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**CASCADE**  
**Abrazo**<sup>®</sup>  
OPERATORS MANUAL



CAT NO. 5710



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Cascade **Abrazo**  
**Operator's Manual**

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## Section 1 – Instrument Purpose

The Cascade® Abrazo is a lightweight, portable instrument designed for *in vitro* diagnostic use in decentralized areas of a hospital. The Cascade Abrazo provides immediate, near-patient-care results using specially developed test cards to monitor hemostasis. The system detects the onset of clot formation in fresh whole blood and citrated whole blood or plasma samples. The Cascade Abrazo is especially suited for professional use in testing near the site of patient care by trained medical professionals. This instrument is for indoor use only.

The entire Operator's Manual should be read and understood before using the Abrazo.

Refer to the procedure supplied with the test cards for information on the following areas:

- Intended Use
- Summary
- Principle
- Reagents
- Specimen Collection and Handling
- Step by Step Procedure
- Quality Control
- Reference Ranges
- Results
- Limitations
- Interferences
- Performance Characteristics
- Bibliography



Figure 1-1 Cascade Abrazo

## Section 2 – Description

The Abrazo, when first initialized, runs a self-test to detect errors or malfunctions. Before the first use, the initial setup menus appear so the user can implement the basic information (for example; date, time, language, etc). On screen step-by-step instructions and easy to hear signals are provided throughout the operation of the Abrazo.

Abrazo test cards, which are the size of a credit card, have a reaction chamber containing paramagnetic iron oxide particle (PIOP) and the required reagents to perform a test using the Abrazo Analyzer. The reagents have been lyophilized, which provides extended stability. Refer to test card package insert for assay specific principles.

The test cards are disposable and individually packaged in a pouch. They are ready for use and do not require any special preparation except warming them to room temperature and then removing them from the packaging. An expiration date for the test card is encoded on the card and is also embossed on the seal of the foil pouch. Only one Abrazo test card at a time can be used in the instrument.

The 2D barcode on the back of the test card tells the Abrazo the type of test, the lot number and expiration date, and other test information. These are entered into the Abrazo by scanning the card at the start of a test.

The user scans the 2D barcode on the back of the card which tells the Abrazo which test needs to be run. Then, after sliding the test card into the unit, the blood sample (fresh whole blood or citrated whole blood/plasma) is dropped onto the reaction well. The Abrazo continuously monitors for conditions that could cause invalid results, and it will stop a test and alert the user of any such conditions.

When a sample drop is added to the reaction chamber on an Abrazo test card, the mixture of particles and reagents is reconstituted. The Abrazo automatically begins the test when the photodetector in the instrument observes a light change from the added sample.

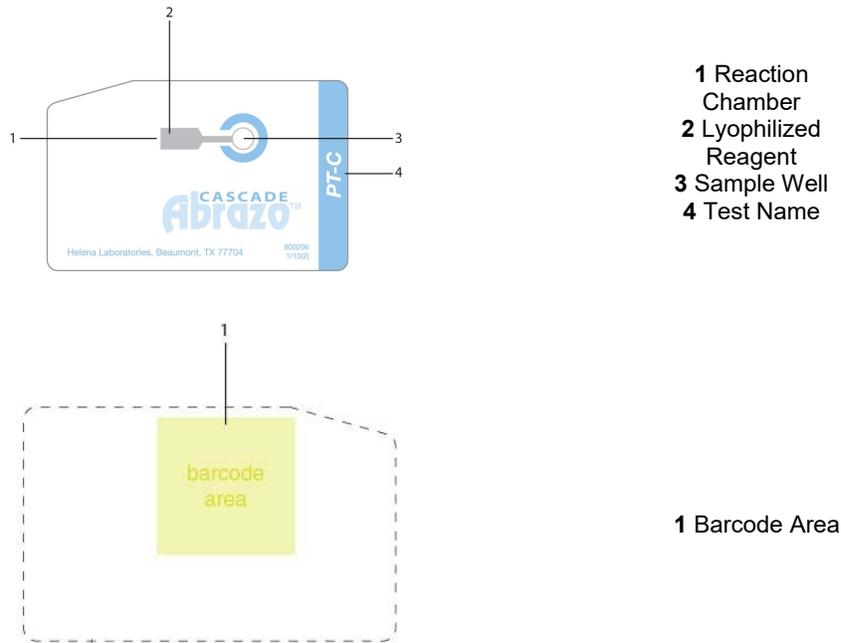
While an Abrazo test is in progress, the electromagnet turns on and off every second. The PIOP particles on the test card stand up when the magnet is on, causing more light to pass to the photodetector. When the magnet is off, the particles fall down, causing less light to be detected. The movement of these particles produces an optical signal which is processed by the analyzer. Clotting of the sample causes slowing and eventual stopping of the particle movement. The analyzer monitors particle movement and records the clotting time in seconds.

The Cascade Abrazo Administrative Software package (also known as CAAS) will be available separately to be used in conjunction with the Abrazo. The CAAS is a configuration manager that can remotely set up or change available test, QC, and Lockout settings on a single or on multiple Abrazo units. This comprehensive software program allows greater flexibility for viewing and sorting patient and quality control results.

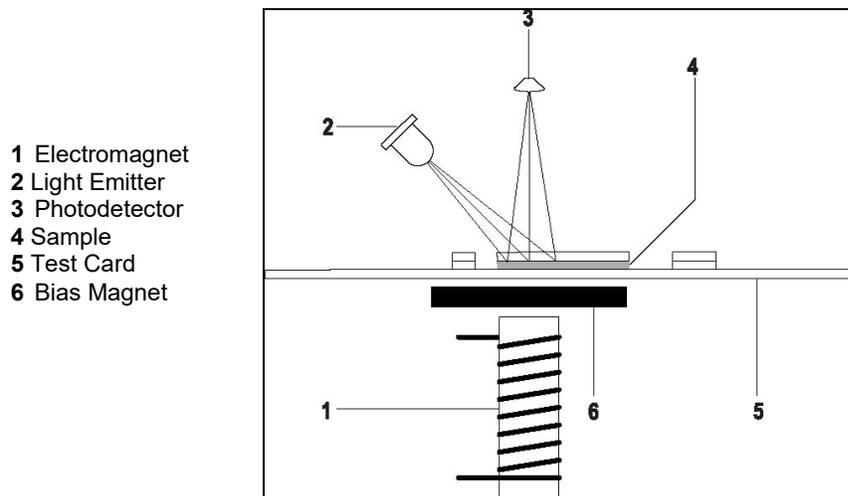
Depending on the institution's needs, numerous Administrators IDs, Operator IDs, and Operator, QC, and EQC Lockouts can be established. The CAAS allows for customized reports and is useful in tracking lot number usage and Levy Jennings reports. These are just a few of the options available with the CAAS.

Also available for use is the Cascade Abrazo Docking Station. It is designed to provide a convenient means of charging the Abrazo while also serving as a communication link between the Abrazo and the network or PC. It is a passive device with no electronic components and is weighted to minimize sliding on surfaces, such as desks or counters

There are two connections on the docking station. The first is a Type B USB cable connection. The second is a power connection which is capable of using the charger provider with the Abrazo unit.



**Figure 2-1 Test Card (Front and Back)**



**Figure 2-2 Method of Detection**

### Section 3 – General Warnings

3.1 Refer to the procedures supplied with the test cards for proper use. Do not insert any material into the Abrazo other than items referred to in the manual.

3.2 The Abrazo is designed for use only with Abrazo test cards. Do not use it with test cards that are expired.

3.3 Do not expose the instrument to drafts or to direct sunlight. Temperature changes may affect results.

3.4 Do not operate at temperatures above 89.6°F/32°C, below 59°F/15°C, or allow prolonged exposure to high humidity. Excessive temperature variations will affect results.

3.5 Do not place the instrument near a strong source of electromagnetic interference, such as an X-ray machine, or excessive vibration, such as a centrifuge. The instrument should be on a flat level surface for proper operation.

3.6 Do not use excessive force when making selections on the instrument display.

3.7 Symbols may be used to provide information to the user. Refer to Section 10.

3.8 All guidelines pertaining to the handling of human blood should be followed when handling the test cards and operating the instrument.

3.9 Used test cards should be considered contaminated and may represent a biohazard. These should be handled and disposed of in accordance with the user's policy regarding contaminated and biohazardous materials.

3.10 Do **not** lubricate the instrument.

3.11 If the Abrazo unit appears to be contaminated by blood or blood derivatives, the user may clean the unit using a mild detergent, followed by a fresh 10%

chlorine bleach solution (EPA Reg. No. 5813-50).

3.12 Acceptable substitutes for the solution listed in 3.11 are as follows:

- CLOROX COMMERCIAL SOLUTIONS® CLOROX® GERMICIDAL WIPES(1,2,3) (EPA Reg. No. 67619-12) Sodium hypochlorite 0.1 - 1%
- CLOROX® BLEACH WIPES (1,2,3) (EPA Reg. No. 67619-12-5813) 0.1 - 1% Sodium hypochlorite
- CLOROX® Ultra BLEACH 2 (1,2,3) (EPA Reg. No. 67619-8)

3.13 Do not use any organic solvents, including alcohol based products. No harsh cleansers, acids, or bases should be used or spilled on inner or outer surfaces. Do not immerse the unit. **ALWAYS DISCONNECT THE POWER SUPPLY OR REMOVE FROM DOCKING STATION BEFORE CLEANING.**

3.14 The most important factor affecting the accuracy of the test is the quality of the blood specimen used. Specimen contamination and inappropriate operating technique will also affect the test results.

3.15 The test results may be affected by hemodilution, hypothermia, pharmacologic compounds and various coagulopathies. Test results should be interpreted with respect to the patient's condition and the clinical circumstances, such as anticoagulation therapy. Test results, which do not agree with expected values or are inconsistent, should be repeated.

3.16 If further validation of the system is required, several tests should be run using Abrazo Control Materials.

3.17 Follow all health and safety regulations as mandated by the operating facility.

3.18 Use gloves when handling blood, blood products, and items that may have come in contact with them.

3.19 The power connector is a low-voltage coaxial type and is located at the rear, right side of the instrument, near the barcode scanner. To charge or operate using supplied power supply, plug the mating coaxial connector located at the end of the power adapter cord into the connector hole. Use a firm motion to insure complete contact.

3.20 The Abrazo must only be used with a power supply and docking station provided by Helena Laboratories. Any modifications to this device not expressly authorized by Helena Laboratories will void the user's warranty for the device.

3.21 The Abrazo is supplied with a properly grounded, external power supply cord for connection into an equivalent receptacle. If such a receptacle is not available, the analyzer should be operated using the internal battery.

3.22 Use of this equipment for anything other than specified negates any protection afforded by design.

3.23 For disposal, send this instrument to a proper recycling center in accordance with applicable federal, state, and local requirements, as it contains a lithium polymer battery.

**Section 4 – Setup Instructions**

**WARNING:** Read Section Three, Precautions and Hazards, before device operation.

**4.1. Unpacking and Inspection**

1. Check the boxes for signs of damage. If damage is found, immediately notify the shipping carrier.
2. Carefully, unpack the Abrazo and accessories from the shipping cartons. The packing material should be removed undamaged, if possible, should repacking be necessary.
3. Remove plastic wrappings from the instrument and accessories. If scissors or a knife is used to cut the plastic or binding tape, take care not to scratch the instrument.
4. Inspect the instrument for any obvious signs of damage. If damage is found, notify the shipping carrier and Helena Laboratories.
5. Inventory all items. If any parts are missing, recheck the packing materials before notifying Helena Laboratories.

**Table 4-1 Inventory**

Cascade Abrazo Analyzer, Cat. No. 5710  
 Abrazo Wall charger  
 Abrazo Owner’s manual  
 2 Lithium Batteries, Cat. No. 5713  
 EQC Renew Sleeve, Cat No. 5849

**Table 4-2 Additional Materials**

Abrazo Docking Station, Cat. No. 5712  
 Abrazo Administrative Software (CAAS), Cat. No. 5716  
 EQC Card, Cat No. 5748

**4.2. Initial Use**

**4.2.1. Charging the Internal Battery Prior to Initial Use**

1. Grip the Abrazo around the bottom of the unit so the Abrazo logo and WAKE button rests in your palm.
2. Flip the unit over so you are looking at the gold interface pins. Press the depressed alcove and slide the battery cover back and off the unit.
3. Insert the connector of the new battery until it is seated properly. Repeat with the second battery.
4. Seat the batteries and replace the back cover.
5. Fully charge the battery by leaving the unit plugged in and asleep for at least 6 hours. The battery charges automatically while connected to the external power supply. To maximize battery life, charge the battery to 100% daily.

**4.2.2. Powering ON**

1. After installing the batteries the Abrazo will automatically boot up and perform several self tests before it will be ready for operation.
2. Upon first time use, several items must be set, including the language, brightness, date, and time.

**4.2.2.1. Language**

1. Press the desired language button, then the checkmark icon to save settings. Pressing the X will select English as the default language.



**4.2.2.2. Brightness**

1. The default brightness setting is 4. Use the up and down arrows to choose an acceptable display look and press the checkmark icon to save settings.



**4.2.2.3. Date and Time**

1. The default setting for the date is Year: 2012, Month: 01, and Day: 01. Use the up and down arrows to select the correct date and press the checkmark icon to save.



2. The default setting for the time and date format is Date: MM-DD-YYYY. Press

the desired format button to select the format and press the checkmark icon to save.

**Note:** The selected button will be highlighted green.

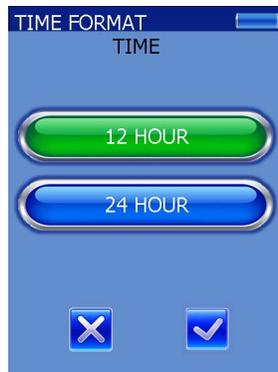


3. The default setting for the time is Hour: 1 and Minutes: 0. Use the up and down arrows to select the correct time and press the checkmark icon to save.



4. The default setting for the time format is 12 Hour. Press the desired format button to select the format and press the checkmark icon to save.

**Note:** The selected button will be highlighted green.



5. The screen displays the MAIN MENU and the Abrazo should be rebooted and is ready for use. Using a pencil or stylus type item, reboot the Abrazo by inserting it into the reset button hole on the side of the Abrazo next to the SD card slot (see Figure 4-2). After the instrument reboots, the screen displays the Main Menu and the Abrazo is ready for use.



**Note:** After daylight savings time occurs, before running a test on the Abrazo, the time needs to be adjusted by either manually changing it or syncing the unit with the CAAS.

**Note:** If the batteries are removed for any reason, check the clock for accuracy before use.

**Note:** After manually rebooting Abrazo, check clock for accuracy before use.

#### 4.2.3. Using the Display Keys

1. The Abrazo can be operated on battery power or while attached to a wall charging unit, or while it is attached to the

optional Docking Station. Figures 4-1 and 4-2 are the various views of the unit.

2. Table 4-3 list all the various display keys or symbols that can be found on the unit. The user can call up various functions by lightly touching the button with his/her finger.

3. All of the settings in Section 4.2.2 can be accessed again at any time through the SETUP button on the Main Menu screen.

**Note:** Unit must be unplugged and not seated in the docking station to perform a system reboot.

#### 4.3. Docking Station

1. After unpacking the docking station, attach the power cord and plug in for charging option.

2. Attach the Type B USB cable end (square) to the docking station and Type A USB end (flat) to the computer.

3. The docking station is ready for use. Figures 4-3 and 4-4 are various views of the docking station.

4. Place the Abrazo into the docking station so the cradle interface pins connect.

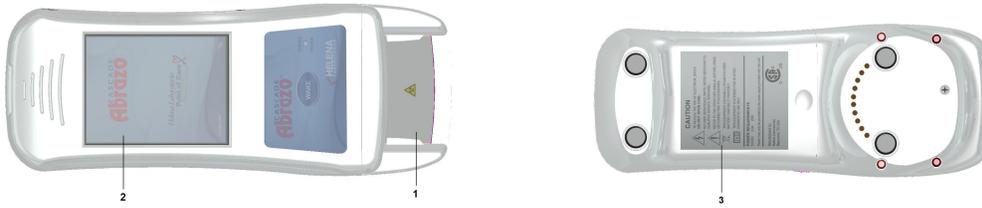
5. There is a slot in the middle of the docking station on top to store the EQC card. Slide the EQC card in face up with the clipped corner end in first.

