



# Apex Reader

## User's Guide

### FOR INVESTIGATIONAL USE ONLY

To be used by qualified investigators only.

The performance characteristics of this device have not been established.

### INSTRUMENT DE RECHERCHE

Réservé uniquement à l'usage de chercheurs compétents

Les spécifications de rendement de l'instrument n'ont pas été établies.

Part Number: 80 510 00  
Revision C

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## **Trademarks**

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## Introduction

### Product Overview

The **Apex Reader** is a portable fluorescence instrument used to measure the results of tests manufactured by **Aspen BioPharma**. The reader is designed for use in a laboratory setting.

The reader uses a Class 1 laser as a light source. Light from the laser hits a test cartridge that has been inserted in the reader. This causes the fluorescent dye in the test cartridge to give off energy. The more energy the fluorescent dye gives off, the stronger the signal.



**Apex Reader and Test Cartridge**

Each test cartridge includes an RFID tag that identifies relevant parameters for evaluating the test results. These parameters include:

- Test name
- Calibration coefficients
- Expiry date
- Sample/Reagent Assembly (SRA) type

Assay specific information is stored on the RFID tag on the test cartridge, so it is not necessary to upload any test-related information prior to running a test. Patient information can be entered in the reader manually or using the optional barcode reader accessory.

After a test sample (plasma) from a patient is added to the test cartridge, the cartridge is inserted in the reader's drawer with the sample application area facing toward the user. The reader's internal scanner reads the RFID tag on the test cartridge and automatically processes the test. The reader measures how much of a particular protein marker is present based on pre-programmed standards, and

interprets and reports the test result. Test results can be printed, sent to the LIS, or exported to an SD card.

### **Kit Components**

The following components are included in the reader kit:

- |                                      |                           |
|--------------------------------------|---------------------------|
| ■ Reader                             | ■ Thermal Paper Rolls (4) |
| ■ Universal Power Transformer        | ■ 1 GB SD Card            |
| ■ Country Extension Cord             | ■ User's Guide            |
| ■ AA Batteries (4)                   | ■ Warranty Card           |
| ■ System Check Cassette              | ■ Quick Start Card        |
| ■ External Barcode Reader (Optional) |                           |

### **Kit Components**

## Reader Features



Reader—Front View

Feature	Description
1 Printer Cover	Covers the printer.
2 Display	Shows screens for navigating, entering data, and reviewing data.
3 Eject button	Used to eject the drawer.
4 Paper Feed Button	Used to advance the paper roll.
5 Main Menu Button	Used to return to the <b>Main Menu</b> screen.
6 Left Soft Key	Used to select the option displayed above the key on the display.
7 Navigation Buttons	Used to navigate within menus and reader screens.
8 Right Soft Key	Used to select the option displayed above the key on the display.
9 Numeric Keypad	Used to enter numbers and decimal points.
10 Delete Button	Used to delete the character to the left of the cursor.
11 Battery Cover	Covers the battery compartment.
12 Drawer	Used for inserting prepared test cartridges and the system check cassette in the reader.



**Reader—Back View**

<b>Feature</b>	<b>Description</b>
<b>1</b> PS/2 Port	Used to connect the optional barcode reader accessory to the reader.
<b>2</b> Ethernet Port	Used to connect the reader to the LIS network.
<b>3</b> AC Power Port	Used to connect the AC power adapter to the reader.
<b>4</b> SD Card Slot	Used for importing and exporting information via the SD card.
<b>5</b> On/Off Switch	Used to turn the reader on and off.

## Understanding Labeling Symbols

Consult the following table to understand the symbols located on the bottom of the reader:

<b>This symbol...</b>	<b>indicates...</b>
	The device meets the requirements of the directive set forth by the European Commission for in vitro diagnostic medical devices.
	The user should consult the instructions for use for proper operation of the device.
	The product is designed for use as an in vitro diagnostic medical device.
	The catalog number for the device.
	The upper and lower relative humidity limits for operation of the device.
	The upper and lower temperature limits for operation of the device.
	The device requires safe disposal in conformance with the WEEE Directive.
	The polarity of the power supply tip is positive.
	The manufacturer of the device.

## Understanding Screens and Menus

The supervisor menu structure is different from the operator menu structure. Refer to the appropriate section below for information about the menu structure for your user mode.

Each of the options available on the supervisor **Main Menu** screen are described below.



**Supervisor Main Menu Screen**

■ Import / Export



When you select **Import / Export** from the supervisor **Main Menu**, a menu with the following options appears:

– **Import / Export User**

Select this option to export user records to or import user records from a compatible SD card. See *Importing and Exporting Users* on page 87 for more information.

– **Export Result List**

Select this option to export test results stored on the reader to a compatible SD card. See *Exporting Stored Test Results* on page 84 for more information.

– **Export Raw Data Scan**

Select this option to export the last 10 raw data scans stored on the reader to an SD card. See *Exporting Raw Test Data* on page 86 for more information.

– **Import Language**

Select this option to update the languages available in the reader. See *Updating Reader Languages* on page 118 for more information.

– **Upgrade Software**

Select this option to upgrade the reader software. See *Upgrading the Reader Software* on page 121 for more information.

## ■ Settings



**Supervisor Settings Screen**

When you select **Settings** from the supervisor **Main Menu**, a menu with the following options appears:

### - **Set Date and Time**

Select this option to change the reader's date and/or time. See *Changing the Date and Time* on page 115 for more information.

### - **Select Language**

Select this option to change the reader's language setting. See *Changing the Language* on page 39 for more information.

### - **Read Temperature**

Select this option to check the ambient temperature detected by the reader. See *Checking Ambient Temperature* on page 105 for more information.

### - **LIS Reviewer Setup**

Select this option to configure the LIS reviewer settings for the reader. See *Providing LIS Settings* on page 36 for more information.

### - **Set Login / Logout**

Select this option to change the logout time, power off time, or auto-login setting. See *Changing Security and Power Saving Settings* on page 44 for more information.

### - **Network Setup**

Select this option to set up the network connection. See *Setting Up the Network Connection* on page 33 for more information.

### - **Printing Setup**

Select this option to change the print setting. See *Changing the Print Setting* on page 43 for more information.

– **Set Patient ID**

Select this option to change patient ID settings. See *Changing Patient ID Settings* on page 40 for more information.

– **Device Info**

Select this option to review software version information, reader settings, supervisor history, and internal check results. See *Reviewing Reader Information* on page 97 for more information.

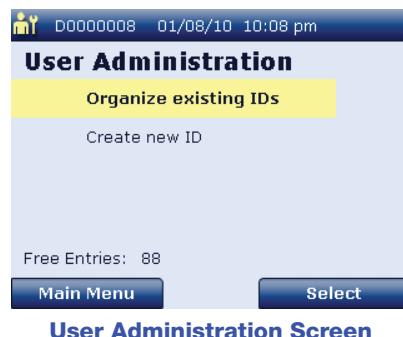
– **Delete Results**

Select this option to delete test results stored in the reader's memory. See *Deleting Stored Test Results* on page 106 for more information.

– **Reset to Default**

Select this option to reset the reader to its default settings. See *Resetting the Reader to Default Settings* on page 109 for more information.

■ **User Administration**



When you select **User Administration** from the supervisor **Main Menu**, a menu with the following options appears:

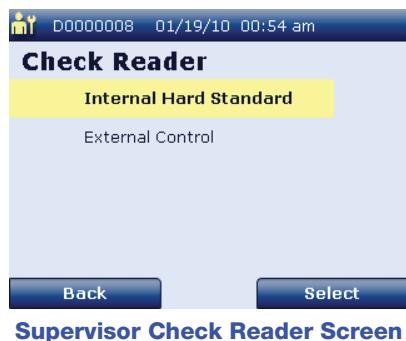
– **Organize existing IDs**

Select this option to modify or delete existing user records. See *Managing Users* on page 47 for more information.

– **Create new ID**

Select this option to add a new user. See *Adding a User* on page 47 for more information.

## ■ Check Reader



When you select **Check Reader** from the supervisor **Main Menu**, a menu with the following options appears:

- **Internal Hard Standard**

Select this option to run an internal QC check on the reader. See *Running Quality Control Checks* on page 63 for more information.

- **External Control**

Select this option to run an external QC check using the system check cassette provided with the reader. See *Running Quality Control Checks* on page 63 for more information.

## ■ Change to Operator

Select this option to access the operator **Main Menu** screen. From this screen, you can run a test and view, send, and print patient results.

Each of the options available on the operator **Main Menu** screen are described below.



Operator Main Menu Screen

- **Run Test**

Select this option to test a patient sample. See *Testing a Patient Sample* on page 68 for more information.

- **Result History**



Result History Screen

When you select **Result History** from the operator **Main Menu**, a menu with the following options appears:

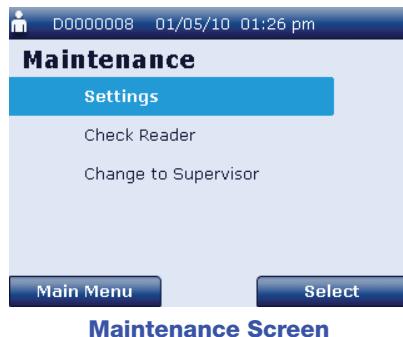
- **Organize Results**

Select this option to view, send, and print patient results stored in the reader's memory. See *Managing Patient Results* on page 72 for more information.

- **Read Cartridge**

Select this option to view an individual result stored on a test cartridge. See *Viewing a Result Stored on a Test Cartridge* on page 78 for more information.

## ■ Maintenance



When you select **Maintenance** from the operator **Main Menu**, a menu with the following options appears:

- **Settings**

Select this option to review software version information, reader settings, and supervisor history. See *Reviewing Reader Information* on page 97 for more information.

- **Check Reader**

Select this option to run an internal QC check on the reader or to run an external QC check using the system check cassette provided with the reader. See *Running Quality Control Checks* on page 63 for more information.

- **Change to Supervisor**

Supervisor users can select this option to access the supervisor **Main Menu** screen. From this screen, you can import and export information, change reader settings, and manage user records.

Each screen is divided into three areas: the header bar, the content area, and the soft keys.



The information displayed in each area is described below.

#### ■ Header Bar

The header bar is the dark blue area at the top of the reader screen that provides the following information:

- The icon shown at the far left of the header bar indicates whether the user is logged in as a supervisor or an operator.
- The number shown next to the user icon is the user ID for the current user. If the auto-login setting is enabled, the header bar shows “Auto-Login” instead of the user ID.
- The current date and time are shown to the right of the user information.
- The icon shown at the far right of the screen indicates whether the reader is using AC power or battery power.

The following table identifies the icons that appear in the header bar.

This icon...	indicates that...
	The user is logged in as a supervisor.
	The user is logged in as an operator.
	<p>The reader is using battery power and the batteries are fully charged.</p> <p>The battery icon is gradually filled with white as the batteries are discharged.</p>
	The AC power adapter is being used to power the reader.

#### ■ Content Area

The content area is the light blue area occupying the majority of the reader screen. This area displays menu options, settings, and data.

When you are logged in as a supervisor, the currently selected option is indicated by a yellow bar with black text. When you are logged in as an operator, the currently selected option is indicated by a blue bar with white text as shown below.



Supervisor Main Menu Screen



Operator Main Menu Screen

#### ■ Soft Key Selections

The soft key selections are the dark blue areas with white text displayed at the lower left and lower right of the reader screen. Some screens have two soft key selections, while other screens have only one option.

To use a soft key selection, press the soft key below the desired option.

## Product Specifications

**AG: CONFIRM ALL AND PROVIDE ANY ADDITIONAL SPECS AND STANDARDS.**

### Product Information

Model Number: **TBD**

Dimensions: **TBD**

Weight: **TBD**

### Power Requirements

AC Operation: 6 VDC at 4.16 A

Battery Operation: 4 AA / LR6 cells  
(Nominal voltage > 1.5 VDC)

### Operating Environment

Altitude: 0 to 2000 m

Temperature: 15°C to 30°C

Humidity: 30% to 80% noncondensing

Degree of Pollution: 2

### Storage Environment

Temperature: -20°C to 55°C for 24 hours

Humidity: 25% to 85% noncondensing

### External Barcode Reader (Optional)

Connector: PS/2

Power: 5 VDC at < 300 mA

Codes Supported: Any 1D code 20 characters or less in length

Model: Dialogic Touch 65 or equivalent

### External Keyboard (Optional)

Connector: PS/2

### Network Connectivity (Optional)

Connector: RJ45

Communications: 10(100)BASE-T using TCP/IP

Data Protocol: POCT 1-A2

### Applicable Standards

EU: **TBD**

Rest of World: **TBD**

## Safety Symbols

The following symbols are used in this user's guide:

This icon...	indicates a...
	<b>BIOHAZARD WARNING:</b> A situation, which if not avoided, could result in a health risk to the user.
	<b>ELECTRICAL SHOCK WARNING:</b> A situation, which if not avoided, could result in electrical damage to the reader or bodily injury to the user.
	<b>CAUTION OR WARNING:</b> A situation, which if not avoided, could result in incorrect operation or damage to the reader.

## Safety Information

Review the safety information below before using the reader. **AG: CONFIRM ALL.**



**CAUTION:** Use the reader only in the operating environment specified. For details, see *Product Specifications* on page 18.



**CAUTION:** To ensure proper operating temperature, do not place the reader near radiators, bright sunlight, heat registers, stoves, or other heat-producing equipment.



**WARNING:** Operate the reader using only the power cord and power supply (AC adaptor) provided. Connect the reader to an earth-grounded outlet that meets the product's power specifications. For details, see *Product Specifications* on page 18.



**WARNING:** The reader is intended for indoor use only. To reduce the risk of electrical shock, always unplug the power supply from the AC power source following use.



**CAUTION:** 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 patient's records.



**CAUTION:** Results are stored in the reader memory for temporary backup purposes only and may be overwritten. The reader memory stores results for the last 100 tests run. When memory capacity is reached, the most recent test result automatically overwrites the oldest test result.



**WARNING:** When using the reader, observe universal precautions for safety and laboratory working practices, and follow laboratory operating procedures regarding personal protective equipment (such as lab coats, gloves, and so forth) and safety.



**WARNING:** Handle and dispose of test cartridges in accordance with standard biohazard practices unless otherwise indicated in the relevant package insert.



**WARNING:** Do not remove external panels to access the interior of the reader. The reader contains a UV LED used to read the test cartridges. UV LEDs are not considered to be hazardous when used as intended.

## How To Use This Guide

The following conventions are used in this manual to help guide you through use of the reader's features:

- Each screen is referenced by the name that appears at the top of the screen.
- Words that appear on the screen (titles, on-screen options and soft key labels) are shown in bold.
- Buttons are referenced only by their icon.

For example:

Use  and  to make the necessary changes.

- To make instructions easy to read, soft keys are referenced only by their label.

For example:

Press **Select** to save this setting.



