irma®

Blood Analysis System

User Manual

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This manual is published by Lifehealth, an EasyDx, Inc. brand, for use with the IRMA Blood Analysis System, Model LH, Version 1.1.3 or above.

Prior to use consult sections A.3, A.4 and B.4.

Table of Contents

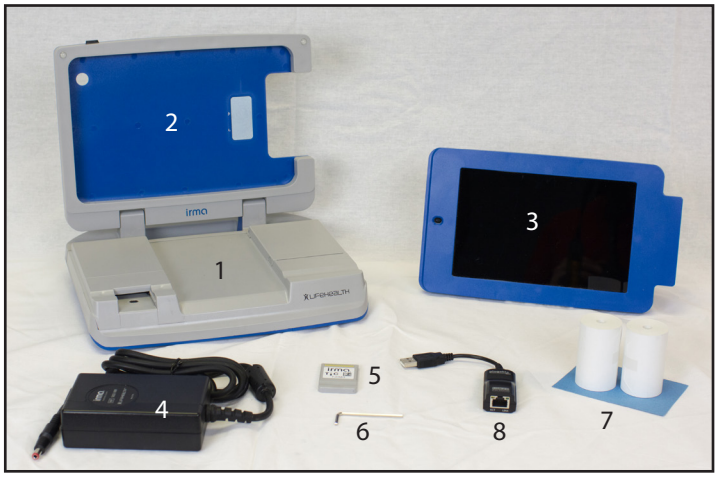
Section 1: The IRMA Blood Analysis System

This section covers general information about the IRMA Blood Analysis System and describes the installation process.

1.1 Getting Started

Unpack and Inspect the System

Figure 1.1



The IRMA Blood Analysis System is shipped with the following components (Figure 1.1):

- The IRMA Base (1) with the dock (2) and removable IRMA Tablet (3). The IRMA Tablet is packaged separately.
- AC power supply (4)
- Temperature card (5) located in the storage area
- IRMA tool (6) located in the storage area
- Thermal paper (7)
- USB 2.0 Fast Ethernet Adapter (8)

Unpack and verify that all components have been received and inspect the components for shipping damage. Immediately report any shipping damage to your service provider.

If multiple IRMA Systems are received, open and assemble only one at a time. The IRMA Tablet and the IRMA base are paired before shipment and should be kept together.

Retain one set of packaging materials. IRMA Systems requiring service by the manufacturer must be returned in the original packaging materials. If the original packaging materials are not available, contact your service provider to obtain a replacement.

Place the IRMA Tablet in the dock

Figure 1.2

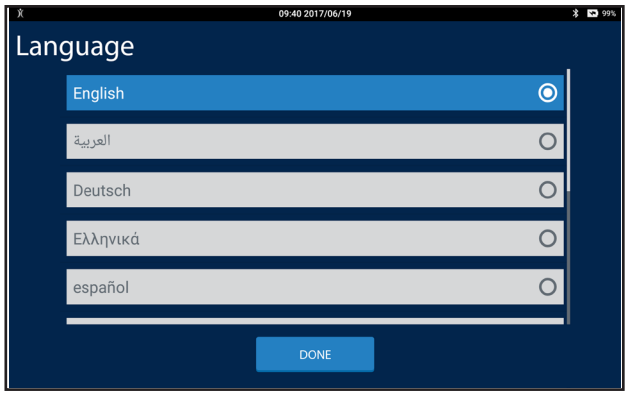
The IRMA Tablet is packaged separately. To place the IRMA Tablet in the dock (Figure 1.2):

- Orient the IRMA Tablet so that the connector pins (10) are on the left side.
- Locate the connector pins (11) on the dock. Holding the IRMA Tablet at a slight angle, match the connector pins and place the IRMA Tablet in the dock. Powerful magnets located on the right side of the IRMA Tablet hold it in place.
- Power on the IRMA Tablet by pressing the button on the top left edge (12) until the screen display lights up.

IRMA System Initial Language Setup

When the IRMA Tablet is powered on for the first time, the Select Language screen appears (Figure 1.3). To keep the IRMA Tablet in English press the DONE button. To change the language, select the desired language and press the DONE button.

Figure 1.3



Connect the AC power supply to the IRMA Base and Power Up

Connect the power cord to the AC power supply. Place the barrel plug of the AC power supply into the barrel jack located on the right side of the base. Plug the power cord into a power outlet.

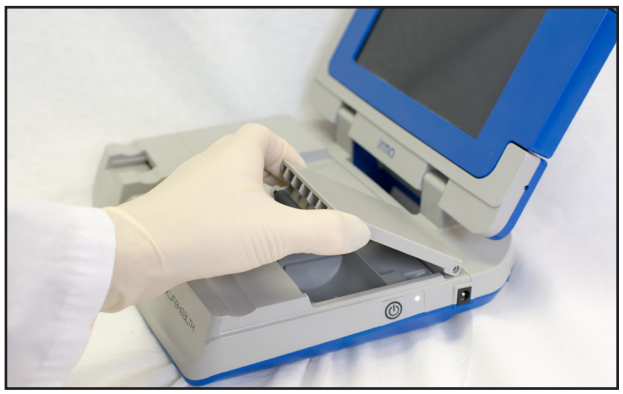
Charge the IRMA System Batteries

When the IRMA Tablet is in the dock, the IRMA Tablet battery as well as the IRMA Base battery are charged as needed when connected to a power source. The IRMA Base and IRMA Tablet are shipped partially charged. To fully charge the IRMA Tablet and IRMA base, connect to a power source for 7 hours.

Install the Printer Paper

Open the door of the printer and storage compartment by placing your fingers in the cut out area located near the front of the door and pull up as illustrated in Figure 1.4. Place the printer paper roll in the depressed paper compartment with the paper unrolling from the bottom of the roll (Figure 1.5). Unroll the paper and close the door leaving about 1 inch (2.5 cm) of paper showing.

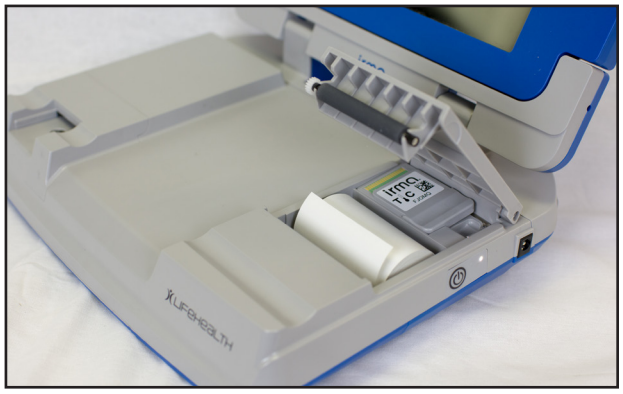
Figure 1.4



Bring the IRMA System to Operating Temperature

The IRMA System must be at operating temperature before use. The operating range of the IRMA Analyzer is 12 to 30° C (54 to 86° F). If the IRMA System is exposed to a temperature outside of that range for a significant period of time, an instrument temperature error message may display. The IRMA System must equilibrate at a temperature within the temperature operating range for a minimum of 30 minutes before testing may begin.

Figure 1.5



1.2 IRMA Blood Analysis System Components

Description

The major components of the IRMA System include the portable, battery-operated IRMA Base with the removable IRMA Tablet, and IRMA cartridges that contain sensors and a calibrant. Cartridges come in a variety of analyte configurations.

Cartridges calibrate with every test using the self-contained calibrant. Instructions displayed on the IRMA Tablet guide the user through the testing process. Patient and sample information is entered during analysis and test results are displayed in as little as 30 seconds after sample injection. Results may be printed or transferred.

1.3 IRMA Base

The IRMA Base has the following features:

Front View (Figure 1.6)

Figure 1.6

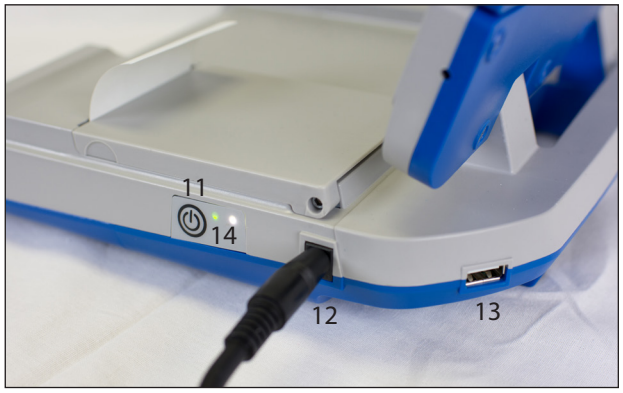
1. IRMA Base: The IRMA Base is paired with the IRMA Tablet via a Bluetooth connection.
2. Integrated printer: Prints hard copies of test results and associated information. The printer is paired with the IRMA Tablet via a Bluetooth connection.
3. Removable IRMA Tablet: Guides the user through all aspects of IRMA operation.
4. Dock: Holds and charges the IRMA Tablet when the IRMA System is connected to the AC power supply.
5. AC power supply barrel jack.
6. Edge connector block: Electrically connects the cartridge to the IRMA System.
7. Infrared (IR) sensor (recessed): Measures and controls the sample temperature.
8. Storage area (accessed by opening the printer door) that holds the IRMA tool, temperature card and thermal paper roll.
9. Temperature card: Used to verify that the temperature control system is operating properly. The temperature card is found in the storage area (8).
10. IRMA tool: Used for locking the IRMA Tablet to the dock, for replacing the printer cover, and for replacing the edge connector, printer, and/or battery, if needed. The IRMA tool is found in the storage area (8).

