



# epoc® Blood Analysis System

Resource Guide

SIEMENS  
Healthineers

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# Hardware Overview

## epoc® Reader

### 1. Test Card Slot

- Internal barcode scanner located within card slot
- Scans test cards for serial number, lot number, expiration date and card type

### 2. Battery Status Indicator

- **Amber:** Fully charged
- **Blinking Amber:** Charging

### 3. Test Status Indicator

- **Green:** Ready for use
- **Blinking Green:** Processing
- **Red:** Error

### 4. Power Button

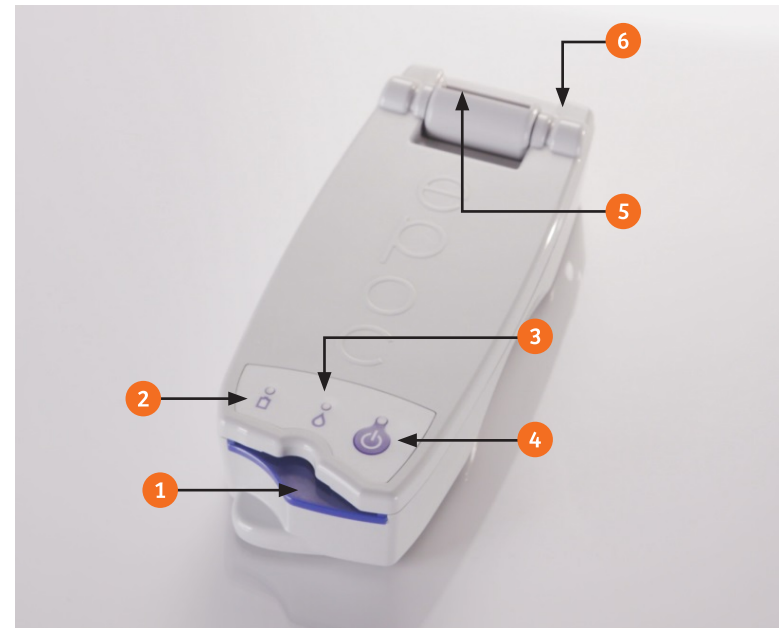
- **Green:** Reader is on

### 5. Docking Pivot

- Insert Host cradle blade to connect to the reader

### 6. Power Jack / AC adapter

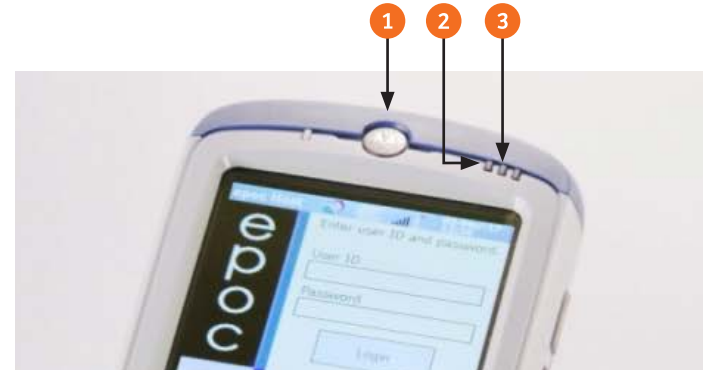
- Located at the back of the reader



# Hardware Overview

## epoc® Host

1. **Barcode Scanner**
  - Located at the top of the Host
2. **Barcode Scan LED**
  - **Red:** Barcode scanning active
  - **Blinking Green:** Successful scan
3. **Charging/Battery LED**
  - **Amber:** Fully charged
  - **Blinking Amber:** Battery charging
4. **Scan Buttons**
  - Activates barcode scanner
5. **Touch Screen**
6. **Manual Keypad**
7. **Power Button**
8. **Cradle Blade**
  - Insert into Docking Pivot to connect to the Reader