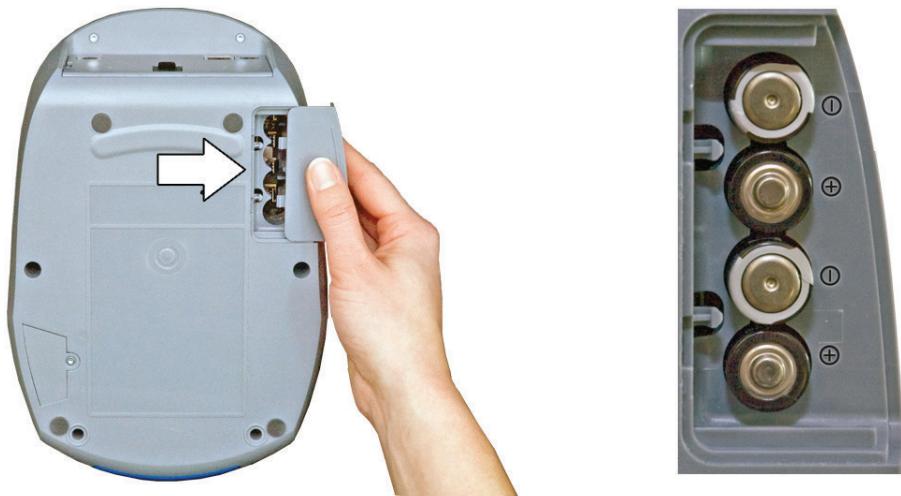
## Setup

### Supplying Power to the Reader

The reader can be powered by four AA batteries or by the AC power adapter. If you use the AC power adapter, it is recommended to install batteries as a backup to prevent loss of data if the AC power adapter is disconnected from the reader.

Perform the following steps to install batteries in the reader:

1. Turn the reader over so that the back of the battery cover is visible.
2. To remove the battery cover, place your thumb in the middle of the cover and exert slight pressure as you slide it in the direction shown below.
3. Insert four size AA 1.5 volt batteries. Be sure that the plus (+) and minus (-) signs on the batteries match the signs embossed in the battery compartment.



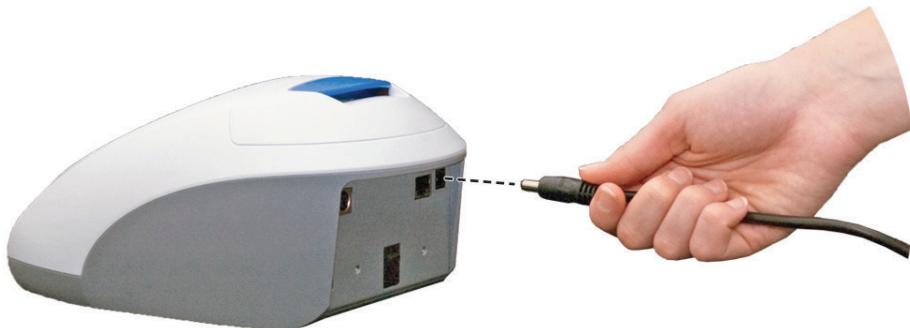
#### Installing the Batteries

4. Replace the battery cover by positioning it at the edge of the battery compartment as shown and sliding it into position.
5. When you have completed battery installation and replaced the battery cover, turn the reader right side up.

 **Note:** If the reader does not power on after replacing the batteries, verify that the batteries are lined up according to the symbols in the battery compartment.

Perform the following steps to use the AC power adapter:

1. Connect the AC power adapter to the reader by inserting the cylindrical end of the adapter into the round hole in the back of the reader.



#### Connecting the AC Power Adapter

 **NOTE:** If necessary, use the extension cord included with the reader to convert to a different type of electrical outlet.

2. Connect the other end of the AC power adapter to a power source.

### Turning On and Configuring the Reader

#### Turning On the Reader

The on/off switch is located on the back of the reader. To turn on the reader, push the on/off switch up until the **Initializing** screen appears, then release it. The reader displays a splash screen during startup, then displays the **Set Date** screen. You must set the date and time before running any patient samples.



**Set Date Screen**



**IMPORTANT:** Allow the reader to warm up for at least 20 minutes before running any patient samples.

## Setting the Date and Time

Perform the following steps to set the date and time:

- When the **Set Date** screen is first displayed, the **Date format** field is highlighted. Use  and  to scroll through the following options for how to display dates on the reader screen and printouts:
  - dd.mm.yyyy:** Select this option to display the day, then the month, then the year with periods used as separators.
  - mm/dd/yyyy:** Select this option to display the month, then the day, then the year with slashes used as separators.
  - yyyy/mm/dd:** Select this option to display the year, then the month, then the day with slashes used as separators.

When the preferred date format is displayed, press  to highlight the **Year** field.

- Use  or  to increment or decrement the year.

When the correct year is displayed, press  to highlight the **Month** field.

- Use  or  to increment or decrement the month.

When the correct month is displayed, press  to highlight the **Day** field.

- Use  or  to increment or decrement the day.

When the correct day is displayed, review the date format, year, month, and day, and confirm that the correct date information is displayed. If you need to change a setting, use  and  to highlight the field. Then use  and  to make the necessary changes.

- When you have confirmed that the correct date is displayed, press **Confirm & Next** to display the **Set Time** screen.



6. When the **Set Time** screen is first displayed, the **Time format** field is highlighted. Use  and  to toggle between the following options for how to display times on the reader screen and printouts:
  - **12h**: Select this option to display times in the 12 hour time format with am and pm.
  - **24h**: Select this option to display times in the 24 hour time format.

When the preferred time format is displayed, press  to highlight the **Hour** field.

7. Use  or  to increment or decrement the hour.

When the correct hour is displayed, press  to highlight the **Minute** field.

8. Use  or  to increment or decrement the minute.

When the correct minute is displayed, review the time format, hour, and minute and confirm that the correct time information is displayed. If you need to change a setting, use  and  to highlight the field. Then use  and  to make the necessary changes.

9. When you have confirmed that the correct time is displayed, press **Confirm** to display the **Enter Patient ID** screen.

After the reader has been allowed to warm up for 20 minutes, you can begin running patient tests. See *Testing a Patient Sample* on page 68 for instructions.

## Installing the Paper

The reader can print test results, device settings, and other information using the thermal paper rolls included in the reader kit.

Perform the following steps to install paper in the reader:

1. Remove the printer cover by pulling up the blue handle on the top of the cover.



**Removing the Printer Cover**

2. If necessary, tear or cut the end of the paper roll to form a straight edge. Then insert the paper roll in the printer so that the end of the paper comes from under the roll toward the reader display, as shown below.



**Inserting the Paper Roll**

3. To replace the printer cover, insert the paper roller between the edge of the paper and the paper roll, as shown below. Then push down on the sides of the printer cover until you hear it snap into place.



**Replacing the Printer Cover**

4. Press .

The reader feeds the paper so that it extends out the top of the printer.

5. After the reader has been allowed to warm up for 20 minutes, you can begin running patient tests. See *Testing a Patient Sample* on page 68 for instructions.

In order to change any reader settings, you will need to add a supervisor user. See *Adding the First Supervisor User* on page 29 for instructions.

### Adding the First Supervisor User

You must add the first supervisor user before you can change any reader settings. In order to add the first supervisor user, you need to obtain a one-shot PIN by calling **AspenBio Pharma Customer Care at 1-303-794-2000**.



**IMPORTANT:** A one-shot PIN can be used only on the day when it is provided. You should add the first supervisor user as soon as you obtain this PIN.

When you have obtained a one-shot PIN, perform the following steps to create the first supervisor user:

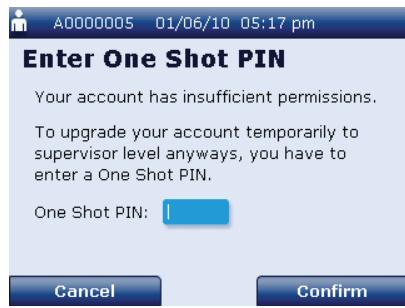
1. Press  to display the operator Main Menu screen.



2. Use  and  to highlight **Maintenance** and press **Select** to display the **Maintenance** screen.



3. Use  and  to highlight **Change to Supervisor** and press **Select** to display the **Enter One Shot PIN** screen.



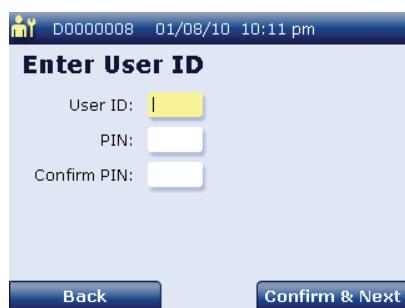
**Enter One Shot PIN Screen**

4. Use the numeric keypad to enter your one-shot PIN in the **One Shot PIN** field, then press **Confirm** to display the **First Change to Supervisor** confirmation screen.



**First Change to Supervisor Confirmation Screen**

5. Press **OK** to display the **Enter User ID** screen.



**Enter User ID Screen**

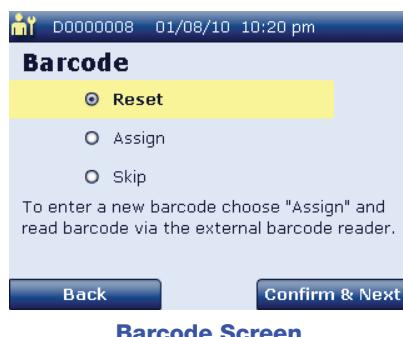
6. When the **Enter User ID** screen is first displayed, the **User ID** field is highlighted. Use the numeric keypad to enter the user ID for the first supervisor user. The user ID must be 4 digits.
7. Press  to highlight the **PIN** field.

 *NOTE: To delete the last character entered, press .*

8. Use the numeric keypad to enter the PIN for this user. The PIN must be 4 digits.
9. Press  to highlight the **Confirm PIN** field.
10. Re-enter the 4-digit PIN for this user.
11. Press **Confirm & Next** to display the **Enter User Name** screen.



12. Perform the following steps to enter the user name for this user:
  - a. Use , , , and  to highlight the desired character.
  - b. Press **Confirm & Next** to add the highlighted character to the user name.
  - c. Repeat Step a and Step b as necessary.
13. When the user name is complete, use , , , and  to highlight **Done**. Then press **Confirm & Next** to display the **Barcode** screen.



 **NOTE:** To delete this user's barcode, return to the Barcode screen and use  and  to highlight **Reset**. Then press **Confirm & Next**.

14. The following options are available on the **Barcode** screen:

- a. *To assign a barcode for this user, use  and  to highlight **Assign**.*  
Then use the external barcode reader to scan the barcode.  
The reader assigns the barcode and displays the **RFID** screen.
- b. *If you do not want to assign a barcode, use  and  to highlight **Skip**.*  
Then press **Confirm & Next** to display the **RFID** screen.



15. The following options are available on the **RFID** screen:

- a. *To assign an RFID for this user, use  and  to highlight **Assign**.*  
Place the user's ID card on the designated location on the reader and press **Confirm**. **AG: CLARIFY**.  
The reader assigns the RFID and displays the **User Administration** screen.
- b. *If you do not want to assign an RFID, use  and  to highlight **Skip**.*  
Then press **Confirm** to display the **User Administration** screen.

16. After the first supervisor user has been added, you can set up the LIS connection, change reader settings, or add more users. Refer to the appropriate section below for instructions:

- **Connecting to the LIS** on page 33
- **Changing Reader Settings** on page 38
- **Managing Users** on page 47

After the reader has been allowed to warm up for 20 minutes, you can begin running patient tests. See **Testing a Patient Sample** on page 68 for instructions.

## Connecting to the LIS

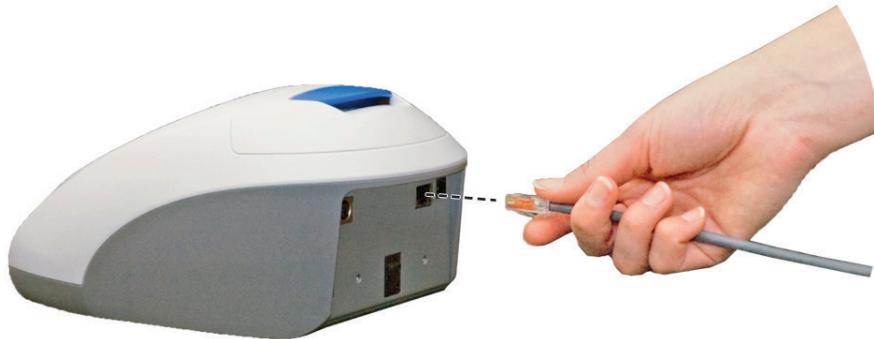
The reader can send test results to the LIS over an Ethernet connection. Complete the following steps to set up the LIS connection.

### Setting Up the Network Connection

Perform the following steps to set up the network connection. If you are not using DHCP, you need to obtain the IP address, port number, subnet mask, and standard gateway for the reader from your network administrator.

 **NOTE:** Only supervisor users can modify these settings. If you are logged in as an operator, select Maintenance > Change to Supervisor to set up the LIS connection.

1. Connect an Ethernet cable to the reader by inserting one end of the cable into the Ethernet port in the back of the reader.



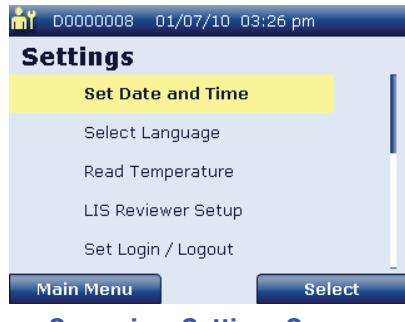
**Connecting the Ethernet Cable**

2. Connect the other end of the Ethernet cable to the LIS network.
3. Press  to display the supervisor **Main Menu** screen.



**Supervisor Main Menu Screen**

4. Use  and  to highlight **Settings** and press **Select** to display the supervisor **Settings** screen.



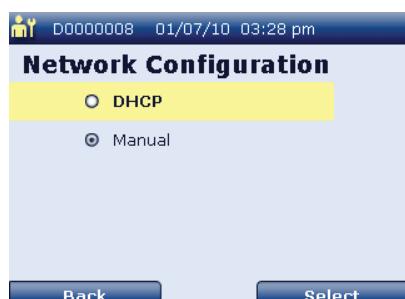
Supervisor Settings Screen

5. Use  and  to highlight **Network Setup** and press **Select** to display the **Network Setup** screen. **AG: UPDATE SCREEN**.



Network Setup Screen

6. Use  and  to highlight **Network Configuration** and press **Select** to display the **Network Configuration** screen.



Network Configuration Screen

7. The following options are available on the **Network Configuration** screen:

- *To obtain the reader's IP address, port number, subnet mask, and standard gateway automatically using DHCP, use  and  to highlight **DHCP**. Then press **Select**.*

The reader obtains the network information and displays the **Network Setup** screen.

- *To enter the reader's IP address, port number, subnet mask, and standard gateway manually, use  and  to highlight **Manual**. Then press **Select** to display the **Manual Network Setup** screen.*

- When the **Manual Network Setup** screen is first displayed, the **IP address** field is highlighted. Use the numeric keypad to enter the IP address for the reader. Then press  to highlight the **Port number** field.*
- Use the numeric keypad to enter the port number for the reader. Then press  to highlight the **Subnet Mask** field.*
- Use the numeric keypad to enter the subnet mask for the reader. Then press  to highlight the **Standard Gateway** field.*
- Use the numeric keypad to enter the standard gateway for the reader.*

*Review the IP address, port number, subnet mask, and standard gateway and confirm that the correct information is displayed. If you need to change a setting, use  and  to highlight the field. Then use the numeric keypad to make the necessary changes.*

- When you have confirmed that the correct information is displayed, press **Confirm** to save these settings and return to the **Network Setup** screen.*

 **NOTE:** To delete the last character entered, press .

### Providing LIS Settings

Perform the following steps to configure the LIS reviewer settings for the reader. You need to obtain the IP address and port number for the LIS reviewer from your network administrator.