Side View (Figure 1.7)

11. Wake button.
12. Power cord connection (barrel jack).
13. USB port.
14. LED Indicators indicate whether the base is in wake or sleep mode (white LED) and if the IRMA System requires charging (green/amber LED) or is charging one or both of the IRMA System's batteries.

The use of unapproved accessories may compromise safety when using the IRMA System.

Figure 1.7



1.4 IRMA Waking and Sleeping Modes

The user can set how long the IRMA Tablet is inactive before entering sleep mode (refer to Section 8.9). To wake the IRMA Tablet and IRMA Base, briefly press the wake button on the IRMA Base. Upon waking, the Main Menu will be displayed or, if the Operator ID feature is enabled, the Operator ID Login screen will be displayed. If the IRMA Tablet is not connected to the IRMA Base, wake the IRMA Tablet by briefly pressing the IRMA Tablet power button.

The state of the base is indicated by the white LED indicator as follows:

Base Sleep/Wake LED	
Wake Mode	Solid white
Sleep Mode	Blinking white

Note: The IRMA Base will only enter Sleep Mode when operating on battery.

1.5 IRMA Battery Operation

When fully charged, the IRMA System can run approximately 40 to 80 tests depending on the type of cartridge used and the amount of printing required. The battery level indicator for the IRMA System is located on the IRMA Tablet screen. The charging time required for the IRMA Base battery or IRMA Tablet battery is approximately 7 hours.

The battery status is indicated by the green/amber LED as follows:

Base Power Indicator LED	
Batteries are charging	Blinking green
IRMA System requires charging	Blinking amber

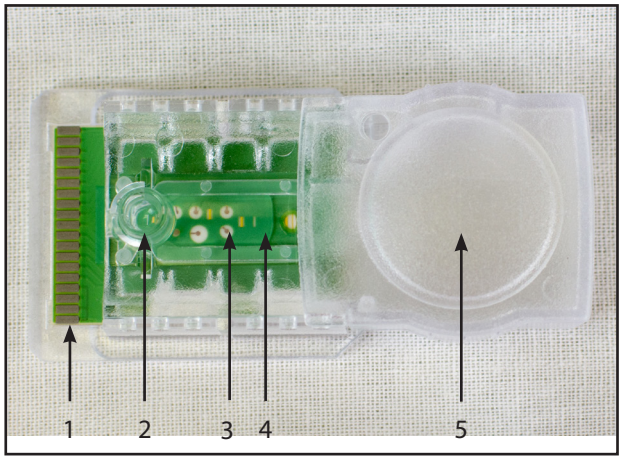
The IRMA Base battery is replaceable. Instructions for replacing the IRMA Base battery are found in Section 6.2. The battery in the IRMA Tablet is not replaceable.

If the IRMA Tablet battery is completely discharged, the IRMA System requires a minimum of ten minutes of charging before it may be used. The IRMA Tablet must be placed in the dock, and the IRMA Base must be connected to the AC power supply, in order for its battery to charge.

CAUTION: During a cartridge test, Patient, LQC or TQC, do not plug or unplug the AC power supply into the IRMA Base if the test is started. Plugging or unplugging the AC power supply into the IRMA Base during a test will result in an error and the test being aborted.

1.6 IRMA Cartridge Components

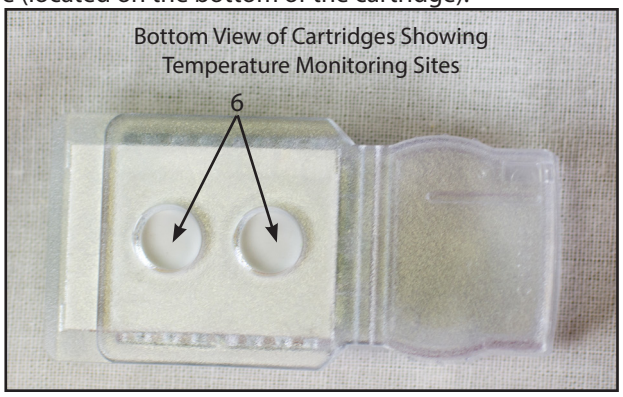
Figure 1.8



Each IRMA cartridge contains a sensor array and self-contained calibrant (Figure 1.8). Each cartridge can perform one patient or liquid QC test.

1. Cartridge leads: electrically connect the cartridge to the IRMA System.
2. Luer injection port: where the sample collection device attaches to the cartridge.
3. Sensors: measure analyte concentrations.
4. Calibrant gel: used to calibrate the sensors for cartridges that do not have a snap cap.
5. Waste reservoir: holds a maximum volume of 5 mL.
6. Temperature monitoring access sites as shown in Figure 1.9: where the IR sensor measures and controls sample temperature (located on the bottom of the cartridge).

Figure 1.9



1.7 IRMA Cartridge Care

Unpacking the IRMA Cartridges

IRMA cartridges are ordered, packaged, and shipped under separate cover in an insulated shipping container. The shipping temperature range is 0 to 50°C. Check the temperature indicators that are included in each shipping container. Refer to the instructions that accompany the indicators. If the temperature indicators show that the shipping temperature range has been exceeded, do not use the cartridges. Call your service provider for replacement cartridges.

Store the cartridges at room temperature. Refer to Appendix B, Section B.7 for additional cartridge storage information.

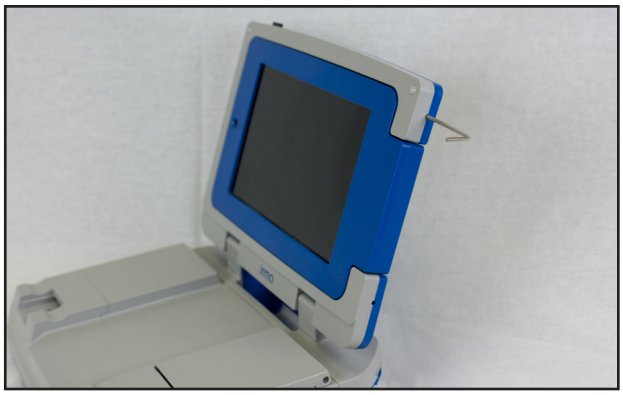
Equilibrating the IRMA Cartridges

All cartridges must be equilibrated before use. Remove the cartridges from their shipping container and equilibrate to room temperature in an area that has a stable temperature between 15 to 30°C (59 to 86°F) with no fluctuations greater than 8°C (14.4°F). Equilibration times vary by product and are found in Appendix B, Section B.7.

If the storage area temperature fluctuations are greater than 8°C or 14.4°F, the cartridges must go through an additional equilibration period before they can be used. Proper conditions should be documented by recording the daily minimum and maximum storage area temperatures.

1.8 IRMA Tablet

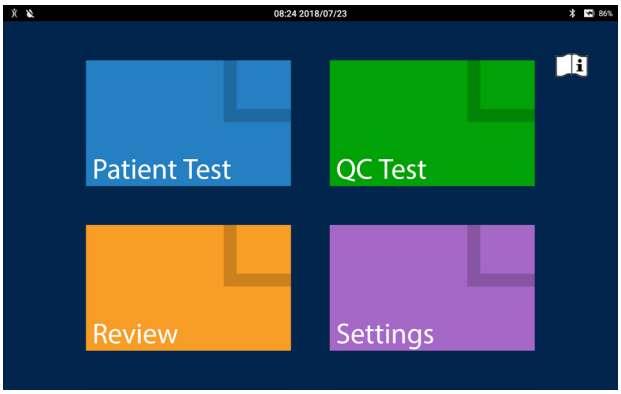
Figure 1.10



Locking the IRMA Tablet into the dock.

The IRMA Tablet can be removed from the dock when needed. To prevent the IRMA Tablet from being removed, there are two recessed screws located on the right side of the dock that can be deployed into the IRMA Tablet using the IRMA tool located under the printer door (Figure 1.10). Tighten each screw until it is finger tight. To remove the IRMA Tablet, loosen the screws with the IRMA tool until resistance is felt. The screws are designed so that they cannot be removed from the dock.

1.9 IRMA Tablet Main Menu



There are five options displayed on the Main Menu. Each are briefly described below.

- **Patient Test:** Used for performing a whole blood patient sample analysis.
- **QC Test:** Used for performing an Electronic Quality Control (EQC) Test, Liquid Quality Control Tests (LQC), and Temperature Verification (TQC) Test.
- **Review:** Used for accessing test results, viewing the logs and other instrument functions.
- **Settings:** Used to configure and/or edit all IRMA System settings including Operator ID and Patient ID settings, Analyte Ranges, Cartridge Settings, QC Lockout Settings, Test Settings, Device Settings, and ABG Test Settings.
- **Instructions For Use icon:** A pdf copy of the IRMA System user manual can also be accessed from the main menu. A searchable pdf copy of the manual may be downloaded from www.lifehealthmed.com.

