for interference studies and CLSI EP5-A2[9] for precision studies.

A. Precision Data

In the precision data tables below, SD_{WR} denotes within run standard deviation and SD_T denotes total standard deviation.

In-house Precision 1: Commercial aqueous blood gas and electrolyte controls run on 20 sequential manufactured lots using at least 8 different epoc Readers, with 16 replicate measurements per lot per each control fluid level.

	Units	Mean	SD_{WR}	%CV	SD_T	%CV
Level 1	mmol/L	2.2	0.02	0.9	0.03	1.5
Level 3	mmol/L	6.7	0.06	0.9	0.07	1.1

In-house Precision 2: Commercial aqueous blood gas and electrolyte controls run in a 20 day precision study[9] with two (2) measurements each day per each control level. four (4) manufactured lots, six (6) different epoc Readers

	Units	Mean	SD_{WR}	%CV	SD_T	%CV
Level 1	mmol/L	2.2	0.02	1.0	0.03	1.2
Level 3	mmol/L	6.6	0.05	0.8	0.06	1.0

In-house Precision 3: Whole blood samples run on 20 sequential manufactured lots using at least 8 different epoc Readers, with 12 replicates per each blood sample per lot.

	Units	Mean	mean SD_{WR}	%CV
Blood level 1	mmol/L	4.3	0.04	1.0
Blood level 2	mmol/L	6.2	0.05	0.8

Clinical Site Precision 1: 10 replicates of commercial aqueous blood gas controls run by operators of the epoc system at 3 different point-of-care sites. Each precision study employed from two (2) to four (4) different epoc Readers.

High potassium level commercial aqueous blood gas control.

	Units	Mean	SD_{WR}	%CV
Operator 1	mmol/L	6.8	0.05	0.7
Operator 2	mmol/L	6.7	0.06	0.9
Operator 3	mmol/L	6.7	0.09	1.3

Low potassium level commercial aqueous blood gas control.

	Units	Mean	SD_{WR}	%CV
Operator 4	mmol/L	2.0	0.01	0.6
Operator 5	mmol/L	2.0	0.03	1.6
Operator 6	mmol/L	2.0	0.05	2.5
Operator 7	mmol/L	2.0	0.02	1.0

Clinical Site Precision 2: 10 replicates of different whole blood Patient samples run by different operators of the epoc system at different point-of-care sites. Each precision study employed 5 different epoc Readers.

		Units	Mean	SD_{WR}	%CV
Site 1	Operator 1	mmol/L	4.0	0.05	1.3
	Operator 2	mmol/L	4.0	0.00	0.0
Site 2	Operator 3	mmol/L	3.7	0.00	0.0
	Operator 4	mmol/L	3.8	0.03	0.8
	Operator 5	mmol/L	3.7	0.03	0.9
Site 3	Operator 6	mmol/L	3.6	0.03	0.9
	Operator 7	mmol/L	4.1	0.05	1.2

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^2
K+	1.5-12	mmol/L	1.006	0.03	0.999

C. Clinical Sites Method Comparison Data

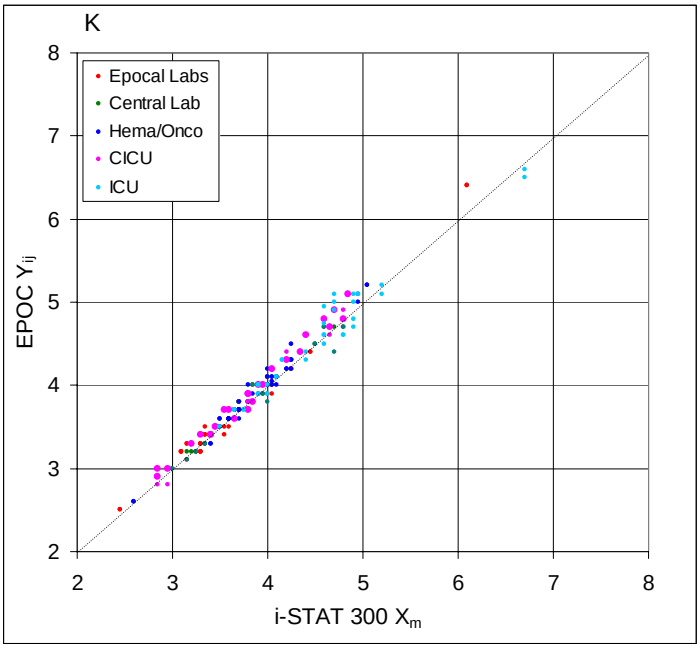
Linear regression analysis was performed on the method comparison data in accordance with CLSI EP9-A2[3]. In the method comparison statistics table, N is the number of Patient specimens in the data set, Sxx and Syy are the pooled pair-wise imprecision of the comparative and epoc test methods respectively, 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) then in 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
X min	2.5	3.0	2.6	2.9	3.3	2.5	2.5
X max	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

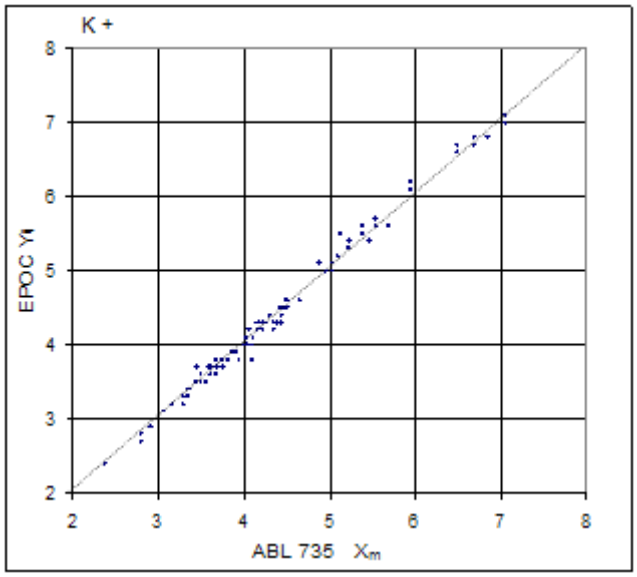
*data set includes Patient samples spiked with KCl for extended data range



Clinical Site Method Comparison 2: In another hospital study the epoc was compared with the Radiometer ABL 735[6] in the lab.

1. Method Comparison Summary Statistics: whole blood
2. X: Radiometer ABL 735
3. Y: epoc test

K+	Lab
N	77
Sxx	0.057
Syy	0.044
Intercept	-0.073
Slope	1.026
Syx	0.090
X min	2.4
X max	7.1
R	0.996



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 Salycilate, 0.4 mmol/L ascorbate, 4.3 mmol/L salycilate, 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 dobutamide, 2.5mmol/L tolbutamide.

The following levels of endogenous interferences were tested and found to be clinically insignificant: 20 mmol/L NaCl, 3mmol/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, 0.8% lipids, 9.1 mmol/L cholesterol, 20 mmol/L β-hydroxybutyrate, 1 mmol/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. Burns 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. Burns eds., Elsevier Saunders, St. Louis, 2006.
3. CLSI. Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline-Second Edition, CLSI document EP9-A2 (ISBN 1-56238-472-4), CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2002.
4. CLSI. Interference Testing in Clinical Chemistry; Approved Guideline, CLSI document EP7-A2 (ISBN 1-56238-480-5), 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. Blood Gas and pH Analysis and Related Measurements; Approved Guideline, CLSI document C46-A (ISBN 1-56238-444-9), CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2001.
8. CLSI. Procedures for the Collection of Arterial Blood Specimens; Approved Standard, CLSI document H11-A4 (ISBN 1-56238-545-3), CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2004.
9. CLSI. Evaluation of Precision in Clinical Chemistry Devices; Approved Guideline-Second Edition, CLSI document EP5-A2 (ISBN 1-56238-542-9), CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2004.

12.5 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.

12.5.1 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 in hospitals, nursing homes or other clinical care institutions.

Measurement of Ionized Calcium is used in diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany.

12.5.2 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.

12.5.3 Traceability

Values of calcium ion concentration assigned to controls and calibrator fluids are traceable to NIST standards

12.5.4 Sample Collection

Refer to 12.2.6 Sample Collection

12.5.5 Additional Information

Refer to section “03 - epoc System Operation” of the epoc System Manual for detailed sample collection and system operating instructions for conducting a blood test.

Refer to section “09 - Quality Assurance” of the epoc System Manual for quality control requirements.

12.5.6 Measurement Range

	Measurement Range	Normal 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

12.5.7 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 EP9-A2[2] for method comparison studies, CLSI EP7-A2[3] for interference studies and CLSI EP5-A2[11] for precision studies.

A. Precision Data

In the precision data tables below, SD_{WR} denotes within run standard deviation and SD_T denotes total standard deviation.

In-house Precision 1: Commercial aqueous blood gas and electrolyte controls run on 20 sequential manufactured lots using at least 8 different epoc Readers, with 16 replicate measurements per lot per each control fluid level.

	Units	Mean	SD_{WR}	%CV	SD_T	%CV
Level 1	mmol/L	2.18	0.03	1.4	0.04	1.7
Level 3	mmol/L	0.66	0.01	1.5	0.01	1.9

In-house Precision 2: commercial aqueous blood gas and electrolyte controls run in a 20 day precision study[11] with 2 measurements each day per each control level. 4 manufactured lots, 6 different epoc Readers

	Units	Mean	SD_{WR}	%CV	SD_T	%CV
Level 1	mmol/L	2.20	0.02	1.0	0.03	1.3
Level 3	mmol/L	0.67	0.01	1.3	0.01	1.8

In-house Precision 3: whole blood samples run on 20 sequential manufactured lots using at least 8 different epoc Readers, with 12 replicates per each blood sample per lot.

	Units	Mean	mean SD_{WR}	%CV
Blood level 1	mmol/L	1.35	0.02	1.4
Blood level 2	mmol/L	2.20	0.03	1.2

Clinical Site Precision 1: 10 replicates of commercial aqueous blood gas controls run by operators of the epoc system at 3 different point-of-care sites. Each precision study employed from 2 to 4 different epoc Readers.

Low ionized calcium level commercial aqueous blood gas control

	Units	Mean	SD_{WR}	%CV
Operator 1	mmol/L	0.57	0.01	1.9
Operator 2	mmol/L	0.56	0.01	0.9
Operator 3	mmol/L	0.57	0.01	1.7

High ionized calcium level commercial aqueous blood gas control

	Units	Mean	SD_{WR}	%CV
Operator 4	mmol/L	1.53	0.02	1.3
Operator 5	mmol/L	1.53	0.02	1.5
Operator 6	mmol/L	1.55	0.03	1.7
Operator 7	mmol/L	1.56	0.02	1.2

Clinical Site Precision 2: 10 replicates of different whole blood Patient samples run by different operators of the epoc system at different point-of-care sites. Each precision study employed 5 different epoc Readers.