1. Press  to display the supervisor **Main Menu** screen.



Supervisor Main Menu Screen

2. Use  and  to highlight **Settings** and press **Select** to display the supervisor **Settings** screen.



Supervisor Settings Screen

3. Use  and  to highlight **LIS Reviewer Setup** and press **Select** to display the **LIS Reviewer Settings** screen.



LIS Reviewer Settings Screen

4. When the **LIS Reviewer Settings** screen is first displayed, the **Set Timeout** field is highlighted. Use  and  to increment or decrement the timeout for the LIS reviewer. The timeout is the amount of time after which the reader will stop trying to communicate with the LIS.
5. When the desired setting is displayed in the **Set Timeout** field, press  to highlight the **Reviewer IP Address** field.
6. Use  and  to increment or decrement the IP address for the LIS reviewer. Then press  to highlight the **Port Number** field.
7. Use  and  to increment or decrement the port number for the LIS reviewer.
8. Review the timeout, IP address, and port number and confirm that the correct information is displayed. If you need to change a setting, use  and  to highlight the field. Then use  and  to make the necessary changes.
9. When you have confirmed that the correct information is displayed, press **Confirm & Exit** to return to the supervisor **Settings** screen.

## Changing Reader Settings

 **NOTE:** Only supervisor users can change reader settings. If you are logged in as an operator, select Maintenance > Change to Supervisor. to change settings.

Supervisor users can modify the following reader settings:

- **Language:** The language setting determines what language is displayed on the reader screen and printouts. For instructions on how to change the language, see *Changing the Language* on page 39.
- **Patient ID Settings:** The patient ID settings determine whether patient IDs can be input by an external barcode reader and whether they can be input by manual entry. For instructions on how to change the patient ID settings, see *Changing Patient ID Settings* on page 40.
- **Print Setting:** The print setting determines whether test results are printed automatically upon completion of a patient test. For instructions on how to change printing setup, see *Changing the Print Setting* on page 43.
- **Logout Time:** The logout time setting is the duration of inactivity after which a user will be automatically logged out of the reader. For instructions on how to change the logout time, see *Changing Security and Power Saving Settings* on page 44.
- **Power Off Time:** The power off time is the duration of inactivity after which the reader will automatically turn off. For instructions on how to change the power off time, see *Changing Security and Power Saving Settings* on page 44.
- **Auto-Login Setting:** The auto-login setting determines whether users are required to enter a login and PIN to use the reader. For instructions on how to change the auto-login setting, see *Changing Security and Power Saving Settings* on page 44.

## Changing the Language

Supervisor users can change the reader's language setting. The language setting determines what language is displayed on the reader screen and printouts.

Perform the following steps to change the language:

1. Press  to display the supervisor **Main Menu** screen.



**Supervisor Main Menu Screen**

2. Use  and  to highlight **Settings** and press **Select** to display the supervisor **Settings** screen.



**Supervisor Settings Screen**

3. Use  and  to highlight **Select Language** and press **Select** to display the **Select Language** screen.

You can scroll through the available languages using  and . The selected radio button indicates the current reader language.



**Set Language Screen**

4. Use  and  to highlight the desired language.
5. When the desired language is highlighted, press **Select** to save this setting.
6. Press **Back** to return to the supervisor **Settings** screen or press  to return to the supervisor **Main Menu** screen.

### Changing Patient ID Settings

Supervisor users can change patient ID settings. The patient ID settings determine whether patient IDs can be input by an external barcode reader and whether they can be input by manual entry.

Perform the following steps to change the patient ID settings:

1. Press  to display the supervisor **Main Menu** screen.



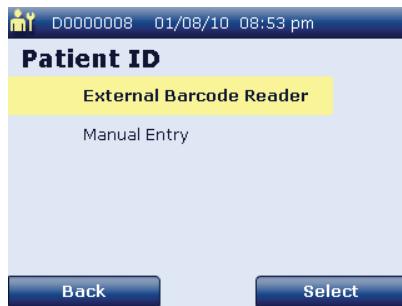
Supervisor Main Menu Screen

2. Use  and  to highlight **Settings** and press **Select** to display the supervisor **Settings** screen.



Supervisor Settings Screen

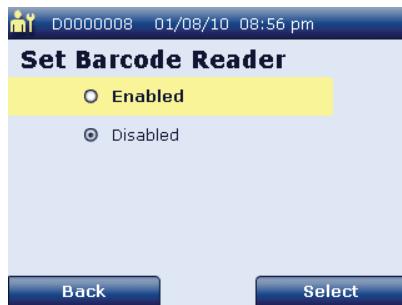
3. Use  and  to highlight **Set Patient ID** and press **Select** to display the **Patient ID** screen.



Patient ID Screen

4. Perform the following steps to enable or disable use of an external barcode reader for reading the patient ID:
- Use  and  to highlight **Set Barcode Reader** and press **Select** to display the **Set Barcode Reader** screen.

The selected radio button indicates the current setting.



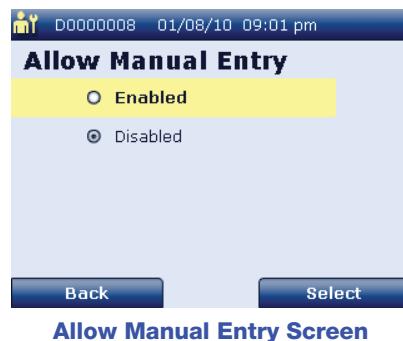
Set Barcode Reader Screen

- Use  and  to highlight the desired setting.
  - If you select **Enabled**, users will be able to use an external barcode reader to enter patient IDs.
  - If you select **Disabled**, users will not be able to use an external barcode reader to enter patient IDs. Patient IDs will have to be input to the reader manually or by RFID.
- When the desired setting is highlighted, press **Select** to save this setting.
- Press **Back** to return to the **Patient ID** screen.

5. Perform the following steps to enable or disable manual entry of the patient ID:

- a. Use  and  to highlight **Manual Entry** and press **Select** to display the **Allow Manual Entry** screen.

The selected radio button indicates the current setting.



- b. Use  and  to highlight the desired setting.
    - If you select **Enabled**, users will be able to enter patient IDs manually.
    - If you select **Disabled**, users will not be able to enter patient IDs manually. Patient IDs will have to be input to the reader by an external barcode reader or by RFID.
- c. When the desired setting is highlighted, press **Select** to save this setting.
- d. Press **Back** to return to the **Patient ID** screen or press  to return to the supervisor **Main Menu** screen.

## Changing the Print Setting

Supervisor users can change the print setting. The print setting determines whether test results are printed automatically upon completion of a patient test.

Perform the following steps to change the patient ID settings:

1. Press  to display the supervisor **Main Menu** screen.



Supervisor Main Menu Screen

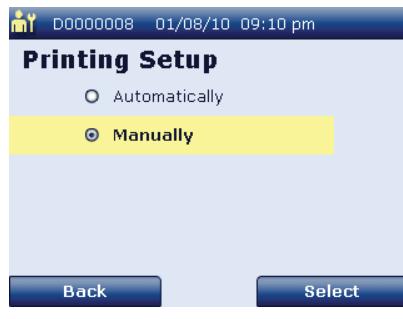
2. Use  and  to highlight **Settings** and press **Select** to display the supervisor **Settings** screen.



Supervisor Settings Screen

3. Use  and  to highlight **Printing Setup** and press **Select** to display the **Printing Setup** screen.

The selected radio button indicates the current setting.



Printing Setup Screen

4. Use  and  to highlight the desired setting.
  - If you select **Automatically**, test results will be printed automatically upon completion of a patient test.
  - If you select **Manually**, test results will not be printed automatically upon completion of a patient test. Results will have to be printed manually by the user.
5. When the desired setting is highlighted, press **Select** to save this setting.
6. Press **Back** to return to the supervisor **Settings** screen or press  to return to the supervisor **Main Menu** screen.

### Changing Security and Power Saving Settings

Supervisor users can change the following security and power saving settings:

- **Logout Time:** The logout time setting is the duration of inactivity after which a user will be automatically logged out of the reader.
- **Power Off Time:** The power off time is the duration of inactivity after which the reader will automatically turn off.
- **Auto-Login Setting:** The auto-login setting determines whether users are required to enter a login and PIN to use the reader.

Perform the following steps to change the logout time, power off time, or auto-login setting:

1. Press  to display the supervisor **Main Menu** screen.



2. Use  and  to highlight **Settings** and press **Select** to display the supervisor **Settings** screen.



**Supervisor Settings Screen**

3. Use  and  to highlight **Set Login / Logout** and press **Select** to display the **Set Login / Logout** screen.

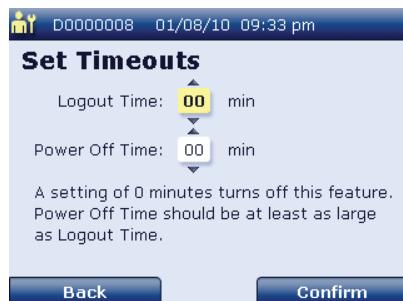


**Set Login / Logout Screen**

4. Perform the following steps to change the logout time and/or power off time:

- a. Use  and  to highlight **Set Timeouts** and press **Select** to display the **Set Timeouts** screen.

The current logout time and power off time are shown.



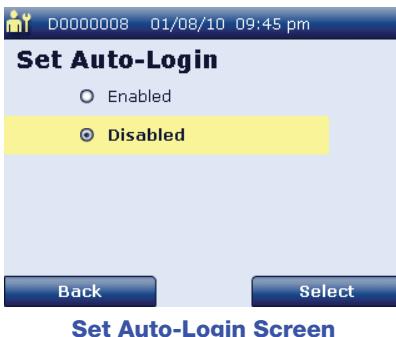
**Set Timeouts Screen**

 **NOTE:** Select a logout time of 0 minutes if you never want users to be automatically logged out of the reader.

 **NOTE:** Select a power off time of 0 minutes if you never want the reader to automatically turn off.

- b. When the **Set Timeouts** screen is first displayed, the **Logout Time** field is highlighted. If necessary, use  and  to increment or decrement the logout time.
  - c. When the desired logout time is displayed, press  to highlight the **Power Off Time** field.
  - d. If necessary, use  and  to increment or decrement the power off time.
  - e. When the desired power off time is displayed, press **Confirm** to save these settings and return to the **Set Login / Logout** screen.
5. Perform the following steps to change the auto-login setting:
    - a. On the **Set Login / Logout** screen, use  and  to highlight **Set Auto-Login** and press **Select** to display the **Set Auto-Login** screen.

The selected radio button indicates the current setting.



The screen shows the following options:

      - Header: D0000008 01/08/10 09:45 pm
      - Section: Set Auto-Login
      - Setting: Enabled (radio button is not selected)
      - Setting: **Disabled** (radio button is selected and highlighted)
      - Buttons: Back, Select
      - Section: Set Auto-Login Screen
    - b. Use  and  to highlight the desired setting.
      - If you select **Enabled**, users will not be required to enter a login and PIN to use the reader.
      - If you select **Disabled**, users will be required to enter a login and PIN to use the reader.
    - c. When the desired setting is highlighted, press **Select** to save this setting.
    - d. Press **Back** to return to the **Set Login / Logout** screen.

## Managing Users

Supervisor users can add new users and modify or delete existing user records. See the following pages for instructions:

- To add a new user, see *Adding a User* on page 47.
- To modify the login information, user name, or user mode for an existing user, see *Changing User Information* on page 51.
- To enable or disable a user record, see *Enabling or Disabling a User* on page 55.
- To delete a user record, see *Deleting a User* on page 57.

 **NOTE:** Only supervisor users can modify user settings. If you are logged in as an operator, select Maintenance > Change to Supervisor to add, modify, or delete a user record.

### Adding a User

Perform the following steps to create a new user:

1. Press  to display the supervisor **Main Menu** screen.



2. Use  and  to highlight **User Administration** and press **Select** to display the **User Administration** screen.

The number at the bottom of the screen indicates the number of available user entries.



3. Use and to highlight **Create new ID** and press **Select** to display the **Enter User ID** screen.

The screenshot shows the 'Enter User ID' screen. At the top, it displays the date and time: D0000008 01/08/10 10:11 pm. Below that is the title 'Enter User ID'. There are three text input fields: 'User ID' (highlighted with a yellow background), 'PIN', and 'Confirm PIN'. At the bottom are two buttons: 'Back' and 'Confirm & Next'.

**Enter User ID Screen**

**NOTE:** To delete the last character entered, press .

4. When the **Enter User ID** screen is first displayed, the **User ID** field is highlighted. Use the numeric keypad to enter the user ID for this user. The user ID must be 4 digits.
5. Press to highlight the **PIN** field.
6. Use the numeric keypad to enter the PIN for this user. The PIN must be 4 digits.
7. Press to highlight the **Confirm PIN** field.
8. Re-enter the 4-digit PIN for this user.
9. Press **Confirm & Next** to display the **Enter User Name** screen.

The screenshot shows the 'Enter User Name' screen. At the top, it displays the date and time: D0000008 01/08/10 10:14 pm. Below that is the title 'Enter User Name'. There is a text input field for 'User name' with a yellow background. Below it is a character selection grid. The grid has two rows: 'A B C D E F G H I J K L M N' and 'O P Q R S T U V W X Y Z , .'. Below the grid are buttons for 'Space', 'Clear all', and 'Done'. At the bottom are two buttons: 'Back' and 'Confirm & Next'.

**Enter User Name Screen**

10. Perform the following steps to enter the user name for this user:
  - a. Use , , , and to highlight the desired character.
  - b. Press **Confirm & Next** to add the highlighted character to the user name.
  - c. Repeat Step a and Step b as necessary.

11. When the user name is complete, use , , , and  to highlight **Done**. Then press **Confirm & Next** to display the **Set Mode** screen.

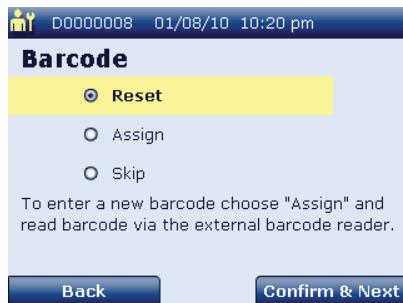


**Set Mode Screen**

12. Use  and  to highlight the desired setting.

- If you select **Operator**, this user will not have access to supervisor functionality.
- If you select **Supervisor**, this user will have access to all reader functionality.

When the desired setting is highlighted, press **Confirm & Next** to display the **Barcode** screen.



**Barcode Screen**

 **NOTE:** To delete this user's barcode, return to the Barcode screen and use  and  to highlight Reset. Then press Confirm & Next.

