pm
product manual

element POC
Blood Gas & Electrolyte Analyzer

HESKA
AN ANTECH® COMPANY

Element POC® Blood Gas & Electrolyte Analyzer

The Element POC Blood Gas and Electrolyte Analyzer portable device consists of the blood analyzer (Reader), mobile computer (Host), and disposable Test Cards. Lab results are available in less than a minute on whole blood samples as small as 100 microliters.

This Product Manual describes the proper use and operation of the Element POC Blood Gas and Electrolyte Analyzer with the Host for veterinary samples.

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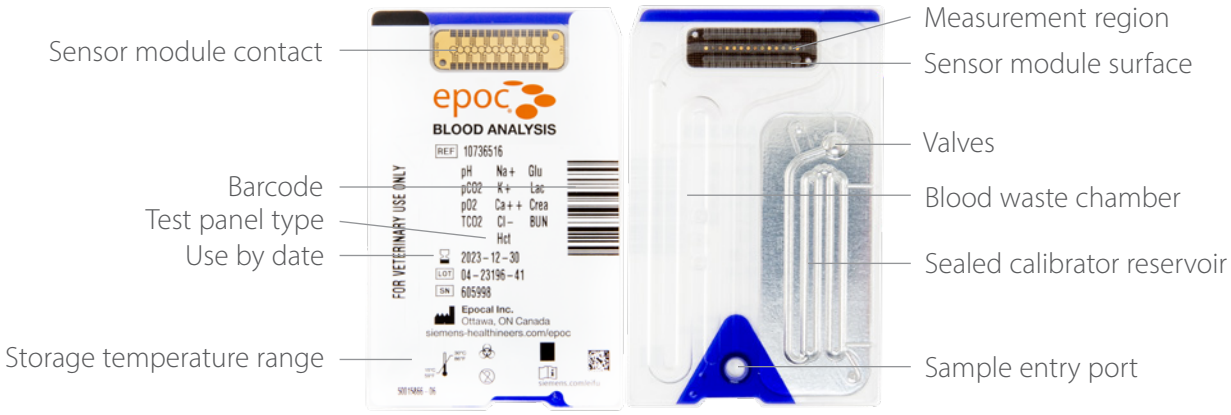
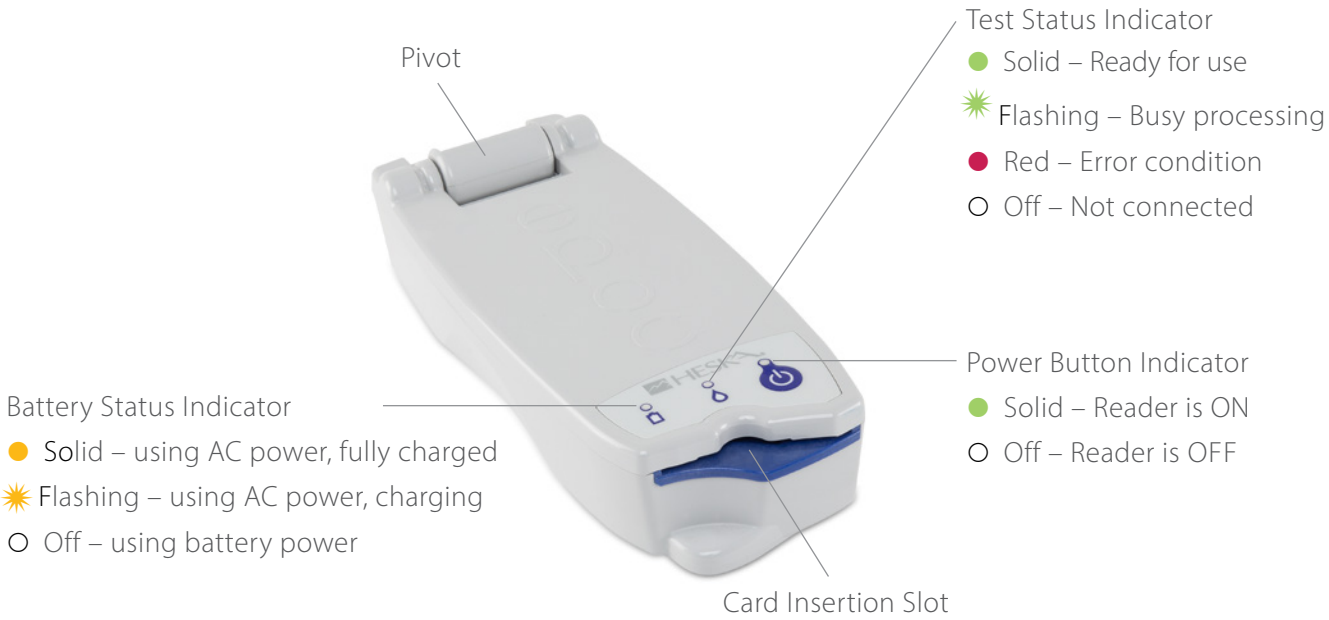
1.1 Test Cards



