Helena Laboratories
Point of Care

Cascade® POC Analyzer

Operator's Manual

Catalog Number 5810, 120V, 60 Hz

Catalog Number 5811, 230V, 50 Hz

Cascade® POC Analyzer

Operator's Manual

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Section 1 – Instrument Use and Function

The **Cascade® POC Analyzer** (Figure 1–1) is a lightweight, portable instrument designed for *in vitro* diagnostic use in decentralized areas of a hospital. The Cascade POC Analyzer provides immediate, near–patient–care results using specially developed Cascade POC test cards to detect the onset of clot formation or lysis* in citrated whole blood, non–citrated whole blood, or plasma samples. The Cascade POC Analyzer is especially suited for professional use in decentralized areas of testing near the site of patient care, as well as for use in the more traditional clinical laboratory.

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

> Intended Use
> Summary
> Principle
> Reagents
> Specimen Collection and Handling
> Procedure
> Quality Control
> Reference Ranges
> Results
> Limitations
> Performance Characteristics
> Bibliography

*An asterisk indicates a test that is not currently being offered by Helena Laboratories.

Figure 1–1 Cascade® POC Analyzer

Section 2 – Principles of Operation

Operation is controlled by a microprocessor, its program and memory.

The computer runs a self–test once powered on to detect error conditions or potential problems.

Setup access is controlled by a Supervisor's access code.

Running a Cascade POC test involves entering the required test parameters by passing the Cascade POC test card through the magnetic card reader, selecting the appropriate sample type, entering patient information, inserting the test card into the analyzer, and adding a sample drop. Visual, step–by–step instructions and audible signals are provided throughout the operation of the Cascade POC Analyzer.

The Cascade POC Analyzer continuously monitors for conditions that could cause invalid results, and it can automatically stop a test. Warnings and other diagnostic messages can also be issued during a test.

Cascade POC test cards, which are the size of a credit card, have a reaction chamber containing paramagnetic iron oxide particles and the required reagents to perform a test using the Cascade POC Analyzer. The reagents have been freeze–dried, which provides extended stability. Refer to test card package insert for assay specific principles.

The magnetic stripe on the back of the test card provides instructions to the instrument about the type of test, card lot characteristics (including lot number and expiration date), and other test parameters. This information is entered into the Cascade POC Analyzer by passing the card through the magnetic card reader at the beginning of a test.

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 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. This expiration date is valid only if the card is properly stored in a refrigerator at 2° to 8°C until used. Only one Cascade POC test card at a time can be used in the instrument.

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

While a Cascade POC Analyzer test is in progress, an electromagnet turns on and off every second. The iron oxide 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 cessation of the particle movement, and lysis* causes the particles to resume movement. The analyzer monitors particle movement and records clotting and lysis* times in seconds.

*An asterisk indicates a test that is not currently being offered by Helena Laboratories.
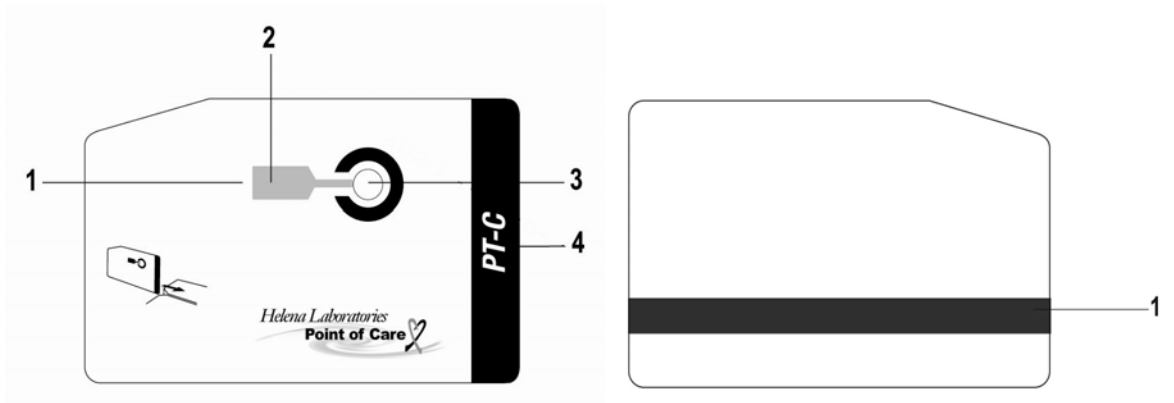
1 Reaction Chamber
2 Lyophilized Reagent
3 Sample Well
4 Test Name

1 Magnetic Stripe

Figure 2–1 Test Card (Front and Back)
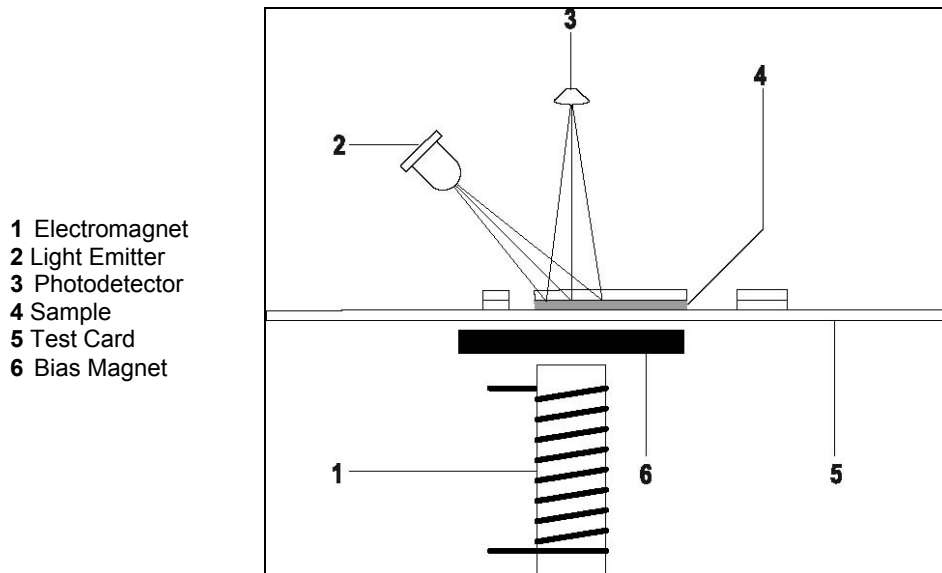
1 Electromagnet
2 Light Emitter
3 Photodetector
4 Sample
5 Test Card
6 Bias Magnet

Figure 2–2 Method of Detection

Section 3 – Precautions and Limitations

3.1 The entire Operator's Manual should be read and understood before attempting instrument operation.

3.2 Refer to the procedures supplied with the test cards for proper testing protocols.

3.3 Provide adequate room at the sides and back of the instrument for good air circulation.

3.4 Do not expose the instrument to drafts or to direct sunlight. Do not operate at temperatures above 32°C (89.6°F), or below 18°C (64.4°F), or allow prolonged exposure to high humidity.

3.5 Do not place the instrument near a strong source of electromagnetic interference, such as a centrifuge, X–ray machine, etc.

3.6 **WARNING:** Do not use the instrument in any area, which has, or is thought to have, been exposed to explosive gases.

3.7 For AC outlet specification, see the appliqué located on the bottom of the Cascade POC Power Supply in use.

3.8 For emergency shut down, unplug the power supply power cord. To unplug, always disconnect from the AC outlet. Firmly grasp the plug and pull. Do not remove the plug by pulling the line cord. With the power cord disconnected, turn the power switch Off.

3.9 No operation or maintenance should be undertaken by the operator, which requires the removal of the instrument's covers.

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

3.11 Do not attempt to insert any material into the instrument other than items this manual indicates as appropriate.

3.12 All guidelines pertaining to the handling of fresh whole human blood should be adhered to when handling the test cards and operating the instrument.

3.13 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.

3.14 Should instruments be contaminated by blood or blood derivatives, clean the contaminated area with a commercial virucidal and germicidal agent. Observe where specimens are used inside the instrument, and confine cleaning to that area. Wipe up the agent residue, as these materials may contain alcohol, which is corrosive to metal surfaces.

No harsh cleansers, acids, or bases should be used or spilled on inner or outer surfaces. Do not immerse the unit. **ALWAYS TURN THE POWER SWITCH OFF AND UNPLUG THE MAIN POWER CORD BEFORE CLEANING.**

3.15 The instrument's systems are designed for use only with Cascade POC test cards. Do not use the instrument with test cards that are past the expiration date.

3.16 With a properly maintained and operated instrument, the prime external factor affecting the accuracy and precision of the test is the quality of the blood specimen used. Specimen contamination, inappropriate operating technique, and excessive temperature variations will also affect the test results.

3.17 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.

3.18 If further validation of the system is required, several tests should be run using Cascade POC Control Materials or other commercial coagulation controls.

3.19 Instructions for the "responsible body" (Under IEC 61010–2–101:2002 — the person(s) responsible for the use and maintenance of equipment and for ensuring that operators are adequately trained for eliminating and reducing hazards involved in removal from use, transportation, or disposal.):

3.19.1 Action(s) to be taken in case of malfunction: See section 3.8 and 10.2.

3.19.2 Requirements for handling biohazards: Due to potential biohazard risk from human blood, guidelines pertaining to Universal Precautions shall be adhered to when handling the samples and operating this instrument. This includes the use of protective gloves and any other protective equipment as warranted for safe handling and disposal of test tubes and use, transportation, and disposal of this device. For information on minimizing biohazard risk, see section 3.14.

3.19.3 Storage and transport environmental requirements:
Operating Temperature range:

18° - 32° C
Storage and shipping temperatures:

5° - 40° C

3.19.4 The Helena Representative/ Distributor shall provide a power cord or adapter of the proper configuration for the country in which the instrument is to be installed. The power cord or adapter will comply with IEC 60227, IEC 60245, or be certified as rated for the power specified in section 9 of this manual.

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

3.21 The Cascade POC Analyzer must only be operated with a power supply provided by Helena Laboratories, Catalog Number 5812 for 120V or Catalog Number 5813 for 230V.

3.22 Any modifications to this device not expressly authorized by Helena Laboratories will void the user's warranty for the device.

3.23 Always treat test samples as biohazardous and ensure proper handling and disposal of these materials.

3.24 Once the analyzer has been run with a test sample, it is considered biohazardous, and should be handled according to procedures for biohazardous materials.

3.25 Wipe surface spills from the Cascade POC Analyzer using a mild detergent, followed by a disinfectant, or a fresh 10% chlorine bleach solution. Do not use any organic solvent other than alcohol.

3.26 The Cascade POC Analyzer 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 (section 5.2.4).

3.27 Do not attempt to charge the battery when the instrument is located in a small, airtight space – explosive gases can be generated.

3.28 Do not attempt to operate the instrument in an explosive atmosphere. There is a risk of explosion if the Cascade POC Analyzer is used in the presence of flammable anesthetics.

3.29 Do not immerse the instrument in water or other liquids.

3.30 If the power supply is lost or damaged, replace it only with a power supply provided by Helena Laboratories. Contact your local technical support provider or distributor for replacement power supplies.

3.31 External equipment that will be connected to signal input and signal output ports or other connectors shall comply with relevant safety standards (i.e., IEC 950 for IT and IEC 60601 series or UL2601–1 for medical electrical systems).

3.32 Any person who connects external equipment to signal input and signal output ports or other connectors has formed a system and is, therefore, responsible for the compliance of that system with the requirements of IEC 60601–1–1 (safety requirements for medical electrical systems). If in doubt, contact a qualified technician or your local technical support provider or distributor.

3.33 Where the integrity of the external protective earth conductor arrangement is in doubt, the analyzer shall be operated from its internal power source.

3.34 This instrument is a Risk Class 1.

Section 4 – Hazards

4.1.   If the instrument is used in a manner not specified by this manual, protection provided by equipment design may be impaired.

4.2.   This unit contains high voltages, which can be extremely dangerous. **ALWAYS TURN OFF THE POWER, DISCONNECT THE MAIN POWER CORD, AND USE EXTREME CARE** when attempting to clean or repair.

4.3.   When operating the instrument on AC power, do not attempt to do so without plugging the power cord of the power supply into an easily accessible, grounded AC wall outlet of the proper voltage and frequency.   This information is contained on the serial number plate located on the bottom of the power supply.

4.4.   Main power supply voltage fluctuations should not exceed 10% of the nominal supply voltage.

4.5.   Do **not** lubricate the instrument.

4.6.   Use only the test cards specified by the Helena Laboratories procedure in use. Damage to the instrument may result from introducing some types of solutions into the instrument.

4.7. Follow safe handling and disposal procedures for test cards used with this device.

4.8.   Keep flammable liquids and flammable vapors away from the instrument at all times.

4.9.   Particular symbols may be used to provide information to the user.   Refer to section 11.

4.10. **WARNING**: External equipment (i.e. printer) that is connected to the instrument must have proper power line isolation.

Section 5 – Installation Instructions

WARNING: Read Section Three-Precautions and Limitations, and Section four-Hazards, before attempting installation or device operation.

5.1. Unpacking and Inspection

1. Check all shipping containers for signs of damage. If damage is found, immediately notify the shipping carrier.

2. Carefully unpack the instrument and accessories from the shipping cartons. The packing material should be removed undamaged, if possible, should repacking become 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 5–1 Inventory

Cascade POC Analyzer with Power Supply, Cat. No. 5810 or 5811

Cascade POC Analyzer, Cat. No. 5814

Cascade POC Power Supply:

    Cat. No. 5812 (120V)

    or Cat. No. 5813 (230V)

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Table 5–2 Additional Materials

5812	Cascade POC Power Supply (120V)
5813	Cascade POC Power Supply (230V)
5814	Cascade POC Analyzer w/o Power Supply
5818	Cascade POC Electronic QC Card (EQC)
5820	Cascade POC PT–WB Assay
5821	Cascade POC PT–C Assay
5822	Cascade POC aPTT Assay
5824	Cascade POC c–ACT Assay
5815	Cascade POC Printer Accessory Kit
5849	Cascade POC EQC Renew Sleeve
1720	Serial Printer Paper
5816	Cascade POC Data Manager Software
5817	Cascade POC DB9 to RS232 Cable
5819	Cascade POC RS232 to USB Adapter Cable

5.2. Installation

5.2.1. Environmental Operating Requirements

1. Select an environment free of drafts, direct sunlight, excessive humidity and dust, and temperature fluctuations.

2. Operating temperature should be between 18°C to 32°C (64.4°F to 89.6°F).

3. The instrument must be placed on a stable, level surface.

5.2.2. Charging the Internal Battery Prior to Initial Use

After completing section 5.2.3, fully charge the battery by leaving the analyzer plugged in and turned off for at least 12 hours. The analyzer battery will charge automatically while connected to the external power supply as described in section 5.2.3.

5.2.3. Operating on AC Power Supply

1. Confirm the Cascade POC Analyzer power switch, located on the right side of the instrument, is in the Off/Recharge position (Fig 5-3). The analyzer must be off before any components are connected or disconnected to/from the analyzer.

2. Connect the 7–pronged plug of the Cascade POC Power Supply onto the connector accessible from the rear of the instrument (Fig 5-2). The power supply plug should be positioned to match the connector, with the crimp on the plug facing up. Note that only Helena Cascade POC Power Supply (Cat.

No. 5812 or 5813) may be used with the Cascade POC Analyzer.

3. Connect the 3–pronged plug of the power supply into a grounded wall outlet of the proper voltage and frequency. As this power cord is the main disconnect device, the wall outlet used should be easily accessible. The voltage and frequency specifications can be found on the labeling located on the power supply. Ensure that the main supply voltage fluctuations do not exceed 10% of the nominal supply voltage.

4. The wall outlet should not be on the same circuit as any large load device such as a refrigerator, compressor, centrifuge, etc. The instrument circuitry contains filters to reduce the effect of line voltage fluctuations; however, they should still be avoided.

5.2.4. Operating on DC Battery Power

Once the Cascade POC Analyzer battery is charged, the instrument can be operated continuously without any loss in overall performance for 8 hours on internal battery power alone.

1. Confirm the instrument power switch, located on the right side of the instrument, is in the *Off/Recharge* position (Fig 5-3). The analyzer must be off before any components are connected or disconnected to/from the analyzer.

2. Disconnect the Cascade POC Power Supply plug from the connector accessible from the rear of the analyzer (Fig 5-2).

5.2.5. Powering On

After completing either section 5.2.4 or 5.2.3:

1. Turn the analyzer on and it will perform several self tests (with 'nn' representing the self–test number).

```
        Cascade POC
         Analyzer
         Performing
      Self Test    nn
```
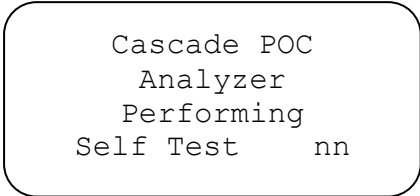
2. Once the self–tests are complete, a screen will briefly display, which shows the software version installed on the analyzer.

```
        Cascade POC
         Analyzer

      Software  V x.xx
```
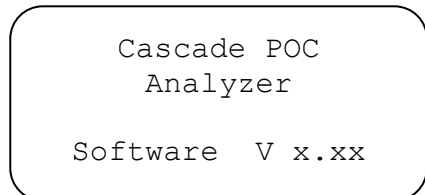
3. The analyzer is ready for operation when the *Ready* screen is displayed.

```
--READY--    mm/dd/yy
             hh:mm ?M

  Pass card thru readr
    or press enter
```
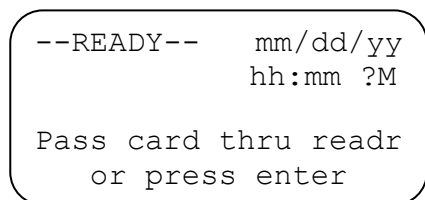
4. Before performing a test, ensure that the displayed date and time are correct. The date displayed on the screen is recorded on the patient test record. If an expired test card is passed through the reader, a warning message will be displayed. To change or correct the date and time, and/or date and time format, see Section 7.1.5 and/or 6.4.

5.2.6. Connecting a Serial Printer

The analyzer can be operated with an optional serial printer connected to the RS–232 port on the back of the instrument. This enables the analyzer to print QC self–diagnostic results (see section 4), results at the end of each test, all stored test records, or groups of test records according to patient ID, test type, or sample type (see section 7.1.6.2).

The printer available from Helena Laboratories is highly recommended. The Helena Laboratories printer option includes a portable serial printer and a customized printer cable.

1. Confirm the Cascade POC Analyzer and the printer are off.

5.2.7. Cascade POC Data Manager Software

The Cascade POC Data Manager software (CPDM) allows Cascade POC users to download Control and Patient data to Microsoft Excel or another spreadsheet program to be reviewed in a user friendly manner. The CPDM performs the following operations:

- Retrieve data using different methods, such as only the last result, all results, or all unarchived results.

- Customize the spreadsheet with pre-programmed or custom labels.

- Add data to the same spreadsheet over time.

- Transfer Operator IDs set up from one POC instrument to another.

- Review or edit Operator IDs.

- Connects to the POC via USB port or RS232 adapter.

Note: *When setting up the CPDM software, follow the installation instructions. Failure to set up the CPDM correctly will lead to errors with the POC.*

5.2.7.1. Installation

1. Insert the provided CPDM CD into a CD-ROM drive.

2. The program will automatically begin to download. If setup does not start on its own, go to the *start* menu and select *My computer*. Select the drive containing the CD, right click and select *Autoplay.*

3. After installation, the CPDM icon will appear on the desktop.

5.2.7.2. General Operating Instructions

1. Connect the POC to the PC with the included serial adapter cable. Turn the POC on and allow it to complete all the self tests and initialization. If it is already powered on, ensure the *READY* screen is displayed.

2. After the POC displays the *READY* screen, double click the CPDM icon on the computer display.

3. After the software establishes communication with the POC, it will display the COM number, indicating the system is properly connected, and the serial number of the POC excluding the first three digits (710).

4. When manipulating Operator IDs in the CPDM software, the mouse copy and paste function is not available to the user. Keyboard shortcut keys must be used; *Ctrl C* to copy, *Ctrl V* to paste, and *Ctrl X* to cut.

5.2.7.3. Setup Menu

1. From the Main Menu screen, select *Setup*.

5.2.7.3.1. Parameter Selection

1. Click the *Parameter Selection* button to open the *List Builder* screen. The *List Builder* screen displays the *Original Labels* and *User Defined Labels* columns, along with add and remove options.

2. To add labels to the *User Defined Labels* column, select the label to be added in the *Original Labels* column. Double-click the label or click the *Add* button to transfer the selection. Each label can only be added once, and can only be added one at a time.

3. All columns may not be needed for everyday transferring of data. A list of suggested labels is shown below:

- Patient and Operator ID
- Result Date and Time
- Review or edit Operator IDs
- Test Name
- Clotting Time
- Result Unit
- Lot number (of card)
- Serial number of POC
- PT INR
- Report Date and Time

Note: Although labels for the following are listed, they are not active at this time and have not been validated by Helena Labs.

- All QC ranges
- Archived flags
- Sample type
- Warning
- Ratio Value
- ProbSpec

4. To remove a label from the *User Defined Labels* column, select the label to be deleted and click the *Remove* button. Labels can only be deleted one at a time.

5. Once a label has been added to the *User Defined Labels* column, it can be edited into a custom label.

6. To edit a label, select the desired label and click the *Edit* button. A ***Change Label*** box appears where the label can be edited.

7. After editing, click OK to save the change. Press Cancel to cancel the request.

8. To save all changes made, click the *Save* button located between the two label columns.

9. To exit from the List Builder screen, press the red "X" in the upper right hand corner.

5.2.7.3.2. Importing Operator IDs

Note: The POC must be on the READY screen to communicate with the CPDM. When transferring data from the POC to the PC, disable the Autoprint function. If it is enabled, an error message is generated.

1. Select the *Import Operator IDs* button on the CPDM *Setup* screen.

2. The CPDM imports all Operator IDs from the POC. The unique ID and name are separated by a vertical bar (located above the backslash on the keyboard).

3. To save imported Operator IDs for use on another POC, use the mouse and select the Operator IDs. Press the Ctrl key and the letter C to copy the names to paste into a Word or Notepad document. After opening the file, click the Ctrl key and the letter V to paste.