1.10 IRMA Touchscreen Interface

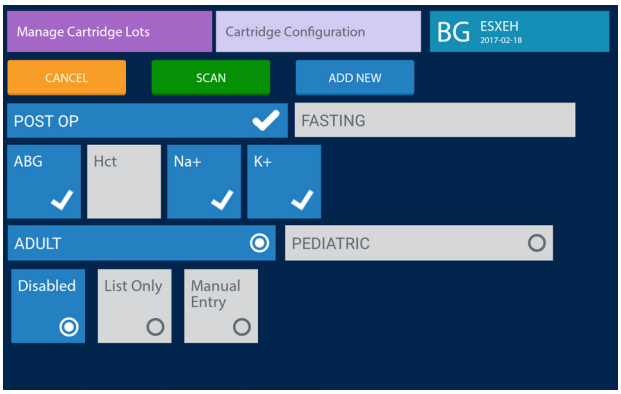
The IRMA Tablet uses a combination of symbols, text, video, controls (buttons, spinners, text entry and checkboxes) and motions (pressing, swiping and pinching) through which the operator interacts and controls the IRMA System to perform testing, review test results and configure the IRMA System. The user is guided through each procedure using screens containing easy to understand directions, buttons, graphics, and video clips (where appropriate).

IRMA Controls

The operator uses buttons, spinners, checkboxes and text entry areas to perform actions and input data into the IRMA System.

Buttons

The various types of buttons the IRMA Touchscreen Interface uses are:



- **Selection:** Selection buttons are used to navigate through the IRMA Touchscreen Interface and vary in shape and color.
- **Action:** Action buttons are green, orange or blue and appear at the bottom of the screen or in the keyboard area. They perform the action of the text displayed on them.
- **Multi-Select:** Used to input data or configure the IRMA System. Zero or more buttons may be selected. A multi-select button turns blue and displays a checkmark in it when selected. When de-selected it is grey with no checkmark.
- **Radio Button:** Used to make a single selection. A radio button turns blue and has a dot inside the circle when selected. When de-selected it is grey with only a circle displayed.

Spinners

The spinner control is primarily used for entering numeric data when there are a limited number of possible entries. To use the spinner control:

- Touch the center of the control and swipe up to change the selection to a selection below the center position. Swipe down to change the selection to a selection above the center position.
- If there is no text above the center position the spinner can only be swiped up. If there is no text below the center position the spinner can only be swpied down.
- The selection in the center blue box is the selected data point.

Checkboxes

The checkbox control is used to turn a function on a screen on or off.

- Press the box once and a checkmark appears in it. The function is on.
- Press the box again and the checkmark is removed. The function is off.

Text Entry Area

The text entry area is used with the keyboard or barcode reader. It is described below under the Keyboard Screen.

Motion Controls

The IRMA Tablet uses a touchscreen that is responsive to the following motions controls:

- **Pressing:** Touch the screen with your finger or a stylus make a selection.
- **Swiping:** Touch the screen and then drag your finger or a stylus either up or down (scrolling) or drag it either to the right or to the left (swiping.) When there is additional information displayed on a screen, as indicated by a thin, vertical, grey line, it is viewed by scrolling the screen.
  - When multiple test records are retrieved from a search (Section 4 - Review), moving from one record to the next is done by swiping to the left or right.
- **Pinching:** Touch the screen with two fingers and slide the tips of each finger together to zoom out of the text. Touch the screen with two fingers close together and spread the tips of each finger away from the other to zoom in on the text. The user manual is the only portion responsive to pinching.

Note: Touchscreen sensitivity varies from individual to individual and may be affected by various factors like the amount of moisture on the skin. As a result, the touchscreen performance experienced by some operators may be compromised. For operators that experience an ongoing issue with touchscreen responsiveness, the use of a touchscreen stylus is recommended.

Note: The IRMA Tablet's touchscreen may be used while wearing nitrile, vinyl or latex gloves. If a glove liner is to be worn, the use of a cotton or nylon glove liner is recommended. The use of polyester glove liners is not recommended as they have been shown to affect the touchscreen's responsiveness.

Common Screen Items

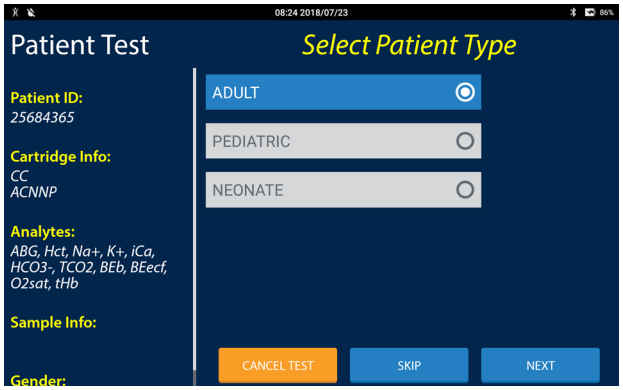
Specific instructions for each section of the Main Menu (Patient Test, QC Test, Review and Settings) are contained in following chapters. Common items to most screens are:

- **Status Bar:** When present, the status bar will be across the top of the screen. It displays the date and time and a series of icons described in the Buttons and Icons section below.
- **Action Buttons:** Action buttons are green, orange or blue and appear at the bottom of the screen or in the keyboard area. They perform the action of the text displayed on them.
- **Keyboard Screen:** The keyboard screen is used to enter alphanumeric information. It may be displayed in only two-thirds of the screen or it may be displayed full screen.

Test Screen

The Patient and QC Test screens that require operator input use a common layout the features of which are:

- **Test Progress:** The left third of the screen displays information regarding the progression of the test. The yellow, bolded text corresponds to the title of the test screen and the white, italicized text is the information entered on the test screen. There may be additional information not displayed on the screen. To view the additional information the test progress area may be scrolled.
- **Test State:** The right two-thirds of the screen displays the current state of the test or requests information to be entered by the operator.



Barcode Reader Screen

The barcode reader is located on the back of the IRMA Tablet in the upper left hand corner. The barcode reader is used to enter information into the IRMA Tablet. Depending on how the IRMA System is configured the barcode reader screen may be displayed automatically or by pressing the SCAN button when available.

To use the reader, place the red cross that appears in the center of the viewfinder on the barcode to be scanned. Center the barcode in the screen area and hold it steady to assist the autofocus in detecting the barcode. If the barcode does not scan after a few seconds, slowly move it closer or further away from the IRMA Tablet. Shadows across the barcode or dim lighting may make the barcode more difficult to detect. The IRMA Tablet will emit a beep when a barcode is successfully scanned. The barcode reader uses image processing technologies and is not an eye hazard.

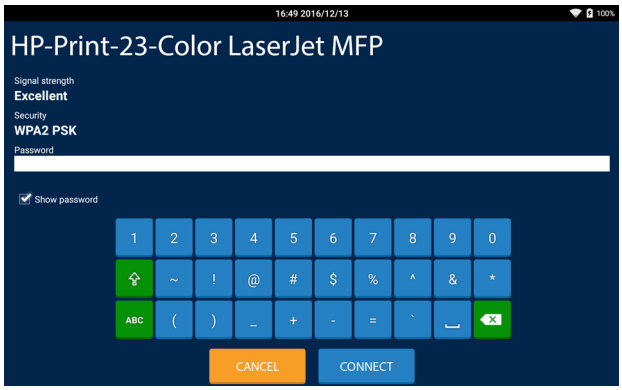
If the barcode reader does not detect a barcode within a certain amount of time it will return to the manual entry screen. The barcode reader timeout feature is found in Device Settings (refer to Section 8.9) and can be set from 10 seconds to 3 minutes.

The features of the barcode reader screen are:

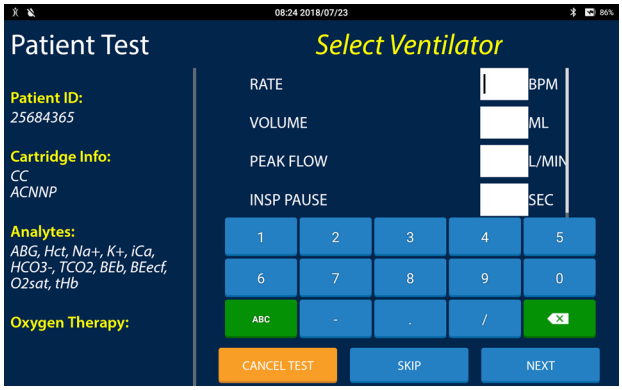
- **Scan Window:** The center of the window displays the barcode imager's field of view with a red cross overlaid on it.
- The barcode reader can read the following symbologies:
- 1D formats - Code 39, Code 93, Code 128 & Codabar
- 2D formats - QR Code & Data Matrix

Keyboard Screen

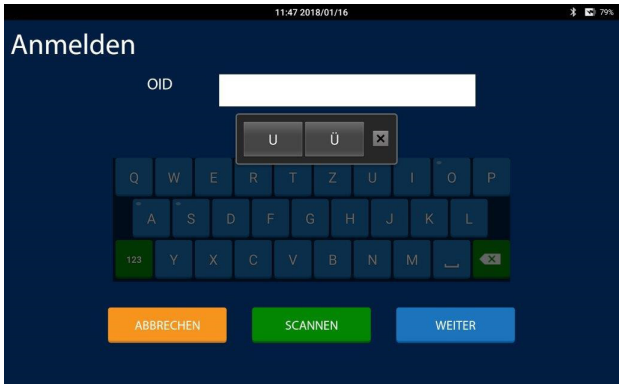
The features of the keyboard screen are:



- **Text Entry Area:** There will be one or more white, text entry areas. To the side of the text entry area, or inside the text entry area in light grey letters, will be text explaining the information that should be entered. The input from the keyboard buttons will be displayed in the selected text entry area. To select a text entry area, press on it. A cursor will appear in it. The cursor may not be moved by dragging it.
  - When there are too many text entry areas to display above the keyboard the text entry areas will scroll as a group while the keyboard remains in its place.
- **Keyboard Area:** The blue keys displayed in the keyboard area enter text in the selected text entry area when pressed. The keys displayed are dependent on the information to be entered in the text entry area. The green buttons are described below:
  - The ABC/123 button toggles between the alpha and numeric keyboards.
  - The ?123 button displays the numeric and symbols keyboard.
  - The backspace button removes the last character in the text entry area.
  - The shift key toggles between the upper and lower case alpha keyboard or the main and alternate numeric and symbols keyboard.

