CRITICAL DIAGNOSTICS

ASPECT Reader™

User Guide - English

Software Version 1.1.0

UG0001 - EN
AW201127 Rev. 2

March 2015

Before You Begin

Several important sources of information are available to help get you started and to refer to as needed to ensure accurate test results. Before using this system, read this entire User Guide and the package insert that comes with the ASPECT-PLUS™ ST2 corresponding test. Take special note of WARNING CAUTION NOTICE throughout this User Guide.

Important Safety Instructions

- Follow proper infection control guidelines for handling all blood samples and anything that comes in contact with blood.
- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.
- Users should adhere to standard precautions when handling or using this device. For more information, refer to "Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007", http: www.cdc.gov/hicpac/2007ip/2007isolationprecautions.html

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ASPECT Reader SERIAL NUMBER: _____

Distributor to Call When Ordering Supplies

NAME: _____

CONTACT INFORMATION: _____

To reorder supplies, contact your Critical Diagnostics distributor:

Product Name	Part Number	Description
ASPECT-PLUS ST2 Test	PLUS0001	ST2 Test (20 cassettes) with (1) Test buffer
ASPECT Reader	READ0001	Complete reader system
ASPECT Reader Paper	PAP0001	Paper roll for ASPECT Reader (5 rolls)
ST2 Controls	LQC0001	ST2 liquid quality controls, Level 1 and Level 2 (2 high, 2 low)
Electronic Quality Control	EQC0001	ASPECT Reader EQC cassette (1 cassette)

User Guide Overview

INTRODUCTION contains a brief description of the features and theory of operation of the ASPECT Reader. It also contains some basic information about interface controls such as keyboard keys and data entry fields and their use in the software.

INSTALLATION contains information about the unpacking and set up, as well as specifications and warranty information about the reader.

INITIAL SET-UP contains information about setting up general reader settings, LIS and Network settings, as well as setting up user access rights and viewing and/or printing error logs.

OPERATION contains detailed information about running samples on the ASPECT Reader and menu items found under the Operator icon.

REVIEW DATA contains information about reviewing patient results, as well as viewing liquid and electronic quality control results. Information about printing results and sending patient results, liquid and electronic quality control results to a LIS system is contained in this chapter.

CONTROLS contains information about setting up and running controls.

MAINTENANCE contains information about routine maintenance of the ASPECT Reader.

TROUBLESHOOTING contains information about troubleshooting the reader.

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INTRODUCTION

Welcome

Congratulations on the decision to test with the ASPECT Reader System by Critical Diagnostics. This user guide will provide useful information on performing tests with this system.

System Overview

The ASPECT Reader System is a semi-automated bench- top reader intended for use with cassette-based immunofluorescent in-vitro diagnostic assays. Utilizing the principles of lateral flow immunoassay technology, samples are analyzed using a test cassette. The test cassette contains a Radio Frequency ID (RFID) tag that identifies parameters such as test name, calibration coefficients, expiry date, Sample/Reagent Assembly (SRA) type. After the test cassette is loaded with a specimen it is inserted into the reader. An internal scanner reads the RFID tag and automatically processes the test. Internal software interprets and reports the test results which are displayed on the screen, where they can be printed and/or electronically exported.

Test specific information is stored on the RFID tag. No upload of any test-related information is required prior to performing a test.

Intended Use

The ASPECT Reader is a benchtop instrument intended to be used with lateral flow cassette-based immunofluorescent in vitro diagnostic assays manufactured by Critical Diagnostics. The ASPECT Reader is used in the professional laboratory environment.

After the patient sample has been added to the Test cassette, the cassette is placed inside of the ASPECT Reader to be analyzed. The ASPECT Reader will scan the test strip and measure the fluorescent signal by processing the results using method-specific algorithms. The ASPECT Reader will display the test results.

Refer to assay-specific package insert for details on specific tests.

Principles of Measurement

The ASPECT Reader detects a fluorescent-label (TF5: Excitation ~ 650nm; Emission ~ 670nm) in a lateral flow immunoassay (LFI) test format. A pre-determined amount of test specimen is pipetted into the sample well of the test cassette. A buffer solution is pipetted into the second well. The test cassette (called cartridge in the software) is then immediately inserted into the ASPECT Reader for analysis. The reader assembly excites the fluorescent label area of the test cassette then measures the fluorescent signal to generate a quantitative result when processed through the calibration curve algorithm. The analyte result is displayed on the screen where it can be printed and/or exported to a LIS system.

Data Entry Fields

Data entry fields are areas in a screen in which information is entered. One screen can have several data entry fields, but only one field can be selected and active for entering data at a time. Pressing a numeric key will input that character into the data entry field. If the number of characters in a field is exceeded, no additional characters may be entered unless others have been deleted.

To select a data entry field, move the cursor via the [↑] or [↓] keys to move up and down in the screen. To move back and forth between left and right text fields, use the [→] or [←] keys. The content of the field is highlighted to show it is selected or active.

To delete characters from a data field, select the field using the reader's [↑] or [↓] keys, then press the [⇐] Delete key at the bottom of the numeric keys. The last character in the field will be deleted.

System Specifications Table

Power Requirements	100 - 240 VAC, 47- 63Hz, self-switching (U.S./International), 0.9-0.34 Amps max
Replaceable Batteries	4x LR6-AA + 6V⎓ 4.16 A
Ambient Operating Temperature	15 – 30° C / 59 – 86° F
Ambient Operating Humidity Range	30 – 80% R.H. (non-condensing)
Shipping & Storage Temperature	-20 – 55 °C
Shipping & Storage Humidity	30 – 80% R.H. (non-condensing)
Keypad	Numeric
Display	3.5 inch diagonal
Weight	3 lb. (6.6 kg)
Width	6.3 in. (~16 cm)
Depth	9.5 in. (~24cm)
Height	3.9 in. (~10cm)
Radio Frequency (RF) Operating Frequency	13.56 MHz
RF Output Power	200 mW

The ASPECT Reader meets the relevant EC harmonized standards for safety: IEC 61010-1, EN 61010-2-101, CSA 61010-1-04, EN61326-1:2002, EN61326-2-6:2006.

FCC ID:YMQ-8048000 This device complies with Part 15 of the FCC rules. Operation is subject to the following conditions:

1. The device may not cause harmful interference.
2. This device must accept any interference received, including interference that may cause undesired operation.
3. Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Warnings, Precautions, Limitations

Before using this system, read this entire User Guide and the Instructions For Use for the specific test being performed on the ASPECT Reader.

- *For in vitro diagnostic use.*
- For use by healthcare professional.
- Results should be interpreted along with clinical findings and other laboratory test results.
- Individuals assigned to operate this reader must be properly trained and fully aware of the potential hazards when using the ASPECT Reader prior to use.
- Do not place the ASPECT Reader in water.
- Do not drop or throw the reader.
- Operate the reader on a dry, level surface.
- Do not move the reader while a test is in process.
- Plug the reader into a grounded power source.
- The ASPECT Reader was tested and has passed all declared EMC compliance standards. However, the use of ancillary equipment may electromagnetically interfere with this reader. Take precautionary measures to minimize electromagnetic interference where possible.
- Always follow universal precautions when handling patient samples. Wear the proper personal protective equipment such as: lab coats, non-powdered disposable gloves, safety glasses, etc. when working with the ASPECT Reader and patient samples.
- Use of new non-powdered disposable gloves will reduce the risk of cross contamination when handling patient samples.
- All samples, controls, etc. should be treated as though they are infectious.
- Dispose of unused reagents and waste in accordance with Country, Federal, Provincial, State and local regulations.
- Clean all work surfaces before and after testing.
- The ASPECT Reader has been designed to work as a system. Performance characteristics have not been established for use of the system with other supplies or equipment.
- Please note that the infected medical equipment must be disposed of as medical biohazard waste and may not be included in used electronic equipment disposal or recycling program.

The following symbols are used in this guide:

Symbol	Meaning
WARNING	The term WARNING is used to inform you about situations or conditions that could result in personal injury.
CAUTION	The term CAUTION is used to inform you about situations or conditions that could result in damage to the ASPECT Reader or related components.
NOTICE	Indicates warnings that are not related directly to personal injury hazards, but concern the proper use of the ASPECT Reader or related components.
NOTE	Presents information that will permit accurate measurement through correct use of the ASPECT Reader, as well as other useful information.

Environmental

Symbol	Meaning
CAUTION	Operating Specifications: • Temperature: 15°C–30°C • Humidity: 30% to 80% Relative Humidity, Non-condensing • Altitude: 0–2000 m • Degree of pollution: 2
CAUTION	To ensure proper operating temperature, do not place the ASPECT Reader near radiators, bright sunlight, heat registers, stoves and/or other heat-producing equipment.

Electrical Warnings

Symbol	Meaning
WARNING	Operate the ASPECT Reader using only the power cord and power supply (AC adaptor). The ASPECT Reader should only be connected to an earth-grounded outlet with: • 100–240 VAC • 47–63 Hz • 0.9-0.34 A
CAUTION	The ASPECT Reader is intended for indoor use only. To reduce the risk of electric shock, always unplug the power supply from the AC power source following use

Date Management

Symbol	Meaning
	The printout is the formal record of the test result. Print out every test result and make 2 photocopies. Place the printed test results and both photocopies in the subject's Case Report Form (CRF) binder.
	Results stored in the ASPECT Reader memory are for temporary back-up purposes only, and may be overwritten. The ASPECT Reader memory stores results for the last 100 tests run. Once memory capacity has been reached, the most recent test result automatically overwrites the oldest test result.

Disposal Information

Symbol	Meaning
	Biohazard Warning Handle and dispose of Test Cassettes in accordance with standard biohazard practices, unless otherwise indicated in the relevant package insert.

Laser Device Caution

Symbol	Meaning
	Do not remove external panels to access the interior of the ASPECT Reader. The ASPECT Reader contains a UV LED used to read the Test Cartridges. UV LED's are not considered to be hazardous when used for their intended purpose.

Biohazard Warning

Symbol	Meaning
	When using the ASPECT Reader, observe universal precautions for safety, laboratory working practices, and follow laboratory operating procedures regarding personal protective equipment (lab coats, gloves, etc.) and safety.

Symbols

Symbols that may be associated with the ASPECT Reader:

Symbol	Meaning
CE	CE Mark
	Do not re-use
IVD	In Vitro Diagnostic device
	Manufacturer
REF	Catalog Number
LOT	Batch Code
	Temperature Limitation
EC REP	Authorized Representative
	Consult instructions for use
	Printer Paper
	Protect from any light source
	Protect from moisture

INSTALLATION

1. Position the shipping container upright and open the top flaps.
2. Open the cardboard box inside the shipping container.