13. The following options are available on the **Barcode** screen:

- a. *To assign a barcode for this user, use  and  to highlight **Assign**. Then use the external barcode reader to scan the barcode.*  
The reader assigns the barcode and displays the **RFID** screen.
- b. *If you do not want to assign a barcode, use  and  to highlight **Skip**. Then press **Confirm & Next** to display the **RFID** screen.*



 **NOTE:** To delete this user's RFID, return to the RFID screen and use  and  to highlight Reset. Then press Confirm.

14. The following options are available on the **RFID** screen:

- a. *To assign an RFID for this user, use  and  to highlight **Assign**. Place the user's ID card on the designated location on the reader and press **Confirm**. **AG: CLARIFY**.*  
The reader assigns the RFID, saves this user, and returns to the **User Administration** screen.
- b. *If you do not want to assign an RFID, use  and  to highlight **Skip**. Then press **Confirm**.*  
The reader saves this user and returns to the **User Administration** screen.

## Changing User Information

Perform the following steps to modify the login information, user name, or user mode for an existing user:

1. Press  to display the supervisor **Main Menu** screen.



Supervisor Main Menu Screen

2. Use  and  to highlight **User Administration** and press **Select** to display the **User Administration** screen.



User Administration Screen

3. Use  and  to highlight **Organize existing IDs** and press **Select** to display the **User ID List** screen.

The reader displays the user ID, user name, user mode, and status for all users that have been added, arranged numerically by user ID. You can use  and  to scroll through user records.



User ID List Screen

4. Use  and  to highlight the user record you want to modify and press **Options ▲** to display the **User ID Options** screen. **AG: UPDATE SCREEN**.



The User ID Options screen displays a table of user records:

ID	Name	Mode	Status
0002	A0000005	Operator	Enabled

Below the table is a 'Changed Mode' menu with the following options:

- Set enabled / disabled
- Edit Name
- Edit ID
- Delete User

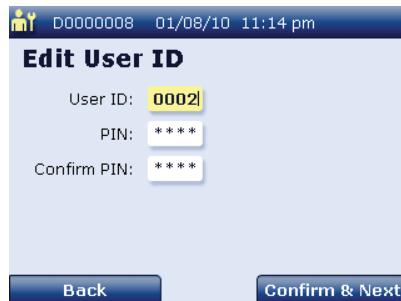
At the bottom are 'Cancel ▾' and 'Select' buttons.

User ID Options Screen

5. To modify the login information for this user:

- a. Use , , , and  to highlight **Edit ID** and press **Select** to display the **Edit User ID** screen.

The user's current user ID and PIN are displayed.



The Edit User ID screen displays the following fields:

User ID:	0002
PIN:	*****
Confirm PIN:	*****

At the bottom are 'Back' and 'Confirm & Next' buttons.

Edit User ID Screen

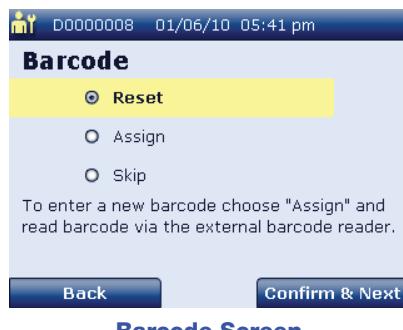
- b. When the **Edit User ID** screen is first displayed, the **User ID** field is highlighted. If necessary, press  to delete characters from the current user ID. Then use the numeric keypad to enter the new user ID for this user. The user ID must be 4 digits.

When the desired user ID is displayed, press  to highlight the **PIN** field.

- c. If necessary, use  to delete characters from the current PIN. Then use the numeric keypad to enter the new PIN for this user. The PIN must be 4 digits.

When the desired PIN has been entered, press  to highlight the **Confirm PIN** field.

- d. If you entered a new PIN, re-enter the 4-digit PIN for this user. Then press **Confirm & Next** to display the **Barcode** screen.



Barcode Screen

- e. The following options are available on the **Barcode** screen:

- If you do not want to assign a barcode, use and to highlight **Skip**. Then press **Confirm & Next** to display the **RFID** screen.
- To delete this user's barcode, use and to highlight **Reset**. Then press **Confirm & Next** to display the **RFID** screen.
- To assign a new barcode for this user, use and to highlight **Assign**. Then use the external barcode reader to scan the barcode. The reader assigns the barcode and displays the **RFID** screen.



RFID Screen

- f. The following options are available on the **RFID** screen:
- If you do not want to assign an RFID, use  and  to highlight **Skip**. Then press **Confirm** to return to the **User ID Options** screen.
  - To delete this user's RFID, use  and  to highlight **Reset**. Then press **Confirm** to return to the **User ID Options** screen
  - To assign a new RFID for this user, use  and  to highlight **Assign**. Place the user's ID card on the designated location on the reader and press **Confirm**. **AG: CLARIFY**. The reader assigns the RFID and returns to the **User ID Options** screen.

6. To modify the user name for this user:

- a. Use , , , and  to highlight **Edit Name** and press **Select** to display the **Edit User Name** screen.

The user's current user name is displayed.



- b. Enter the new user name.

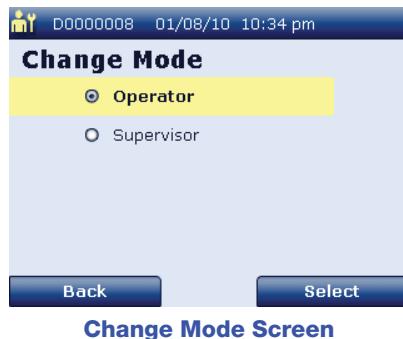
- To delete a character, press .
- To add a character, use , , , and  to highlight the desired character. Then press **Confirm & Next** to add the highlighted character to the user name.

- c. When the user name is complete, use , , , and  to highlight **Done**. Then press **Select** to return to the **User ID Options** screen.

7. To modify the user mode for this user:

- Use and to highlight **Change Mode** and press **Select** to display the **Change Mode** screen.

The user's current user mode is highlighted.



- Use and to highlight the desired setting.
    - If you select **Operator**, this user will not have access to supervisor functionality.
    - If you select **Supervisor**, this user will have access to all reader functionality.
  - When the desired setting is highlighted, press **Select** to save this setting.
  - Press **Back** to return to the **User ID Options** screen.
8. When you have finished modifying the settings for this user, press **Cancel** to return to the **User ID List** screen or press to return to the supervisor **Main Menu** screen.

#### Enabling or Disabling a User

Perform the following steps to enable or disable an existing user record:

- Press to display the supervisor **Main Menu** screen.



**NOTE:** You can disable the user record for a user who does not currently need to use the reader, but might need to use it in the future.

2. Use  and  to highlight **User Administration** and press **Select** to display the **User Administration** screen.

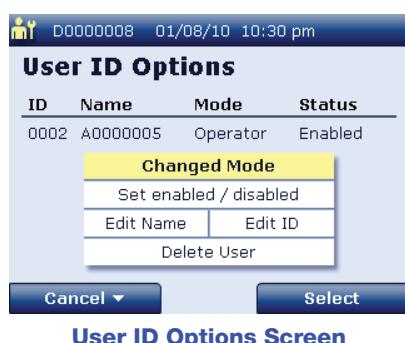


3. Use  and  to highlight **Organize existing IDs** and press **Select** to display the **User ID List** screen.

The reader displays the user ID, user name, user mode, and status for all users that have been added, arranged numerically by user ID. You can use  and  to scroll through user records.



4. Use  and  to highlight the user record you want to enable or disable and press **Options ▲** to display the **User ID Options** screen.



5. Use , , , and to highlight **Set enabled / disabled** and press **Select** to display the **Change Status** screen.

The user's current status is highlighted.



6. Use and to highlight the desired setting.
- If you select **Enabled**, this user will be able to log in to the reader.
  - If you select **Disabled**, this user will no longer be able to log in to the reader.
7. When the desired setting is highlighted, press **Select** to save this setting.
8. Press **Back** to return to the **User ID Options** screen.
9. When you have finished modifying the settings for this user, press **Cancel** to return to the **User ID List** screen or press to return to the supervisor **Main Menu** screen.

#### Deleting a User

Perform the following steps to delete a user record:

1. Press to display the supervisor **Main Menu** screen.



**NOTE:** You can delete the user record for a user who no longer needs to use the reader.

2. Use  and  to highlight **User Administration** and press **Select** to display the **User Administration** screen.



User Administration Screen

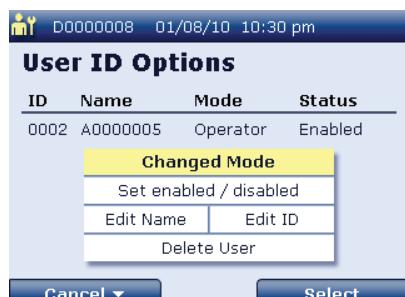
3. Use  and  to highlight **Organize existing IDs** and press **Select** to display the **User ID List** screen.

The reader displays the user ID, user name, user mode, and status for all users that have been added, arranged numerically by user ID. You can use  and  to scroll through user records.



User ID List Screen

4. Use  and  to highlight the user record you want to delete and press **Options ▲** to display the **User ID Options** screen.



User ID Options Screen

5. Use , , , and  to highlight **Delete User** and press **Select** to display the **Delete User** confirmation screen.

The screen displays the user name for the selected user.



6. The following options are available on the **Delete User** confirmation screen.
  - To delete this user record, press **Delete**. The selected user record is deleted and the reader returns to the **User ID List** screen.
  - To keep this user record and return to the **User ID Options** screen, press **Cancel**.
7. When you have finished deleting user records, press  to return to the supervisor **Main Menu** screen.



## Daily Operations

### Startup

This section provides information on preparing the reader for daily use. The following tasks must be completed prior to testing patient samples:

- The reader must be powered on.
- A user must log in to the reader (unless the reader's auto-login feature is enabled).
- A quality control check must be performed if required by laboratory procedures.

#### Turning On the Reader

The on/off switch is located on the back of the reader. To turn on the reader, push the on/off switch up until the **Initializing** screen appears, then release it. The reader displays a splash screen during startup, then displays one of the following screens:

- The **Login** screen is displayed if the reader's auto-login feature is disabled.
- The **Enter Patient ID** screen is displayed if the reader's auto-login feature is enabled.



**IMPORTANT:** Allow the reader to warm up for at least 20 minutes before running any patient samples.

## Logging In

If necessary, perform the following steps to log in to the reader:

 **NOTE:** To delete the last character entered, press .

1. On the Login screen, enter your 4-digit user ID or barcode number using one of the following methods:
  - Place your ID card on the designated location on the reader. Then go to Step 4. **AG: CLARIFY.**
  - Use the numeric keypad to enter your user ID manually.
  - Use the external barcode reader to scan your barcode.



2. Press  to highlight the **PIN** field.
3. Enter your 4-digit PIN. **AG: CONFIRM FOR USE OF AN ID CARD OR BARCODE.**
4. Press **Login** to log in as an operator.

 **NOTE:** You can also press **Supervisor Login** to log in as a supervisor. If you log in as a supervisor, you will need to select **Change to Operator** to test patient samples.

## Running Quality Control Checks

Quality control (QC) testing ensures that the reader is operating within acceptable ranges. QC routines are mandatory and patient tests should not be performed unless required. QC is complete. The manufacturer's recommendation for QC testing is to test 1 high control and 1 low control per box of test cartridges.

The reader performs initialization and self-checks each time it is powered on. These checks ensure that:

- Communication between the different reader modules is working.
- The optics are functioning properly.
- The carriage is free to move correctly.
- The carriage position is zeroed.



**IMPORTANT:** Each day that testing is to be performed, the reader should be powered on and allowed to complete its initialization and self-checks.

From the **Check Reader** screen, you can run an internal QC check on the reader. You can also run an external QC check using the system check cassette provided with the reader. The result of a QC check can be sent to the LIS or printed. This result is stored in the reader until the next QC check is performed, then the previous result is over-written with the new result.



**IMPORTANT:** Follow laboratory procedures regarding how frequently to perform QC checks and how to document the results.



**NOTE:** To send the result of a QC check to the LIS, the reader must be connected to the LIS and the LIS must have been set up by a supervisor. See *Connecting to the LIS* on page 33 for instructions.

Perform the following steps to run an internal QC check:

1. Press  to display the **Main Menu** screen.



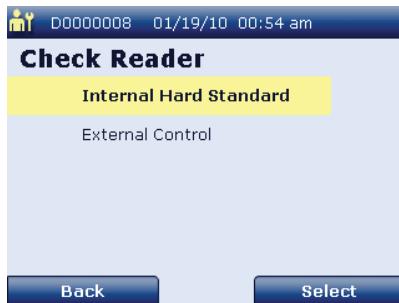
2. If you are logged in as a supervisor, skip this step and go to Step 3.

If you are logged in as an operator, use  and  to highlight **Maintenance** and press **Select** to display the **Maintenance** screen.

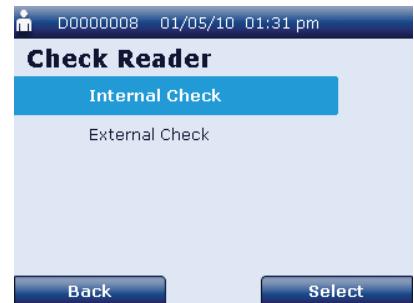


Maintenance Screen

3. Use  and  to highlight **Check Reader** and press **Select** to display the **Check Reader** screen.



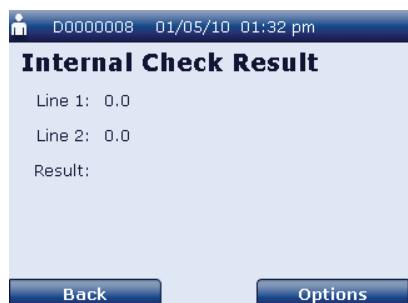
Supervisor Check Reader Screen



Operator Check Reader Screen

4. Use  and  to highlight **Internal Hard Standard** or **Internal Check** and press **Select**.

The reader performs an internal check, then displays the **Internal Check Result** screen.



Internal Check Result Screen

5. To send the result of the internal check to the LIS:

- Press **Options**.
- Use  and  to highlight **Send Result** and press **Select**.

The reader sends the result, then returns to the **Check Reader** screen.



Internal Check Result Screen – Options

6. To print the result of the internal check:

- Press **Options**.
- Use  and  to highlight **Print Result** and press **Select**.

The reader prints the result, then returns to the **Check Reader** screen.

7. Press **Back** to return to the **Check Reader** screen or press  to return to the **Main Menu** screen.

Perform the following steps to run an external QC check:

- Press  to display the **Main Menu** screen.