		Units	Mean	SD_{WR}	%CV
Site 1	Operator 1	mmol/L	1.20	0.02	1.5
	Operator 2	mmol/L	1.21	0.02	1.9
Site 2	Operator 3	mmol/L	1.19	0.02	1.7
	Operator 4	mmol/L	1.21	0.03	2.1
	Operator 5	mmol/L	1.20	0.02	1.6
Site 3	Operator 6	mmol/L	1.23	0.02	1.8
	Operator 7	mmol/L	1.24	0.02	1.9

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^2
Ca++	0.6-3.7	mmol/L	1.017	-0.01	0.998

C. Clinical Sites Method Comparison Data

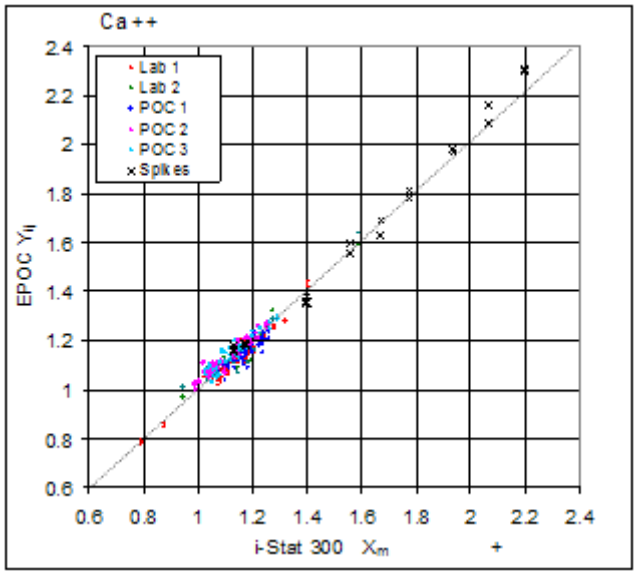
Linear regression analysis was performed on the method comparison data in accordance with CLSI EP9-A2[2]. In the method comparison statistics table, N is the number of Patient specimens in the data set, Sxx and Syy are the pooled pair-wise imprecision of the comparative and epoc test methods respectively, Syx is the standard error and R is the correlation coefficient.

Clinical Site Method Comparison 1: In one hospital study the epoc was compared with the i-Stat 300[4] in the lab (two test occasions) then in 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
X min	0.8	0.9	1.1	1.0	1.0	0.8	0.80
X max	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

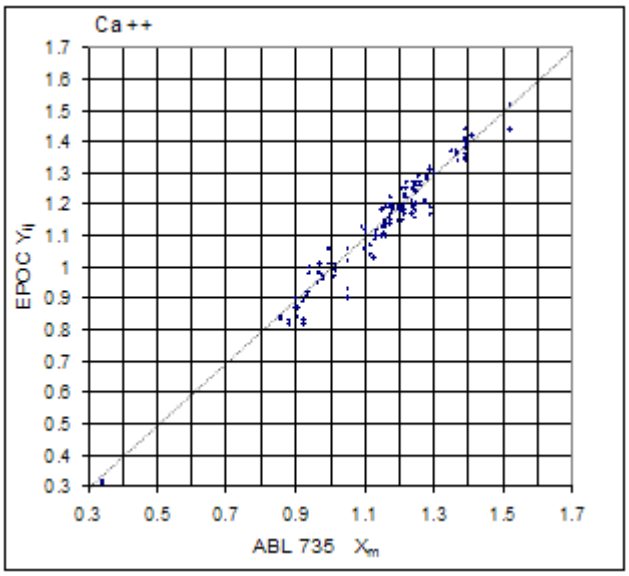
*data set includes Patient samples spiked with $CaCl_2$ for extended data range



Clinical Site Method Comparison 2: In another hospital study the epoc 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++	Lab
N	77
Sxx	0.023
Syy	0.016
Intercept	-0.045
Slope	1.025
Syx	0.040
X min	0.34
X max	1.52
R	0.981



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

10 mmol/L lactate will decrease Ca++ by 0.04 mmol/L

4.3 mmol/L salycilate or acetyl salycilate will decrease Ca++ by 0.06 mmol/L

10 mmol/L bromide will increase Ca++ by 0.05 mmol/L

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 H-11[10].

Highly heparinized samples will decrease the iCa[6]; balanced heparin or low heparin collection tubes/syringes are recommended.

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 dobutamide, 2.5mmol/L tolbutamide.

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, 7 mmol/L lactate, +20% PCV Hct, 0.8% lipids, 9.1 mmol/L cholesterol, 1 mmol/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. Burns eds., Elsevier Saunders, St. Louis, 2006.
2. CLSI. Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline-Second Edition, CLSI document EP9-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 EP7-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.
6. CLSI. Ionized Calcium Determinations: Pre-collection Variables, Specimen Choice, Collection and Handling. Approved Guideline, CLSI document C31-A2 (ISBN 1-56238-436-8), CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2001.
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10. CLSI. Procedures for the Collection of Arterial Blood Specimens; Approved Standard, CLSI document H11-A4 (ISBN 1-56238-545-3), CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2004.
11. CLSI. Evaluation of Precision in Clinical Chemistry Devices; Approved Guideline-Second Edition, CLSI document EP5-A2 (ISBN 1-56238-542-9), CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2004.

12.6 Hematocrit (Hct) and Calculated Hemoglobin (cHgb)

12.6.1 Measured values

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.

12.6.2 Calculated Values

Hemoglobin concentration is calculated from the measured hematocrit according to the relation[1,2]

cHgb (g/dL) = Hct (decimal fraction) x 34

The relation above assumes a normal Mean Corpuscular Hemoglobin Concentration, MCHC of 34%[1,2].

12.6.3 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 in hospitals, nursing homes or other clinical care institutions.

Measurement of Hct distinguishes normal from abnormal states of blood volume, such as anemia and erythrocytosis.

12.6.4 Contents

Each Test Card incorporating a Hct test contains two (2) gold sensing electrodes and a calibrator fluid containing a known concentration of dissolved electrolytes with a known conductivity.

12.6.5 Traceability

Hematocrit values assigned to controls and calibrator fluids are traceable to the standard method for measuring packed cell volume by the microhematocrit method – applicable standard CLSI H7-A3[3]

12.6.6 Sample Collection

Refer to 12.2.6 Sample Collection

12.6.7 Additional Information

Refer to section “03 - epoc System Operation” of the epoc System Manual for detailed sample collection and system operating instructions for conducting a blood test.

Refer to section “09 - Quality Assurance” of the epoc System Manual for quality control requirements.

12.6.8 Measurement Range

	Measurement Range	Normal Range[4]
Hct	10 – 75 %	38 – 51 %
	0.10 – 0.75	0.38 – 0.51 L/L
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

12.6.9 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 EP9-A2[5] for method comparison studies, CLSI EP7-A2[6] for interference studies and CLSI EP5-A2[9] for precision studies.

A. Precision Data

In the precision data tables below, SD_{WR} denotes within run standard deviation and SD_T denotes total standard deviation.

In-house Precision 1*:* commercial hematocrit controls run in a 20 day precision study[9] with 2 measurements each day per each control level. 4 manufactured lots, 6 different epoc Readers

	Units	Mean	SD_{WR}	%CV	SD_T	%CV
Level 1	%PCV	25.3	0.4	1.5	0.4	1.6
Level 3	%PCV	46.1	0.7	1.5	0.7	1.5

In-house Precision 2: whole blood samples run on 20 sequential manufactured lots using at least 8 different epoc Readers, with 12 replicates per each blood sample per lot.

	Units	Mean	mean SD_{WR}	%CV
Blood level 1	%PCV	44.0	0.7	1.6
Blood level 2	%PCV	22.0	0.7	3.0

Clinical Site Precision: 10 replicates of whole blood Patient samples run by different operators of the epoc system at different point-of-care sites. Each precision study employed 5 different epoc Readers.

		Units	Mean	SD_{WR}	%CV
Site 1	Operator 1	%PCV	40	0.6	1.4
	Operator 2	%PCV	40	0.5	1.3
Site 2	Operator 3	%PCV	39	0.6	1.6
	Operator 4	%PCV	41	0.5	1.2
	Operator 5	%PCV	40	0.6	1.4
Site 3	Operator 6	%PCV	40	0.8	2.0
	Operator 7	%PCV	38	0.7	1.9

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^2
Hct	0-75	% PCV	1.005	-0.58	0.999

C. Clinical Sites Method Comparison Data

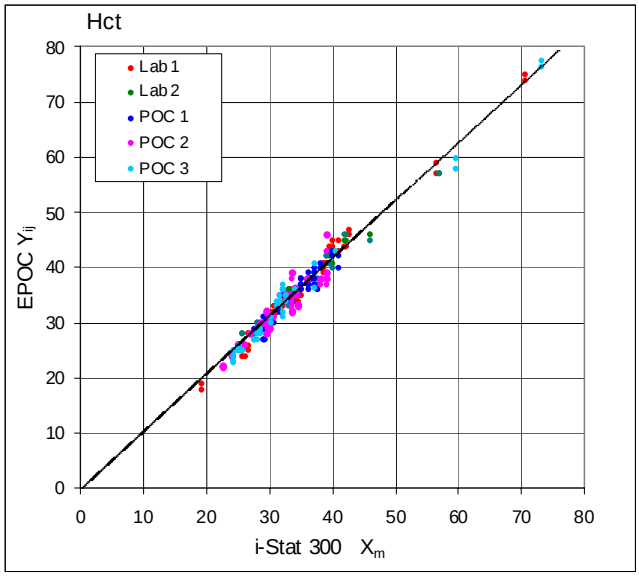
Linear regression analysis was performed on the method comparison data in accordance with CLSI EP9-A2[5]. In the method comparison statistics table, N is the number of Patient specimens in the data set, Sxx and Syy are the pooled pair-wise imprecision of the comparative and epoc test methods respectively, 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 (two test occasions) then in three (3) point-of-care sites.

Method Comparison Summary Statistics: whole blood

1. X: i-Stat 300 test
2. 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
X min	19	24	28	23	24	19
X max	73	57	41	39	60	73
R	0.995	0.990	0.964	0.955	0.976	0.987

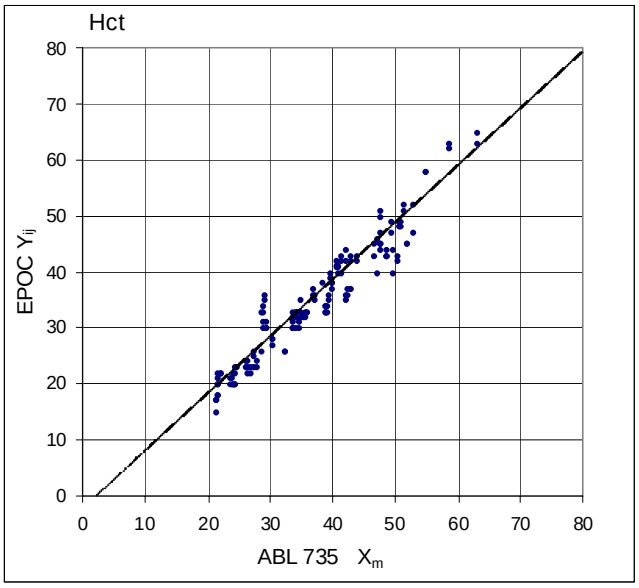


Clinical Site Method Comparison 2: In another hospital study the epoc was compared with the Radiometer ABL 735[8] in the lab. (The ABL 735 hematocrit value is calculated from the measured hemoglobin.)

Method Comparison Summary Statistics: whole blood

1. X: Radiometer ABL 735
2. Y: epoc test

Hct	Lab
N	77
Sxx	1.42
Syy	1.16
Intercept	-2.3
Slope	1.006
Syx	2.84
X min	21
X max	63
R	0.964



D. Limitations and Interferences

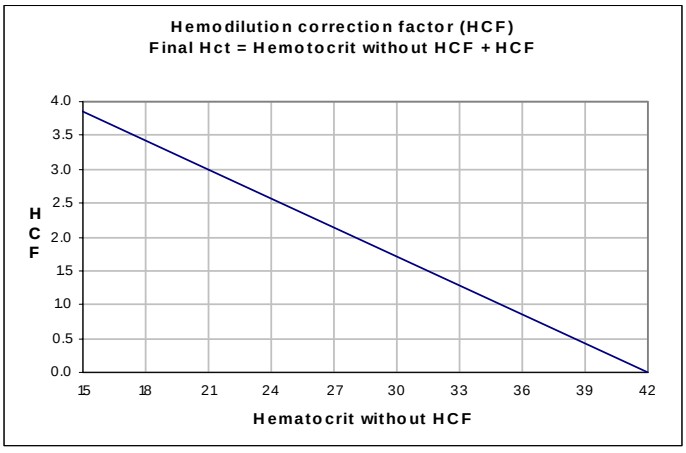
Blood samples must be well mixed in order to obtain accurate hematocrit results. The best way to ensure this is to test the sample immediately after collection. For samples where testing delays of greater than one minute occur, cells should be thoroughly re-mixed by rolling the sample between the hands 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[6] 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.