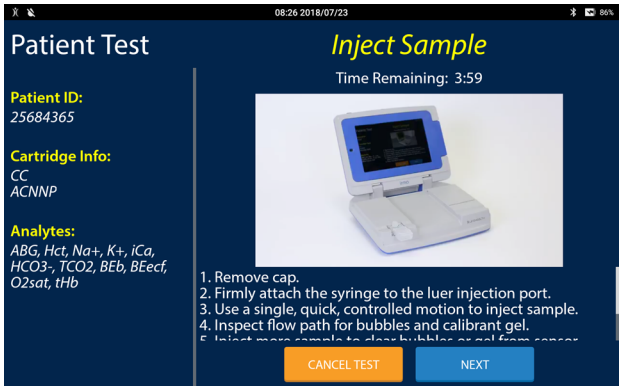


- **Alternate Keys:** Depending on the keyboard, and/or the language, different characters may be entered using the same key. Keys with alternate characters are distinguished with a small dot in the upper corner of the key. To enter an alternate character:
  - Press and hold a key with a smal dot. The characters that may be entered will be displayed. Select the desired character by pressing it.
  - Tap a key with a small dot multiple times. Tapping twice will enter the second alternate character. Tapping three times will enter the third alternate character, etc...



Instructional Screen

The Patient and QC Test screens use a common layout the features of which are:

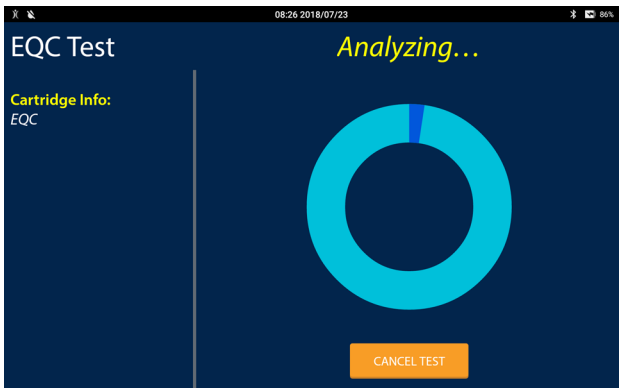


- **Test Progress:** Instructional screens that are displayed during a test use the same test progress area displayed in the Test Screen section. Instructional screens that are not displayed during a test will not have a test progress area.
- **Instructions:** Instructions to guide the operator through the operator action are displayed in the center of the screen.
- **Video Loop:** A short video loop showing the action to be taken may be displayed next to the instructions.
- **Timer:** Some operator actions must be completed within a defined timeframe. A countdown will be displayed indicating the time remaining before the IRMA System will cancel the test or action.

Wait Screen

When no action is required of the operator a wait screen will display the features of which are:

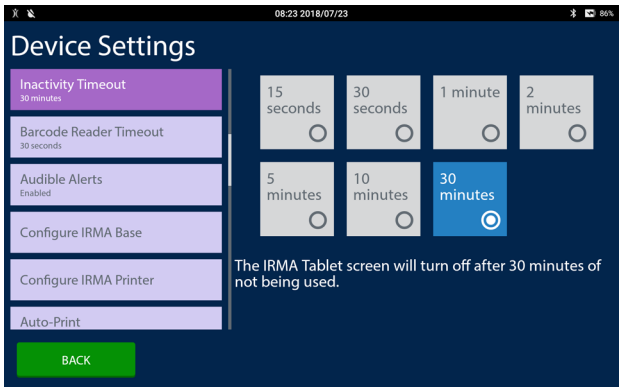
- **Test Progress:** Wait screens that are displayed during a test use the same test progress area displayed in the Test Screen section. Wait screens that are not displayed during a test will not have a test progress area.
- **Progress Animation:** An animation showing the approximate time until the next screen is presented is displayed in the center of the screen.



Settings And Review Screen

Most of the screens in the Settings and Review area use a common layout the features of which are:

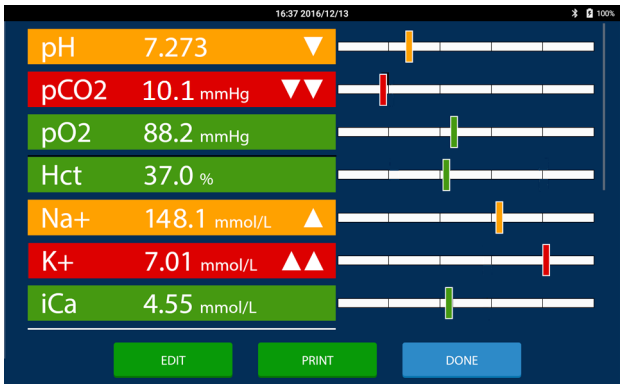
- **Submenu list:** The left third of the screen displays a column of selection buttons (orange in Review, purple in Settings.) Only one button may be selected at a time. The selected button is a brighter shade than the deselected buttons. When more buttons are contained in the list than will display on the screen, the submenu buttons are scrollable.
- **Entry Area:** The right two-thirds of the screen may display informational text or, more commonly, groups of buttons, spinners, a keyboard or another form of data input.



Results Screen

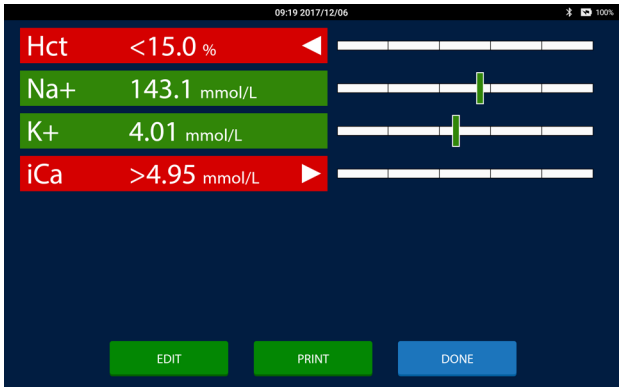
Patient and QC test results are displayed on the Results screen. The Results screen is displayed at the end of a test and when test records are retrieved in the Review area. Each measured and calculated analyte is displayed on its own row. The features of the Results screen are:

- **Analyte Button:** The analyte button displays the name of the analyte, the analyte result, the analyte's unit of measure, and any flags, in white text on a colored button or in black text on a white button. The button color represents:
  - **Green:** When the result is evaluated against a normal or a normal and a critical reference range and is within the normal range the analyte button is green.
  - **Orange:** When the result is evaluated against only a normal reference range and is outside the normal range the analyte button is orange. When the result is evaluated against a normal reference range and a critical reference range and the result is outside the normal range and inside the critical reference range the analyte button is orange.
  - **Red:** When the result is evaluated against a normal reference range and a critical reference range and the result is outside the critical range the analyte button is red. When the result is outside of the reportable range and is inside the IRMA System machine range, the

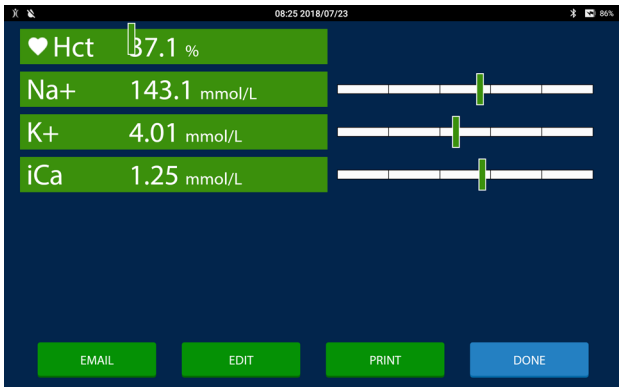


analyte result is reported as greater than or less than the reportable range limit and the analyte button is red.

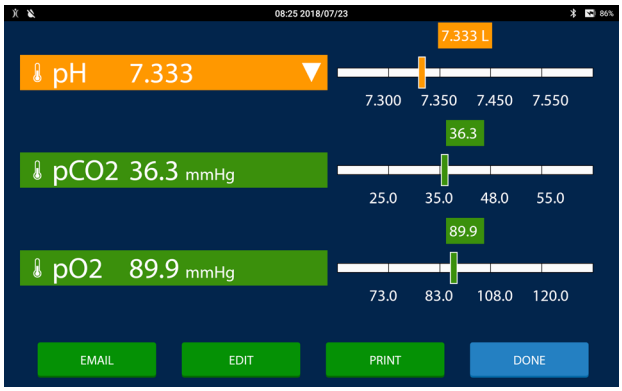
- **White:** When the result is not evaluated against a reference range the analyte button is white.
- **Grey:** When the result cannot be calculated or when the result is outside the IRMA range the result value is suppressed. Three dashes are displayed instead of a result value.