Supervisor Main Menu Screen



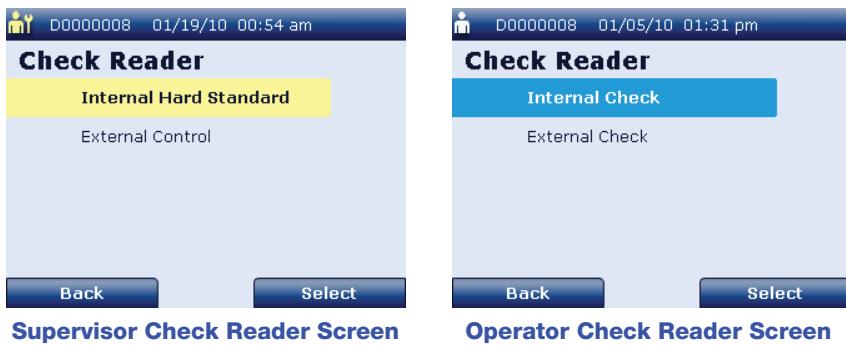
Operator Main Menu Screen

2. If you are logged in as a supervisor, skip this step and go to Step 3.

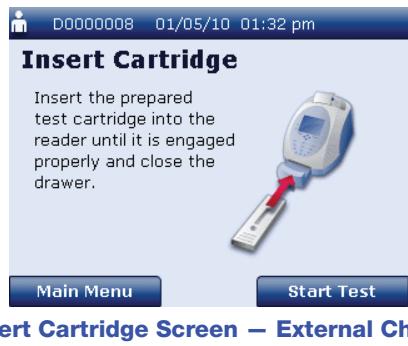
If you are logged in as an operator, use  and  to highlight **Maintenance** and press **Select** to display the **Maintenance** screen.



3. Use  and  to highlight **Check Reader** and press **Select** to display the **Check Reader** screen.



4. Use  and  to highlight **External Control** or **External Check** and press **Select** to display the **Insert Cartridge** screen.



5. Press  to eject the drawer. **AG: TBD IF THIS STEP IS NECESSARY.**

6. Insert the system check cassette in the reader with the sample application area facing toward you. Then close the drawer and press **Start Test**.

The reader performs a check using the system check cassette, then displays the **External Check Result** screen.

#### External Check Result Screen

7. To send the result of the external check to the LIS:

- a. Press **Options**.
- b. Use  and  to highlight **Send Result** and press **Select**.

The reader sends the result, then returns to the **Check Reader** screen.

 **NOTE:** You can select **Send All** to send the results of all external checks performed using this system check cassette. **AG: CONFIRM**

#### External Check Result Screen – Options

8. To print the result of the external check:

- a. Press **Options**.
- b. Use  and  to highlight **Print Result** and press **Select**.

The reader prints the result, then returns to the **Check Reader** screen.

 **NOTE:** You can select **Print All** to print the results of all external checks performed using this system check cassette. **AG: CONFIRM**

9. Press  to eject the drawer. Remove the system check cassette and store it in its original foil pouch.



**IMPORTANT:** To avoid light exposure, store and reseal the system check cassette in its original foil pouch immediately after each use.

10. Press **Back** to return to the **Check Reader** screen or press  to return to the **Main Menu** screen.

## Testing a Patient Sample



**IMPORTANT:** Allow the reader to warm up for at least 20 minutes before running any patient samples.

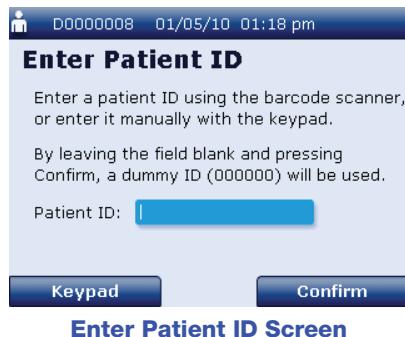
Perform the following steps to test a patient sample:

 **NOTE:** The **Run Test** menu item is not available on the supervisor Main Menu screen. If you are logged in as a supervisor, select **Change to Operator** to display the operator Main Menu screen.

1. Press  to display the operator **Main Menu** screen.



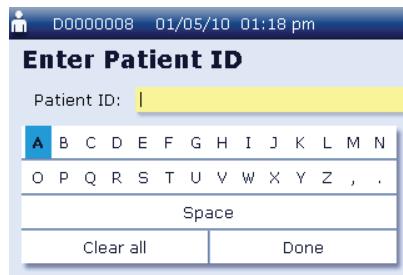
2. Use  and  to highlight **Run Test** and press **Select** to display the **Enter Patient ID** screen.



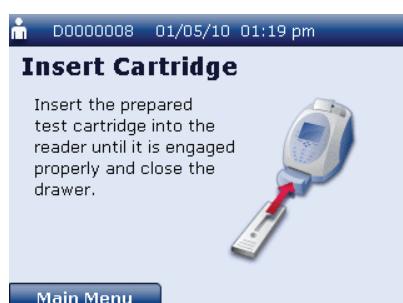
## 3. Enter the patient ID using one of the following methods:

- Use the external barcode reader to scan the patient's barcode.
- Use the numeric keypad to enter the patient ID.
- Press **Keypad** to enter letters, spaces, and punctuation.
  - a. When the keypad is displayed on the reader's screen, use , , , and  to highlight the desired character.
  - b. Press **Confirm & Next** to add the highlighted character to the patient ID.
  - c. Repeat Step a and Step b as necessary.
  - d. When the patient ID is complete, press **Back** to exit the Keypad feature.

 **NOTE:** To delete the last character entered, press .



Keypad Screen

4. On the Enter Patient ID screen, press **Confirm** to display the **Insert Cartridge** screen.

Insert Cartridge Screen – Run Test

5. Press  to eject the drawer.
6. Prepare the test sample in accordance with the instructions provided in the package of test cartridges.

7. Gently insert the prepared test cartridge in the drawer with the sample application area facing toward you as shown below. Then close the drawer.



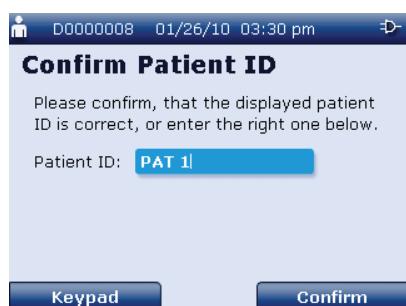
**Test Cartridge in Reader Drawer**

The reader displays the status of the test on the **Run Test** screen, then displays the **Test Result** screen when the test is complete.



**Test Result Screen**

8. Press **Next** to display the **Confirm Patient ID** screen.



**Confirm Patient ID Screen**

9. Confirm that the patient ID displayed on this screen is correct.
  - If the patient ID is correct, press **Confirm** to view the test result on the **Result List** screen. If the reader's automatic printing feature is enabled, the result is printed automatically.

Result List			
ID	Date	Time	Result
..KLMN	06/04/08	09:22AM	Err 2
..JKLM	06/03/08	09:21AM	28.0 +
..IJKL	06/02/08	09:20AM	26.0 +
..HIJK	06/01/08	09:19AM	Err L

Result List Screen

- If the patient ID is incorrect:
  - Enter the appropriate patient ID and press **Confirm** to display the **Patient ID does not match** screen.

Patient ID does not match!!	
The confirmed Patient ID does not match the first one entered. Please confirm Patient ID again.	
Patient ID:	<input type="text"/>
<b>Keypad</b>	<b>Confirm</b>

Patient ID Does Not Match Screen

10. Press  to eject the drawer. Remove the test cartridge and dispose or store as appropriate. **AG: NEED INPUT.**

 **NOTE:** To delete the last character entered, press .

## Managing Patient Results

The **Result List** screen displays basic information for each patient test result stored in the reader's memory. From the **Result List** screen you can:

- view details for a patient test result
- send patient test results to the LIS
- print patient test results

You can also view, send, and print an individual result stored on a test cartridge.

 **NOTE:** To send a patient result to the LIS, the reader must be connected to the LIS and the LIS must have been set up by a supervisor. See Connecting to the LIS on page 33 for instructions.



**IMPORTANT:** Results are stored in the reader's memory for temporary backup purposes only. The reader can store up to 100 patient test results. When the reader's memory is full, a warning message is displayed prompting user action. If no action is taken, results are overwritten as new tests are completed, starting with the oldest result in memory.

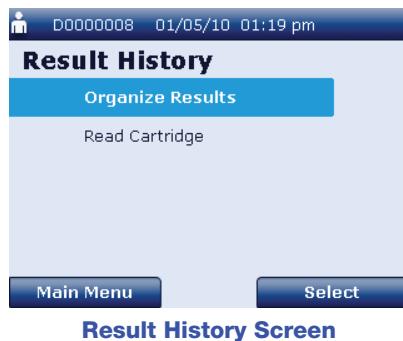
### Viewing Detailed Test Results

Perform the following steps to view detailed information for test results stored in the reader's memory:

1. Press  to display the operator **Main Menu** screen.



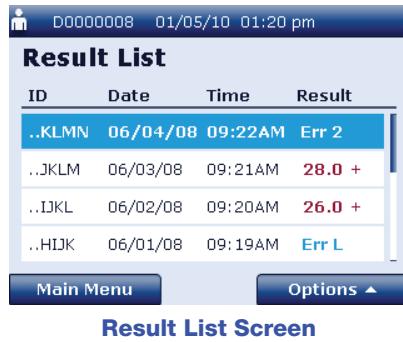
2. Use  and  to highlight **Result History** and press **Select** to display the **Result History** screen.



 **NOTE:** The Result History menu item is not available on the supervisor Main Menu screen. If you are logged in as a supervisor, select Change to Operator to display the operator Main Menu screen.

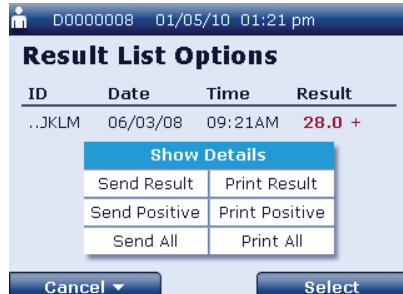
3. Use  and  to highlight **Organize Results** and press **Select** to display the **Result List** screen.

The reader displays the patient ID, date, time, and test result for all results stored in the reader's memory, starting with the most recent test performed. You can scroll through results using  and .



**Result List Screen**

4. Use  and  to highlight the desired result and press **Options ▲** to display the **Result List Options** screen.

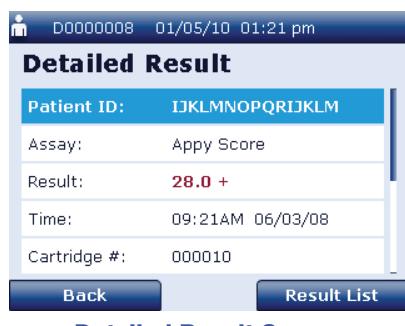


**Result List Options Screen**

5. Use  and  to highlight **Show Details** and press **Select** to display the **Detailed Result** screen.

The following information is available on the **Detailed Result** screen:

- **Patient ID:** The complete patient ID recorded for the test.
- **Assay:** The assay type that was performed (Appy Score).
- **Result:** The result of the test.
- **Time:** The time and date the test was performed.
- **Cartridge #:** The number of the cartridge used for the test.
- **Op ID:** The ID for the operator that performed the test.
- **Buffer #:** The lot number of the buffer used for the test.
- **Conjugate #:** The lot number of the conjugate used for the test.
- **Temperature:** The temperature recorded in the reader at the time the test was performed.
- **Last LQC:** The date of the last LQC performed on the reader.



6. When you have finished viewing result details, press **Back** to return to the **Result List** screen.

## Sending Patient Results

Perform the following steps to send patient results stored in the reader's memory to the LIS:

1. Press  to display the operator **Main Menu** screen.



Operator Main Menu Screen

2. Use  and  to highlight **Result History** and press **Select** to display the **Result History** screen.



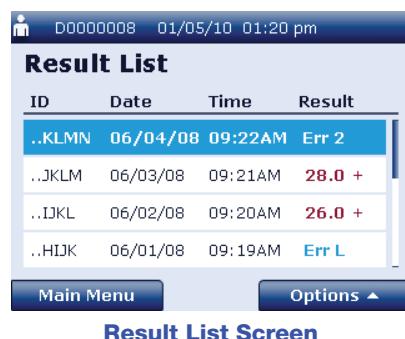
Result History Screen

3. Use  and  to highlight **Organize Results** and press **Select** to display the **Result List** screen.

The reader displays the patient ID, date, time, and test result for all results stored in the reader's memory, starting with the most recent test performed.

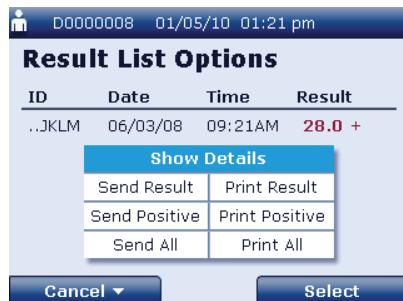
You can scroll through results using  and .

 **NOTE:** The Result History menu item is not available on the supervisor Main Menu screen. If you are logged in as a supervisor, select Change to Operator to display the operator Main Menu screen.



Result List Screen

4. Use and to highlight the result you want to send and press **Options ▲** to display the **Result List Options** screen.



5. To send only the selected result:
  - a. Use and to highlight **Send Result** and press **Select**.
  - b. The reader sends the result, then returns to the **Result List** screen.
6. To send all patient results stored in the reader's memory:
  - a. Use and to highlight **Send All** and press **Select**.
  - b. The reader sends the results, then returns to the **Result List** screen.
7. To send all positive results stored in the reader's memory:
  - a. Use and to highlight **Send Positive** and press **Select**.
  - b. The reader sends the results, then returns to the **Result List** screen.

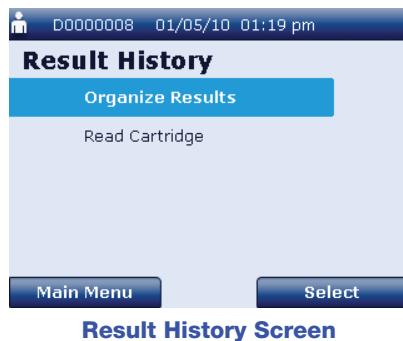
### Printing Patient Results

Perform the following steps to print patient results stored in the reader's memory:

1. Press to display the operator **Main Menu** screen.



2. Use  and  to highlight **Result History** and press **Select** to display the **Result History** screen.

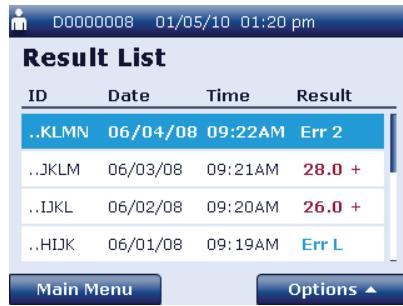


Result History Screen

 **NOTE:** The Result History menu item is not available on the supervisor Main Menu screen. If you are logged in as a supervisor, select Change to Operator to display the operator Main Menu screen.

3. Use  and  to highlight **Organize Results** and press **Select** to display the **Result List** screen.

The reader displays the patient ID, date, time, and test result for all results stored in the reader's memory, starting with the most recent test performed. You can scroll through results using  and .



Result List Screen

4. Use  and  to highlight the desired result and press **Options ▲** to display the **Result List Options** screen.



Result List Options Screen

5. To print only the selected result:
  - a. Use  and  to highlight **Print Result** and press **Select**.
  - b. The reader prints the result, then returns to the **Result List** screen.
6. To print all patient results stored in the reader's memory:
  - a. Use  and  to highlight **Print All** and press **Select**.
  - b. The reader prints the results, then returns to the **Result List** screen.
7. To print all positive results stored in the reader's memory:
  - a. Use  and  to highlight **Print Positive** and press **Select**.
  - b. The reader prints the results, then returns to the **Result List** screen.