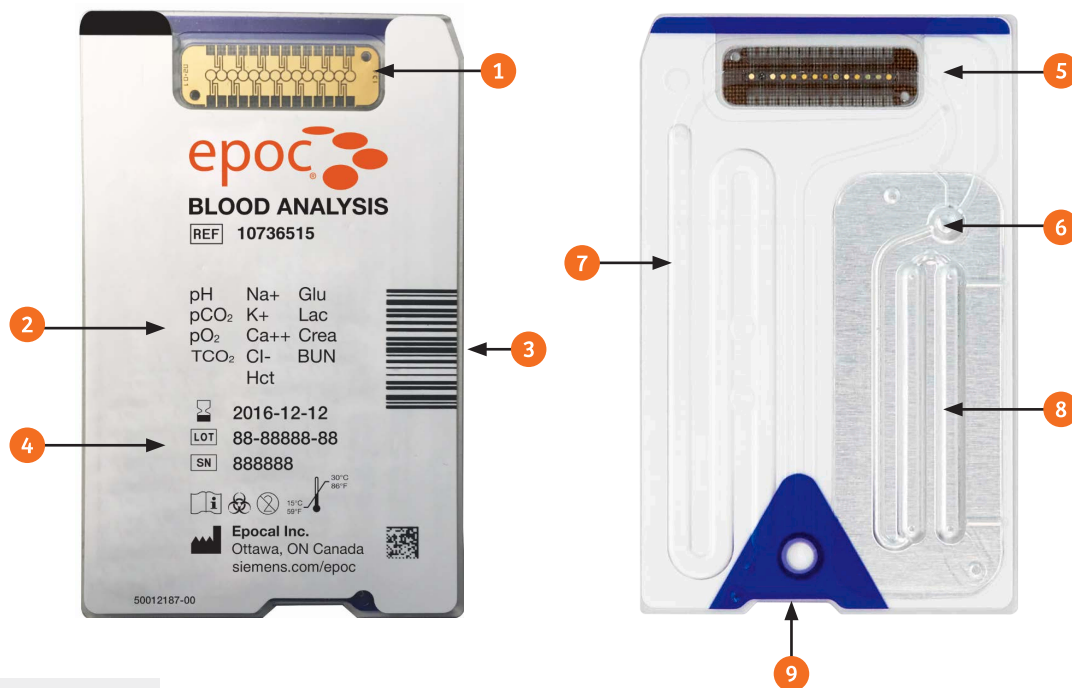
# Hardware Overview

## epoc® Test Card (Bottom)

1. Sensor Module Contact Surface
2. Test Panel Type
3. Barcode
4. Lot Number and Expiration Date

## epoc® Test Card (Top)

5. Measurement Region
6. Sealed Valve
7. Blood Waste Chamber
8. Calibrator Reservoir
9. Sample Entry Port



### Note:

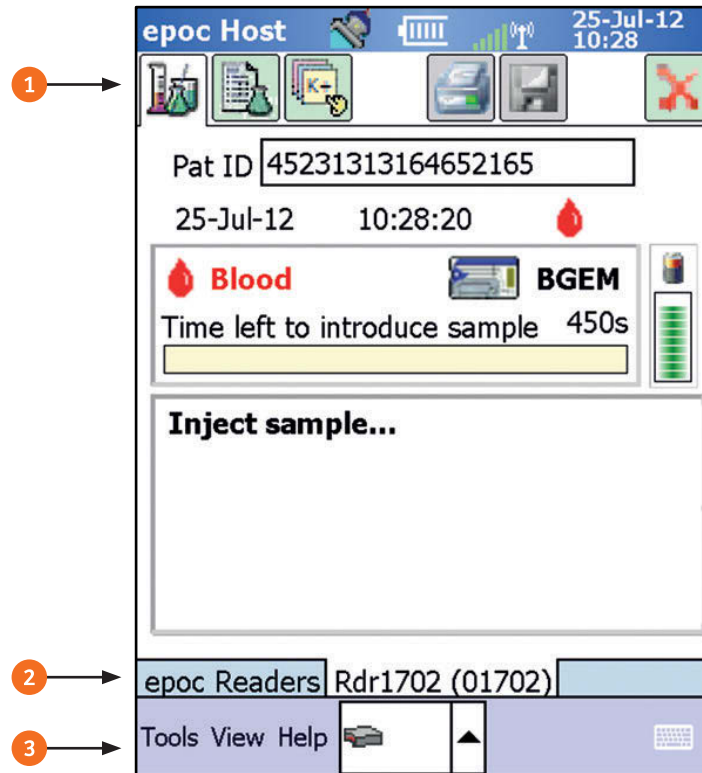
Test Card shipping cartons include two Temperature Monitors, which turn red when the shipping temperature is  $< 2^{\circ}\text{C}$  or  $> 30^{\circ}\text{C}$

Test Cards are stored at room temperature

Test cards are single use only

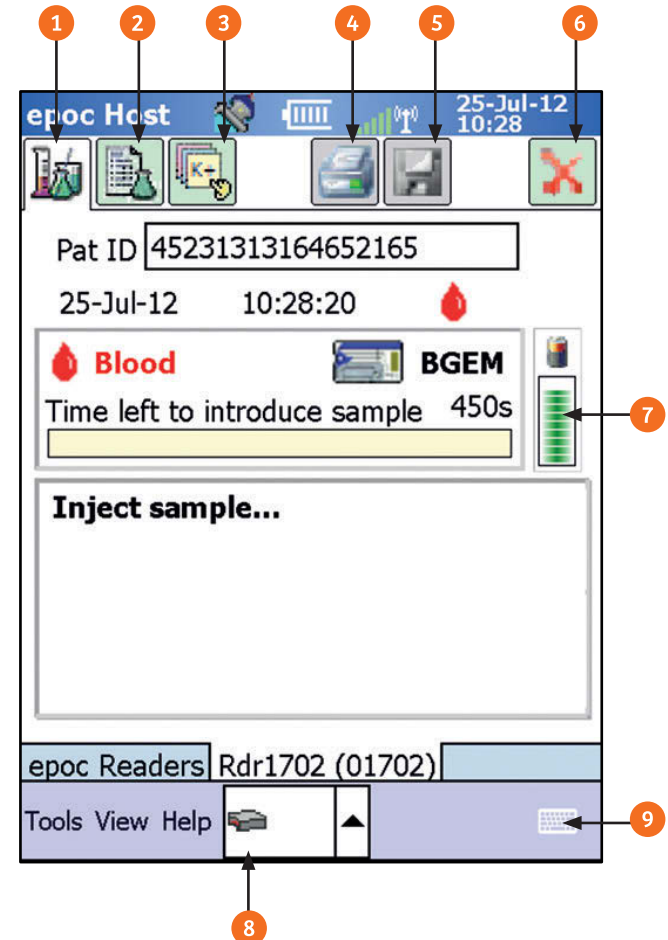
# Software Overview

1. Page Tabs
2. Screen Tabs
3. Toolbar



# Software Overview

1. **Test Results**  
Displays test progress and results once testing is complete
2. **Test Information**  
Allows for user input of additional information
3. **Test Selection**  
Allows selection of which analytes will be tested
4. **Print**  
Sends test results to a printer connected to the Host
5. **Save**  
Saves information entered after a test is completed
6. **Exit/Cancel**  
Cancels testing and closes the connection to the current reader
7. **Reader Battery Level**
8. **Reader**  
Displays a menu when selected
9. **Onscreen Keyboard**