**Note:** When placing the Abrazo in the docking station, confirm it is powered on first.

**Note:** The Cascade Abrazo has a battery life of approximately eight hours during typical use although this can be affected by many factors, particularly the number of controls and patients run in that period of time.

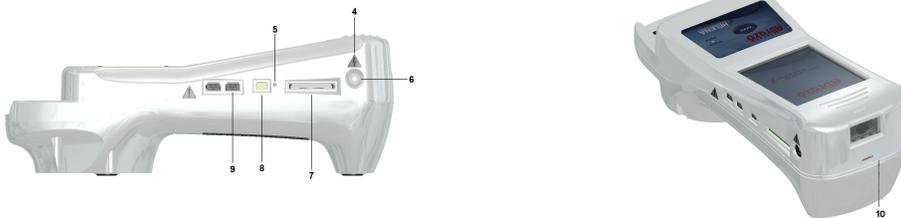
**Note:** The Cascade Abrazo can store 600 test results, after which time the

*memory will begin to overwrite the oldest result.*



**Figure 4-1 Abrazo Analyzer – Top and Bottom View**

- 1** Card Slot Retaining Wall
- 2** Display
- 3** Warnings and Information
- 4** Caution: Danger of Electrical Shock
- 5** Reset button
- 6** Power
- 7** SD Card
- 8** Serial Port
- 9** USB
- 10** Barcode Reader



**Figure 4-2 Side and Barcode Reader View**



**Figure 4-3 Docking Station – Front and Back Views**



**Figure 4-4 Docking Station – Side Views**

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**Table 4-3 Abrazo Display Icons**

Icon	Description
	OK, Save Setting
	Cancel, Discard Setting
	Back arrow, Return to previous Menu
	Scroll up one value
	Scroll down one value
	Move up one screen
	Move down one screen
	Access additional data
	QC Lockout
	EQC Lockout
	Operator Lockout

	Insert test card
	Remove test card
	Error
	Battery with full charge is shown as blue. As the battery depletes, it turns green and the color bar then decreases in 10% increments. Once the battery level has dropped to approximately 5%, the battery bar will be shown in red.
	Apply sample to test card
	Test card
	EQC Warning
	QC Warning
	Data needs to be transferred
	Print

**Section 5 – Setup/Administrator ID**

The Abrazo has two levels of user IDs; Operator and Administrator. An Operator ID allows the operator to perform basic analyzer operations while an Administrator ID allows an administrator with a password to perform the following operations:

- Set the date and time format
- Select display language
- Set mean values
- Set test units (sec., etc.)
- Set how data is displayed
- Set specimen types
- Set auto off
- Add/Edit/Delete Operator ID with password
- Add/Edit/Delete Administrator ID with password
- Set Patient ID on/off
- Set Lockout for QC, EQC, Operator, and Auto Log Out
- Set Data Sync options
- Set keypad on/off
- Set power frequency

**Note:** An optional result format for all test result formats is “Disable” which allows the administrator to disable a test type and prevent it from being run.

**5.1. Setting up Tests / Units**

Each test for the Abrazo can be customized in how the result is viewed or what type of specimen can be used. During the process, at any time the user can return to the main menu by pressing the Main Menu icon or go back one screen by pressing the “X” icon.

**Note:** ISI value cannot be entered. The encoded card default value must be used.

**Note:** The Abrazo unit allows expired controls to be scanned during test setup, but Helena Laboratories recommends **not** using expired material.

**5.1.1. PT-WB (Fresh whole blood only)**

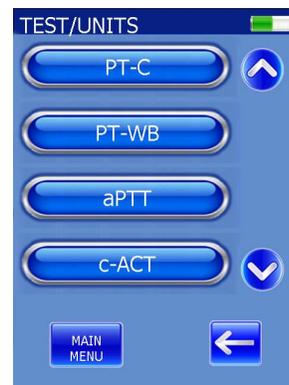
1. From the Main Menu, press SETUP to display the Setup menu.



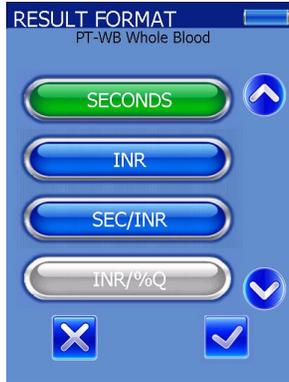
2. Press DISPLAY to view the Display menu.



3. Press TEST/UNITS. The Test/Units screen displays all the available tests.

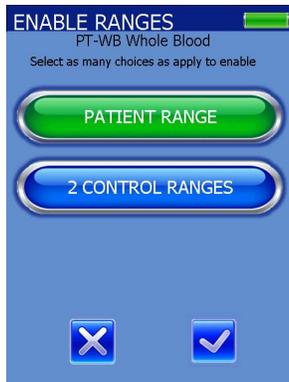


4. Using the up and down arrows on the right side of the screen if necessary, find the PT-WB button and press it. The Result Format menu displays all available formats.



5. Choose one of the result formats of SECONDS, INR, SEC/INR, or DISABLED. (Whenever a selection is made, the button turns green, as shown above.) Press the checkmark icon to advance to the Enable Ranges menu.

**Note:** Once a Result Format has been setup the user must select disable from the Result Format screen to change this selection. After the test has been disabled the user may re-enable the test for the desired result type.

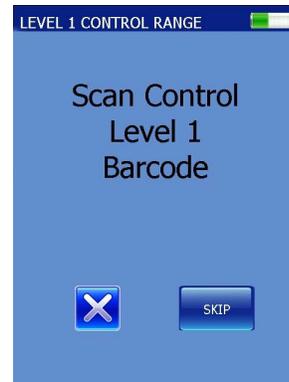


6. Choose from the following: PATIENT RANGE or 2 CONTROL RANGES. Select as many choices as apply to enable. At least one selection must be made before pressing the checkmark icon. (Whenever a selection is made, the button turns green.)



7. If the control ranges are included, the Level 1 Control Range screen appears allowing alerting the user to scan the Control Level 1 barcode.

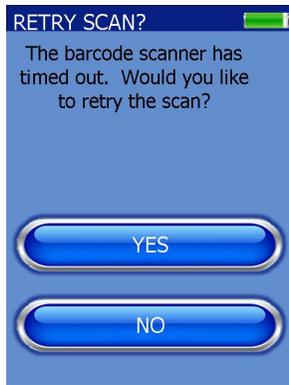
**Note:** Scanned control values will override any existing manual values that have already been entered.



8. If the scan is successful, the lot number, and high and low values will be displayed on the screen.



9. If the scan was not successful, the Abrazo allows the user the option to rescan.



10. If NO is selected, the Abrazo returns to the TEST/UNITS screen. If YES is selected, the screen returns to Step 7, scanning the Control 1. From here, the SKIP button allows the user to manually enter the values while selecting the X button returns the user to the enable ranges screen.

**Note:** The lower range value cannot be higher than the upper range value and the upper range value cannot be lower than the lower range value. If the user accepts the incorrect range, he/she can press the X to return to the previous screen.



11. After the Level 1 Control Range has been entered, the Level 2 Control Range screen appears allowing the user to scan the Control Level 2 barcode.



12. If the scan is successful, the lot number, and high and low values will be displayed on the screen. As with the Level 1 Control Plasma, the values can be entered manually also.



13. Press the checkmark icon to save the entered value and go to the next screen.



**Note:** The lower range value cannot be higher than the upper range value and the upper range value cannot be lower than the lower range value. If the user accepts the incorrect range, he/she can press the X to return to the previous screen.

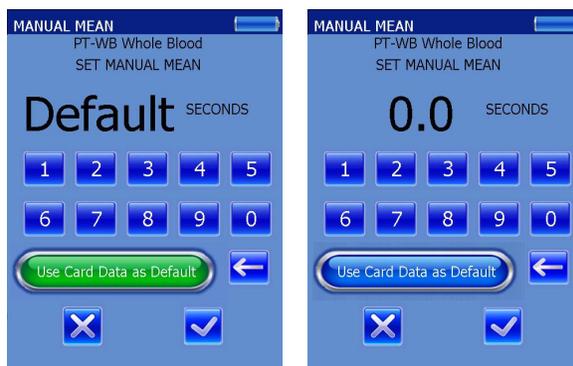
14. For the Patient range, enter the values using the numbers on the screen. Press the checkmark icon to save the entered value and go to the next screen.

**Note:** If the user accepts the incorrect range, he/she can press the X to return to the previous screen.



15. At the PT-WB Whole Blood Mean screen, the user may enter the desired manual mean or press the “Use Card Data as Default” button. (If Default is chosen, the button turns green and ‘Default’ is shown. If a mean is to be entered, the number is shown instead.)

**Note:** Using encoded data from the card is the default setting. To enter a known mean, press the “Use Card Data as Default” button and it will “toggle” from “Default” being shown to “0.0”, after which the new mean may be entered.

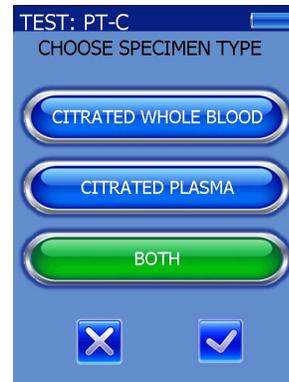


**Note:** The mean must fall between the patient range values, cannot be equal to the upper or lower range values, and must be greater than 1.0.

16. Pressing the checkmark icon will accept all changes made and will take the user back to the Test / Units screen.

### 5.1.2. PT-C using Citrated Whole Blood

1. From the Main Menu, press SETUP to display the Setup menu.
2. Press DISPLAY to view the Display menu.
3. Press TEST/UNITS. The Test/Units screen displays all the available tests.
4. Using the up and down arrows on the right side of the screen if necessary, find the PT-C button and press it. The CHOOSE SPECIMEN TYPE menu displays all possible specimen types.



5. Select CITRATED WHOLE BLOOD and press the checkmark icon to advance to the Result Format menu. (Whenever a selection is made, the button turns green.)
6. Choose one of the result formats of SECONDS, INR, SEC / INR, or DISABLED. (Whenever a selection is made, the button turns green.) Press the checkmark icon to advance to the Enable Ranges menu.

**Note:** Once a Result Format has been setup the user must select disable from the Result Format screen to change this selection. After the test has been disabled the user may re-enable the test for the desired result type.

7. Choose from the following: PATIENT RANGE or 2 CONTROL RANGES. Select as many choices as apply to enable. (Whenever a selection is made, the button turns green.) At least one selection must be made before pressing the checkmark icon.

8. For the Control ranges (if chosen), enter the values using the numbers on the screen or by using the barcode scanner. The back arrow can be used to erase incorrect numbers. Press the checkmark icon to save the entered value and go to the next screen.

**Note:** *Scanned control values will override any existing manual values that have already been entered.*

9. For the Patient range, enter the values using the numbers on the screen. The back arrow can be used to erase incorrect numbers. Press the checkmark icon to save the entered value and go to the next screen.

10. At the PT-C Citrated Whole Blood Mean screen, the user may enter the desired manual mean or press the "Use Card Data as Default" button. (If Default is chosen, the button turns green and 'Default' is shown. If a mean is to be entered, the number is shown instead.) Pressing the checkmark icon will accept all changes made and will take the user back to the TEST / UNITS screen.

**Note:** *Using encoded data from the card is the default setting. To enter a known mean, press the "Use Card Data as Default" button and it will "toggle" from "Default" being shown to "0.0", after which the new mean may be entered.*

**Note:** *The mean must fall between the patient range values, cannot be equal to the upper or lower range values, and must be greater than 1.0.*

### **5.1.3. PT-C using Citrated Plasma**

1. From the Main Menu, press SETUP to display the Setup menu.

2. Press DISPLAY to view the Display menu.

3. Press TEST/UNITS. The Test/Units screen displays all the available tests.

4. Using the up and down arrows on the right side of the screen if necessary, find the PT-C button and press it. The CHOOSE SPECIMEN TYPE menu displays all possible specimen types.

5. Select CITRATED PLASMA and press the checkmark icon to advance to the Result Format menu. (Whenever a selection is made, the button turns green, as shown above.)

6. Choose one of the result formats of SECONDS, INR, SEC / INR, or DISABLED. (Whenever a selection is made, the button turns green.) Press the checkmark icon to advance to the Enable Ranges menu.

**Note:** *Once a Result Format has been setup the user must select disable from the Result Format screen to change this selection. After the test has been disabled the user may re-enable the test for the desired result type.*

7. Choose from the following: PATIENT RANGE or 2 CONTROL RANGES. Select as many choices as apply to enable. (Whenever a selection is made, the button turns green, as shown above.) At least one selection must be made before pressing the checkmark icon.

8. For the Control ranges (if chosen), enter the values using the numbers on the screen or by using the barcode scanner. The back arrow can be used to erase incorrect numbers. Press the checkmark icon to save the entered value and go to the next screen.

**Note:** Scanned control values will override any existing manual values that have already been entered.

**Note:** If the user accepts the incorrect range, he/she can press the X to return to the previous screen.

9. For the Patient range, enter the values using the numbers on the screen. The back arrow can be used to erase incorrect numbers. Press the checkmark icon to save the entered value and go to the next screen.

10. At the PT-C Citrated Plasma Mean screen, the user may enter the desired manual mean or press the "Use Card Data as Default" button. (If Default is chosen, the button turns green and 'Default' is shown. If a mean is to be entered, the number is shown instead.) Pressing the checkmark icon will accept all changes made and will take the user back to the TEST / UNITS screen.

**Note:** Using encoded data from the card is the default setting. To enter a known mean, press the "Use Card Data as Default" button and it will "toggle" from "Default" being shown to "0.0", after which the new mean may be entered.

**Note:** The mean must fall between the patient range values and cannot be equal to the upper or lower range values.

#### 5.1.4. PT-C using both Citrated Whole Blood and Citrated Plasma

**Note:** If the sample type needs to be changed from one type to another (and the Abrazo unit is not being used with a CAAS system), the test will need to be "disabled" first and then "re-enabled" and then the new sample type selected. This will clear the original setup and allow it to be changed.

1. From the Main Menu, press SETUP to display the Setup menu.

2. Press DISPLAY to view the Display menu.

3. Press TEST/UNITS. The Test/Units screen displays all the available tests

4. Using the up and down arrows on the right side of the screen if necessary, find the PT-C button and press it. The CHOOSE SPECIMEN TYPE menu displays all possible specimen types.

5. Select BOTH and press the checkmark icon. This takes the user to the Result Format menu. The Citrated Whole blood values are entered as in Section 5.1.2 followed by the Citrated Plasma values as in Section 5.1.3.

#### 5.1.5. aPTT using Citrated Whole Blood

1. From the Main Menu, press SETUP to display the Setup menu.

2. Press DISPLAY to view the Display menu.

3. Press TEST/UNITS. The Test/Units screen displays all the available tests.

4. Using the up and down arrows on the right side of the screen if necessary, find the aPTT button and press it. The CHOOSE SPECIMEN TYPE menu displays all possible specimen types.

5. Select CITRATED WHOLE BLOOD and press the checkmark icon to advance to the Result Format menu.

6. Choose one of the result formats of SECONDS or DISABLED. (Whenever a selection is made, the button turns green.) Press the checkmark icon to advance to the Enable Ranges menu.

7. Choose from the following: PATIENT RANGE or 2 CONTROL RANGES. Select as many choices as apply to enable. (Whenever a selection is made, the button turns green.) At least one selection must be made before pressing the checkmark icon.

8. For the Control ranges (if chosen), enter the values using the numbers on the screen or by using the barcode scanner. The back arrow can be used to erase incorrect numbers. Press the checkmark icon to save the entered value and go to the next screen.

**Note:** *Scanned control values will override any existing manual values that have already been entered.*

**Note:** *If the user accepts the incorrect range, he/she can press the X to return to the previous screen.*

9. For the Patient range, enter the values using the numbers on the screen. The back arrow can be used to erase incorrect numbers. Press the checkmark icon to save the entered value and go to the next screen.