NOTE: If using a utility knife, extend the blade to an appropriate length to avoid cutting any internal components.

3. Lift out the top cardboard spacer. The side boxes of this spacer contain the:
   - power cord
   - adaptor plugs for US and ex-US power
   - power adaptor
   - paper roll
   - four (4) LR6-AA batteries (1.5V)

4. Lift the next cardboard spacer from the box.
5. Remove the reader by slowly lifting it vertically out of the shipping container.
6. Place the reader on a stable surface. The reader is contained in a sealed plastic bag containing a desiccant pouch. Remove the reader from the plastic bag.
7. Replace all packing materials in the shipping container for storage.
8. Check the contents of the box with the shipping list shown below:
   - ASPECT Reader
   - External power supply
   - Power cord
   - Power Supply Adaptors (US, EU)
   - ASPECT Reader User Guide
   - 1 roll of thermal paper

NOTE: If the reader is stored at a temperature below 59°F or above 90°F (below 15°C and above 32°C) or at a humidity below 20% or above 80% relative humidity (RH), allow the reader to acclimate to the final environment temperature for a minimum of two (2) hours.

Reader

Number	Description	Function
1	Display Screen	Displays user function
2	Eject	Opens cassette drawer
3	Paper Advance	Advances printer paper
4	Main Menu	Cancels current operation, return to Main Menu
5	Soft Keys	Multi-function keys
6	Navigation Arrows	Used to move cursor between data fields
7	Numeric Keys	Enters selected number
8	⇐	Deletes last numeric entry
9	.	Adds a decimal point
10	Paper Roll Cover	Printer
11	Cassette Drawer	Holds cassette during testing

Accessories

Number	Description	Reference No.
1	ASPECT Reader	READ0001-03
2	Power Cord	
3	External Power Supply	READ0001-6
4	Power Supply Adapters (EU, US)	READ0001-7
5	4 — LR6-AA Batteries (1.5V)	
6	ASPECT Reader User Guide	
7	Paper Roll	READ0001-5

Back of Reader

Number	Description
1	Power Cord in Power Port
2	On/Off Switch
3	LIS Port
4	USB Ports
5	Printer Port

Installation

CAUTION

To ensure proper operating temperature, do not place the ASPECT Reader near radiators, bright sunlight, heat registers, stoves and/or heat-producing equipment.

Operate the ASPECT Reader using only the power cord and power supply (AC adaptor) supplied. The ASPECT Reader should only be connected to an earth-grounded outlet with:

- 100-240 VAC
- 47-63Hz
- 0.9-0.34 A

1. Place the ASPECT Reader on a clean, dry, and flat surface.

NOTE: Always make sure the reader is powered off before connecting or disconnecting the cables or accessories.

2. Attach the power adaptor to the power cord.
3. Attach the correct adaptor plug (appropriate for your wall socket) to the external power adaptor.
4. Attach the power supply's cable plug into its receptor located on the back of the reader (Figure 1).

FIGURE 1

5. Plug the external power supply into a wall power outlet. Make sure the reader is plugged into a grounded power line that meets voltage requirements in the Specification section of this manual (See "System Specifications Table" on page 7).
6. If the reader is to be connected to a LIS system, insert the data transmit cable to the LIS port (Figure 2).

FIGURE 2

7. Press and hold the power switch located at the back of the reader to power the reader on (Figure 3). An initializing screen will be displayed.

FIGURE 3

8. Batteries may be inserted into the base of the reader for an optional power source. Refer to "Battery Power" on page 49.
9. Install the paper roll in the printer cavity. Refer to "Replacing the Paper Roll" on page 48-49.
10. Perform EQC (electronic quality control) on reader. Refer to "Electronic Quality Control (EQC)" on page 42-43.

NOTE: The EQC is a required function that checks the Internal analyzer optics and systems. EQC should be performed:
- on initial setup of the reader
- if the reader is transported or moved
- whenever there is a question concerning the performance of the ASPECT Reader
- once at the beginning of the day

11. If EQC and Liquid Quality Control (LQC) performance intervals are desired, refer to "QC Settings" on page 16-17.
12. If specific laboratory or hospital information for the print out of the reader is desired, refer to "Printer Settings" on page 19.
13. Review sections of this manual such as "Operation" prior to analyzing specimens for the first time.
14. To power off the reader, press and hold the power switch for two seconds. If reader is in sleep mode, press any button prior to holding the power swtich.

INITIAL SET-UP

The Supervisor Menu is only accessible for logon by a supervisor, and contains all supervisory functions.
In this chapter you will learn how to:

- set the displayed time and time format for the reader
- select a desired language for the reader
- select QC Settings for Electronic QC (EQC)
- select transmit setup to LIS System
- set up printer settings
- read Reader information (current network configuration)
- export data to a USB stick
- set the displayed date and date format for the reader
- select QC settings for Liquid QC (LQC)
- select Time-out setup
- select transmit setup to Network Settings
- add, edit, delete users
- update firmware or languages

The Main Menu contains the following items:

Run Patient –used to run patient samples. (The software defaults to this icon when powered on.)

LQC (Liquid Quality Control)–used to run control samples whenever specified by your laboratory's quality control requirements.

Review Data–used to review patient results, liquid control results (LQC), electronic control results (EQC) and transmit results to a LIS.
Note: Menu items will be grayed out until data is available for review.

EQC (Electronic Quality Control)–used to perform an electronic control when the reader is set up; transported or moved; whenever specified by your laboratory's quality control requirements; or whenever there is a question regarding the performance of the ASPECT Reader.

Operator–used to view error logs and change operator settings such as time and date formats and language.

Supervisor–used to access all supervisory functions. (This icon is only accessible by supervisor)

1. Using the [→] or [←] and the [↑] or [↓] keys, select the Supervisor Menu icon from the Main Menu screen (Figure 4).

FIGURE 4

The *Supervisor* screen is displayed (Figure 5).

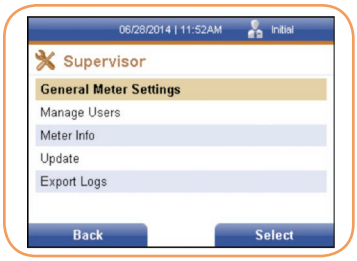

FIGURE 5

The *Supervisor* screen allows the supervisor to:

- set general reader settings, such as time, date, language, QC settings, i.e. QC intervals and Time-out setup.
- add or delete users and edit existing users
- view reader information, i.e. relevant network information
- update firmware or languages
- view and print both instrument and handling error logs

General Reader Settings

1. Using the right soft key, select General Reader Settings. The General Settings screen is displayed (Figure 6).

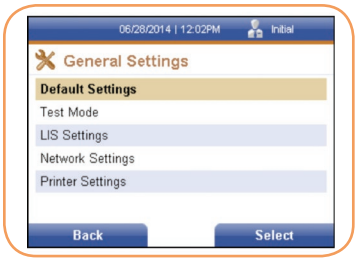

FIGURE 6

The General Settings screen allows the supervisor to:

- set default reader settings, such as time, date, language, QC settings, i.e. QC intervals, and reader Time- out.
- select Test Mode settings
- set up LIS settings such as LIS availability, IP Address, Time-out, etc.
- set up Network settings such as IP Address and Port
- set up Printer settings such as auto print and facility information

Language

1. Use the [↓] key to cursor down to the Language menu item. Press the right soft key to select it. The Language screen is displayed (Figure 7).

FIGURE 7

2. Use the [↑] or [↓] keys to toggle through the available languages listed:
   - English
   - German
   - French
   - Spanish
   - Italian
3. Select the desired language, then press the right soft key to accept the changes or the left soft key to discard any changes. Either returns the user to the previous menu (Figure 8).

FIGURE 8

Default Settings

The *General Settings* screen defaults to the Default Settings menu item. Press the right soft key to select it. The *Default Settings* screen is displayed (Figure 9).

FIGURE 9

Time & Time Format

1. Press the right soft key to select Time & Time Format. The Set Time & Time Format screen is displayed (Figure 10).

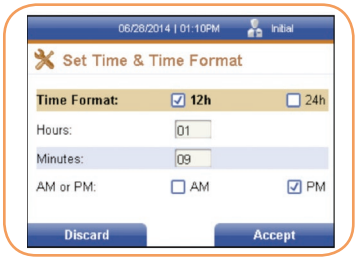

FIGURE 10

2. To set the time format, use the [←] or [→] keys to select the desired format, either 12 hour or 24 hour.
3. To set the current time, use the [↓] key to access the Hours: and Minutes: text fields, then use the numeric keys to enter the desired time.
4. To set either AM or PM, use the [←] or [→] keys to select the desired format.
5. Press the right soft key to Accept the changes to the time and time format, or press the left soft key to discard the changes. Either selection returns the user to the previous screen (Figure 11).

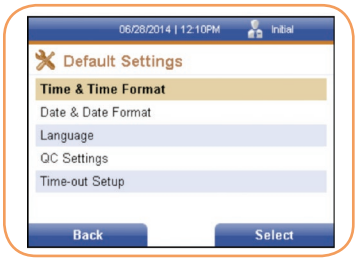

FIGURE 11

Date & Date Format

1. Use the [↓] key to cursor down to the Date & Date Format menu item. Press the right soft key to select it. The Date & Date Format screen is displayed (Figure 12).

FIGURE 12

2. Use the [←] or [→] keys to toggle through the available date formats listed:
   - mm/dd/yyyy
   - dd/mm/yyyy
3. Select the desired format, then use the [↓] key to cursor down to the Day:, Month: and Year: text fields.
4. Using the numeric keypad, enter the desired information into the text fields, then press the right soft key to accept the changes made, or the left soft key to discard any changes. Either returns the user to the previous menu (Figure 13).

FIGURE 13

QC Settings

The *QC Settings* screen allows the supervisor to enter QC intervals for Liquid QC testing in days, and QC intervals for electronic QC (EQC) testing in hours. Zeros can also be entered into the text fields to set the QC settings to off.

1. Use the [↓] key to cursor down to the QC Settings menu item.
2. Press the right soft key to select it. The QC Settings (Figure 14)

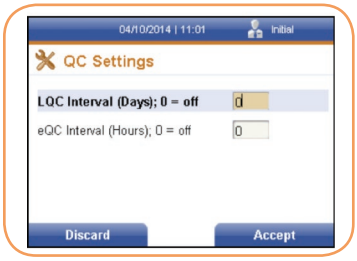

FIGURE 14

3. Enter the desired numbers in the text fields using the numeric keys on the reader, then press the right soft key to accept the changes made, or select the left soft key to discard any changes made to the time selections. Either selection will return the user to the previous menu (Figure 15).