#### Viewing a Result Stored on a Test Cartridge

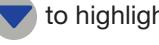
Perform the following steps to view an individual result stored on a test cartridge:

1. Press  to display the operator **Main Menu** screen.



Operator Main Menu Screen

 **NOTE:** The Result History menu item is not available on the supervisor Main Menu screen. If you are logged in as a supervisor, select Change to Operator to display the operator Main Menu screen.

2. Use  and  to highlight **Result History** and press **Select** to display the **Result History** screen.



Result History Screen

3. Place the test cartridge on the designated location on the reader. **AG:**  
**CLARIFY.**

4. Use  and  to highlight **Read Cartridge** and press **Select** to display the **Read Result on Cartridge** screen.

The reader displays the patient ID, date, time, and test result for the result stored on the test cartridge.

#### **Read Result on Cartridge Screen**

5. To view detailed information for the test result:
  - a. Press **Options**  to display the **Read Cartridge Options** screen.

#### **Read Cartridge Options Screen**

- b. Use  and  to highlight **Show Details** and press **Select** to display the **Read Cartridge Details** screen.

The following information is available on the **Read Cartridge Details** screen:

- **Patient ID:** The complete patient ID recorded for the test.
- **Assay:** The assay type that was performed (Appy Score).
- **Result:** The result of the test.
- **Time:** The time and date the test was performed.
- **Cartridge #:** The number of the cartridge used for the test.
- **Op ID:** The ID for the operator that performed the test.
- **Buffer #:** The lot number of the buffer used for the test.
- **Conjugate #:** The lot number of the conjugate used for the test.
- **Temperature:** The temperature recorded in the reader at the time the test was performed.
- **Last LQC:** The date of the last LQC performed on the reader.

#### **Read Cartridge Details Screen**

- c. When you have finished viewing result details, press **Back** to return to the **Read Cartridge Options** screen.
6. To send the test result to the LIS:
  - a. Press **Options ▲** to display the **Read Cartridge Options** screen.
  - b. Use  and  to highlight **Send to LIS** and press **Select**.
  - c. The reader sends the result, then returns to the **Read Cartridge Options** screen.
7. To print the test result:
  - a. Press **Options ▲** to display the **Read Cartridge Options** screen.
  - b. Use  and  to highlight **Print Result** and press **Select**.
  - c. The reader prints the result, then returns to the **Read Cartridge Options** screen.

## **Daily Shutdown**

Turn off the reader at the end of each day. To turn off the reader, push the on/off switch up, then release it.



## Export / Import Features

Supervisor users can export information to and import information from an SD card.

To install the SD card, insert the card into the SD card slot in the back of the reader as shown below. Ensure that the metallic contacts on the edge of the card are facing toward the outside of the reader as shown in the figure below. Push in the card until you feel resistance.



**Installing the SD Card**

- To export test results stored on the reader to the SD card, see *Exporting Stored Test Results* on page 84.
- To export the last 10 raw data scans stored on the reader to the SD card, see *Exporting Raw Test Data* on page 86.
- To export user records to or import user records from the SD card, see *Importing and Exporting Users* on page 87.

 **NOTE:** Only supervisor users can use the reader's export / import features. If you are logged in as an operator, select Maintenance > Change to Supervisor to export or import information.

## Exporting Stored Test Results

Perform the following steps to export test results stored on the reader to the SD card:

1. Install the SD card in the reader. For instructions, see page 83.
2. Press  to display the supervisor **Main Menu** screen.



3. Use  and  to highlight **Import / Export** and press **Select** to display the **Import / Export** screen.



4. Use  and  to highlight **Export Result List** and press **Select** to display the **Export Result List** screen.

The reader displays the patient ID, date, time, and test result for all results stored in the reader's memory, starting with the most recent test performed. You can scroll through results using  and .



ID	Date	Time	Result
..KLMN	08/06/04	09:22AM	Err 2
..JKLM	08/06/03	09:21AM	28.0 +
..IJKL	08/06/02	09:20AM	26.0 +
..HIJK	08/06/01	09:19AM	Err L

**Export Result List Screen**

5. Press **Export** to export the result list.

The reader displays the **Export Successful** screen when the result list has been exported to the SD card.



**Export Successful Screen — Result List**

6. Press **OK** to return to the **Export Result List** screen or press **Main Menu** to return to the supervisor **Main Menu** screen.

## Exporting Raw Test Data

Perform the following steps to export the last 10 raw data scans stored on the reader to the SD card:

1. Install the SD card in the reader. For instructions, see page 83.
2. Press  to display the supervisor **Main Menu** screen.



3. Use  and  to highlight **Import / Export** and press **Select** to display the **Import / Export** screen.



4. Use  and  to highlight **Export Raw Data Scan** and press **Select** to export the last 10 raw data scans.

The reader displays the **Export Successful** screen when the data has been exported to the SD card.



5. Press **OK** to return to the **Import / Export** screen or press  to return to the supervisor **Main Menu** screen.

## Importing and Exporting Users

Supervisor users can export user records to or import user records from the SD card.

- To export the user record for a selected user to the SD card, see *Exporting a User* on page 87.
- To export user records for multiple users to the SD card, see *Exporting All Users* on page 89.
- To import the user record for a selected user from the SD card, see *Importing a User* on page 91.
- To import user records for multiple users from the SD card, see *Importing All Users* on page 93.

 **NOTE:** Only supervisor users can use the reader's export / import features. If you are logged in as an operator, select Maintenance > Change to Supervisor to export or import information.

### Exporting a User

Perform the following steps to export the user record for a selected user to the SD card:

1. Install the SD card in the reader. For instructions, see page 83.
2. Press  to display the supervisor **Main Menu** screen.

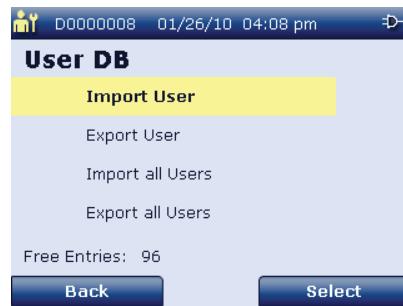


3. Use  and  to highlight **Import / Export** and press **Select** to display the **Import / Export** screen.



**Import / Export Screen**

4. Use  and  to highlight **Import / Export User** and press **Select** to display the **User DB** screen.



**User DB Screen**

5. Use  and  to highlight **Export User** and press **Select** to display the **User DB on Reader** screen.

The reader displays the user ID, user name, and user mode for all users that have been added, arranged numerically by user ID. You can use  and  to scroll through user records.

A screenshot of the 'User DB on Reader' screen. The header shows 'D0000008 01/26/10 03:59 pm'. Below the header is a yellow bar with 'User DB on Reader'. A table follows, with columns 'ID', 'Name', and 'Mode'. The first row is highlighted with a yellow background and shows '1111 D0000008 Supervisor'. Other rows show '2222 A0000005 Operator', '3333 B0000006 Operator', and '4444 C000007 Supervisor'. At the bottom are 'Export' and 'Select' buttons. The 'User DB on Reader' bar is highlighted with a yellow background.

**User DB on Reader Screen**

6. Use  and  to highlight the user record you want to export and press **Select**.

A checkmark appears in the box next to the user ID to indicate the selected user.

7. Press **Export** to copy the user information for the selected user to the SD card.

The reader displays the **Export Successful** screen when the user record has been exported to the SD card.

 **NOTE:** To remove the checkmark, highlight the user record and press **Select** again.



**Export Successful Screen — User**

8. Press **OK** to return to the **Import / Export** screen or press **Main Menu** to return to the supervisor **Main Menu** screen.

### Exporting All Users

Perform the following steps to export multiple user records to the SD card:

1. Install the SD card in the reader. For instructions, see page 83.
2. Press  to display the supervisor **Main Menu** screen.



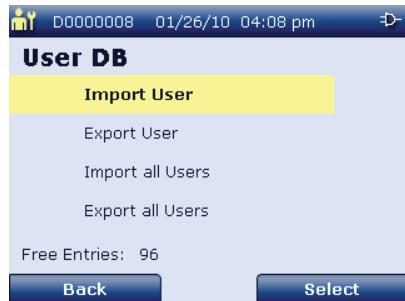
**Supervisor Main Menu Screen**

3. Use  and  to highlight **Import / Export** and press **Select** to display the **Import / Export** screen.



**Import / Export Screen**

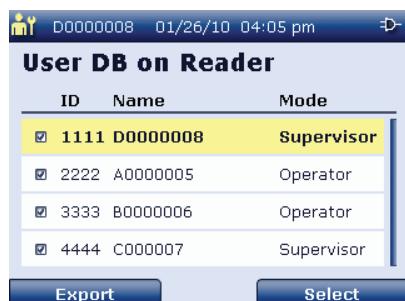
4. Use  and  to highlight **Import / Export User** and press **Select** to display the **User DB** screen.



**User DB Screen**

5. Use  and  to highlight **Export all Users** and press **Select** to display the **User DB on Reader** screen.

The reader displays the user ID, user name, and user mode for all users that have been added, arranged numerically by user ID. You can use  and  to scroll through user records. A checkmark is shown in the box next to each user ID to indicate that all users have been selected to be exported.



**User DB on Reader Screen**

6. If there is a user record that you do not want to export, use and to highlight the user record. When the user record is highlighted, press **Select**.

The checkmark is removed from the box next to the user ID.

7. Repeat Step 6 as necessary.
8. When all desired user records are selected, press **Export** to copy the user information for the selected users to the SD card.

The reader displays the **Export Successful** screen when the user records have been exported to the SD card.



**Export Successful Screen – User**

9. Press **OK** to return to the **Import / Export** screen or press **Main Menu** to return to the supervisor **Main Menu** screen.

### Importing a User

Perform the following steps to import the user record for a selected user from the SD card:

1. Install the SD card in the reader. For instructions, see page 83.
2. Press to display the supervisor **Main Menu** screen.

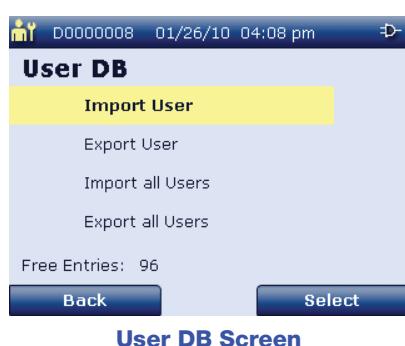


**Supervisor Main Menu Screen**

3. Use  and  to highlight **Import / Export** and press **Select** to display the **Import / Export** screen.

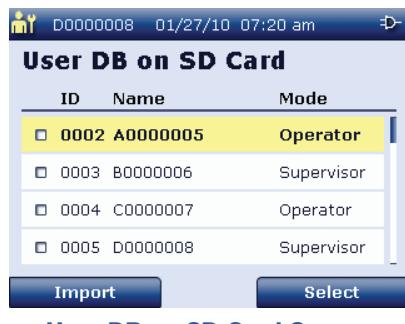


4. Use  and  to highlight **Import / Export User** and press **Select** to display the **User DB** screen.



5. Use  and  to highlight **Import User** and press **Select**.

The user records are read from the SD card and displayed on the **User DB on SD Card** screen. This screen displays the user ID, user name, and user mode for all user records on the SD card, arranged numerically by user ID. You can use  and  to scroll through user records.



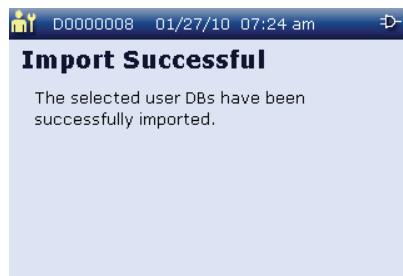
6. Use  and  to highlight the user record you want to import. When the desired user record is highlighted, press **Select**.

A checkmark appears in the box next to the user ID to indicate the selected user.

7. Press **Import** to copy the user information for the selected user to the reader.

The reader displays the **Import Successful** screen when the user record has been imported to the reader.

 **NOTE:** To remove the checkmark, highlight the user record and press **Select** again.



**Import Successful Screen**

8. Press **OK** to go to the **User ID List** screen or press **Main Menu** to return to the supervisor **Main Menu** screen.

### Importing All Users

Perform the following steps to import multiple user records from the SD card:

1. Install the SD card in the reader. For instructions, see page 83.
2. Press  to display the supervisor **Main Menu** screen.



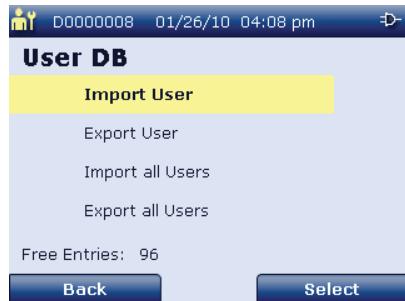
**Supervisor Main Menu Screen**

3. Use  and  to highlight **Import / Export** and press **Select** to display the **Import / Export** screen.



**Import / Export Screen**

4. Use  and  to highlight **Import / Export User** and press **Select** to display the **User DB** screen.



**User DB Screen**

5. Use  and  to highlight **Import all Users** and press **Select**.

The user records are read from the SD card and displayed on the **User DB on SD Card** screen. This screen displays the user ID, user name, and user mode for all user records on the SD card, arranged numerically by user ID. You can use  and  to scroll through user records. A checkmark is shown in the box next to each user ID to indicate that all users have been selected to be imported.

ID	Name	Mode
<input checked="" type="checkbox"/> 0002 A0000005		Operator
<input checked="" type="checkbox"/> 0003 B0000006		Supervisor
<input checked="" type="checkbox"/> 0004 C0000007		Operator
<input checked="" type="checkbox"/> 0005 D0000008		Supervisor

**User DB on SD Card Screen**

6. If there is a user record that you do not want to import, use  and  to highlight the user record. When the user record is highlighted, press **Select**.

The checkmark is removed from the box next to the user ID.

7. Repeat Step 6 as necessary.
8. When all desired user records are selected, press **Import** to copy the user information for the selected users to the reader.

The reader displays the **Import Successful** screen when the user records have been imported to the reader.



**Import Successful Screen**

9. Press **OK** to go to the **User ID List** screen or press **Main Menu** to return to the supervisor **Main Menu** screen.



## Other Features

### Reviewing Reader Information

Supervisor users and operator users can review information about the reader. Some information is only available to supervisor users.

- All users can review the version information for the reader's software. See *Checking the Software Version* on page 97 for instructions.
- All users can review a summary of the reader's settings, including login/logout settings, patient ID settings, and the reader's serial number. See *Reviewing Global Settings* on page 101 for instructions.
- All users can review a listing of actions that have been performed by supervisors. See *Reviewing the Supervisor History* on page 99 for instructions.
- Supervisor users can review the results of the last internal check that was performed on the reader. See *Reviewing Internal Check Results* on page 103 for instructions.

#### Checking the Software Version

Supervisor users and operator users can review the version information for the reader's software. Perform the following steps to check the software version:

1. Press  to display the **Main Menu** screen.

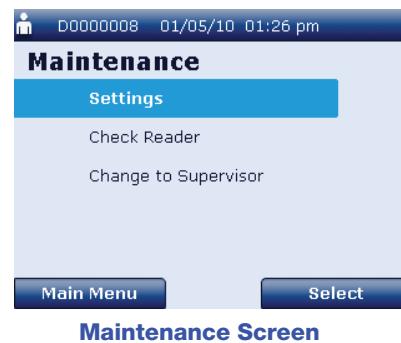


2. If you are logged in as a supervisor, use  and  to highlight **Settings** and press **Select** to display the supervisor **Settings** screen.