10. At the aPTT Citrated Whole Blood Mean screen, the user may enter the desired manual mean or press the "Use Card Data as Default" button. (If Default is chosen, the button turns green and 'Default' is shown. If a mean is to be entered, the number is shown instead.) Pressing the checkmark icon will accept all changes made and will take the user back to the Test/Units screen.

**Note:** *Using encoded data from the card is the default setting. To enter a known mean, press the "Use Card Data as Default" button and it will "toggle" from "Default" being shown to "0.0", after which the new mean may be entered.*

**Note:** *The mean must fall between the patient range values, cannot be equal to the upper or lower range values, and must be greater than 1.0.*

#### **5.1.6. aPTT using Citrated Plasma**

1. From the Main Menu, press SETUP to display the Setup menu.

2. Press DISPLAY to view the Display menu.

3. Press TEST/UNITS. The Test/Units screen displays all the available tests.

4. Using the up and down arrows on the right side of the screen if necessary, find the aPTT button and press it. The CHOOSE SPECIMEN TYPE menu displays all possible specimen types.

5. Select CITRATED PLASMA and press the checkmark icon to advance to the Result Format menu.

6. Choose one of the result formats of SECONDS or DISABLED. (Whenever a selection is made, the button turns green.) Press the checkmark icon to advance to the Enable Ranges menu.

7. Choose from the following: PATIENT RANGE or 2 CONTROL RANGES. Select as many choices as apply to enable. (Whenever a selection is made, the button turns green.) At least one selection must be made before pressing the checkmark icon.

8. For the Control ranges (if chosen), enter the values using the numbers on the screen or by using the barcode scanner. The back arrow can be used to erase incorrect numbers. Press the checkmark icon to save the entered value and go to the next screen.

**Note:** *Scanned control values will override any existing manual values that have already been entered.*

**Note:** *If the user accepts the incorrect range, he/she can press the X to return to the previous screen.*

9. For the Patient range, enter the values using the numbers on the screen. The back arrow can be used to erase incorrect numbers. Press the checkmark icon to save the entered value and go to the next screen.

10. At the aPTT Citrated Plasma Mean screen, the user may enter the desired manual mean or press the "Use Card Data as Default" button. (If Default is chosen, the button turns green and 'Default' is shown. If a mean is to be entered, the number is shown instead.) Pressing the checkmark icon will accept all changes made and will take the user back to the Test/Units screen.

**Note:** *Using encoded data from the card is the default setting. To enter a known mean, press the "Use Card Data as Default" button and it will "toggle" from "Default" being shown to "0.0", after which the new mean may be entered.*

**Note:** *The mean must fall between the patient range values, cannot be equal to the upper or lower range values, and must be greater than 1.0.*

#### **5.1.7. aPTT using both Citrated Whole Blood and Citrated Plasma**

**Note:** *If the sample type needs to be changed from one type to another (and the Abrazo unit is not being used with a CAAS system), the test will need to be "disabled" first and then "re-enabled" and then the new sample type selected. This will clear the original setup and allow it to be changed.*

1. From the Main Menu, press SETUP to display the Setup menu.
2. Press DISPLAY to view the Display menu.
3. Press TEST/UNITS. The Test/Units screen displays all the available tests
4. Using the up and down arrows on the right side of the screen if necessary, find the aPTT button and press it. The CHOOSE SPECIMEN TYPE menu displays all possible specimen types.
5. Select BOTH and press the checkmark icon. This takes you to the Result Format

menu. The Citrated Whole blood values are entered as in Section 5.1.5 followed by the Citrated Plasma values as in Section 5.1.6.

#### **5.1.8. c-ACT (Fresh whole blood only)**

1. From the Main Menu, press SETUP to display the Setup menu.
2. Press DISPLAY to view the Display menu.
3. Press TEST/UNITS. The Test/Units screen displays all the available tests.
4. Using the up and down arrows on the right side of the screen if necessary, find the c-ACT button and press it. The Result Format menu displays all available formats.
5. SECONDS is the only option besides DISABLED. Press the checkmark icon to advance to the Enable Ranges menu.
6. Choose from the following: PATIENT RANGE or 2 CONTROL RANGES. Select as many choices as apply to enable. (Whenever a selection is made, the button turns green.) At least one selection must be made before pressing the checkmark icon.
7. For the Control ranges (if chosen), enter the values using the numbers on the screen or by using the barcode scanner. The back arrow can be used to erase incorrect numbers. Press the checkmark icon to save the entered value and go to the next screen.

**Note:** *Scanned control values will override any existing manual values that have already been entered.*

**Note:** *If the user accepts the incorrect range, he/she can press the X to return to the previous screen.*

8. For the Patient range, enter the values using the numbers on the screen. The back arrow can be used to erase incorrect

numbers. Pressing the checkmark icon will accept all changes made and will take the user back to the TEST/UNITS screen.

**5.1.9. c-ACT-LR (Fresh whole blood only)**

1. From the Main Menu, press SETUP to display the Setup menu.
2. Press DISPLAY to view the Display menu.
3. Press TEST/UNITS. The Test/Units screen displays all the available tests.
4. Using the up and down arrows on the right side of the screen if necessary, find the c-ACT-LR button and press it. The Result Format menu displays all available formats.
5. SECONDS is the only option besides DISABLED. Press the checkmark icon to advance to the Enable Ranges menu.
6. Choose from the following: PATIENT RANGE or 2 CONTROL RANGES. Select as many choices as apply to enable. (Whenever a selection is made, the button turns green.) At least one selection must be made before pressing the checkmark icon.
7. For the Control ranges (if chosen), enter the values using the numbers on the screen or by using the barcode scanner. The back arrow can be used to erase incorrect numbers. Press the checkmark icon to save the entered value and go to the next section.

**Note:** Scanned control values will override any existing manual values that have already been entered.

**Note:** If the user accepts the incorrect range, he/she can press the X to return to the previous screen.

8. For the Patient range, enter the values using the numbers on the screen. The back arrow can be used to erase

incorrect numbers. Pressing the checkmark icon will accept all changes made and will take the user back to the TEST/UNITS screen.

**5.2. Administrator ID**

**Note:** This section is for first time setup of an administrator ID. It does not apply to an Abrazo unit that has previously synced with the CAAS software. If no administrators are entered, then ALL operators have access to the administrative functions.

**5.2.1. Adding a new administrator**

1. From the MAIN MENU screen, press the SETUP button.



2. From the SETUP Screen, press the ID SETUP button.



3. From the ID SETUP menu, press the ADMINISTRATOR button.



4. The Administrator screen appears with the options to ADD, EDIT, or DELETE ALL administrators.



5. Press the ADD button and the ADMIN NAME screen appears.



6. From either the alphanumeric or the numeric keyboards (press the 123 icon to call up the numeric), enter up to a 50 character name. Alternatively, the name can be scanned in using the bar code reader. Press the checkmark icon.

7. Two operators with the same name cannot be entered into the software.



8. From either the alphanumeric or the numeric keyboards (press the 123 icon to call up the numeric), enter up to a 50 character password. Press the checkmark icon.



9. Confirm the password and press the checkmark icon again. If the password is confirmed, the display returns to the ADMINISTRATOR Screen.



10. Once the Administrator ID has been enabled, the only unprotected functions available to the user will be Sounds, Sort, and Brightness. All others will require the Administrator password.

11. Whenever the administrator exits from a function and then returns to the Main Menu, he/she will be automatically logged out and will need to re-enter the ID and password.

**Note:** At any point, the MAIN MENU can be accessed by pressing the MAIN MENU button in the lower left hand corner. Pressing the checkmark icon confirms a selection while pressing the X icon will back the operator into the previous screen, not saving changes made.

**5.2.2. Editing an administrator**

1. From the MAIN MENU screen, press the SETUP button.
2. From the SETUP Screen, press the ID SETUP button.
3. The ADMIN NAME LOG screen will appear and ask the use for an ID barcode or name selection. Select a name.



4. The Abrazo will prompt the user for the password. Enter the password and press the checkmark icon.



5. From the ID SETUP menu, press the ADMINISTRATOR button.
6. The ADMINISTRATOR screen appears with the options to ADD, EDIT, or DELETE ALL. Press EDIT.

**Note:** Pressing EDIT or DELETE ALL will generate an error if no administrators have been added.



7. The ADMIN NAME LOG screen appears with all the current administrators.



8. Select the desired administrator.
9. The ADMIN EDIT screen appears with the following options: CHANGE PASSWORD and DELETE ADMINISTRATOR.

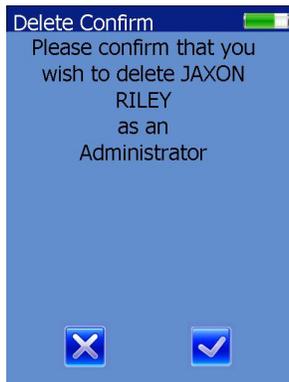


**5.2.2.1. Change Password**

1. Select CHANGE PASSWORD.
2. The SET PASSWORD screen appears.
3. From either the alphanumeric or the numeric keyboards (press the 123 icon to call up the numeric), enter up to a 50 character password. Press the checkmark icon.
4. Confirm the password and press the checkmark icon again. If the password is confirmed, the display returns to the ADMINISTRATOR Screen.

**5.2.2.2. Delete Administrator**

1. Select DELETE ADMINISTRATOR.
2. The Delete Confirm screen appears.



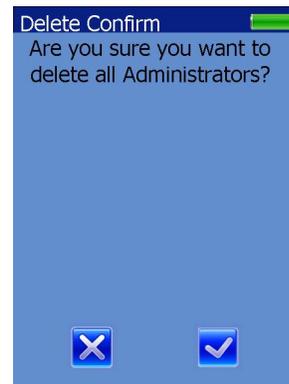
3. Press the Checkmark Icon to confirm or press the “X” to decline.
4. The Abrazo returns to the ADMINISTRATOR screen.

**5.2.3. DELETE ALL**

1. From the MAIN MENU screen, press the SETUP button.
2. From the SETUP screen, press the ID SETUP button.
3. From the ID SETUP menu, press the ADMINISTRATOR button.
4. Press DELETE ALL.
5. The Delete Confirm screen appears and displays, “Delete yourself as well?” Pressing the checkmark icon will advance the Abrazo to the next screen. Pressing the “X” button will take the user back to the ADMINISTRATOR screen.



6. After pressing the checkmark icon, another Delete Confirm screen appears and displays, “Are you sure you want to delete all Administrators?”



7. Pressing the checkmark icon will delete all administrators. Pressing the “X” button will cancel the action.

8. The Abrazo returns to the ADMINISTRATOR screen after deleting all listed administrators.

### 5.3. Operator ID

#### 5.3.1. Adding a new operator

1. From the MAIN MENU screen, press the SETUP button.



2. From the SETUP screen, press the ID SETUP button.



3. If an administrator has been added, the ADMIN NAME LOG appears. Select an administrator and enter the correct password. The ID SETUP screen appears.



4. From the ID SETUP menu, press the OPERATOR button. The OPERATOR screen appears the options to ADD, EDIT, or DELETE ALL.



5. Press the ADD button and the OPERATOR NAME screen appears.



6. From either the alphanumeric or the numeric keyboards (press the 123 icon to call up the numeric), enter up to a 50 character name. Alternatively, the name can be scanned in using the bar code reader. Press the checkmark icon.

7. Two operators with the same name cannot be entered into the software.



MONTHLY, EVERY 3 MONTHS, SEMI-ANNUAL, or ANNUAL.



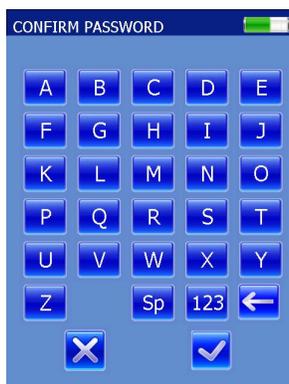
8. From either the alphanumeric or the numeric keyboards (press the 123 icon to call up the numeric), enter up to a 50 character password. Press the checkmark icon.



11. From the OPER LOCKOUT WARNING menu, select the desired Warning Time frame and press the checkmark icon to confirm (1, 4, 8, 24, or 48 hours).



9. Confirm the password and press the checkmark icon again.



12. The Abrazo returns to the OPERATOR screen.

**5.3.2. Editing an Operator**

1. From the MAIN MENU screen, press the SETUP button.
2. From the SETUP screen, press the ID SETUP button.
3. If an administrator has been added, the ADMIN NAME LOG appears. Select an administrator and enter the correct password. The ID SETUP screen appears
4. From the ID SETUP menu, press the OPERATOR button.
5. The OPERATOR screen appears with the options to ADD, EDIT, or DELETE ALL.

10. If the password is confirmed, the OPER LOCKOUT screen appears. Select the desired time frame (NO is default) and press the checkmark icon to confirm. The available options are NO, WEEKLY,



6. Select EDIT.

**Note:** Pressing *EDIT* or *DELETE ALL* will generate an error if no operators have been added.



7. The OPERATOR NAME LOG appears with the list of current operators.



8. Select the desired operator. The OPER EDIT screen appears with the following options: Change Password, Change/Reset Lockout, or Delete Operator.

**5.3.2.1. Change Password**

1. Press Change Password. The SET PASSWORD screen appears. From either the alphanumeric or the numeric keyboards (press the 123 icon to call up the numeric), enter up to a 50 character password. Press the checkmark icon.



2. Confirm the password and press the checkmark icon again. If the password is confirmed, the display returns to the OPERATOR NAME LOG Screen.



### 5.3.2.2. Change/Reset Lockout

1. Press the Change/Reset Lockout button. Select the desired time frame (NO is default) and press the checkmark icon to confirm. The available options are NO, WEEKLY, MONTHLY, EVERY 3 MONTHS, SEMI-ANNUAL, or ANNUAL. For more detail on how operator lockout works, see Section 5.6.3.



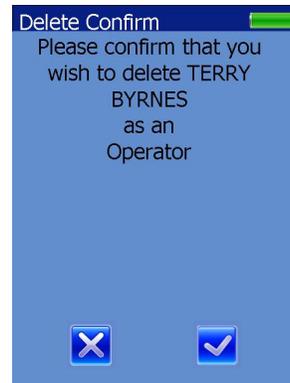
2. From the OPER LOCKOUT WARNING menu, select the desired Warning Time frame and press the checkmark icon to confirm (1, 4, 8, 24, or 48 hours).



3. The Abrazo returns to the OPERATOR NAME LOG screen.

### 5.3.2.3. Delete Operator

1. Press Delete Operator. The Delete Confirm screen appears and asks if the user wishes to delete the operator.



2. Press the X to decline or the checkmark icon to accept the deletion and to return to the OPERATOR NAME LOG screen.

### 5.3.3. DELETE ALL

1. From the MAIN MENU screen, press the SETUP button.

2. From the SETUP screen, press the ID SETUP button.

3. If an administrator has been added the ADMIN NAME LOG appears. Select an administrator and enter the correct password. The ID SETUP screen appears.

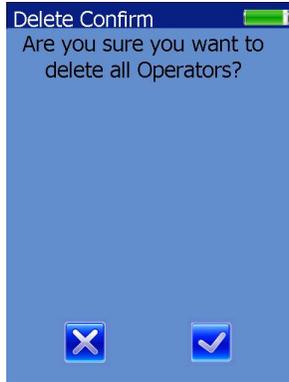
4. From the ID SETUP menu, press the OPERATOR button.

5. The OPERATOR screen appears with the options to ADD, EDIT, or DELETE ALL.

6. Select DELETE ALL.

**Note:** Pressing EDIT or DELETE ALL will generate an error if no administrators have been added.

7. A Delete Confirm screen appears and displays, "Are you sure you want to delete all Operators?"



8. Pressing the checkmark icon will delete all administrators. Pressing the "X" button will cancel the action

9. The Abrazo returns to the OPERATOR screen after deleting all listed operators.

**5.4. Patient ID**

1. From the MAIN MENU screen, press the SETUP button.

2. From the SETUP screen, press the ID SETUP button.

3. If enabled, the ADMIN NAME LOG screen will appear and ask the user for an ID barcode or name selection. Select a name.

4. The Abrazo will prompt the user for the password. Enter the password and press the checkmark icon. The ID SETUP screen appears.