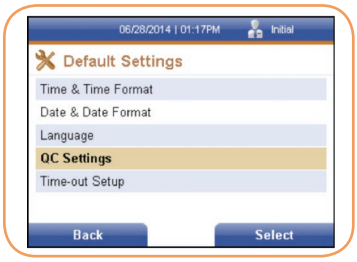

FIGURE 15

Time-out Setup

The *Time-out Setup* screen allows the supervisor to switch the battery on or off, or set a time limit for switching the battery off. Also available is the Switch Off Time Mains option. It can be set to off, or a time limit can be set for switching it off. These time-out options force the reader to power down after the selected time interval, in minutes, after a period of inactivity on the reader, i.e., no key strokes, no measurement, etc.

1. Use the [↓] key to cursor down to the Time-out Setup menu item.
2. Press the right soft key to select it. The Time-out Setup screen is displayed (Figure 16).

FIGURE 16

1. Enter the desired times in the text fields using the numeric keys on the reader, then press the right soft key to accept the changes made to the timing, or select the left soft key to discard any changes made to the time selections. Either selection will return the user to the previous menu (Figure 17).

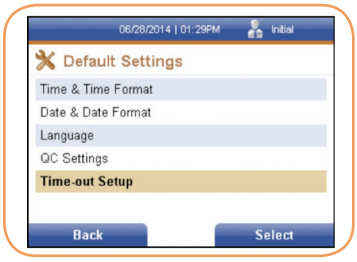

FIGURE 17

2. Press the left soft key to return to the General Settings screen (Figure 18).

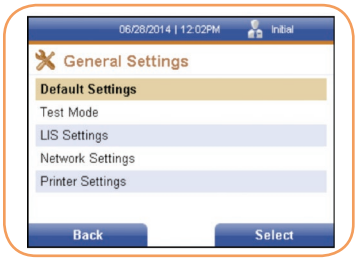

FIGURE 18

Test Mode

The Test Mode screen allows the supervisor to select the default mode of the reader.

1. Under the *General Settings* menu, use the [↓] key to select/highlight the Test Mode menu item.
2. Press the right soft key to select it. The *Test Mode Settings* screen is displayed (Figure 19).

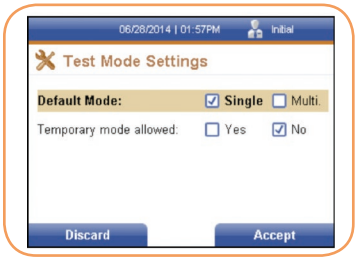

FIGURE 19

3. Use the [←] or [→] keys to check the desired Default Mode option and the Temporary mode allowed option.
4. Once all information has been entered, select the right soft key to accept the information, or the left soft key to discard any changes made. Either selection will return the user to the previous menu (Figure 20).

FIGURE 20

LIS Settings

The *LIS Settings* screen allows the supervisor to set LIS information, such as whether a LIS system is available, if the system should auto-transmit the data and enter the LIS IP Address, Port Number and Time-out (in seconds).

1. Under the General Settings menu, use the [↓] key to select/highlight the LIS Settings menu item.
2. Press the right soft key to select it. The LIS Settings screen is displayed (Figure 21).

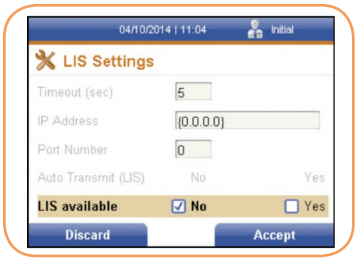

FIGURE 21

3. Enter the desired information using the numeric keys on the reader.
4. Use the [←] or [→] keys to check the Auto Transmit option and the LIS available option.
5. Once all information has been entered, select the right soft key to accept the information, or the left soft key to discard any changes made. Either selection will return the user to the previous menu (Figure 22).

FIGURE 22

Network Settings

The *Network Settings* screen allows the supervisor to set network information, such as IP Setup, IP Address and Port Number.

1. Under the General Settings menu, use the [↓] key to select/highlight the Network Settings menu item.
2. Press the right soft key to select it. The Network Settings screen is displayed (Figure 23).

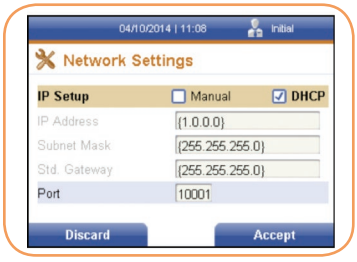

FIGURE 23

3. Use the [←] or [→] keys to check the IP Setup option.
4. Enter the desired information using the numeric keys on the reader.
5. Once all information has been entered, press the right soft key to accept the information, or the left soft key to discard any changes made. Either selection will return the user to the previous menu (Figure 24).

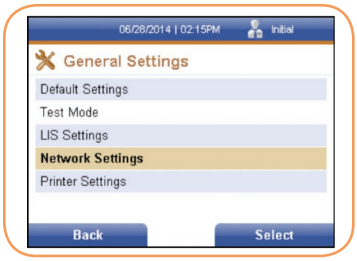

FIGURE 24

Printer Settings

The *Printer Settings* screen allows the supervisor to set printer information, such as Auto Print, and information to be displayed on the result print out. A standard keyboard with a USB connector will be required (not supplied).

1. Under the General Settings menu, use the [↓] key to select/highlight the Printer Settings menu item.
2. Press the right soft key to select it. The Printer Settings screen is displayed (Figure 25).

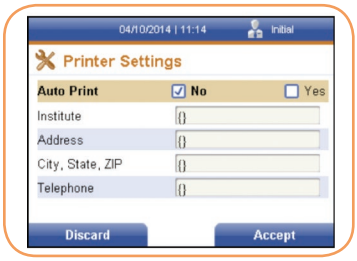

FIGURE 25

3. Use the [←] or [→] keys to check the Auto Print option.
4. Using an external keyboard enter the desired information into each text field. Use the [↓] key to cursor down to the desired text field.
5. Once all information has been entered, press the right soft key to accept the information, or the left soft key to discard any changes made. Either selection will return the user to the previous menu (Figure 26).

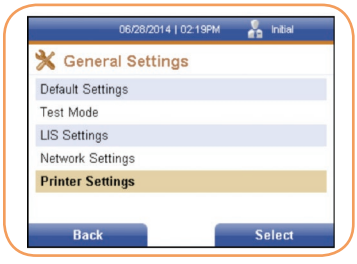

FIGURE 26

6. Press the left soft key to return to the *Supervisor* screen.

Manage Users

Under the *Manage Users* menu item, the supervisor is able to:

- view list of existing users by ID number, name and access mode
- edit existing users
- delete users
- add new users

1. Using the [→] or [←] and the [↑] or [↓] keys, select the Supervisor Menu icon from the Main Menu screen (Figure 27).

FIGURE 27

The *Supervisor screen* is displayed (Figure 28).

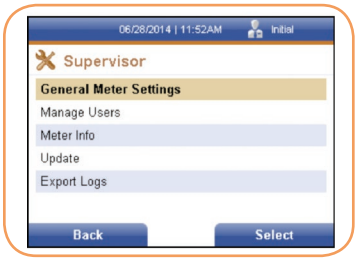

FIGURE 28

1. Use the [↓] key to cursor down to the Manage Users menu item. Press the right soft key to select it. The Existing User List screen is displayed (Figure 29).

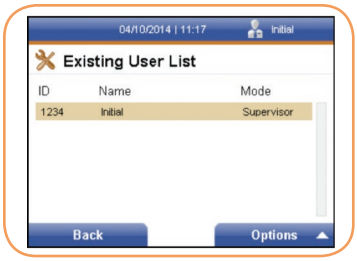

FIGURE 29

Edit User

1. Select the desired user. Press the right soft key to access the Options menu (Figure 30).

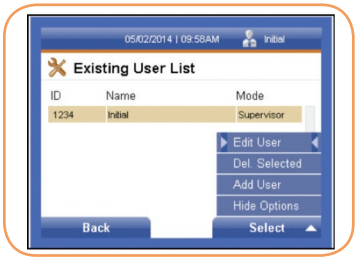

FIGURE 30

2. The Edit User menu item is already selected. Press the right soft key. The Change User screen is displayed (Figure 31).

FIGURE 31

3. Make the desired changes to the existing user information using the numeric keypad or keyboard.

NOTE: Use a standard keyboard with a USB connector.

4. Then press the right soft key to accept the changes made, or the left soft key to discard any changes. The *Existing User* List screen is displayed (Figure 32).

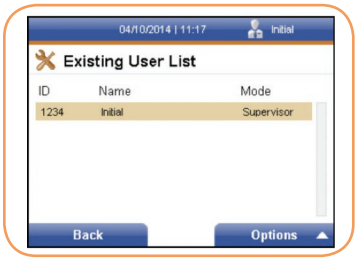

FIGURE 32

Delete Selected User

1. Select/highlight the user to be deleted from the existing user list.
2. Press the right soft key to access the Options menu. Using the [↓] key cursor to the Del. Selected menu item and press the right soft key to select it. The Delete User screen is displayed (Figure 33).

FIGURE 33

3. The Delete User is a confirmation window asking if the user listed in the screen is to be deleted. If the answer is yes, press the left soft key to delete the user. If the answer is no, press the right soft key to cancel the deletion and return to the previous menu. Use the [←] or [→] keys to check the Auto Print option.

Add User

NOTE: A standard keyboard with a USB connector is optional (not supplied). From the Existing User screen, press the right soft key to access the Options menu.

1. Using the [↓] key cursor to the Add User menu item and press the right soft key to select it. The Create New User screen is displayed (Figure 34).

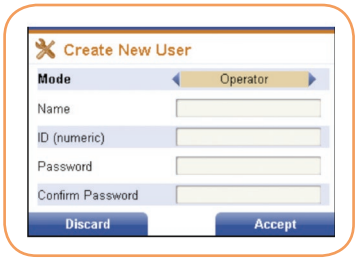

FIGURE 34

2. Select whether the user will have supervisor or operator access mode by using the [→] or [←] keys.
3. Using the [↓] key cursor to the next text fields and enter the information needed using a keyboard.

NOTE: The User ID and Passwords are numeric. These text fields will not accept alphabetic characters, unless a keyboard is connected.

4. When all information has been entered, press the right soft key to accept the information. The new user will be displayed on the Existing User List screen.
5. If no changes are desired, press the left soft key to discard any changes made and return to the previous screen.