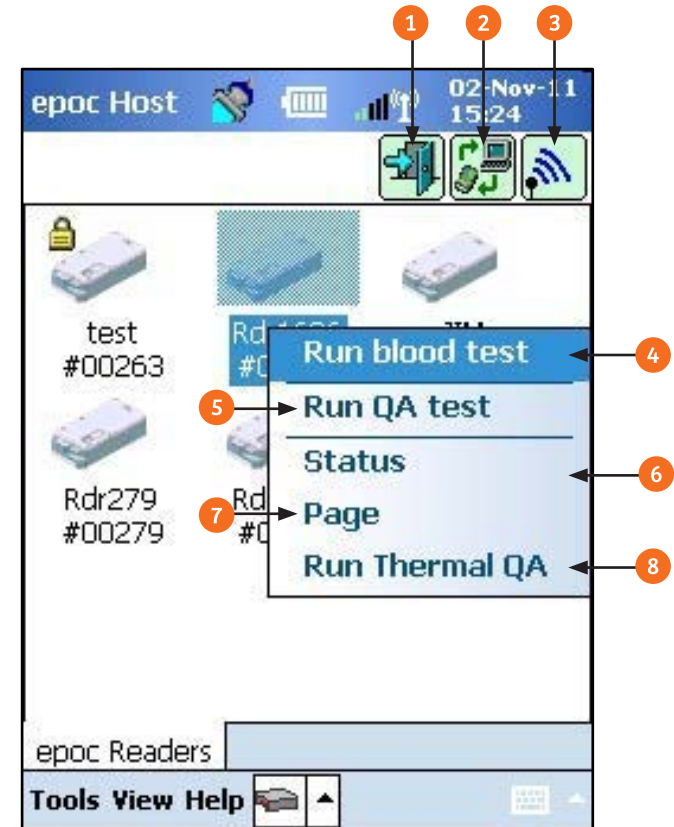
# Software Overview

## epoc Readers Tab

1. **Logout**
2. **Data Manager Synchronization - If configured**  
Used to exchange information (test results, configuration information) between Host and Data Manager
3. **Discovery**  
Select to locate additional Readers

Select and hold a Reader shown in the epoc Readers tab to display the following options

4. **Run blood test**
5. **Run QA test** (not available to all operators)
6. **Status**  
Reader reports to Host with Reader status information
7. **Page**  
Reader beeps five times in order to locate it's position
8. **Run Thermal QA** (not available to all operators)



**Note:**

Dedicated Readers are listed with a Lock icon



# Sample Processing

## Logging In

1. Enter a User ID manually or scan a valid ID badge
2. Enter Password (if applicable)
3. Select **Login**. After a successful login, the epoc Host will search for available readers

**Note:**

The login screen appears when an operator powers on the Host, after any Reset, or after an operator logs out of the epoc Host Application

epoc Host

06-Jan-21 11:52

Enter user ID and password.

User ID

Password

Login

epoc Host 3.33.3

Login

# Sample Processing

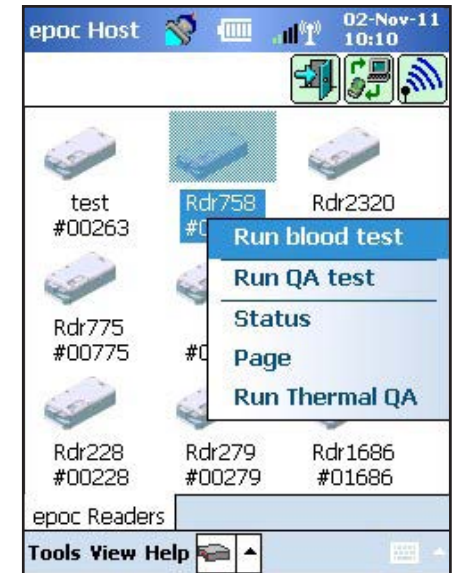
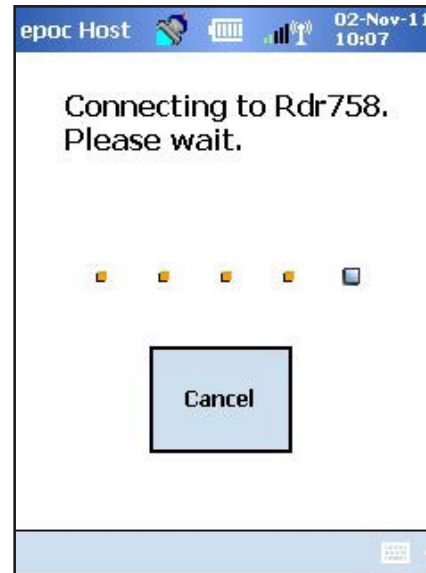
## Running a Blood Test

### Option 1

1. Upon login, if the epoc Host is already configured to connect with a single dedicated epoc Reader, the epoc Host will automatically connect to that epoc Reader to run a blood test.

### Option 2

1. Upon login, if the system administrator has configured the system for use with multiple epoc Readers, all epoc Readers available for connection are listed.
2. Select and hold the desired Reader
3. Select **Run blood test**.



# Sample Processing

## Inserting a Test Card

1. When the Host displays the message “Insert test card to begin test,” open a test card pouch
2. Position the test card with the sample port facing upwards
3. Insert the test card. Upon successful insertion, the epoc reader will beep once and calibration will begin. The reader must remain on a flat surface throughout testing
4. After calibration is complete, the message “Inject Sample” will appear on the Test Results page tab

**Note:**


Calibration takes approximately 165 seconds

After calibration is complete, the Host will display a status bar indicating the time remaining to inject a sample (450 seconds)



# Sample Processing

## Entering Test Information

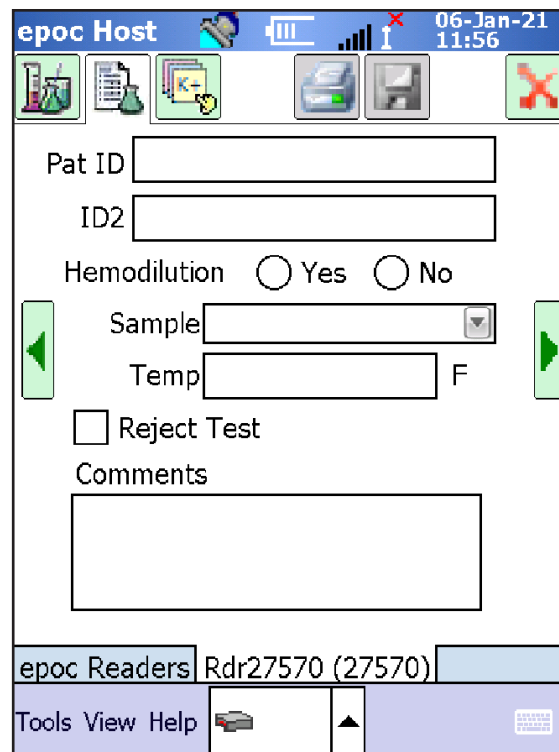
1. Select **Test Information** 
2. Enter or scan patient ID and secondary ID (if applicable) in the **Pat ID** and **ID2** fields
3. Select **Yes** or **No** next to Hemodilution (if configured) to select the hemodilution correction factor for Hematocrit
4. Select **Sample** to select a sample type from the drop-down menu
5. Enter the patient's body temperature in the **Temp** field to obtain corrected values for pH, pCO2 and pO2
6. Enter any test related comments in the **Comments** field
7. Select the green arrow on the right side of the Host screen to continue