5. From the ID SETUP menu, toggle the PATIENT ID button to PATIENT ID (ON).



6. Press either the Back arrow to return to the SETUP menu or the MAIN MENU button to return to the main menu.

**5.5. Auto Log Out**

If the instrument remains idle longer than the fixed auto log out time (15 minutes) or the Abrazo goes to sleep, the operator is automatically logged out.

1. From the MAIN MENU screen, press the SETUP button.

2. From the SETUP screen, press the ID SETUP button.

3. If enabled, the ADMIN NAME LOG screen will appear and ask the user for an ID barcode or name selection. Select a name.

4. The Abrazo will prompt the user for the password. Enter the password and press the checkmark icon. The ID SETUP screen appears.



5. From the ID SETUP menu, toggle the AUTO LOG OUT button to AUTO LOG

OUT (OFF). (The default setting for AUTO LOG OUT is ON)



6. Press either the Back arrow to return to the SETUP menu or the MAIN MENU button to return to the main menu

### 5.6. Enabling Lockout Modes

An operator with an Administrator password can enable the Abrazo to run in one or all of the following Lockout modes with separate warning times. Once enabled and the warning time frame has been reached, the warning time will appear at the bottom left of the main screen and will show the remaining time. If multiple Lockouts are to be displayed, they will alternate every 4 seconds.

The Operator Lockout is set up through each Operator ID and can be customized for each Operator (see Section 5.3).

- QC Lockout
- EQC Lockout
- Operator Lockout

#### 5.6.1. QC Lockout

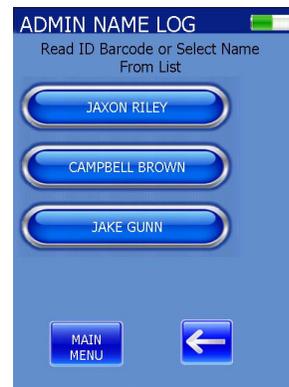
**Note:** When the QC Lockout is enabled, the Administrator can set up predetermined times and levels of control sample(s) requiring testing before beginning a patient test.

1. From the MAIN MENU screen, press the SETUP button.



2. From the SETUP screen, press the LOCKOUT button.

3. If enabled, the ADMIN NAME LOG screen will appear and ask the user for an ID barcode or name selection. Select a name.



4. The Abrazo will prompt the user for the password. Enter the password and press the checkmark icon.



5. The SETUP screen appears with ID SETUP and LOCKOUT no longer greyed out. Select the LOCKOUT Button.

6. The LOCKOUT screen appears.



7. From the LOCKOUT menu, press the QC LOCKOUT button. Select the desired time frame (NO is default) and press the checkmark icon to confirm. The available options are NO, DAILY, WEEKLY, MONTHLY, EVERY 3 MONTHS, SEMI-ANNUAL, or ANNUAL.



8. From the QC LOCKOUT WARNING menu, select the desired Warning Time frame and press the checkmark icon to confirm (1, 4, 8, 24, or 48 hours). The display will automatically return to the LOCKOUT screen.



9. If DAILY has been selected for the QC Lockout, the available options for the warning time are 1, 4, or 8 hours.

**5.6.2. EQC Lockout**

1. From the MAIN MENU screen, press the SETUP button.

2. From the SETUP Screen, press the LOCKOUT button.

3. If enabled, the ADMIN NAME LOG screen will appear and ask the user for an ID barcode or name selection. Select a name.

4. The Abrazo will prompt the user for the password. Enter the password and press the checkmark icon.

5. From the LOCKOUT menu, press the EQC LOCKOUT button.

6. The EQC LOCKOUT menu appears. Select the desired Lockout time frame (NO, HOURS, WEEKLY, or MONTHS) and press the checkmark icon to confirm.



7. If HOURS is selected, the unit allows the user to choose between 1 and 24 hours using the up and down arrows. After selecting the desired number, press the checkmark icon.



8. If WEEKLY is selected, the Abrazo goes directly to Step 10, EQC LOCKOUT WARNING TIME.

9. If MONTHS is selected, the unit allows the user to choose from 1 up to 12 months using the up and down arrows. After selecting the desired number, press the checkmark icon.



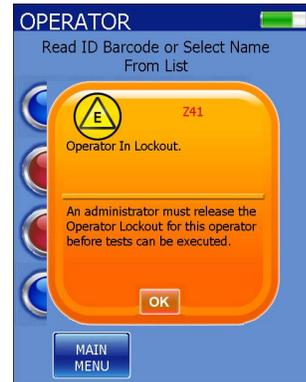
10. Select the desired warning time frame and press the checkmark icon to confirm (1, 4, 8, 24, or 48 hours).



11. The display will automatically return to the LOCKOUT screen.

### 5.6.3. Operator Lockout

1. For instructions on Operator lockout, see Section 5.3.
2. If an operator is locked out, when that operator attempts to run a test by scanning the barcode on the back of the test card, the Abrazo displays the error, Z41, *Operator in Lockout*. An administrator must release the Operator Lockout for this operator before tests can be executed.



3. The only option for the operator is to return to the Main Menu until an Administrator resets the lockout.

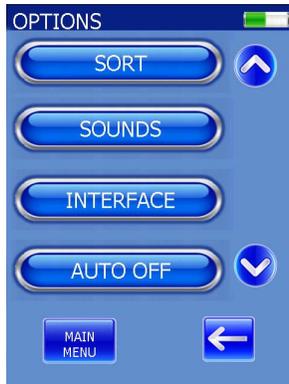
### 5.7. Options

The Abrazo has several options that can be altered to fit the user's needs such as displaying the patients in different ways or how the results are transferred to other computers or laboratory systems.



**5.7.1. Sort**

1. From the MAIN MENU screen, press the SETUP button.
2. From the SETUP Screen, press the OPTIONS button.
3. From the OPTIONS menu, press the SORT button.



4. Choose to retrieve results by DATE/TIME or by PATIENT ID. After selecting one, press the checkmark icon to return to the Options menu.



**5.7.2. Sounds**

1. From the MAIN MENU screen, press the SETUP button.
2. From the SETUP Screen, press the OPTIONS button.
3. From the OPTIONS menu, press the SOUNDS button.
4. Choose from OFF, SOFT, MODERATE, or LOUD. After selecting one, press the checkmark icon to save.

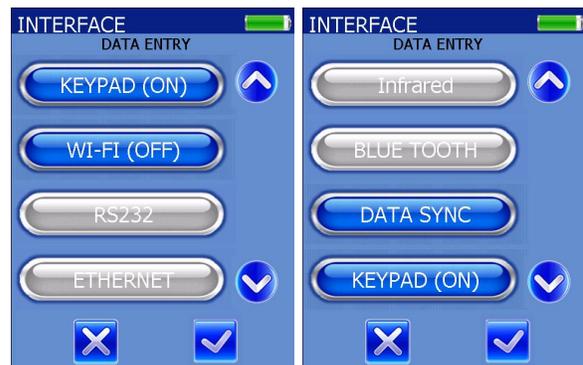


5. Choose from ON or OFF for key click sounds then press the checkmark icon to return to the Options menu.



**5.7.3. Interface**

1. From the MAIN MENU screen, press the SETUP button.
2. From the SETUP Screen, press the OPTIONS button. If the Administrator ID has been enabled, enter the password.
3. From the OPTIONS menu, press the INTERFACE button.



### 5.7.3.1. Keypad

1. From the MAIN MENU screen, press the SETUP button.
2. From the SETUP Screen, press the OPTIONS button. If the Administrator ID has been enabled, enter the password.
3. From the OPTIONS menu, press the INTERFACE button.
4. The KEYPAD button can be toggled back and forth by pressing it between ON and OFF. After selecting one, press the checkmark icon to save the choice and the display returns to the INTERFACE screen.

### 5.7.3.2. WI-FI

1. From the MAIN MENU screen, press the SETUP button.
2. From the SETUP Screen, press the OPTIONS button. If the Administrator ID has been enabled, enter the password.
3. From the OPTIONS menu, press the INTERFACE button.
4. The WI-FI button can be toggled back and forth by pressing it between ON and OFF. After selecting one, press the checkmark icon to save the choice and the display returns to the INTERFACE screen.

**Note:** For assistance in configuring the Abrazo unit to the Wi-fi connection, contact Helena Technical Services at (800) 231-5663.

**Note:** Once the Wi-Fi has been enabled, data sync to the CAAS will only occur through the Wi-Fi and not the docking station. To change this, unselect the Wi-Fi (OFF) option under the INTERFACE screen.

**Note:** If the Abrazo is moved from one Wi-fi access point to another, the instrument may need to be rebooted before it can connect to the new access point.

### 5.7.3.3. RS232

**Note:** This feature will be available in a later release.

### 5.7.3.4. Ethernet

**Note:** This feature will be available in a later release.

### 5.7.3.5. Infrared

**Note:** This feature will be available in a later release.

### 5.7.3.6. Bluetooth

**Note:** This feature will be available in a later release.

### 5.7.3.7. Data Sync

**Note:** This feature will be available in a later release.

### 5.7.4. Auto Off

1. From the MAIN MENU, press SETUP.
2. From the SETUP screen, press OPTIONS.
3. From the OPTIONS screen, press AUTO OFF. If the Administrator ID has been enabled, enter the password.
4. Using the up and down arrows, set a number of minutes for the Abrazo to wait before shutting itself off automatically between 1 and 60 or choose not to have the unit turn off automatically (OFF). Press the checkmark icon to save choices and return to the OPTIONS menu.

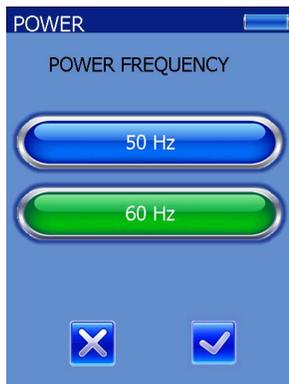
**Note:** it is recommended to enable the Auto Off function and allow the unit to “fall asleep”. The WAKE button functions only as a wake button and will not put the unit to sleep.



**5.7.5. Power**

1. From the MAIN MENU, press SETUP.
2. From the SETUP screen, press OPTIONS.
3. From the OPTIONS screen, press POWER. If the Administrator ID has been enabled, enter the password.
4. Select either 50 or 60 Hz (default is 60 Hz). This is based on the AC main power in use.

**Note:** *Fluorescent lighting produces pulsating light at the frequency of the power system. This flicker is either 50 Hz or 60 Hz and must be filtered from the optics signal in the Abrazo for accurate readings.*

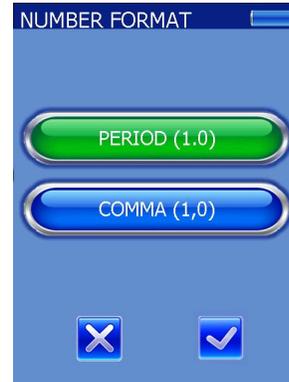


5. Press the checkmark icon to save choices and return to the Options menu.

**5.7.6. Number Format**

1. From the MAIN MENU, press SETUP.

2. From the SETUP screen, press OPTIONS.
3. From the OPTIONS screen, press NUMBER FORMAT. If the Administrator ID has been enabled, enter the password.



4. Select either PERIOD (1.0) or COMMA (1,0).

**5.7.7. Cleaned**

This option allows the user to document when the Abrazo was last sanitized.

1. From the MAIN MENU, press SETUP.
2. From the SETUP screen, press OPTIONS.
3. From the OPTIONS screen, press CLEANED.



4. The Abrazo displays the message "Cleaned. Instrument cleaning data has been saved." This option is available to everyone. If an administrator or operator has been added, the Abrazo will prompt the user with the ADMIN name log so that

a name may be included with the date and time of cleaning.



**5.7.8. Printer**

Abrazo results may be printed using a serial or Bluetooth printer.

1. From the SETUP screen, press OPTIONS.
2. From the OPTIONS screen, press PRINTER.



3. The default printer setting is Serial. If the PRINT: Serial is toggled on, the Bluetooth options will be greyed out and inaccessible.
4. If the PRINT: BT is toggled on, the Bluetooth options will be accessible.
5. To connect a Bluetooth printer, press the BT SEARCH button. Once it connects, the printer name will be displayed at the bottom of the screen.



6. If pairing is unsuccessful, “No supported Bluetooth printers found”.

***Note:** Occasionally, no message is displayed. This will be resolved in a future version of software.*

7. To disconnect the printer, press the UNPAIR BT button.

## Section 6 – Operating Instructions

### 6.1. General Operating Instructions

#### 6.1.1. Data Review

With the Data Review option, patient, QC, and EQC test records can be viewed and sorted. Using the CAAS, they can also be sent to a computer or LIS.

Patient Data Review displays the Patient Data screen where results are listed by either Patient ID or by the date/time the testing occurred. If the results are listed by ID, clicking on the patient name or ID will bring up history screen with all the tests for that patient. If the results are listed by date/time, click on the desired date. The Search function can be used with a numeric or alphanumeric Patient ID.

QC and EQC test results are viewed by pressing either the QC DATA or the EQC DATA button. Clicking a particular test will display a screen which lists the result full screen and includes sample type, date/time, test result, and patient name (if supplied). EQC results are broken out by the three individual levels of results and are viewed separately in history.

On any of the History screens, additional test records can be viewed by using the arrows indicated in the upper and lower corners of the screen display.

##### 6.1.1.1. Viewing Patient Data

1. From the MAIN MENU screen, press DATA REVIEW.



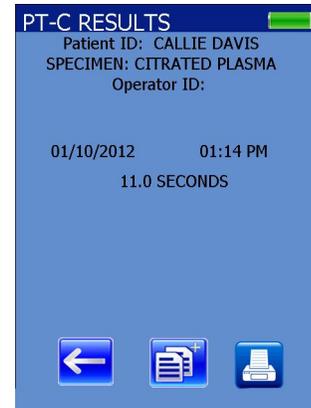
2. From the DATA REVIEW screen, press PATIENT DATA.



3. The PATIENT DATA screen appears. If this is the first time use, the screen will be empty.

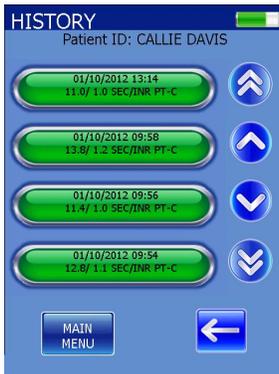


4. If this is not the first use and the results are sorted by Patient ID, all patients will be displayed as a separate tab in alphabetical order. If the Date/Time option has been selected, the most recent result will be displayed first.



**Note:** If Patient ID has been turned off, the Abrazo will show the Sequential Run Number, the Date and Time, and the unit serial number in the Patient ID field.

5. The HISTORY screen appears listing all results for the desired selection (shown below for both Patient ID and Date/Time options). Failing results will be displayed identically to passing except the result will be in red.



7. The results are displayed as well as the time/date stamp for the test, patient ID, operator ID, and the specimen type. Pressing the back-arrow or additional information button, returns the Abrazo unit to the HISTORY screen. The result may also be printed by pressing the Print button.

8. Another feature available is the Search feature.



6. Using the up and down arrows if shown, find the desired test and select it.

9. Press the SEARCH button from the PATIENT DATA screen.



10. Type in the desired patient's Identification or part of it and press the checkmark icon.



11. Any matching results will be displayed.



**6.1.1.2. Viewing QC Test Data**

**Note:** For more information on quality samples, see Section 7, Quality Control.

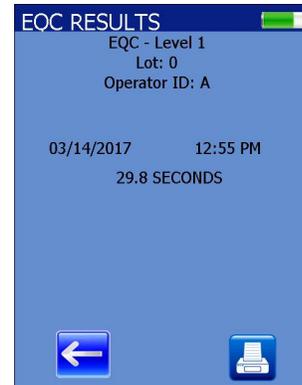
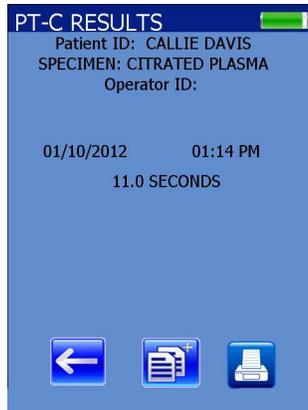
1. From the MAIN MENU screen, press DATA REVIEW.
2. From the DATA REVIEW screen, press QC DATA.
3. The QC HISTORY screen appears listing all test types. Tests not setup will be greyed out. Select the desired test type.