4. Save the document in the desired location.

Note: Once the CPDM software is closed, it will not save imported names; they must be saved elsewhere.

5.2.7.3.3. Exporting Operator IDs

Note: Any existing Operator IDs in the POC will be overwritten, and not added to, when the CPDM software exports names to the instrument.

1. The unique Operator ID preceding the Vertical bar may only consist of 6 alphanumeric characters. Any individual Operator name may have no more than 16 characters.

2. Type the Operator ID|Operator Name in the *Operator ID List* field on the computer screen in the CPDM *Setup* box. The vertical bar separating the ID|Name must be present or the item will not be exported. There should be no spaces next to the vertical bar.

3. If exporting previously saved Operator IDs, open the file and copy the information. Using the Ctrl V function, paste into the CPDM Setup box.

4. Click the *Export Operator ID* button. The Operator IDs will transfer to the POC.

5. Disconnect the POC and verify that Operator IDs were transferred correctly.

6. To exit the Setup menu, click the red "X" in the upper right hand corner.

5.2.7.4. Transferring Data to the PC

Note: The POC must be at the READY screen for the CPDM to properly connect with it. For items such as QC Lock, Operator ID that are an ON or OFF function, the data will be transferred as a 0 or a 1. Off is represented by 0 while ON is represented by 1.

Note: *Only Operator IDs may be exported into the POC; data can only be imported from the POC to the PC.*

5.2.7.4.1. Get Last Result Only

1. Choose to transfer with or without labels by checking the *Include Labels* box.

2. If only the last result is needed, select *Get Last Result Only.*

3. The user is prompted with a Save menu. After selecting the appropriate location, name the file click *Save*.

4. The file is saved as a .CSV file. All data pertinent to the last result is saved.

5. The file may now be opened in a spreadsheet program, such as Excel, and then resaved with the appropriate extension. The data is now available for statistical analysis and review.

6. To continue to update the same file with results and information, select *Get Last Result Only.* Choose the previously saved file and click *Save*. The user is prompted with the message "Delete all previous data from file before writing new?"

7. If the user chooses yes, all data will be overwritten in the original file.

8. If the user chooses no, new data will be added to the original data.

5.2.7.4.2. Get All Unarchived Results

1. Choose to transfer with or without labels by checking or unchecking the *Include Labels* box.

2. If all unarchived results are needed, select *Get All Unarchived Results.*

3. The user is prompted with a Save menu. After selecting the appropriate location, name the file and click *Save*.

4. The file is saved as a .CSV file. All data pertinent to Unarchived results is saved.

5. The file may now be opened in a spreadsheet program, such as Excel, and then resaved with the appropriate extension. The data is now available for statistical analysis and review.

6. To continue update the same file with results and information, select *Get All Unarchived Results.* Choose the previously saved file and click *Save*. The user is prompted with the message "Delete all previous data from file before writing new?"

7. If the user chooses yes, all data will be overwritten in the original file.

8. If the user chooses no, new data will be added to the original data.

5.2.7.4.3. Get All Results

1. Choose to transfer with or without labels by checking or unchecking the *Include Labels* box.

2. If all results are needed, select *Get All Results.*

3. The user is prompted with a Save menu. After selecting the appropriate location, name the file and click *Save*.

4. The file is saved as a .CSV file. All pertinent data is saved.

5. The file may now be opened in a spreadsheet program, such as Excel, and then resaved with the appropriate extension. The data is now available for statistical analysis and review.

6. To continue update the same file with results and information, select *Get All Results.* Choose the previously saved file and click *Save*. The user is prompted with the message "Delete all previous data from file before writing new?"

7. If the user chooses yes, all data will be overwritten in the original file.

8. If the user chooses no, new data will be added to the original data.

5.2.7.4.4. Continuous Automatic Collection

Note: This feature is not available at this time.
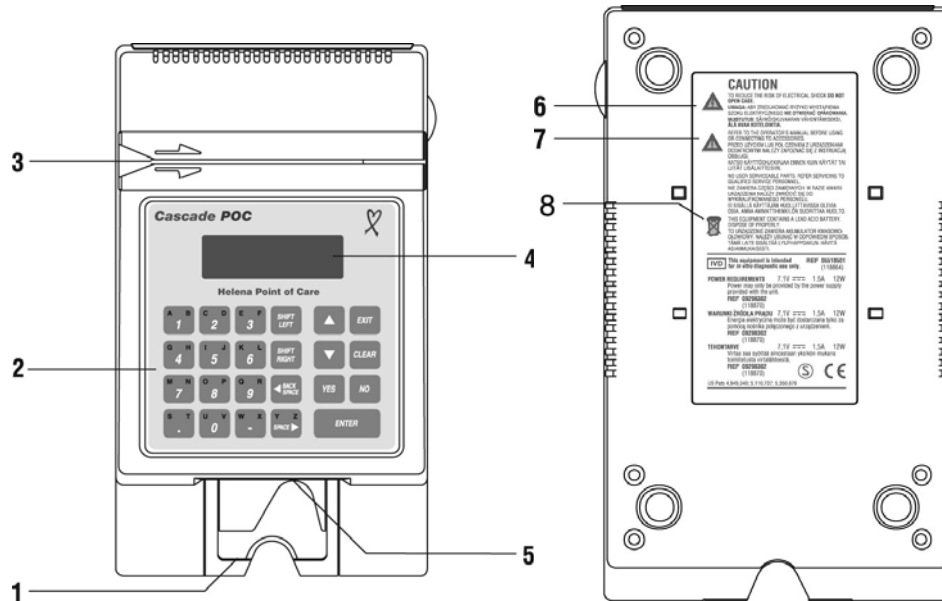
Figure 5–1 Cascade POC Analyzer – Top and Bottom View

1 Card Slot Retaining Wall

2 Keypad

3 Card Reader Slot

4 Display

5 Optical Sensor Head

6 Caution: Danger of Electrical Shock

7 Attention

8 Lead Acid Battery – Dispose of Properly
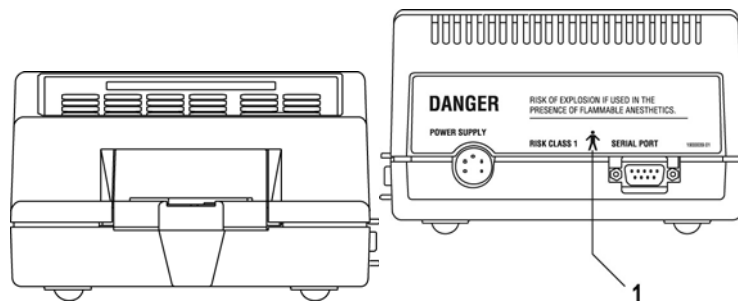
Figure 5–2 Cascade POC Analyzer – Front and Back View
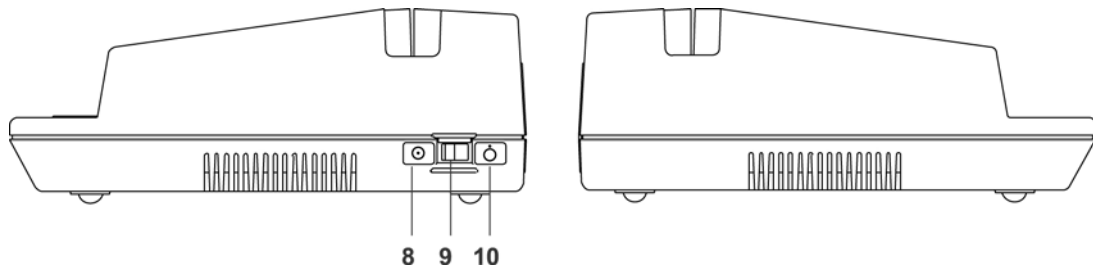
Figure 5–3 Cascade POC Analyzer – Side Views
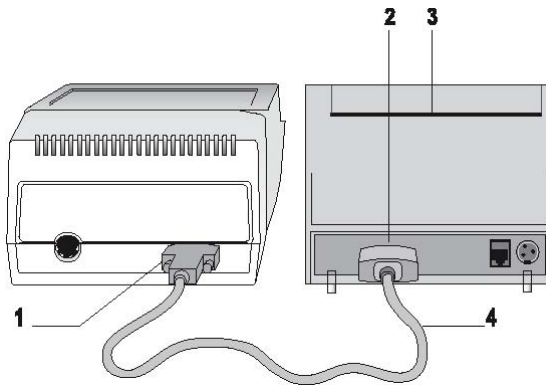
1 9–pin serial connector

2 9–pin serial connector

3 Serial printer

4 Custom printer cable

Figure 5–4 Printer Connection

Section 6 – Setup/Supervisory Functions

The Cascade POC Analyzer has two sets of functions, User Functions and Supervisory Functions. The User Functions allow the operator to perform basic analyzer operations, and the Supervisory Functions allow an operator with access to a supervisor's code to perform the following operations:
• Set operating modes
• Manage Operator IDs
• Clear stored test records
• Set the date and time format
• Define custom PT and aPTT normal values
• Set aPTT ratio mode
• Select display language
• Set control ranges
• Set normal ranges
• Set modem options
• Set ISI values

Supervisory Functions are used to change the analyzer default settings. Settings are retained in analyzer memory until the Supervisory Functions are used to modify them.

The Supervisory Functions menu is displayed on multiple analyzer screens. Use the cursor and display movement keys to display additional menu options. Follow the display symbols on the screen to perform the indicated functions. See section 6.2 for instructions on accessing the supervisory menus.

6.1. Analyzer Default Settings

For reference, the following table shows the settings of the analyzer at initial startup. All listed settings may be adjusted by the supervisor.

Setting	Default Value
Date and Time	Date and time of manufacture/release testing
Operator ID	Not active
Auto Print	Not active
QC Printout	Not active
QC Lockout (EQC and liquid)	0 hours; Disable
Standard International Units (SI)	SI Units Off (not usable with current tests)
Beeper	Beeper On

Setting	Default Value
PT Normal	Set by encoding on lot specific test card
aPTT Normal	Set by encoding on lot specific test card
aPTT Ratio	Not active
Language	English
Control Range Checking	Disable
Number of Control Range Levels	One Level
High/Low Control Ranges	0.0
Normal Range Checking	Not active
Modem Setup	Not active
ISI Values	Card

6.2. Accessing the Supervisory Menu

1. From the Ready screen, press the key sequence of the supervisor's code in rapid succession.

```
--READY--   mm/dd/yy
            hh:mm ?M


Pass card thru readr
   or press enter
```

2. The Supervisory Functions menu will be displayed after successful entry of the supervisor's code.

Note: *The supervisor's code is provided in Section 13 – but may have been removed from the manual for security.*

```
--Select one-- ↵ ↓↗
SET OPERATOR ID ON
set auto print on
set qc printout on
```

3. Use the cursor and display movement keys indicated by the symbols on the analyzer screen to scroll through menu options.

4. To return to the Ready screen, press **EXIT**.

6.2.1. Enabling/ Disabling Operating Modes

An operator with supervisory access can enable the analyzer to run in one or all six of the following operating modes:

- Operator ID
- Auto Print
- QC Printout
- QC Lockout
- SI Units
- Beeper

6.2.2. Setting the Operator ID Mode

When the Operator ID mode is enabled, the analyzer requires entry of a valid operator identification code before beginning a test. Operator identification codes can be assigned to operators who have been trained and are authorized to perform tests using the analyzer.   This   will   prevent   unauthorized operators from accessing test functions.

The User Function Menu option MODE CONFIG displays OPERATOR ID ON when Operator ID is enabled, and displays OPERATOR ID OFF when Operator ID is disabled.

```
--MODE CONFIG-- ↑↓↗
auto print off
OPERATOR ID OFF
eqc lockout DISABLE
```

1. On the Supervisory Functions menu, only one of the following choices will exist:

    a. If **operator id on** is the option displayed, then the operator ID is currently off and the choice to turn it on is offered.

    b. If **operator id off** is the option displayed, then the operator ID is currently on and the choice to turn it off is offered.

2. The selected option is displayed in uppercase characters. Select enter to change or select exit to save as is.

3. Press **ENTER**.

    a. If the Operator ID mode is enabled, the analyzer briefly displays the message, OPERATOR ID MODE IS NOW ON, and returns to the Supervisory Functions menu. The menu option now displays the message, SET OPERATOR ID OFF because the device is offering the operator the option to change to off.

    b. If the Operator ID mode is disabled, the analyzer briefly displays the message, OPERATOR ID MODE IS NOW OFF, and returns to the Supervisory Functions menu. The menu option now displays the message, SET OPERATOR ID ON.

4. The menu option indicates the available setting – not the current setting. For example, if the menu option displays the message, SET OPERATOR ID ON, the Operator ID mode is currently off (disabled). When the menu option displays the message, SET OPERATOR ID OFF, the Operator ID mode is currently on (enabled).

6.2.3. Setting the Auto Print Mode

When the Auto Print mode is enabled and the analyzer is connected to a printer, the analyzer automatically prints a report at the end of a test.

The User Function Menu option MODE CONFIG displays AUTO PRINT ON when this function is enabled and AUTO PRINT OFF when this function is disabled.

```
--MODE CONFIG-- ↑↓↗
AUTO PRINT OFF
operator id off
eqc lockout DISABLE
```

Note: The Auto Print mode requires installation of the printer option (see section 5.2.6).

1. From the Supervisory Functions menu, do one of the following:

    a. To enable the Auto Print mode, choose the **set auto print on** option.

    b. To disable the Auto Print mode, choose the **set auto print off** option.

2. The selected option is displayed in uppercase characters.

3. Press **ENTER**.

a. If the Auto Print mode is enabled, the analyzer briefly displays the message, AUTO PRINT MODE IS NOW ON, and returns to the Supervisory Functions menu. The menu option now displays the message, SET AUTO PRINT OFF.

b. If the Auto Print mode is disabled, the analyzer will briefly display the message, AUTO PRINT MODE IS NOW OFF, and will return to the Supervisory Functions menu. The menu option will then display the message, SET AUTO PRINT ON.

Note: The menu option indicates the available setting – not the current setting. For example, if the menu option displays the message, SET OPERATOR ID ON, the Operator ID mode is currently off (disabled). When the menu option displays the message, SET OPERATOR ID OFF, the Operator ID mode is currently on (enabled).

6.2.4. Setting the QC Printout Mode

When the QC Printout mode is enabled, the analyzer will automatically print a report to verify that the following QC diagnostic self–tests were successful:
• Boot ROM self–test
• Flash Memory self–test
• Static RAM self–test
• Dynamic RAM self–test
• Temperature Regulation
• Test Record self–test

The User Function Menu option MODE CONFIG displays QC PRINTOUT ON when this function is enabled, and QC PRINTOUT OFF when this function is disabled.

```
--MODE CONFIG-- ↑↓↗
qc lockout DISABLE
beeper on
QC PRINTOUT OFF
```
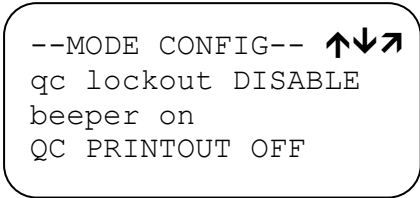
Note: The QC Printout mode requires installation of the printer option (see section 5.2.6).

1. From the Supervisory Functions menu, do one of the following:

a. To enable the QC Printout mode, choose the **set qc printout on** option.

b. To disable the QC Printout mode, choose the **set qc printout off** option.

2. The selected option will be displayed in uppercase characters.

3. Press **ENTER**.

a. If the QC Printout mode is enabled, the analyzer briefly displays the message, QC PRINTOUT MODE IS NOW ON, and then returns to the Supervisory Functions menu. The menu option now displays the message, SET QC PRINTOUT OFF.

b. If the QC Printout option is disabled, the analyzer briefly displays the message, QC PRINTOUT MODE IS NOW OFF, and then returns to the Supervisory Functions menu. The menu option now displays the message, SET QC PRINTOUT ON.

Note: The menu option indicates the available setting – not the current setting. For example, if the menu option displays the message, SET OPERATOR ID ON, the Operator ID mode is currently off (disabled). When the menu option displays the message, SET OPERATOR ID OFF, the Operator ID mode is currently on (enabled).

6.2.5. Setting the QC Lockout Mode

The analyzer operates with the QC Lockout mode for control plasma and EQC set in one of three states: Warning, Lockout, or Disabled. If QC Lockout is set to Warning or Lockout for control plasma or EQC, the analyzer requires that a control plasma sample for each defined level or EQC be run within a specified interval of time. An operator with access to Supervisory Functions can set these time intervals from 1 to 999 hours within which control plasma samples or EQC must be run. Once set, if control plasma samples or

EQC are not run before the end of this time period, the user will be alerted that time has expired. If QC Lockout is set for both EQC and control plasma, the EQC lockout conditions must be satisfied first followed by the control plasma lockout conditions.

The three QC Lockout states for control plasma and EQC are:

1. **Disable –** The QC time period is ignored. No warning messages are supplied to the user.

2. **Warning –** When the QC time period has expired, the analyzer will display a warning message.

a. The operator can, however, continue to run all blood sample types for any test.

b. The warning messages will continue until the required control plasma samples or EQC are run.

c. If QC Lockout is set for both control plasma and EQC, the warning message for EQC will be displayed first, followed by the warning message for the control plasma. The EQC test must be run first, followed by the defined levels of control plasma.

3. **Lockout –** When the QC time period for EQC has expired, the analyzer will display a message instructing the operator to press EXIT to abort.

a. When the EXIT key is pressed to abort the test, the READY screen will display.

b. The EQC tests must be successfully run because no other options will be offered by the analyzer.

c. If the QC time period for control plasmas is also set, the analyzer will display a message instructing the operator to either exit to the READY screen or continue. If the operator continues, the only sample type available will be CONTROL SAMPLE.

Note: The QC Lockout mode options, Warning and Lockout for control plasma, operate in a dependent relationship with the control range settings. If either of the QC Lockout

*options, Warning or Lockout, is selected, acceptable ranges for control plasma samples **must** be defined and set for one or more of the three control range levels (section 6.8).*

6.2.6. Setting Control Plasma Lockout

1. From the Supervisory Functions menu, scroll down to **Set QC Lockout**. The SET QC LOCKOUT option will be displayed in uppercase characters.

2. Press **ENTER**. The following menu options will be displayed.

```
--Select One-- ↵ ↓↗
CONTROL PLASMA
eqc
```
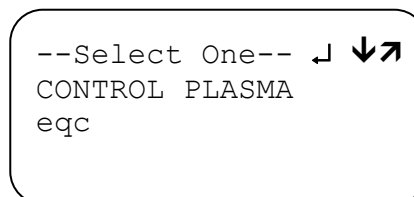
3. Select **Control Plasma.** The CONTROL PLASMA option will be displayed in uppercase characters.

4. Press **ENTER**. The following menu options will be displayed:

```
--Select One-- ↵ ↓↗
DISABLE
warning
lockout
```
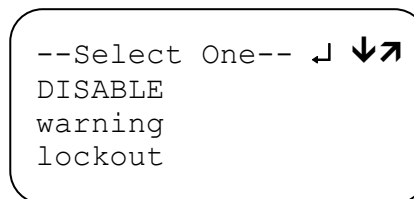
5. Do one of the following:

a. Choose the **DISABLE** option. All QC Lockout functions will be disabled. When this option is selected, the User Menu MODE CONFIG option will display DISABLE for the QC LOCKOUT selection, indicating that control plasma QC Lockout is in the DISABLE mode.

b. Choose the **WARNING** option. This selection displays a data entry field into which the maximum time interval of hours between QC samples is entered. When this option is selected, the User Menu MODE CONFIG option will display WARNING for the QC LOCKOUT selection indicating that control plasma QC Lockout is in the WARNING mode.

c. Choose the **LOCKOUT** option. This selection will display a data entry field into which the maximum time interval of hours between QC samples will be entered. When this option is selected, the User Menu MODE CONFIG option will display LOCKOUT for the QC LOCKOUT selection indicating that control plasma QC Lockout is in the LOCKOUT mode.

6. Press **ENTER**.

a. If the DISABLE option is chosen, the analyzer will return to the QC Lockout Type menu.

b. If the WARNING or LOCKOUT option is chosen, the QC Time Period screen will be displayed.

```
Max interval between
  control samples
     hours:_____
  Select: 1 to 999
```

7. Enter a value from 1 to 999 to set the maximum number of hours between QC samples.

```
Max interval between
  control samples
     hours:6
  Select: 1 to 999
```

8. Press **ENTER**. The defined QC time period is accepted, and the analyzer will return to the QC Lockout Type menu.

*Note: To avoid lockout, run all defined control levels for a test type during the 60 minutes immediately prior to expiration of the QC Lockout time period. The results of all defined control levels **must** fall within the ranges defined for each level in SET CONTROL RANGES (section 6.8).*

6.2.7. Setting EQC Lockout

1. From the Supervisory Functions menu, scroll down to **Set QC Lockout**. The SET QC LOCKOUT option will be displayed in

upper case characters. The following menu options will be displayed:

```
--Select One-- ↵ ↓↗
control plasma
EQC
```

2. Select EQC. The EQC option will be displayed in uppercase characters.

3. Press **ENTER**. The following menu options will be displayed.

```
--Select One-- ↵ ↓↗
DISABLE
warning
lockout
```

4. Do one of the following:

a. Choose the **DISABLE** option. All EQC Lockout functions will be disabled. When this option is selected, the User Menu MODE CONFIG option will display DISABLE for the EQC LOCKOUT selection indicating that EQC Lockout is in the DISABLE mode.

b. Choose the **WARNING** option. This selection displays a data entry field into which the maximum time interval of hours between EQC tests is entered. When this option is selected, the User Menu MODE CONFIG option will display WARNING for the EQC LOCKOUT selection indicating that EQC Lockout is in the WARNING mode.

c. Choose the **LOCKOUT** option. This selection will display a data entry field into which the maximum time interval of hours between EQC tests will be entered. When this option is selected, the User Menu MODE CONFIG option will display LOCKOUT for the EQC LOCKOUT selection indicating that EQC Lockout is in the LOCKOUT mode.