### Note:

Select the Reject test box (if configured) if it is desired to not send results to the Lab Information System

### Note:

Hemodilution is used to correct hematocrit results for patients undergoing cardiopulmonary bypass, ECMO, or patients receiving large amounts of IV fluids. Please see section 12.13 in the epoc System Manual for more information.



The screenshot shows the 'epoc Host' software window. The title bar includes the text 'epoc Host' and the date/time '06-Jan-21 11:56'. The interface contains several input fields and controls: 'Pat ID' and 'ID2' text boxes; 'Hemodilution' with radio buttons for 'Yes' and 'No'; a 'Sample' drop-down menu; a 'Temp' text box followed by a unit selector 'F'; a 'Reject Test' checkbox; and a 'Comments' text area. On the left and right sides of the main form area are green arrow buttons. At the bottom, there is a status bar with 'epoc Readers' and 'Rdr27570 (27570)', and a menu bar with 'Tools View Help'.

# Sample Processing

## Entering Test Information (continued)

8. Enter respiratory parameters (Optional)
9. Select the green arrow on the right side of the Host screen to continue
10. Enter additional respirator parameters (Optional)
11. Select the green arrow on the right side of the Host screen to continue
12. Enter patient age in the **Age** field
13. Select **Gender** to select a patient gender using the drop down menu
14. Enter patient height in the **Height** field

The screenshot shows the 'epoc Host' interface. At the top, the status bar includes icons for signal strength, battery, and a red 'X' icon, along with the date '06-Jan-21' and time '11:58'. Below the status bar is a toolbar with icons for a test, a document, a printer, and a red 'X' icon. The main area contains a 'Pat ID' field with the value '12345'. Below this are several input fields for respiratory parameters: TR, PEEP, PS, IT, ET, PIP, and MAP. Each field has a corresponding green arrow on its right side. At the bottom, there is a section for 'epoc Readers' with the value 'Rdr27570 (27570)' and a 'Tools View Help' button.


The screenshot shows the 'epoc Host' interface. At the top, the status bar includes icons for signal strength, battery, and a red 'X' icon, along with the date '06-Jan-21' and time '11:58'. Below the status bar is a toolbar with icons for a test, a document, a printer, and a red 'X' icon. The main area contains a 'Pat ID' field with the value '12345'. Below this are input fields for 'Age' (with a unit of 'years'), 'Gender' (with a dropdown menu), and 'Height' (with a unit of 'inches'). Each field has a corresponding green arrow on its right side. At the bottom, there is a section for 'epoc Readers' with the value 'Rdr27570 (27570)' and a 'Tools View Help' button.

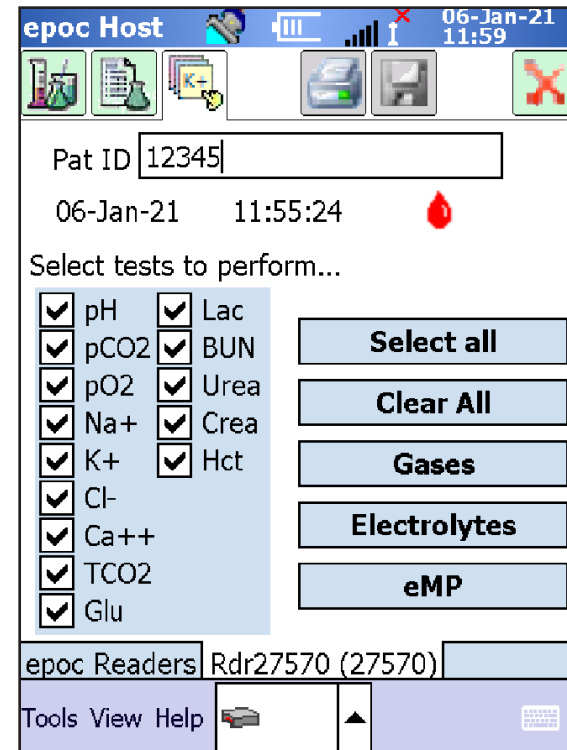
### Note:

Respiratory parameters entered are for reference purposes only. Values entered do not impact test results.

# Sample Processing

## Test Selection

1. Select **Test Selection**  to edit tests to perform during analysis
2. Select the check box next to the desired test to include or exclude results from analysis. Use **Select all**, **Clear All**, **Gases**, **Electrolytes** and **eMP** for quick selection of desired tests



The screenshot shows the 'epoc Host' software interface. At the top, the title bar reads 'epoc Host' and the status bar shows '06-Jan-21 11:59'. Below the title bar is a toolbar with icons for test selection, a printer, and a red 'X' button. The main area contains a 'Pat ID' field with the value '12345', a date and time display '06-Jan-21 11:55:24', and a red flame icon. Below this is a section titled 'Select tests to perform...' with two columns of checkboxes. The first column contains: pH, pCO2, pO2, Na+, K+, Cl-, Ca++, TCO2, and Glu. The second column contains: Lac, BUN, Urea, Crea, and Hct. All checkboxes are checked. To the right of the checkboxes are five buttons: 'Select all', 'Clear All', 'Gases', 'Electrolytes', and 'eMP'. At the bottom, there is a field for 'epoc Readers' with the value 'Rdr27570 (27570)' and a 'Tools View Help' menu.