4. The QC HISTORY screen appears listing all results starting with the most recent completed test. Included is the type of QC test, time and date, Lot number, and result. Using the up and down arrows if necessary, find the desired QC test and select it.



5. The results are displayed full screen as well as the type, time and date, and Lot number. A print icon is also shown.



**Note:** Pressing the Additional Pages button will bring up all the stored QC results for the test shown.

**6.1.1.3. Viewing EQC Data**

1. From the MAIN MENU screen, press DATA REVIEW.
2. From the DATA REVIEW screen, press EQC DATA.
3. The EQC HISTORY screen appears listing all results starting with the most recent test. If this is the first time use, the screen will be empty. If not, the data will be listed by the date and time of the test.



4. Each time the EQC card is run, three separate results are generated and broken out by the three levels. Also included are the date/time, lot number, and level.
5. Using the up and down arrows if needed, find the desired QC test and select it. The same result is shown full screen as well as the EQC lot number.

**6.1.1.4. Clean Data**

1. From the MAIN MENU screen, press DATA REVIEW.
2. From the DATA REVIEW screen, press CLEAN DATA.
3. The CLEAN DATA HISTORY screen appears listing all results starting with the most recent test. If this is the first time use, the screen will be empty. If not, the data will be listed by the date and time of the test.



**6.2. Basic Test Instructions (no Operator, Patient, or Admin ID, or Lockout)**

The same basic procedure is used to initiate and perform all Abrazo tests. Differences in the Abrazo tests can be found in the summary, specimen collection and preparation, quality control, limitations, results, expected values, and performance characteristics. Test-specific procedures in the test card package insert should be consulted when running tests.

**Note:** The basic instructions cover the test procedure of a running a test card with no Operator ID, no Patient ID, no Admin ID, and no Lockouts enabled.

### 6.2.1. Getting Ready

Refer to the package insert instructions provided with the test cards for test-specific information and quality control procedures.

1. Awaken the Abrazo by pressing the WAKE button.
2. The MAIN MENU screen is displayed.
3. The Abrazo is ready to run a sample.
4. Follow package insert quality control procedures for the specific test being run.
5. Allow the test card to warm to room temperature while still sealed in its foil pouch.
6. Collect a blood sample as instructed in the test card package insert.
7. Remove the test card from its pouch.

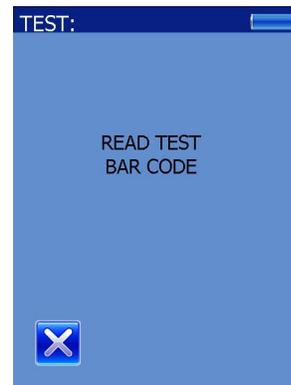
### 6.2.2. Reading a Test Card

Information for each test card lot is encoded on the printed barcode on the back of the Abrazo test card. This information is transferred to the Abrazo when the card is scanned with the barcode reader.

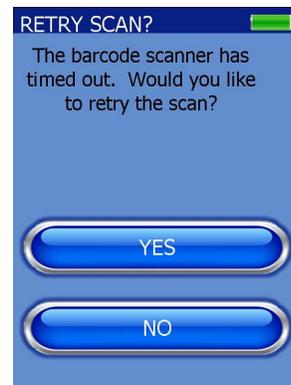
1. On the MAIN MENU, press the PATIENT TEST button.



2. The screen displays, "READ TEST BARCODE" and the barcode reader is activated.



3. Hold the test card backwards 6-8 inches from the unit, tilted slightly back (approximately 15 degrees) with the barcode facing the Abrazo, and scan the test card.
4. If the card was not successfully read, the screen displays the message "The barcode scanner has timed out. Would you like to retry the scan?"



**Note:** Barcode time out messages and Error messages MUST be addressed in a timely manner to prevent "memory full" errors.

5. Repeat Step 3 and scan the barcode.
6. If the card has been successfully read, the analyzer displays a picture of how the card should be inserted, including the test card type.

### 6.2.3. Test Card Time Out Errors

The user has 5 minutes to insert the test card after it has been scanned by the barcode reader. After the time has elapsed, if no card has been inserted the Z16 error will alert the user, "Test card insertion has timed out. Open new card and restart test."

Once a test card is scanned, a 15 minute "air damage" timer starts. If the user tries to rescan the card after the 15 minute window of use (see card procedure), he/she will get the Z20 error alerts the user, "Test card used or timed out. Open new card and restart test".



Once the card is inserted, the user has 15 minutes to choose the sample type and start the test before getting a test card time out error. If the card is removed after the sample type has been chosen and rescanned, the Abrazo will not accept it and will prompt the user for a new card.

Helena strongly recommends **not** to open or scan the test card until the user is ready to complete the test in its entirety or reusing cards that have been scanned previously.

### 6.2.4. Inserting a Test Card



**Note:** Do not insert the test card until prompted to do so. It is important to position the test card correctly into the analyzer to correctly perform a test. The screen displays a picture of the proper orientation.

1. When the prompt is displayed, hold the test card face up, leading with the angled corner on the right side of the card.
2. If Patient ID is not enabled, the date and serial number will be used as a Patient ID.
3. Slide the test card completely into the card holder making sure the outside edge of the card rests against the card slot retaining wall.
4. The Abrazo simultaneously runs an internal EQC and warms the card.



5. After the EQC is completed, it starts the 300 second window countdown to add sample to the card.

**NOTE:** If the test card is inserted prematurely into the card slot, the message, **CARD INSERTED TOO EARLY. PLEASE REMOVE CARD** is displayed.

**NOTE:** Do not remove the test card until prompted to do so by the Abrazo or the test will be stopped.

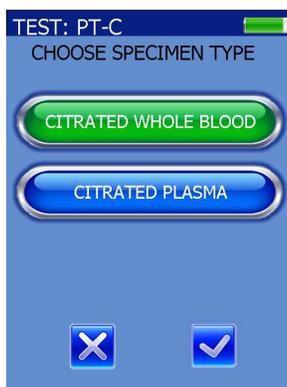
**NOTE:** After insertion of the test card and before sample drop is added, avoid intense/direct incandescent lighting above the Abrazo or contact with the card. This could cause an auto-start prior to the sample drop being added.

**NOTE:** To manually stop a test, press the "X" button. Do NOT turn off by pressing the WAKE button, which can lead to communication errors and subsequent reboot.

### 6.2.5. Selecting the Sample Type

The Abrazo may prompt the user to select the sample type being used with the test card. Depending on which card is being used, the user **may or may not** be given this option since some test cards only take one type of specimen. Data encoded on the back of each test card controls which sample types are available.

1. If prompted on the Sample Type screen, select the appropriate test sample type and press the checkmark icon.



2. The Abrazo prompts the user to add the drop.

### 6.2.6. Adding a Sample Drop

**NOTE:** One of the following methods is recommended to withdraw the sample from a citrated collection tube:

- If a whole blood sample is being tested, invert the sample several times.
- Carefully remove the rubber stopper from the collection tube, using a device designed to minimize the formation of aerosols. Use a device capable of dispensing a drop of approximately 30 to 35µL (0.030 to 0.035cc).
- Pierce the stopper of the collection tube, using a tuberculin needle with attached syringe. Slowly aspirate 0.1mL or more of the sample into the syringe. Carefully disconnect the syringe from the needle hub with a twisting motion without removing the needle from the stopper. Press the plunger to dispense a drop of sample. This method is **not** recommended for use with plasma samples.

**CAUTION:** Do not touch the test card with the device used to add the sample.

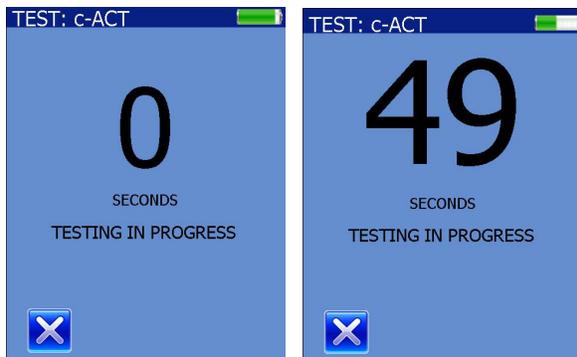
1. Add approximately 30 to 35µL (0.030 to 0.035cc) of sample to the sample well on the Abrazo test card when prompted to do so.
2. The entire gray area of the reaction chamber on the analyzer test card should be covered by the sample. If the reaction chamber has not been completely covered by the sample, repeat the test, using a new test card



3. The sample drop automatically enters the reaction chamber on the test card, and the analyzer detects its presence and begins testing.

4. 0 is displayed above the message, TESTING IN PROGRESS, while the test is being performed.

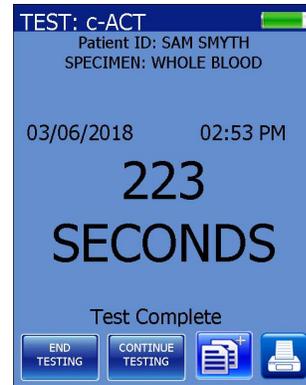
**Note:** While running a c-ACT or c-ACT-LR test, the display will indicate testing time in seconds and will blink and update approximately every 20-30 seconds as the test progresses until the testing endpoint is reached.



5. Additionally, for c-ACT or c-ACT-LR, once the endpoint has been reached, the Abrazo will post the result only first before the final screen appears.

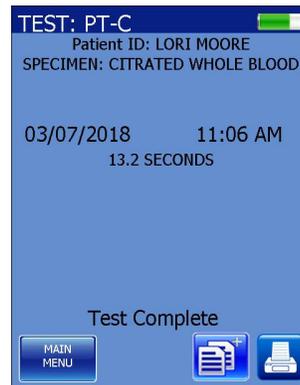


6. Press Continue to proceed to the final screen. The user may then end the testing by pressing End Testing or run another sample by pressing Continue Testing.



**6.2.7. Reviewing Results**

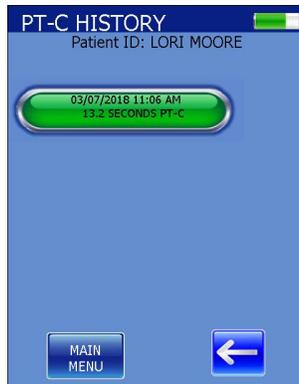
When the appropriate endpoint of a test is reached, the analyzer emits an audible sound and displays the results. The display also shows the test type, date and time, and the final result. If a problem is encountered in determining the test result, a diagnostic message is displayed (section 6.2.10).



1. Press the Additional Data button  and the user is prompted to remove the card.



2. After the card is removed, the latest test results are sorted in chronological order or by Patient ID depending on which option has been selected.



3. Pressing either the Back arrow or Main Menu button will take the user back to the Main Menu.

4. Refer to the test card package insert for Safe Disposal of Reagents.

**6.2.8. Sufficient Sample Verification**

After each test is performed, verify that the entire gray area of the reaction chamber on the test card is covered by the sample. If the reaction chamber has not been covered completely by the sample, repeat the test using a new test card.

**Sufficient and Insufficient Samples**



1 Sufficient sample 2 Insufficient sample

Abrazo test cards do not require as much precision in sample dispensing as conventional methods – the reaction chamber is self-filling and only requires one drop (approximately 30 to 35 µL) of sample to sufficiently fill the reaction chamber. A transfer pipette should **never** be used to dispense sample. Helena recommends a 35 uL Micropipette (Cat No. 5718) for sample addition.

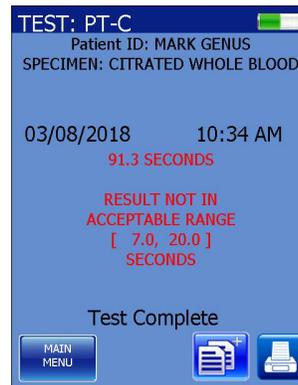
**6.2.9. Sample Type Verification**

After each test is performed, verify that the correct sample type was selected. Calibration settings are read from the test card according to the sample type selected by the operator (section 6.2.5). Selection of the proper sample type is critical to valid test results.

The sample type is at the top of the screen above the test result.

**6.2.10. Irregular Test Results**

Irregular test results are sometimes encountered when endpoints are outside the expected limits for a test.



If this occurs, the result is shown in red as well as the expected limits. The operator should repeat the test to verify the result.

**6.3. Patient ID on**

1. Using the same basic format described in Section 6.2, press the PATIENT TEST button.

2. The screen displays "Patient ID" as well as an alphanumeric keyboard to manually enter the ID.



3. Scan the ID barcode using the scanner or enter the Patient ID using the keyboard and press the checkmark icon. The numeric keyboard can be accessed by pressing the 123 icon.
4. The screen advances and prompts the user to add the card.

**6.4. Operator and Patient IDs on**

When the Operator ID is enabled, it can be entered one of two ways; it may be scanned using the barcode reader or it may be selected from a list stored on the Abrazo unit using the up and down arrows.

1. Using the same basic format described in Section 6.2, press the PATIENT TEST button.
2. The NAME LOG appears with a list of all operators and/or administrators. Use the arrows to find the correct one and press it. Alternatively, the name may be scanned using the barcode reader.



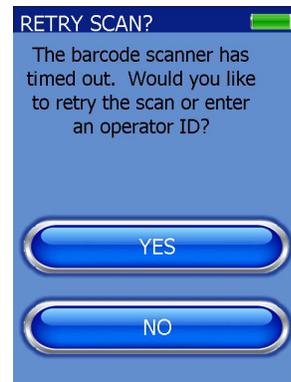
3. The Abrazo will prompt the operator for the password. Enter the password and press the checkmark icon.



4. The patient ID screen appears. Scan the ID barcode using the scanner or enter the Patient ID using the alphanumeric (or numeric) keyboard and press the checkmark icon.



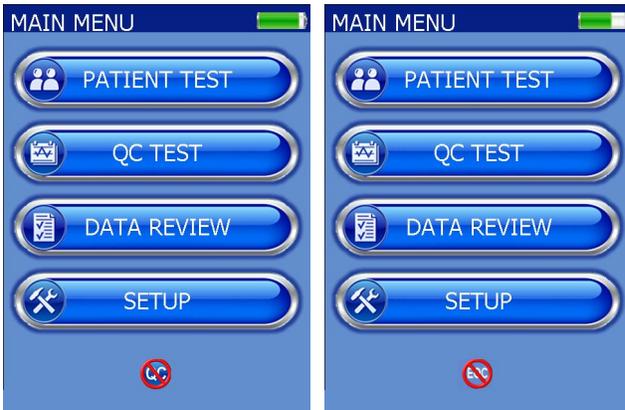
5. If the barcode scanner failed to read the patient ID, the Abrazo will alert the user. Pressing Yes will reactivate the scanner and keypad, while pressing No will bring up the Main Menu.



6. After the Patient ID has been entered, the screen advances and prompts the user to scan the test card barcode.

**6.5. Operator ID and QC Lockout on**

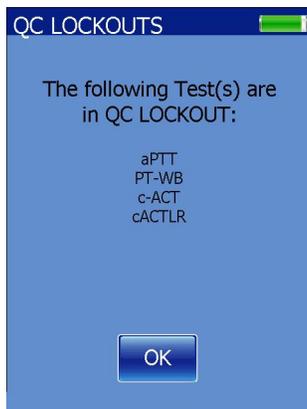
The QC Lockout can be visibly seen when engaged in the lower center of the screen as a “QC” circled in red with a line through



it.

**Note:** If the EQC Lockout is also on, the EQC symbol will alternate with the QC symbol every few seconds.

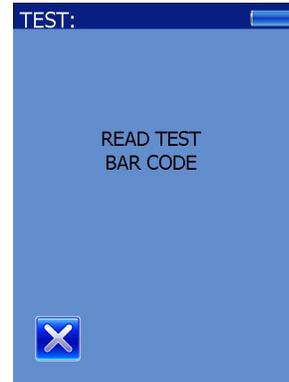
Tapping the QC Lockout icon will bring up a screen displaying which tests are currently locked out.



1. Using the same basic format described in Section 6.2, press the PATIENT TEST button.
2. After the Operator ID has been entered, the screen displays “Read ID barcode or Select Name from List”.
3. Scan ID barcode using the barcode scanner, select the Operator Name from

the list and press the name, or enter the name using the keyboard.