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[4]. 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 sections 6 and 7 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%. The differences between no HCF and HCF algorithm are illustrated in the figure to the right.



  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.

- 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 salycilate, 0.4 mmol/L ascorbate, 4.3 mmol/L salycilate, 1 mmol/L iodide, 2.2 mmol/L ibuprofen, 4 mmol/L lithium, 19 mmol/L bromide.

The following levels of endogenous interferences were tested and found to be clinically insignificant: 0.8% lipids, 9.1 mmol/L cholesterol, 20 mmol/L β-hydroxybutyrate, 1 mmol/L cysteine, 0.26 mmol/L bilirubin, +2 mmol/L phosphate.

E. References

1. M.L. Turgeon, *Clinical Hematology-Theory and Procedures*, Little, Brown and Co., Boston/Toronto, 1985.
2. J.D. Bower, P.G. Ackerman and G. Toto, Eds., *Clinical Laboratory Methods*, Chapter 5: Evaluation of formed elements in blood, St. Louis, The C.V. Mosby Company, 1974.
3. CLSI. *Procedure for determining Packed Cell Volume by the Microhematocrit method; Approved Standard-Third Edition*, CLSI document H7-A3 (ISBN 1-56238-413-9), CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2000.
4. B.E. Statland, *Clinical Decision Levels for Lab Tests*, Medical Economic Books, Oradell, NJ, 1987.
5. CLSI. *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline-Second Edition*, CLSI document EP9-A2 (ISBN 1-56238-472-4), CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2002.
6. CLSI. *Interference Testing in Clinical Chemistry; Approved Guideline*, CLSI document EP7-A2 (ISBN 1-56238-480-5), CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2002.
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. Radiometer ABL 735, Radiometer Medical Aps, Åkandevej 21, DK-2700 Brønshøj, Denmark, “Radiometer” and “ABL” are registered trademarks of Radiometer Medical Aps.
9. CLSI. Evaluation of Precision in Clinical Chemistry Devices; Approved Guideline-Second Edition, CLSI document EP5-A2 (ISBN 1-56238-542-9), CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2004.

12.7 pH

pH is measured by potentiometry using an pH selective membrane electrode. The concentration of hydrogen ions is obtained from the measured potential using the Nernst equation.

12.7.1 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 in hospitals, nursing homes or other clinical care institutions.

Measurement of pH, pCO_2, pO_2 (blood gases) is used in the diagnosis and treatment of life-threatening acid-base disturbances.

12.7.2 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.

12.7.3 Traceability

Values of pH 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 “03 - epoc System Operation” of the epoc System Manual for detailed sample collection and system operating instructions for conducting a blood test.

Refer to section “09 - Quality Assurance” of the epoc System Manual for quality control requirements.

12.7.6 Measurement Range

	Measurement Range	Normal Range[1]
pH	6.5 – 8.0	7.35 – 7.45 arterial
		7.32 – 7.43 venous

12.7.7 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 epoc System Operation section of System Manual).

The pH at the Patient’s temperature (T) is calculated as follows[2]

$$pH\,(T) = pH - 0.0147(T - 37) + 0.0065(7.4 - pH)\,(T - 37)$$

12.7.8 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 EP9-A2[3] for method comparison studies, CLSI EP7-A2[4] for interference studies and CLSI EP5-A2[10] for precision studies.

A. Precision Data

In the precision data tables below, SD_{WR} denotes within run standard deviation and SD_T denotes total standard deviation.

In-house Precision 1: commercial aqueous blood gas and electrolyte controls run on 20 sequential manufactured lots using at least 8 different epoc Readers, with 16 replicate measurements per lot per each control fluid level.

	Units	Mean	SD_{WR}	%CV	SD_T	%CV
Level 1	pH units	6.992	0.007	0.10	0.010	0.15
Level 3	pH units	7.673	0.007	0.09	0.011	0.14

In-house Precision 2: commercial aqueous blood gas and electrolyte controls run in a 20 day precision study[10] with 2 measurements each day per each control level. 4 manufactured lots, 6 different epoc Readers

	Units	Mean	SD_{WR}	%CV	SDT	%CV
Level 1	pH units	6.986	0.006	0.09	0.008	0.11
Level 3	pH units	7.676	0.005	0.07	0.006	0.08

In-house Precision 3*:* whole blood samples run on 20 sequential manufactured lots using at least 8 different epoc Readers, with 12 replicates per each blood sample per lot.

	Units	Mean	mean SD_{WR}	%CV
Blood level 1	pH units	7.200	0.007	0.09
Blood level 2	pH units	7.700	0.009	0.12

Clinical Site Precision 1: 10 replicates of commercial aqueous blood gas controls run by operators of the epoc system at 3 different point-of-care sites. Each precision study employed from 2 to 4 different epoc Readers.

High pH level commercial aqueous blood gas control

	Units	Mean	SD_{WR}	%CV
Operator 1	pH units	7.679	0.004	0.05
Operator 2	pH units	7.672	0.005	0.07
Operator 3	pH units	7.685	0.009	0.12

Low pH level commercial aqueous blood gas control

	Units	Mean	SD_{WR}	%CV
Operator 4	pH units	7.101	0.005	0.07
Operator 5	pH units	7.094	0.006	0.08
Operator 6	pH units	7.088	0.013	0.18
Operator 7	pH units	7.079	0.006	0.08

Clinical Site Precision 2: 10 replicates of different whole blood Patient samples run by different operators of the epoc system at different point-of-care sites. Each precision study employed 5 different epoc Readers.

		Units	Mean	SD_{WR}	%CV
Site 1	Operator 1	pH units	7.365	0.006	0.08
	Operator 2	pH units	7.368	0.005	0.07
Site 2	Operator 3	pH units	7.322	0.005	0.07
	Operator 4	pH units	7.335	0.006	0.08
	Operator 5	pH units	7.303	0.009	0.12
Site 3	Operator 6	pH units	7.266	0.006	0.08
	Operator 7	pH units	7.381	0.004	0.05

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^2
pH	6.4-7.9	pH units	1.021	-0.15	0.998

C. Clinical Sites Method Comparison Data

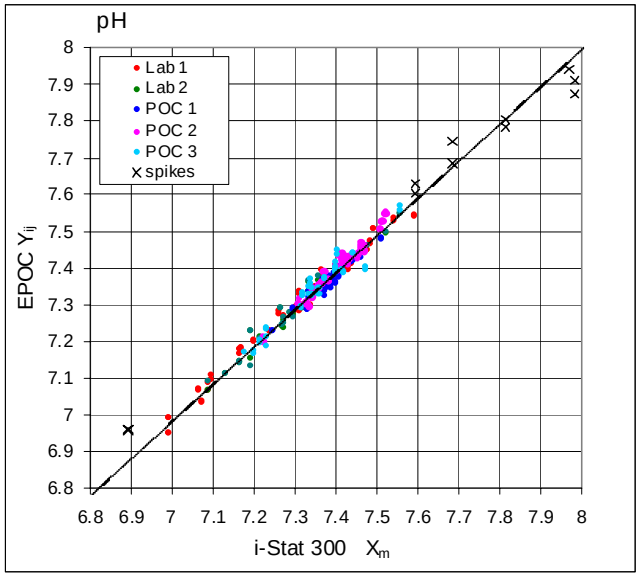
Linear regression analysis was performed on the method comparison data in accordance with CLSI EP9-A2[3]. In the method comparison statistics table, N is the number of Patient specimens in the data set, Sxx and Syy are the pooled pair-wise imprecision of the comparative and epoc test methods respectively, Syx is the standard error and R is the correlation coefficient.

Clinical Site Method Comparison 1: In one hospital study the epoc was compared with the i-Stat 300[6] in the lab (two test occasions) then in 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
X min	6.991	7.085	7.243	7.223	7.174	6.991	6.770
X max	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

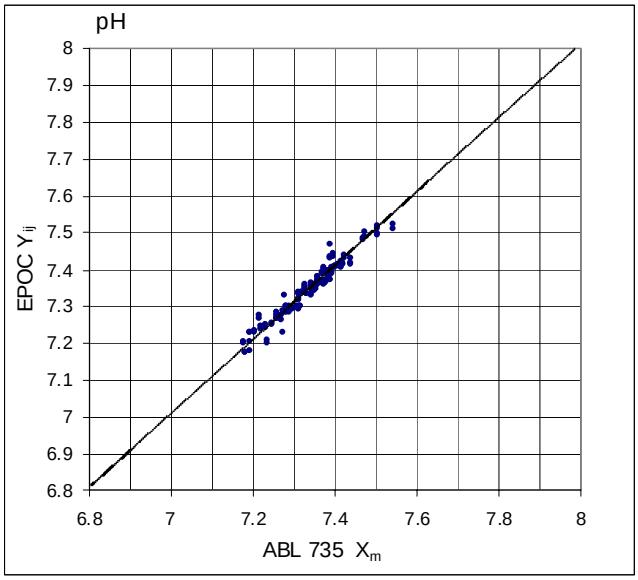
*data set includes Patient samples spiked with NaOH for extended data range



Clinical Site Method Comparison 2: In another hospital study the epoc 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	Lab
N	77
Sxx	0.011
Syy	0.010
Intercept	0.366
Slope	0.952
Syx	0.017
X min	7.175
X max	7.542
R	0.975



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 salycilate, 0.4 mmol/L ascorbate, 4.3 mmol/L salycilate, 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.

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, 0.8% lipids, 9.1 mmol/L cholesterol, 20 mmol/L β-hydroxybutyrate, 1 mmol/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. Burns eds., Elsevier Saunders, St. Louis, 2006.
2. CLSI. Blood Gas and pH Analysis and Related Measurements; Approved Guideline, CLSI document C46-A (ISBN 1-56238-444-9), CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2001.
3. CLSI. Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline-Second Edition, CLSI document EP9-A2 (ISBN 1-56238-472-4), CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2002.
4. CLSI. Interference Testing in Clinical Chemistry; Approved Guideline, CLSI document EP7-A2 (ISBN 1-56238-480-5), CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2002.
5. CLSI. Procedures for the Collection of Arterial Blood Specimens; Approved Standard, CLSI document H11-A4 (ISBN 1-56238-545-3), CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2004.
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. 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. Burns eds., Elsevier Saunders, St. Louis, 2006.
9. 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. Burns eds., Elsevier Saunders, St. Louis, 2006.
10. CLSI. Evaluation of Precision in Clinical Chemistry Devices; Approved Guideline-Second Edition, CLSI document EP5-A2 (ISBN 1-56238-542-9), CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2004.

12.8 pCO_2 and Calculated Values: $cHCO_3$-, $cTCO_2$ and BE

12.8.1 Measured values

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.

12.8.2 Calculated Values[1]

NOTE *– alternate analyte acronyms for* ***$cHCO_3$-*** *are* ***HCO_3-act*** *or* ***HCO_3-***

Calculated bicarbonate: LOG $cHCO_3$- = pH + LOG pCO_2 – 7.608

Calculated TCO_2: $cTCO_2$ = $cHCO_3$- + 0.0307pCO_2

Base Excess (extra cellular fluid): BE(ecf) = $cHCO_3$- – 24.8 + 16.2(pH – 7.4)

Base Excess (blood): BE(b) = (1 – 0.014cHgb)*($cHCO_3$- – 24.8 + (1.43*cHgb + 7.7)*(pH – 7.4))

Applicable standards: CLSI C46-A[1].