- The potential flags are:
  - **High:** When the result is greater than the upper normal reference range and less than the upper critical reference range limit (if one is defined) a triangle pointing up is displayed on the right hand side of the analyte button.
  - **Critical High:** When the result is greater than the upper critical reference range and less than the upper reportable range limit two triangles pointing up are displayed on the right hand side of the analyte button.
  - **Out of Range High:** When the result is greater than the upper reportable range and less than the upper IRMA range a triangle pointing to the right is displayed on the right hand side of the analyte button and a > sign is displayed in front of the result.

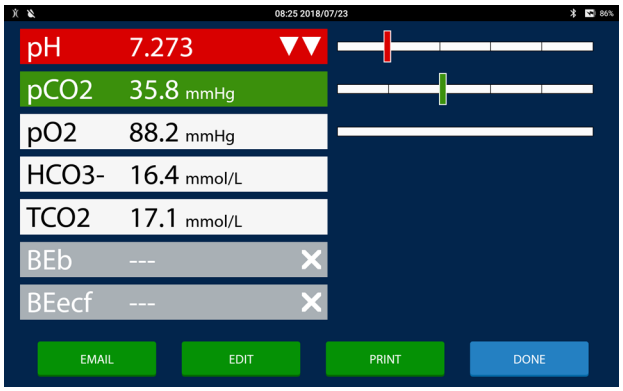


  - **Low:** When the result is less than the lower normal reference range and greater than the lower critical reference range limit (if one is defined) a triangle pointing down is displayed on the right hand side of the analyte button.
  - **Critical Low:** When the result is less than the lower critical reference range and greater than the lower reportable range limit two triangles pointing down are displayed on the right hand side of the analyte button.
  - **Out of Range Low:** When the result is less than the lower reportable range and greater than the lower IRMA range a triangle pointing to the left is displayed on the right hand side of the analyte button and a < sign is displayed in front of the result.



  - **Suppressed:** When the result cannot be calculated or is less than the lower IRMA limit or greater than the upper IRMA limit a X is displayed on the right hand side of the analyte button.
  - **Correlated Result:** When On Bypass is selected a heart icon will appear on the left hand side of the analyte button to indicate the hematocrit result was adjusted using the Hct Bypass Correlation slope and intercept values.
  - **Temperature Corrected Result:** A thermometer icon will appear on the left hand side of the analyte button to indicate the result was corrected for the patient temperature.
- **Detail view:** Press the Results Graph or the Analyte Button to toggle between the summary view of the analyte and the detail view of the analyte. In detail view the result displays above the vertical results bar and the reference ranges display below the bar graph.

- **Results Graph:** A bar graph of where the result falls inside its range is displayed opposite the analyte button. The results graph is divided into one, three or five sections depending on how many reference ranges are defined for the analyte.



  - If both a normal and a critical reference range are defined for the analyte, a bar with five sections is displayed. Results that are inside the normal range are displayed in the center section. The sections just to the left and right of the normal section are where the low and high results are displayed. The outside two sections are where the critical low and critical high results are displayed.
  - If only a normal reference range is defined for the analyte, a bar with three sections is displayed. Results that are inside the normal range are displayed in the center section. The two outside sections are where the low and high results are displayed.
  - If there are no reference ranges defined for the analyte a bar with one section is displayed.

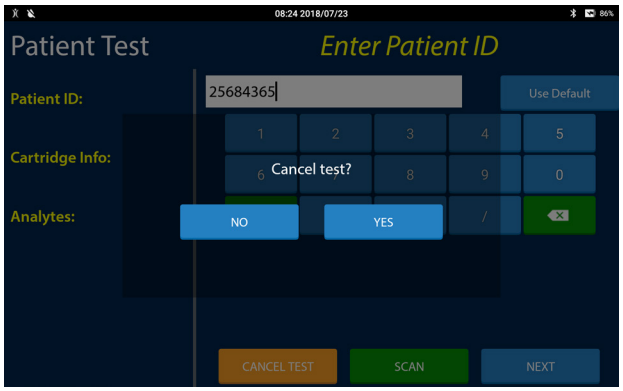
Note: For results that cannot have a reference range defined there is no Results Graph displayed.

Note: The vertical bar will be displayed relative to where the result falls within that reference range.

Message Dialog

If the operator attempts an action that is not allowed, or the IRMA System needs to inform the operator of an issue requiring immediate attention a message dialog is displayed. The message dialog is partially transparent, covers the center of the screen and must be addressed before returning to the screen behind it. The features of the message dialog are:

- **Instructions:** Instructions to inform the operator of what is required.

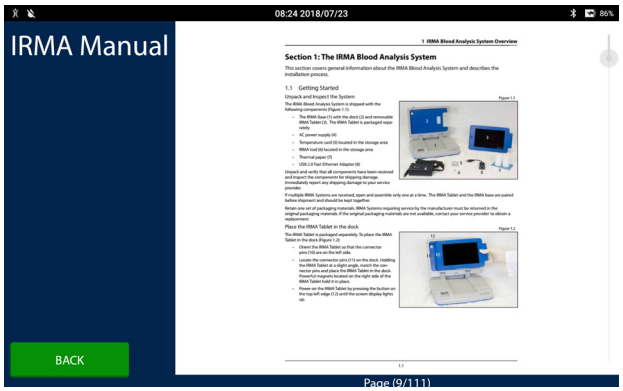


PDF Viewer Screen

Pdf formatted files are displayed in a screen with a pdf viewer. The features of the PDF Viewer screen are:

- **PDF View:** The right, three-quarters of the screen is used to display the pdf document. The document may be zoomed by pinching. For multi-page documents scrolling will move through the document one page at a time. On the far right hand side of the document is a vertical line with a grey circle. Sliding the circle up and down the vertical line will quickly move through multiple pages of the document.

  Note: The current page of the document must be at its smallest size, fully zoomed out, in order to either scroll to the next page or to use the slider bar.



Buttons and Icons

Below is a list of commonly used buttons and icons:

Button or Icon	Description
NEXT	Proceeds to the next screen of the task
BACK	Returns to the previous screen
SKIP	The requested data will be blank in the database
DONE	Completes the task
OK	Positive acknowledgement of an informational message
CANCEL	Reverts any changes or cancels an action
SCAN	Displays the barcode reader screen
MANUAL ENTRY	Displays the manual entry screen
EDIT	Opens an item or test record for editing
VIEW	Opens the test result Edit screen as read only
ADD NEW	Displays a screen for adding a new item
DELETE	Deletes a single item
DELETE ALL	Deletes the entire collection
PRINT	Prints directly to a printer or opens the printer dialog screen
Disabled	The feature will be disabled
Enabled	The feature will be enabled
ABC/123	Toggles between the alpha keyboard and numeric keyboard
?123	Toggles between the numeric and symbol keyboard and the alternative symbol keyboard
	Toggles between the upper and lower case keyboard or between the standard and alternate keyboard
	Displays the user manual
	Indicates the amount of charge remaining in the IRMA System's batteries
	Indicates the IRMA Base is connected to AC power
	Indicates the IRMA System's batteries are charging
	Indicates the IRMA System is connected to WiFi
	Indicates the IRMA System is connected to the Wired Ethernet
	Indicates the IRMA System is connected to a device via Bluetooth
	Indicates a storage device is connected to the USB port

Button or Icon	Description
	Indicates the test has completed
	Indicates the operator should view the logs
	Indicates an EQC test has failed and the operator should view the logs
	Indicates the IRMA System is printing a report or document
	The Bluetooth Connect icon used for pairing the IRMA Tablet.
	The hematocrit result is correlated
	The result is corrected for patient temperature
	The result is greater than the normal reference range
	The result is greater than the critical reference range
	The result is greater than the reportable range
	The result is less than the normal reference range
	The result is less than the critical reference range
	The result is less than the reportable range
	The result is suppressed
	Testing is under QC lockout
1	The number of QC tests required to clear lockout

1.11 IRMA Barometer

The IRMA System utilizes two built-in barometers to measure the barometric pressure for use in calculating blood gas results. They are calibrated by LifeHealth and do not require adjustment.

1.12 IRMA System Conventions

The IRMA System operates according to some common conventions.

- A test result is accepted when the DONE button is pressed or the IRMA Tablet enters sleep mode when the results screen is displayed.
- The editable fields of a test record may be edited until the result is transferred to an external data sink. Printing the test record is not considered to be a transfer to an external data sink.

  Note: not all fields of a test record may be edited.
- The test record stores the information associated with it when the test was performed. For example, if Dr. Andersen was the ordering physician when the test was performed and later Dr. Andersen's name is changed to Dr. Anderson, the physician name in the test record will be Dr. Andersen.

  Note: The only exception to this rule is an analyte's unit of measure. If the unit of measure for iCa in the IRMA System was mmol/L when the test was run and later is changed to mg/dL, the iCa result will be reported in mg/dL.
- In general there is no BACK button displayed during a task. If a data entry error is made, correct it by using Edit once the task is complete.
- The SAVE button is displayed only for configuration items that require a keyboard for entry. Most configuration items are immediately saved when changed and therefore do not require the operator to save.

- For configuration items added by the operator, for example Operator IDs, the convention is to delete the current item and add a new item instead of editing the existing item.

1.13 Before Initial Testing

Prior to initial testing, complete the following:

- A QA level Operator ID (OID) is required to change most of the IRMA System settings. Identify the QA User(s) that will supervise the setup of the IRMA System and add them to the Operator ID (OID) list. Instructions are found in Section 8.2.
- Once the QA level OIDs have been created delete the default OID, 123456. Refer to Section 8.2.