5. Press **ENTER**.

a. If the DISABLE option is chosen, the analyzer will return to the QC Lockout Type menu.

b. If the WARNING or LOCKOUT option is chosen, the QC Time Period screen will be displayed.

```
Max interval between
    EQC tests
   hours:_____
Select: 1 to 999
```

6. Enter a value from 1 to 999 to set the maximum time interval of hours between EQC samples.

```
Max interval between
  control samples
      hours:6
Select: 1 to 999
```

7. Press **ENTER**. The defined QC time period is accepted, and the analyzer will return to the QC Lockout Type menu.

Note: To avoid lockout, run EQC during the 60 minutes immediately prior to expiration of the EQC Lockout time period. The EQC test must pass successfully.

Note: If QC lockout is set to WARNING or LOCKOUT for both control plasma and EQC, the QC Lockout time expired, warning message for the EQC will be displayed first followed by the warning message for the control plasma. The EQC time out condition must be satisfied first before satisfying the control plasma time out condition.

Note: If the operator resets the max interval for LOCKOUT or WARNING to a value that is less than the previous max interval, and the difference between the previous max interval and the new max interval is less than the expiration time (the time remaining before the EQC tests or control plasma sample must be run), the difference between the previous max interval and the new max interval shall be subtracted from the expiration time.

EXAMPLE: The lockout period had been set for four (4) hours and the test has been running for an hour. The supervisor sets the new lockout period for two (2) hours. The time

remaining before lockout expires will be one (1) hour. (Four hours minus two hours. Then two hours minus the one hour that has already run.)

Note: If the operator resets the max interval for LOCKOUT or WARNING to a value that is greater than the previous max interval and there is time remaining before the EQC test or control plasma sample must be run, the difference between the new max interval and the previous max interval shall be added to the expiration time.

EXAMPLE: The lockout period had been set for four (4) hours and the test has been running for an hour. The supervisor sets the new lockout period for eight (8) hours. The time remaining before lockout expires will be (7) hours. (Eight hours minus four hours yields a difference of 4 hours. Then the three hours remaining from the previous test are added to that difference.)

EXAMPLE: The following table shows a hypothetical schedule for running controls. This schedule is set up to avoid lockout. In this example, the analyzer has the following settings:

• PT Control Levels I, II, and III defined and set.
• QC Lockout enabled. Control plasma set to Lockout.
• QC Lockout time period: 9 hours.
• Time and date: U.S. 24–hour clock.

		Controls Run			
		Time First	Time Second	Time Third	Time Fourth
Level	I	Monday, 07:00 hrs.	Monday, 15:00 – 16:00 hrs.	Monday, 23:00 – 00:00 hrs.	Tuesday, 07:00 – 08:00 hrs.
	II	Monday, 07:05 hrs.	Monday, 15:00 – 16:00 hrs.	Monday, 23:00 – 00:00 hrs.	Tuesday, 07:00 – 08:00 hrs.
	III	Monday, 07:10 hrs.	Monday, 15:00 – 16:00 hrs	Monday, 23:00 – 00:00 hrs.	Tuesday, 07:00 – 08:00 hrs.

6.2.8. Setting Standard International (SI) Units Mode

The analyzer has been programmed to report SI units for the Low Range Fibrinogen* (LRF) test only. When running LRF tests with the SI Units mode disabled, LRF test results are

reported and printed in mg/dL. When the SI Units mode is enabled, the LRF test results are reported and printed in g/L.

*An asterisk indicates a test that is not currently being offered by Helena Laboratories.

The User Function Menu option MODE CONFIG displays SI UNITS ON when this function is enabled, and SI UNITS OFF when this function is disabled.

```
--MODE CONFIG-- ↑↓↗
aptt ratio off
SI UNITS ON
modem comm off
```

1. From the Supervisory Functions menu, do one of the following:

   a. To enable SI units, choose the **set SI units on** option.

   b. To disable SI units, choose the **set SI units off** option.

2. The selected option will be displayed in uppercase characters.

3. Press **ENTER**.

   a. If the SI Units feature is enabled, the analyzer will briefly display the message, SI UNITS NOW ON, and will then return to the Supervisory Functions menu. The menu option will then display the message, SET SI UNITS OFF.

   b. If the SI Units feature is disabled, the analyzer will briefly display the message, SI UNITS NOW OFF, and will then return to the Supervisory Functions menu. The menu option will then display the message, SET SI UNITS ON.

Note: The menu option indicates the available setting – not the current setting. For example, if the menu option displays the message, SET OPERATOR ID ON, the Operator ID mode is currently off (disabled). When the menu option displays the message, SET OPERATOR ID OFF, the Operator ID mode is currently on (enabled).

6.2.9. Setting the Beeper Mode

When the Beeper mode is enabled, the analyzer will emit a beeping sound when keys are pressed and when a sample drop is added to the sample well of the test card. Multiple beeps are emitted when the card is successfully passed through the card reader, when the test is complete, and when an operator error is made. Multiple beeps are also emitted when the analyzer battery is low (section 5.2.4).

When the Beeper mode is disabled, multiple beeper sounds are modified. The analyzer will emit only one beep when a drop is added to the well and when the test is completed. No sounds will be emitted when the test card is passed through the reader. The Beeper mode does not affect beeper operation when operator error or low battery occurs.

The Beeper mode can be enabled or disabled by toggling the Set Beeper option on the Supervisory Functions menu. This setting is retained when the analyzer is turned off and then back on. Reset the feature when required, using the Supervisory Functions menu.

The User Function Menu option MODE CONFIG will display BEEPER ON when this function is enabled and BEEPER OFF when this function is disabled.

```
--MODE CONFIG--↵↑↓↗
eqc lockout DISABLE
qc lockout DISABLE
BEEPER ON
```

1. From the Supervisory Functions menu, do one of the following:

   a. To enable the Beeper, choose the **set beeper on** option.

   b. To disable the Beeper, choose the **set beeper off** option.

2. The option will be displayed in uppercase characters when selected.

3. Press **ENTER**.

a. If the Beeper mode is enabled, the analyzer will briefly display the message, BEEPER MODE IS NOW ON, and then will return to the Supervisory Functions menu. The menu option will then display the message, SET BEEPER OFF.

b. If the Beeper is disabled, the analyzer will briefly display the message, BEEPER MODE IS NOW OFF, and will return to the Supervisory Functions menu. The menu option will then display the message, SET BEEPER ON.

Note: The menu option indicates the available setting – not the current setting. For example, if the menu option displays the message, SET OPERATOR ID ON, the Operator ID mode is currently off (disabled). When the menu option displays the message, SET OPERATOR ID OFF, the Operator ID mode is currently on (enabled). ID mode is currently on (enabled).

6.3. Managing Operator IDs

The analyzer can store up to 100 unique operator identification codes. An operator with supervisory access can perform the following activities:
• Add a new ID
• Delete an existing ID
• View stored IDs
• Print stored IDs

6.3.1. Adding Operator IDs

When the Operator ID mode is enabled, only operators assigned an ID can initiate a test. Adding an Operator ID involves defining a code and assigning it to an operator. (See Section 7.1.1 for instructions on use of the keypad.)

The Operator ID is made up of 2 to 6 unique characters. These characters can be any of the alphanumeric keys, including the decimal, hyphen, or space. In addition to the 2 to 6 character code name, assign a description of 2 to 16 characters that identifies the operator (for example, the operator's name or employee number).

A new Operator ID can be added to the analyzer if fewer than 100 IDs are stored and an identical ID does not already exist in the instrument. An error message is displayed if these conditions are not satisfied.

1. From the Supervisory Functions menu, choose the **Add Operator ID** option. The ADD OPERATOR ID option is displayed in uppercase characters.

```
--Select one--↵↑↓↗
set qc printout off
set si units on
ADD OPERATOR ID
```

2. Press **ENTER**. The **New operator id** prompt will be displayed, and the cursor will be placed in the first character position of the Operator ID field.

```
New operator id:  ↗
_
Assign to:
```

3. Enter 2 to 6 unique alphanumeric key characters to define the new Operator ID. The entered characters will be displayed in the New Operator ID field.

4. Press **ENTER**. The Operator ID is accepted, and the cursor will move to the first position of the 16–character field displayed under the prompt, Assign to.

5. Enter 2 to 16 alphanumeric key characters to describe the operator (for example, the operator's name or employee number). The description will be displayed under the prompt, Assign to.

6. Press **ENTER**. The entered code and description are accepted, and the analyzer will return to the Supervisory Functions menu.

*Note: Press **EXIT** at any time to cancel the Add Operator ID function and return to the Supervisory Functions menu.*

Note: If the entered code matches an existing Operator ID, the analyzer will briefly display the message, OPERATOR ID ALREADY EXISTS, and will return to the Supervisory Functions menu. The newly entered code wil not be accepted.

Note: The message, OPERATOR MEMORY IS FULL, will be displayed when the memory limit of 100 operator IDs has been reached. An Operator ID must be removed before a new ID can be added (section 6.3.2).

6.3.2. Removing Operator IDs

Existing Operator IDs can be removed from the analyzer using the Delete Operator ID option on the Supervisory Functions menu. If 100 Operator IDs have already been entered into the analyzer, an Operator ID must be removed before a new ID can be added.

1. From the Supervisory Functions menu, choose the **Delete Operator ID** option. The DELETE OPERATOR ID option is displayed in uppercase characters.

```
--Select one--↵↑↓↗
set si units on
add operator id
DELETE OPERATOR ID
```

2. Press **ENTER**. The message **Enter operator id to delete** will be displayed, and the cursor will be placed at the first character position of the six character code.

```
Enter operator id ↗
      to delete

    _____
```

3. Enter the characters of the Operator ID to be removed. The entered characters will be displayed in the code field.

4. Press **ENTER**. The operator ID will be removed from the list, and the analyzer will return to the Supervisory Functions menu.

Note: If the Operator ID has been entered incorrectly or does not exist, the analyzer will display the message, UNKNOWN OPERATOR ID, and will return to the Supervisory Functions menu. Go to the View Operator IDs option to verify an Operator ID (section 6.3.3).

6.3.3. Viewing Operator IDs

Existing Operator IDs in the analyzer memory can be viewed using the View Operator IDs option on the Supervisory Functions menu. The first column on the screen displays the ID code, and the second column displays the name or description assigned to that ID.

Operator IDs are displayed in the order in which they are entered into the analyzer memory, so the last Operator ID entered appears at the end of the Operator ID list. Use the cursor and display movement function keys as indicated by the symbols on the analyzer screen to display additional operator ID entries.

1. From the Supervisory Functions menu, choose the **View Operator IDs** option. The VIEW OPERATOR IDS option is displayed in uppercase characters.

```
--Select one--↵↑↓↗
add operator id
delete operator id
VIEW OPERATOR IDS
```

2. Press **ENTER**. The list of Operator IDs will be displayed in the order in which they were entered into the analyzer.

```
id:      name:    ↑↓↗
123456 JONES, BOB
121212 DAVIS, RUTH
1AC56L HERNDON, JANE
```

3. Press ▼ or ▲ as indicated by the symbols on the analyzer screen to scroll down or up through the list of Operator ID entries.

4. To return to the Supervisory Functions menu, press **EXIT**.

6.3.4. Printing Operator IDs

Existing Operator IDs in the analyzer memory can be printed using the Print Operator IDs option on the Supervisory Functions menu.

Operator IDs are printed in the order in which they were entered into analyzer memory.

1. From the Supervisory Functions menu, choose the **Print Operator IDs** option. The PRINT OPERATOR IDS option is displayed in uppercase characters.

```
--Select one--↵↑↓↗
delete operator id
view operator ids
PRINT OPERATOR IDS
```

2. Press **ENTER**. The list of Operator IDs will be printed in the order in which they were entered into the analyzer. The first column on the printout lists the ID code, and the second column lists the name or description assigned to that ID.

The message, PRINTING...PRESS EXIT TO STOP, will be displayed briefly as the records are sent to the printer. If the EXIT key is pressed, the printer will continue printing records until the printer buffer is empty.

3. To return to the Supervisory Functions menu, press **EXIT**.

If a printer is not attached to the analyzer, the following error message will be displayed briefly. The analyzer will then return to the Supervisory Functions menu.

```
Warning!!
No Printer Attached
Operator Ids are
Unavailable
```

6.3.5. Clearing Stored Test Records

The analyzer can store a total of 1000 test records. Once the limit of 1000 stored test records is reached, additional test results cannot be stored in the analyzer without overwriting existing records.

When test record storage reaches 1000, the analyzer will display the following message when a test is initiated:

```
PATIENT RECORD
MEMORY FULL
Press enter to cont.
Press EXIT to cancel
```

If testing continues, the oldest test record will be overwritten and cannot be recovered. To avoid this loss of data and to remove the memory full condition, test records should be printed or otherwise documented, and then cleared from the analyzer.

The Clear Patient Recs. option on the Supervisory Functions menu can be used to delete every test record stored in the analyzer memory so that new test results can be stored. The Clear Patient Recs. option removes all stored test results. *Stored test results cannot be deleted individually.*

CAUTION: Cleared test results cannot be recovered from the analyzer. Therefore, it is important to print or otherwise document stored results before clearing them from the analyzer memory (section 7.1.6.2).

1. From the Supervisory Functions menu, choose the **Clear Patient Recs.** option. The CLEAR PATIENT RECS. option is displayed in uppercase characters.

```
--Select one--↵↑↓↗
view operator ids
print operator ids
CLEAR PATIENT RECS.
```

2. Press **ENTER**. A prompt will be displayed to confirm the decision to clear memory.

```
╭─────────────────────────╮
│    Clear All Patient    │
│        Records?         │
│     Press yes or no     │
│                         │
╰─────────────────────────╯
```

3. Do one of the following:

a. To clear all stored test results from memory, press **YES**. All stored test results will be removed from analyzer memory and the analyzer will return to the Supervisory Functions menu.

b. To cancel the clear function, press **NO**. All stored test results will remain in analyzer memory and the analyzer will return to the Supervisory Functions menu.

6.4. Setting the Date and Time Format

The analyzer supports multiple date and time formats that can be set from the Supervisory Functions menu using the Format Date/Time option. The Format Date/Time option provides a choice of four date and time combinations and supports both 12–hour and 24–hour time formats. The date and time formats cannot be selected individually.

Once the default format is changed with the Supervisory Functions, the analyzer will retain that format setting each time the analyzer is turned on.

1. From the Supervisory Functions menu, choose the **Format Date/Time** option. The FORMAT DATE/TIME option is displayed in uppercase characters.

```
╭─────────────────────────╮
│ --Select one--↵↑↓↗      │
│ print operator ids      │
│ clear patient recs.     │
│ FORMAT DATE/TIME        │
╰─────────────────────────╯
```

2. Press **ENTER**. The Select Format screen will be displayed.

```
╭─────────────────────────╮
│ -Select Format-↵ ↓↗     │
│ MM/DD/YY HH:MM 12HR      │
│ mm/dd/yy hh:mm 24hr      │
│ dd.mm.yy hh.mm 24hr      │
╰─────────────────────────╯
```

3. Do one of the following:

a. Choose the **MM/DD/YY HH:MM 12HR** option. The selected option is displayed in uppercase characters, and the analyzer time will be displayed as AM or PM, U.S. format.

b. Choose the **MM/DD/YY HH:MM 24HR** option. The selected option is displayed in uppercase characters, and the analyzer time will be displayed in 24–hour, U.S. format.

c. Choose the **DD.MM.YY HH.MM 24HR** option. The selected option is displayed in uppercase characters, and the analyzer time will be displayed in 24–hour, international format.

d. Choose the **YY.MM.DD HH.MM 24HR** option. The selected option is displayed in uppercase characters, and the analyzer time will be displayed in 24–hour, international format.

4. Press **ENTER**. The selected date and time format combination is accepted, and the analyzer will return to the Supervisory Functions menu. The new date and time format will be displayed on the Ready screen.

6.5. Defining PT and aPTT Normal Values

A mean normal value is used to calculate results for certain tests (see individual test card package inserts). Test–specific mean normal values are encoded on each test card. The value can be read from the test card, or it can be customized for each valid sample type using the Set *<Test>* Normals options on the Supervisory Functions menu.

If a mean normal value is not defined using the analyzer Supervisory Functions, the value will be read from the test card and will appear on the screen as "card". Settings for mean

normal values can be viewed by using the User Functions (section 0).

If a custom mean normal value has been set using the Supervisory Function, that value will be used for all tests of that type until Supervisory Functions are used to change the value or reset it to the default.

6.5.1. Entering a Custom Normal Value

A custom, mean normal value can be entered into the analyzer for each valid sample type, using the Set *<Test>* Normals options on the Supervisory Functions menu to override the default value read from the test card.

Once a custom, mean normal value is entered for a sample type and test, that custom, mean normal value will be used for that sample type and test until it is changed, using the Supervisory Functions.

1. From the Supervisory Functions menu, choose the **Set *<Test>* Normals** option for a specific test. The SET *<TEST>* NORMALS option is displayed in uppercase characters.

```
-Select one-   ↵↑↓↗
clear patient recs.
format date/time
SET <TEST> NORMALS
```

2. Press ENTER. The Select Sample Type menu will be displayed for selection of the sample type to be defined with a custom, mean normal value.

```
-Select One-    ↵ ↓↗
NON-CIT BLOOD CARD
citrated blood card
citrated plasma card
```

Note that the Non–Citrated Blood option will only be available when Set PT Normals is selected.

3. Do one of the following:

a. To define a mean normal value for Non–Citrated Blood samples, choose the **NON–CITRATED BLOOD** option.

b. To define a mean normal value for Citrated Blood samples, choose the **CITRATED BLOOD** option.

c. To define a mean normal value for Citrated Plasma samples, choose the **CITRATED PLASMA** option.

4. The selected option will be displayed in uppercase characters.

5. Press **ENTER**. The ENTER *<TEST>* NORMAL screen will be displayed for the selected sample type, and the cursor will be positioned under the first digit.

```
ENTER <TEST> NORMAL ↗
    CITRATED BLOOD
      xx.x sec.
00.0 reads from card
```

6. Enter three numbers to define the mean normal value, where the third number represents tenths of a second. The cursor will move to the next position in the mean normal value field each time a number is entered. The decimal point is fixed in place. Do not enter the decimal point.

7. Press **ENTER**. The defined mean normal value is accepted, and the analyzer will return to the Select Sample Type menu where the new value will be displayed.

```
-Select One-    ↵ ↓↗
NON-CIT BLOOD   15.9
citrated blood  12.7
citrated plasma 13.0
```

8. Do one of the following:

a. To define another mean normal value, choose a sample type and repeat steps 5 through 7.

b. To return to the Supervisory Functions menu, press **EXIT**.

6.5.2. Resetting a Mean Normal Value to Default

In order for the analyzer to use default mean normal values encoded on a test card once a custom, mean normal value has been defined, the mean normal value must be reset in the analyzer using the Set *<Test>* Normals option on the Supervisory Function menu.

1. From the Supervisory Functions menu, choose the **Set *<Test>* Normals** option for a specific test. The SET *<TEST>* NORMALS option is displayed in uppercase characters.

```
 ┌──────────────────────────┐
 │ --Select One--↵↑↓↗       │
 │ clear patient recs.      │
 │ format date/time         │
 │ SET PT NORMALS           │
 └──────────────────────────┘
```

2. Press **ENTER**. The Select Sample Type menu will be displayed for selection of the sample type to be defined or reset.

```
 ┌──────────────────────────┐
 │ -Select One-     ↵ ↓↗    │
 │ non-cit blood    15.9    │
 │ CITRATED BLOOD   12.7    │
 │ citrated plasma 13.0     │
 └──────────────────────────┘
```

3. Choose the sample type for which a mean normal value is to be reset to read from the test card. The selected option will be displayed in uppercase characters.

Note: The Non–Citrated Blood option will only be available when Set PT Normals is selected.

4. Press **ENTER**. The Enter *<Test>* Normal screen will be displayed for the selected sample type, and the cursor will be positioned under the first digit.

```
 ┌──────────────────────────┐
 │ ENTER <TEST> NORMAL ↗    │
 │    CITRATED BLOOD        │
 │      xx.x sec.           │
 │ 00.0 reads from card     │
 └──────────────────────────┘
```

5. Enter three zeroes in the field for the mean normal value. The cursor will move to the next position in the mean normal value field each time a number is entered. The decimal point is fixed in place. Do not enter the decimal point.

```
 ┌──────────────────────────┐
 │ ENTER<TEST>NORMALS ↗     │
 │    CITRATED BLOOD        │
 │      00.0 sec.           │
 │ 00.0 reads from card     │
 └──────────────────────────┘
```

6. Press **ENTER**. The defined mean normal value will be reset to be read from the test card, and the analyzer will return to the Select Sample Type menu where CARD will be displayed.

```
 ┌──────────────────────────┐
 │ -Select One-     ↵ ↓↗    │
 │ non-cit blood    15.9    │
 │ CITRATED BLOOD CARD      │
 │ citrated plasma 13.0     │
 └──────────────────────────┘
```

7. Do one of the following:

a. To define or reset another mean normal value, choose a sample type and repeat steps 3 through 6.

b. To return to the Supervisory Functions menu, press **EXIT**.

6.6. Enabling/Disabling the aPTT Ratio Mode

An operator with supervisory access can enable the analyzer to report activated Partial Thromboplastin Time (aPTT) ratio values. When the aPTT Ratio mode is enabled, the analyzer uses aPTT test results from a sample of citrated plasma or citrated whole blood to automatically calculate the aPTT ratio for that sample. The aPTT ratio is calculated as follows:

aPTT ratio = aPTT Clot Time/aPTT Mean Normal

When the aPTT ratio is enabled, the aPTT ratio value will be displayed at the end of each aPTT test and stored in memory with the test result.

The User Function Menu option MODE CONFIG displays APTT RATIO ON when this

function is enabled, and APTT RATIO OFF when this function is disabled.

```
--MODE CONFIG--↵↑↓↗
control checking off
normal checking off
APTT RATIO ON
```

1. From the Supervisory Functions menu, do one of the following:

a. To enable the aPTT Ratio mode, choose the **Set APTT Ratio On** option.

b. To disable the aPTT Ratio mode, choose the **Set APTT Ratio Off** option. The selected option will be displayed in uppercase characters.