4. The screen displays, “READ TEST BARCODE” and the barcode reader is activated. Scan the test card barcode.



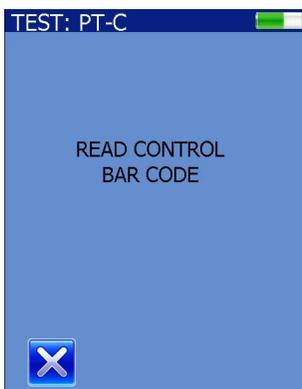
5. The words QC LOCKOUT appear in red letters and only two choices are offered; either Liquid QC or Cancel.



6. Pressing CANCEL takes the user back to the Main Menu.
7. Pressing LIQUID QC allows the user to run the plasma controls and reset the Lockout timer. See Section 8 for more information on QC Controls.
8. Press the LIQUID QC button. The screen advances and prompts the user to add the test card.

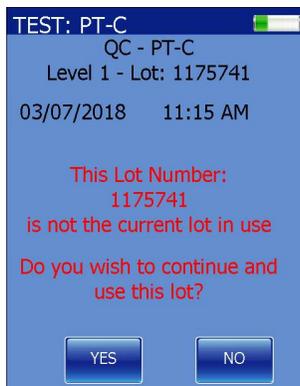


9. The Abrazo prompts the user for the plasma control barcode.



10. After a brief warming and EQC check, the Abrazo prompts the user to add a drop of the control plasma (either Level 1 or Level 2 can be run first).

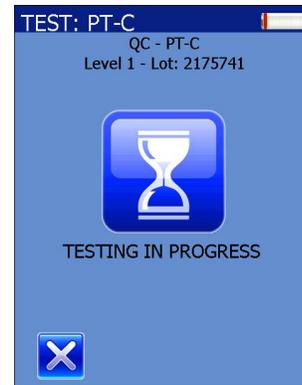
11. If the control lot scanned is not the same as the lot previously entered, the Abrazo will ask the user if they wish to use the lot.



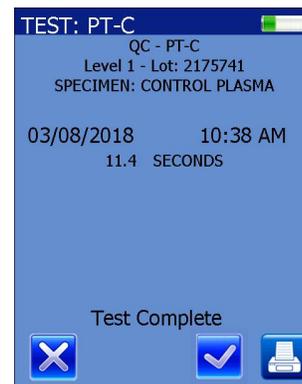
12. The user may select YES or NO. Selecting YES will continue the test. Selecting NO will allow the user to scan another control.



13. An hourglass is displayed above the message, TESTING IN PROGRESS, while the test is being performed.



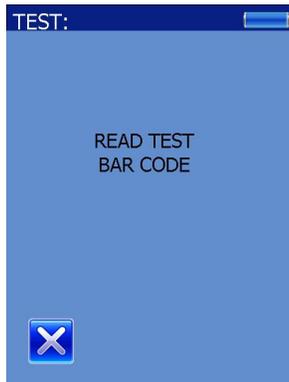
14. The result is displayed with an "x" and a checkmark icon to accept or reject the result. Rejecting the results prompts the user to remove the card and the unit returns to the Main Menu.



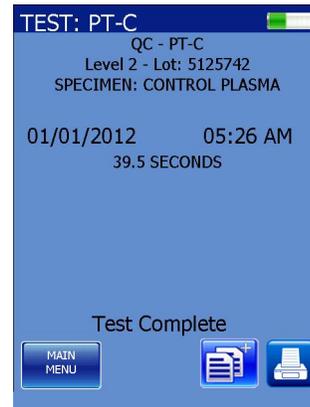
15. Press the checkmark icon to accept the result.

16. If the lot tested is different from the lot in use, a pound sign (number sign) will be displayed after the result.

17. The user is prompted to remove the used card and scan a fresh test card.

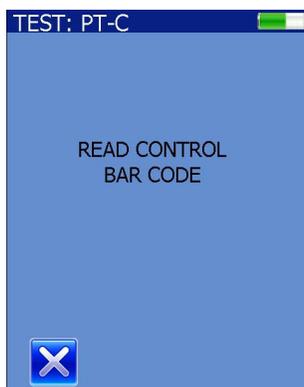


21. After the test is finished, the result is displayed.



18. Scan the test card and add it when prompted. Then scan the control barcode.

**Note:** If the same plasma level is rescanned, the Abrazo will alert the user it has already been tested. See Section 7.5.4.



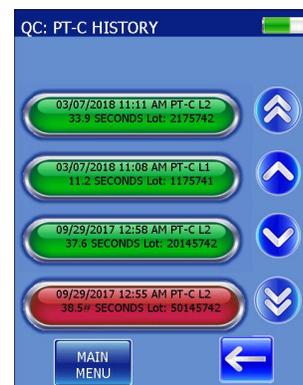
22. Press the Additional Pages button to accept. The Abrazo prompts the user to remove the card.



19. After an internal EQC check, the Abrazo prompts the user to add a drop of the control plasma.



23. The QC history is shown. Pressing the Main Menu button will return the user to the main menu and the QC Lockout will be removed from the screen.



**Note:** See Section 7 for more information on running EQC and QC controls.

20. An hourglass is displayed above the message, TESTING IN PROGRESS, while the test is being performed.

### 6.6. Operator ID, Patient ID, and EQC Lockout on

The EQC Lockout can be visibly seen when engaged in the lower center of the screen as an “EQC” circled in red with a line through it.

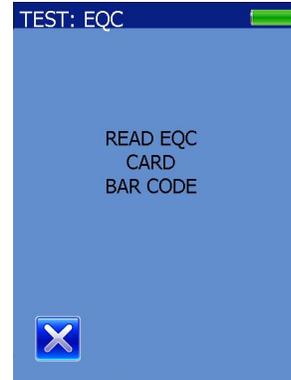


1. Using the same basic format described in Section 6.2, press the PATIENT TEST button.
2. After the Operator ID has been entered, the screen displays “Read ID barcode or Select Name from List”.
3. Scan ID barcode using the barcode scanner or select the Operator Name from the list and press the name.
4. The patient ID screen appears. Scan the ID barcode using the scanner or enter the Patient ID using the alphanumeric (or numeric) keyboard and press the checkmark icon.
5. The words EQC LOCKOUT appear in red letters and only two choices are offered; either EQC or CANCEL.

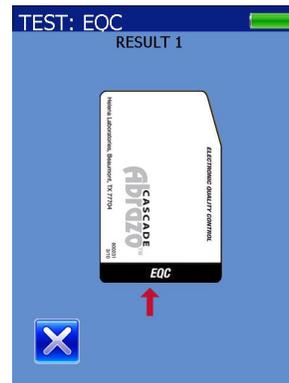


6. Pressing CANCEL takes the user back to the Main Menu.

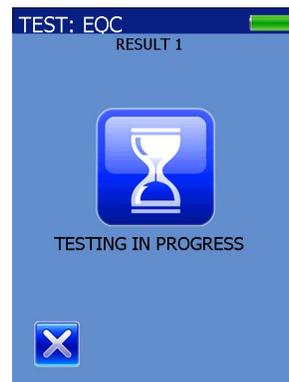
7. Pressing EQC allows the user to run the EQC card to clear the EQC Lockout.



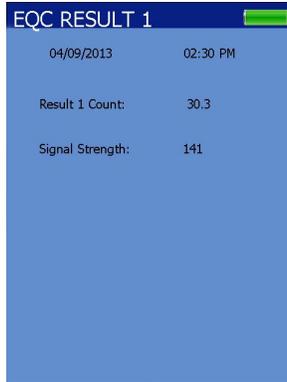
8. Insert the EQC card when prompted.



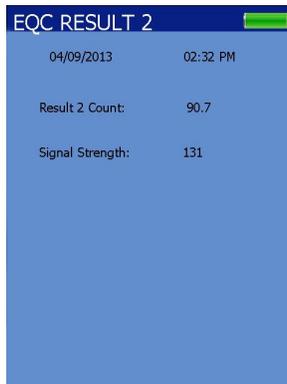
9. An hourglass is displayed above the message, TESTING IN PROGRESS, while the test is being performed.



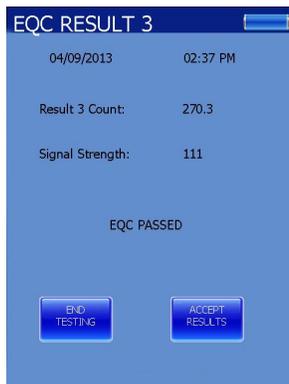
10. The unit briefly displays Result 1 and then continues the test.



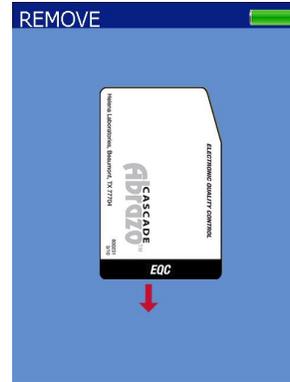
11. The unit briefly displays Result 2 and then continues the test.



12. Click to ACCEPT RESULTS button to accept the EQC results and clear the EQC Lockout. If END TESTING button is selected the User will be returned to the MAIN MENU and the EQC Lockout will still be present.



13. The unit prompts the user to remove the EQC card and returns to the Main Menu.



**Note:** See Section 7 for more information on running EQC and QC controls.

### 6.7. Operator Lockout on

Refer to Section 5.3, Operator ID.

### 6.8. Administrator Lockout on

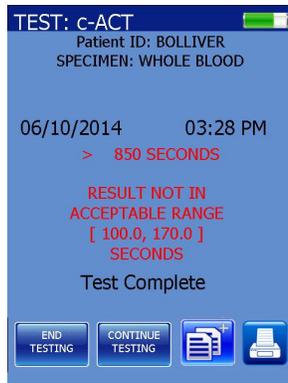
With an Administrator password in place, the User will be able to run patient samples and controls, but will be unable to change parameters. The only unlocked functions are Brightness, Sound, and Sort.

### 6.9. Proficiency Survey Samples

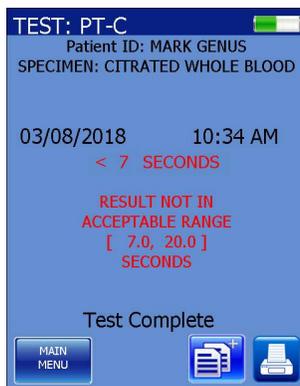
If a proficiency sample needs to be run, instead of manually changing the values back to default, an optional temporary override can be used. The patient ID "PROF" shall be used as a signal to the software to put it into the temporary proficiency survey mode that will utilize the default card settings. After the sample is finished, the Abrazo will revert to its previous settings.

### 6.10. Exceeding Test Limits Results

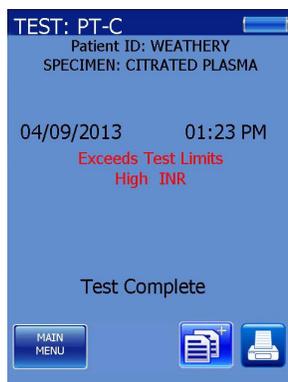
If no test endpoint is found and the test time has exceeded the defined range of the test, the (>) greater than sign is displayed with the defined range of the test.



For results that have an endpoint before the defined range of the test, the operator will receive a (<) less than sign with the defined range of the test.



If the result is based off a calculation using the seconds result (INR or SEC/INR for PT-C) and the test endpoint is found to be shorter than the defined range of the test, the (<) less than sign is displayed with the defined range of the test and a message of Exceeds Test Limits Low. For tests that have no endpoint, the (>) greater than sign is displayed with the defined range of the test and a message of Exceeds Test Limits High.



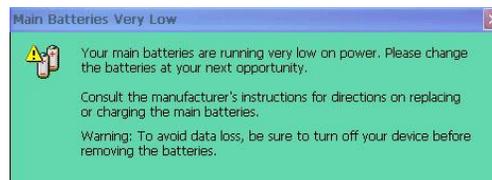
If any of the above scenarios should occur, the operator should repeat the test to verify results.

If the INR is out of range and the seconds are within test limits, then the results are displayed in red. Prior to repeating test or reporting the result, the user should verify the mean is entered correctly.

### 6.11. Low Battery Conditions

**Note:** Place the Abrazo on the charger after use and charge until the charger shuts off, then remove from charger. If instrument is not used for a day then place it on the charger until charge is completed before use. Remove the charger when fully charged.

1. As an internal quality control measure, the analyzer verifies that sufficient power is available for proper test performance when the instrument is turned ON and each time a test is initiated. If battery power is low, the screen will display a message that the battery level is low in blue.



2. When this message is displayed, connect it to the Abrazo Power Supply. Turn it back ON after connected if it's going to be used. The battery will recharge from the power supply while running or while powered OFF.

3. If the analyzer is not recharged after the initial warning is displayed, the Abrazo will display another message "Main battery critically low" (in red), after which the analyzer can no longer be used without recharging the battery. Shortly after the second message, the unit goes to sleep. Fully charge the battery by leaving the unit

plugged in and asleep for at least 6-8 hours (see Section 4.2.1).

4. If the battery power has become so low that the analyzer is unable to turn on or check the power level, the analyzer might have blank or incomplete displays and will not allow test initiation. Recharge the battery as described above.

5. Do not allow the battery to become completely discharged. An excessively discharged battery can lose capacity and fail to recharge.

## Section 7 – Quality Control

### 7.1. Quality Control

Daily quality control (QC) is a good laboratory practice and is required by most states in the US and the Clinical Laboratory Improvement Amendment, 1988 (CLIA '88). Quality control procedures are part of an overall quality assurance program to ensure the accuracy and reliability of patient results and reports.

Monitoring the results of QC analyses can alert you to possible system performance problems. Healthcare professionals should follow proper local and national guidelines for quality control and check with appropriate licensing/accrediting bodies to ensure that QC programs meet established standards.

It is recognized nationally that medical and laboratory instrumentation be enrolled in a quality assurance program. Participation in inter-laboratory QC survey programs allows for the comparison with systems in other laboratories and may identify possible errors not detected by intra-laboratory QC testing alone.

Quality control testing for the Abrazo should be performed regularly by the operator. Abrazo products make routine quality control convenient and affordable.

To ensure accurate results, routine quality control procedures should be followed by the operator each day a test is performed.

See the package insert provided with the Abrazo test cards and controls for specific instructions on the test that is being performed.

The relationship of the results obtained by the Abrazo and results from any other methods used should be established by the operator during implementation of the Abrazo and whenever there is a change in test card lots, reference methods, or reagent lots.

An extensive level of quality control testing is performed automatically by the Abrazo at the time it is turned on and while the instrument is in use. These internal instrument quality controls do not; however, take the place of regular, operator performed, quality control testing.

### 7.2. Calibration

The Abrazo is calibrated at the factory to maintain a constant card slot temperature and optimum sensitivity and performance for the clot detection module inside the instrument.

Other calibration settings vary by test card lot and selected sample type. These lot-specific calibration parameters are encoded on the 2D barcode on the back of each test card. The parameters are read from the test card and automatically set within the instrument when a test is initiated.

The only calibration procedure required by an operator is to set the correct date and time when necessary.

### 7.3. Instrument Self-Tests

When the instrument is turned on, it automatically performs a series of self-tests to verify proper hardware operation of the magnet, light source, and heater.

After completion of the self-tests, the Abrazo software version appears briefly in the lower right hand corner before the Main Menu screen is displayed. If an instrument self-test fails, an error message is displayed.

**Note:** *The operator should reboot if performance problems are suspected.*

**Note:** *If rebooting the instrument, remove it from the charging device if connected to ensure the reboot occurs properly.*

### 7.4. Diagnostic Messages

While the Abrazo is in use, it continuously monitors certain conditions and issues

error messages when these conditions are abnormal.

The following aspects of operation are examples of some of the conditions it monitors while in use:

- Temperature
- Sensor head temperature (temperature in the card slot)
- Low battery condition (when operating on battery power)
- Presence or absence of a test card in the instrument
- Presence of a sample in the reaction space of the test card

### **7.5. Operator Quality Control Procedures**

Quality control testing for the Abrazo should be performed regularly by the operator. An extensive level of quality control testing is also performed automatically by the analyzer when it is turned on and while the instrument is in use. These internal instrument quality controls do not, however, take the place of regular, operator performed, quality control testing.