OPERATION

In this section you will learn how to:

- log on and off the reader as Operator
- run a sample
- insert cassette
- remove cassette
- view results
- transmit results
- print results
- view Operator settings
- view error logs

Log in

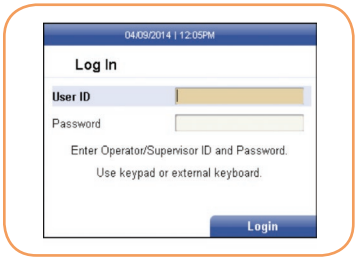

FIGURE 35

1. Enter the desired User ID number using the numeric keypad, then cursor down using the [↓] arrow to the next text field

NOTE: Initial set-up User ID and Password will be 1234 for both entries. It is recommended that a new User ID and Password be established for Supervisor after initial set-up.

2. Enter the user password, then press the right soft key to select Login. The Main Menu will be displayed (Figure 36).

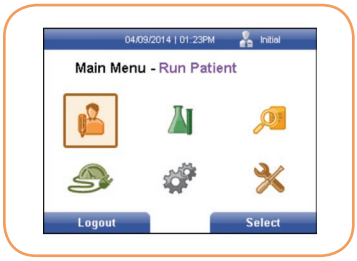

FIGURE 36

Running a Sample

NOTE: Prior to running any sample, it is recommended that an EQC (Electronic Quality Control) cassette be run to verify the performance of the reader. Refer to "Electronic Quality Control (EQC)" on page 42-43.

Once EQC has been successfully performed, select the Run Patient icon on the Main Menu.

1. Press the right soft key to select the Run Patient icon. The Run Patient screen will be displayed (Figure 37).

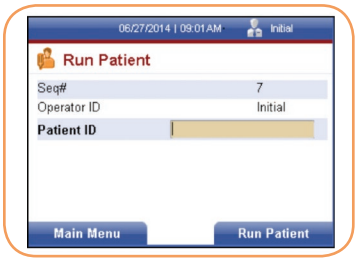

FIGURE 37

The latest sequence number will be displayed, as well as the Operator ID of the person logged into the reader. The Patient ID text field is selected.

2. Enter the Patient ID using the numeric keys, then select the right soft key. The Insert Cartridge screen will be displayed (Figure 38).

FIGURE 38

3. The cassette drawer will open (Figure 39).

FIGURE 39

Cassette Preparation

Follow proper infection control guidelines for handling all blood samples and anything that comes in contact with blood.

1. Follow the Instructions For Use for the test being performed to prepare the test cassette for the reader.
2. After preparing the test cassette, immediately insert the cassette into the reader. (Figure 40).

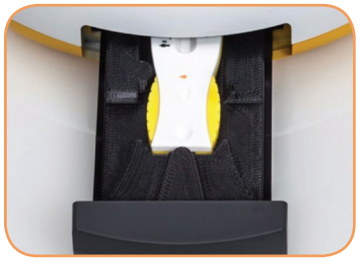

FIGURE 40

3. Close the drawer. A reading cartridge screen will be displayed (Figure 41).

FIGURE 41

NOTE: Each test cassette includes an internal control check (control line on test cassette) that is run automatically with every sample to ensure that there is proper flow in the cassette. If the automatic check of this built-in control is not within acceptable limits, a test result will not be reported. The reader will display an error message and the test must be repeated using a new cassette.

Once the RFID cassette information has been read and verified by the ASPECT Reader the analysis will start.

The *Patient ID* screen will be displayed, showing the time remaining for the testing (Figure 42).

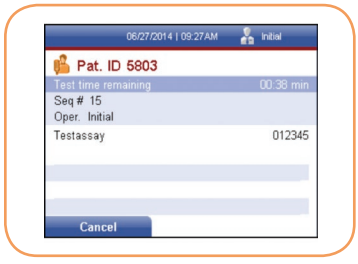

FIGURE 42

The ASPECT Reader measures the test automatically and the result is displayed on the screen in ng/mL (Figure 43).

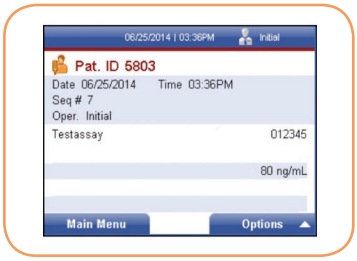

FIGURE 43

Removing Cassette

1. To open the cassette drawer, press the eject button. The reader will automatically open the cassette drawer to allow removal of the cassette.
2. Dispose of cassette according to Country, Federal, Provincial, State and local regulations.

Printing Results

1. To print patient results, press the right soft key to select Options. The Option menu will be displayed (Figure 44).

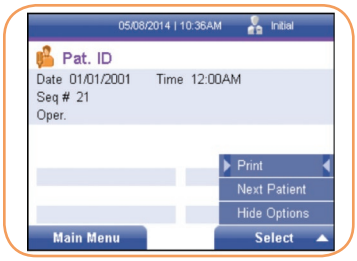

FIGURE 44

2. The Print option is selected. Press the right soft key to print patient results. Printing will appear at the bottom of the Pat. ID screen, and the reader will print out the result.

NOTE: Auto print may be selected by the Supervisor under "Printer Settings" on page 19 to automatically print any patient results once testing is finished.

3. To run another test, use the [↓] key to Next Patient menu item. Press the right soft key to select it. The Run Patient screen will be displayed, ready for the next Patient ID number to be entered (Figure 45).

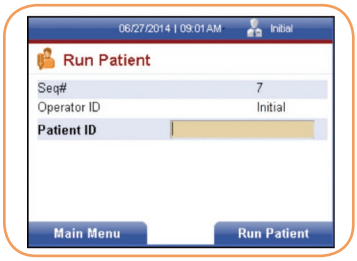

FIGURE 45

Transmitting Results

Patient results may be transmitted to a LIS system if desired. Refer to "LIS Settings" on page 18 of the Supervisor chapter.

REVIEW DATA AND ERROR LOG

In this chapter you will learn how to:

- review patient results
- review Liquid QC results (LQC)
- review Electronic QC results (EQC)
- reviewing Error Log
- send results to LIS

1. Using the [→] or [←] keys, select the Review Data icon from the Main Menu screen (Figure 46).

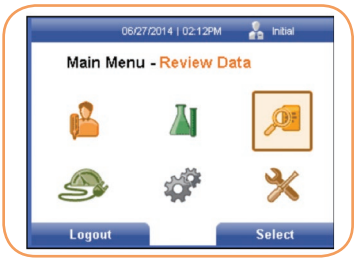

FIGURE 46

The *Review Results* screen is displayed (Figure 47).

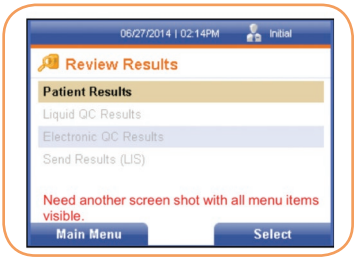

FIGURE 47

The *Review Results* screen allows the user to:

- review patient results by either start and end date, start and end sequence numbers, patient ID or operator ID.
- review Liquid QC (LQC) results by start and end date
- review (EQC) by start and end date
- send results to a LIS system

Review Patient Results by Date

1. Using the right soft key, select Patient Results. The Patient Results screen is displayed (Figure 48).

FIGURE 48

2. To view desired results by date, enter a start date using the numeric keys on the keypad in the format shown.
3. Use the [↓] key to cursor to the next text field.

4. Enter an end date using the format shown (Figure 49).

FIGURE 49

5. Press the right soft key to select to view the desired results. The Patient Results screen will be displayed with the patient's sequence number, date, lot number and result (Figure 50).

FIGURE 50

Show Details Option

1. Press the right soft key to view options available under the *Patient Results* screen. The Options menu is displayed (Figure 51).

FIGURE 51

Under the Options menu, the user can choose to show details of the results displayed, or print a list of displayed results.

2. Use the right soft key on the keypad to select Show Details. The date and time the result was obtained is displayed, along with the sequence number and the operator (Figure 52).

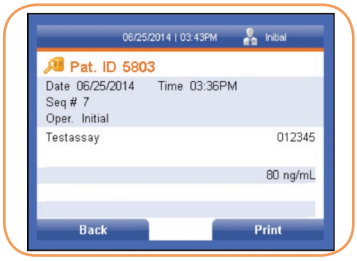

FIGURE 52

NOTE: The Patient ID screen may be printed by pressing the right soft key. A screen will appear stating that the Patient ID information is printing, please wait.

3. Select the left soft key to return to the previous screen.

Print List Option

1. From the *Patient Results* screen, press the right soft key to display the Option menu (Figure 53).

FIGURE 53

2. Use the [↓] key to cursor down to the Print List option. Press the right soft key to select it. A screen will appear stating that the list is printing, please wait.
3. Once the list has been printed, press the left soft key to return to the previous menu.

Review Patient Results by Sequence

1. From the Main Menu, select the Review Data icon by using the [↓] or [↑] or [←] or [→] keys to highlight/select it (Figure 54).

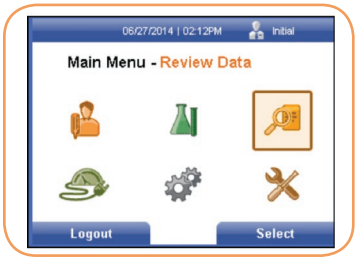

FIGURE 54

2. Press the right soft key to select it. The Patient Results screen is displayed (Figure 55).

FIGURE 55

3. Using the [↓] key, cursor to the Start Seq# text field. Enter the desired Start Seq# in the text field using the numeric keypad (Figure 56).

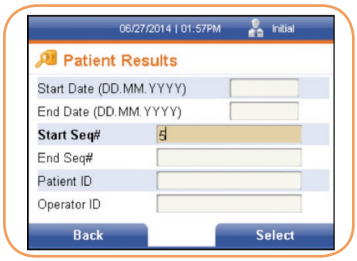

FIGURE 56

4. Using the [↓] key, cursor to the *End Seq#* text field. Enter the desired End Seq# in the text field using the numeric keypad.

5. Press the right soft key to select to view the patient results by sequence number (Figure 57).

FIGURE 57

6. Press the right soft key to select to view the desired results. The Patient Results screen will be displayed with the patient's sequence number, date, lot number and result.

Show Details Option

1. Press the right soft key to view options available under the Patient Results screen. The Options menu is displayed (Figure 58).

FIGURE 58

2. Using the [↓] key, select the desired result line. Use the right soft key on the keypad to select Show Details. The date and time the result was obtained is displayed, along with the sequence number, the operator, test number, test lot, and patient result (Figure 59).