2. Press **ENTER**.

a. If the aPTT Ratio mode is enabled, the analyzer will briefly display the message, APTT RATIO MODE IS NOW ON, and will return to the Supervisory Functions menu. The menu option will then display the message, SET APTT RATIO OFF.

b. If the aPTT Ratio mode is disabled, the analyzer will briefly display the message, APTT RATIO MODE IS NOW OFF, and will return to the Supervisory Functions menu. The menu option will then display the message, SET APTT RATIO ON.

Note: The menu option indicates the available setting – not the current setting. For example, if the menu option displays the message, SET APTT RATIO ON, the aPTT Ratio mode is currently off, or disabled. When the menu option displays the message, SET APTT RATIO OFF, the aPTT Ratio mode is currently on, or enabled.

6.7. Selecting a Display Language

The analyzer is capable of displaying all operator messages in the following languages:
- English
- German
- French
- Italian
- Spanish

The language option is selected from the Supervisory Functions menu, using the Select Language option.

The default language is English. Once the default language is changed, the analyzer will retain that language setting until changed again, using the Supervisory Functions.

1. From the Supervisory Functions menu, choose the **Select Language** option.

The SELECT LANGUAGE option is displayed in uppercase characters.

2. Press **ENTER**. The Select Language screen will be displayed.

```
--Select One-- ↵ ↓↗
ENGLISH
french
german
```

3. Select the language. The selected option will be displayed in uppercase characters.

4. Press **ENTER**. The selected language is accepted, and the analyzer will return to the Supervisory Functions menu. The display will now show all operator messages in the selected language.

6.8. Setting Control Ranges

Control ranges are used to monitor whether a control test result falls within a set range. This range is defined and set in the analyzer by an operator with supervisory access. Expected ranges for control test results can be defined for both normal and abnormal control samples.

Control ranges for up to three levels can be set for each test type, using the Set Control Ranges option on the Supervisory Functions menu.

If a control range for a specific test is **not** defined in the Supervisory Functions, no control range checking is done. There are **no** default range settings for control samples. To range check control samples, the ranges

must be defined in the Set Control Ranges option and the Control Checking option must be **on.**

Once the expected control ranges for a test have been entered in the Set Control Ranges option, these ranges are used for all controls defined for that test type until changed in Supervisory Functions.

6.8.1. Enabling/Disabling Control Range Checking

When Control Range Checking is enabled, the analyzer checks control test results against the ranges set with the Set Control Ranges option. The Control Range Checking feature can also be disabled.

The feature can be turned on or off by toggling the Set Control Check option on the Supervisory Functions menu. When the analyzer is turned off, then back on, the settings will be retained.

The User Function Menu option MODE CONFIG displays CONTROL CHECKING ON when this function is enabled and CONTROL CHECKING OFF when this function is disabled.

```
--MODE CONFIG--↵↑↓↗
CONTROL CHECKING ON
normal checking on
aptt ratio on
```

1. From the Supervisory Functions menu, do one of the following:

   a. To enable Control Range Checking, choose the **set control check on** option.

   b. To disable Control Range Checking, choose the **set control check off** option.

2. The option is displayed in uppercase characters when selected.

3. Press **ENTER**.

Note: If Control Range Checking is enabled, the analyzer will briefly display the message, CONTROL CHECK MODE IS NOW ON, and will return to the Supervisory Functions menu.

The menu option will then display SET CONTRL CHECK OFF.

Note: If Control Range Checking is disabled, the analyzer will display the message, CONTROL CHECK MODE IS NOW OFF, and will return to the Supervisory Functions menu. The menu option will then display SET CONTRL CHECK ON.

6.8.2. Setting the Number of Control Range Levels

One to three levels of expected ranges for control test results can be entered for each test type, by using the Set Control Ranges option.

1. From the Supervisory Functions menu, choose the **Set Control Ranges** option. The SET CONTROL RANGES option is displayed in uppercase characters.

```
--Select One-- ↵↑ ↗
select language
set QC lockout
SET CONTROL RANGES
```

2. Press **ENTER**. From the Test Selection menu, do one of the following:

```
 Select Test    ↵↑↓↗
_APCR*
 aptt
 athi*
```

*An asterisk indicates a test that is not currently being offered by Helena Laboratories.

   a. Select the first test.

   b. Use the down and up arrows to scroll through the test selection list to locate the appropriate test. Select the required test.

   c. Using the keypad, press the first letter of the desired test to skip through the test selection list to the test names beginning with that letter. Then scroll down to the appropriate test. Select the required test.

The selected option will be displayed in uppercase characters.

d. Press **ENTER**. The Set Levels/Ranges menu will be displayed for the selected test type.

```
--Select One-- ↵ ↓↗
SET NUMBER OF LEVELS
set high/low ranges
```

3. Select **Set Number of Levels**. The SET NUMBER OF LEVELS menu is displayed in uppercase characters.

4. Press **ENTER**. The Set Number of Levels menu will be displayed for selection of the number of control range levels to be set and checked.

```
--Select One-- ↵ ↓↗
ONE LEVEL
two levels
three levels
```

5. Do one of the following:

a. Choose **ONE LEVEL** if only the Level I control range is to be set and checked.

b. Choose **TWO LEVELS** if both Level I and Level II control ranges are to be set and checked.

c. Choose **THREE LEVELS** if Level I, Level II, and Level III control ranges are to be set and checked.

6. The selected option will be displayed in uppercase characters.

7. Press **ENTER**. The selected number of levels is accepted, and the analyzer will automatically display the Set High/Low Ranges screen (section 6.8.3). If the number of levels selected is the same number currently set in the analyzer, the analyzer will return to the Test Selection menu.

Note: If more than one control level is selected and defined for a specific test type, controls for each level must be run within a 60–minute time period to prevent QC Lockout. Control results also must fall within the

ranges set in the analyzer in order to prevent QC Lockout .

6.8.3. Setting High/Low Values for Control Ranges

In order for the analyzer to monitor whether a control test result falls within the correct parameters for a normal or abnormal control sample, an expected range for control test results must be defined and entered as Level I, II, or III.

Once a control range is entered, it will be used for all controls defined for that test type until the high and/or low value is changed again, using the Supervisory Functions.

1. From the Set Levels/Ranges menu, choose the **Set High/Low Ranges** option. The SET HIGH/LOW RANGES option is displayed in uppercase characters.

```
--Select One-- ↵ ↓↗
set number of levels
SET HIGH/LOW RANGES
```

2. Press **ENTER**. The Set High/Low Ranges screen will be displayed. The cursor is positioned in the low value field of Level I. Previously set values will be displayed. The first time values are set, XXXX.X appears in each field until values are entered in the field. Only the number of levels selected will appear on the screen.

```
LEVEL     LOW      HIGH
I          ▂▆      15.0
II        0.0       0.0
III       0.0       0.0
```

3. Enter a value between 0.0 and 9999.9, including the decimal point, to define the low value for Level I.

4. Press **ENTER**. The defined low value for the Level I control range is accepted, and the cursor will advance to the high value field for the Level I control range.

5. Enter a value between 0.0 and 9999.9, including the decimal point, to define the high value for the Level I control range. The high value must be greater than the low value or the analyzer will not accept it.

```
LEVEL    LOW      HIGH
I        10.0     13.0
II       45.0      ▄■
III       0.0      0.0
```

6. Press **ENTER**. The defined high value for the Level I control range is accepted. If more than one level was selected, the cursor will skip to the next line and will be positioned in the low value field for Level II. When all selected levels have been entered, the analyzer will return to the Test Select menu.

7. Define high/low values for Level II and Level III control ranges by repeating steps 3 through 6.

```
LEVEL    LOW      HIGH
I         5.0     15.0
II       45.0     90.0
III     200.0     300.■
```

8. To save high/low values and return to the Test Select menu, advance the cursor to the last data entry position and press **ENTER**.

9. Use the arrows to select another test or press **EXIT** to return to the Supervisory Functions menu.

*Note: To restore the value previously entered in the currently selected field, press ▲ or press **ENTER**.*

6.9. Setting Normal Ranges

Normal ranges are used to monitor whether patient test results fall within the normal ranges set by the supervisor for a specific test. When a test is performed with Normal Range checking enabled and a valid range has been defined for a specified test and sample type, results will be compared against the high and low range values that were set using Supervisory Functions. Normal ranges can be determined by conducting a normal range study, using samples taken from patients whom are representative of the local population.

Once set, Normal Ranges will remain set until changed using the Supervisory Functions.

6.9.1. Enabling/ Disabling Normal Range Checking

When Normal Range Checking is enabled, the analyzer will check test results against the ranges set with the Set Normal Range option. The Set Normal Range feature can also be disabled. The feature can be enabled or disabled by toggling the Set Normal Check option on the Supervisory Functions menu. When the analyzer is turned off, then back on, the settings are retained.

The User Function Menu option MODE CONFIG displays NORMAL CHECKING ON when this function is enabled and NORMAL CHECKING OFF when this function is disabled.

```
--MODE CONFIG--  ↑↓↗
qc printout off
control checking off
NORMAL CHECKING OFF
```

1. From the Supervisory Functions menu, do one of the following:

a. To enable Normal Range Checking, choose the **set normal check on** option.

b. To disable Normal Range Checking, choose the **set normal check off** option.

2. The selected option will be displayed in uppercase characters.

3. Press **ENTER**.

a. If Normal Range Checking is enabled, the analyzer will briefly display the message, NORMAL CHECK MODE IS NOW ON, and will return to the Supervisory Functions menu. The menu option will then display SET NORMAL CHECK OFF.

b. If Normal Range Checking is disabled, the analyzer will briefly display the message, NORMAL CHECK MODE IS NOW OFF, and will return to the Supervisory Functions menu. The menu option will then display SET NORMAL CHECK ON.

Note: The menu option indicates the available setting – not the current setting. For example, if the menu option displays the message, SET OPERATOR ID ON, the Operator ID mode is currently off (disabled). When the menu option displays the message, SET OPERATOR ID OFF, the Operator ID mode is currently on (enabled).
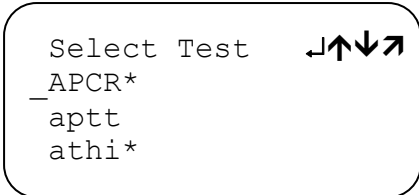
6.9.2. Setting Low/High Values for Normal Ranges

The high and low values defined for a test establish a normal range. Define ranges for a specific test according to sample type.

1. From the Supervisory Functions menu, choose the **Set Normal Ranges** option. The SET NORMAL RANGES option is displayed in uppercase characters.

```
--Select One--↵↑↓↗
set control ranges
set control check on
SET NORMAL RANGES
```
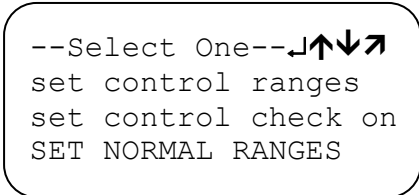
2. Press **ENTER**. The Test Selection menu will be displayed.

```
 Select Test    ↵↑↓↗
_APCR*
 aptt
 athi*
```

3. From the Test Selection menu, do one of the following:

   a. Select the first test.

   b. Use the down and up arrows to scroll through the test selection list to locate the appropriate test. Select the required test.

c. Using the keypad, press the first letter of the desired test to skip through the test selection list to the test names beginning with that letter, then scroll down to the appropriate test. Select the required test.

4. The selected option will be displayed in uppercase characters.

5. Press **ENTER**. The Sample Type menu will be displayed for selection of the sample type to be defined or reset.

```
-Sample Type-  ↵↑↓↗
_CITRATED PLASMA
 citrated wh. blood
 non-cit whole blood
```
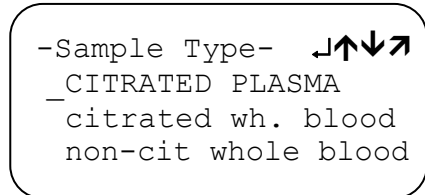
6. Choose the sample type for which normal values are to be defined. The selected option will be displayed in uppercase characters.

7. Press **ENTER**. The Normal High/Low Range entry screen will be displayed for the selected test and sample types.

```
    <TEST NAME>
    <SAMPLE TYPE>
  LOW       HIGH
  _____ ■   xxxx.x
```
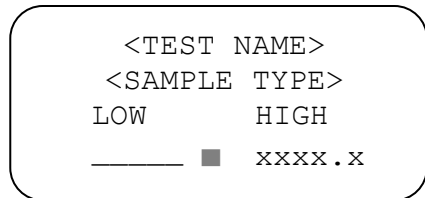
8. The cursor will be positioned on the right side of the Low Normal Value field.

9. Enter the Low Normal Value, including the decimal point.

10. Press **ENTER**. The cursor will then move to the High Normal Value field.

11. Enter the High Normal Value, including the decimal point.

12. To restore previously entered values, press ▲ or **press ENTER**.

13. Press **ENTER**. After accepting both the low and the high values, the analyzer will return to the Sample Type menu.

14. The Test Selection menu will display a plus (+) sign beside the test type in the Test Selection menu and Sample Type menu to

indicate that Normal Range values have been set for that test type.

15. Do one of the following:

 a. To set Normal Ranges for another sample type, repeat steps 5 through 13.

 b. To set Normal Ranges for another test type, press **EXIT** and repeat steps 2 through 13.

 c. To return to the Supervisory Functions menu, press **EXIT**.

Note: There is no default Normal Range for any sample type of any test.

6.10. Modem Setup

The analyzer can be connected to a modem, permitting remote access to analyzer records. The Modem Setup menu has five operational options in the Supervisory Functions menu:
• Set Modem Communications
• Adjust Modem Speaker Volume
• Enter Host Phone Number
• Set Number of Dialing Connection Retries
• Set Auto–Communications with Host Computer

6.10.1. Enabling/Disabling Modem Communications

1. From the Supervisory Functions menu, choose the **modem setup** option. The MO-DEM SETUP option appears in uppercase characters.

```
--Select One-- ↵↑↓↗
set normal check on
MODEM SETUP
set beeper off
```

2. Press **ENTER**. The Modem Setup menu will be displayed. From this menu, do one of the following:

 a. To enable Modem Communications option, choose the **set modem comm on** option.

 b. To disable the Modem Communications option, choose the **set modem comm off** option.

3. The selected option will be displayed in uppercase characters.

```
--Select One-- ↵ ↓↗
SET MODEM COMM ON
modem speaker volume
host phone number
```

4. Press **ENTER**.

 a. If Set Modem Comm On is enabled, the analyzer will briefly display the message, MODEM COMMUNICATIONS IS NOW ON, and will return to the Modem Setup menu. The menu option will then display the message, SET MODEM COMM OFF.

 b. If Set Modem Comm Off is disabled, the analyzer will briefly display the message, MODEM COMMUNICATIONS IS NOW OFF, and will return to the Modem Setup menu. The menu option will then display the message, SET MODEM COMM ON.

5. The User Function Menu option MODE CONFIG will display MODEM COMM ON when this function is enabled and MODEM COMM OFF when this function is disabled.

Note: Auto–dialing is automatically disabled when Modem Communications is disabled.

Note: The menu option indicates the available setting – not the current setting. For example, if the menu option displays the message, SET OPERATOR ID ON, the Operator ID mode is currently off (disabled). When the menu option displays the message, SET OPERATOR ID OFF, the Operator ID mode is currently on (enabled).

```
--MODE CONFIG--↵↑↓↗
aptt ratio off
si units off
MODEM COMM OFF
```

6.10.2. Setting the Modem Speaker Volume

The modem dial–up and connection volume can be adjusted according to operator prefer-

ence with the Modem Speaker Volume option on the Modem Setup screen.

1. On the Modem Setup menu, select the **Modem Speaker Volume** option. The MODEM SPEAKER VOLUME option appears in uppercase characters.

```
--Select One-- ↵↑↓↗
MODEM SPEAKER VOLUME
host phone number
connection retries
```

2. Press **ENTER**. The Speaker Volume options will be displayed.

3. Scroll down the screen until the desired option is highlighted in uppercase characters.

```
--Select One-- ↵↑↓↗
SPEAKER OFF
speaker on low
speaker on high
```

4. Press **ENTER**. The analyzer will return to the Modem Setup menu.

6.10.3. Entering a Host Telephone Number

In order for the modem to connect to the host computer, a host telephone number must be entered into the analyzer.

1. From the Modem Setup screen, select the **Host Phone Number** option. The HOST PHONE NUMBER option appears in uppercase characters.

```
--Select One-- ↵↑↓↗
modem speaker volume
HOST PHONE NUMBER
connection retries
```

2. Press **ENTER**. If no Host Phone Number is stored in the analyzer, the following screen will be displayed.

```
ENTER HOST      ↵   ↗
     PHONE NUMBER

_____
```

3. The cursor will appear in the first space on the left. The number entered can contain up to 20 digits consisting of numbers from 0 through 9, and must contain at least 3 digits. Hyphens (–) may be used to separate the numbers.

4. When delayed dialing is required, place a comma [,] (press [.] for a comma) where the delay in dialing is desired. (An example of delayed dialing: Dial 9 and wait for a dial tone to obtain an outside line.)

Note: If an error is made while entering the Host Phone Number, press the Backspace key one time to move back one space. Press the CLEAR key to erase the entire entry.

5. Press **ENTER**. The analyzer will return to the Modem Setup menu. Host Phone Number will be retained when the analyzer is turned off and then back on.

6.10.4. Reentering a Host Phone Number

1. From the Modem Setup screen, select the **Host Phone Number** option. The HOST PHONE NUMBER option is displayed in uppercase characters.

```
--Select One-- ↵↑↓↗
modem speaker volume
HOST PHONE NUMBER
connection retries
```

2. Press **ENTER**. The following screen will be displayed.

```
 ╭─────────────────────────╮
 │                         │
 │  ENTER HOST     ↵   ↗   │
 │  PHONE NUMBER           │
 │  -------------------    │
 │                         │
 │  ↑ Previous Number      │
 │                         │
 ╰─────────────────────────╯
```

3. Do one of the following:

a. Press ▲ to reenter the previous Host Phone Number.

b. Enter a new Host Phone Number.

4. Press **ENTER** to select the displayed number. The number on the screen is accepted, and the analyzer will return to the Modem Setup menu.

6.10.5. Setting Connection Retries

The analyzer can be set up to automatically redial a number that did not respond to previous attempts to dialup.

1. From the Modem Setup menu, select the **Connection Retries** option. The CONNECTION RETRIES option appears in uppercase characters.

```
 ╭─────────────────────────╮
 │                         │
 │  --Select One-- ↵↑↓↗    │
 │  host phone number      │
 │  CONNECTION RETRIES     │
 │  set auto-comm on       │
 │                         │
 ╰─────────────────────────╯
```

2. Press **ENTER**. The Connection Retries menu will be displayed.

3. Select the required number of connection retries. The selected option will appear in uppercase characters.

```
 ╭─────────────────────────╮
 │                         │
 │  --Select One-- ↵↑↓↗    │
 │  two retries            │
 │  FIVE RETRIES           │
 │  ten retries            │
 │                         │
 ╰─────────────────────────╯
```

4. Press **ENTER**. The analyzer will return to the Modem Setup menu.

The User Function Menu option MODE CONFIG will display MODEM COMM ON when this function is enabled and MODEM COMM OFF when this function is disabled.

```
 ╭─────────────────────────╮
 │                         │
 │  --MODE CONFIG--↵↑↓↗    │
 │  aptt ratio off         │
 │  si units off           │
 │  MODE COMM OFF          │
 │                         │
 ╰─────────────────────────╯
```

6.10.6. Enabling/Disabling the Auto–Dialing Feature

When the Auto–Dialing feature is enabled, the modem connected to the analyzer will automatically dial up the host computer every hour to upload test results. If there are no test results to upload, the analyzer will not dial up the host computer.

The User Function Menu option MODE CONFIG will display AUTO–DIALING ON when this function is enabled and AUTO–DIALING OFF when this function is disabled.

```
 ╭─────────────────────────╮
 │                         │
 │  --MODE CONFIG--↵↑↓↗    │
 │  si units off           │
 │  mode comm off          │
 │  SET AUTO-DIALING OFF   │
 │                         │
 ╰─────────────────────────╯
```

1. From the Modem Setup menu, select the **Set Auto–Dialing On (Off)** option. The selected option will be displayed in uppercase characters.

```
 ╭─────────────────────────╮
 │                         │
 │  --Select One-- ↵↑↓↗    │
 │  host phone number      │
 │  connection retries     │
 │  SET AUTO-DIALING ON    │
 │                         │
 ╰─────────────────────────╯
```

Note: When SET AUTO–DIALING ON is selected from the Supervisors Menu, the following screen will appear momentarily if the modem communication is not enabled:

```
 ╭─────────────────────────╮
 │                         │
 │       WARNING!!         │
 │  Modem Communications   │
 │      not enabled        │
 │  Auto-Dialing is OFF    │
 │                         │
 ╰─────────────────────────╯
```

2. Press **ENTER**.

a. If the Auto–Dialing feature is enabled and Modem Communications is enabled, the analyzer will briefly display the message, Auto–Dialing is ON, and will return to the Modem Setup menu.

b. If the Auto–Dialing feature is disabled, the analyzer will briefly display the message, Auto–Dialing is OFF, and will return to the Modem Setup menu.

3. Press **EXIT** two times to return to the Ready screen.

Note: Detailed instructions for setting up and using a modem with the analyzer can be obtained by contacting your local support provider or distributor.

6.11. Defining International Sensitivity Index (ISI) Values for PT Tests

An International Sensitivity Index (ISI) value is used to calculate the International Normalized Ratio (INR). Cascade POC PT-WB and PT–C test cards are encoded with an ISI value assigned from data obtained using patient test samples collected in 109 mM (3.2%) citrate tubes. The ISI value encoded in the card is specific to that lot of cards and may change when a new lot of cards is used. The POC handles this change automatically if no ISI has been entered into the instrument.

A laboratory may choose to determine their own ISI values if they have access to Certified INR plasmas as described in CLSI Guideline H 47-A2. The ISI values can be set using Supervisory Functions. The ISI values encoded in the cards are provided in the INR table enclosed in PT-WB and PT-C test card cartons for your information. The analyzer will use the entered values instead of the values encoded on the test cards to calculate the INR if an ISI is entered in the POC and that ISI number must be verified with each new lot of cards and altered if necessary. It is **strongly recommended** the default ISI on the test card is used.