1.2 Reader

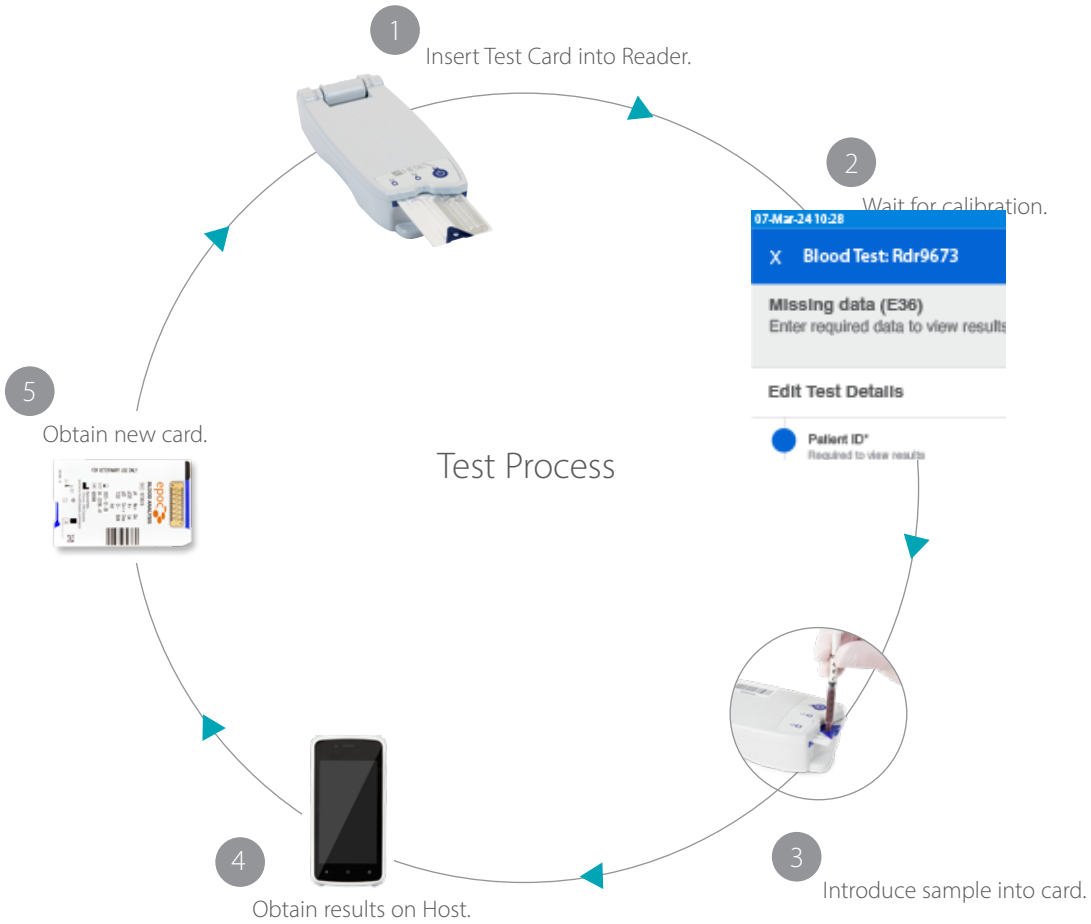


1.3 Host

1.4 System Assembled

2.1 Test Process Overview

1. The initiation of a test starts with establishing a communications link between the Host and Reader.
2. A Test Card is removed from its card pouch.
3. The Test Card should be inserted immediately into the Reader.
4. During the approximately 2.75 minute (165 seconds) calibration period, the user acquires a blood sample for the test.
5. After calibration is complete, the Reader Indicator and the Host inform user that the Test Card is ready to receive a blood sample. The sample can be introduced at any time thereafter within 7.5 minutes. After 7 minutes (450 seconds) the sample introduction period times-out, and the Test Card can no longer accept a sample.
6. Approximately 45 seconds after sample introduction the Host displays analytical test results.
7. The Test Card should be removed from Reader and discarded. It must be discarded as biohazard waste.



3.1 User Interface

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

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

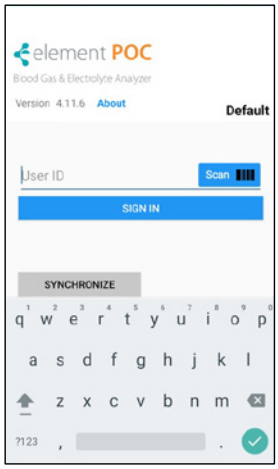
- Tap on an item to select it.
- Scroll down or up by swiping your finger along the screen.

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

3.1.1 Using the Soft Keyboard

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

NOTE: During the test, the Scan button changes to Next when you start typing on the soft keyboard. Touch NEXT to confirm the currently entered text.



3.1.2 Additional Functionality

Select text already entered by pressing gently on the screen while sweeping across one or more characters.

 Touch to toggle between upper and lower-case characters before the next character.

 Touch to toggle between text and number/symbol screens.

 The Backspace key removes the last character.

 The Enter key confirms the currently entered text.

4.1 Storage and Handling

⚠ CAUTION

Always store Test Cards at room temperature 59°F–86°F (15°C–30°C). Never refrigerate or allow Test Cards to freeze.

⚠ CAUTION

The shipping boxes are not to be used for storage. It is the responsibility of the customer facility to constantly maintain the temperature above 59°F and below 86°F (15°C and below 30°C).

⚠ CAUTION

Test Card pouches provide a low humidity environment for card storage. The card pouch should be opened and the Test Card removed only when conducting blood or QA testing. Never store Test Cards outside of the card pouch or near intense light or heat sources.