FIGURE 59

NOTE: The Patient ID screen may be printed by pressing the right soft key. A screen will appear stating that the Patient ID information is printing, please wait.

3. Press the left soft key to return to the previous menu.

Print List Option

1. From the *Patient Results* screen, press the right soft key to display the Options menu (Figure 60).

FIGURE 60

2. Use the [↓] key to cursor down to the Print List option. Press the right soft key to select it. A screen will appear stating that the list is printing, please wait.
3. Once the list has been printed, press the left soft key to return to the previous menu.

Review Patient Results by Patient ID

1. From the Main Menu, select the Review Data icon by using the [↓] or [↑] or [←] or [→] keys to highlight/select it (Figure 61).

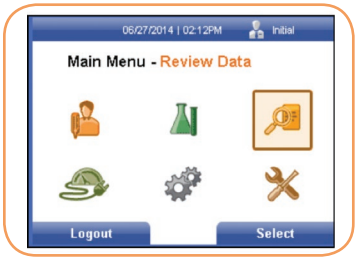

FIGURE 61

2. Press the right soft key to select it. The *Patient Results* screen is displayed (Figure 62).

FIGURE 62

3. Using the [↓] key, cursor to the Patient ID text field. Enter the desired ID number in the text field using the numeric keypad (Figure 63).

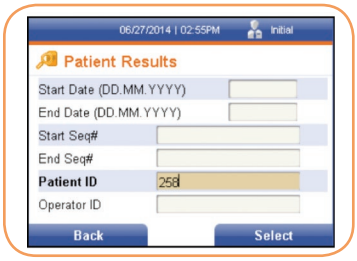

FIGURE 63

4. Press the right soft key to select to view the patient results by Patient ID (Figure 64).

FIGURE 64

Show Details Option

1. Press the right soft key to view options available under the Patient Results screen. The *Options* menu is displayed (Figure 65).

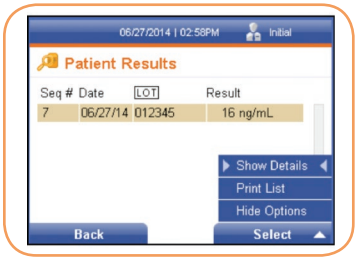

FIGURE 65

2. Use the right soft key on the keypad to select Show Details. The date and time the result was obtained is displayed, along with the sequence number, the operator, test number, test lot, and patient result (Figure 66).

FIGURE 66

NOTE: The Patient ID screen may be printed by pressing the right soft key. A screen will appear stating that the Patient ID information is printing, please wait.

3. Press the left soft key to return to the previous menu.

Print List Option

1. From the *Patient Results* screen, press the right soft key to display the Options menu (Figure 67).

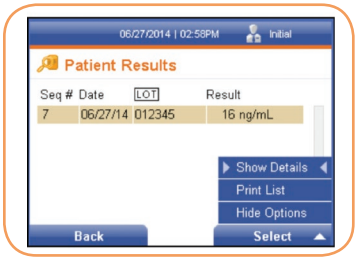

FIGURE 67

2. Use the [↓] key to cursor down to the Print List option. Press the right soft key to select it. A screen will appear stating that the list is printing, please wait.
3. Once the list has been printed, press the left soft key to return to the previous menu.

Review Patient Results by Operator ID

1. From the Main Menu, select the Review Data icon by using the [↓] or [↑] or [←] or [→] keys to highlight/select it (Figure 68).

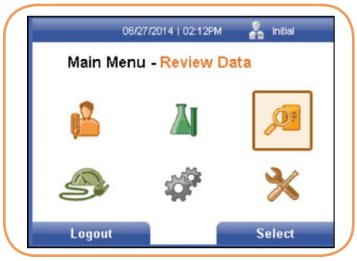

FIGURE 68

2. Press the right soft key to select it. The *Patient Results* screen is displayed (Figure 69).

FIGURE 69

3. Using the [↓] key, cursor to the Operator ID text field. Enter the desired ID number in the text field using the numeric keypad (Figure 70).

FIGURE 70

4. Press the right soft key to select to view the patient results by Operator ID (Figure 71).

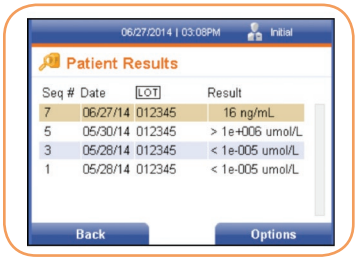

FIGURE 71

Show Details Option

1. Press the right soft key to view options available under the Patient Results screen. The Options menu is displayed (Figure 72).

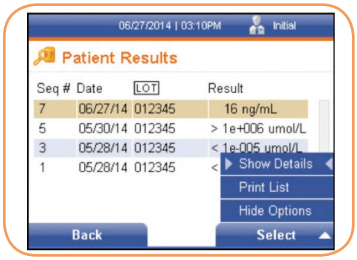

FIGURE 72

2. Using the [↓] key, select the desired result line. Use the right soft key on the keypad to select Show Details. The date and time the result was obtained is displayed, along with the sequence number, the operator, test number, test lot, and patient result (Figure 73).

FIGURE 73

NOTE: The Patient ID screen may be printed by pressing the right soft key. A screen will appear stating that the Patient ID information is printing, please wait.

3. Press the left soft key to return to the previous menu.

Print List Option

1. From the *Patient Results* screen, press the right soft key to display the *Options* menu (Figure 74).

FIGURE 74

2. Use the [↓] key to cursor down to the Print List option. Press the right soft key to select it. A screen will appear stating that the list is printing, please wait.
3. Once the list has been printed, press the left soft key to return to the previous menu.

Review Liquid QC (LQC) Results

1. Using the [→] or [←] keys, select the Review Data icon from the *Main Menu* screen (Figure 75).

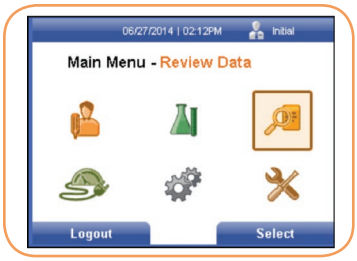

FIGURE 75

The Review Results screen is displayed (Figure 76).

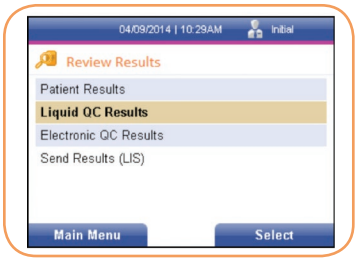

FIGURE 76

2. Using the [↓] key, cursor to the Liquid QC Results text field, then press the right soft key to select it. The *Review LQC Results* screen is displayed (Figure 77).

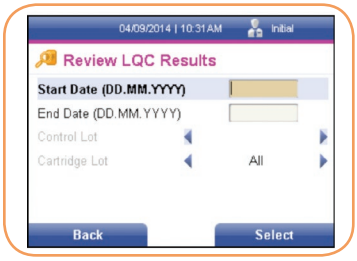

FIGURE 77

3. Enter a start date using the numeric keys on the keypad in the format shown.
4. Use the [↓] key to cursor to the next text field.
5. Enter an end date using the format shown (Figure 78).

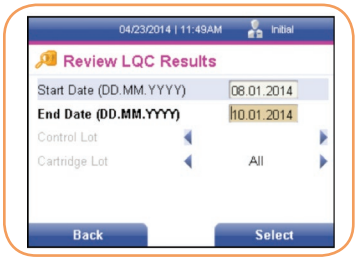

FIGURE 78

The *LQC Result List* screen is displayed (Figure 79).

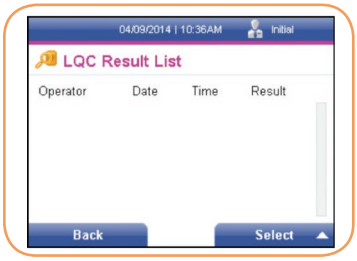

FIGURE 79

Show Details Option

1. Press the right soft key to view options available under the *LQC Result List* screen. The Options menu is displayed (Figure 80).

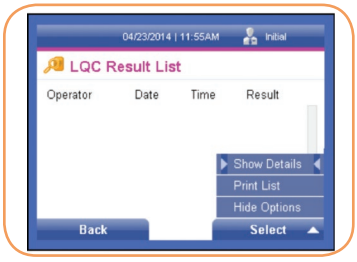

FIGURE 80

2. Use the right soft key on the keypad to select Show Details. The date and time the QC result was obtained is displayed, along with the sequence number, the operator, test and lot number, as well as the control result and if the result passed or failed (Figure 81).

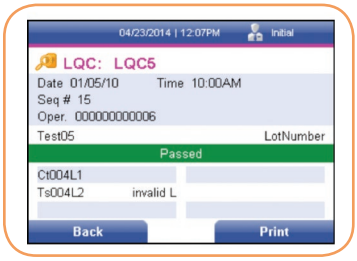

FIGURE 81

NOTE: The LQC screen may be printed by pressing the right soft key. A screen will appear stating that the LQC information is printing, please wait.

3. Press the left soft key to return to the previous menu.

Print List Option

1. From the *LQC Result List* screen, press the right soft key to display the Options menu (Figure 82).

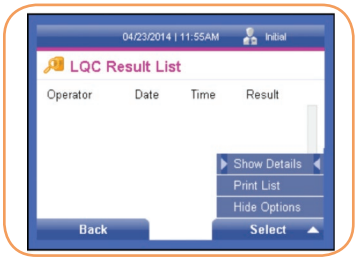

FIGURE 82

2. Use the [↓] key to cursor down to the Print List option. Press the right soft key to select it. A screen will appear stating that the list is printing, please wait.
3. Once the list has been printed, press the left soft key to return to the previous menu.

Review Electronic QC (EQC) Results

1. Using the [→] or [←] keys, select the Review Data icon from the Main Menu screen (Figure 83).

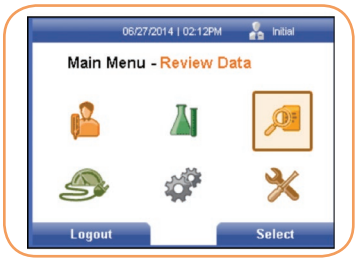

FIGURE 83

The *Review Results* screen is displayed (Figure 84).