#### **7.5.1. Test Method Quality Control**

Routine quality control procedures should be followed by the operator each time a test is performed to ensure that the proper test methodology is used.

These routine procedures include:

- Test Card Validation
- Date and Time Verification
- Sufficient Sample Verification
- Sample Type Verification

#### **7.5.2. Test Card Validation**

Before using a test card, be sure the card has been stored in acceptable conditions. Verify that the card has not passed its

expiration for the conditions in which it was stored (see the package insert).

The expiration date encoded on the test card is verified against the date on the analyzer when a test is performed. This verification is valid only if the test card has been refrigerated at 2 to 8°C (36 to 46°F) and the analyzer system date is correct.

**Note:** *If the test card has been stored at room temperature, the encoded expiration date and the date embossed on the foil pouch are no longer valid (see the package insert).*

#### **7.5.3. Date and Time Verification**

Before beginning a test, verify that the correct date and time are displayed on the Ready screen. An accurate system date and time are necessary to validate the test card expiration and to properly record test records. To change the analyzer date and time, see Section 4.2.2.4.

#### **7.5.4. Testing Procedure**

##### **Materials Required**

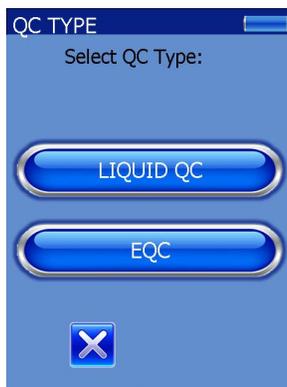
- Abrazo Test Card
- Abrazo Plasma Controls
- Abrazo Analyzer
- Abrazo Operator's Manual

**Note:** *For explanation purposes, the PT-C test will be used as an example but this applies for all tests.*

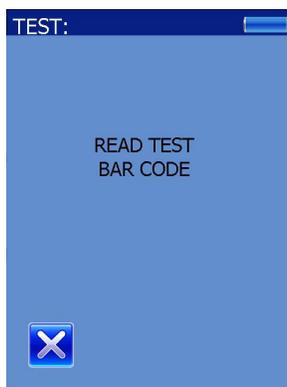
1. From the MAIN MENU, press the QC TEST button.



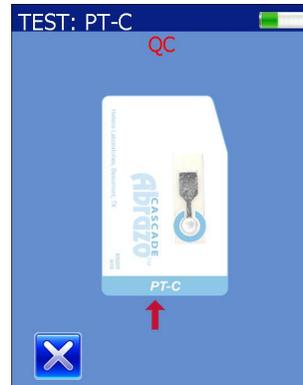
2. On the QC TYPE menu, select LIQUID QC.



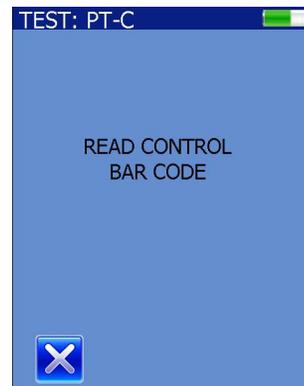
3. The unit prompts the user to scan the test barcode to determine which QC test will be run.



4. After an internal EQC check, the unit prompts the user to add the test card.



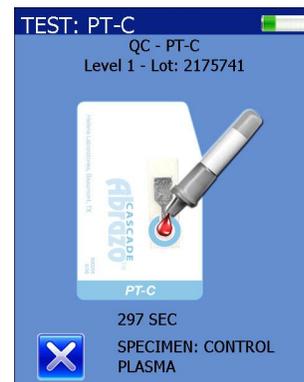
5. The Abrazo prompts the user for the plasma control barcode. For the two levels of QC, either the Level 1 or Level 2 control may be run first.



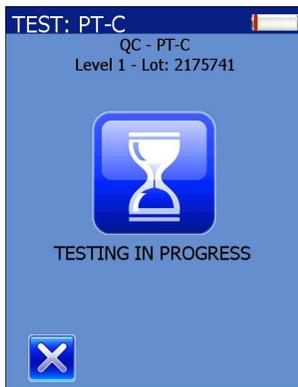
6. Scan the plasma barcode, which can be found on the label of the control vial or assay card that came with the Control Kit.

7. After a brief warming and EQC check, the Abrazo prompts the user to add a drop of the control plasma.

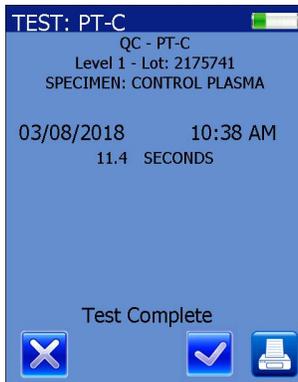
**Note:** Follow the package insert's instructions for reconstituting liquid control plasmas.



8. An hourglass is displayed above the message, TESTING IN PROGRESS, while the test is being performed.



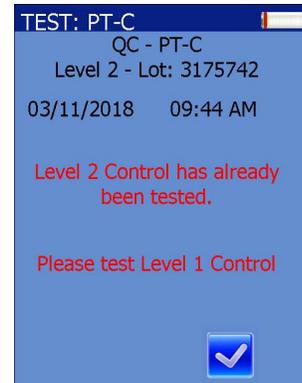
9. The result is displayed with an “x” and a checkmark icon to accept or reject the result. Rejecting the results prompts the user to remove the card and the unit returns to the Main Menu.



10. Press the checkmark icon to accept the result.

11. The user is prompted to remove the used card and scan a fresh test card.

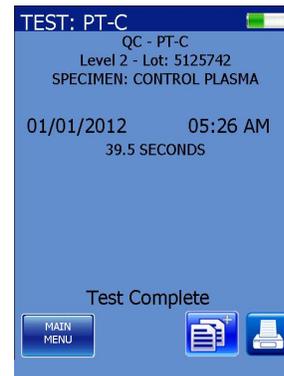
12. Scan the test card and insert it, then scan the control barcode when prompted. If the user scans a control barcode that has already been run, it alerts the user.



13. After an internal EQC check the Abra-zo prompts the user to add a drop of the control plasma.

14. An hourglass is displayed above the message, TESTING IN PROGRESS, while the test is being performed.

15. After the test is finished, the result is displayed as well as Main Menu, Additional Data, and Print buttons.

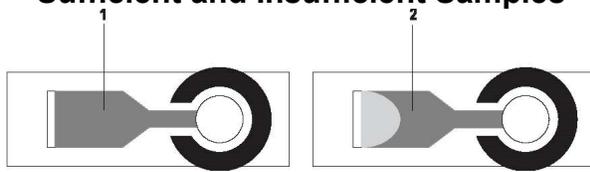


16. Pressing the Main Menu button will prompt the user to remove the card and then return the display to the main menu.

### 7.5.5. Sufficient Sample Verification

After each test is performed, verify that the entire gray area of the reaction chamber on the test card is covered by the sample. If the reaction chamber has not been covered completely by the sample, repeat the test using a new test card.

**Sufficient and Insufficient Samples**



1 Sufficient sample    2 Insufficient sample

Abrazo test cards do not require as much precision in sample dispensing as conventional methods – the reaction chamber is self-filling and self-limiting. One drop (approximately 30 to 35  $\mu$ L) of sample should be sufficient to fill the reaction chamber. A transfer pipette should **never** be used to dispense sample.

**7.5.6. Liquid Quality Control Plasma**

Generally, at least two levels of quality control plasma should be tested on each Abrazo for each type of test card used.

See the package insert provided with the Abrazo test cards for specific instructions.

Establishment of reference ranges vary by the test being performed. See the package insert provided with the Abrazo test cards and controls for specific instructions on the test being performed.

**7.5.7. Viewing QC Test Results**

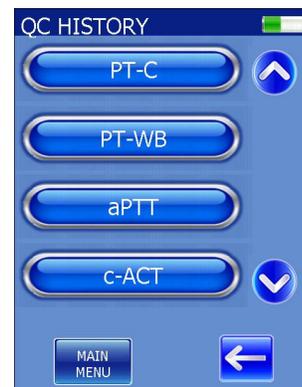
1. From the MAIN MENU screen, press DATA REVIEW.



2. From the DATA REVIEW screen, press QC DATA.



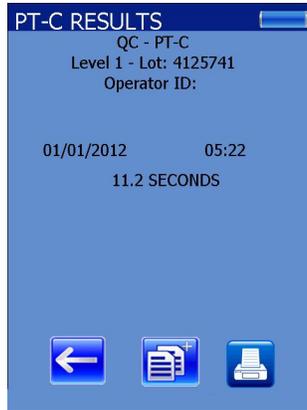
3. The QC HISTORY screen appears listing all the Abrazo tests.



4. Select the desired test. Displayed will be all QC test results starting with the most recent test. If this is the first time use, the screen will be empty. If not, the data will be listed by the date and time of the test.



5. Using the up and down arrows if shown, find the desired QC result and select it. The same result is shown full screen as well as the QC lot number.



6. Pressing either the '←' or the additional data button returns the unit to the QC history screen.

### 7.5.8. Out of Range QC Test Results

If a QC result is found to be out of the assigned range, the Abrazo alerts the user and gives the choice to retest it or return to the main menu.



The operator should repeat the test to verify the result using a new test card and new control plasma vial.

**Note:** Do **NOT** reuse the QC control plasma vial. The reconstituted control is not stable. This preparation must be used immediately after reconstitution, since the clotting reaction begins **immediately** upon mixing the diluent with the plasma.

If the control is still out of the assigned range, check the following items:

- Test card storage conditions and expiration date
- Control plasma storage condition and expiration date
- Control plasma is fully reconstituted.

## 7.6. EQC (Electronic Quality Control) Test Card

### 7.6.1. About EQC Testing

To assist in accomplishing daily quality control, the EQC test card is available and can provide a three-level check of the analyzer. The EQC test card augments the built-in system checks. It is similar in appearance to the Abrazo reagent test cards. When a QC test is run with the EQC test card, the data collected are analyzed, and a clotting time (CT) and optical signal strength value (S) are reported to the operator. Both values must be within defined limits for proper operation of the analyzer. If the limits are exceeded during a test, the analyzer will automatically display an error message. This information is also stored in the analyzer memory for later viewing.

**Note:** The EQC card is designed for use with only the Abrazo, Version 1.0 or higher.

The maximum acceptable error for the EQC-simulated clotting time is preset at 3% of the 30-, 90-, or 270-second target clotting time of the test. A minimal signal strength value (S) is set during the manufacture of each EQC test card lot. This information is encoded on the 2D barcode on the EQC test card. As on all Abrazo test cards, the barcode on the back of the EQC test card contains specific test parameter information, such as test type and lot number, which is transferred to the instrument on initiation of a test.

Expiration date is encoded in the 2D barcode. **After first use, the EQC test card can be used for up to six months or 600 uses.** Next to the barcode is a “date of first use” and “Exp.” area where the user can record the information.

**7.6.2. Storage**

Store the EQC test card at a temperature of 20 to 25°C in the case provided and away from strong sunlight and magnetic fields. The EQC test card may be used up to six months after the date of first use. An area is provided on the back of each EQC test card for recording the expiration date. Use a permanent marker pen to record the expiration date on the case label and on the back of the card.

On the optional docking station, a slot is provided for EQC test card storage and rejuvenation.

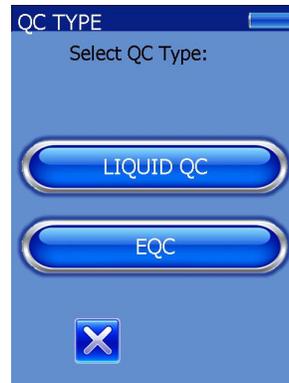
**7.6.3. EQC Testing Procedure**

No preparation of the EQC test card is necessary before initiating a test. All necessary calibrations are encoded on each EQC test card. Please refer to Section 6.6 of this manual for additional details.

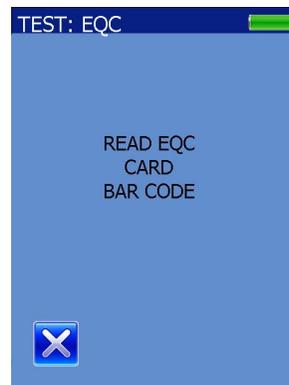
**Materials Required**

- Abrazo EQC Test Card
- Abrazo Analyzer
- Abrazo Operator’s Manual

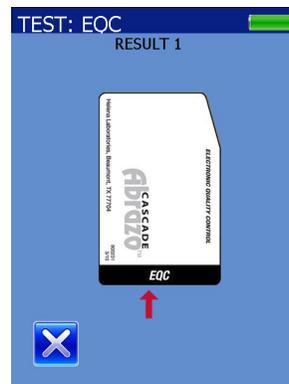
1. At the MAIN MENU screen, press the QC TEST button. The QC TYPE screen appears with the two types of QC tests available.



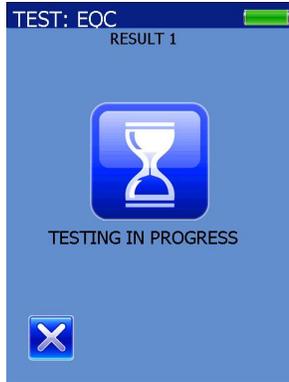
2. Press the EQC button. The Abrazo prompts the user to scan the barcode on the back of the EQC card.



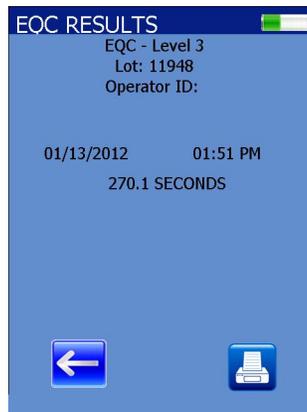
3. When prompted, insert the EQC test card. The analyzer warms the card before performing the EQC test.



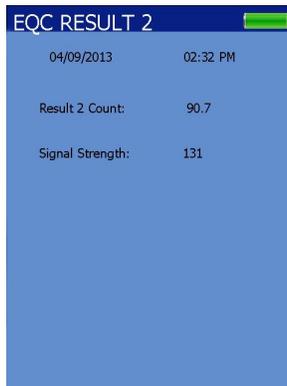
4. An hourglass is displayed above the message, TESTING IN PROGRESS, while the test is being performed.



5. Level 1 clotting time count (CT) and the signal strength are displayed on the screen. The CT results represent the clotting time returned by the algorithm analyzing the AC signal collected from the EQC test card. The unit briefly displays Result 1 and then continues the test.

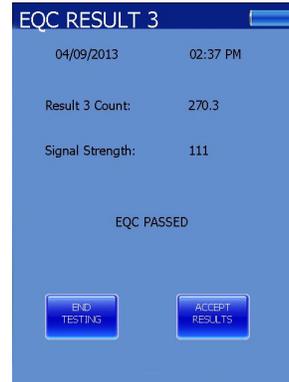


6. The unit briefly displays Result 2 and then continues the test.

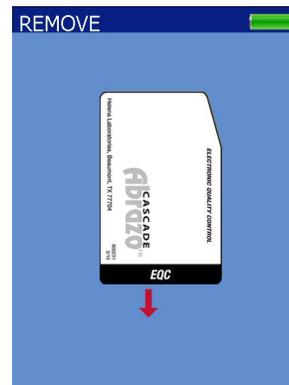


7. At the end of this test, Level 3 EQC clotting time and signal strength are displayed. If the test was valid, it will display EQC PASSED. Click to ACCEPT RESULTS button to accept the results. If

END TESTING is selected, the results will not be saved.



8. The unit prompts the user to remove the EQC card and returns to the Main Menu. Results may only be printed from the EQC HISTORY menu.



#### 7.6.4. Failed EQC Test

As each level of the test is completed, the actual result is verified by the analyzer. If any of the three tests fails, it alerts the user immediately.



1. When prompted, remove the EQC test card. The main menu screen is displayed.

2. Repeat the EQC test. If the test results continue to fall out of range, contact a supervisor qualified to resolve the problem, or contact your analyzer distributor.

**CAUTION:** *If the repeat EQC test fail, do not report any patient test results obtained from Abrazo tests before contacting a supervisor or your local technical support provider or distributor, until the test failure is resolved.*

### 7.6.5. Electronic Quality Control (EQC) Results

The EQC test card checks clotting times at three levels, and reports clotting time and optical signal strength values that correspond to 30-, 90-, and 270-second clotting times. The Abrazo analyzer will automatically report an error message if either the clotting time or the optical signal strength values is out of range.