12.8.3 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 in hospitals, nursing homes or other clinical care institutions.

Measurement of pH, pCO_2, pO_2 (blood gases) is used in the diagnosis and treatment of life-threatening acid-base disturbances.

12.8.4 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.

12.8.5 Traceability

Dissolved carbon dioxide concentration values assigned to controls and calibrator fluids are traceable to NIST standards via commercially available certified medical gas standards.

12.8.6 Sample Collection

Refer to 12.2.6 Sample Collection

12.8.7 Additional Information

Refer to section “03 - epoc System Operation” of the epoc System Manual for detailed sample collection and system operating instructions for conducting a blood test.

Refer to section “09 - Quality Assurance” of the epoc System Manual for quality control requirements.

12.8.8 Measurement Range

	Measurement Range	Normal Range[2]	
		Arterial	Venous
pCO_2	5 – 250 mm Hg	35 – 48 mm Hg	41 – 51 mm Hg
	0.7 – 33.3 kPa	4.7 – 6.4 kPa	5.4 – 6.8 kPa
$cHCO_3^-$	1 – 85 mmol/L	21 – 28 mmol/L	22 – 29 mmol/L
	1 – 85 mEq/L	21 – 28 mEq/L	22 – 29 mEq/L
$cTCO_2$	1 – 85 mmol/L	22 – 29 mmol/L	23 – 30 mmol/L
	1 – 85 mEq/L	22 – 29 mEq/L	23 – 30 mEq/L
BE	-30 – 30 mmol/L	-2 – +3 mmol/L	-2 – +3 mmol/L
	-30 – 30 mEq/L	-2 – +3 mEq/L	-2 – +3 mEq/L

12.8.9 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 epoc System Operation section of System Manual).

The pCO_2 at the Patient's temperature (T) is calculated as follows[1]

$pCO_2\ (T) = pCO_2 \times 10^{0.019(T - 37)}$

12.8.10 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 EP9-A2[4] for method comparison studies, CLSI EP7-A2[7] for interference studies and CLSI EP5-A2[11] for precision studies.

A. Precision Data

In the precision data tables below, SD_{WR} denotes within run standard deviation and SD_T denotes total standard deviation.

In-house Precision 1: commercial aqueous blood gas and electrolyte controls run on 20 sequential manufactured lots using at least 8 different epoc Readers, with 16 replicate measurements per lot per each control fluid level.

	Units	Mean	SD_{WR}	%CV	SD_T	%CV
Level 1	mm Hg	86.2	1.9	2.2	2.4	2.8
Level 3	mm Hg	24.1	0.5	2.1	0.7	3.0

In-house Precision 2: commercial aqueous blood gas and electrolyte controls run in a 20 day precision study[11] with 2 measurements each day per each control level. 4 manufactured lots, 6 different epoc Readers

	Units	Mean	SD_{WR}	%CV	SD_T	%CV
Level 1	mm Hg	80.6	1.9	2.4	2.4	2.9
Level 3	mm Hg	22.5	0.4	1.6	0.6	2.5

In-house Precision 3: whole blood samples run on 20 sequential manufactured lots using at least eight (8) different epoc Readers, with 12 replicates per each blood sample per lot.

	Units	Mean	mean SD_{WR}	%CV
Blood level 1	mm Hg	65.0	1.5	2.3
Blood level 2	mm Hg	90.0	2.9	3.2

Clinical Site Precision 1: 10 replicates of commercial aqueous blood gas controls run by operators of the epoc system at three (3) different point-of-care sites. Each precision study employed from two (2) to four (4) different epoc Readers.

Low pCO_2 level commercial aqueous blood gas control

	Units	Mean	SD_{WR}	%CV
Operator 1	mm Hg	21.2	0.4	1.9
Operator 2	mm Hg	21.2	0.5	2.3
Operator 3	mm Hg	20.5	1.1	5.2

High pCO_2 level commercial aqueous blood gas control

	Units	Mean	SD_{WR}	%CV
Operator 4	mm Hg	69.0	1.2	1.7
Operator 5	mm Hg	70.2	1.2	1.7
Operator 6	mm Hg	68.2	1.3	1.8
Operator 7	mm Hg	67.2	1.3	1.9

Clinical Site Precision 2: 10 replicates of different whole blood Patient samples run by different operators of the epoc system at different point-of-care sites. Each precision study employed 5 different epoc Readers.

		Units	Mean	SD_{WR}	%CV
Site 1	Operator 1	mm Hg	52.3	2.0	3.8
	Operator 2	mm Hg	49.9	0.9	1.9
Site 2	Operator 3	mm Hg	56.9	0.9	1.5
	Operator 4	mm Hg	55.4	1.4	2.5
	Operator 5	mm Hg	58.9	1.1	1.9
Site 3	Operator 6	mm Hg	61.7	1.8	2.9
	Operator 7	mm Hg	41.5	0.9	2.1

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^2
pCO_2	10-230	mm Hg	1.058	-3.6	0.998

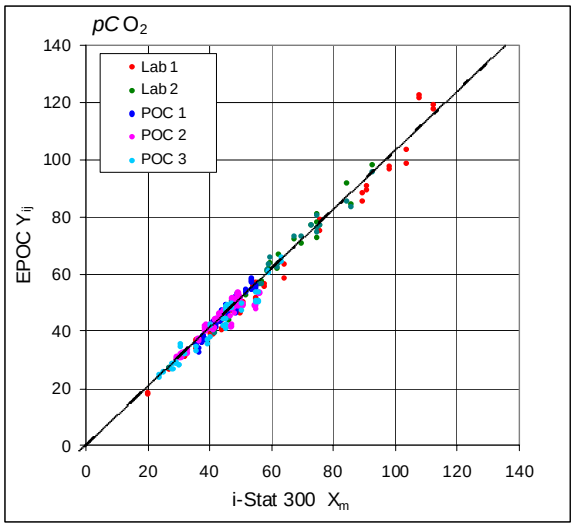
C. Clinical Sites Method Comparison Data

Linear regression analysis was performed on the method comparison data in accordance with CLSI EP9-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 was compared with the i-Stat 300[5] in the lab (two test occasions) then in three (3) point-of-care sites.

Method Comparison Summary Statistics: whole blood
X: i-Stat 300 test
Y: epoc test

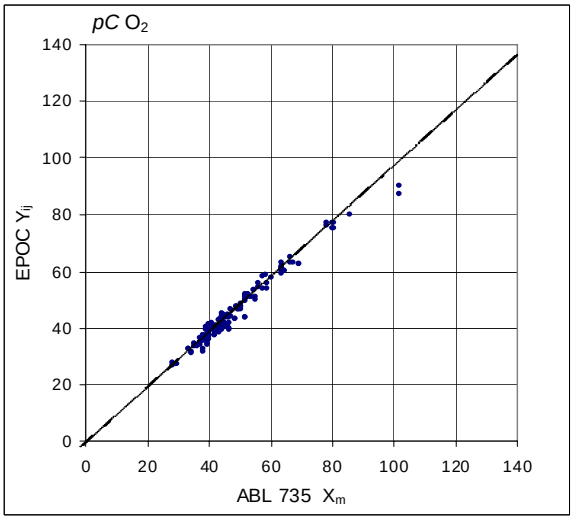
pCO_2	Lab 1	Lab 2	POC 1	POC 2	POC 3	All
N	34	24	35	28	22	143
Sxx	1.4	2.1	0.6	1.5	1.7	1.5
Syy	1.3	1.3	0.6	1.1	1.2	1.1
Intercept	-2.0	-1.2	-6.1	5.0	1.0	-0.9
Slope	1.048	1.055	1.167	0.911	0.983	1.041
Syx	3.1	2.3	1.6	2.3	2.4	2.4
X min	19.7	26.7	35.6	29.1	23.6	19.7
X max	112.2	92.5	54.4	55.6	63.0	112.2
R	0.993	0.991	0.967	0.949	0.978	0.990



Clinical Site Method Comparison 2: In another hospital study the epoc was compared with the Radiometer ABL 735[6] in the lab.

Method Comparison Summary Statistics: whole blood
X: Radiometer ABL 735
Y: epoc test

pCO2	Lab
N	77
Sxx	1.5
Syy	0.8
Intercept	1.6
Slope	0.924
Syx	1.97
X min	27.6
X max	101.5
R	0.987



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 salycilate, 0.4 mmol/L ascorbate, 4.3 mmol/L salycilate, 2.2 mmol/L ibuprofen, 1.66 mmol/L acetaminophen, 2 mmol/L ammonium, 4 mmol/L lithium, 0.4 mmol/L iodide, 25 mmol/L bromide.

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, 0.8% lipids, 9.1 mmol/L cholesterol, 20 mmol/L β-hydroxybutyrate, 1 mmol/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 document C46-A (ISBN 1-56238-444-9), CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2001.
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. Burns 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. Burns eds., Elsevier Saunders, St. Louis, 2006.
4. CLSI. Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline-Second Edition, CLSI document EP9-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 EP7-A2 (ISBN 1-56238-480-5), CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2002.
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9. Stow, R.W, Baer, R.F., Randall, B.F., Rapid measurement of the tension of carbon dioxide in blood, Arch.Phys.Med.and Rehabilit., 39, 646-650, 1957.
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12.9 pO_2 and Calculated Oxygen Saturation: cSO_2

12.9.1 Measured values

pO_2 is measured by amperometry using a membrane covered oxygen sensing cathode electrode. The oxygen reduction current is proportional to the dissolved oxygen concentration[10]

12.9.2 Calculated Values[1]

NOTE *– alternate analyte acronym for* ***cSO_2*** *is* ***O2SAT***

$cSO_2 = 100(X^3 + 150X) / (X^3 + 150X + 23400)$

$X = pO_2 * 10^{(0.48(pH-7.4)-0.0013(cHCO3-25))}$

Because oxygen saturation also depends on the level of carbon monoxide and 2,3 diphosphoglycerate in the blood, as well as the effects of dysfunctional hemoglobins (carboxy-, met– and sulfhemoglobin), 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[2, 3]. 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.

12.9.3 Indications for Use

The pO_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 in hospitals, nursing homes or other clinical care institutions.

Measurement of pH, pCO_2, pO_2 (blood gases) is used in the diagnosis and treatment of life-threatening acid-base disturbances.

12.9.4 Contents

Each Test Card incorporating a pO_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.

12.9.5 Traceability

Dissolved oxygen concentration values assigned to controls and calibrator fluids are traceable to NIST standards via commercially available certified medical gas standards.

12.9.6 Sample Collection

Refer to 12.2.6 Sample Collection

12.9.7 Additional Information

Refer to section “03 - epoc System Operation” of the epoc System Manual for detailed sample collection and system operating instructions for conducting a blood test.

Refer to section “09 - Quality Assurance” of the epoc System Manual for quality control requirements.

12.9.8 Measurement Range

	Measurement Range	Normal Range[4] Arterial
pO_2	5 - 750 mm Hg	83 – 108 mm Hg
	0.7 – 100 kPa	11.1 – 14.4 kPa
cSO_2	0 – 100 %	94 – 98 %

12.9.9 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 epoc System Operation section of System Manual).

The pO_2 at the Patient's temperature (T) is calculated as follows[2]

$$pO_2\ (T) = pO_2 \times 10^{\frac{5.49x10^{-11}\,pO_2^{3.88}+0.071}{9.71x10^{-9}\,pO_2^{3.88}+2.30}(T-37)}$$

12.9.10 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 EP9-A2[5] for method comparison studies, CLSI EP7-A2[6] for interference studies and CLSI EP5-A2[11] for precision studies.

A. Precision Data

In the precision data tables below, SD_{WR} denotes within run standard deviation and SD_T denotes total standard deviation.

In-house Precision 1: commercial aqueous blood gas and electrolyte controls run on 20 sequential manufactured lots using at least 8 different epoc Readers, with 16 replicate measurements per lot per each control fluid level.