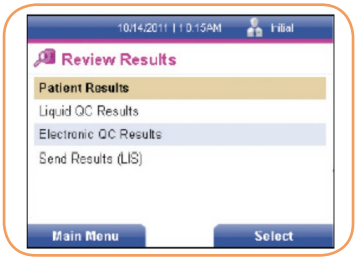

FIGURE 84

2. Using the [↓] key, cursor to the Electronic QC Results text field, then press the right soft key to select it. The *Review eQC Results* screen is displayed (Figure 85).

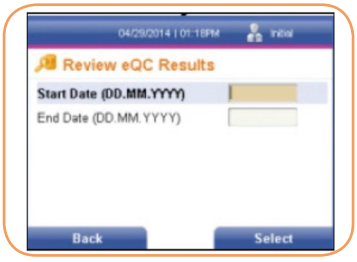

FIGURE 85

3. Enter a start date using the numeric keys on the keypad in the format shown.
4. Use the [↓] key to cursor to the next text field.
5. Enter an end date using the format shown.
6. Press the right soft key to select the entered dates. The EQC Result List screen is displayed (Figure 86).

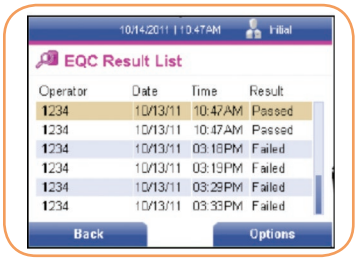

FIGURE 86

Show Details Option

1. Press the right soft key to view options available under the *eQC Result List* screen. The *Options* menu is displayed (Figure 87).

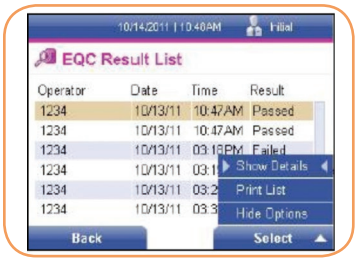

FIGURE 87

2. Use the right soft key on the keypad to select Show Details. The date and time the QC result was obtained is displayed, along with the sequence number, the operator, test and lot number, as well as the control result and if the result passed or failed (Figure 88).

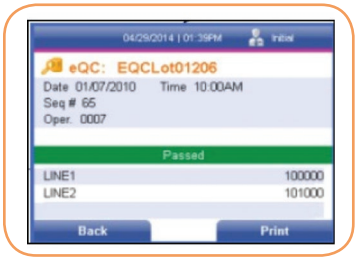

FIGURE 88

NOTE: The EQC screen may be printed by pressing the right soft key. A screen will appear stating that the LQC information is printing, please wait.

3. Press the left soft key to return to the previous menu.

Print List Option

1. From the *EQC Result List* screen, press the right soft key to display the Options menu (Figure 89).

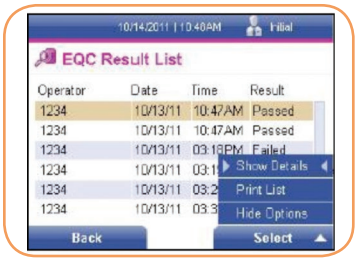

FIGURE 89

2. Use the [↓] key to cursor down to the *Print List* option. Press the right soft key to select it. A screen will appear stating that the list is printing, please wait (Figure 90).

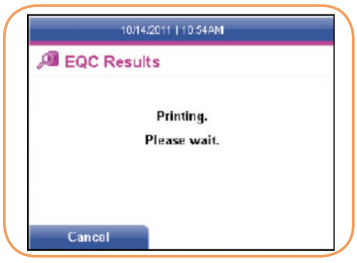

FIGURE 90

3. Once the list has been printed, press the left soft key to return to the previous menu.

Send Results to LIS

1. Using the [→] or [←] keys, select the Review Data icon from the Main Menu screen (Figure 91).

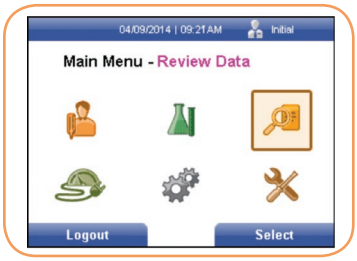

FIGURE 91

The *Review Results* screen is displayed (Figure 92).

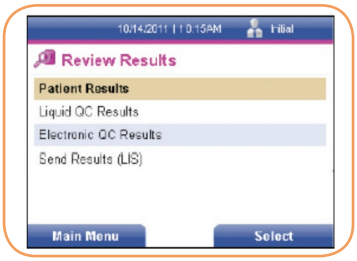

FIGURE 92

2. Using the [↓] key, cursor to the Send Results (LIS) text field, then press the right soft key to select it. The Send *Results to LIS* screen is displayed (Figure 93).

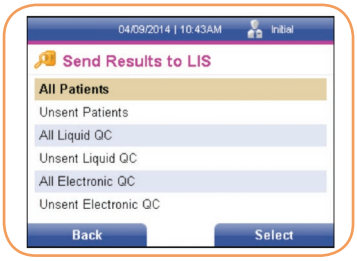

FIGURE 93

3. Under the *Send Results to LIS* screen, the user can select one of several options:
   - Send all patient results
   - Send all unsent patient results
   - Send all Liquid QC (LQC) results
   - Send all unsent Liquid QC (LQC) results
   - Send all electronic QC (EQC) results
   - Send all unsent electronic QC (EQC) results

4. Using the [↓] key, select the desired option, then press the right soft key. A screen will appear stating that the reader is sending the results to LIS (Figure 94).

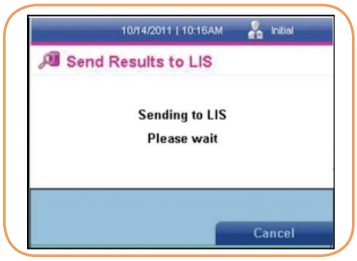

FIGURE 94

5. Press the right soft key to cancel the send request.
6. Press the left soft key to return to the previous menu.

View Error Log

The ASPECT Reader will display Instrument Errors and Handling Errors. Instrument Errors are errors that are directly associated with the reader's hardware, software, and/or firmware. Instrument Errors often require contacting Technical Support to resolve. Handling Errors are errors that are associated with sample or pre-analytical handling and preparation of the test cassette.

7. From the Operator screen, use the [↓] key to cursor down to the View Error Log text field (Figure 95).

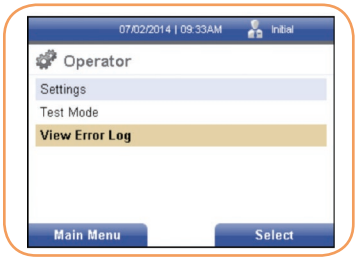

FIGURE 95

8. Press the right soft key to select it. The Error Log screen is displayed (Figure 96).

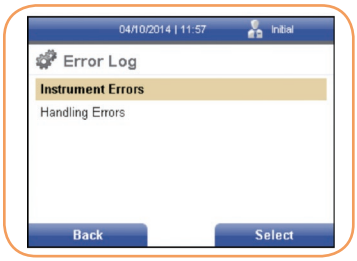

FIGURE 96

Instrument Errors Log

1. Press the right soft key to select *Instrument Errors*. The Instrument Errors Log screen is displayed (Figure 97).

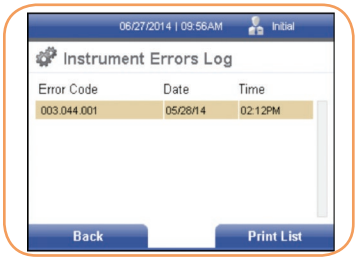

FIGURE 97

The *Instrument Errors* Log displays instrument errors by error code, date and time. Refer to "Troubleshooting/Error Codes" on page 51 for more details about the errors.

2. Press the right soft key to print the Instrument Errors List. A screen will appear stating that the list is "Printing Please Wait".
3. Once the error list is printed, the screen returns to the *Instrument Errors Log* screen.
4. To cancel the print request, press the left soft key once. Wait a few seconds for the reader to stop printing and return to the previous screen.
5. Press the left soft key to return to the *Error Log* screen.

Handling Errors Log

1. Use the [↓] key to cursor down to the Handling Errors text field from the Error Log screen (under Operator→ *View Error Log*) (Figure 98).

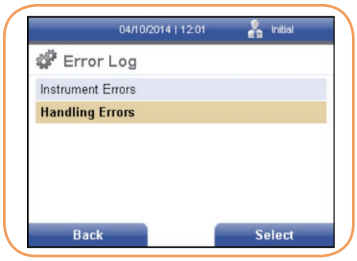

FIGURE 98

2. Press the right soft key to select Handling Errors. The *Handling Error Log* screen is displayed (Figure 99).

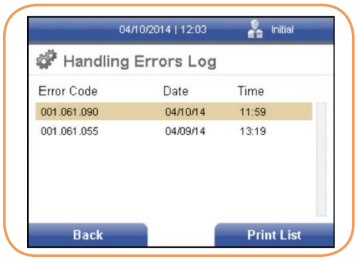

FIGURE 99

The *Handling Errors Log* displays handling errors by error code, date and time. Refer to "Troubleshooting/Error Codes" on page 51 for more details about the errors.

3. Press the right soft key to print the Handling Errors List. A screen will appear stating that the list is printing, to please wait. Once the error list is printed, the screen returns to the *Handling Errors Log* screen.
4. You may cancel the print request by pressing the left soft key once. It will take a few seconds for the reader to stop printing, then return to the previous screen.
5. Press the left soft key to return to the *Error Log* screen.

CONTROLS

Quality Control is important to ensure the integrity of the reader. Provided separately from the reader is the EQC cassettes (Electronic Quality Control), which checks the internal reader optics and systems. If the EQC result is outside of the specified range, the reader will display the test as Failed and must be repeated. If the EQC is within the specified range, the test result is valid and confirms that the reader is performing within specifications. If the repeated EQC tests fails a second time, please call Technical Support.

Also available, but not provided with the reader are liquid quality controls (LQC) which can be set up to be run at the discretion of the laboratory. These controls will test the performance of the cassette, reader and also the testing technique used.

In this section you will learn how to:

- run liquid controls (LQC)
- run electronic controls (EQC)

Running Liquid Quality Controls

External Level 1 and Level 2 Liquid Quality Controls (LQC) should be tested to demonstrate that the test reagents, cassettes and test procedures are performing properly. Refer to the Instructions For Use for specific details on performing the LQC test.

Good Laboratory Practice suggests that external controls should be tested with each new lot or shipment of test materials, or every 30 days, and as otherwise required by your laboratory's standard quality control procedures. Controls should be tested in the same manner as if testing patient specimens. When running patient specimens or external controls, if an analyte fails for any reason (built-in control failure or an external control out of range) no patient results will be reported.