If you are logged in as an operator, use  and  to highlight **Maintenance** and press **Select** to display the **Maintenance** screen.



Supervisor Settings Screen



Maintenance Screen

3. If you are logged in as a supervisor, use  and  to highlight **Device Info** and press **Select** to display the **Device Info** screen.

If you are logged in as an operator, use  and  to highlight **Settings** and press **Select** to display the operator **Settings** screen.



Device Info Screen



Operator Settings Screen

4. Use  and  to highlight **Software Version** and press **Select** to display the **Current Software Version** screen.

The version information for the reader's software is displayed.



Current Software Version Screen

5. Press **Back** to return to the previous screen or press  to return to the **Main Menu** screen.

### Reviewing the Supervisor History

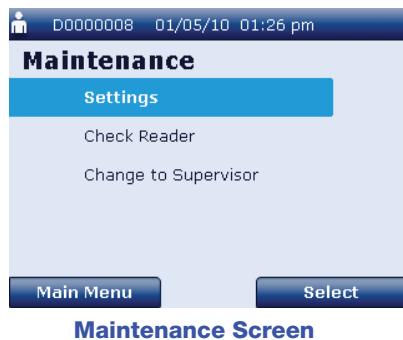
Supervisor users and operator users can review a listing of actions that have been performed by supervisors. Perform the following steps to review supervisor history:

1. Press  to display the **Main Menu** screen.

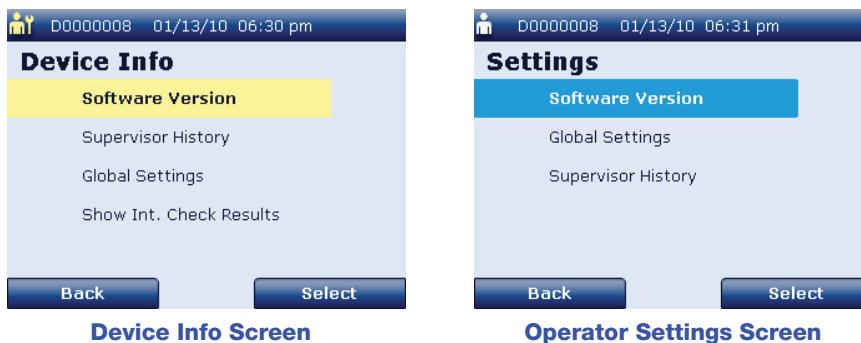


2. If you are logged in as a supervisor, use  and  to highlight **Settings** and press **Select** to display the supervisor **Settings** screen.

If you are logged in as an operator, use  and  to highlight **Maintenance** and press **Select** to display the **Maintenance** screen.



3. If you are logged in as a supervisor, use  and  to highlight **Device Info** and press **Select** to display the **Device Info** screen.  
*If you are logged in as an operator, use  and  to highlight **Settings** and press **Select** to display the operator **Settings** screen.*



4. Use  and  to highlight **Supervisor History** and press **Select** to display the **Supervisor History** screen.

The reader displays the user ID, date, time, and action identifier for actions that have been performed by supervisor users. You can scroll through actions using  and .

**AG: CAN WE GET A KEY FOR SUPERVISOR ACTIONS?**

Supervisor History			
ID	Date	Time	Action
0011	06/04/08	09:22AM	10
0010	06/03/08	09:21AM	09
0009	06/02/08	09:20AM	08
0008	06/01/08	09:19AM	07

**Supervisor History Screen**

5. If you want to print the supervisor history, press **Print**.
6. Press **Back** to return to the previous screen or press  to return to the **Main Menu** screen.

## Reviewing Global Settings

Supervisor users and operator users can review a summary of the following reader settings:

- **Logout Time:** The logout time setting is the duration of inactivity after which a user will be automatically logged out of the reader. For instructions to change the logout time, see *Changing Security and Power Saving Settings* on page 44.
- **APO Time:** The automatic power off time is the duration of inactivity after which the reader will automatically turn off. For instructions to change the automatic power off time, see *Changing Security and Power Saving Settings* on page 44.
- **Auto Login:** The auto-login setting determines whether users are required to enter a login and PIN to use the reader. For instructions to change the auto-login setting, see *Changing Security and Power Saving Settings* on page 44.
- **Immediate Print:** The immediate print setting determines whether test results are printed automatically upon completion of a patient test. For instructions to change printing setup, see *Changing the Print Setting* on page 43.
- **Manual Patient ID:** The manual patient ID setting determines whether patient IDs can be input by manual entry. For instructions to change the manual patient ID setting, see *Changing Patient ID Settings* on page 40.
- **External Barcode Reader:** The manual patient ID setting determines whether patient IDs can be input by an external barcode reader. For instructions to change the external barcode reader setting, see *Changing Patient ID Settings* on page 40.
- **Cutoff:** The cutoff setting is the minimum test result that will be considered positive when the reader tests a patient sample. **AG: CONFIRM THAT THIS SETTING WILL BE AVAILABLE.**
- **Serial Number:** The serial number for the reader is available on this screen.
- **Language:** The language setting determines what language is displayed on the reader screen and printouts. For instructions to change the language, see *Changing the Language* on page 39.



**NOTE:** Operator users cannot modify these settings.

Perform the following steps to review global settings:

1. Press  to display the **Main Menu** screen.



Supervisor Main Menu Screen



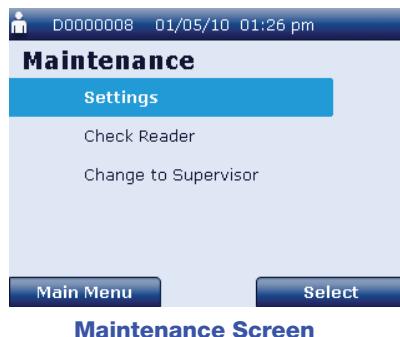
Operator Main Menu Screen

2. If you are logged in as a supervisor, use  and  to highlight **Settings** and press **Select** to display the supervisor **Settings** screen.

If you are logged in as an operator, use  and  to highlight **Maintenance** and press **Select** to display the **Maintenance** screen.



Supervisor Settings Screen



Maintenance Screen

3. If you are logged in as a supervisor, use  and  to highlight **Device Info** and press **Select** to display the **Device Info** screen.

If you are logged in as an operator, use  and  to highlight **Settings** and press **Select** to display the operator **Settings** screen.



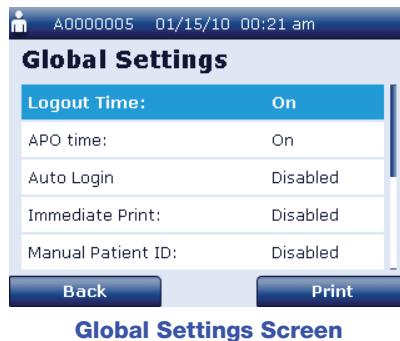
Device Info Screen



Operator Settings Screen

4. Use  and  to highlight **Global Settings** and press **Select** to display the **Global Settings** screen.

The reader's current settings are displayed. You can scroll through settings using  and .



Global Settings Screen

5. If you want to print the global settings, press **Print**.  
 6. Press **Back** to return to the previous screen or press  to return to the **Main Menu** screen.

### Reviewing Internal Check Results

Supervisor users can review the results of the last internal check that was performed on the reader. Perform the following steps to review the internal check results:

1. Press  to display the supervisor **Main Menu** screen.



Supervisor Main Menu Screen

 **NOTE:** Only supervisor users can use this feature. If you are logged in as an operator, select Maintenance > Change to Supervisor to review internal check results.

2. Use  and  to highlight **Settings** and press **Select** to display the supervisor **Settings** screen.



Supervisor Settings Screen

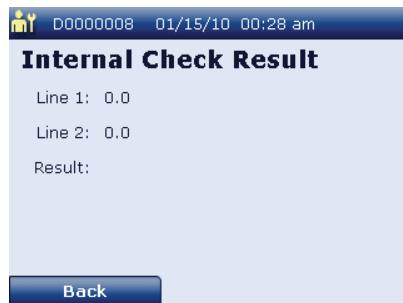
3. Use  and  to highlight **Device Info** and press **Select** to display the **Device Info** screen.



Device Info Screen

4. Use  and  to highlight **Show Int. Check Results** and press **Select** to display the stored **Internal Check Result** screen.

The reader displays the results of the last internal check that was performed.



Stored Internal Check Result Screen

5. Press **Back** to return to the **Device Info** screen or press  to return to the **Main Menu** screen.

## Checking Ambient Temperature

Supervisor users can check the ambient temperature detected by the reader.

Perform the following steps to check the temperature:

1. Press  to display the supervisor **Main Menu** screen.



 **NOTE:** Only supervisor users can use this feature. If you are logged in as an operator, select Maintenance > Change to Supervisor to check the temperature.

2. Use  and  to highlight **Settings** and press **Select** to display the supervisor **Settings** screen.



3. Use  and  to highlight **Read Temperature** and press **Select** to display the **Temperature** screen.

The current temperature is displayed.



4. Press **Back** to return to the supervisor **Settings** screen or press  to return to the supervisor **Main Menu** screen.

## Deleting Stored Test Results

 **NOTE:** Only supervisor users can use this feature. If you are logged in as an operator, select Maintenance > Change to Supervisor to delete results.

Supervisor users can delete test results stored in the reader's memory.



**IMPORTANT:** Test results cannot be retrieved from the reader after they are deleted. Before you delete any test results, make sure that you have archived the results appropriately.

Perform the following steps to delete stored test results:

1. Press  to display the supervisor **Main Menu** screen.



Supervisor Main Menu Screen

2. Use  and  to highlight **Settings** and press **Select** to display the supervisor **Settings** screen.



Supervisor Settings Screen

3. Use  and  to highlight **Delete Results** and press **Select** to display the **Delete Results** screen.

The reader displays the patient ID, date, time, and test result for all results stored in the reader's memory, starting with the most recent test performed. You can scroll through results using  and .



**Delete Results Screen**

4. Use  and  to highlight the result you want to delete and press **Options ▲** to display the **Result List Options** screen.



**Result List Options Screen — Delete Results**

5. To delete only the selected result:
  - a. Use  and  to highlight **Delete Result** and press **Select**.
  - b. The reader displays the **Delete Results** confirmation screen to inform you that the selected results have been deleted.
6. To delete all patient results stored in the reader's memory:
  - a. Use  and  to highlight **Delete All** and press **Select**.
  - b. The reader displays the **Delete Results** confirmation screen to inform you that the selected results have been deleted.

7. To delete all positive results stored in the reader's memory:
  - a. Use  and  to highlight **Delete pos** and press **Select**.
  - b. The reader displays the **Delete Results** confirmation screen to inform you that the selected results have been deleted.
8. To delete all negative results stored in the reader's memory:
  - a. Use  and  to highlight **Delete neg** and press **Select**.
  - b. The reader displays the **Delete Results** confirmation screen to inform you that the selected results have been deleted.



**Delete Results Confirmation Screen**

9. Press **OK** to return to the **Delete Results** screen or press  to return to the supervisor **Main Menu** screen.

## Resetting the Reader to Default Settings

Supervisor users can reset the reader to its default settings. Perform the following steps to reset the reader settings:

1. Press  to display the supervisor **Main Menu** screen.



 **NOTE:** Only supervisor users can use this feature. If you are logged in as an operator, select Maintenance > Change to Supervisor to reset the reader settings.

2. Use  and  to highlight **Settings** and press **Select** to display the supervisor **Settings** screen.



3. Use  and  to highlight **Reset to Default** and press **Select** to display the **Reset to Default** confirmation screen.



4. Press **Reset** to reset the reader's settings or press **Cancel** to retain the current settings and return to the supervisor **Settings** screen.

## **Using the Barcode Reader Accessory**

The reader kit may include a barcode reader accessory that can be used to enter information.

To use the barcode reader, connect it to the reader by inserting the end of the cable into the PS/2 port in the back of the reader. You can now use the barcode reader to enter patient IDs and user IDs.

### **Connecting the Barcode Reader**

## Care & Maintenance

### Maintaining the Reader

Standard maintenance activities for the reader, which can be performed by an operator, include:

- periodically cleaning the exterior of the reader (see page 111)
- changing the paper (see page 111)
- replacing the batteries (see page 113)

Other maintenance activities that might be performed on occasion and can only be performed by a supervisor include:

- changing the date and time (see page 115)
- updating languages available in the reader (see page 118)
- upgrading the reader software (see page 121)

If any other service or maintenance is required, the reader should be sent to the manufacturer. See *Returning the Reader* on page 126.

#### Cleaning the Reader

The reader requires minimal maintenance. Occasional cleaning of the exterior is usually sufficient. If blood or other fluids are not allowed enough time to fully absorb into test devices, the reader drawer may occasionally require cleaning. Use a damp, not wet, lint-free cloth to apply a 70% ethanol solution on the outside of the reader or to the inside of the reader drawer.

Do not allow water to seep into the printer. Do not immerse the reader in water or other liquids.

If the Apex Reader is moved or returned for replacement or repair, the reader should be cleaned prior to transfer.



**NOTE:** Never insert any tools, swabs, or cleaning materials into the reader drawer.

#### Changing the Paper

You can change the paper in the reader anytime. If the reader runs out of paper while in the middle of a printing task and displays the **Empty Paper Tray** message, the paper may be changed and the print job restarted.

Perform the following steps to change the paper:

1. Remove the printer cover by pulling up the blue handle on the top of the cover.



**Removing the Printer Cover**

2. Remove the empty paper spindle and any unused paper.
3. If necessary, tear or cut the end of the new paper roll to form a straight edge. Then insert the paper roll in the printer so that the end of the paper comes from under the roll toward the reader display, as shown below.



**Inserting the Paper Roll**

4. To replace the printer cover, insert the paper roller between the edge of the paper and the paper roll, as shown below. Then push down on the sides of the printer cover until you hear it snap into place.



**Replacing the Printer Cover**

5. Press .

The reader feeds the paper so that it extends out the top of the printer.

If a print job was interrupted, you need to restart this print job.

## Replacing the Batteries

### **AG: CONFIRM ALL.**



**IMPORTANT:** The reader is designed to perform and print at least 50 tests before replacement batteries are required. If you are using batteries to power the reader, it should be turned off when not in use. You can use the automatic Power Off Time setting to help preserve battery life.

The battery power level is indicated by the icon displayed at the top right of the reader screen. The battery icon is gradually filled with white as the batteries are discharged.