⚠ CAUTION

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.

⚠ CAUTION

For a blood or QA test, a Test Card must be taken directly from the card pouch. Do not touch sensor contacts or sample entry port. Ensure Test Card is free of animal hair or other debris which may interfere with analysis. Never place a Test Card on any surface prior to use.

⚠ CAUTION

Test Cards brought from a warmer or colder storage environment (even within the same building) must be allowed to adjust to the same temperature as the testing room ambient temperature before use. The testing environment, Reader, and Test Cards must all be at the same temperature before conducting any testing.

⚠ CAUTION

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.

⚠ CAUTION

Veterinary Test Cards must be used in veterinary blood analyzers.

4.2 Element POC BGEM Test Card Specifications

Test Name	Acronym	Units	Measurement Range	Measured	Calculated
pH	pH	pH units	6.5–8.0	√	
Carbon Dioxide Partial Pressure	pCO_2	mm Hg kPa	5–250 0.7–33.3	√	
Oxygen Partial Pressure	pO_2	mm Hg kPa	5–750 0.7–100	√	
Sodium	Na^+	mmol/L mEq/L	85–180	√	
Potassium	K^+	mmol/L mEq/L	1.5–12.0	√	
Ionized Calcium	Ca^{++}	mmol/L mg/dL mEq/L	0.25–4.0 1.0–16.0 0.5–8.0	√	
Chloride	Cl^-	mmol/L	65–140	√	
Total Carbon Dioxide	TCO_2	mmol/L mEq/L	5–50.0 5–50.0	√	
Glucose	Glu	mmol/L mg/dL g/L	1.1–38.5 20–700 0.20–7.00	√	
Lactate	Lac	mmol/L mg/dL g/L	0.30–20.0 2.7–180.2 0.03–0.18	√	
Blood Urea Nitrogen	BUN	mg/dL	3–120	√	
Urea	Urea	mmol/L mg/dL g/L	1.1–42.8 7–257 0.07–2.57	√	
Creatinine	Crea	mg/dL µmol/L	0.30–15.00 27–1326	√	
Hematocrit	Hct	% PCV L/L mEq/L	10–75 0.10–0.75 1–85	√	
Hemoglobin	cHgb	g/dL mmol/L g/L	3.3–25 2.0–15.5 33–250		√
Actual Bicarbonate	$cHCO_3^-$	mmol/L mEq/L	1–85 1–85		√
Calculated Total Carbon Dioxide	$cTCO_2$	mmol/L mEq/L	5–50 5–50		√
Base Excess of Extra Cellular Fluid	BE(ecf)	mmol/L	(–30)–(+30)		√
Base Excess of Blood	BE(b)	mmol/L	(–30)–(+30)		√
Oxygen Saturation	cSO_2	%	0–100		√
Anion Gap, K+	AGapK	mmol/L	(–10)–(+99)		√

5.1 Sample Handling

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

Sample Type: Fresh whole blood from arterial, venous, or capillary sources

Sample Volume: > 92 µL, non-volumetric quantity

Sample Collection: 23 gauge or larger needle
(See table below for details on sample tubes and syringes.)

Anticoagulant: When needed use Li, Na or balanced heparin only
(See table below for restrictions on Heparin use. Cat blood should be drawn into anticoagulant to prevent clotting.)

IV or Indwelling Line: avoid Avoid using line if possible. If using, draw and discard three to six times the volume of the line to contamination of sample

⚠ WARNING

Always wear protective gloves when handling blood samples.

⚠ CAUTION

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.

5.2 Sample Collection Method

Options for specific tests and sample collection methods:

Test	Syringes 1 or 3 ml plastic, non-iced	Evacuated Tubes With Li or Na heparin Without anticoagulant must be run immediately
pO_2	• Non-iced syringes • Test in less than 30 min	• Not recommended
pH/pCO_2	• Test in less than 30 min	• Test in less than 30 min
TCO_2	• Test in less than 30 min to avoid possible air contamination and/or artifacts of metabolic activity	• Do not underfill • Test in less than 30 min to avoid artifacts of metabolic activity
Ca++	• With Li or Na heparin only if <10 IU/ml • With balanced heparin only if <70 IU/ml • Test in less than 30 min to avoid artifacts of metabolic activity	• Test in less than 30 min to avoid artifacts of metabolic activity • With Li or Na heparin only if < 10 IU/ml
Glu	• Test in less than 30 min to avoid effects of glycolysis	• With Li or Na heparin only (do not use NaF) • Test in less than 30 min to avoid effects of glycolysis
Lac	• Test in less than 5 min to avoid effects of glycolysis	• With Li or Na heparin only (do not use NaF) • Test in less than 5 min to avoid effects of glycolysis

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

6.1 Power Up Host and Reader

1. Turn ON Reader.
   - Press **POWER** to turn ON the Reader.

INFORMATION

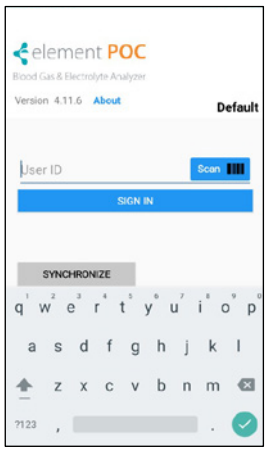
The power indicator will turn green indicating the Reader is ON and ready for use. Press and hold POWER for several seconds to turn OFF the Reader when not in use in order to conserve battery power.