NOTE: Users should follow government guidelines (for example, federal, state or local) and/or accreditation requirements for quality control.

6. Using the [→] or [←] keys, select the Liquid Control icon from the *Main Menu* screen (Figure 100).

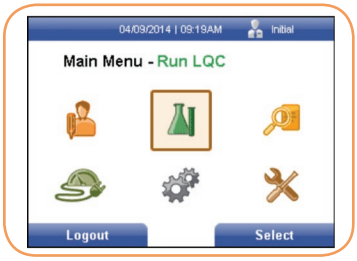

FIGURE 100

7. Press the right soft key to select Run LQC (Figure 101).

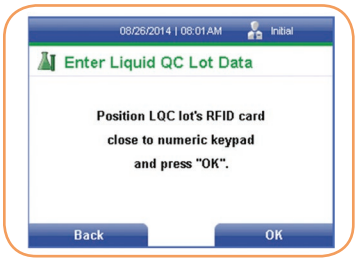

FIGURE 101

8. Scan the LQC RFID card included with the control kit by placing it over the keypad of the reader.
9. Select HI or LO control.

NOTE: Ensure that the correct control level is performed after selecting HI or LO from Step 9.

10. Prepare the controls as outlined in the Instructions For Use.
11. When preparing to test, follow the Instructions For Use included with the specific test being performed, and perform the control testing as if is a patient specimen.
12. The *Insert Cartridge* screen will be displayed (Figure 102).

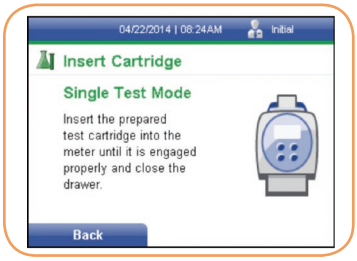

FIGURE 102

13. Immediately insert the cassette into the drawer as instructed, then close the drawer. The reader will automatically start the LQC testing and a *Run LQC* screen will be displayed (Figure 103).

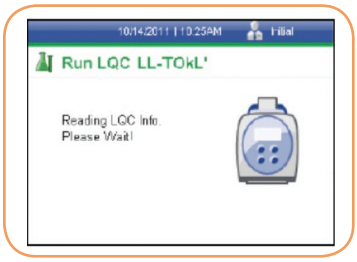

FIGURE 103

14. Once completed the reader will display the results (Figure 104).

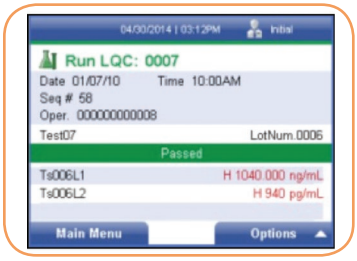

FIGURE 104

15. Press the eject button to remove the cassette once the test is finished.
16. Dispose of cassette according to Country, Federal, Provincial, State and local regulations.
17. Repeat Steps 6 through 14 if a second level control is required.

Printing Liquid Control Results

1. To print control results, press the right soft key to select Options. The *Option* menu will be displayed (Figure 105).

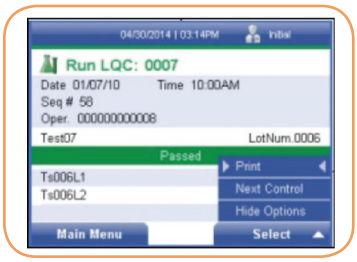

FIGURE 105

2. The Print option is selected. Press the right soft key to print control results.

Auto print may be selected by the Supervisor under "Printer Settings" on page 106 to automatically print any control results once testing is finished.

3. To run another liquid control, use the [↓] key to Next Control menu item. Press the right soft key to select it. The Prepare to Perform QC Tests screen will be displayed, ready for the next QC Barcode number to be scanned (Figure 106).

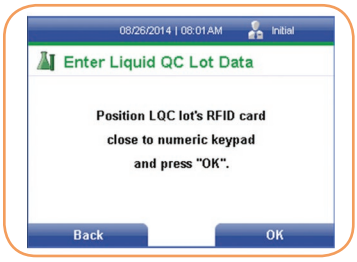

FIGURE 106

4. Once all desired controls have been run, press the left soft key to return to the Main Menu.

Electronic Quality Control (EQC)

Electronic Quality Control ensures the proper function of the ASPECT Reader.

CAUTION

The EQC cassette is light sensitive. Be sure to store the EQC cassette in the provided foil pouch to ensure accurate test results.

EQC should be performed:

- on initial setup of the reader
- if the reader is transported or moved
- whenever required by your laboratory's quality control requirements
- whenever there is a question concerning the performance of the ASPECT Reader
- once at the beginning of each day

NOTE: If an EQC interval has been entered into the ASPECT Reader by a supervisor and the interval has elapsed, a passed EQC result is required before any patient testing is permitted. The following screen will be displayed (Figure 107).

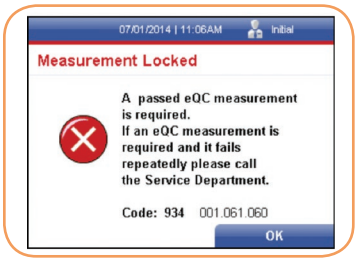

FIGURE 107

Perform the EQC

1. Using the [→] or [←] and[↓] or [↑] keys, select the EQC icon from the Main Menu screen (Figure 108).

FIGURE 108

2. Press the right soft key to select Run eQC. The *Insert eQC Device* screen is displayed (Figure 109).

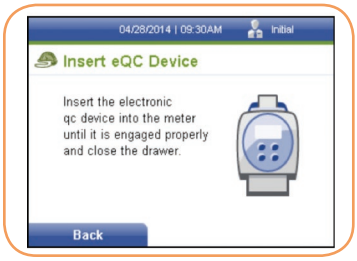

FIGURE 109

3. Remove the EQC cassette from foil pouch.
4. Insert the cassette into the reader drawer.
5. Close the drawer. The reader will automatically start the EQC testing (Figure 110).

FIGURE 110

6. Once completed the reader will display the results of the testing (Figure 111).

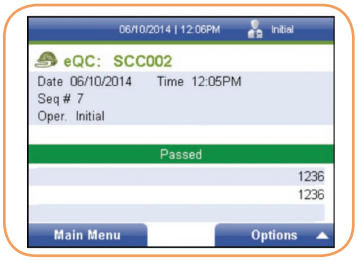

FIGURE 111

7. Once EQC has passed, remove the cassette from the cassette drawer by pressing the eject button. See Figure 4-7.
8. Replace the EQC cassette into its foil pouch for storage.
9. If EQC fails (Figure 112), repeat steps 1 to 7. If EQC fails again, contact Technical Support.

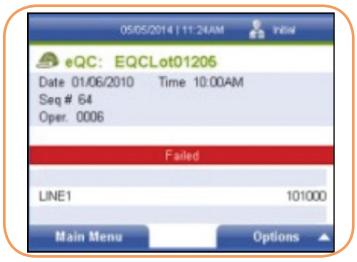

FIGURE 112

Printing EQC Results

1. To print control results, press the right soft key to select Options. The Option menu will be displayed (Figure 113).

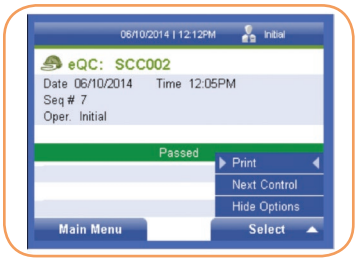

FIGURE 113

2. The Print option is selected. Press the right soft key to print control results.
3. Press the left soft key to return to the *Main Menu*.

UPDATING READER

Reader Info displays the current network configuration of the reader and current version numbers for the hardware, firmware and bootware, as well as the reader's serial number and current IP address.

1. From the *Supervisor* screen, use the [↓] key to cursor down to the Reader Info menu item. Press the right soft key to select it. The *Reader Information* screen is displayed (Figure 114).

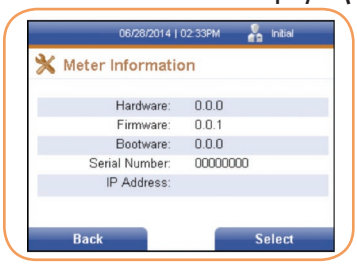

FIGURE 114

2. Press the left soft key to return to the *Supervisor* screen.

Update

The *Update* screen allows the user to upload new firmware to the reader, using a USB stick.

1. From the *Supervisor* screen, use the [↓] key to cursor down to the Update text field.
2. Press the right soft key to select it. The *Update* screen is displayed (Figure 115).

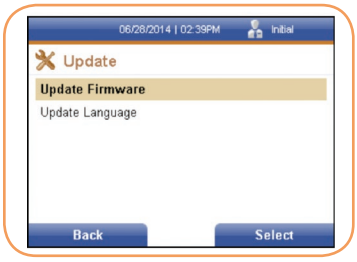

FIGURE 115

Update Firmware

1. The *Update* screen defaults to the Update Firmware text field. Press the right soft key to select it.
2. The Firmware Upgrade screen is displayed (Figure 116).

FIGURE 116

3. Insert the USB stick containing the new firmware into a USB Port on the back of the reader (Figure 117).

FIGURE 117

4. Press the right soft key to select OK to download the new firmware.
5. Once the new firmware has been downloaded, the reader will reboot and the new firmware version will be installed.
6. Press the left soft key to return to the *Update* screen.

EXPORT LOGS

Under the Export Logs screen, the supervisor is able to export patient results, liquid QC results, EQC results, users, and raw scans to a USB stick.

NOTE: Insert a USB stick in a USB port on the back of the reader. Refer to picture of "Back of Reader" on page 12.

1. From the *Supervisor* screen, use the [↓] key to cursor down to the Export Logs text field (Figure 118).

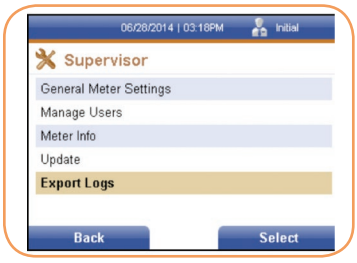

FIGURE 118

2. Press the right soft key to select it. The Export Logs screen is displayed (Figure 119).

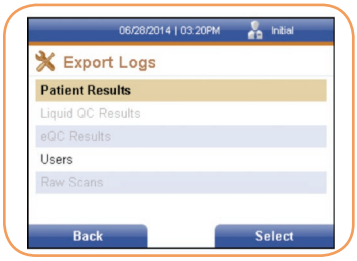

FIGURE 119

Patient Results

1. Press the right soft key to select Patient Results. A window confirming that the data has been successfully saved to a USB stick is displayed (Figure 120).