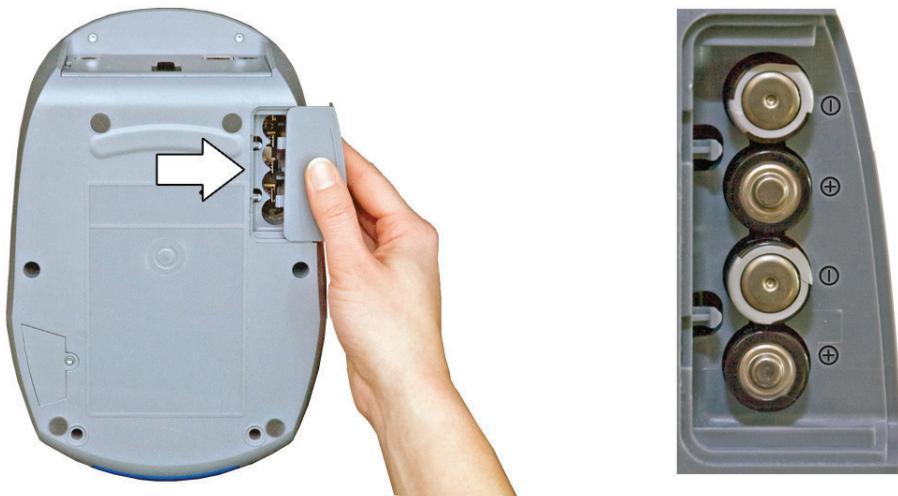


**IMPORTANT:** Rechargeable batteries are authorized for use with the reader. However, due to the nature of these types of batteries, it is expected they will require recharging more frequently. The reader does not contain a built-in battery charger, and rechargeable batteries must be recharged outside of the reader.

Perform the following steps to replace the batteries in the reader:

1. Turn the reader off by pushing the on/off switch up, then releasing it.
2. Turn the reader over so that the back of the battery cover is visible.
3. To remove the battery cover, place your thumb in the middle of the cover and exert slight pressure as you slide it in the direction shown below.
4. Remove the old batteries and discard them in an appropriate waste container.

5. Insert four size AA 1.5 volt batteries. Be sure that the plus (+) and minus (-) signs on the batteries match the signs embossed in the battery compartment.



#### Installing the Batteries

6. Replace the battery cover by positioning it at the edge of the battery compartment as shown and sliding it into position.
7. When you have completed battery installation and replaced the battery cover, turn the reader right side up.



**IMPORTANT:** If the reader does not power on after replacing the batteries, verify that the batteries are lined up according to the symbols in the battery compartment.

#### Changing the Date and Time

Perform the following steps to change the reader's date and/or time:

1. Press  to display the supervisor **Main Menu** screen.



Supervisor Main Menu Screen

 **NOTE:** Only supervisor users can use this feature. If you are logged in as an operator, select Maintenance > Change to Supervisor to change the reader's date and time.

2. Use  and  to highlight **Settings** and press **Select** to display the supervisor **Settings** screen.



Supervisor Settings Screen

3. Use  and  to highlight **Set Date and Time** and press **Select** to display the **Set Date** screen.



Set Date Screen

4. When the **Set Date** screen is first displayed, the **Date format** field is highlighted. Use  and  to scroll through the following options for how to display dates on the reader screen and printouts:

- **dd.mm.yyyy**: Select this option to display the day, then the month, then the year with periods used as separators.
- **mm/dd/yyyy**: Select this option to display the month, then the day, then the year with slashes used as separators.
- **yyyy/mm/dd**: Select this option to display the year, then the month, then the day with slashes used as separators.

When the preferred date format is displayed, press  to highlight the **Year** field.

5. Use  or  to increment or decrement the year.

When the correct year is displayed, press  to highlight the **Month** field.

6. Use  or  to increment or decrement the month.

When the correct month is displayed, press  to highlight the **Day** field.

7. Use  or  to increment or decrement the day.

When the correct day is displayed, review the date format, year, month, and day, and confirm that the correct date information is displayed. If you need to change a setting, use  and  to highlight the field. Then use  and  to make the necessary changes.

8. When you have confirmed that the correct date is displayed, press **Confirm & Next** to display the **Set Time** screen.



9. When the **Set Time** screen is first displayed, the **Time format** field is highlighted. Use  and  to toggle between the following options for how to display times on the reader screen and printouts:

- **12h:** Select this option to display times in the 12 hour time format with am and pm.
- **24h:** Select this option to display times in the 24 hour time format.

When the preferred time format is displayed, press  to highlight the **Hour** field.

10. Use  or  to increment or decrement the hour.

When the correct hour is displayed, press  to highlight the **Minute** field.

11. Use  or  to increment or decrement the minute.

When the correct minute is displayed, review the time format, hour, and minute and confirm that the correct time information is displayed. If you need to change a setting, use  and  to highlight the field. Then use  and  to make the necessary changes.

12. When you have confirmed that the correct time is displayed, press **Confirm** to save the selected time and date settings and return to the supervisor **Settings** screen.

### Updating Reader Languages

 **NOTE:** Only supervisor users can use this feature. If you are logged in as an operator, select Maintenance > Change to Supervisor to update the reader languages.

The reader's language setting determines what language is displayed on the reader screen and printouts. Supervisor users can add new language selections to the reader by importing them from an SD card. Perform the following steps to update the reader languages:

1. Install the SD card in the reader. For instructions, see page 83.
2. Press  to display the supervisor **Main Menu** screen.



Supervisor Main Menu Screen

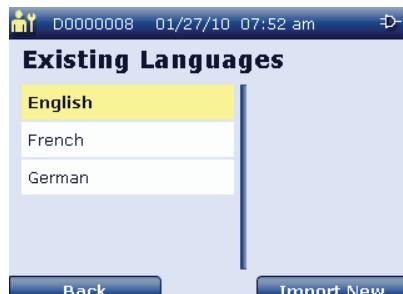
3. Use  and  to highlight **Import / Export** and press **Select** to display the **Import / Export** screen.



Import / Export Screen

4. Use  and  to highlight **Import Language** and press **Select** to display the **Existing Languages** screen.

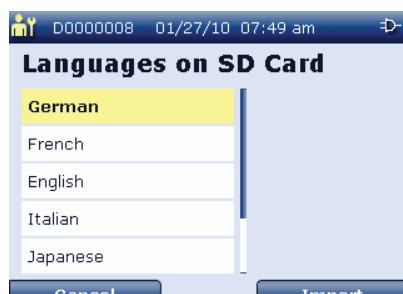
This screen displays all languages currently available on the reader. You can scroll through the available languages using  and .



Existing Languages Screen

5. Press **Import new** to import a new language from the SD card.

The new languages are read from the SD card and displayed on the **Languages on SD Card** screen. You can scroll through the new languages using  and .



Languages on SD Card Screen

6. Use  and  to highlight the language you want to import.

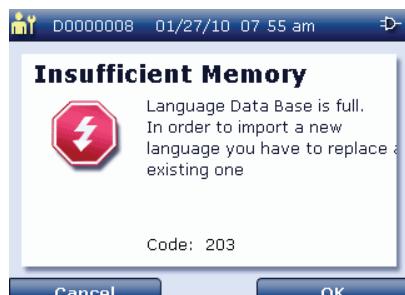
7. When the desired language is highlighted, press **Import**.

- If the reader's language database has room for this language, the reader imports the new language and displays the **Import Successful** screen. If this screen appears, go to Step 12.



**Import Successful Screen**

- If the reader's language database does not have room for this language, the **Insufficient Memory** screen is displayed. If this screen appears, you will need to replace an existing language on the reader with the new language.



**Insufficient Memory Screen**

8. Press **OK** to display the **Replace Language** screen.

This screen displays the languages currently available on the reader. You can scroll through the available languages using and .



**Replace Language Screen**

9. Use  and  to highlight the current language you want to replace with the new language.
10. When the desired language is highlighted, press **Replace**.
11. The reader imports the new language and displays the **Import Successful** screen.



12. Press **OK** to return to the **Existing Languages** screen or press  to return to the supervisor **Main Menu** screen.
13. To change reader's language setting, see *Changing the Language* on page 39.

### Upgrading the Reader Software

Supervisor users can upgrade the reader's software by importing the new software from an SD card. Perform the following steps to upgrade the reader software:

1. Install the SD card in the reader. For instructions, see page 83.
2. Press  to display the supervisor **Main Menu** screen.

 **NOTE:** Only supervisor users can use this feature. If you are logged in as an operator, select Maintenance > Change to Supervisor to upgrade the reader software.



3. Use  and  to highlight **Import / Export** and press **Select** to display the **Import / Export** screen.



**Import / Export Screen**

4. Use  and  to highlight **Upgrade Software** and press **Select** to display the **Software upgrade available** screen.

This screen displays the version information for the reader's current software and the version of software available on the SD card.

**Software Upgrade Available Screen**

5. Press **Upgrade** to upgrade the reader's software.

The reader performs the upgrade, then shuts down and restarts. **AG: CONFIRM.** To confirm that the software was upgraded, see *Checking the Software Version* on page 97.

## Troubleshooting

### Troubleshooting Tips

Refer to the table below for instructions for troubleshooting problems.

Problem Condition	Corrective Actions
Paper jam	<ol style="list-style-type: none"> <li>1. Remove the printer cover to reveal the paper compartment.</li> <li>2. Remove the paper roll and reinsert it so that the end of the paper comes from under the roll toward the reader display.</li> <li>3. Replace the printer cover.</li> <li>4. Press  to advance the paper.</li> <li>5. If the error continues, contact Technical Support for assistance.</li> </ol>
Keypad or other keys do not work	Reset the reader by disconnecting the AC power adapter from the reader or removing the four batteries. Wait 30 seconds and reconnect the power adapter or reinsert the batteries.
Reader will not turn on	Ensure that the AC power adapter is connected securely to the reader and to the power outlet or that the four batteries are installed correctly. If the problem continues, connect the AC power adapter to a different power supply or replace the four AA batteries with all new batteries.
Reader is locked up	Reset the reader by disconnecting the AC power adapter from the reader or removing the four batteries. Wait 30 seconds and reconnect the power adapter or reinsert the batteries.
Drawer / test cartridge is jammed	<p><b>Do not</b> pull or force the drawer/test cartridge out of the reader. Reset the reader by disconnecting the AC power adapter from the reader or removing the four batteries. Wait 30 seconds and reconnect the power adapter or reinsert the batteries.</p> <p>If you are still unable to open the drawer and/or remove the test cartridge, contact Technical Support.</p>

### Understanding Error Messages

Refer to the table below for instructions for responding to error messages. **AG:**  
**CONFIRM THIS LIST IS COMPLETE AND PROVIDE ANY ADDITIONAL RECOMMENDATIONS.**

Error Message	Corrective Action
Barcode Scan Failed	Attempt to read the barcode again.
	If the problem persists, check the connection to the barcode reader.
Battery Low	Replace the reader's 4 AA batteries or connect the AC power adapter. Try again to print.
Battery Too Low	Replace the reader's 4 AA batteries or connect the AC power adapter.
Empty Paper Tray	Replace the paper roll in the reader.
Expired Cartridge	Remove the expired test cartridge and repeat the test with a new test cartridge.
ID Already Exists	The selected user ID is already in use. Enter a different 4-digit user ID.
Invalid One Shot PIN	The entered PIN is invalid. Try again to enter the one shot PIN that was provided.
	If the problem persists, contact Technical Support to obtain a new one shot PIN.
Invalid Patient ID	The patient ID must be 1 to 15 digits. Try again to enter the patient ID.
Invalid User ID	The user ID must be 4 characters. Try again to enter the user ID.
LAN Error (Cannot Get IP Address)	The DCHP server is not responding with an IP address. Contact your network administrator for assistance.
LAN Error (Network Cannot Be Configured)	The network connection cannot be configured. Contact your network administrator for assistance.
LIS Error (LIS Connection Interrupted)	The connection to the LIS was interrupted. Try the operation again.
LIS Error (LIS Connection Not Available)	The reader failed to connect to the LIS. Try again to establish the connection. If the problem persists, check the network settings or contact your network administrator for assistance.

Error Message	Corrective Action
LIS Error (Reviewer Not Available)	The LIS is currently unavailable. Try again to establish the connection. If the problem persists, contact your network administrator.
Login Failed	The user ID / PIN combination is invalid. Try again to log in.
Multiple ID Tags Detected	Ensure that only one RFID tag is on or near the reader.
No Control Line Found	Remove the test cartridge and repeat the test with a new cartridge.
No ID Tag Detected	Place the RFID on the designated area of the reader and try again.
No SD Card Found	Make sure a valid SD card is properly inserted in the reader.
No Upgrade Available	No software upgrade was found on the SD card. Make sure a valid SD card with a software upgrade is properly inserted in the reader.
PIN Mismatch	The confirmed PIN must match the entered PIN.
Printer Temperature High	The printer temperature is too high for printing. Allow the printer to cool off and try again to print.
RFID Error	There was an error during RFID communication. Try again. If the problem persists, move the reader away from possible sources of RF interference.
SD Card Read Error	The SD card may be wrong type or may be damaged. Make sure a valid SD card is properly inserted in the reader.
SD Card Write Error	The SD card may be wrong type or may be damaged. Make sure a valid SD card is properly inserted in the reader.
Temperature Error	The ambient temperature is outside the measurement range of the reader (15°C to 30°C).
Too Many Users Selected	The user database is full. To import more users, you must first delete existing users.
Used Cartridge	Remove the test cartridge and repeat the test with a new cartridge.

## Quality Assurance

### **AG: PROVIDE A QUALITY ASSURANCE STATEMENT.**

## Returning the Reader

### **AG: PROVIDE INSTRUCTIONS FOR RETURNING THE READER.**

## Disposing of the Reader

In conformance with the WEEE (Waste Electrical and Electronic Equipment) Directive, do not dispose of this product in municipal waste. Please contact Aspen BioPharma to arrange disposal and recycling.

## Glossary

<b>Assay</b>	Test to determine the presence of a substance.
<b>Barcode reader</b>	Scanning device that can interpret a barcode, which is a series of vertical bars of varying widths that each represent a digit from 0 to 9.
<b>Calibration</b>	Process of checking the accuracy of a measuring instrument by comparison of a result to a reference standard.
<b>Internal QC</b>	Quality controls built into the reader's software and / or the test cartridge.
<b>Operator user</b>	User with operator access privileges, which allow performance of day-to-day operations with the reader.
<b>QC</b>	Quality control. QC refers to steps taken to make sure that a system is of sufficiently high quality.
<b>Reader</b>	The <b>Aspen BioPharma Apex Reader</b> .
<b>Reagent</b>	Chemical substance that is used to create a reaction when combined with another substance for the purpose of analysis.
<b>RFID</b>	Radio frequency identification; a data collection technology that uses electronic tags for storing data and allows automatic identification of items. Unlike barcode technology, RFID provides 'out of line of sight' identification and operates at distances much greater than those at which barcode readers operate.
<b>SD card</b>	Secure digital memory card. An SD card is a small flash memory card used for portable storage of digital data that can be imported to and exported from the reader.
<b>Supervisor user</b>	User with supervisor access privileges, which allow performance of advanced reader activities.
<b>Test cartridge</b>	Item that holds the sample (for example, blood) from the patient so it can be inserted into the reader for testing. The test cartridge contains reagent that reacts with blood so that the reader can determine the level of specific chemical substances in the patient.

**FEDERAL COMMUNICATIONS COMMISSION INTERFERENCE STATEMENT**

This device complies with Part 15 of the FCC rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

NOTE: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

**CAUTION:**

Any changes or modifications not expressly approved by the grantee of this device could void the user's authority to operate the equipment.