	Units	Mean	SD_{WR}	%CV	SD_T	%CV
Level 1	mm Hg	74.9	2.4	3.1	2.8	3.8
Level 3	mm Hg	140.1	2.4	1.7	2.8	2.0

In-house Precision 2: commercial aqueous blood gas and electrolyte controls run in a 20 day precision study[11] with 2 measurements each day per each control level. 4 manufactured lots, 6 different epoc Readers

	Units	Mean	SD_{WR}	%CV	SD_T	%CV
Level 1	mm Hg	78.4	1.9	2.5	2.6	3.3
Level 3	mm Hg	141.2	1.8	1.3	2.2	1.6

In-house Precision 3*:* whole blood samples run on 20 sequential manufactured lots using at least 8 different epoc Readers, with 12 replicates per each blood sample per lot.

	Units	Mean	mean SD_{WR}	%CV
Blood level 1	mm Hg	38.0	2.2	5.9
Blood level 2	mm Hg	70.0	2.4	3.5

Clinical Site Precision 1: 10 replicates of commercial aqueous blood gas controls run by operators of the epoc system at 3 different point-of-care sites. Each precision study employed from 2 to 4 different epoc Readers.

High pO_2 level commercial aqueous blood gas control

	Units	Mean	SD_{WR}	%CV
Operator 1	mm Hg	136.3	4.1	3.0
Operator 2	mm Hg	139.8	2.0	1.4
Operator 3	mm Hg	138.1	3.1	2.2

Low pO_2 level commercial aqueous blood gas control

	Units	Mean	SD_{WR}	%CV
Operator 4	mm Hg	67.5	2.3	3.5
Operator 5	mm Hg	67.4	3.3	4.9
Operator 6	mm Hg	70.1	3.2	4.6
Operator 7	mm Hg	70.8	4.0	5.6

Clinical Site Precision 2: 10 replicates of different whole blood Patient samples run by different operators of the epoc system at different point-of-care sites. Each precision study employed 5 different epoc Readers.

		Units	Mean	SD_{WR}	%CV
Site 1	Operator 1	mm Hg	28.6	1.7	6.0
	Operator 2	mm Hg	32.9	1.8	5.5
Site 2	Operator 3	mm Hg	33.9	1.2	3.5
	Operator 4	mm Hg	30.0	1.5	5.0
	Operator 5	mm Hg	40.1	1.2	3.1
Site 3	Operator 6	mm Hg	61.8	3.5	5.6
	Operator 7	mm Hg	74.6	2.9	3.9

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^2
pO2	10-750	mm Hg	1.022	-3.9	0.999

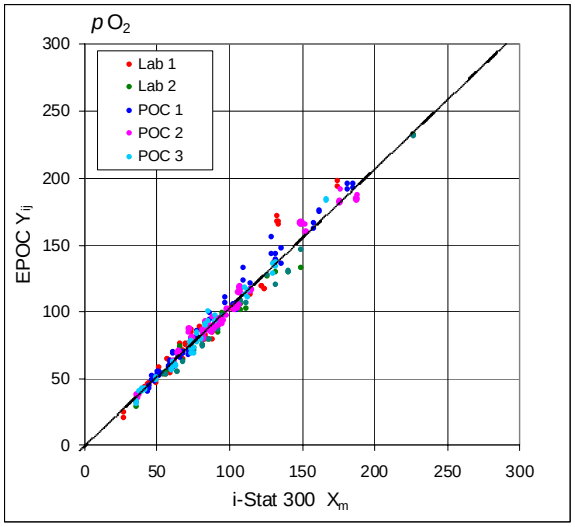
C. Clinical Sites Method Comparison Data

Linear regression analysis was performed on the method comparison data in accordance with CLSI EP9-A2[5]. 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 was compared with the i-Stat 300[6] in the lab (two test occasions) then in three point-of-care sites.

Method Comparison Summary Statistics: whole blood
X: i-Stat 300 test
Y: epoc test

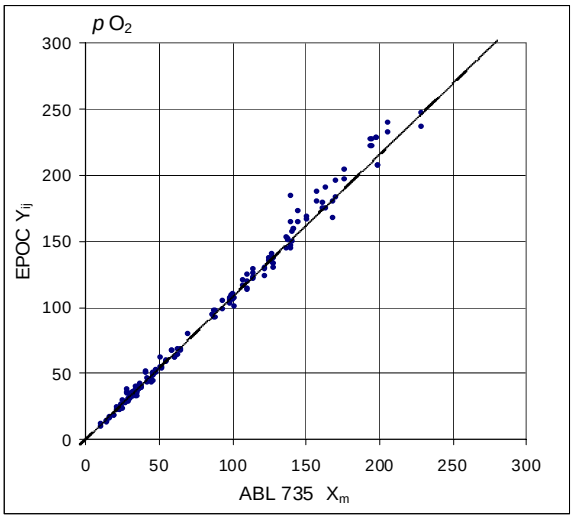
pO2	Lab 1	Lab 2	POC 1	POC 2	POC 3	All
N	34	23	35	28	22	142
Sxx	2.6	4.3	3.2	6.2	2.7	4.6
Syy	1.7	3.5	3.0	2.9	2.6	2.7
Intercept	-6.5	-3.1	-1.3	0.3	-3.9	-1.7
Slope	1.142	1.006	1.083	1.041	1.090	1.053
Syx	8.5	4.5	4.5	4.9	4.2	6.6
X min	26.0	35.0	43.5	36.0	35.5	26.0
X max	174.5	226.5	185.0	187.5	166.0	226.5
R	0.977	0.995	0.995	0.990	0.994	0.978



Clinical Site Method Comparison 2: In another hospital study the epoc was compared with the Radiometer ABL 735[7] in the lab.

Method Comparison Summary Statistics: whole blood
X: Radiometer ABL 735
Y: epoc test

pO2	Lab
N	77
Sxx	3.4
Syy	3.7
Intercept	-0.8
Slope	1.117
Syx	5.1
X min	10.2
X max	278.5
R	0.997



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[2] and ionized calcium affected by the pH change[9]. 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[8] 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: None identified.

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 salycilate, 0.4 mmol/L ascorbate, 4.3 mmol/L salycilate, 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.

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, 0.8% lipids, 9.1 mmol/L cholesterol, 20 mmol/L β-hydroxybutyrate, 1 mmol/L cysteine, 0.26 mmol/L bilirubin, +2 mmol/L phosphate.

E. References

1. J.W. Severinghaus, Simple and accurate equations for human blood O2 dissociation computations, J. Appl. Physiol., 46, 1979, p. 599-602.
2. CLSI. Blood Gas and pH Analysis and Related Measurements; Approved Guideline, CLSI document C46-A (ISBN 1-56238-444-9), CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2001.
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. Burns eds., Elsevier Saunders, St. Louis, 2006.
4. 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. Burns eds., Elsevier Saunders, St. Louis, 2006.
5. CLSI. Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline-Second Edition, CLSI document EP9-A2 (ISBN 1-56238-472-4), CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2002.
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. CLSI. Interference Testing in Clinical Chemistry; Approved Guideline, CLSI document EP7-A2 (ISBN 1-56238-480-5), CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2002.
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12.10 Lactate (Lac)

12.10.1 Measured values

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,

$$\beta\text{-D-lactate} + O_2 + H_2O \xrightarrow{\text{Lactate Oxidase}} \text{Pyruvic acid} + H_2O_2 \quad (1)$$

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.

$$H_2O_2 + HRP^{red} \rightarrow HRP^{ox} \quad (2)$$

$$HRP^{ox} + Red \rightarrow Ox + HRP^{red} \quad (3)$$

$$Ox + e^- \rightarrow Red \quad (4)$$

The reduction current is proportional to the concentration of lactate in the test fluid.

12.10.2 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 in hospitals, nursing homes or other clinical care institutions.

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).

12.10.3 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.

12.10.4 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.

12.10.5 Sample Collection

Refer to 12.2.6 Sample Collection

12.10.6 Additional Information

Refer to section "03 - epoc System Operation" of the epoc System Manual for detailed sample collection and system operating instructions for conducting a blood test.

Refer to section "09 - Quality Assurance" of the epoc System Manual for quality control requirements.

12.10.7 Measurement Range

	Measurement Range	Normal Range[2]
Lactate	2.7 – 180.2 mg/dL	5.0 – 12 mg/dL
	0.30 - 20.00 mmol/L	0.56 - 1.39 mmol/L
	0.03 – 0.18 g/L	0.05 – 0.12 g/L

12.10.8 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 EP9-A2[3] for method comparison studies, CLSI EP7-A2[4] for interference studies, CLSI EP6-A[7] for linearity studies and CLSI EP5-A[5] for precision studies.

A. Precision Data

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.

In-house Precision (CLSI EP5-A): Four (4) card lots using at least 40 epoc Readers with replicate measurements were run in-house twice a day for twenty days for each fluid.

Lactate mM	All	
	L1	L3
N	320	320
Mean	7.99	0.94
SWD	0.39	0.03
SDD	0.32	0.03
ST	0.51	0.04
Total CV%	6.3%	4.7%

Aqueous Clinical Site Precision: 14-15 replicates of commercial aqueous blood gas, electrolytes and metabolites controls were run by potential end users of the epoc system at 2 different point-of-care sites. Each precision study employed at least 5 different epoc Readers. Three lots of cards were used.

Aqueous Control Precision				Lactate, mM		
Site	User	QC Level	N	Mean	SD	%CV
1	Operator 1	L3	15	0.95	0.031	3.3%
1	Operator 2	L3	15	0.94	0.027	2.9%
1	Operator 3	L2	14	2.88	0.05	1.8%
1	Operator 4	L2	15	2.91	0.08	2.8%
2	Operator 1	L1	15	7.34	0.57	7.8%
2	Operator 2	L1	15	7.45	0.42	5.6%

Blood Clinical Site Precision: 15 replicates of venous whole blood at two (2) different lactate concentrations were run by potential end users of the epoc system at two (2) different point-of-care sites. Each precision study employed at least five (5) different epoc Readers. Four (4) card lots were used in this study.

Whole Blood Precision				Lactate, mM		
Site	User	Level	N	Mean	SD	%CV
1	Operator 1	WB L1	15	10.24	0.62	6.0%
1	Operator 2	WB L1	15	10.27	0.34	3.3%
2	Operator 1	WB L2	15	2.77	0.07	2.7%
2	Operator 2	WB L2	15	2.67	0.12	4.7%

B. Linearity Data

Whole Blood Linearity Study (CLSI EP6-A): 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 (as measured using an in-house standard whole blood lactate method with traceability to NIST standards). Four (4) card lots were used in this study.

Test Range	Slope	Intercept	R^2
0.3 - 20.1 mM	1.001	0.271	0.999

C. Clinical Sites Method Comparison Data

Linear regression analysis was performed on the method comparison data in accordance with CLSI EP9-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.

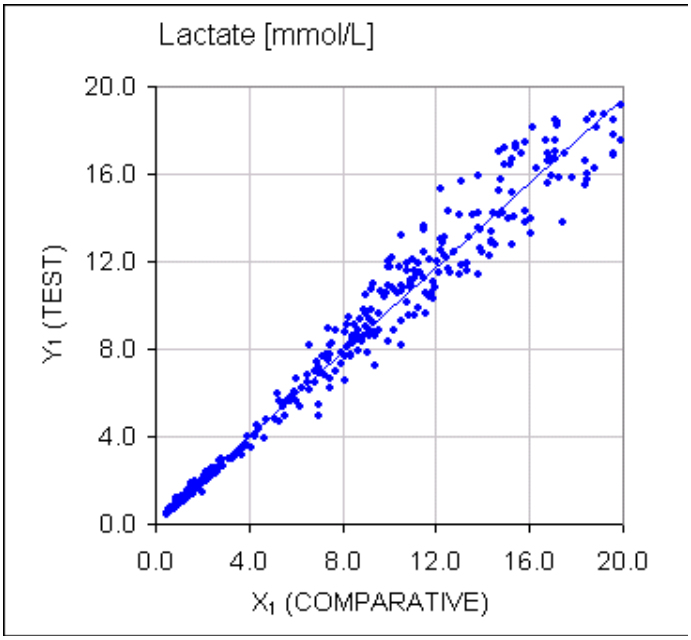
Method comparison studies were performed at two (2) hospitals. At one hospital 99 venous samples were tested. At another hospital both 43 arterial and 44 capillary samples were tested. Sample lactate concentrations on the comparison device varied from 0.57 to 14.57 mmol/L.