*Note: To return to the default card reading capability of the POC, enter 0.00 as the ISI number.*

6.11.1. Defining an ISI Value

An ISI value can be defined and entered into the analyzer for each valid sample type, using the Set ISI Values Supervisory Function to override the default value from the test card.

1. From the Supervisory Functions menu, choose the **Set ISI Values** option. The SET ISI VALUES option is displayed in upper-case characters.

```
--Select One-- ↵↑↓↗
modem setup
set beeper on
SET ISI VALUES
```
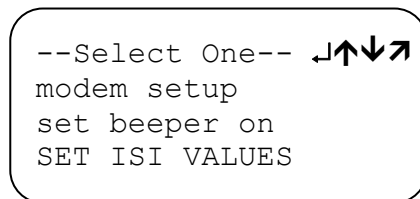
2. Press **ENTER**. The ISI Value menu will be displayed for selection of the sample type to be defined and reset. The initial default value for all sample types will be shown as "card", which is the ISI value en-coded on the PT card.

```
-Select One-  ↵ ↓↗
NON-CIT BLOOD CARD
citrated blood card
citrated plasma card
```
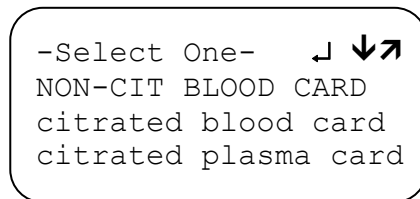
3. To define an ISI value other than the card value, choose the sample type. The se-lected sample type will appear in uppercase characters.

4. Press **ENTER**. The ISI Value Entry screen will be displayed. The cursor will be positioned under the first digit of the entry field.

```
ENTER ISI VALUE ↗
   <SAMPLE TYPE>
        x.xx
00.0 reads from card
```

5. Enter three numbers to define the required ISI value, where the second and third numbers represent the ISI decimal value.

The cursor moves to the next position in the ISI field each time a number is entered. The decimal point is fixed in place. Do not enter the decimal point.

6. Press **ENTER**. If the newly defined ISI value is accepted by the analyzer, the ISI Value menu will be displayed on the screen.

7. Do one of the following:

a. To define an ISI value for another sample type, repeat steps 2 through 6.

b. To return to the Supervisory Functions menu, press **EXIT**.

6.11.2. Resetting an ISI Value to the Card Value

Once an ISI value has been defined and set in the analyzer, that value must be reset using the Set ISI Values Supervisory Function to again use the ISI values encoded on the test card.

1. From the Supervisory Functions menu, choose the **Set ISI Values** option. The SET ISI VALUES option is displayed in uppercase characters.

```
--Select One-- ↵↑↓↗
modem setup
set beeper on
SET ISI VALUES
```

2. Press **ENTER**. The ISI Value menu will be displayed for selection of the sample type to be defined and reset.

```
-Select One-    ↵ ↓↗
non-cit blood    card
citrated blood   1.58
citrated plasma  1.43
```

3. Choose the sample type for which the ISI value is to be reset to read from the test card. The selected option will be displayed in uppercase characters.

4. Press **ENTER**. The ISI Value Entry screen will be displayed. The cursor will be positioned under the first digit of the entry field.

```
ENTER ISI VALUE ↗
   <SAMPLE TYPE>
        x.xx
00.0 reads from card
```

5. Enter three zeroes (000) in the field for the ISI Value. The cursor will move to the next position in the ISI Value field each time that a number is entered. The decimal point is fixed in place. Do not enter the decimal point.

6. Press **ENTER**. The ISI value will now be reset to be read from the test card, and the ISI Value menu will again be displayed on the screen.

7. Do one of the following:

a. To reset another ISI value, choose a sample type and repeat steps 3 through 6.

b. To return to the Supervisory Functions menu, press **EXIT**.

Section 7 – Operating Instructions

7.1. General Operating Instructions
(For operation of the optional Cascade POC Data Manager Software See Section 5.2.7)

7.1.1. Using the Keypad

Use the analyzer keypad to respond to visual instructions provided on the analyzer display. Symbols and other prompts will be provided on the display to help you determine valid keypad responses (section 7.1.2). The analyzer will beep once each time a valid keypad entry is made. Two beeps indicate an invalid keypad entry.

The analyzer keypad has four key categories:
• Data Entry Keys
• Cursor and Display Movement Keys
• Command Keys
• Confirmation Keys

Cascade POC Analyzer Keypad
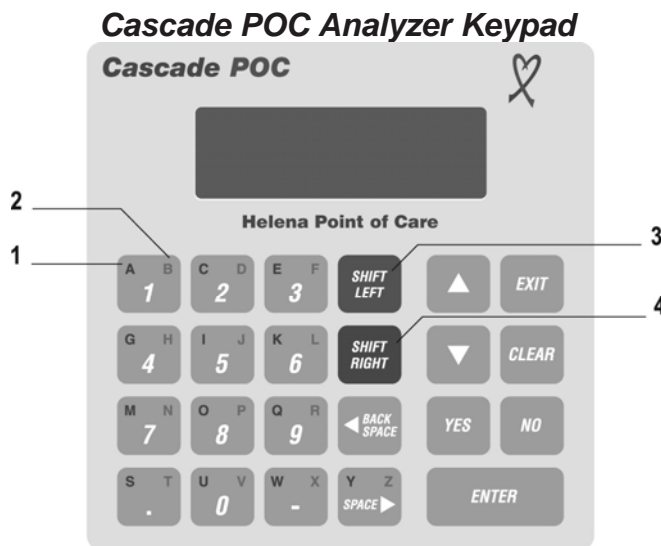
1 Red
2 Blue
3 Red enables the left (red) alphabetic character on the keys
4 Blue enables the right (blue) alphabetic character on the keys

7.1.1.1. Data Entry Keys

The analyzer data entry keys consist of alphanumeric keys and shift keys. The alphanumeric keys contain color–coded alphabetic characters and numeric or special characters

on the same key. The red and blue shift keys are used in combination with these alphanumeric keys to enter the alphabetic characters.

Key	Action
A B **1**	Displays the "1" character in the cursor position on the display.
SHIFT LEFT	Enables the entry of the alphabetic characters in the upper left corners of the alphanumeric keys.
SHIFT RIGHT	Enables the entry of the alphabetic characters in the upper right corners of the alphanumeric keys.

Press	Followed by	Action
SHIFT LEFT	**A B** **1**	Displays the "A" character in the cursor position on the display.
SHIFT RIGHT	**A B** **1**	Displays the "B" character in the cursor position of the display.

7.1.1.1.1. Entering Numeric or Special Characters

When the shift keys are disabled, numeric characters, or the period, hyphen, and space can be entered by pressing the alphanumeric key that contains that character.

7.1.1.1.2. Entering Alphabetic Characters Using the Shift Keys

You must use a shift key followed by an alphanumeric key to enter an alphabetic character. The shift keys enable the entry of one alphabetic character at a time. When a shift key is pressed and then released, the shift left or right function will be enabled for the indicated cursor position only, and the alphabetic character corresponding to the enabled shift key can be entered. The cursor will change from a line to a blinking box to indicate a shift key is enabled.

Alphabetic characters are identified on the upper left and upper right corners of each alphanumeric key. The LEFT alphabetic character is red, and the RIGHT alphabetic

character is blue. The color and location of the alphabetic character indicates the shift key that needs to be used with the alphanumeric key in order to enter the alphabetic character.

A shift key will only be enabled for the current cursor position, so a shift key must always precede the entry of an alphabetic character. For example, to enter the patient name "Jones", press each of the following keys in sequence:

SHIFT RIGHT–J SHIFT LEFT–O SHIFT RIGHT–N SHIFT LEFT–E SHIFT LEFT–S

To enter a left (red) alphabetic character:

1. Press and release the red, **SHIFT LEFT** toggle key. The cursor will change to a blinking box on the display and the red or LEFT alphabetic characters will be enabled for data entry.

2. Press and release the alphanumeric key containing the red or LEFT alphabetic character you want to enter.

The selected alphabetic character will be entered in the cursor position on the display, and the shift key will be disabled.

To enter a right (blue) alphabetic character:

1. Press and release the blue, **SHIFT RIGHT** toggle key. The cursor will change to a blinking box on the display and the blue or RIGHT alphabetic characters will be enabled for data entry.

2. Press and release the alphanumeric key containing the blue or RIGHT alphabetic character you want to enter.

The alphabetic character will be entered in the cursor position on the display, and the shift key will be disabled.

7.1.1.2. Cursor and Display Movement Keys

The analyzer cursor and display movement keys are used to position the cursor for editing, to select a menu option, to move forward to the next display, or to move backward to the previous display.

Key	Action
BACK SPACE	Deletes the character to the left of the cursor and moves the cursor backward, or to the left, on the display.
▲	Selects the option above the current option on a menu, or moves backward to the previous display.
▼	Selects the option below the current option on a menu, or moves forward to the next display.

7.1.1.3. Command Keys

The analyzer command keys are used to send operation instructions to the analyzer.

Key	Action
EXIT	Cancels the current selection or operation and returns to the previous menu.
ENTER	Accepts the selected option; displays the User Function menu if the —READY— screen is displayed.
CLEAR	Erases all characters on the display that were entered from the keypad.

7.1.1.4. Confirmation Keys

The analyzer confirmation keys are used to respond positively or negatively when the analyzer issues a YES/No prompt.

Key	Action
YES	Returns a YES response to an analyzer YES/No prompt.
NO	Returns a No response to an analyzer YES/No prompt.

7.1.2. Reading the Display

The analyzer provides visual instructions on the display for each step of an operation or test. Many of the analyzer options will be presented on the display in the form of a menu or a list of options. Symbols and other prompts also are provided on the display to help you determine the valid keypad responses for a given screen.

7.1.2.1. Working with Menus

To select a menu option, use one of the cursor and display movement keys indicated on the display to move between menu options.

The option that is selected will appear in uppercase characters on the analyzer display. Other possible menu options will appear in lowercase characters.

To activate the selected menu option, press **ENTER**.

To cancel the current operation, press **EXIT**.

7.1.2.2. Display Symbols and Prompts

The following table shows the relationship between the symbols that can appear on the display and the associated keypad options that are available:

Symbol	Valid Keypad Option
←	ENTER
↑	▲
↓	▼
↗	EXIT

7.1.3. Editing Keypad Entries

Use the **BACKSPACE** key or the **CLEAR** key to edit the data entered on the display. The **BACKSPACE** key erases characters one at a time as it moves the cursor backward, while the **CLEAR** key erases all characters that have been entered.

1. Do one of the following:

  a. Press **BACKSPACE** to position the cursor under the character to be edited. The entered characters will be erased one at a

time as the cursor moves backward with each entry of the backspace key.

  b. Press **CLEAR** to erase all characters that have been entered. All entered characters will be erased, and the cursor will be positioned at the beginning of the data entry field.

2. Reenter the correct character or group of characters at the cursor position.

3. When all characters appear correctly on the display, press **ENTER** to accept the changes.

Note: *To save keystrokes, verify each of the keypad entries on the display as they are made. If an entry needs to be edited, the backspace key can be used to make the correction.*

7.1.4. Displaying the User Functions

The analyzer has two sets of functions: Supervisory Functions and User Functions. The Supervisory Functions allow an operator to perform certain setup operations. The User Functions allow the operator to perform the following analyzer operations:

• Set the date and time
• View or print test records
• View the PT and aPTT mean normal values
• View QC Lockout settings
• View or print control ranges
• View or print normal ranges
• View version number of analyzer software
• View ISI values
• View or print Configuration Modes

1. From the Ready screen, press **ENTER**.

```
--READY--    mm/dd/yy
             hh:mm ?M

Pass card thru readr
   or press enter
```
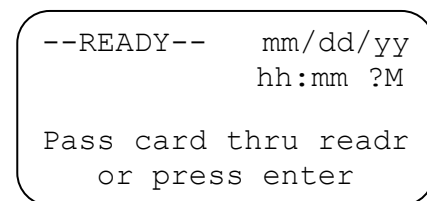
The User Function menu will be displayed showing the available user functions. In the following example, the VIEW PATIENT RECS is displayed in uppercase characters and

would be the option selected if you pressed **ENTER**.

```
Select Function ↵↓↗
VIEW PATIENT RECS
set date/time
view pt normal
```
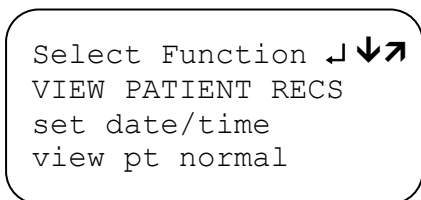
2. To return to the Ready screen, press **EXIT**.

7.1.5. Setting the Date and Time

The analyzer will notify the operator when a test card has expired. The analyzer will also record the time and date on each test record. Each time the analyzer is used, verify that the system time and date are accurate. The system date and time are displayed on the analyzer Ready screen.

7.1.5.1. Date Format

The analyzer default system date is entered in the following format:

mm/dd/yy
mm – Month
dd – Day
yy – Year

A number must be entered for each data entry field shown on the display; any months or days represented by a single digit must be preceded by a zero (0). For example, the month of August is represented as 08. The analyzer will issue an error message if an invalid date is entered, and will return to the Set Date screen so it can be reentered.

The analyzer can be configured to use the alternative date formats, *dd.mm.yy* or *yy.mm.dd,* using the supervisory functions to change the date and time setting (section 6.4).

7.1.5.2. Time Format

The analyzer default system time is the 12–hour clock, and is entered in the following format:

hh:mm ?M
hh – Hour

mm – Minute
?M – AM or PM

A number must be entered for each of the characters shown on the display, and an A or a P must be entered for AM or PM. The analyzer will issue an error message if an invalid time is entered, and will return to the Set Time screen so it can be reentered.

The analyzer can be configured to use the alternative international 24–hour time format, hh:mm, using the Supervisory Functions to change the date and time setting (section 6.4). An A or P is not required for the 24–hour time format.

1. From the Ready screen, press **ENTER.** The Select Function menu will be displayed showing available user functions.

```
--READY--   mm/dd/yy
            hh:mm ?M

Pass card thru readr
   or press enter
```
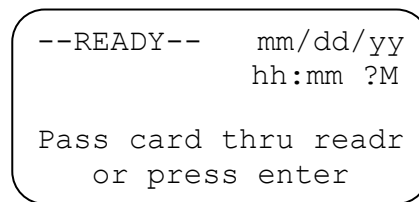
2. Choose the **Set Date/Time** option, using the cursor movement keys. The SET DATE/TIME option is displayed in upper-case characters.

```
Select Function ↵↑↓↗
view patient recs
SET DATE/TIME
view pt normal
```
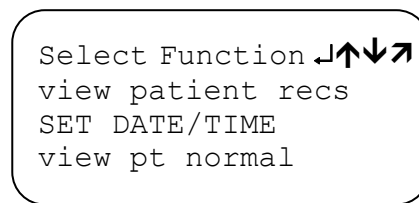
3. Press **ENTER**. The Set Date screen will be displayed with the cursor positioned under the first *m.*

```
    SET DATE      ↗
    mm/dd/yy
Enter digits. Press
  ENTER when done
```
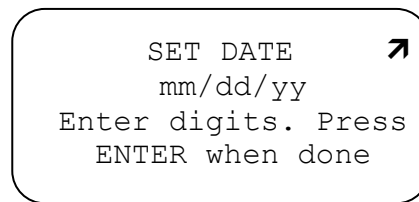
4. Enter the two numbers representing the current month. The entered numbers will replace the two *m's,* and the cursor will move below the first *d.*

5. Enter the two numbers representing the current day. The entered numbers will replace the two *d's*, and the cursor will move below the first *y.*

6. Enter the last two numbers representing the current year. The entered numbers will replace the two *y's.*

7. Press **ENTER**. If the entered date is invalid, an error message will be displayed. Press any key to return to the Set Date screen.

```
   Date is invalid
   Re-enter date

 Hit any key to cont.
```

8. If ENTER is pressed before specifying a number for every available data entry field, the Set Date screen will remain on the display.

9. If the entered date is valid, the Set Time screen will be displayed, and the cursor will be positioned under the first *h.*

```
   SET TIME      ↗
   hh:mm   ?M
 Enter digit for HH &
 MM, A or P for "?".
```

10. Enter the two numbers representing the current hour. The entered numbers will replace the two *h's*, and the cursor will move below the *m.*

11. Enter the two numbers representing the current minute. The entered numbers will replace the two *m's*, and the cursor will move below the question mark symbol.

12. Enter an A or a P to indicate the time of day as AM or PM. The question mark will be replaced by the entered character, and AM or PM will be displayed.

13. Press **ENTER**. If the entered time is invalid, an error message will be displayed.

14. Press any key to return to the Set Time screen.

```
   Time is invalid
   Re-enter time.

 Hit any key to cont.
```

15. If ENTER is pressed before specifying a number for every available data entry field, the Set Time screen will remain on the display.

16. If the entered time is valid, the Ready screen will be displayed.

17. The date and time are displayed in the upper right corner of the screen.

Note: The date and time cannot be updated independently. Values for both the date and time must be entered in order for the date selection to be accepted.

Note: EXIT can be pressed at any time from the Set Date and Set Time screens to cancel the selections and return to the Ready screen.

7.1.6. Working with Stored Test Records

The analyzer can store up to 1000 test records. These records can be viewed or printed by the operator using the basic User Functions provided by the analyzer. When the analyzer memory is full, it will issue the following message:

```
   PATIENT RECORD
    MEMORY FULL
 Press enter to cont.
 Press exit to cancel
```

If testing continues, the oldest test record contained in memory will be overwritten and cannot be recovered.

Note: To avoid the warning message, PA-TIENT RECORD MEMORY FULL, and overwriting stored test records that have not been saved to a permanent record, an opera-

tor with supervisory access should periodically print all test records before the 1000 test record limit is reached. After the records have been printed, the memory should be cleared (section 6.3.5).

7.1.6.1. Viewing Test Records

Using the View Patient Recs option on the user Select Function menu, test records can be viewed in four ways:

• All test records stored in the analyzer
• All test records stored for a specified patient
• All test records stored by a specific test type
• All test records stored by a specific sample type

With each of the above viewing options, the most recent test record will be displayed first. Each test record has two information screens. The first screen displays the record counter, test name, patient identification (or control level number), and the date and time the test was performed. The second screen displays the sample type and the test result.

The variables in the first screen are defined as follows:

First Screen of Test Records

```
xxx/yyy test    ↓↗
mm/dd/yy      hh:mm
patient id
p-print all ↵ more
```
```
xxx/yyy test *✓↓↗
mm/dd/yy      hh:mm
control level
p-print all ↵ more
```

patient id – Identifies the patient ID
mm/dd/yy – Identifies the date the test was performed
xxx – Identifies the test record number
yyy – Identifies the total number of test records for the selected category
test – Identifies the test name
* – Identifies a result that is out of range
✓ – Indicates the result is in range, no indicates the test results were not range checked
hh:mm – Identifies the time the test was performed
control level – Identifies the control level number

Second Screen of Test Records

```
Sample Type:     ↗
Control plasma
results=37.4 sec.
press p to print rec
```

The number of test records stored in the analyzer for the selected viewing option is indicated by the record counter on the first screen of the test record in the form, xxx of *yyy*. The record counter displays the number of the current test record being viewed out of the total number of possible records available for display. Additional test records can be viewed by using the display movement key indicated in the upper right corner of the screen display.

7.1.6.1.1. Viewing All Stored Test Records

Every test record currently stored in the analyzer can be viewed through the All Records option. Stored test records can also be printed if the analyzer printer option is enabled (section 7.1.6.2).

1. From the Ready screen, press **ENTER.** The Select Function menu will be displayed showing the available user functions.

```
--READY--   mm/dd/yy
            hh:mm ?M

Pass card thru readr
   or press enter
```

2. From the Select Function menu, choose the **View Patient Recs** option. The VIEW PATIENT RECS option is displayed in uppercase characters.

```
Select Function ↵↓↗
VIEW PATIENT RECS
set date/time
view pt normal
```

3. Press **ENTER**. The View By menu will be displayed.

```
--View By--    ↵↓↗
ALL RECORDS
patient id
test name
```

4. Choose the **All Records** option. The ALL RECORDS option is displayed in uppercase characters.

5. Press **ENTER**.   The first screen of the most recent test record will be displayed.

```
xxx/yyy  test    ↓↗
mm/dd/yy         hh:mm
            patient id
p-print all   ↵ more
```

6. Press the required key:

Key	Action
ENTER	To display the second screen of the test record.
▼	To display the previous test record.
SHIFT RIGHT–P	To print all test records stored in the analyzer.
EXIT	To return to the Ready screen.

7.1.6.1.2. Viewing All Test Records for a Specific Patient

The Patient ID option of the View Patient Records user function is used to display (or print) all test records stored in the analyzer for a specific patient ID. Stored test records can be printed if the analyzer printer option is enabled (section 7.1.6.2).

1. From the Ready screen, press **ENTER.** The Select Function menu will be displayed showing available user functions.

```
--READY--   mm/dd/yy
            hh:mm ?M

Pass card thru readr
   or press enter
```

2. From the Select Function menu, choose the **View Patient Recs** option. The VIEW PATIENT RECS option is displayed in uppercase characters.

```
Select Function ↵↓↗
VIEW PATIENT RECS
set date/time
view pt normal
```

3. Press **ENTER**. The View By menu will be displayed.

```
--View By--    ↵↑↓↗
all records
PATIENT ID
test name
```

4. Choose the **Patient ID** option. The PATIENT ID option is displayed in uppercase characters.

5. Press **ENTER**.   The Enter Patient ID screen will be displayed.

```
    Enter Patient ID

   _____
```

6. Enter the name or identification of the patient whose records you want to display. The entered identification will be displayed in the cursor position.

7. Press **ENTER**.   The first screen of the most recent test record will be displayed.

```
xxx/yyy  test    ↓↗
mm/dd/yy         hh:mm
            patient id
p-print all   ↵ more
```

8. Press the required key:

Key	Action
ENTER	To display the second screen of the test record.
▼	To display the previous test record.
SHIFT	To print all test records for the speci-

Key	Action
RIGHT–P	fied patient ID stored in the analyzer.
EXIT	To return to the Ready screen.