INFORMATION

The Reader can be operated on battery power or while the battery is being charged using the AC adapter provided with the Reader.

2. Turn ON Host.
   - Press and hold the Power Button to turn on the Host.
     Briefly press the Power Button to wake up a running Host if the screen goes dark.

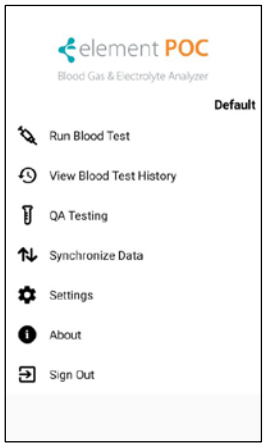
3. Login to Host software.
   - Enter a valid user ID and password and press the sign in button. If no user ID and password have been assigned, users can login by inputting any character into user ID field.



INFORMATION

After a reset or signing out, Host software application displays the Sign In page.

4. The Host will display the Home page.
5. Touch Run Blood Test to continue with a blood test.
   Touch QA Testing to continue with a QA test (if authorized).



6.2 Begin a Test

INFORMATION

To discover the appropriate Reader, touch REFRESH at the top right of the Host screen. Once found on the list of available Readers, touch the Reader name to connect to it.

NOTE: If the Reader appears on the list, but still is not able to connect, make sure that the required Reader is within range. Initiate discovery again by touching REFRESH at the top right of the screen and proceed. If Reader is still not found, reset Host and log into Host Application again. Attempt reset and discovery sequence twice if necessary.

When there are multiple Readers:

If the system administrator has configured the system for multiple Readers, all Readers available for connection are shown.

The Reader icon ◇ displays the Reader name and serial number.

Once the desired Reader is displayed:

- Press and hold the Reader icon to select it for testing. A drop down menu is displayed.
- For a blood test, select: [Run blood test].
  OR
- For a QA test (if authorized), select: [Run QA test].

6.3 Initialization of Test Cycle

The Reader comes equipped with automated internal quality control procedures which are performed electronically during the initialization of the Reader when connecting with the Host and immediately before the testing process each time a test is run. Electronic QC is automated, so no User procedures are required.

- A two-level internal electronic QC test of the Reader is run automatically.
- Configuration data is sent by the Host to the Reader.
- The motorized mechanism inside the Reader can be heard as it resets.
- Reader information (name, serial number) is displayed on the bottom tab.
- The test status indicator of the Reader turns on and stays green.

8 Hour Electronic QC Check

INFORMATION

The Host checks that the electronic QC test of the Reader has been run within the past eight hours.

If the Host has been connected to the Reader continuously for eight hours or more, the Host will disconnect from the Reader and inform the user they must reconnect to the Host so that another electronic QC test can be performed.

NOTE: Unlike QA Test Records, Electronic QC records are removed from the Host after each synchronization.

6.4 Information

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

CAUTION

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 Host screen displays:

- The patient ID or lot number field
- Current date and time
- The type of test: blood test or QA test
- The battery charge level of the Reader

INFORMATION

Additional tabs are accessible for other test information entries that may be used to ensure a complete test record.

6.5 Test Card

6.5.1 Obtain Test Card

1. Select a properly stored veterinary Test Card.
2. Starting at the notch, tear open the card pouch.

CAUTION

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

6.5.2 Remove Test Card Pouch

1. Carefully remove the Test Card from the card pouch.
2. Place the Test Card directly into the Reader's card insertion slot.
3. Discard the empty pouch.

CAUTION

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

CAUTION

Never touch the sensor module's contact surface or blood sample entry port.

CAUTION

Never place the Test Card on any surface before running a test. Ensure Test Card is free of animal hair and other debris which can interfere with analysis.

6.5.3 Insert Test Card Into Reader

Position the Test Card with the blue label side facing upwards and the sensor module towards the Reader.


THIS SIDE UP

INFORMATION

Test Cards are keyed using a notch in the corner to ensure correct card orientation during insertion.

CAUTION

The 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.

1. Position the Test Card with the Blue Label side facing upwards and the Sensor Module towards the Reader.
2. Using both thumbs, insert the test card swiftly and smoothly, immediately after removing from package. Continue inserting the Test Card until slight resistance is felt.
3. Push the Test Card past this point to "lock" it into place. This is the final Test Card position.
4. The Reader beeps once, and the test status indicator turns solid green to notify the user that the Test Card has been successfully inserted.

INFORMATION

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

INFORMATION

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.

INFORMATION

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.

6.6 Test Card Calibration

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

INFORMATION

The calibration process takes approximately 2.75 minutes to complete.

NOTE: Do not inject the sample until calibration is complete.

INFORMATION

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

⚠ CAUTION

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

⚠ CAUTION

Read information on sample collection method in, *Section 5: Sample Collection*, to ensure that blood samples are properly collected and handled for testing.

6.7 Enter Test Information

Test information can be entered at any time during the test.

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

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

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

⚠ CAUTION

Exercise care when entering Patient ID and other information.