In these studies epoc 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

epoc Lactate vs. i-STAT	
N	373
Sxx	0.215
Syy	0.530
intercept	0.132
slope	0.967
Syx	0.948
X min	0.48
X max	19.95
R^2	0.9711



Lactate Scatter Plot versus i-STAT 300 with CG4+ cartridges

F. Limitations and Interferences

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 306 µM/mM Tylenol. 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 -3.3mM/mM of Iodide for an Iodide concentration under 0.3 mM. Above 0.3 mM Iodide, the Lactate bias will be a constant -1.0mM.
- Bromide will have no significant effect up to 25.4 mM after which it will decrease the lactate reading up to 14.6 µM/mM Bromide.
- Thiocyanate will have no significant effect up to 2.7 mM after which it will decrease the lactate reading by up to 96.6 µM/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 96.3 µM/mM N-Acetylcysteine.

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 142 µM/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 373 µM/mM glyoxylic acid.

The following levels of exogenous interferences were tested and found to be insignificant: 1.66mM (25mg/dL) acetaminophen, 630µmol/L (12.5mg/dL) Na ascorbate, 20mmol/L (588 mg/dL) citrate, 100 µmol/L (~2mg/dL) L-dopa, 9mmol/L (263mg/dL) EDTA, 4.84mmol/L (30mg/dL) ethylene glycol, 105 µmmol/L (0.441mg/dL) Na fluoride, 71 µmol/L Methyldopa, 2.55mmol/L oxidized glutathione, 2.55mmol/L reduced glutathione, 132 µmol/L (1.0mg/dL) hydroxyurea, 292µmol/L (4mg/dL) isoniazide (nydrazid), 81 µmol/L (1.5 mg/dL) K Oxalate, 0.037 mmol/L (1.2 mg/dL) Quinidine.

The following levels of endogenous interferences were tested and found to be insignificant: +342µmol/L (+29.0mg/dL) bilirubin conjugated, +342 µmol/L (+20.1mg/dL) bilirubin unconjugated, +13mmol/L (+503.1mg/dL) cholesterol, +1500µmol/L (+18mg/dL) L-cysteine, +0.8% 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 (1430 mg/dL). pO2 partial pressures below 20mmHg (2.67kPa) may decrease lactate values.

G. References

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12.11 Glucose (Glu)

12.11.1 Measured values

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,

$$\beta\text{-D-glucose} + O_2 + H_2O \xrightarrow{\text{Glucose Oxidase}} \text{D-gluconic acid} + H_2O_2 \quad (1)$$

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.

$$H_2O_2 + HRP^{red} \rightarrow HRP^{ox} \quad (2)$$

$$HRP^{ox} + Red \rightarrow Ox + HRP^{red} \quad (3)$$

$$Ox + e^- \rightarrow Red \quad (4)$$

The reduction current is proportional to the concentration of glucose in the test fluid.

12.11.2 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 in hospitals, nursing homes or other clinical care institutions.

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

12.11.3 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.

12.11.4 Traceability

Glucose concentration values assigned to controls and calibrator fluids are traceable to NIST standards.

12.11.5 Sample Collection

Refer to 12.2.6 Sample Collection

12.11.6 Additional Information

Refer to section "03 - epoc System Operation" of the epoc System Manual for detailed sample collection and system operating instructions for conducting a blood test.

Refer to section "09 - Quality Assurance" of the epoc System Manual for quality control requirements.

12.11.7 Measurement Range

	Measurement Range	Normal Range[2]
Glucose	20 - 700 mg/dL	74 – 100 mg/dL
	1.1 – 38.5 mmol/L	4.1 – 5.5 mmol/L
	0.20 -7.00 g/L	0.74 – 1.00 g/L

12.11.8 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 EP9-A2[3] for method comparison studies, CLSI EP7-A2[4] for interference studies and CLSI EP5-A[5] for precision studies.

A. Precision Data

In the precision data tables below, SD_{WR} denotes within run standard deviation and SD_T denotes total standard deviation.

In-house Precision 1: commercial aqueous blood gas and electrolyte controls run on 5 sequential manufactured lots using at least 8 different epoc Readers, with 16 replicate measurements per lot per each control fluid level.

	Units	Mean	SD_{WR}	%CV	SD_T	%CV
Level 3	mg/dL	51.1	1.2	2.3	1.6	3.1
Level 1	mg/dL	242.6	5.5	2.3	6.0	2.5

In-house Precision 2: commercial aqueous blood gas and electrolyte controls run in a 20 day precision study[5] with 2 measurements each day per each control level for each of 4 manufactured lots using 6 different epoc Readers

	Units	Mean	SD_{WR}	%CV	SD_T	%CV
Level 3	mg/dL	50.2	1.1	2.2	1.2	2.3
Level 1	mg/dL	241.9	4.7	2.0	5.5	2.3

In-house Precision 3: whole blood samples run on 5 sequential manufactured lots using at least 8 different epoc Readers, with 12 replicates per each blood sample per lot.

	Units	Mean	mean SD_{WR}	%CV
Blood level 1	mg/dL	80.0	1.2	1.5
Blood level 2	mg/dL	210.0	5.8	2.7

In-house Precision 4: whole blood samples were spiked at five levels of glucose and were tested with 100 replicates per each blood sample; each sample was tested within 12 minutes in two runs; each run was performed simultaneously on 50 different epoc Readers; a mix of four manufactured lots were included in this test.

	Units	Mean	mean SD	%CV
Blood level 1	mg/dL	22.5	1.2	5.4
Blood level 2	mg/dL	123.7	3.0	2.4
Blood level 3	mg/dL	215.9	8.5	3.9
Blood level 4	mg/dL	311.8	13.1	4.2
Blood level 5	mg/dL	548.3	17.6	3.2

Clinical Site Precision 1: 12 replicates of venous blood where glycolysis was allowed for a certain period of time was run by four different operators of the epoc system in a clinical environment. Each precision study employed 6 different epoc Readers.

Low glucose level blood

	Units	Mean	SD_{WR}	%CV
Operator 1	mg/dL	42.8	1.9	4.4
Operator 2	mg/dL	43.2	1.8	4.3
Operator 3	mg/dL	41.6	1.6	3.8
Operator 4	mg/dL	50.0	1.1	2.2

Clinical Site Precision 2: 12 replicates of venous blood spiked with glucose was run by four different operators of the epoc system in a clinical environment. Each precision study employed 6 different epoc Readers.

High glucose level blood

	Units	Mean	SD_{WR}	%CV
Operator 5	mg/dL	242.8	6.6	2.7
Operator 6	mg/dL	229.0	5.3	2.3
Operator 7	mg/dL	233.4	6.8	2.9
Operator 8	mg/dL	228.5	7.0	3.1

Clinical Site Precision 3: 10-12 replicates of commercial aqueous blood gas, electrolytes and metabolites controls were run by operators of the epoc system at 2 different point-of-care sites. Each precision study employed 5-6 different epoc Readers.

Low glucose level commercial aqueous blood gas electrolyte and metabolite control

	Units	Mean	SD_{WR}	%CV
Operator 1	mg/dL	48.0	1.5	3.2
Operator 2	mg/dL	46.6	1.0	2.1

Medium glucose level commercial aqueous blood gas electrolyte and metabolite control

	Units	Mean	SD_{WR}	%CV
Operator 3	mg/dL	109.7	3.6	3.3
Operator 4	mg/dL	106.8	1.8	1.7

High glucose level commercial aqueous blood gas electrolyte and metabolite control

	Units	Mean	SD_{WR}	%CV
Operator 5	mg/dL	258.9	9.0	3.5
Operator 6	mg/dL	256.9	2.3	0.9

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^2
43% Hct, 30mmHg pO2	20-700	mg/dL	1.022	-3.32	0.9997
62% Hct, 30mmHg pO2	20-700	mg/dL	1.018	-4.04	0.9996
43% Hct, <20mmHg pO2	20-700	mg/dL	0.955	+0.33	0.9995

C. Clinical Sites Method Comparison Data

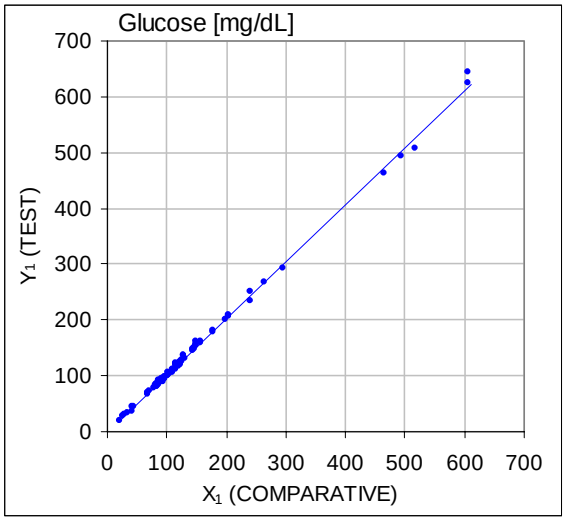
Linear regression analysis was performed on the method comparison data in accordance with CLSI EP9-A2[3]. In the method comparison statistics table, N is the number of Patient specimens in the data set, Sxx and Syy are the pooled pair-wise imprecision of the comparative and epoc test methods respectively, Syx is the standard error and R is the correlation coefficient.

Clinical Site Method Comparison 1: In one hospital study the epoc was compared with the i-Stat 300[6] in the lab and in one point-of-care site.

Method Comparison Summary Statistics: whole blood

X: i-Stat 300 CG8 cartridges test
Y: epoc test

Glu	All
N	80
Sxx	0.93
Syy	3.4
Intercept	-2.2
Slope	1.031
Syx	5.6
X min	20.0
X max	605.5
R	0.999



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.

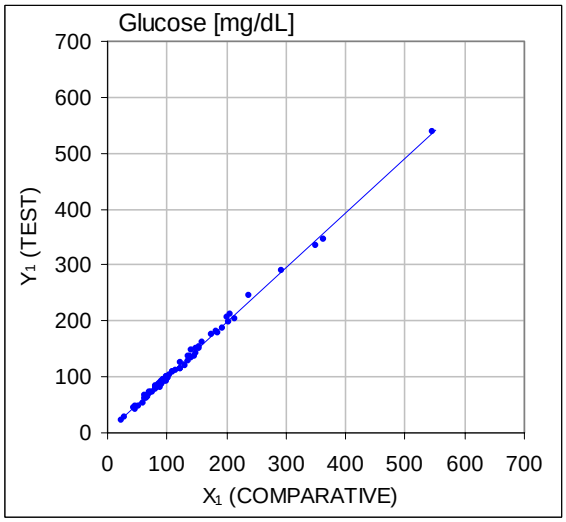
	Glucose [mg/dL]		
Range	20-70	70-200	200-700
N	10	59	11
Average reading	44.8	116.4	383.8
Pair Precision (SD)	0.80	2.44	7.08
%CV	1.8%	2.1%	1.8%

Clinical Site Method Comparison 2: In another hospital study the epoc was compared simultaneously with the Roche-Hitachi[7] instrument in the lab and with iSTAT 300[6]. The summaries are presented in the tables below. The correlation plots are illustrated on the next page.