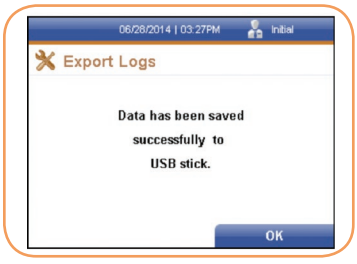

FIGURE 120

2. Press the right soft key to select OK and return to the *Export Logs* screen.
3. Remove the USB stick from the back of the reader.

Liquid QC Results

1. Insert the desired USB stick into a USB port on the back of the reader.
2. Use the [↓] key to cursor down to the *Liquid QC Results* menu item from the Export Logs screen (under Supervisor→ Export Logs) Press the right soft key to select Liquid QC Results.
3. A window confirming that the data has been successfully saved to a USB stick is displayed (Figure 121).

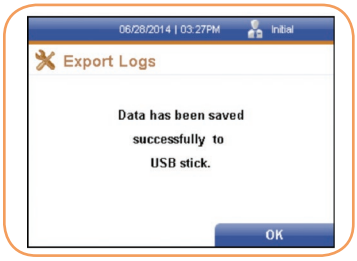

FIGURE 121

4. Press the right soft key to select OK and return to the *Export Logs* screen.
5. Remove the USB stick from the back of the reader.

EQC Results

1. Insert the desired USB stick into a USB port on the back of the reader.
2. Use the [↓] key to cursor down to the *EQC Results* menu item from the *Export Logs* screen (under Supervisor→ Export Logs) Press the right soft key to select EQC Results.
3. A window confirming that the data has been success- fully saved to a USB stick is displayed (Figure 122).

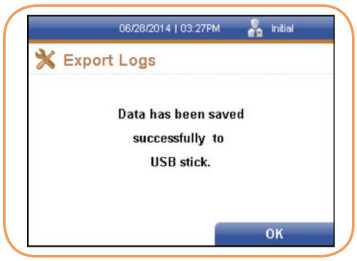

FIGURE 122

4. Press the right soft key to select OK and return to the *Export Logs* screen.
5. Remove the USB stick from the back of the reader.

Users

1. Insert the desired USB stick into a USB port on the back of the reader.
2. Use the [↓] key to cursor down to the *Users* menu item from the *Export Logs* screen (under Supervisor→ Export Logs) (Figure 123).

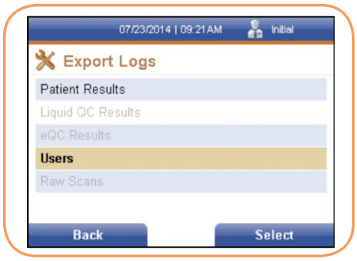

FIGURE 123

3. Press the right soft key to select Users.
4. A window confirming that the data has been successfully saved to a USB stick is displayed (Figure 124).

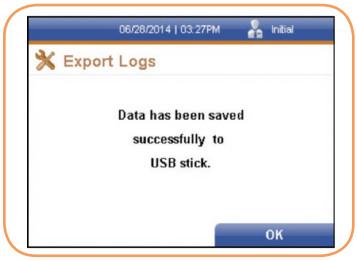

FIGURE 124

5. Press the right soft key to select OK and return to the *Export Logs* screen.
6. Remove the USB stick from the back of the reader.

Raw Scans

1. Insert the desired USB stick into a USB port on the back of the reader.
2. Use the [↓] key to cursor down to the Raw Scans menu item from the Export Logs screen (under Supervisor→ Export Logs) Press the right soft key to select Raw Scans.
3. A window confirming that the data has been success- fully saved to a USB stick is displayed (Figure 125).

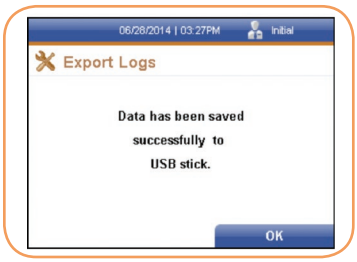

FIGURE 125

4. Insert the USB stick containing the new firmware into a USB Port on the back of the reader.
5. Remove the USB stick from the back of the reader.

SERVICE AND MAINTENANCE

The ASPECT Reader does not require any regular service. If you have any questions or require assistance, please contact Technical Support at techsupport@criticaldiagnostics.com or +353 1 691 7061.

System Shipping and Storage

Environmental Conditions for ASPECT Reader Shipping and Storage:

- Humidity: 10 - 85% (non-condensing)
- Temperature: -25°C to 45°C

Recommended Maintenance & Cleaning

The reader parts that may be cleaned or disinfected:

- main housing of the reader
- cassette drawer

CAUTION Do not wash or rinse LCD display screen, electrical or computer connections.

Main Housing of the Reader

1. Power off reader.
2. Wipe surfaces that come into contact with specimens with a fresh solution of 0.6% bleach. Wipe with a cloth dampened with water and dry with a soft cloth or paper towel. Avoid excess moisture.

Cassette Drawer

1. Power on the reader. Allow the self test to complete.
2. Press the eject button located on the top left of the reader.
3. Gently pull the drawer out, until it stops.
4. Lift the reader to display the bottom of the drawer slide (Figure 126).

FIGURE 126

5. Gently press the V-shaped slot on the underside of the drawer and slowly slide the drawer out.

NOTE: Additional pressure may be required to release the drawer.

6. Use a soft cloth dampened with 70% alcohol or 0.6% bleach solution to clean the cassette drawer. Dry with a soft cloth.

CAUTION

DO NOT clean the interior of the reader. DO NOT submerge the drawer in cleaning solution.

7. After cleaning, reinsert the drawer carefully by aligning the rails of the drawer into the tracks of the cassette reader.
8. Go to the Main Menu and perform EQC. Refer to “Electronic Quality Control (eQC)” on page 42-43.

Replacing the Paper Roll

1. Lift the gray handle up and towards the front of the reader to open the paper cover (Figure 127).

FIGURE 127

2. Place the paper in the paper holder with the paper tail coming from under the roll towards the front of the reader.

3. Holding the paper tail towards the front of the reader, replace the paper cover and snap it in place (Figure 128).

FIGURE 128

4. Press the Paper Feed button on the reader to advance the paper.

NOTE: The reader must be powered on.

Battery Power

The batteries provide an optional power source if electric power is unavailable. The reader does not automatically switch to batteries in the event of a power failure. Unplugging the external power cord from the back of the reader will automatically switch the reader to battery power.

Changing Batteries

1. Make sure there are no cassettes in the reader.
2. Power the reader off.
3. Gently turn the reader upside down and slide the battery cover to the right to remove it (Figure 129).

FIGURE 129

4. Replace the batteries using the diagram on the reader according to positive or negative polarity.
5. Replace the battery cover, place the instrument right side up and power on the instrument.

NOTE: The batteries act as an alternative power source with limited capacity.

System Decontamination

The following decontamination protocol is to be followed before transporting the system out of the laboratory for servicing.

1. Wear proper personal protective equipment including non-powdered disposable gloves, lab coat and eye protection when conducting decontamination.
2. Power off the reader.
3. Disconnect power supply for the reader.
4. Open the drawer and remove any ASPECT Reader cassettes.
5. For all external parts of the system and the interior drawer compartment, clean with the following protocol:
    - Thoroughly wipe all areas with a lint-free cloth dampened with a 0.6% bleach solution.
    - Thoroughly wipe all areas with a lint-free cloth dampened with water. Wipe several times to ensure all bleach is removed from the reader parts.
    - Thoroughly wipe all areas with a lint-free cloth dampened with 70% alcohol to remove any residue.

6. Package the reader for shipment following the reverse of the unpacking of the Reader. Refer to “Installation” on page 10.

70% Alcohol Preparation:
Combine 700mL 100% Ethanol or Isopropanol and 300mL of DH2O, or 70mL 100% Ethanol or Isopropanol and 30mL DH2O.

Long Term Shutdown

1. Remove any cassettes from the reader.
2. Power off the system by pressing and holding for 2 seconds the power switch. If reader is in sleep mode, press any key prior to holding power switch button.
3. Disconnect the power cord from the wall outlet and the system.
4. Wipe down all surfaces with a disinfectant solution ~ 0.6% bleach solution, followed by water. Wipe all surfaces dry using a lint-free cloth.
5. Close the drawer to maintain a dust-free interior.

TROUBLESHOOTING

Troubleshooting/Error Codes

Several problem scenarios with possible causes and recommended actions:

Error Codes	Description	Recommended Action
.044.001	Self test failed	Discontinue use. Contact Technical Support.
.060.006	Drawer blocked	1. Unblock drawer. 2. Press eject key again. 3. If error continues, contact Technical Support.
.061.002	Reader has recognized a used cassette.	Retest using a new cassette.
.061.008	Cassette Lot locked.	QC for this lot of cassette is expired. Run controls.
.061.012	Supervisor ID Error	Supervisor ID should have between 4 - 12 characters.
.061.032	Analyzer calibration failed.	Contact Technical Support.
.061.040	User ID already exists	Choose another User ID.
.061.043	Expired cassette	Retest using a new cassette.
.061.044	Device type is incorrect	Retest using a cassette of the correct device type.
.061.046	QC card is expired	Retest with a non-expired QC card.
.061.050	Abort Test	User selected to abort test. If aborted, the test will need to be repeated with a new cassette.
.061.051	Low Battery Warning	Replace batteries before running another test.
.061.055	Wrong Entry. Wrong format or range. Please correct the entry.	Check the entered information and correct accordingly.
.061.060	Reader locked	EQC failed. Repeat test with new EQC. If EQC continues to fail, contact Technical Support.
.061.085	Invalid User Error: The user is not stored, or it has no proper rights for this function.	Select a different user or check with a supervisor about user rights.
.061.094	RFID Error. Wrong Cassette	Retest using a new cassette.
.061.116	Write failure on USB stick	Ensure that a USB stick is connected.

WARRANTY

Critical Diagnostics warrants that the ASPECT Reader (the "Product") will be free from defects in materials and workmanship under normal use and when used in accordance with the instructions for use for a period of twelve (12) months from the date of shipment (the "Warranty Period"). This limited warranty extends to the first end-user purchaser only and is not assignable or transferable.

Critical Diagnostics, at its option, will at no charge either repair the Product (with new and/or reconditioned parts) or replace the Product during the Warranty Period. All replaced parts become the property of Critical Diagnostics.

This warranty does not apply to any Product damaged through abnormal use, misuse, mishandling, neglect, accident, negligence, tampering or unauthorized service.

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