ⓘ INFORMATION

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

ⓘ INFORMATION

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

6.8 Using Barcode Scanner

1. Press the Patient ID field and a cursor appears.
2. Activate the Barcode Scanner by pressing either of the Scan buttons on the sides of the Host. Point the light coming from the top of the Barcode Scanner towards the desired barcode until a beep is heard.
3. 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.

ⓘ INFORMATION

The Barcode Scanner can also be activated by tapping the Scan button. The Scan button is located to the right of applicable text fields. Alternatively, the Patient ID may also be entered using the soft keyboard activated by tapping the entry field.

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

6.9 Sample Introduction Window

After about three minutes of calibration, the Test Status Indicator stops flashing green indicating that the Test Card is ready to receive a test sample. The Host displays the message, "Inject sample…"

The screen has a bar indicating the time remaining to introduce a sample. The blood sample must be introduced into the Test Card during this 450 seconds (or 7.5 minutes) period.

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

⚠ CAUTION

Introducing the sample too soon or too late will cause an error and abort the test. In this case, a new Test Card must be inserted and the test procedure started again.

6.10 Sample Introduction Method

⚠ CAUTION

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

1. Confirm there are no air bubbles in sample syringe. Dispose of the first drop of sample on a paper towel to ensure air bubbles are removed.

⚠ CAUTION

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

ⓘ INFORMATION

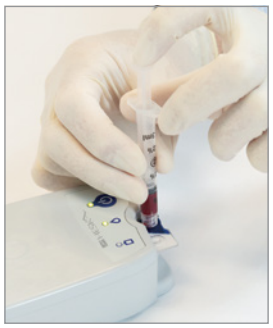
Complete steps 3 and 4 below in one continuous motion to ensure best performance of sample introduction.

2. If using a luer lock syringe, use a slight downward pressure, secure the syringe's luer tip in the center recess of the sample entry port of the Test Card. Rotate the syringe ¼ turn either right or left to ensure a good seal.

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

   If using a slip tip syringe, push the tip of the syringe into the sample well firmly to engage the syringe tip with the blue rubber seal.

3. While maintaining downward pressure, use the index finger of your other hand to steadily depress the syringe plunger smoothly until prompted to stop. There is no need to rotate.



The Reader provides an audible beep and the Test Status Indicator flashes green indicating enough sample for analysis was received. The Host also displays sample acceptance.

4. Adequate sample has been injected when calibration fluid is seen in the sample path at the bottom left of the card. Visualization of this fluid should coincide with the audio beep and flashing green status indicator on Reader.

INFORMATION

Learn to use the audio and visual feedback to perform this step easily and reliably.

CAUTION

Sample introduction should never exceed two seconds. Failure to heed the audio or visual prompts may cause the sample to flow from the vent hole at the end of the Test Card waste chamber and possibly into the Reader.

CAUTION

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.

6.11 Sample Analysis

The Reader automatically analyzes the test sample. The analysis process takes about 45 seconds.

6.12 Test Completion

Once the analysis is complete:

1. The Host displays the test results. Test results can be viewed in three sub-tabs "Gases+," "Chem+," and "Meta+".
2. 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.
3. Remove the Test Card from the Reader and dispose of it using appropriate biohazard precautions.

CAUTION

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

CAUTION

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

4. Press SAVE & CLOSE to complete the test.

6.13 Print Results (Optional)

To print a test result:

1. Ensure all desired data fields have been completed.
2. Press Print icon on upper right corner of screen.
3. Follow the on-screen instructions.

Select a printer from the drop-down list, and press Print. Results will be printed along with any flags, and the appropriate reference ranges for the species selected.

6.14 Running Another Test

After a used Test Card is removed, the Reader's test status Indicator will turn solid green, indicating that the Reader is ready to perform another test. Repeat same procedure to complete another test.

⚠ CAUTION

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

⚠ CAUTION

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

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

6.15 Close Test and Disconnect Reader

When all testing with a Reader is complete and all data entries are made, the test is closed by pressing **CLOSE** ⍈ in the top right corner 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.

⚠ CAUTION

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

6.16 EDM Synchronization

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

NOTE: When using a data manager, CLOSE & TRANSMIT is displayed on the Test Results page instead of SAVE & CLOSE.

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

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

During a full synchronization:

1. The Host uploads Test Results (both Blood and QA Tests), Electronic QC records, and Raw Data (if applicable) to the data manager.
2. The Host retrieves Configuration Information from the data manager such as Units, Ranges, and Operator Lists (if required), as well as current Date and Time.
3. The Host may receive a software upgrade if a new version exists in the data manager, and the System Administrator has enabled the automatic upgrade feature.
4. When synchronization is complete, leave the screen by touching ⍈ at the top left.

6.17 Log Out and Turn Power OFF

Log out of the Host application when finished testing and viewing test results.

1. Touch Sign Out on the Home page.

The Host device can be suspended by briefly pressing the Power button.

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

a. The Reader is NOT plugged in
   AND
b. The Reader is NOT connected to a Host

7.1 General Cleaning Methods

Wipe the Element POC Reader and Host using a damp soft cloth or gauze pad with one of the following:

- Mild detergent or non-abrasive cleaner
- Alcohol
- Soap and water
- 10% household bleach solution (9 parts tap water to 1 part household bleach)

Avoid using excess fluids that may enter the Reader or Host and possibly come in contact with the electrical components.

Allow surfaces to dry before turning ON any of the Element POC System components.