  Note: If the password feature is enabled (refer to Section 8.2) passwords must be created for all OIDs after the password feature is set to Enabled and prior to the IRMA Tablet entering sleep mode.
- Review the default IRMA System settings in Appendix E and make any adjustments. Instructions are found in Section 8.
- Perform an EQC test as described in Section 3.5.
- Perform a TQC test as described in Section 3.7.
- Establish quality control procedures and set-up liquid controls (control type, lot, level, and limits). Refer to Sections 3 and 8.
- If a WiFi network is avaliable connect the IRMA System to the WiFi network (refer to Section 8.9). Once connected, configure Use Network Date and Time to Enabled (refer To Section 8.9).

1.14 IRMA System Shipping and Long Term Storage

Prior to shipping the IRMA System or storing it for an extended period of time do the following.

1. Plug the AC power supply into the IRMA Base.
2. Press the wake button on the IRMA Base.
3. Remove the IRMA Tablet from the dock.
4. Press and hold the IRMA Tablet's power button until a screen is displayed asking to either Power off or Reboot. Select Power off.
5. Temporarily set the IRMA Tablet to the side.
6. Press and hold the wake button on the IRMA Base for at least fifteen seconds.
7. The two LEDs by the wake button will turn off. Release the wake button.
8. Wait for the white LED to flash.
9. Unplug the AC power supply.
10. If the IRMA System is to be placed into storage, insert the IRMA Tablet into the dock.
11. If the IRMA System is to be shipped, retrieve the original shipping materials or obtain a set from your service provider.
12. Follow the packing instructions to place the IRMA Tablet and the IRMA Base into their respective shipping inserts and then place both of them in the shipping box.

1.15 IRMA Intended Use

Intended Use

The IRMA Blood Analysis System is intended for professional use with IRMA cartridges for the in vitro measurement of blood gases (pCO2 and pO2), pH, sodium (Na+), potassium (K+), ionized calcium (Ca++), and hematocrit in human whole blood.

- pH, pCO2 and pO2 measurements are used in the diagnosis, monitoring and treatment of respiratory disturbances and metabolic and respiratory based acid-base disturbances.
- Sodium (Na+) measurements are used in the diagnosis and treatment of aldosteronism, diabetes insipidus, adrenal hypertension, Addison's disease, dehydration, inappropriate antidiuretic secretion, or other diseases involving electro-

lyte imbalance.

- Potassium (K+) measurements are used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high blood potassium levels.
- Ionized calcium (Ca++) measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany.
- Hematocrit measurements can aid in the determination and monitoring of normal or abnormal total red cell volume status including but not limited to conditions such as anemia and erythrocytosis and blood loss related to trauma and surgery.

CLIA Complexity Classification

The IRMA Blood Analysis System has a “moderate complexity” CLIA classification.

Section 2: Patient Sample Analysis

This section describes the procedure for performing a whole blood patient sample analysis using the IRMA System, including sample requirements, sample collection, and sample handling requirements.

2.1 Sample Requirements

Acceptable Specimens Include:

- Fresh arterial or venous whole blood collected in a 1, 2, or 3 mL lithium heparin syringe. Most standard ABG syringes are compatible with IRMA cartridges. Balanced or low-volume heparin is recommended for ionized calcium testing; sodium heparin may be used, but sodium values may be elevated 1 to 2 mmol/L.
- Fresh capillary whole blood collected in the IRMA Capillary Collection Device, which contains balanced lithium heparin.
- Fresh venous whole blood collected in a lithium heparin collection tube. Balanced or low-volume heparin is recommended for ionized calcium testing; sodium heparin may be used, but sodium values may be elevated 1 to 2 mmol/L. The sample should be transferred to a non-heparinized 1, 2, or 3 mL syringe for injection into a cartridge.

Note: The following general types of syringes should not be used with IRMA cartridges:

- Frictionless or "pulsating" syringes. These syringes have plungers that will continue to travel downward after the user has stopped injecting. This may result in a sensor error.
- Syringes that contain a mixing ball or non-dissolving disk impregnated with heparin. The ball or disk may become lodged in the tip of the syringe, and the sample may hemolyze when it is forced through or around the plug during injection.
- Syringes that have a non-standard Luer hub that does not fit the IRMA cartridge Luer injection port.
- Samples collected in EDTA anticoagulant may not be used with the IRMA cartridge. EDTA will cause a clinically significant error in sodium, potassium and hematocrit results and may affect other chemistry tests.

Capillary Requirements

Capillary samples must be collected in the IRMA Capillary Collection Device. Refer to the instructions for use that accompanies the Capillary Collection Device for detailed information.

Sample Size

The minimum whole blood sample volumes are:

- 200 µL if the sample is collected in a 1 mL syringe
- 125 µL if the sample is collected in an IRMA Capillary Collection Device.

Ensure that sufficient sample is collected to meet the minimum volumes required for injection into the cartridge.

General Sample Collection Guidelines

- Time sample collections to minimize delays between collection and analysis.
- Avoid drawing samples above an IV line to prevent dilution of the sample with IV fluid.
- When drawing a sample from an indwelling line, back-flush and clear the line of IV fluids prior to sampling to remove anticoagulants or medications which might interfere with the test results.
- Allow the blood collection site to dry after being cleansed with alcohol to prevent hemolysis.
- Fill the collection device to the appropriate capacity. Incomplete filling may cause high heparin to blood ratios which may lower ionized calcium results and may affect other results.
- Thoroughly mix samples collected in syringes.
- Capillary samples must be free-flowing from an "arterialized" site. Avoid excessive squeezing of the puncture site to prevent erroneous results that could result from dilution of analytes or hemolysis.

Blood Gas Sample Handling

- Expel any air present in the syringe immediately after collection and before the sample is mixed. If a portion of the

sample must be separated for other testing, do not expose the sample to air.

- If a sample cannot be tested within 5 minutes of collection:
  - Expel all air from the syringe.
  - Store the blood gas sample in an ice slurry.
  - Before injection, thoroughly mix the sample while the cartridge is calibrating.

Electrolyte Sample Handling

- A blood sample should be tested within 20 minutes of collection to minimize pH changes that could affect the ionized calcium concentration.
- Do not ice samples that are to be analyzed for potassium; iced samples may hemolyze.

Preparing the Sample for Injection When Using a Syringe

- Remove any entrapped air from the syringe sample by pointing the syringe at an upward angle to allow air bubbles to rise to the surface; expel the air, along with a small amount of blood, onto an absorbent surface.
- Check the expelled sample for blood clots. A clot usually indicates inadequate sample anticoagulation. If a clot is injected near or over the cartridge sensors, erroneous test results or sensor errors could occur. Do not use clotted samples.
- Mix the sample thoroughly using the following technique:
  - Roll the syringe between the palms of both hands with the syringe tip pointing up.
  - Invert the syringe (i.e., tip down) after 15 to 30 seconds. Continue to roll the sample, alternating syringe orientation, until thoroughly mixed.
- When using the IRMA Capillary Collection Device, analyze the sample immediately.

2.2 Sample Injection

With each test, the cartridge automatically calibrates before the sample is injected into the cartridge. Following calibration, the calibrant that is present in the sample path must be completely displaced by the blood sample that is being analyzed. The sample path is the area of the cartridge that houses the sensors and must be completely filled with blood (see Figures 2-2 and 2-3). Proper sample injection technique will ensure that the calibrant is completely displaced, and that no air bubbles are introduced during the injection step. If calibrant or bubbles are present in the sample path following the initial sample injection from a syringe, the user can displace them by injecting additional sample from the same syringe. This prevents sensor errors and sample loss.

Injecting a Syringe Sample

The following injection technique should be used for all syringe samples, regardless of syringe size (1, 2, or 3 mL) or sample volume:

1. Firmly attach the syringe to the cartridge luer injection port. If the syringe does not have a luer lock tip, place the syringe tip in the injection port and give the syringe a slight twist to firmly seat it in the port.
2. Place your fingers around the syringe so that your thumb rests on top of the plunger (Figure 2-1). Inject the sample by depressing the syringe plunger in a single, quick, controlled motion, similar to the motion used to press a stopwatch button. This initial injection should be done forcefully enough to eject the calibrant from the sample path (Figure 2-2).
3. Continue to inject until the sample path is covered (Figure 2.3). If you can see the sample pushing the calibrant out of the sample path, you are injecting too slowly.

   Note: Do not inject the entire syringe contents (i.e., do not push the syringe plunger all the way down until it bottoms out) during the initial sample injection. Doing so may hemolyze the sample.
4. Following initial sample injection, confirm that the sample path is completely filled with sample, and that no bubbles or calibrant are present (Figure 2-3). Bubbles or calibrant should rarely be seen if

Figure 2.1

proper injection technique is being used.

5. The sample path was designed to be easily viewed. If bubbles or calibrant are present in the sample path and you have sufficient sample remaining, slowly inject additional sample to push them out of the sample path and into the waste area.
6. Note: Do not pull sample from the waste area back into the sample path. Doing so may cause inaccurate results.
7. If bubbles or calibrant do not move when additional sample is injected, tap the top of the plunger to dislodge them, then slowly inject additional sample from the same syringe to push them into the waste area. The entire contents of the syringe may be injected if necessary, to either reach the minimum sample volume injection requirement (200 µL) or to displace bubbles or calibrant.
8. If air bubbles or calibrant gel cannot be displaced from the sample path, select cancel to stop the test, discard the single-use cartridge, and begin again with a new cartridge.
9. Once the sample path is completely filled with a minimum of 200 µL of sample, select CONTINUE to begin sample analysis. Leave the syringe attached to the cartridge until the analysis is complete.