7.1.6.1.3. Viewing All Test Records for a Selected Test Type

The Test Name option of the View Patient Records user function is used to display (or print) all records stored in the analyzer for a certain test category. Test records can be printed if the analyzer printer option is enabled (section 7.1.6.2).

1. From the Ready screen, press **ENTER.** The Select Function menu will be displayed showing available user functions.

```
--READY--    mm/dd/yy
             hh:mm ?M

Pass card thru readr
   or press enter
```

2. From the Select Function menu, choose the **View Patient Recs** option. The VIEW PATIENT RECS option is displayed in uppercase characters.

```
Select Function ↵↓↗
VIEW PATIENT RECS
set date/time
view pt normal
```

3. Press **ENTER**. The View By menu will be displayed.

```
--View By--      ↵↑↓↗
all records
patient id
TEST NAME
```

4. Choose the **Test Name** option. The TEST NAME option is displayed in uppercase characters.

5. Press **ENTER**. The Select Test menu will be displayed. This menu lists all test types currently stored in the analyzer's memory.

Note: Due to the four–line maximum for the screen, all available choices contained in the menu may not appear on screen at one time. In this situation, the ▼ key will allow the user to scroll down and view the remainder of the menu.

```
-Select Test-  ↵↑↓↗
APTT
c-ACT
pt
```

6. Choose the name of a test type. The selected test name will be displayed in uppercase letters.

```
-Select Test-  ↵↑↓↗
APTT
c-ACT
pt
```

Note: To view EQC results, select EQC on the Select Test menu.

```
--Select Test--↵↑ ↗
c-ACT
pt
EQC
```

7. Press **ENTER**. The first screen of the most recent test recorded for the specified test name will be displayed.

```
xxx/yyy test         ↓↗
mm/dd/yy        hh:mm
            patient id
p-print all    ↵ more
```

8. Press the required key:

Key	Action
ENTER	To display the second screen of the test record.
▼	To display the previous test record.
SHIFT RIGHT–P	To print all test records for a specified test name stored in the analyzer.
EXIT	To return to the Ready screen.

7.1.6.1.4. Viewing All Test Records for a Sample Type

The Sample Type option under View Patient Records is used to display (or print) all records stored in the analyzer for a certain sample type. Test records can be printed if the analyzer printer option is enabled (section 7.1.6.2).

1. From the Ready screen, press **ENTER.** The Select Function menu will display available user functions.

```
--READY--    mm/dd/yy
             hh:mm ?M

Pass card thru readr
   or press enter
```

2. From the Select Function menu, choose the **View Patient Recs** option. The VIEW PATIENT RECS option is displayed in uppercase characters.

```
Select Function ↵↓↗
VIEW PATIENT RECS
set date/time
view pt normal
```

3. Press **ENTER**. The View By menu will be displayed.

4. Choose the **Sample Type** option. The SAMPLE TYPE option is displayed in uppercase characters.

```
--View By--     ↵↑↓↗
patient id
test name
SAMPLE TYPE
```

5. Press **ENTER**. The Sample Type menu will be displayed. This menu lists all of the sample types recognized by the analyzer.

```
-Sample Type-  ↵↑↓↗
CITRATED PLASMA
citrated wh. blood
control plasma
```

6. Choose the name of a sample type. The selected sample type will be displayed in uppercase characters.

7. Press **ENTER**. The first screen of the most recent test recorded for the specified sample type will be displayed.

```
xxx/yyy test      ↓↗
mm/dd/yy      hh:mm
           patient id
p-print all    ↵ more
```

8. Press the required key:

Key	Action
ENTER	To display the second screen of the test record.
▼	To display the previous test record.
SHIFT RIGHT–P	To print all test records for the specified sample type stored in the analyzer.
EXIT	To return to the Ready screen.

7.1.6.2. Printing Test Records

Test records can be printed to an externally attached serial printer from the analyzer (section 5.2.6). Test records are automatically stored in the analyzer memory each time a test is performed. These records remain in memory until overwritten or erased (section 6.3.5).

Individual test records can be printed automatically upon test completion if the Auto Print Mode is enabled (section 4). Individual test records or groups of test records categorized by patient ID, test type, or sample type can be printed using the View Patient Records user function.

7.1.6.2.1. To print every test record stored in memory:

1. From View Patient Records, choose **All Records**. The most recent test record in the analyzer memory will be displayed

2. Enter **P** to print all of the records in the viewing category.

3. The message, PRINTING...PRESS EXIT To STOP, will be displayed as the records are sent to the printer. If **EXIT** is pressed, the printer will continue to print until the printer buffer is empty.

7.1.6.2.2. To print all stored test records in a particular viewing category:

1. From View Patient Records, select Patient ID, Test Name, or Sample Type to print stored test records in that category. Press **ENTER**.

2. The most recent test record from the selected viewing category will be displayed.

3. Enter **P** to print all of the records in the selected option.

4. The message, PRINTING...PRESS EXIT To STOP, will be displayed as the records are sent to the printer. If **EXIT** is pressed, the printer will continue to print until the printer buffer is empty.

7.1.6.2.3. To print individually stored test records from a particular viewing category:

5. From View Patient Records, select the test record category. Press **ENTER**.

6. The most recent test record from the selected category will be displayed.

7. Use the display movement keys to scroll through the available records to the test record to be printed.

8. The first screen of the test record will be displayed.

9. Press **ENTER**. The second screen of the test record will be displayed.

10. Enter **P** to print the selected test record.

The message, PRINTING...PRESS EXIT To STOP, will be displayed as the record is sent to the printer.

7.1.6.3. PT Test Result Sample Report

```
CASCADE POC ANALYZER
SERIAL # 000001 mm/dd/yy hh:mm ?M

Patient ID: 12345678901234567890
 Test Name:PT
 Test Result:= 9.7 sec.
 ratio = 0.8
 Calculated inr = 0.72
 Sample type:citrated plasma
 Test Date   :mm/dd/yy
 Test Time   :hh:mm ?M
 Card Lot    :124040
 Operator    :
```

7.1.6.4. Understanding the Cascade POC Analyzer Printout

7.1.6.4.1. Cascade POC Reagent Kit Lot Numbers

Helena uses a three-part lot numbering system for Cascade POC test kits. (See Figure 7-1)The first one or two digits represent the manufacturing sequence, the second two are the year of manufacture, and the final four are the four digit catalog number.

The Cascade POC Analyzer reads lot numbers from the test cards and represents that lot as a 6-digit number on the printout. The lot sequence is represented as a two digit number, followed by the year and the last two digits of the catalog number.

Lot 7-08-5821 of Cascade POC PT-C would read 070821 on the Cascade POC analyzer's printout. The first two digits of the catalog


```
LOT 7-08-   5821
EXP: 2009-07-16
```
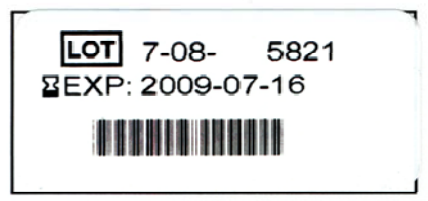
number, i.e. "58", are dropped.

7.1.6.4.2. Cascade POC Analyzer Serial Numbers

Each Cascade POC is assigned a 9-digit serial number. (See Figure 2) The first two digits represent a product code, the next two are the year of manufacture, followed by the Julian day and finally, the sequence number of instruments assembled that day.

For instance, the serial number on instrument plate pictured below tells us this is the 4th Cascade POC assembled on the 100th day of the year 2008. Only the last six digits of the serial number would appear on the Cascade POC Analyzer's printout. The Cascade POC Analyzer with serial number 710810004 would read 810004 on the analyzer's printout. The first three digits are dropped.

Note: Be sure to check the printed record for accuracy.

Note: Though the analyzer can operate with any serial printer, the printer available from Helena Laboratories is highly recommended. The Helena Laboratories printer option includes a portable serial printer and a customized printer cable.

Note: To avoid the warning message, PATIENT RECORD MEMORY FULL, and the possible overwriting of previously stored test records that have not been saved to a permanent record, an operator with supervisory access should periodically print all test records before the 1000 test record limit is reached. After the records have been printed, the memory should be cleared (section 6.3.5).

Note: If a record has a control sample test result that is out of range, the message, *** RESULT OUT OF RANGE ***, will be printed immediately following the "Test Result" line.

Note: Pressing the EXIT key will discontinue the printing function. However, the printer will continue to print more records until all the records in its internal buffer memory are printed.

7.1.7. Viewing PT and aPTT Normal Values

The geometric mean of the normal range is used to calculate results for certain Cascade POC tests. Test specific means are encoded on each Cascade POC test card. The mean value can be read from the test card, or it can be customized for each valid sample type by an operator with supervisory access (section 6.5). If the mean of the normal range is not entered in the analyzer by an operator, the encoded mean value from the Cascade POC test card will be used as the default.

The setting for the PT or aPTT Normal can be viewed from the User Functions. If a custom mean value has been set using the Set PT or Set aPTT Normals Supervisory Function, the analyzer will display the custom value. If a custom mean value has not been set, the analyzer will display "card" by the sample type.

1. From the Ready screen, press **ENTER.** The Select Function menu will display available user functions.

```
--READY--    mm/dd/yy
             hh:mm ?M


Pass card thru readr
   or press enter
```
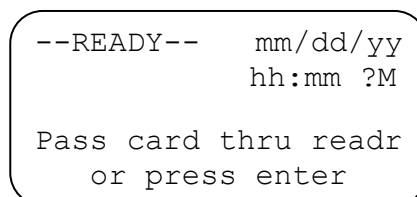
2. From the Select Function menu, choose the **View** *(Test)* **Normal** option. The VIEW *(TEST)* NORMAL option is displayed in uppercase characters.

```
Select Function  ↵↑↓↗
view patient recs
set date/time
VIEW PT NORMAL
```

3. Press **ENTER**.

```
Sample          Norm  ↗
non-cit blood   15.9
citrated blood  card
citrated plasma card
```

Note: The *Non–Citrated Blood option will only be available when View PT Normal is selected.*

4. If the analyzer is customized with a mean normal range value, the analyzer will display that value in seconds.

5. If the analyzer is configured to read the mean normal range value from the Cascade POC test card, the analyzer will display "card" by the sample type.

7.1.8. Viewing QC Lockout Settings

The QC Lockout time period ensures that a control plasma or EQC is run within an operator defined time period of 1 to 999 hours.

The setting for QC Lockout can be viewed from the User Functions. If a time period for the control plasma or EQC has been defined, the analyzer will display that time period and the QC Lockout setting.

1. From the Ready screen, press **ENTER.** The Select Function menu will display available user functions.

```
--READY--    mm/dd/yy
             hh:mm ?M

Pass card thru readr
    or press enter
```

2. From the Select Function menu, choose the **View QC Lockout** option. The VIEW

QC LOCKOUT option is displayed in upper-case characters.

```
Select Function  ↵↑↓↗
view pt normal
view aptt normal
VIEW QC LOCKOUT
```

3. Press **ENTER**. The following QC Lockout submenu will be displayed:

```
--Select One--  ↵ ↓↗
CONTROL PLASMA
eqc
```

*Note: CONTROL PLASMA will be displayed in uppercase letters when the submenu is first displayed. Use the down and up arrow keys to toggle between the two available options: **Control Plasma** or **EQC**.*

4. Press **ENTER.** Depending upon the option selected, one of the following screens will be displayed.

```
QC 4hrs between ↗        QC 4hrs between ↗
 control samples          EQC Tests
     hrs: 12                hrs: 12
  Level: WARNING         Level: WARNING
```
Or

5. The value for *hours* ranges from 1 to 999; 0 indicates the value has not been set.

6. The possible options for QC Lockout are: DISABLE, WARNING, or LOCKOUT (section 6.2.5).

7.1.9. Viewing Control Ranges

Control ranges are used to monitor whether a control test result falls within the parameters set by the operator for a specific Cascade POC test. See section 6.8.1 to enable or disable control range checking using the Supervisory Functions.

The settings for control ranges can be viewed from the User Functions. If a control range has been defined, the analyzer will show each level number and its associated high/low values.

1. From the Ready screen, press **ENTER.** The Select Function menu will display available user functions.

```
╭─────────────────────────────╮
│ --READY--    mm/dd/yy        │
│              hh:mm ?M        │
│                              │
│  Pass card thru readr        │
│    or press enter            │
╰─────────────────────────────╯
```

2. From the Select Function menu, choose the **View Control Ranges** option. VIEW CONTROL RANGES is displayed in uppercase letters.

```
╭─────────────────────────────╮
│ Select Function ⏎↑↓↗         │
│ view aptt normal             │
│ view qc lockout              │
│ VIEW CONTROL RANGES          │
│                              │
╰─────────────────────────────╯
```

3. Press **ENTER**. The Select Test menu will be displayed showing the available test types.   A (+) indicates that at least one control range level has been set for the test.

```
╭─────────────────────────────╮
│ Select Test     ⏎↑↓↗         │
│ +APTT                        │
│  c-ACT                       │
│  pt                          │
│                              │
╰─────────────────────────────╯
```

4. Do one of the following:

   a. Select the first test.

   b. Use the down and up arrows to scroll through the test selection list.

   c. Press the first letter of the required test to skip through the test selection list to the assays beginning with that letter.

5. The selected test will be displayed in uppercase characters.

6. Press **ENTER.** If high and low values for a Level I, II, or III control range have been set, the analyzer will display those values in seconds. Where values have not been set, the analyzer will display xxxx.x in the field.

```
╭─────────────────────────────╮
│ LEVEL    LOW     HIGH        │
│ I      xxxx.x   xxxx.x       │
│ II     xxxx.x   xxxx.x       │
│ III    xxxx.x   xxxx.x       │
│                              │
╰─────────────────────────────╯
```

7. Press **ENTER** to return to the Select Test menu.

7.1.10. Printing Control Ranges

Settings for control ranges can be printed to an externally attached serial printer from the User Functions.

When a printer is properly attached (section 5.2.6), the analyzer can print the levels and associated high/low range values for every control sample test type.

1. From the Ready screen, press **ENTER.** The Select Function menu will display available user functions.

```
╭─────────────────────────────╮
│ --READY--    mm/dd/yy        │
│              hh:mm ?M        │
│                              │
│  Pass card thru readr        │
│    or press enter            │
╰─────────────────────────────╯
```

2. From the Select Function menu, choose the **Print Control Ranges** option. The PRINT CONTROL RANGES option is displayed in uppercase characters**.**

```
╭─────────────────────────────╮
│ Select Function ⏎↑↓↗         │
│ view qc lockout              │
│ view control ranges          │
│ PRINT CONTROL RANGES         │
│                              │
╰─────────────────────────────╯
```

3. Press **ENTER.** A printout will be generated, by test type, for the associated high and low range values of each defined control sample level. If high and low control range values were not defined, the message, ***NO DEFINED RANGES***, will print.

4. A sample report of the control ranges is shown below.

```
<TEST NAME>

LEVEL     LOW    HIGH
I       xxxx.x xxxx.x
II      xxxx.x xxxx.x
III     xxxx.x xxxx.x
```

7.1.11. Viewing Normal Range Values

When Normal Range Checking is enabled and a valid range has been defined for a specified test and sample type, the analyzer will compare tests results against the high and low range values set in Supervisory Functions.

1. From the Ready screen, press **ENTER.** The Select Function menu will display available user functions.

```
--READY--    mm/dd/yy
             hh:mm ?M

Pass card thru readr
   or press enter
```

2. From the Select Function menu, choose the **View Normal Ranges** option. The VIEW NORMAL RANGES option is displayed in uppercase characters.

```
Select Function ↵↑↓↗
view control ranges
print control ranges
VIEW NORMAL RANGES
```

3. Press **ENTER.** The Select Test menu will be displayed, showing the available test types. A (+) indicates that normal ranges have been set for one or more sample types for the test.

```
Select Test     ↵↑↓↗
+APTT
 c-ACT
 pt
```

4. Do one of the following:

a. Select the first test.

b. Use the up and down arrows to scroll through the test selection list.

c. Press the first letter of the required test to skip through the test selection list to the assays beginning with that letter.

5. Press **ENTER**. The Sample Type menu will be displayed showing the available sample types. A plus (+) sign by the sample type indicates that normal ranges have been set for that sample type. A (+) indicates that normal ranges have been set for that sample type.

```
--Sample type--↵ ↓↗
+CITRATED PLASMA
+citrated wh. blood
 non-cit whole blood
```

6. Use the up and down arrows to scroll through the Sample Type selection menu. The selected sample type will be displayed in uppercase characters.

7. Press **ENTER**.

```
     TTTT Test
    Sample Type
   LOW        HIGH
  xxxx.x     xxxx.x
```

TTTT – Identifies the test name
xxxx.x – Identifies the normal range values set for the test

8. Press **EXIT** to return to the Ready screen, or press **ENTER** to return to the Sample Type menu.

7.1.12. Printing Normal Ranges

Settings for normal ranges can be printed to an externally attached serial printer.

When a printer is correctly attached (section 5.2.6), the analyzer can print the high and low normal range values by test and sample type.

Only test and sample types with defined ranges will be printed.

1. From the Ready screen, press **ENTER.** The Select Function menu will display available user functions.

```
--READY--    mm/dd/yy
             hh:mm ?M

Pass card thru readr
   or press enter
```

2. From the Select Function menu, choose the **Print Normal Ranges** option. The PRINT NORMAL RANGES option is displayed in uppercase characters.

```
Select Function ⏎↑↓↗
view normal ranges
PRINT NORMAL RANGES
view version number
```

3. Press **ENTER.** A report will be printed by test type, showing the low and high values of the defined normal range.

```
<TEST NAME>
<Sample Type>
Low    High
xxxx.x xxxx.x
```

4. If a normal range has not been defined and set for a particular test, the message No DEFINED RANGES will be printed on the report for that test.

7.1.13. Viewing Version Numbers

You can view the version number for the currently installed software.

1. From the Ready screen, press **ENTER.** The Select Function menu will display available user functions.

```
--READY--    mm/dd/yy
             hh:mm ?M

Pass card thru readr
   or press enter
```

2. From the Select Function menu, choose the **View Version Numbers** option. The VIEW VERSION NUMBERS option is displayed in uppercase characters.

```
Select Function ⏎↑↓↗
print normal ranges
VIEW VERSION NUMBERS
view isi values
```

3. Press **ENTER**.

```
SOFTWARE VERSION     ↗
  Application: x.xx
    Bootup:  x.xx
      UART: x.xx
```

4. Press **EXIT** to return to the Ready screen.

7.1.14. Viewing ISI Values

An International Sensitivity Index (ISI) value is used to calculate the International Normalized Ratio (INR). Cascade POC PT test cards are encoded with an ISI value assigned by a World Health Organization (WHO) laboratory, using patient test samples collected in 109 mM (3.2%) citrate tubes.

1. From the Ready screen, press **ENTER.** The Select Function menu will be displayed, showing available User Functions.

```
--READY--    mm/dd/yy
             hh:mm ?M

Pass card thru readr
   or press enter
```

2. From the Select Function menu, choose the **View ISI Values** option. The VIEW ISI VALUES option is displayed in uppercase characters.

```
Select Function ⏎↑↓↗
print normal ranges
view version number
VIEW ISI VALUES
```

3. Press **ENTER.** The screen for the ISI values by sample type will be displayed. When ISI values are set, the analyzer will use these ISI values. If ISI values are not set, they will be read from the card and the analyzer will display "card" by the sample type.

```
Sample ISI            ↗
non-cit blood       card
citrated blood      1.16
citrated plasma     card
```

Card – Indicates that the ISI value has not been set for the sample type

1.16 – Indicates the ISI value set for the sample type

4. Press **EXIT** to return to the Ready screen.

7.1.15. Viewing Mode Configuration

To view the operational mode configuration set by the user, begin at the Ready Screen, and press **ENTER**. The Select Function menu will be displayed showing available User Functions. Due to the four line limit of the display, all options cannot be viewed at one time.

1. From the Ready screen, press **ENTER**.

```
--READY--    mm/dd/yy
             hh:mm ?M

Pass card thru readr
   or press enter
```

2. From the Select Function menu, use the Down Arrow key to scroll down until the VIEW MODE CONFIG option is displayed in upper case letters.

```
Select Function ↵↑↓↗
view version number
view isi values
VIEW MODE CONFIG.
```

3. Press **ENTER**.

```
--MODE CONFIG-- ↵↑ ↗
AUTO PRINT      SSS
operator id     sss
eqc lockout     sss
```

*Note: The SSS denotes the mode status which is either **On** or **Off** except for QC and EQC Lockout which are either **Disable**, **Warning** or **Lockout**.*

By using the up and down arrow keys, the operator is able to view the status of the following options:
• Auto Print
• Operator ID
• EQC Lockout
• Beeper
• QC Printout
• Control Checking
• Normal Checking
• aPTT Ratio
• SI Units
• Modem Comm
• Auto Dialing.

7.1.16. Printing Mode Configuration

Settings for the operational modes configuration can be printed when sent to a correctly attached serial printer (section 5.2.6)

1. From the Ready screen, press **ENTER**.

```
--READY--    mm/dd/yy
             hh:mm ?M

Pass card thru readr
   or press enter
```

2. The Select Function menu will be displayed, showing available User Functions.

```
Select Function ↵↑ ↗
view version number
view isi values
VIEW MODE CONFIG.
```

3. From the Select Function menu, choose the **Print Mode Config.** option.

```
Select Function ↵↑ ↗
view isi values
view mode config.
PRINT MODE CONFIG.
```

4. Press **ENTER**. If a printer is not properly attached to the analyzer, the following screen will appear momentarily.

```
        WARNING
  No Printer Attached
```

5. Press the appropriate key where:

Key	Action
ENTER	Aborts the screen and returns to the Ready screen.
EXIT	Aborts the screen and returns to the Ready screen.
▼	Moves down one item in the list.
▲	Moves up one item in the list.
OTHER KEYS	Sound an error beep and have no effect on the display.