7.2 Date and Time Settings

1. At the Login screen, scan the administrator barcode (located on the Reader) for both the user ID and password. Alternatively, type Administrator in both the user ID and password fields and press **LOGIN**.
2. Press **TOOLS** ▶ **SET DATE /TIME**. Input correct date, time, and time zone, and press **OK**.
3. Check for correct Date and Time in upper right corner of Host screen. It may take up to ~10 seconds to update.

⚠ CAUTION

The date and time displayed become part of the test record.

7.3 Reset

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

⚠ CAUTION

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

7.4 Charge Reader Battery with AC Adapter

The Reader contains a lithium ion rechargeable battery. The battery compartment is not accessible to the user.

1. The AC adapter plugs into the power jack located on the backside of the Reader.
2. The AC adapter recharges the Reader when the Reader is either ON or OFF.

⚠ CAUTION

Exercise caution if using an extension cord or power bar with the Reader AC adapter. These devices may void the product safety certification if not appropriately certified or approved for medical use.

⚠ CAUTION

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

3. When the Reader is charging, the amber battery status indicator will flash. When charging is complete, this indicator will stay solid amber.

4. When the indicator is off, it indicates that the AC adapter is not connected and the Reader is operating on battery power.
5. It takes approximately 4 hours to recharge a fully discharged Reader battery.

CAUTION

The Reader battery must be replaced by authorized Heska/Antech service personnel only.

7.5 Host Battery

7.5.1 Charge Host Battery Using Reader

INFORMATION

The Host contains a lithium ion rechargeable battery that cannot be removed or replaced without assistance from Heska/Antech.

1. To re-charge the battery, insert the Host Cradle Blade into the Reader Docking Pivot.
2. Connect the Reader AC adapter to the power jack at the rear of the Reader and also into the wall receptacle.
3. An LED charging indicator shows when the battery is charging and when charging is complete. Refer to Heska's Element POC Blood Gas & Electrolyte Analyzer Quick Steps Guide for more information.

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

Aqueous blood gas, electrolyte, and metabolite control fluids are commercially available for verifying integrity of newly received Test Card lots. Recommended products are described in the table below.

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

QA test feature of the Element POC System provides the following characteristics:

- Ranges are increased, so the user can test analyte levels at, or just outside of, the measurement range.
- QA test results are stored separately from blood test results in the data manager.

8.1 QC Fluids Recommended for Verification of epoc Test Cards

QC Fluids Recommended for Verification of Test Cards

Manufacturer	Description	Ref. No.	Usage	Level	Quantity	Volume	Heska CAT No.
Eurotrol Inc., Ede, The Netherlands	Eurotrol GAS-ISE-Metabolite QC	179–1–B913	BGEM	1	10 Ampoules	2.5 ml	CAT 5430–1
Eurotrol Inc., Ede, The Netherlands	Eurotrol GAS-ISE-Metabolite QC	179–1–B913	BGEM	2	10 Ampoules	2.5 ml	CAT 5430–2
Eurotrol Inc., Ede, The Netherlands	Eurotrol GAS-ISE-Metabolite QC	179–1–B913	BGEM	3	10 Ampoules	2.5 ml	CAT 5430–3

⚠ CAUTION

Always follow manufacturer's storage instructions.

⚠ CAUTION

All aqueous control fluids must be run as QA test when using the Element POC System.

8.2 QC Fluids with Blood Gases

Quality control fluids contain dissolved gases, so they become very unstable over time after opening the ampoule.

⚠ CAUTION

Always use a fresh ampoule for each Test Card when multiple tests are being run on a single Reader. Multiple Test Cards can be tested using one ampoule only if tested at the same time on multiple Readers.

⚠ CAUTION

Once opened, fluid should be analyzed immediately.

⚠ CAUTION

Never use the last 0.5 mL of control fluid in syringe.

⚠ CAUTION

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.

8.2.1 Procedure

1. If ampoules are taken from a cool storage, equilibrate the ampoule to room temperature 68°–77°F (20–25°C). Equilibration time for blood gas QC fluids is four hours minimum.
2. Immediately before use, shake the ampoule vigorously for five to 10 seconds to equilibrate liquid and gas phases.
3. Always hold the ampoule at the tip and bottom with your forefinger and thumb to minimize the increase in fluid temperature. If necessary, tap the ampoule tip to return fluid into the bottom section of the ampoule. Protect your fingers with gauze, tissue, or glove, or use an ampoule breaker to snap off the ampoule tip at neck.
4. Immediately transfer fluid from the ampoule into a plain sterile 1 mL or 3 mL syringe with a 16–20 gauge blunt needle. When loading the syringe, slowly draw about 1 mL of fluid from the bottom of the ampoule. Never invert the syringe to expel the air trapped between the leading edge of fluid and syringe plunger (this will not affect the solution near the syringe tip).
5. If air bubbles are continually drawn into the syringe, or if a bubble is trapped near the syringe tip, discard the ampoule and the syringe. Begin the process again with a fresh ampoule and syringe.
6. Before injecting fluid in the Test Card, expel one or two drops from the syringe.
7. Transfer fluid immediately into the Test Card. Remove the blunt needle and apply the syringe luer in the Test Card's sample introduction port as during a normal blood test procedure.