Select tests to perform...	
<input checked="" type="checkbox"/> pH	<input checked="" type="checkbox"/> Lac
<input checked="" type="checkbox"/> pCO2	<input checked="" type="checkbox"/> BUN
<input checked="" type="checkbox"/> pO2	<input checked="" type="checkbox"/> Urea
<input checked="" type="checkbox"/> Na+	<input checked="" type="checkbox"/> Crea
<input checked="" type="checkbox"/> K+	<input checked="" type="checkbox"/> Hct
<input checked="" type="checkbox"/> Cl-	
<input checked="" type="checkbox"/> Ca++	
<input checked="" type="checkbox"/> TCO2	
<input checked="" type="checkbox"/> Glu	

Buttons: **Select all**, **Clear All**, **Gases**, **Electrolytes**, **eMP**

epoc Readers: Rdr27570 (27570)

Tools View Help

# Sample Processing

## Sample Injection (Syringe)

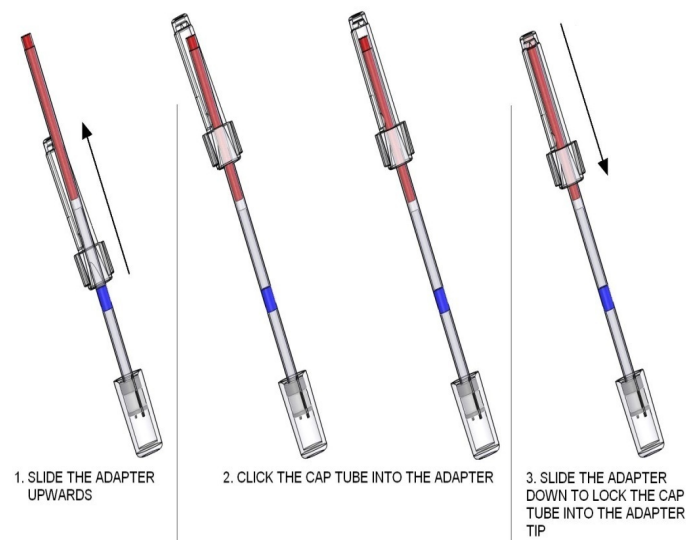
1. When ready for sample injection, the Host will display the message **Inject sample** on the Test Results page tab
2. Once sample is obtained, discard a drop of blood as volume permits
3. Hold the syringe barrel vertically between fingertips and thumb and perpendicular to the test card
4. Using slight downward pressure, secure the syringe's tip into the sample entry port of the test card. Rotate the syringe clockwise  $\frac{1}{4}$  turn to ensure a good seal
5. While maintaining downward pressure, use the index finger of the other hand to steadily depress the syringe plunger with one continuous motion until the Reader provides an audible beep and the Test Status Indicator flashes green indicating enough sample was received. The Host will display the message **Analyzing sample** on the Test Results page tab



# Sample Processing

## Sample Injection (Care-Fill™ Capillary Tube)


1. Once the sample has been collected, hold the capped tube by the blue band and point the end of the capped tube upwards
2. Slide the adapter towards the end of the capped tube and insert the tube into the adapter
3. Gently push the capped tube into the adapter end and gently push until it clicks and locks in place
4. Hold the capped tube by the large end of the adapter and insert into the sample entry port of the test card. Rotate the capillary tube clockwise  $\frac{1}{4}$  turn to ensure a good seal
5. While maintaining downward pressure, use the index finger of the other hand to steadily depress the plunger with one continuous motion until the Reader provides an audible beep and the Test Status Indicator flashes green indicating enough sample was received. The Host will display the message **Analyzing sample** on the Test Results page tab

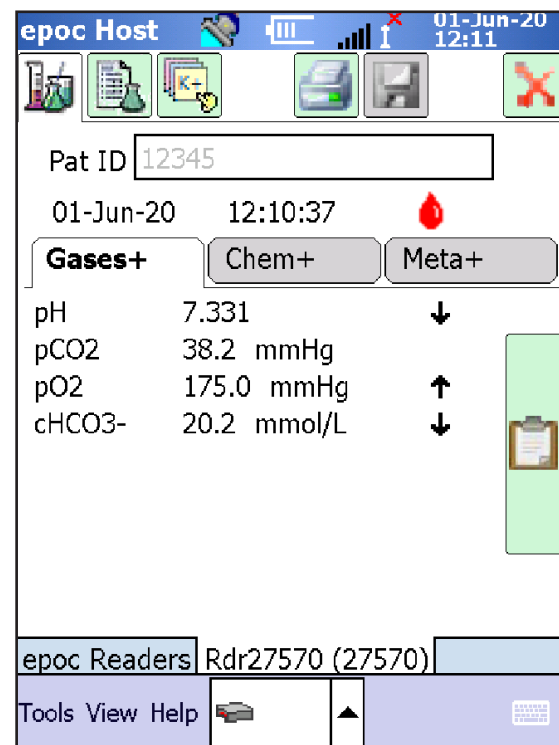




# Sample Processing

## Reviewing Results

1. Once analysis is complete, test results will display on the Test Results page tab
  - If the prompt “To view results: Enter patient ID” appears, enter the patient ID number. Select **Save**
2. Select **Gases+** to view blood gas results
3. Select **Chem+** to view chemistry results
4. Select **Meta+** to view metabolite results
5. If a test was not selected prior to sample analysis and is needed, select **Test Selection**; select the check box for the desired test, select **Save**
6. If needed, select the test information page tab to enter additional patient information, select **Save**
7. Select the Additional Documentation icon  (if configured) to display additional options
8. Remove the used test card and dispose in a biohazard receptacle
9. Insert a new test card and repeat previous sample processing steps if desired
10. When all testing with the Reader is complete, close testing by selecting the Red X at the top right to close the Reader Screen for that Reader.



epoc Host 01-Jun-20 12:11

Pat ID 12345

01-Jun-20 12:10:37

**Gases+** Chem+ Meta+

pH	7.331	↓
pCO2	38.2 mmHg	
pO2	175.0 mmHg	↑
cHCO3-	20.2 mmol/L	↓

epoc Readers Rdr27570 (27570)

Tools View Help

### Note:

Sample analysis takes approximately 35 seconds to complete

### Note:


After disconnecting all Readers from running tests, test results can be sent to a data manager by pressing the data manager synchronization button.