6. If a printer is properly attached to the analyzer when Print Mode Config. is selected from the User menu, the print out will print in the following format after printing the print header.

```
    MODE CONFIGURATION

    Auto Print            On/Off
    Operator ID           On/Off
    EQC Lockout           Disable/Warning/Lockout
    QC Lockout            Disable/Warning/Lockout
    Beeper                On/Off
    QC Printout           On/Off
    Control Checking      On/Off
    Normal Checking       On/Off
    APTT Ratio            On/Off
    SI Units              On/Off
    Modem Communications  On/Off
    Auto Dialing          On/Off
```

7.1.17. Turning System Off

To turn the analyzer off, move the power switch to the OFF/RECHARGE position.

7.2. Basic Test Instructions

The same basic procedure is used to initiate and perform all Cascade POC tests. Differences in the Cascade POC tests can be found in 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.

7.2.1. Getting Ready

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

1. Turn the analyzer on. The analyzer will perform a series of self–diagnostic tests.

2. If the self–diagnostic tests are successfully completed, the Ready screen will be displayed.

```
--READY--    mm/dd/yy
             hh:mm ?M

Pass card thru readr
  or press enter
```

a. If the QC Printout mode is enabled, the analyzer is connected to a serial printer, and the analyzer has successfully completed all self–diagnostic tests, a summary of self–test results will print. If a printer is not attached to the analyzer, the following error message will appear briefly.

```
       Warning!!
  No Printer Attached
  QC self-test results
    are unavailable
```

3. Follow the package insert quality control procedures for the specific test being run.

4. Allow the test card to warm to room temperature while still sealed in its foil pouch.

5. Collect a blood sample as instructed in the test card package insert.

6. Remove the test card from its pouch.

7.2.2. Reading a Test Card

Calibration information for each test card lot is encoded on the magnetic stripe on the back of the Cascade POC test card. This information will be transferred to the analyzer microprocessor when the card is passed through the card reader slot during test initiation.

1. Hold the test card face–forward, with the magnetic stripe toward the back of the analyzer.

2. Pass the card at a steady rate from left to right through the card reader.

If the card has been successfully read, the analyzer will display the next appropriate screen for the test card. If the QC Lockout mode is enabled, and a control sample has not been run within the QC Lockout time period, a warning message will be displayed (section 6.2.5).

Reading a Test Card
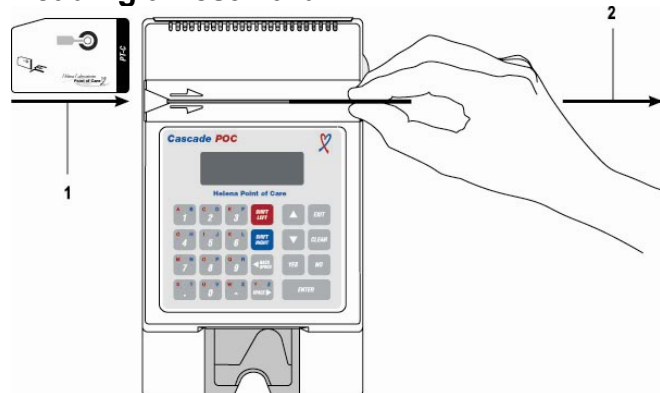
1 Pass through reader slot in this direction.
2 Pull card through reader slot in this direction.

7.2.3. Entering an Operator ID

When the Operator ID mode is enabled (section 6.2.2), the Cascade POC analyzer will require the operator to enter a personal

access code (two to six characters) before running a test. After reading a test card, the analyzer will prompt you to enter your operator identification.

1. On the Operator Identification screen, enter a valid access code. The entered code will be displayed in the Operator Identification field.


```
    Enter Operator  ↗
      Identification

    _____
```
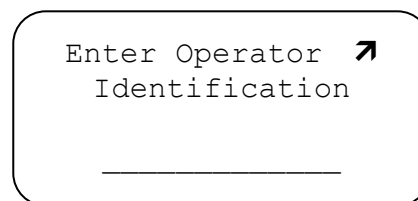
2. Press **ENTER**.

3. When a valid access code is entered, the analyzer will display the prompt, INSERT TEST CARD. If an invalid access code is entered, the analyzer will display the message, UNKNOWN OPERATOR ID. Access will be denied until a valid code is entered and accepted.

7.2.4. Inserting a Test Card
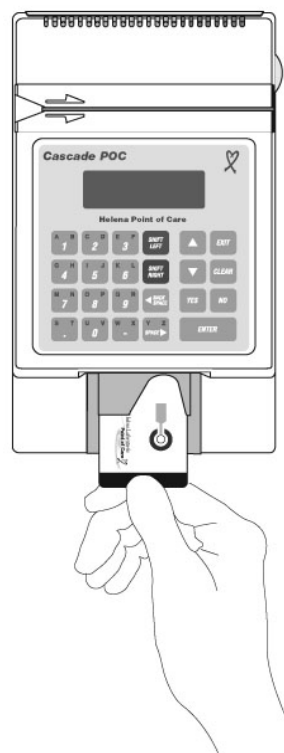
The analyzer will prompt the operator to insert the test card either after entry of the operator

identification code (when required) or after successfully reading a test card. 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.

1. When the prompt, *Insert Test Card*, is displayed, hold the test card face up, leading with the angled corner on the right side of the card.

```
  tttt TEST


INSERT TEST CARD
```
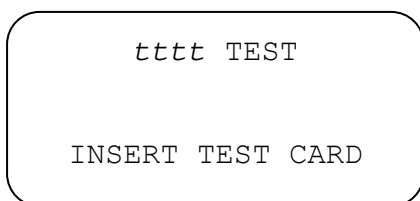
tttt – Identifies the test name

2. Slide the test card completely into the card holder making sure the outside edge of the card rests against the card slot retaining wall.

3. The analyzer will warm the test card to approximately 37°C (body temperature).

Note: If the test card is inserted prematurely into the card slot while the Ready screen is displayed, the message, PLEASE REMOVE CARD, will be displayed.

Note: Do not remove the test card until prompted to do so by the analyzer, or the test will be stopped.

Note: After insertion of the test card, upon being prompted to ADD SAMPLE DROP, avoid intense/direct incandescent lighting above the analyzer. This could cause the analyzer to auto-start prior to the sample drop being added.

*Note: To manually stop a test, press **EXIT** while the Insert Test Card screen is displayed.*

7.2.5. Selecting the Sample Type

After the test card is inserted, the analyzer will prompt the operator to select the sample type being used with the test card. Accurate selection of the sample type is essential to obtain correct test results. Calibration factors can be different for the various sample types available for a test; therefore, invalid test results could be reported if the sample type is incorrectly selected. In addition, using a sample type other than those indicated for a given test can produce invalid results. Data encoded on the back of each test card controls which sample types are available in the sample type menu.

Note: If QC Lockout is set to Lockout for EQC and the conditions necessary to prevent a Lockout have not been met, the EQC test must be performed.

Note: If QC Lockout is set to Lockout for Control Plasma and the conditions necessary to prevent a Lockout have not been met, the only sample type available will be Control Plasma (section 6.2.6).

1. On the Sample Type screen, select the appropriate test sample type. The selected sample type will be displayed in uppercase letters. Scroll through the menu for additional options.

```
-SAMPLE TYPE-   ↵↑↓↗
CITRATED PLASMA
citrated wh. blood
control plasma
```
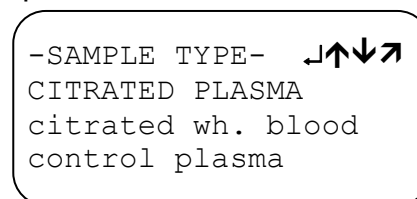
2. Press **ENTER**. One of the following will occur:

a. If a test sample type other than a control is selected, the analyzer will prompt the operator to enter the patient identification before running the test (Section 7.2.6).

b. If control plasma is selected, the Level Select menu will be displayed.

```
Select Level    ↵↑↓↗
Level II
Level III
CUSTOM ID
```
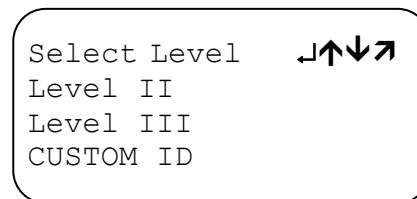
3. Select either a Control Level or Custom ID. With a Custom ID, the operator can run

```
    tttt TEST        ↗

  Enter Custom ID


  _____
```
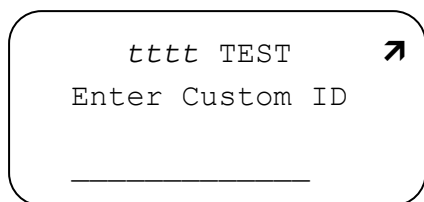
_____ – Identifies the Custom ID entry field
tttt – Identifies the test name

4. If you selected Custom ID, enter a control identifier for the Custom ID and then press **ENTER**. The Custom ID can be up to 20 alphanumeric characters long.

Note: If Custom ID is selected, range checking by Level will be *bypassed, and QC Lockout status will not be affected.*

7.2.6. Entering Patient Identification

After a sample type (other than a control) is selected for a test, the analyzer will prompt the operator to enter up to 20 alphanumeric characters to identify the patient on whom the test is being run. The test being run will be linked to the entered Patient ID.

1. On the Patient Identification screen, enter the patient's name or a unique identifier for the patient.

```
    tttt TEST        ↗
  Enter Patient ID
  _____
  ↑  Previous ID
```
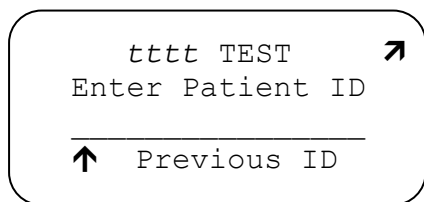
_____ – Identifies the Patient ID entry field
tttt – Identifies the test name

2. The entered identifier will be displayed in the patient identification field.

3. If a test has been performed and the results stored, and if it was not a control sample, the ↑ symbol will be displayed. Pressing the ▲ key reenters the Patient ID from the previous test in the current test's patient identification field.

*Note: To manually stop a test, press **EXIT**. The analyzer will display the Ready screen.*

4. Press **ENTER**. The patient identification is accepted, and the analyzer will display the message, WARMING CARD...PLEASE WAIT.

Note: The analyzer will warm the test card for 20 seconds before it is ready for the sample to be added. If more than 20 seconds have elapsed between inserting the card and entering the patient identification and sample type, the message, Warming Card ... Please Wait, will not be displayed.

7.2.7. Adding a Sample Drop
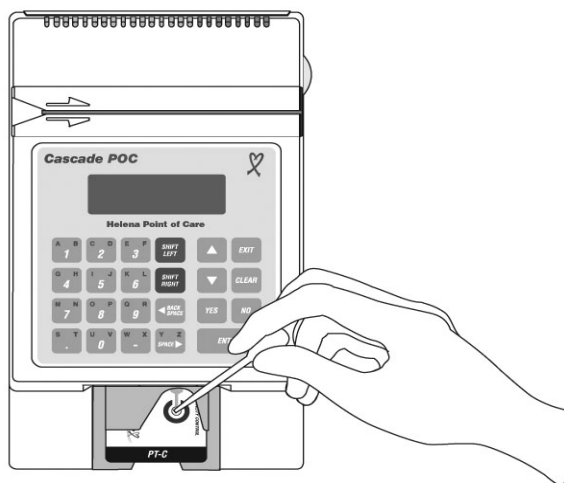
Note: One of the following methods is recommended to withdraw the sample from a citrated collection tube:

• Carefully remove the rubber stopper from the collection tube, using a device designed to minimize the formation of aerosols. Use a transfer pipette or other 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 an attached syringe. Slowly aspirate 0.1 mL 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.

1. If a whole blood sample is being tested, invert the sample several times.

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

2. When the analyzer displays, *Add Sample Drop*, add approximately 30 to 35µL (0.030 to 0.035cc) of sample to the sample well on the test card.

```
╭─────────────────────────╮
│      tttt  TEST         │
│                         │
│                         │
│    ADD SAMPLE DROP      │
│                         │
╰─────────────────────────╯
```
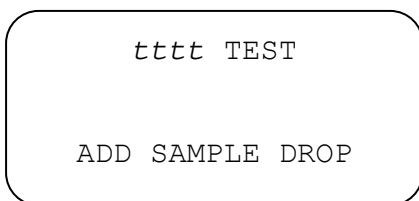
tttt – Identifies the test name

3. The sample drop will automatically enter the reaction chamber on the test card, and the analyzer will automatically detect the presence of the sample and emit an audible beep when the testing begins.

```
╭─────────────────────────╮
│      tttt  TEST         │
│                         │
│   TEST IN PROGRESS      │
│   ■                     │
╰─────────────────────────╯
```
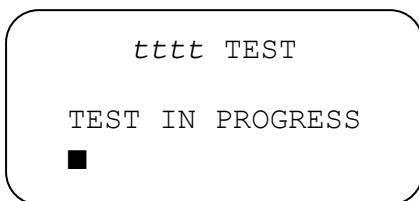
tttt – Identifies the test name

4. A moving cursor will be displayed beneath the message, TEST IN PROGRESS, while most tests are being performed. The test time in seconds will be displayed in place of the moving symbol for c-ACT.

7.2.8. Reviewing Results

When the appropriate endpoint of a test is reached, the analyzer will emit an audible beep and prompt the user to remove the test card from the instrument. If a problem is encountered in determining the test result, a diagnostic message will be displayed (section 7.2.10).

Refer to the test card package insert for Interferences and Limitations.

7.2.9. Endpoint of test

1. When prompted by the analyzer, remove the test card from the instrument.

```
╭─────────────────────────╮
│      tttt  TEST         │
│                         │
│    TEST COMPLETE        │
│   please remove card    │
╰─────────────────────────╯
```
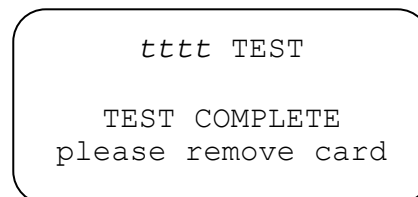
tttt – Identifies the test name

2. Verify that a sufficient amount of sample was added to the card.

3. 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 (section 8.5.1).

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

7.2.9.1. Range Checking

When control plasmas are run in Control Plasma Mode, the Range Checking screen will be displayed after removing the test card from the analyzer.

• 　　If control ranges have been set and control range checking enabled, using the Supervisory Functions menu, one of the following screens will be displayed:

```
╭────────────────────────╮  ╭────────────────────────╮
│   control plasma       │  │   control plasma       │
│  Result in range       │  │  RESULT OUT OF RANGE   │
│  xxxx.x to xxxx.x      │  │   xxxx.x to xxxx.x     │
│ Hit any key to cont.   │  │ Hit any key to cont.   │
╰────────────────────────╯  ╰────────────────────────╯
```
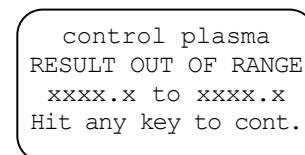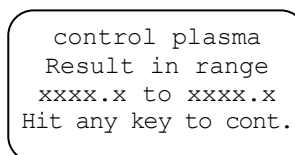
7.2.9.2. Viewing Test Results

Test results will be displayed next on one of the following analyzer screen formats:

```
╭──────────────────────╮  ╭──────────────────────╮
│   tttt Test   ↓↗    │  │   tttt Test   ↓↗    │
│ Clot Time=sss.s sec  │  │  Lysis Onset Time    │
│    inr=xx.xx         │  │     < ss sec         │
│   range check*       │  │                      │
╰──────────────────────╯  ╰──────────────────────╯
```
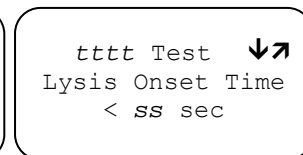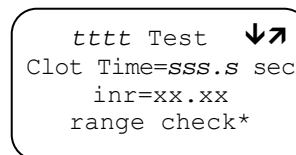
tttt – Identifies the test name
sss.s – Identifies the time in seconds

xx.xx – Identifies a numerical value
range check* – Identifies the range check message

Note: There are three possible range check messages:

• result in range

• result out of range

• not range checked

Note: INR values are displayed for the PT–WB and PT–C tests.

Note: Ratios are also displayed with aPTT results if the aPTT ratio function is enabled, using Supervisory Functions.

Note: Ratios are available only for the aPTT test. An INR is available only for PT–WB and PT–C tests.

1. Use the cursor and display movement keys to review additional information about the test performed, such as test card lot number, sample type selected, patient ID, or control level/custom ID, if a control test was run.

```
Card Lot #xxxxxx ↓↗          Card Lot #xxxxxx ↓↗
     sample type                  sample type
     Patient ID:                  Patient ID:
     Smith, John                    Level X
```
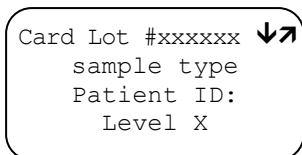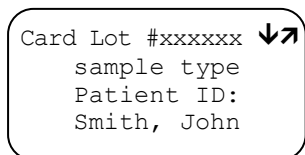
xxxxxx – Identifies the test card lot number
X – Identifies the control level or Custom ID

2. If the Auto Print mode is enabled and the analyzer is correctly connected to a printer, the analyzer will automatically print the test record.

3. After reviewing the information and ensuring that the patient ID and sample type have been accurately recorded, press **EXIT.**

4. The analyzer will return to the Ready screen.

7.2.10. Irregular Test Results

Irregular test results are sometimes encountered when endpoints are outside the expected limits for a test. If this occurs, a diagnostic message will be displayed on the analyzer screen. The operator should repeat the test to verify the result.

7.2.10.1. Irregular Result

If a test endpoint is found to be outside the defined range, the message, IRREGULAR RESULT, will be displayed.
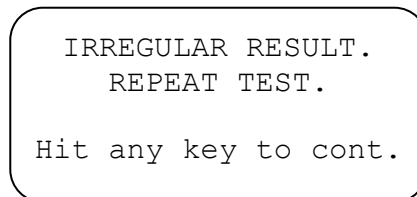
```
IRREGULAR RESULT.
   REPEAT TEST.

Hit any key to cont.
```

After pressing any key, one of the following results screens will be displayed:

```
 tttt Test    ↓↗            tttt Test   ↓↗
Clot Time < ss sec         Lysis Onset Time
                                < ss sec
   INR = ***.**
```
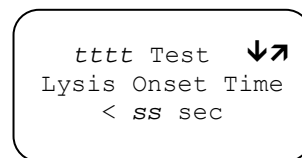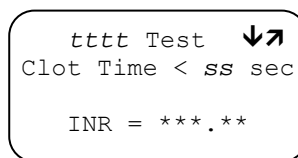
tttt – Identifies the test name
ss – Identifies a time in seconds
***.** – Identifies a numerical value out of range

Use the cursor to scroll through irregular results information. The operator should repeat the test to verify the result.

7.2.10.2. No Clot Found

If the sample has insufficient intact fibrinogen to form a detectable clot, the message, NO CLOT FOUND, will be displayed in tests whose endpoint is the onset of clot lysis*.

```
                        ↗
     NO CLOT FOUND
  NO RESULT TO REPORT.
```
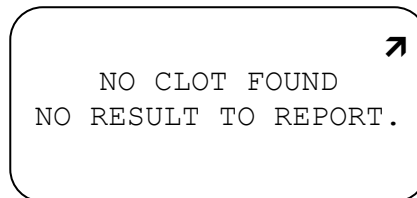
After pressing any key, the analyzer will return to the Ready screen. Repeat the test to verify the result.

7.2.10.3. Possible Error

If no test endpoint is found and the test time has exceeded the defined range of the test, the message, POSSIBLE ERROR, will be displayed.

```
    POSSIBLE ERROR.
  REPEAT TO VERIFY.

 Hit any key to cont.
```

After pressing any key, one of the following results screens will be displayed:

```
  tttt Test    ↓↗
Clot Time > sss sec

   INR = ***.**
```

```
  tttt Test    ↓↗
Lysis Onset Time
    < ss sec
```

tttt – Identifies the test name
sss – Identifies a time in seconds
***.** – Identifies a numerical value out of range

Use the cursor to scroll through irregular results information. Repeat the test to verify results.

7.2.10.4. Control Sample Out of Range

When Control Range checking is enabled, control ranges are defined and the results of a control sample fall outside the expected range, the message, RESULT OUT OF RANGE, will be displayed.

```
      Level X
RESULTS OUT OF RANGE
   xxxx.x to xxxx.x
 Hit any key to cont.
```

X – Identifies Control Level I, II, or III
Xxxx.x to xxxx.x – Identifies high and low values for the control range

After pressing any key, the following results screen will be displayed:

```
   tttt Test    ↓↗
Clot Time=sss.s sec

    OUT OF RANGE
```

tttt – Identifies the test name
sss.s – Identifies a time in seconds

Use the cursor to scroll through irregular results information. Repeat the test to verify the result.

Test	Upper Limit Timeout
aPTT	300 seconds
PT	150 seconds
c-ACT	850 seconds

7.2.10.5. Custom ID

If Custom ID is selected instead of a control level, the following screen will be displayed:

```
   tttt TEST     ↓↗
Clot Time=sss.s sec

  Not range checked
```

Note: If Custom ID is selected, range checking by Level will be bypassed, and QC Lockout status will not be affected.

7.3. Low Battery Conditions

1. As an internal quality control measure, the analyzer will verify 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 analyzer will provide an audible warning and flash the following message on the Ready screen every 10 seconds until the battery is recharged.
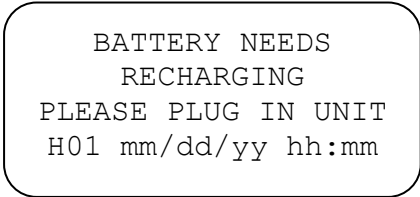
```
 ***BATTERY LOW***
            10:44AM

Press card thru readr
   or press enter
```

2. When this message is displayed, turn the analyzer Off and then connect it to the Cascade POC Power Supply, and turn it back On.

3. The battery will gradually recharge from the power supply while running. To recharge more efficiently, turn the analyzer

Off, connect it to the power supply, and allow it to recharge for at least 12 hours.