Temperature Correction for Blood Gas QC Fluids

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

Temperature Correction for pCO_2 and pO_2 Targets for Aqueous Control Fluids

Parameter	Level	59–62.6°F (15–17°C)	64.4–68°F (18–20°C)	69.8–73.4°F (21–23°C)	75.2–78.8°F (24–26°C)	80.6–82.4°F (27–28°C)	84.2–86°F (29–30°C)
pCO_2	~70 mmHg	1.6	0.8	0.0	-0.8	-1.5	-2.0
pO_2	~55 mmHg	4.0	2.0	0.0	-2.0	-3.6	-5.0
pO_2	~95 mmHg	6.9	3.5	0.0	-3.5	-6.3	-8.6
pO_2	~145 mmHg	9.5	4.8	0.0	-4.8	-8.7	-11.9
pCO_2	~9.33 kPa	0.22	0.11	0.00	-0.11	-0.20	-0.27
pO_2	~7.33 kPa	0.53	0.26	0.00	-0.26	-0.48	-0.66
pO_2	~12.66 kPa	0.92	0.46	0.00	-0.46	-0.84	-1.15
pO_2	~19.33 kPa	1.27	0.63	0.00	-0.63	-1.16	-1.59

For example, if ambient temperature in the laboratory is 59°–62.6°F (15–17°C) and pO_2 range is 135 to 155 mmHg, the Range can be adjusted by adding 9.5 mmHg to upper and lower limits to obtain the adjusted range: (135+9.5) to (155+9.5) = 144.5 to 164.5 mmHg.

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

pO_2 corrected = pO_2 reading + (2 mmHg + 6% · pO_2 reading) · (760 mmHg - BP [mmHg])/100 mmHg

For example, if pO_2 reading is 150 mmHg and BP = 630mmHg the corrected pO_2 reading for this altitude would be pO_2 corrected = 150 + (2 + 6% · 150) · (760 - 630) / 100 = 150 + (2 + 9) · 1.3 = 164.3 mmHg.

8.3 Value Assignment Data Sheets

The Value Assignment Data Sheets (VAD) contain target values and acceptable ranges for aqueous control and calibration verification fluids specific to theElement POC Blood Gas and Electrolyte Analyzer analyzer.

Download the current Value Assignment Data Sheets at http://www.epocal.com or contact Heska's Technical Support Services at 800.464.3752, option 3.

Each VAD sheet is identified by fluid name, level, lot number and Element POC System sensor configuration version. Assure all information is correct when using VAD to determine acceptability of results. The Element POC System sensor configuration version is located in the Host Help, About menu.

Ranges displayed represent the maximum deviation expected when fluids and Test Cards are performing properly. If the results are outside the specified ranges, refer to *Section 9: Troubleshooting* of this guide.

⚠ CAUTION

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

9.1 Troubleshooting

⚠ CAUTION

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

Selected Host application messages are listed in the table below. To resolve errors encountered while using the Host application, first attempt solutions in the action section in the order recommended. If the problem persists, contact Heska's Technical Support Services at 800.464.3752, option 3.

Error Message	Action
Unable to connect to Reader	1. Verify the Reader is turned ON; 2. Verify the Reader is not connected to another Host. If used by another Host, wait until test is complete; 3. Verify that the Reader is within range of the Host, approximately 30 ft (10 meters); 4. Ping Reader. Log in as Admin, go to settings, reader settings, choose ping to ping reader If the Reader is not discovered, turn the Reader OFF and ON, and then try to connect to the Reader again; 5. If still unable to connect, reset the Host and log into Host application again. Attempt reset and ping sequence twice if necessary.
Connection failure: Connection to Reader lost	1. Verify the Reader is always in range, and always turned ON;
Reader failure: General error	1. Remove the Test Card 2. Close the Reader tab, then turn the Reader OFF and ON again; Reconnect and insert another Test Card to begin a new test.
Unable to read barcode	Remove the Test Card and insert it again with a swift, smooth motion. If unsuccessful after multiple attempts, use another Test Card.
Invalid barcode	1. Remove the Test Card; check that the barcode is not damaged. If the barcode is damaged, use another Test Card; If the barcode appears to be undamaged, insert the Test Card again with a swift, smooth motion. If unsuccessful after multiple attempts, use another Test Card.
Ambient temperature too low to use Reader OR Ambient temperature too high to use Reader	1. Move the Reader to a location where the ambient temperature is within acceptable limits described in this user guide; 2. Allow the Reader enough time to adjust to the new temperature. If the actual ambient temperature is within specified limits, contact Heska's Technical Support Services at 800.464.3752, option 3.
Ambient pressure too low to use Reader OR Ambient pressure too high to use Reader	1. Move the Reader to a location where the atmospheric pressure is within acceptable limits; 2. Allow Reader enough time to adjust to the new environment. If the actual atmospheric pressure is within specified limits, contact Heska's Technical Support Services at 800.464.3752, option 3.
Ambient pressure sensor failed QC	Close the Reader tab, turn the Reader OFF and ON, and then try again.
Failed Reader electronic QC	If a Reader fails electronic QC: 1. Close the Reader screen; 2. Turn the Reader OFF and ON, and then try to connect to the Reader again; 3. If the Reader connects successfully, (and therefore, passes the electronic QC) it is acceptable for use.