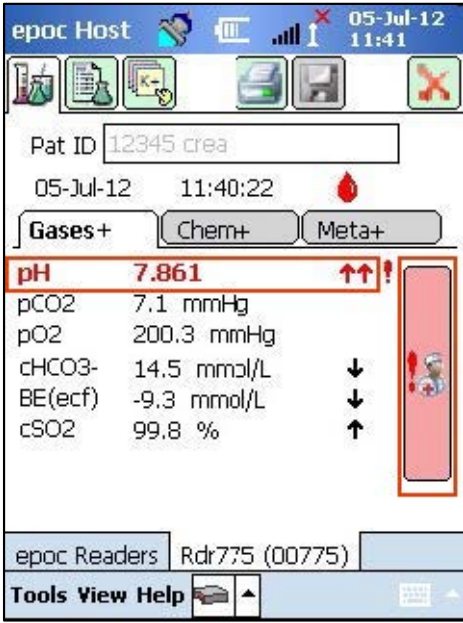
### Note:

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

# Sample Processing

## Reviewing Critical Results

1. After analysis is complete, any results outside of critical range will appear in red with a critical-range indicator. The Critical Actions button is displayed on the right side of the Host screen
2. Select the **Critical Actions** icon  to display additional options (if configured)
3. Select the **Action** drop down menu to select the healthcare professional notified
4. Enter the name of the healthcare professional in the **Notify** field
5. Select **Yes** or **No** if the results were read back to the operator
6. If needed, select **Change** to enter the appropriate Time and Date
7. Select **Save**
8. Remove the used test card and dispose in a biohazard receptacle
9. Insert a new test card and repeat previous sample processing steps if desired
10. When all testing with the Reader is complete, close testing by selecting the Red X at the top right to close the Reader Screen for that Reader.



epoc Host 05-Jul-12 11:41

Pat ID 12345 crea

05-Jul-12 11:40:22

Gases+ Chem+ Meta+

**pH 7.861** ↑↑!

pCO2 7.1 mmHg

pO2 200.3 mmHg

CHCO3- 14.5 mmol/L ↓

BE(ecf) -9.3 mmol/L ↓

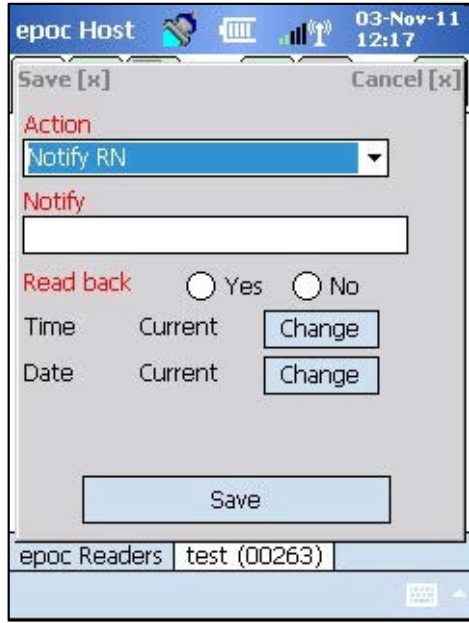
cSO2 99.8 % ↑

epoc Readers Rdr775 (00775)

Tools View Help

### Note:

After disconnecting all Readers from running tests, test results can be sent to a data manager by pressing the data manager synchronization button.



epoc Host 03-Nov-11 12:17

Save [x] Cancel [x]

Action Notify RN

Notify

Read back ☒ Yes ☐ No

Time Current Change

Date Current Change

Save



epoc Readers test (00263)

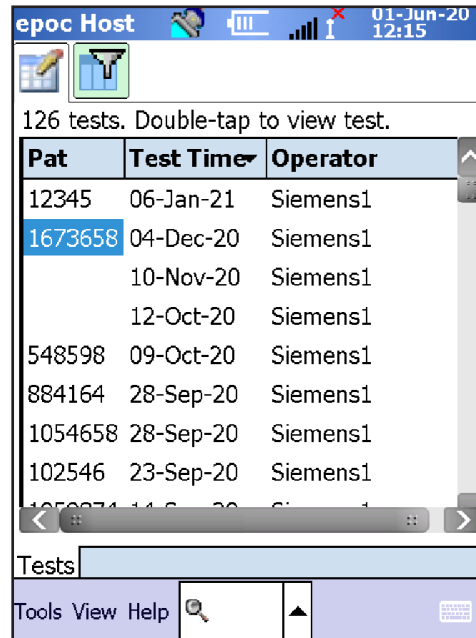
### Note:

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

# Sample Processing

## Viewing Historic Results

1. Select the  icon on the toolbar
2. Select **View Test**
3. Select the **Filter** icon to narrow test result search parameters. Toggle between Simple and Advanced filter modes for more options
4. Select **Apply**
5. Select and hold the desired record
6. Select **View this test**, or **Print this test** to view or print the record
7. Use the page tabs at the top of the displayed test record to view test details
8. Select the  icon on the toolbar
9. Select **Run Test** to return to testing mode



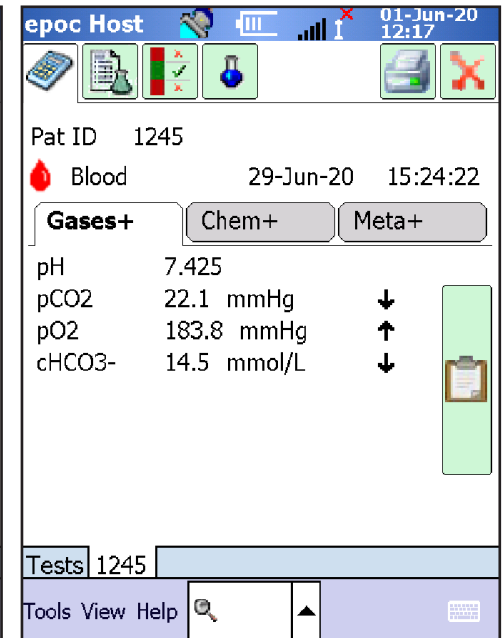
epoc Host 01-Jun-20 12:15

126 tests. Double-tap to view test.