Injecting a Capillary Sample

The IRMA Capillary Collection Device must be used to collect and inject capillary samples into IRMA cartridges. Refer to the IRMA Capillary Collection Device package insert for instructions.

Figure 2.2

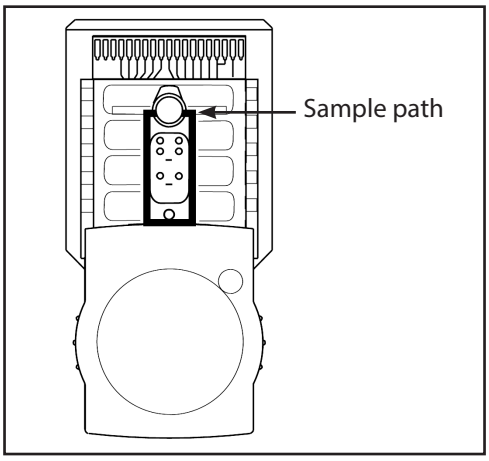
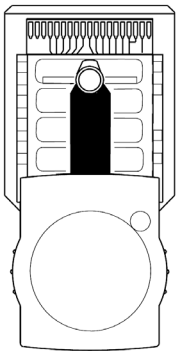
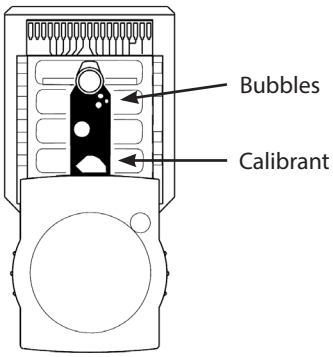


Figure 2.3



Sample path is properly filled.

Figure 2.4



Sample path is improperly filled.
Bubbles and calibrant are present.

2.3 Patient Test Procedure

Performing a Patient Test

Do not insert a cartridge into the IRMA System until instructed.

1. Press the wake button on the IRMA Base to wake the IRMA System.

   Note: If the IRMA Tablet is not in the dock press the IRMA Tablet's power button to wake it. If the IRMA Tablet is off the IRMA Tablet's power button must be pressed and held until the screen comes on.

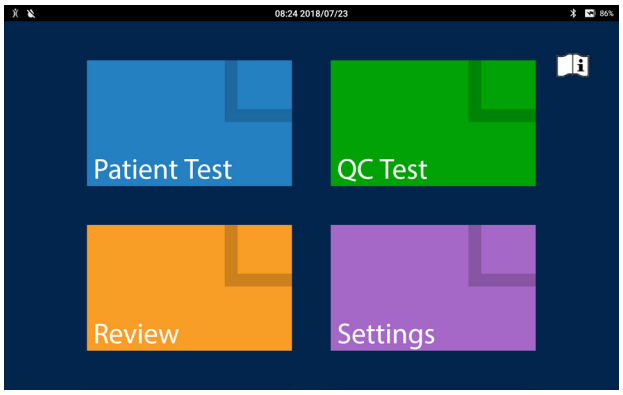
2. If the operator ID (OID) is enabled, scan or enter your operator ID. If the OID and password is enabled, both need to be entered. Press NEXT.
3. When the Main Menu appears, select Patient Test.
4. One of the following 3 screens will appear*:

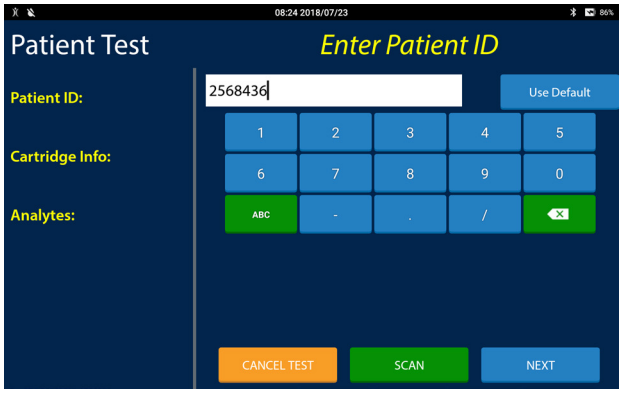
- If Patient ID is enabled, the Enter Patient ID screen will appear. Scan or enter the Patient ID and press NEXT. If no Patient ID is available select User Default. For more information about the User Default feature, see Section 8.3.
- If Patient Details is enabled, the Enter Patient Details screen will appear. Enter the patient information and press NEXT.
- If Patient ID is disabled, the Scan Cartridge Pouch screen will appear.

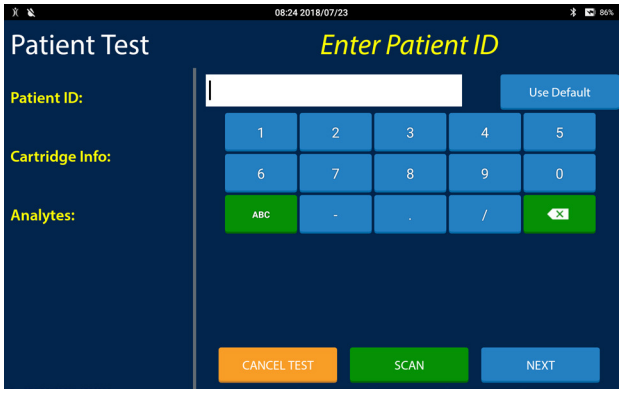
5. Check the expiration date on the IRMA cartridge pouch label. The IRMA System will NOT allow testing if the cartridge is expired.
6. Scan the 2D barcode on the cartridge pouch label or select the lot by pressing MANUAL ENTRY. To manually select the lot (the manual selection screens are not shown):

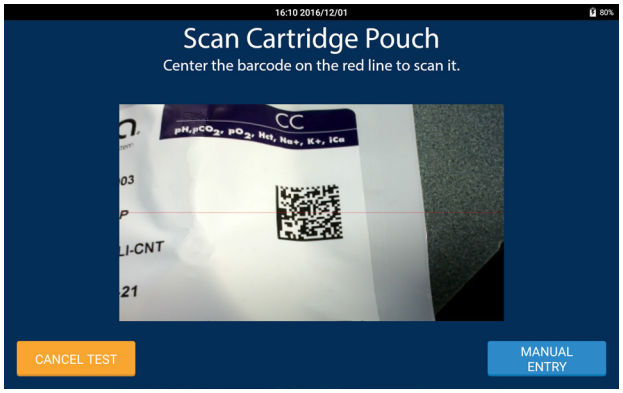
- Select the Product Type by choosing the correct IRMA cartridge type. The Select Cartridge Lot Code screen will appear next.
- A listing of available lot codes to choose from will appear. Select the correct lot code and press NEXT.
  - If the lot code does not appear on the IRMA Tablet screen see a QA User.

Note: The 2D barcode must be scanned from the IRMA Cartridge pouch label. Scanning the 1D barcode will result in an invalid barcode message.





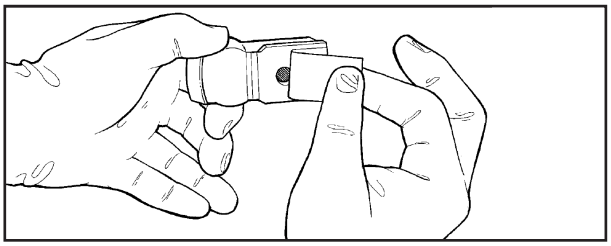




***If a lock symbol appears on the Patient Test button the instrument is in QC lockout mode. A combination of passing EQC, TQC and/or LQC tests are required before patient testing may be resumed. More information can be found in Section 3 - Quality Control Testing.**

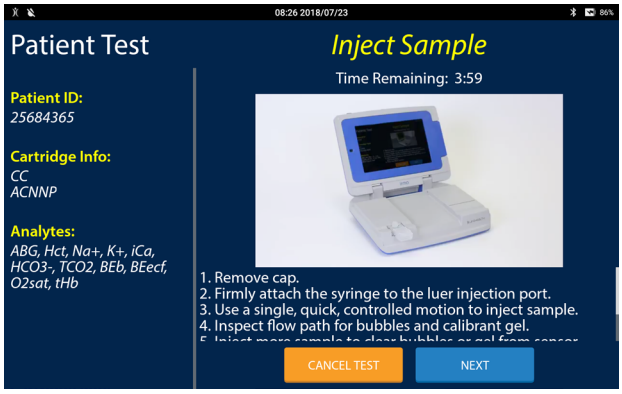
7. If the User Selects option is enabled, the Select Analytes to Test screen will appear (screen not shown). Select the analytes to be tested and press NEXT. If this option is not enabled, the Insert cartridge screen appears.
8. When the Insert Cartridge screen appears, remove the cartridge from the package.
9. Remove the protective tape from the leads on the end of the cartridge (Figure 2.5). After removing the tape, do not touch the leads. Do not remove the cartridge cap.

Figure 2.5



10. Insert the cartridge into the IRMA System within 15 minutes of opening the cartridge pouch (Figure 2.6). Discard the cartridge if not inserted into the IRMA System within 15 minutes and press CANCEL TEST.