Error Message	Action
Failed iQC: Calibration fluid not detected Fluidics check Humidity check Early injection Resistance check Sensor check	Remove the old Test Card and insert a new Test Card to begin another test. If this message persists, try using a different Reader if available or contact Heska's Technical Support Services at 800.464.3752, option 3.
Failed iQC: Thermal check	Use a different Reader, if available. If the Reader is well equilibrated within environmental limits, but this message persists on Reader, contact Heska's Technical Support Services at 800.464.3752, option 3.
Failed iQC: Fast sample injection	Remove the Test Card. Insert a new card and repeat the test. Inject the test sample a little slower.
Failed iQC: Insufficient sample detected	Remove the Test Card. Insert a new card and repeat the test. Ensure that the sample is fully injected within 3.4 seconds from the start of sample injection.
Failed iQC: Sample delivery	Remove the Test Card. Insert a new card and repeat test. Ensure a smooth, steady injection. Avoid injecting air into the Test Card.
Fluid detected in Test Card	1. Remove and discard the old Test Card; 2. Insert a new Test Card into Reader.
Out-of-range results on the Test Card for liquid quality control	From the Host, disconnect from the Reader and then reconnect. If the wireless connection is successful and the electronic QC passes, verify the following: 1. Is the control Value Assignment Data Sheet correct? 2. Has the use by date of controls been exceeded? 3. Have the controls been handled correctly? 4. Have Test Cards and controls been stored correctly? Repeat the test. If the repeat results are in range, the cards are acceptable for use. If the results are still out of range despite meeting the above criteria, repeat the test using a new box of control solutions and/or Test Cards.
Failed iQC on result display	Remove the Test Card. Insert a new card and repeat the test. ℹ Sometimes, Failed iQC is reported next to certain results (sample bubbles, contaminated sensor, *etc.*), whereas other parameters on the same test report OK. The reason for this could be non-conformities in individual sensors of the Test Card. Because each sensor is checked individually after sample injection, the user is still able to see valid test results obtained on remaining good sensors.
cnc on result display	Remove the Test Card. Insert a new card and repeat the test. ℹ This message means "Could not calculate. Component required for calculation was not available." It should be noted that if the response of a failed sensor is needed to compute the result of a good sensor, the iQC failure may trigger cnc. This would happen even when the user had not selected the sensor which eventually failed the iQC.

10.1 Specifications

Measured Parameters	Measurement Range
Blood Gas Parameters	
pH	6.5–8.0
pCO_2	5–250 mm Hg
TCO_2	5–50 mmol/L
pO_2	5–750 mm Hg
Electrolyte Parameters	
Na^+	85–180 mmol/L
K^+	1.5–12.0 mmol/L
Cl^-	65–140 mmol/L
iCa^{++}	0.25–4.0 mmol/L
Chemistry Parameters	
BUN	3–20.0 mg/dL
Creatinine	0.3–15.0 mg/dL
Glucose	20–700 mg/dL
Lactate	0.30–20.00 mmol/L
Hematocrit (Hct)	10–75% PCV
Calculated Parameters	
$cHCO_3$, BE (ECF), AG, cSO_2, cHgb	
Reference Ranges	
Species	Dog, Cat and Horse
Operating Parameters	
Sample volume	> 92 µL
Analysis time	~ 45 seconds after sample introduction.
Sample throughput	~17/h
Sample Processing	
Sample type	Whole blood from arterial, venous or capillary source should be tested immediately after drawing to obtain most accurate results.
Sample containers	1–3 mL syringe: Li, Na or balanced heparin, or without anticoagulant (test immediately).
Calibration	**Duration**
Test Card	165 seconds

Processor	
Processor	MT6762 8* Cortex-4* A53 2.0 GHz/4* A53 1.5 GHz
Software	Android™ 9.0
Memory	2 GB RAM, 16 GB ROM
Display	PenTile® 3.5 in color VGA, super bright 650+ NITS
Bluetooth	Touchscreen 5.0 in diagonal, resolution HD 1280 × 720 pixels Bluetooth BT4.2 (BLE HS compliant) BT Smart Ready
Wireless LAN	LAN 802.11 a/b/g/n/ac/r (2.4 GHz and 5 GHz)
Electrical	
AC input (Reader)	100–240 Vac, 0.5 amps, 50–60 Hz
Battery (Reader)	Lithium ion rechargeable
Battery (Host)	Lithium ion rechargeable
Environmental	
Operating temperature (Host)	-20°C to 55°C (-4°F to 130°F)
Operating temperature (Reader)	59°F to 86°F (15°C to 30°C)
Operating humidity (Host)	Up to 85% relative humidity, non-condensing
Operating humidity (Reader)	Up to 85% relative humidity, non-condensing
Barometric pressure (Reader)	400–825 mmHg (53–110 kPa)
Dimensions	**(L x W x H)**
Host	Touchscreen 5.0 in diagonal, resolution HD 1280 × 720 pixels 3.07 in (w) x 6.30 in (h) x .87 in (d)
Reader	3.35 in (w) x 8.46 in (h) x 2 in (d)
Weight	
Host	8.82 oz with battery (250 g)
Reader	< 1.1 lb

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For further assistance, please call Heska's Specialty Products Technical Support

US 800 464 3752 www.heska.com
CA 866 382 6937 www.heskavet.ca
AU 1300 437 522 www.heska.com