### 7.6.6. Viewing EQC Test Results

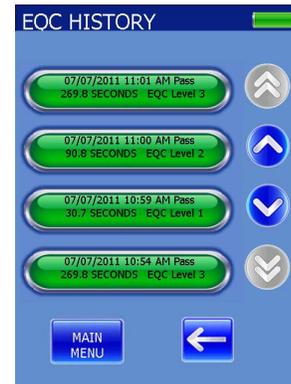
1. From the MAIN MENU screen, press DATA REVIEW.



2. From the DATA REVIEW screen, press EQC DATA.

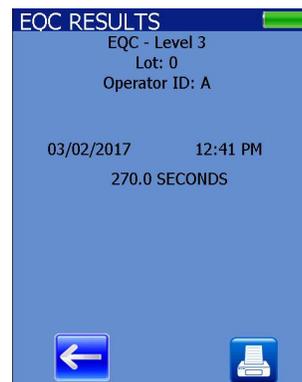


3. The EQC HISTORY screen appears listing all results starting with the most recent test. If this is the first time use, the screen will be empty. If not, the data will be listed by the date and time of the test.



4. Each time the EQC card is run, three separate results are generated and broken out by the three levels. Also included are the date/time, lot number, and level.

5. Using the up and down arrows if necessary, find the desired EQC result and select it. The same result is shown full screen as well as the EQC lot number.



6. Pressing the back arrow returns the unit to the EQC history screen.

**Section 8 – Performance Specifications**

Width: 89 mm (3.5 in)

Height: 86 mm (3.4 in)

Length: 215 mm (8.5 in)

Weight: 0.8 kg (1.65 lb)

Internal Battery Type:

2 rechargeable 3.7 VDC 3000 mAh batteries

External Power Supply:

Input: 100 – 240 V AC, 50-60 Hz, 25 Watts Max, 5 AMP

Output: 5.0 V DC

Temperature Regulation:

$37 \pm 0.3^{\circ}\text{C}$  ( $98.6 \pm 0.5^{\circ}\text{F}$ )

Storage Temperature:

15 - 32°C (59 – 89.6°F)

Humidity: 10 – 90%, non-condensing

Operating Temperature:

15 - 32°C (59 – 89.6°F)

Relative Humidity - 10 - 90%

Altitude - 2000 meters

Shipping Temperature:

-9 - 60°C (15 – 140°F)

Altitude - 4269 meters

Installation category II

Pollution Degree: 2

## Section 9 – Maintenance, Troubleshooting, Warranty

### 9.1. Maintenance

The Abrazo runs a series of self-tests upon start-up to verify that the analyzer is functioning properly. It should be handled carefully; with proper care and maintenance, the unit should last a period of 3 years (or more).

Regularly inspect the device for signs of deterioration such as excessive discoloration, cracking or deformation of the outer case, optics tray, or display. If noted, contact Helena Technical Services at (800) 231-5663, ECS.

**ALWAYS INSURE THE INSTRUMENT IS UNPLUGGED BEFORE CLEANING.**

#### 9.1.1. General Cleaning

1. Wipe with a soft cloth. Do not use any organic solvents, alcohol based, or harsh cleansers. No acids or bases should be used or spilled on inner or outer surfaces. Do not immerse the unit.

**Note:** See Section 3 for approved list of chemicals and wipes.

#### 9.1.2. Disinfection Procedure

1. Cleaning and disinfection should be performed on the Abrazo unit “as necessary in conjunction with exposure to bodily fluids in accordance with the OSHA Universal Precautions standard 1910.1030, Toxic and Hazardous and Substances, Bloodborne Pathogens.

2. The analyzer should be cleaned with a disinfectant wipe routinely after each patient. The recommended cleaning agent for the disinfecting wipe is a fresh 10% bleach solution, which consists of 1 part bleach and 9 parts purified water (EPA, Reg. No. 5813-50).

**Note:** The use of any other cleaning agent has not been validated by Helena Laboratories.



3. With the unit OFF, wipe the Abrazo’s outside surfaces with a disinfecting wipe. DO NOT let liquid pool near the Optics area.



4. Wipe away any residual moisture with a lint free tissue. Allow to dry for 10 minutes.

5. Dispose of gloves in a biological hazard container and wash hands with an antibacterial soap.

**Note:** If for any reason, blood contaminates the internal circuit board above the optics, DO NOT ATTEMPT TO CLEAN. Contact Helena Technical Services at 800-231-5663, ECS.

#### 9.1.3. Cleaning the Optics Area

The Optics Area should be cleaned once a week or if it becomes con-

taminated with sample or control plasma.

1. With the unit sitting on a table, place both hands on either side of WAKE button. With the thumbs, slide up and remove the plastic optics door.



2. Wipe the inside and outside of the plastic optics door with a gauze pad (or lint free cloth) saturated with 10% bleach solution.

3. Gently pull straight out the black lower optics cover.



4. If noticeably soiled, wash with warm water and an antibacterial soap. Rinse with clean water.



5. Immerse the optics tray in a 500 ml beaker filled with the 10% bleach solution for 10 minutes. Do NOT store the optics tray in the bleach solution.

6. Swab the tongue area with the 10% bleach gauze pad.

7. Inspect the inside. The optics is a small, black, rectangular box on the right, top center. If necessary, use a cotton swab and mild detergent to clean. Do **not** touch the electronic components in the back of the optics area.



8. When sliding optics back into instrument, press side wings and push back in until it clicks.

9. Ensure the optics door is seated properly inside the groove and the plastic side tabs are clearing the platform sides before pressing down.

10. Replace the plastic optics door.

**Note:** Do not pry the optic door with any foreign object; this will damage the latches.

## 9.2. Troubleshooting

If the unit appears to be malfunctioning for any reason, thoroughly check for physical damage to the case, indicators, etc. caused by dropping or excessive mishandling. Should instrument problems be suspected, it is recommended that several tests be

run using Quality Control material and whichever test cards are used clinically. Results from these tests will be helpful in identifying any potential trend in test results that could indicate a fault within the system. For further information, refer to the Quality Control Package Insert.

The following table list other symptoms and possible fault conditions and causes (Table 9–2, Prompts and Error Messages).

The analyzer notifies the operator both visually and audibly if a problem occurs while operating the instrument. The analyzer continuously monitors for conditions that can cause invalid results and will stop a test, if necessary.

Diagnostic messages are provided on the analyzer display. If an error code is associated with the message, it is displayed also.

If the analyzer displays a diagnostic message, note the error code and see Table 9-2 for a description of the message and possible actions to resolve the error condition. If the prescribed actions do not resolve the problem, or the diagnostic message continues to occur, note any error codes and call for customer support.

There are not operator serviceable components in the analyzer. If the prescribed actions for an error message fail to correct the problem, call Helena Laboratories' customer support.

### 9.3. Changing the battery

**Note:** *The batteries should always be changed in pairs.*

1. Grip Abrazo around the bottom of the unit so the Abrazo logo and WAKE button rests in your palm.

2. Flip the unit over so you are looking at the gold interface pins. Press the depressed alcove and slide the battery cover back and off of the unit.

3. Gently lift the batteries until the white connectors can be seen.

4. Gently pull the wires until the connector is removed. Repeat with second battery.

5. Insert the connector of the new battery until it is seated properly. Repeat with the second battery.

6. Seat the batteries and replace the back cover.

7. For battery disposal, follow the proper federal, state, or local requirements for lithium batteries.

**Note:** *Insufficient battery charge may trigger a “heater malfunction” or “magnet” error. Fully charge new batteries and press the reset button when complete.*

Table 9-1 Prompts and Error Messages

Message	Possible Cause(s)	Action Required
<b>Note:</b> Barcode time out messages and Error messages MUST be addressed in a timely manner to prevent “memory full” errors.		
B11 System failure. Internal error. Please contact Helena ECS.	Low battery Instrument failure	Reboot the unit by pressing the reset button. Recharge the Abrazo. Contact Helena Laboratories
C04 Test Card Expired.	Test card is expired.	Repeat test with card that is not expired.
C01, C05 Invalid data on test card. Please contact Helena ECS.	Test not enabled Scratched barcode	Repeat test, using a new card.
C06 Card Inserted Too Early Please Remove Card and Restart Test.	An Abrazo test card was inserted into the test card holder before it was passed through the reader.	Remove the card from the analyzer and re-insert the card when prompted.
D01 Sample added Too Early. Please discard test card and restart test.	A sample was added to the Abrazo test card before the analyzer displayed the prompt.	Repeat test, using a new card, and add the sample only when prompted by the analyzer.
D02 Card has been removed before test started.	An Abrazo test card was removed from the analyzer before the sample was added.	Repeat test, using the same card.
D03 Card has been removed before test completed.	An Abrazo test card was removed from the analyzer after the sample was added but before the test was completed.	Press any key to continue. Repeat test, using a new card.
D04 This test type has not been configured and cannot be run.	The test parameters have not been entered.	Enter test parameters and then repeat test.
G01 Gain error Rerun test. If problem persists, please contact Helena ECS.	The analyzer received a false “start test” signal.	Remove the test card to continue. Repeat test, using the same card.
T05 Heater Malfunction Restart Abrazo. If problem persists, please contact Helena ECS.	Incomplete reset of heater micro-controller or heater element failure. Low battery. Operating environment too hot or too cold.	Reboot Abrazo. If necessary, recharge. If environment is outside operating conditions, remove instrument from conditions and allow to cool or warm up the restart.

<b>Message</b>	<b>Possible Cause(s)</b>	<b>Action Required</b>
<b>Note:</b> Barcode time out messages and Error messages <b>MUST</b> be addressed in a timely manner to prevent "memory full" errors.		
Z01 Lower Limit is Greater than or Equal to Upper Limit.	The value entered for the lower end of the control or patient range is greater than or equal to the upper limit.	Check values and enter the correct range values.
Z05 Invalid Input.	Pressing the checkmark icon without entering the required information.	Check entry and correct if necessary.
Z08 Invalid operator name	Scanned or entered an operator ID not previously entered	Enter a valid operator ID
Z09 Invalid password. Please input a valid password.	The password is not correct.	Use the correct password.
Z10 Barcode scanner error. Restart Abrazo. If problem persists, please contact Helena ECS.	Barcode Failure Scratched barcode	Restart Abrazo.  Repeat test, using a new card.
Z11 Magnet error. Restart Abrazo. If problem persists, please contact Helena ECS.	Low battery. Instrument failure.	Reboot the unit by pressing the reset button. Recharge the Abrazo. Contact Helena Laboratories.
Z12 EQC Card Not Expected. The EQC card should only be used in QC mode.	The EQC card was scanned as a patient test.	Scan the desired test card.
Z13 Magnet error. Restart Abrazo. If problem persists, please contact Helena ECS.	The unit was shut off during a test. Low battery. Instrument failure.	Reboot the unit by pressing the reset button. Recharge the Abrazo. Contact Helena Laboratories.
Z14 Communication error. Restart Abrazo. If problem persists, please contact Helena ECS.	Low battery. Instrument failure.	Reboot the unit by pressing the reset button. Recharge the Abrazo. Contact Helena Laboratories.
Z16 Test Card Insertion has timed out. Open new card and restart test.	The card wasn't inserted into the Abrazo.	Open a new test card and repeat the test.
Z17 Test card has timed out. No sample Detected. Open a new card and restart test.	The sample volume was insufficient or not added.	Repeat test with sufficient sample.

Message	Possible Cause(s)	Action Required
<b>Note:</b> Barcode time out messages and Error messages <b>MUST</b> be addressed in a timely manner to prevent "memory full" errors.		
Z18 Premature start. Open new card and restart test.	The test card was inserted before the instrument was ready.	Repeat the test and add the card when prompted.
Z19 EQC Card failure. Retry with new EQC card. If problem persists, please contact Helena ECS.	EQC card is expired.	Retry with new EQC card.
Z20 Test card used or timed out. Open new card and restart test.	Card has already been used or scanned.	Open a new test card
Z21 This Is Not An EQC Card. Retry with EQC card. If problem persists, please contact Helena ECS.	A regular test card was scanned instead of an EQC card.	Repeat test with EQC card.
Z23 This QC test type has not been configured and cannot be run.	The Abrazo was synced with the CAAS and no test parameters were inputted.	The test parameters must be entered into the CAAS and then the unit needs to be synced again to transfer the test parameters to the Abrazo. Needs to be corrected in the department setting section of the CAAS.
Z24 Invalid data on control label. Please contact Helena ECS.	Wrong or damaged bar code.	Scan another barcode.
Z25, Z30 Invalid QC Date. Confirm expiration date in Admin software. If correct, please contact Helena ECS.	The QC date scanned doesn't match the QC date entered into CAAS.	Confirm expiration date in CAAS software.
Z26 QC Mismatch Test card name and control test name do not match.	The scanned control isn't the correct control needed.	Verify the label is correct.
Z28 No selection made. Please make a selection or cancel.	A selection needs to be made before the Abrazo can proceed.	Make a selection or return to the Main Menu.
Z29 Invalid patient ID. Please input a valid patient ID.	Patient ID scanned was not valid.	Enter a valid patient ID.

Message	Possible Cause(s)	Action Required
<b>Note:</b> Barcode time out messages and Error messages <b>MUST</b> be addressed in a timely manner to prevent "memory full" errors.		
Z31 Test Scan Mismatch Test card name does not match previous (air damaged) card scan.	During the c-ACT test, another type of test card was scanned.	Scan a c-ACT card
Z32 Invalid Barcode Scanned. The data on the barcode is invalid.	A control barcode (or other barcode) was scanned instead of a test card.	Scan a valid test card.
Z33 Mean is less than the lower limit	The mean value is not within the designated patient range.	Check value (and range) and correct if necessary.
Z34 Mean is greater than the Upper limit.	The entered mean is greater than the value of the upper patient limit.	Enter a mean inside the upper and lower patient limits.
Z35 Mean is less than 1.0.	Mean was entered incorrectly.	Add a mean value.
Z36 That operator already exists.	The operator is already entered in the Abrazo.	Check operator name.
Z39 There are no operators listed.	No operators exist.	Select ADD and enter an operator name.
Z40 There are no administrators listed.	No administrators exist.	Select ADD and enter an Administrator name.
Z41 Operator in Lockout. An administrator must release the Operator Lockout for this operator before tests can be executed.	The operator attempting to run a test has been locked out by an administrator.	An administrator must release the Operator Lockout for this operator.

#### **9.4. Warranty**

Helena Laboratories warrants its products to meet Helena's published specifications and to be free from defects in materials and workmanship. Helena's liability under this contract or otherwise shall be limited to replacement or refund of any amount not to exceed the purchase price attributable to the goods as to which such claim is made. These alternatives shall be the buyer's exclusive remedies. In no case will Helena Laboratories be liable for consequential damages even if Helena has been advised as to the possibility of such damages.

The foregoing warranties are in lieu of all warranties expressed or implied, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose. In no event will Helena Laboratories be liable for indirect, incidental or consequential damages; the original user's remedies being limited to repair or replacement at the manufacturer's option.

#### **Warranty Duration**

This warranty is provided to the original purchaser for ***one year from date of sale.***

#### **Particular Exclusions**

Unauthorized modification of any part of the instrument will void this Warranty.

**Section 10 – Symbology**

NOTE: The following symbols may be used in this manual, or on the instrument, to provide information necessary to the user, if applicable.

	Caution, electric shock hazard, high voltages capable of causing personal injury – shut down the instrument and unplug the power cord before touching – do not operate with the cover(s) removed
	Caution, general hazard – see Precautions and Hazards (Sections 3 and 4) of Operator’s Manual before proceeding
	Direct current
	Alternating current
	Both direct and alternating current
	Protective conductor terminal (grounded conductors)
	European authorized representative
	Manufacturer
	Indicates "do not place in trash" in countries or regions requiring recycling and other specific handling, such as in Europe, under the WEEE (Waste Electrical and Electronic Equipment) Directive, 2002/96/EC

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**Cascade® Abrazo®**

**Catalog Number 5710**

**Software Version 1.4**

**Operator's Manual**

**For additional information, call  
Helena Laboratories at 800-231-5663, toll free.**



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