4. If the analyzer is not recharged after the initial warning is displayed, the following message will be displayed, after which the analyzer can no longer be used without recharging the battery.

```
      BATTERY NEEDS
       RECHARGING
  PLEASE PLUG IN UNIT
   H01 mm/dd/yy hh:mm
```

5. If the battery power has become so low that the analyzer is unable to turn on or check the power level, the analyzer will demonstrate noticeably erratic behavior with blank or incomplete displays and will not allow test initiation. Recharge the battery as described above.

6. Do not allow the battery to become com-pletely discharged. An excessively discharged battery can lose capacity when recharged.

Section 8 – Test Functions and Quality Control

8.1. Quality Control

The Joint Commission on Accreditation of Health Care Organizations recommends that medical and laboratory instrumentation be enrolled in a quality assurance program that adequately maintains accurate and reliable performance of the equipment. Complete records of such quality control must be kept.

Quality control testing for the Cascade POC Analyzer should be performed regularly by the operator. Cascade POC 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.

Functional testing requirements vary by the test being performed. See the package insert provided with the Cascade POC test cards for specific instructions on the test that is being performed.

The relationship of the results obtained by the Cascade POC Analyzer and results from any other methods used should be established by the operator 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 Cascade POC Analyzer 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.

8.2. Calibration

The analyzer 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 magnetic stripe 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.

8.3. Instrument Self–Tests

When the analyzer is turned on, it automatically performs a series of self–tests to verify hardware integrity. The Self Test screen increments the test number *(nn)* as it successfully completes each test.

```
   Cascade POC
    Analyzer
   Performing
  Self Test    nn
```
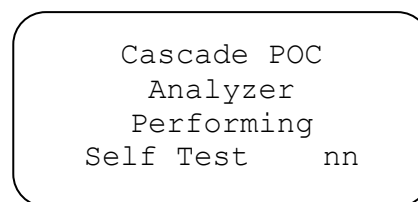
nn – Identifies the self-test number

After completion of the instrument self–tests, a screen with the analyzer software version will appear briefly before the Ready screen is displayed. If an instrument self–test fails, an error message will be displayed (section 10.2).

Note: If the analyzer is kept on continuously, the operator should periodically turn it off and on again as part of routine quality control procedures to ensure that the instrument self–tests are performed regularly. This should also be done if analyzer performance problems are suspected.

8.4. Diagnostic Messages

While the analyzer is in use, it continuously monitors certain conditions and issues error messages when these conditions are abnormal (section 10.2).

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

• Room 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

8.5. Operator Quality Control Procedures

Quality control testing for the analyzer 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.

Quality Control Timetable Test Method Quality Control

Quality Control Procedure	Schedule
Test Card Validation	Each Test.
Date and Time Verification	Each Test.
Sufficient Sample Verification	Each Test.
Sample Type Verification	Each Test.
Functional Testing with Control Plasma	See the package inserts provided with the test cards for test–specific instructions.
Reference Range Establishment	Verify when changing test card lots. See the package inserts provided with the test cards for test–specific instructions.

8.5.1. 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

8.5.2. 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).

8.5.3. 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 6.4.

8.5.4. 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

Cascade POC test cards do not require as much precision in sample dispensing as conventional methods – the reaction chamber is self–filling and self–limiting. One large drop (approximately 30 to 35 µL) of sample should be sufficient to fill the reaction chamber.

8.5.5. 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 7.2.5). Selection of the proper sample type is critical in order to achieve valid test results.

The sample type is displayed on the second screen of the patient test result.

```
Sample Type:        ↗
    control plasma
result=37.4 sec.
```
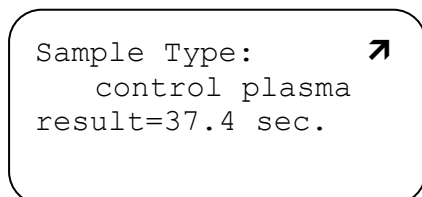
control plasma – Identifies the self-test number

8.5.6. Functional Quality Control Plasma

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

Functional testing requirements vary according to the test being performed. See the package insert provided with the Cascade POC test cards for specific instructions on the test that is being performed.

8.5.7. Reference Range Quality Control

The relationship between the results obtained by the analyzer and the results obtained by any other test methods used should be established by the operator when changes in test card lots, reference methods, or reference reagent lots occur.

Establishment of reference ranges vary by the test being performed. See the package insert

provided with the test cards for specific instructions on the test being performed.

8.6. EQC (Electronic Quality Control) Test Card

8.6.1. 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 Cascade POC 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 Cascade POC analyzer, Version 4.58 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 magnetic stripe of the EQC test card. As on all Cascade POC test cards, the magnetic stripe 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 analyzer on initiation of a test. Unlike other Cascade POC test cards, an expiration date is not encoded on the magnetic stripe on the back of the EQC test card. After first use, the EQC test card can be used for up to six months.

CAUTION: *Exposure of the EQC test card at any time to magnetic objects or fields, such as Magnetic Resonance Imaging (MRI), can*

corrupt the encoded information and prevent the analyzer from performing the test.

8.6.2. 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.

8.6.3. EQC Testing Procedure

No preparation of the EQC test card is necessary before initiating a test. All necessary calibrations are magnetically encoded on each EQC test card. Please refer to previous sections of this manual for details of instrument use.

Materials Required
• Cascade POC EQC Test Card
• Cascade POC Analyzer
• Cascade POC Software (Version 4.58 or higher)
• Cascade POC Operator's Manual

1. At the Ready screen, pass the EQC test card, from left to right through the card reader as described in Section 7.2, *Basic Test Instructions.* The EQC Test screen will be displayed.

```
    EQC TEST          ↗


   INSERT TEST CARD
```
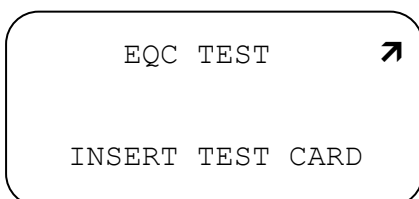
2. When prompted, insert the EQC test card. The analyzer will warm the card before performing the EQC test.

```
    EQC TEST


  WARMING CARD...
    PLEASE WAIT
```
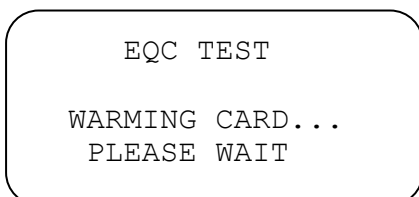
3. When the card is warmed, the EQC test will automatically begin.

```
    EQC TEST


  TEST IN PROGRESS
  ■
```
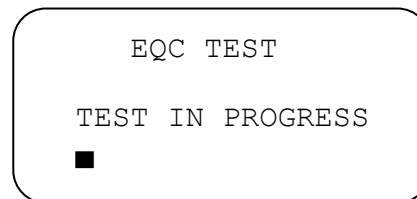
4. At the end of this test, Level 1 clotting time (CT) and signal strength (Signal) will be displayed on the screen. The CT results represent the clotting time returned by the algorithm analyzing the AC signal collected from the EQC test card.

```
    EQC TEST
 RESULT1  CT=NNN.N sec
     Signal=MMM
  ENTER FOR RESULT2
```
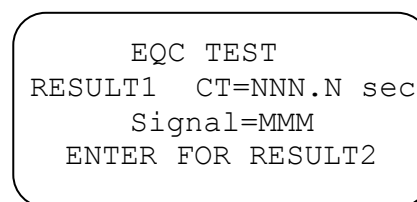
CT – Identifies the clotting time
NNN.N – Identifies the time in seconds
MMM – Identifies the optical signal strength

5. Press **ENTER** to obtain Level 2 clotting time and signal strength. The EQC TEST IN PROGRESS screen will display. At the end of this test, Level 2 EQC clotting time and signal strength will be displayed.

```
    EQC TEST
 RESULT2  CT=NNN.N sec
     Signal=MMM
  ENTER FOR RESULT3
```
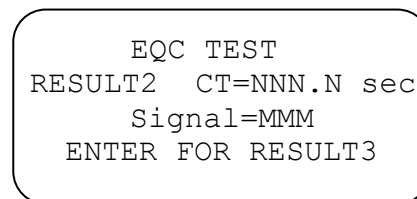
6. Press **ENTER** to obtain Level 3 clotting time and signal strength. The EQC TEST IN PROGRESS screen will display. At the end of this test, Level 3 EQC clotting time and signal strength will be displayed.

```
    EQC TEST
 RESULT3  CT=NNN.N sec
     Signal=MMM
  ENTER TO CONTINUE
```
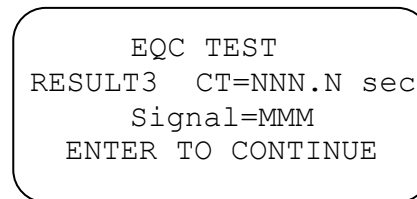
7. Press **ENTER**. If the tests pass, the following screen will be displayed:

```
    EQC TEST

   TEST PASSED
 please remove card
```

8. When prompted, remove the EQC test card. The Ready screen will be displayed.

8.6.4. Failed EQC Test

As each level of the test is completed, the actual result will be verified by the analyzer. If any of the three tests fails, the following message will be displayed:

```
    EQC TEST FAIL
 RESULT r CT=NNN.N sec
      Signal=MMM
   ANY KEY TO EXIT
```

r – Identifies the result level (1, 2, or 3)

Note: If the POC reaches its limit of test data storage, an internal storage error can occur and it may not read the EQC card. See Section 6.3.5 for clearing stored test records.

1. Press any key. The following screen will be displayed:

```
    EQC TEST

   TEST FAILURE

 please remove card
 C06 MM\DD\YY MM:HH
```

2. When prompted, remove the EQC test card. The Ready screen will be displayed.

3. 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 tests fail, do not report any patient test results obtained from Cascade POC tests before contacting a

supervisor or your local technical support provider or distributor, and the test failure is resolved.

8.6.5. Interpretation of EQC Test Results

The clotting time results for periodic testing with the EQC test card should fall within the reference ranges shown in the following table. The Cascade POC analyzer will automatically report an error message if either the clotting time or the optical signal strength values is out of range.

EQC Test	Maximum error (sec)	% Error	Acceptable range (sec)
1	0.9	3.0	29.1–30.9
2	2.7	3.0	87.3–92.7
3	8.1	3.0	261.9–278.1

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.

8.6.6. Viewing Test Result Records

The View Patient Records user function displays (and prints) EQC test records stored in the analyzer. Test records can be printed if the analyzer printer option is enabled (section 7.1.6.2).

1. From the Ready screen, press **ENTER**. The Select Function menu will be displayed, showing available user functions.

```
 Select Function ↵ ↓↗
 VIEW PATIENT RECS
 set date/time
 view pt normal
```

2. From the Select Function menu, choose the **View Patient Recs** option. The VIEW PATIENT RECS option will appear in uppercase characters when selected.

3. Press **ENTER**. The View By menu will be displayed.

```
--View By--        ↵↑↓↗
all records
patient id
TEST NAME
```

Note: EQC results can also be viewed by selecting ALL RECORDS or SAMPLE TYPE.

4. Choose the **Test Name** option. The TEST NAME option will be displayed in uppercase characters when selected.

5. Press **ENTER**. The Select Test menu will be displayed. This menu lists in alphabetical order all of the test types currently stored in analyzer memory.

```
-Select Test-  ↵↑ ↗
atlo*
ect
EQC
```

6. Scroll up or down through the selections, using the up and down arrow keys, until EQC is displayed in uppercase characters.

7. Press **ENTER**. The Target CT (clotting time) and Target Signal (S) for Level 3, the last test run, will be displayed.

```
006-006 EQC      ↑ ↗
mm/dd/yy   hh:mm  ?M
TARGET  CT=270  S=59
p-print all   ↵-more
```

006/006 – The sixth record of six total records
CT – Clotting time
S=59 – Signal strength

8. Press **ENTER** to view Level 3 actual test results.

```
    TEST PASSED    ↗
      Signal=152
  Clot Time=269.8 sec.
  press p to print rec
```

9. Press **EXIT** to return to the Level 3 Target Results screen. Use the down arrow to view Level 2 Target Results.

```
005/006 EQC      ↵↑↓↗
 mm/dd/yy   hh:mm ?M
TARGET  CT=90  S=59
 p-print all ↵-more
```

10. Press **ENTER** to view Level 2 actual results.

```
    TEST PASSED    ↗
      Signal=192
  Clot Time=89.9 sec.
  press p to print rec
```

11. Press **EXIT** to return to the Level 2 Target Results screen. Use the down arrow to view Level 1 Target Results.

```
004/006 EQC      ↑↓↗
 mm/dd/yy   hh:mm ?M
 TARGET  CT=90  S=59
 p-print all ↵-more
```

12. Press **ENTER** to view Level 1 Actual Results.

```
    TEST PASSED    ↗
      Signal=233
  Clot Time=29.8 sec.
  press p to print rec
```

13. Press **EXIT** two times to return to the Ready screen.

Section 9 – Performance Specifications

Width: 152 mm (6 in)

Height: 100 mm (3.9 in)

Length: 265 mm (10.5 in)

Weight: 1.9 kg (4.25 lb)

Fuses:
  F1: 2.5A, 125V, Fast Acting
  F2: 2.0A, 125V, Fast Acting

Internal Battery Power:
  6V, 5.0 AH, lead acid battery

External Power Supply:

  Cat. No.: 5812
    Input: 120 VAC, 60Hz   (+\-10%)
    Output: 7.1 VDC

  Cat. No.: 5813
    Input: 230V VAC, 50Hz (+\-10%)
    Output: 7.1 VDC

Temperature Regulation:
  37 ±0.3°C (98.6 ±0.5°F)

Operating Temperature Range:
  18–32°C (64.4–89.6°F)

Storage and Shipping Temperature:
  5–40°C (41–104°F)

Pressure: 500–1080 hPa

Humidity: 35-70%, non-condensing

Altitude: Up to 2,000 meters

Installation Category: II

Pollution Degree: 2

Equipment Class: I

Section 10 – Maintenance, Troubleshooting, Warranty

10.1. Maintenance

The Cascade POC runs a series of self tests upon start-up to verify that the analyzer is functioning properly.

External maintenance (cleaning) to the analyzer is described in Section 3.

10.2. 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 tables list other symptoms and possible fault conditions and causes (Table 10–2, Prompts and Error Messages).
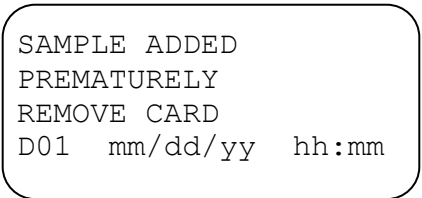
The analyzer will notify the operator both visually and audibly if a problem occurs while operating the instrument. The analyzer continuously monitors for conditions that can cause invalid results and will stop a test, if necessary.

Diagnostic messages are provided on the analyzer display. If an error code is associated with the message, it will be displayed in the lower left corner of the screen as three alphanumeric characters.

```
SAMPLE ADDED
PREMATURELY
REMOVE CARD
D01  mm/dd/yy  hh:mm
```

SAMPLE ADDED – Diagnostic message
D01 – Error Code

If the analyzer displays a diagnostic message, note the error code and see Table 10-2 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.

Table 10–2 Prompts and Error Messages

Message	Possible Cause(s)	Action Required
B*nn* System Failure Call Distributor	Main Memory Failure.	Note error code and call Helena Laboratories. Reinstall Software.
B11 System Failure *nnnn** corrupted results *(*nnnn* = no. of corrupt files)	Five (5) or more corrupt records were detected.	Note error code and call Helena Laboratories.
C01 Invalid Card Data Hit any key to cont.	The inserted card is not recognized as a valid Cascade POC test card.	Press any key to continue. Repeat test, using a new card. If error continues, call Helena Laboratories.
C02 Invalid Card Data Hit any key to cont.	The title of the Cascade POC test card could not be read.	Press any key to continue. Attempt to read the card again, or replace with a new card. If error continues, call Helena Laboratories.
C03 Invalid Card Data Hit any key to cont.	The Cascade POC test card contains an unknown title.	Press any key to continue. Repeat test, using a new card. If error continues, call Helena Laboratories.
C04 Warning! Card Expired on *mm/dd/yy*	The expiration date has passed on the Cascade POC test card.	Press any key to continue. Verify system date and time. Remove the test card and repeat the test using a new card from a lot that has not expired.
C05 Invalid Card Data Hit any key to cont.	The Cascade POC test card contains invalid data.	Press any key to continue. Repeat test, using a new card. If error continues, call Helena Laboratories.
C06 Please Remove Card	A Cascade POC 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 prematurely Hit any key to cont.	A sample was added to the Cascade POC test card before the analyzer displayed the ADD SAMPLE DROP prompt.	Press any key to continue. Repeat test, using a new card, and add the sample only when prompted by the analyzer.
D02 Card has been removed	A Cascade POC test card was removed from the analyzer before the sample was added.	Press any key to continue. Repeat test, using the same card.
D03 Test Aborted Card removed Hit any key to cont.	A Cascade POC 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.

Message	Possible Cause(s)	Action Required
G01 No Signal From Sample Remove card to cont.	The analyzer received a false "start test" signal.	Remove the test card to continue. Repeat test, using the same card.
G02 Signal Too Large Test Aborted Remove card to cont.	The analyzer signal is larger than the predetermined threshold. This condition could occur with samples that have unexpected physical properties or unusual chemical properties.	Remove the test card to continue. Repeat test, using a new card and the same sample. If a repeat test also fails, obtain a new sample and re–test using a new card.
G03 Could Not Set Gain Remove card to cont.	The analyzer detects an unusual reading from the test card (the card may have been stored improperly).	Remove the test card to continue. Repeat test, using a new card. If the error continues, call Helena Laboratories.
H01 Battery Needs Recharging Please Plug in Unit	Battery voltage is below 5.8 volts.	See section 7.3 .
Inn* System Failure. Call Distributor *(nn = 01–18)	Internal hardware failure.	Note error code and call Helena Laboratories.
Irregular Result Repeat Test Hit any key to cont.	A test endpoint is found to be outside the expected test limits (see section 7.2.10).	Press any key to display the results screen. Repeat the test to verify test results.
M03 Modem not responding Hit any key to cont.	Modem did not respond to the "modem present" command, sent by an analyzer.	Hit any key.
M04 Modem Error Received Hit any key to cont.	Unexpected modem response.	Hit any key.
M05 Modem Error While Connecting	Modem responded with an error during the connection attempt.	Hit any key.
M06 Modem could not connect Hit any key to cont.	Connection attempt failure.	Hit any key.
Memory Error *n** corrupted results deleted from memory Hit any key to cont. *(*n* = number of records).	Less than five (5) corrupt records detected.	Hit any key.
K01 System Failure Call Distributor		Note error code and call Helena Laboratories.

Message	Possible Cause(s)	Action Required
No Clot Found No Result to Report Hit any key to cont.	Test endpoint is the onset of clot lysis*. The sample has insufficient intact fibrinogen to form a detectable clot (see section 7.2.10).	Press any key to return to the Ready screen. Repeat the test to verify results.
Possible Error Repeat to Verify Hit any key to cont.	No test endpoint is found within the maximum test time limit (see section 7.2.10).	Press any key to display the Results screen. Repeat the test to verify results.
Q03 System Failure Call Distributor		Note error code and call Helena Laboratories.
Rnn Remote Diagnostic test *nn* failed Call Distributor	The specified remote diagnostic test failed.	Note error code and call Helena Laboratories.
T01 Ambient Temp Too High Turn Off Then On.	The ambient temperature is too high for analyzer operation.	Turn off the analyzer, move to a cooler area (see section 5.2.1), and turn the analyzer back on (it may be necessary to let the analyzer cool before using it again).
T02 Heater Malfunction Turn Off Then ON	Internal hardware failure.	Turn the analyzer off and then back on. If the error message continues, turn the analyzer off and call Helena Laboratories.
T03 Heater Timeout Turn Off Then On	The ambient temperature is too low for operation of the analyzer (see section 5.2.1). It may be necessary to allow the analyzer to warm for a short time before it can be used.	Turn the analyzer off, move the unit to a warmer area, and turn the unit back on.
U02 Serial Port Failure Call Distributor	A hardware failure has occurred on the analyzer's serial port.	Note the error code and call Helena Laboratories.
U03 Serial Port Failure Call Distributor	A hardware failure has occurred on the analyzer's serial port.	Note the error code and call Helena Laboratories.
Analyzer starts test without sample being applied	Card may have been moved after it was inserted or intense/direct incandescent lighting above the analyzer	Reposition unit. Repeat the test to verify results.
The Analyzer Instrument will not read EQC card.	The POC has reached the limit on data storage.	Clear the stored test records.

10.3. 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 or 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 11 – 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, heat hazard – allow heated components to cool before handling
⚠	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
⏚	Ground (earth) terminal
⏚	Protective conductor terminal (grounded conductors)
⏛	Frame or chassis terminal
▽	Equipotentiality (conductor with all parts at a single potential)
│	On (power switch)
○	Off (power switch)
▣	Equipment protected throughout by double insulation or reinforced insulation (equivalent to Class II of IEC 536)
EC REP	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
☣	Caution, biohazard: this symbol applies where potential biohazards exist and universal precautions should be exercised.

Section 12 – Index

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**Section 13 – Supervisor's Code -
Accessing the Supervisory Menu**

The Cascade POC Analyzer Supervisory
Function Code is provided within this section,
separate from the instructions for the Super-
visory Menu (section 6), so that customers
have the option to remove this information
from the Operator's Manual and control
distribution of the code.

To access the supervisory menu:

1. From the Ready screen, press the follow-
ing key sequence in rapid succession:

   a. EXIT

   b. 14139

   c. ENTER

2. The supervisor's code has been success-
fully entered when the following screen
displays:

```
--Select one-- ↵ ↓↗
SET OPERATOR ID ON
set auto print on
set qc printout on
```

3. If key sequence is not done rapidly, the
following screen displays:

```
Select Function ↵↓↗
View Patient RECS
Set date/time
New pt normal
```

These are user functions. Select exit and
repeat the key sequence in Step 1 faster.

4. See section 6 for further instructions.

$$C\!\epsilon$$

Cascade® POC

Catalog Number 5810 and 5811

Software Version 4.58

Operator's Manual

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

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EC REP

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