Method Comparison Summary Statistics: whole blood

X: Roche-Hitachi P800-D2400 test
Y: epoc test

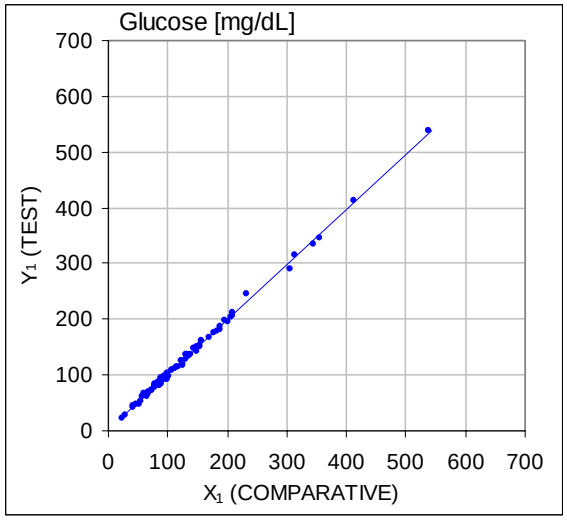
Glu	All
N	73
Sxx	
Syy	3.6
Intercept	-0.2
Slope	0.971
Syx	3.0
X min	23.0
X max	546.0
R	0.998



Method Comparison Summary Statistics: whole blood

X: i-Stat 300 G cartridges test
Y: epoc test

Glu	All
N	80
Sxx	3.25
Syy	4.25
Intercept	-1.33
Slope	1.003
Syx	4.45
X min	22.5
X max	517.5
R	0.999



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

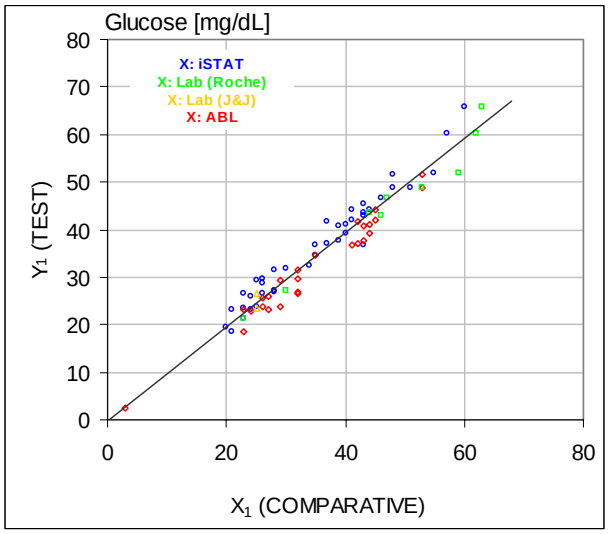
We evaluated the performance of the epoc glucose sensor in the low end range of glucose concentrations on Patient samples in clinical settings including at the point of care at several different hospitals. The results shown below include method comparison data against i-STAT[6] (whole blood method), ABL 800 Flex[8] (whole blood method), Roche-Hitachi[7] (plasma method) and J&J (plasma method). We supplemented the above mentioned clinical results with an in-house full duplicate method comparison[3] against iSTAT[6] and ABL705[8]. 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[10] and found to be ~62%, i.e. characteristic to the upper range of the neonatal blood[9]. After the glucose reached ~20mg/dL, it was spiked to cover uniformly the low range glucose, i.e. 20-80 mg/dL specific to neonatal population[9]. 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 EP9-A2 recommendations[3]. 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)	iSTAT	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	
X min	1.5	23.0	20	1.5	23	25
X max	63.0	63.0	60	53	63	25
R^2	0.947	0.960	0.948	0.971	0.946	
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	

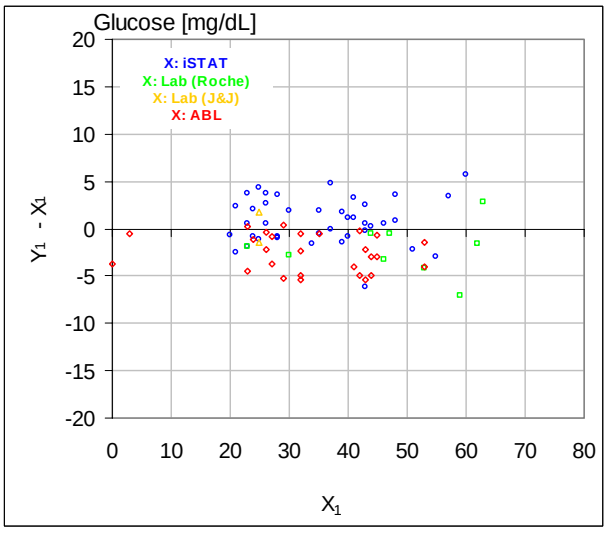
Method Comparison Summary Statistics: whole blood

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



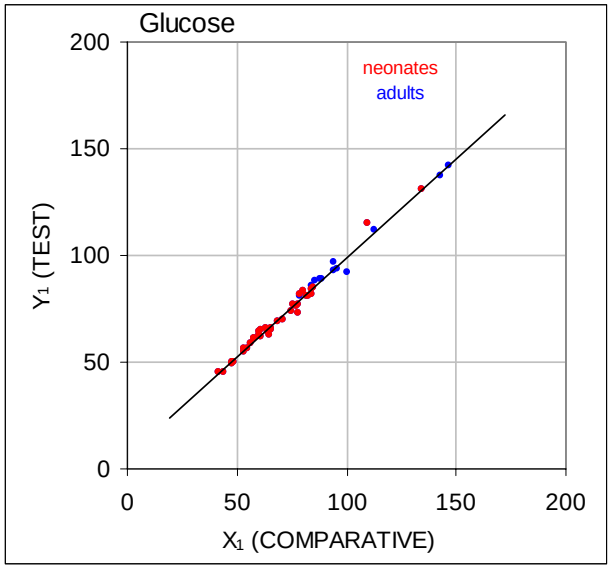
E. Method Comparison Study Focusing on Capillary Blood Specimens

We evaluated the performance of the epoc tests on authentic capillary blood specimens in clinical settings at the point of care. The comparative method was i-STAT Abbott Point of Care[6] analyzers using 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, represented with blue and red respectively in the figures below.

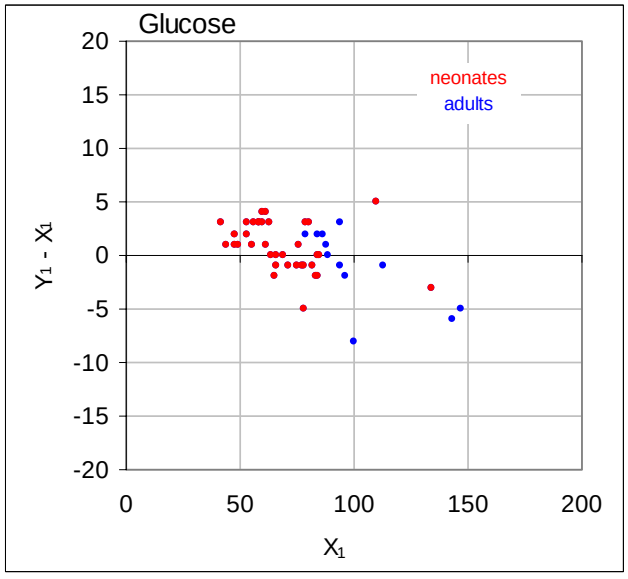
The data was processed as per CLSI EP9-A2 recommendations[3]. The correlation plot and bias plot are presented in the figures below. The test results versus the patient age are color coded.

Method Comparison Summary Statistics: capillary blood

X: i-Stat 300 test
Y: epoc test



N	48
Sxx	1.13
Syy	1.80
intercept	5.1
slope	0.935
Syx	2.42
X min	42.5
X max	147
R	0.9942



F. Limitations and Interferences

Interference testing[4] 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:

- Anticoagulants:
  - Citrate will have no significant effect up to 15mM (441mg/dL), after which it will decrease the glucose reading by -0.28%/$mM_{Citrate}$, i.e. -0.01%/(mg/$dL_{Citrate}$); therefore we do not recommend using collection devices containing citrate as additive.
  - Na fluoride will have no significant effect up to 10mM (42mg/dL), after which it will decrease the glucose reading by -0.1%/mM_{NaF}, i.e. -0.024%/(mg/dL_{NaF}); therefore we do not recommend using collection devices containing Na fluoride as additive.
  - Oxalate will have no significant effect up to 20mM (128mg/dL), after which it will decrease the glucose reading by -0.29%/$mM_{Oxalate}$, i.e. -0.045%/(mg/$dL_{Oxalate}$); therefore we do not recommend using devices tubes containing oxalate as additive.
- Iodide will have no significant effect up to 28µM (0.47mg/dL_{KI}), after which it will decrease glucose reading by as much as (-0.16mg/dL)/μM_{I-}, i.e. (-9.5mg/dL)/(mg/dL_{KI}). Iodide concentrations higher than 0.4mM_{I-} (6.7mM_{KI}) will trigger iQC.
- Bromide will have no significant effect up to 28mM (224mg/dL_{NaBr}), after which it will decrease glucose reading by (-0.23 mg/dL)/mM_{Br}, i.e. (-0.029mg/dL)/(mg/dL_{NaBr}).
- N-acetyl cysteine will have no significant effect up to 500µM (8mg/dL), after which it will trigger iQC.
- L-cysteine will have no significant effect up to 750µM (9mg/dL), after which it will trigger iQC.
- Gallamine triethiodide (Flaxedil) will have no significant effect up to 11µM (1mg/dL), after which it will decrease the glucose reading by (–0.27mg/dL)/$\mu M_{gallamine\ triethiodide}$, i.e. (–3mg/dL)/(mg/$dL_{gallamine\ triethiodide}$).
- Thiocyanate will have no significant effect up to 1mM (5.9mg/dL_{KSCN}), after which it will decrease the glucose reading with -1.7%/mM_{SCN}, i.e. (–0.29mg/dL)/(mg/dL_{KSCN}).
- Uric acid will have no significant effect up to 700µM (11.8mg/dL), after which it will decrease the glucose reading by (-3.5mg/dL)/$mM_{Uric\ Acid}$, i.e. (–0.21mg/dL)/(mg/$dL_{Uric\ Acid}$).
- Mannose will have no significant effect up to 3.5mM (63mg/dL), after which it will increase the glucose reading by +3.8%/$mM_{Mannose}$, i.e. (+0.21%)/(mg/$dL_{Mannose}$).
- Xylose will have no significant effect up to 3mM (45mg/dL), after which it will increase the glucose reading by +7.5%/mM_{Xylose}, i.e. (+0.5%)/(mg/dL_{Xylose}).