Pat	Test Time	Operator
12345	06-Jan-21	Siemens1
1673658	04-Dec-20	Siemens1
	10-Nov-20	Siemens1
	12-Oct-20	Siemens1
548598	09-Oct-20	Siemens1
884164	28-Sep-20	Siemens1
1054658	28-Sep-20	Siemens1
102546	23-Sep-20	Siemens1
1050074	14-Sep-20	Siemens1

Tests

Tools View Help



epoc Host 01-Jun-20 12:17

Pat ID 1245

Blood 29-Jun-20 15:24:22

**Gases+** Chem+ Meta+

pH 7.425

pCO2 22.1 mmHg ↓

pO2 183.8 mmHg ↑

cHCO3- 14.5 mmol/L ↓

Tests 1245




Tools View Help

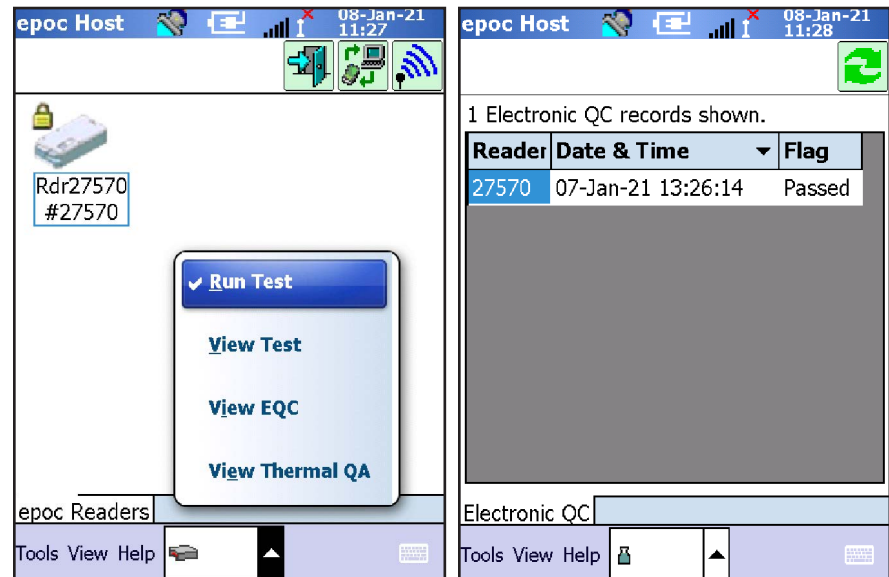
# Electronic Quality Control (EQC)

## Performing Electronic Quality Control

Every time a Host and Reader connect, or when a Host and Reader have been connected continuously for 8 hours or more, the Reader begins a two-level Electronic QC Test. Configuration data is sent by the Host to the Reader, and preparations begin for a test. No operator interaction is required to run EQC.

## Viewing Electronic Quality Control

1. Select the  icon on the toolbar
2. Select **View EQC**
3. Press and hold the desired record
4. Select **View this record**
5. Refresh the list by selecting the  icon if required
6. Select the  icon on the toolbar
7. Select **Run Test** to return to testing mode



### Note:

Unlike Test Records, Electronic QC Records are removed from the Host after each synchronization

# Additional Quality Assurance

## Quality Control Fluid

Commercially available control fluids can be processed as determined by facility policy, federal, state and local requirements. It is recommended to perform external quality control for each lot in each shipment of test cards. Refer to the epoc System Manual for recommended products.

## Calibration Verification

Calibration verification is performed to verify accuracy of Test Results over an extended measurement range of a test. Performance of this procedure may be required by regulatory or accreditation bodies. Refer to the epoc System Manual for recommended products.

## 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.


## Electronic Value Assignment Datasheet (eVAD)

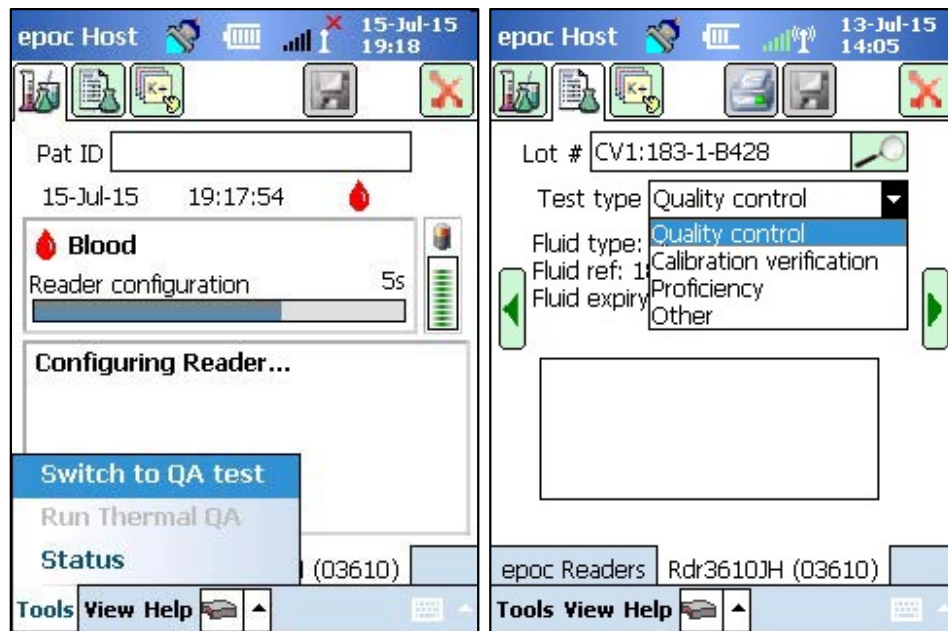
Download the current electronic Value Assignment Datasheets from Siemens Document Library.

eVADs are available for quality control and calibration verification fluids specific to the epoc system. eVADs are lot and software specific.