The following levels of exogenous interferences were tested and found to be clinically insignificant: 1.66mM (25mg/dL) acetaminophen, 0.09mmol/L (10mg/dL) anidulafungin, 500µmol/L (8.2mg/dL) N-acetyl cysteine, 3.3mmol/L (60mg/dL) acetyl salycilate, 630µmol/L (12.5mg/dL) Na ascorbate, 28mmol/L (224mg/dL)bromide, 15mmol/L (441mg/dL) citrate, 89.2µmol/L (4.5mg/dL) clindamycin hydrochloride, 0.1mmol/L (0.65mg/dL) K cyanide, 6.15nmol/L (507ng/dL) digoxin, 66µmol/L (2.2mg/dL) dobutamine, 100µmol/L (1.9mg/dL) dopamine HCl, 50µmol/L (~1mg/dL) L-dopa, 9mmol/L (263mg/dL) EDTA, 12µmol/L (0.2mg/dL) ephedrine, 87mM (400mg/dL) ethanol, 4.84mmol/L (30mg/dL) ethylene glycol, 1.78µmol/L (60µg/dL) famotidine, 10mmol/L (42mg/dL) Na fluoride, 1mmol/L (18mg/dL) fructose, 181µmol/L (6mg/dL) furosemide,

3.3mmol/L (59mg/dL) galactose, 11µmol/L (1mg/dL) gallamine triethiodide (flaxedil), 238µmol/L (10mg/dL) gentamicin, 4.5µmol/L (200µg/dL) glipizide, 1.1mmol/L (28.5mg/dL) glucosamine, 2.55mmol/L_{RBC} oxidized glutathione, 2.55mmol/L_{RBC} reduced glutathione, 400µmol/L (5mg/dL) guaiacol, 80U/ml heparin, 0.4mmol/L (14.5mg/dL) hydrocortisone, 2.5mmol/L (19mg/dL) hydroxyurea, 292µmol/L (4mg/dL) isoniazide (nydrazid), 48.6µmol/L (1.76mg/dL) levofloxacin, 1mmol/L (34mg/dL) linezolid, 13.3mmol/L (479mg/dL) maltose, 3.5mmol/L (90mg/dL) mannose, 71µmol/L (1.7mg/dL) methyldopa, 77.4µmol/L (2.9mg/dL) 6α-methyl prednisolone, 0.7mM (12mg/dL) metronidazole, 17.4µM (0.6mg/dL) omeprazole, 102µmol/L (2.4mg/dL) procainamide, 4.22µmol/L (0.12mg/dL) promethazine hydrochloride, 37µmol/L (1.2mg/dL) quinidine, 1.67µmol/L (40µg/dL) salbutamol (albuterol), 4.34mmol/L (60mg/dL) salycilic acid, 1.96µmol/L (60µg/dL) sertaline, 1mmol/L (5.8mg/dL)thiocyanate, 413µmol/L (10mg/dL) sodium penthotal, 1mmol/L (31mg/dL) tolazamide (tolinase), 2.37mmol/L (64mg/dL) tolbutamide, 69µmol/L (10mg/dL) vancomycin, 21.3µmol/L (1mg/dL) vitamin K1, 3mmol/L (45mg/dL) xylose.

The following levels of endogenous interferences were tested and found to be clinically insignificant: +20mmol/L (168mg/dL) Na bicarbonate, +86µmol/L (+7.3mg/dL) bilirubin conjugated, +510 µmol/L (+30mg/dL) bilirubin unconjugated, +13mmol/L (+298mg/dL) cholesterol, 15 to 140 mmHg pCO_2, +500µmol/L (+6mg/dL) L-cysteine, +20mmol/L (+256mg/dL) Na β-hydroxybutyrate, +20mmol/L (+180mg/dL) Na L-lactate, +0.8% lipids, +59.2µmol/L (+1.9mg/dL) norepinephrine, pH 6.7 to 7.7, +20% PCV Hct, 3.4% to 10.4% total protein, +11.2mmol/L (+1g/dL) triglycerides, +500µmol/L (+8.4mg/dL) uric acid.

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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. Roche-Hitachi are registered trademarks of F. Hoffman-La Roche Ltd., 4070 Basel, Switzerland.
8. 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.
9. 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.
10. CLSI. Procedure for determining Packed Cell Volume by the Microhematocrit method; Approved Standard-Third Edition, CLSI document H7-A3 (ISBN 1-56238-413-9), CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2000.

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	50 Test Cards (approximately)
STAND-BY BATTERY TIME	30 hours with fully charged Battery (approximately)
TIME TO RECHARGE	4 hours (approximately)
RECHARGE DURING USE	Yes
OPERATING TEMPERATURE	15° – 30° C [59 - 86° F]
STORAGE TEMPERATURE	0° – 45° C [32 - 113° F]
BAROMETRIC PRESSURE	400 – 825 mmHg [53-110 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 or Globtek Inc., Model GTM41060-1505 AC input: 100-240 Vac, .5 amps, 50-60 Hz DC output: 5 volts, 3 amps Continuous Operation, Class 2
SAFETY:	Reader with AC adapter: Medical Grade: IEC 60601-1, CSA/UL 601
EMC:	Reader with AC adapter: IEC60601-1-2
BATTERY:	Ultralife, Lithium Ion Rechargeable Battery, UBP103450A
EMBEDDED BAR CODE 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	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

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
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]
STANDARD LITHIUM ION RECHARGEABLE BATTERY	3.7v 1200 mAh (regular) 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 35 (regular) or 70 (extended) Test Cards (Dependent on battery and use)
TIME TO RECHARGE	2 (regular) or 4 (extended) hours (approximately)
BLUETOOTH	V2.0 + EDR Class 2
WIRELESS LOCAL AREA NETWORK	IEEE® 802.11 b/g 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)
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]
OPERATING HUMIDITY	95% RH non-condensing
WATER INGRESS	IPX0

13.4 epoc Host Accessories

AC ADAPTER (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
PRINTER(S) (OPTIONAL)	1. Epson TM-P60, IEEE820.11b (Wi-Fi) with WPA2 security, Portable Thermal Printer
	2. Epson TM-T88IV, Model Name M129H, with UB-R02 Wireless (Wi-Fi) Interface Device, Thermal Printer
	3. Epson TM-P60, Bluetooth, Portable Thermal Printer
BARCODE SCANNER (INCLUDED WITH EPOC HOST)	1. Socket Communications, Model CFSC5P Class 2 Laser - IEC 60825-1 compliant 3.3Vdc, 4mA standby (typical), 90mA scanning (typical)

13.5 epoc System Compliance

SAFETY CERTIFICATION	IEC-60601-1 – Medical Electrical Equipment - Part 1-1: General Requirements for Safety - Collateral Standard: Safety Requirements for Medical Electrical Systems
	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 MARK	c CSA us
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 61326-2-6 – Electrical equipment for measurement, control and laboratory use – EMC Requirements
	IEC 60601-1-2: Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
IMMUNITY	IEC 61000-3-2: Part 3-2: Limits for harmonic current emissions (equipment input current ≤16 A per phase)
	IEC 61000-3-3: Part 3-3: Limits . Limitation of voltage fluctuations and flicker in low-voltage supply systems for equipment with rated current ≤16 A
	IEC 61000-4-2: Part 4-2: Electrostatic discharge immunity test
	IEC 61000-4-3: Part 4-3: Radiated, radio-frequency, electromagnetic field immunity test
	IEC 61000-4-4: Part 4-4: Electrical fast transient/burst immunity test
	IEC 61000-4-5: Part 4-5: Surge immunity test
	IEC 61000-4-6: Part 4-6: Immunity to conducted disturbances, induced by radio-frequency fields
	IEC 61000-4-8 Part 4-8: Testing and measurement techniques - Power frequency magnetic field immunity test
	IEC 61000-4-11: Part 4-11: Voltage dips, short interruptions and voltage variations immunity tests
EMISSIONS	CISPR 11: Limits and methods of measurement of electromagnetic disturbance characteristics of industrial, scientific and medical (ISM) radio-frequency equipment
	CISPR 22: Information technology equipment . Radio disturbance characteristics . Limits and methods of measurement

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.

The epoc System has no User serviceable parts or adjustments. Do not attempt to open the Reader, Host or tamper with epoc Test Cards. 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 Epocal Distributor for Technical Support and/or 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 or if electronic QC fails, 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 Epocal Distributor Technical Support 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 Epocal Distributor for Technical Support.

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 Epocal Distributor for Technical Support.

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 Epocal Distributor for Technical Support.

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 Epocal Distributor for Technical Support.

---------- 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- log in Error Message is displayed and remains on Screen. It is not possible to exit this Error Page.

Response: Ask System Administrator to contact Epocal technical support.

---------- 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 log in 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 a 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 a synchronization is done.

---------- Login Page----------

Message#6: **“User account temporarily locked. Try again in five minutes.”. “Error”**

Description: After three (3) unsuccessful log in attempts in succession, Administrator Account is temporarily locked for five (5) minutes from last log in 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 Epocal Distributor, 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 log in.

---------- 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”.

---------- Login Page----------

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 Epocal Distributor for Technical Support.

---------- 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 Epocal Distributor for Technical Support.

---------- 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 Epocal Distributor for Technical Support.

---------- 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 Epocal Distributor for Technical Support.

----------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 Epocal Distributor for Technical Support.

----------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 Epocal Distributor for Technical Support.

----------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 Epocal Distributor for Technical Support.

----------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 Epocal Distributor for Technical Support.

----------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 Epocal Distributor for Technical Support.

----------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 Epocal Distributor for Technical Support.

----------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 Epocal Distributor for Technical Support.

----------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: There is fluid in Test Card inserted or there is defect on Test Card.

Response: Insert new Test Card into Reader. Discard old Test Card.

----------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 Epocal Distributor for Technical Support.

----------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 five (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 injection”. “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 Epocal Technical Support.

----------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----------

14.5.6 Card Options

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----------

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----------

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----------

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----------

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----------

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----------

Message#7: **“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----------

Message#8: **“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----------

14.5.7 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----------

14.5.8 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 Epocal Distributor for Technical Support.

----------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----------

14.5.9 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 Epocal Distributor 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----------

14.5.10 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----------

14.5.11 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----------

14.5.12 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

----------Print to Compatible Printer Device----------

15 Glossary

15.1 Symbols

Interpretation of Symbols from epoc System labeling:


Warning, Biological Risks


Warning, Biohazard


Warning, Radiation of Laser Apparatus


Caution, Consult Accompanying Documents


Consult Instructions For Use


Single Use Only. Do Not Reuse


Do Not Touch


Temperature limitation


Use By YYYY-MM-DD or YYYY-MM


Manufacturer


Date of Manufacture YYYY-MM


Separate Collection for Disposal of Electrical / Electronic Equipment

European Union Authorized Representative

In Vitro Diagnostic Medical Device

Batch or Lot Code

Model and/or Catalog Number

Serial Number


Non-ionizing Radiation


Direct Current

15.2 Terminology and Abbreviations

Interpretation of Terms and Abbreviations from epoc System labeling:

AC	Alternating Current
Alias	Name used for identification purposes
Analyte	Substance being measured
Arterial Puncture	Small hole made in the artery for obtaining arterial blood sample
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
BGE	Blood Gas and Electrolyte
BGEM	Blood Gas, Electrolyte and Metabolite
BT	Bluetooth
Ca++, iCa	Ionized Calcium
Calibration mode	Process that establishes measurement references
Connect	Establish a wireless communication link
CSA	Canadian Standards Association
CISPR	International Special Committee on Radio Interference
CLIA	Clinical Laboratory Improvement Amendments
CLSI	Clinical and Laboratory Standards Institute (Formerly NCCLS)
DC	Direct Current
Discovery mode	Process of locating wireless devices
EDTA	Ethylenediaminetetracetic acid
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

IVDD	In vitro diagnostic device
K+	Potassium ion
K2	di Potassium
K2EDTA	di Potassium EDTA
LAN	Local area network
LED	Light emitting diode
MCHC	Mean cell hemoglobin concentration
Na+	Sodium ion
Na2EDTA	di Sodium EDTA
NCCLS	Clinical and Laboratory Standards Institute (CLSI)
PC	Personal computer
PCV	Packed cell volume
pCO_2	Partial pressure of carbon dioxide
pH	Hydrogen ion concentration to a given standard
PDA	Personal digital assistant
PIN	Personal identification number
POC	Point of care
POCT	Point of care testing
pO_2	Partial pressure of oxygen
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
RH	Relative humidity
Sensor	Device transforming a chemical signal into an electrical signal
sO_2	Oxygen saturation
TCO_2	Total carbon dioxide
Test Card	epoc BGE or 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
Venipuncture	Puncture of a vein in order to withdraw blood for analysis