# Additional Quality Assurance

## Performing Quality Assurance

1. While connected to a Reader, select **Tools**
2. Select **Switch to QA test**  
or  
From the epoc Readers screen tab, select and hold the desired Reader
1. Select **Run QA test**
2. Follow the instructions found in the sample processing section for inserting a test card
3. Scan the appropriate VAD or box barcode, or Enter lot number manually and select the  icon to search
4. Using the Test type drop down menu, select the desired QA test
5. Use the Test Selection page tab to select the desired analytes for the QA test. Depending on the fluid type, all applicable analytes will be selected automatically as soon as the barcode is scanned.
6. Follow the instructions found in the sample processing section for injecting a sample
7. When the QA test is complete, the screen will display Pass or Fail
10. Select the green bar to view the completed results
11. Remove the used test card and dispose in a biohazard receptacle
12. Insert a new test card and repeat previous steps if desired
13. When all testing with the Reader is complete, close testing by selecting the Red X at the top right to close the Reader Screen for that Reader.



### Note:

Only authorized users will see the QA Test option available

# As Needed Maintenance

## Cleaning the Reader or Host

1. Using a soft cloth or gauze pad, moisten with soap and water
2. Gently rub any areas of dried blood or contamination with one or more moist pads until the stains are soft enough to wipe clean
3. After removal of stained areas, clean all surfaces twice with fresh pads soaked in 70% isopropyl alcohol. Ensure the cleaned surface is wet with 70% isopropyl alcohol for at least 5 seconds with each cleaning
4. Discard all pads after use in a biohazard receptacle



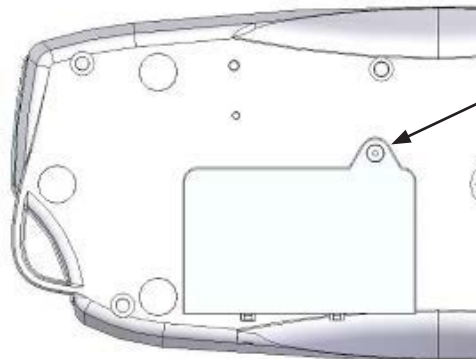
# As Needed Maintenance

## Replacing the Reader Battery

1. Remove the battery door screw using a Philips #0 or 3/16" slotted screwdriver
2. Lift the battery door from the Reader
3. Remove the battery from its compartment and unplug the battery from the Reader. Use tweezers if necessary
4. Insert the new battery connector to the Reader. The connector orientation tab should be visible

**Note:**

epoc Reader Battery Replacement SMN: 10736373



Battery door screw

Orientation tab





# As Needed Maintenance

## Replacing the Reader Battery (continued)

5. Place the new battery into the Reader compartment. Place the wires in the area next to the battery connection. Ensure that the battery is lying flat without any wires underneath or on top
6. Install the battery door by inserting its hinge behind the battery. Snap the hinges into place by applying pressure
7. Secure the battery door screw, using a Philips #0 or 3/16" slotted screwdriver

Battery wires



# Troubleshooting

## Troubleshooting Result Error Messages

For each type of test result, messages may appear next to test names if data cannot be determined or displayed

### Result Error Troubleshooting

Error	Meaning	Corrective Action
cnc	Could not calculate. Component required for calculation was not available	Verify sample integrity and re run test
iQC failure	Failed internal quality control	View the epoc Host screen for specific failure and instructions to resolve error. Ex. "iQC Failure: Calibration fluid not detected." "Insert new card and repeat test."
expired	Card was expired. Test results not displayed	Use a non expired test card and re run test

**Note:**

Refer to the epoc System Manual, Section 14, for additional Troubleshooting and Error Messages

# Troubleshooting

## Troubleshooting Hardware

In addition to the corrective action listed for common hardware troubleshooting, the following is recommended:

- Do not submerge the epoc Host or Reader into liquid
- Fold the Host and Reader together while carrying to prevent dropping
- Do not remove the test card during sample analysis, damage to the reader could occur

## Hardware Troubleshooting

Scenario	Corrective Action
Host not charging	Ensure the Host blade is seated into the Reader docking pivot
Host barcode reader unable to scan	<ul style="list-style-type: none"><li>• Clean barcode reader with a dry lint free cloth</li><li>• Perform a soft reboot by holding the power button for 5 seconds</li></ul>
Host screen frozen	Perform a hard reboot by holding the 9, 1 and power buttons
Reader red test indicator light on	View epoc Host screen for error message and troubleshoot using the epoc System Manual

# Troubleshooting

## Troubleshooting Failed EQC


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. Complete the following troubleshooting steps if the message, "Electronic QC failure," displays on the Host.

1. Close the Reader screen
2. Turn the Reader OFF and back ON
3. If the Reader connects successfully to the Host and passes EQC, it is acceptable for use. If EQC continues to fail, contact Technical Support



# Troubleshooting

## Troubleshooting Failed Quality Control or Calibration Verification

From the epoc Host, disconnect from the Reader by selecting Exit/Cancel , then reconnect by selecting and holding the desired Reader from the epoc Readers screen tab. Select **Run QA test**. If Electronic QC passes, verify the following and repeat the test.

1. Confirm use of the correct Control or Calibration Verification Value Assignment Datasheet
2. Review the preparation, storage conditions and expiration date of the Test Card, Calibrator Verifier, or Control product used

If the repeated results pass, the cards are acceptable for use. If the repeated results fail, repeat the test using a new box of control solutions, calibrator verifiers and/or Test Cards. Contact Technical Support if results continue to fall outside of specified ranges.



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