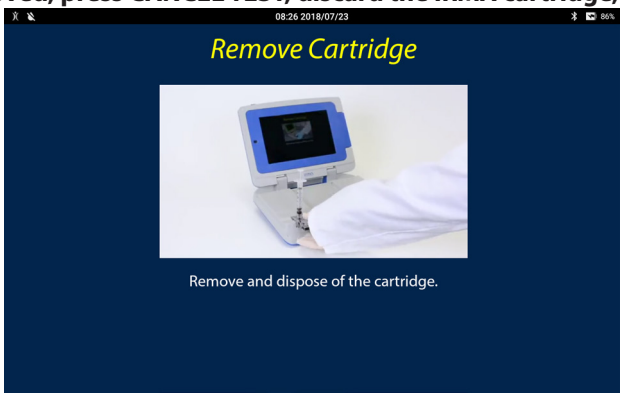
Figure 2.6



11. Depending on how the IRMA System is configured, and the amount of time the calibration phase takes to complete, patient information screens (i.e Patient Type, Oxygen Therapy Information, On Bypass, etc... (screens not shown)), may be displayed to collect this information. Refer to Section 2.5 and Section 8 for more detailed information.
12. When the Inject Sample screen appears, remove the Luer cap from the cartridge by twisting and lifting the cap. Inject the sample using the IRMA Capillary Collection Device or syringe within 4 minutes - a count down timer is displayed on the screen. Leave the collection device attached to the cartridge. See Section 2.2 for sample injection details.
13. Ensure that no air bubbles or calibrant gel are present in the sample path and press NEXT.

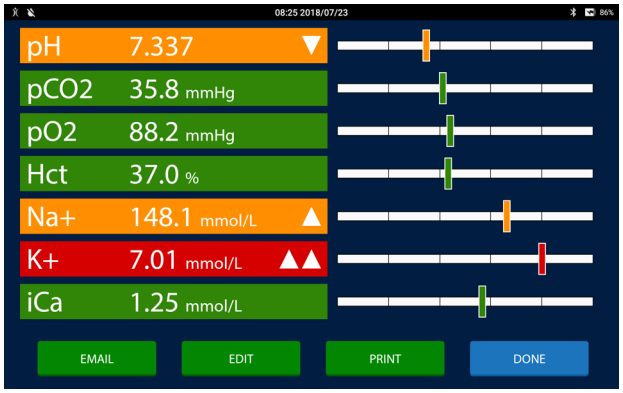
Note: If air bubbles or calibrant gel are present in the sample path, they must be removed. See Section 2.2 for removal instructions. If the bubbles or gel cannot be removed, press CANCEL TEST, discard the IRMA cartridge, and begin again with a new IRMA cartridge.

14. If there is still patient information to be entered the appropriate screens will be displayed. When all required information has been entered, and if the test is not yet complete, the Analyzing screen will be displayed.
15. When the test is complete, the test results screen will be displayed.
16. Remove the cartridge with the collection device attached. Dispose of both in accordance with established guidelines for your facility.



2.4 Test Results

For information on how results are displayed on the test results screen refer to Section 1.10.



- To review patient information entered during the test press EDIT. All of the patient test record details are displayed in the test progress area. In the list of test details, press the test detail to display it in the right two-thirds of the screen.
  - If the test detail may not be edited it will not display in the right two-thirds of the screen.
  - If the information is incorrect edit it and press NEXT.
  - To delete the information press SKIP. The entry will be recorded as blank.
  - Select another item from the list or select Done to return to the test results screen.
- To print the test results press PRINT.

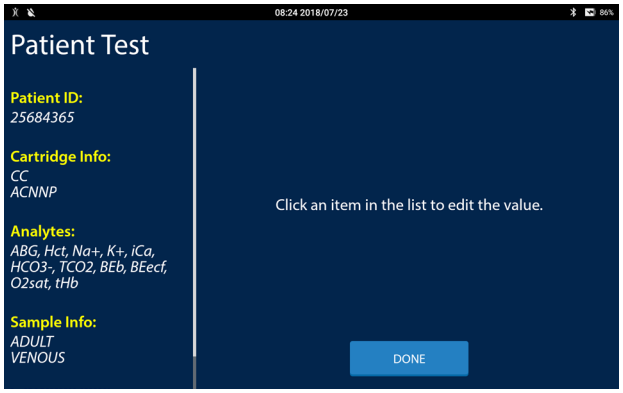
  Note: The results may print in English.
- To email the test report press EMAIL.
  - Select an email address from the list and press SEND.
  - To email the report to an address not in the list, press the Manual Entry Button. Enter the recipient's email address and press ADD ITEM or press CANCEL to return to the list of email addresses.
  - To return to the results view press DONE.

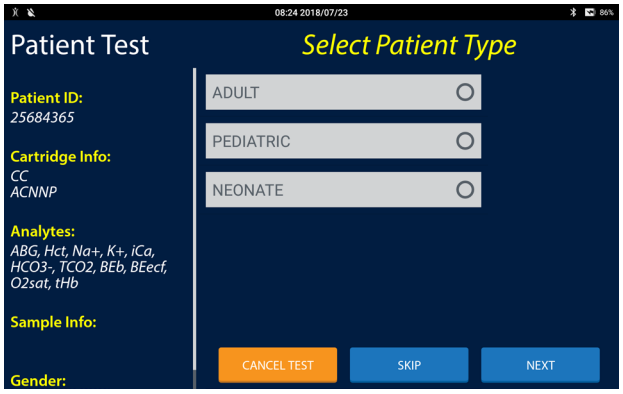
  Note: The Email button only appears if the email feature has been configured (see Section 8.9).

  Note: The Manual Entry button only appears if the email feature has been configured to allow the manual entry of email addresses (see Section 8.9).

  Note: Any manually entered email address will remain in the list until the Done button is pressed. It will not be added to the configured list of email addresses.
- To accept the test and return to the Main Menu press DONE.

  Note: If the cartridge has not been removed the Remove Cartridge screen will be displayed.





2.5 Additional Test Information

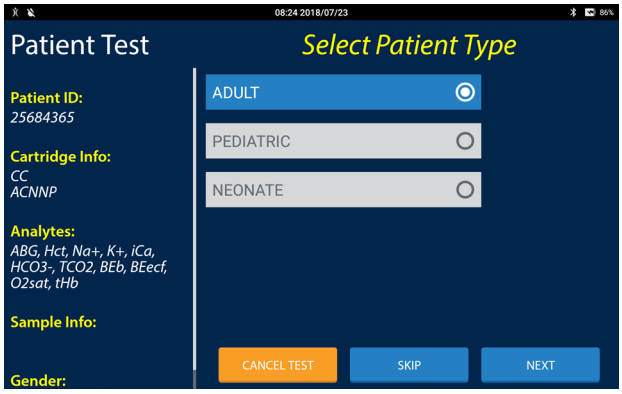
Additional patient test information may be entered if configured in the Settings Menu (refer to Sections 8.5, 8.7 and 8.8). The additional patient test information is listed below by IRMA cartridge type.

All Cartridges	Blood Gas (BG) and Combo Cartridge (CC)	CC and H3
Patient Type	Oxygen Therapy Information	Bypass Status
Patient Gender	Patient Temperature	
Sample Type	Hemoglobin	
Sample Site and Subsite	SpO_2	
Allen's Test		
Ordering Physician		
Patient Notes		

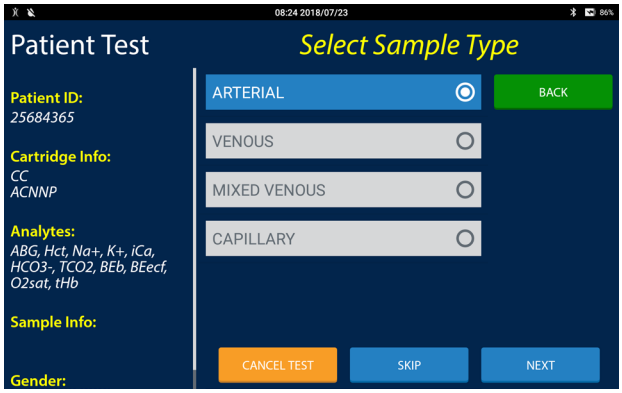
All Cartridges

The following information may be entered for all cartridges:

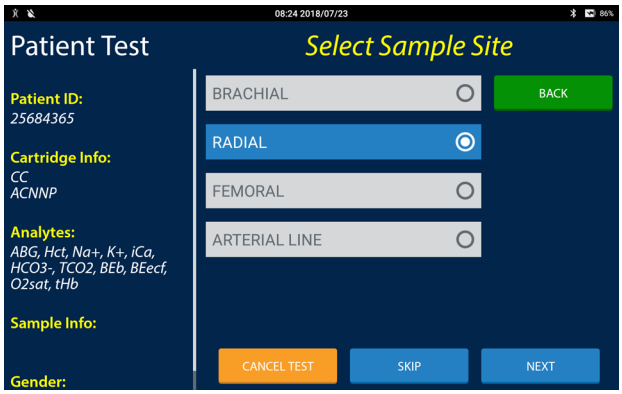
- **Patient Type:** The default patient type information that may be selected includes Adult, Pediatric, and Neonate. Additional patient types can be added, and the default types removed, from the Analyte Ranges Menu (refer to Section 8.5). Select the correct patient type and press NEXT.



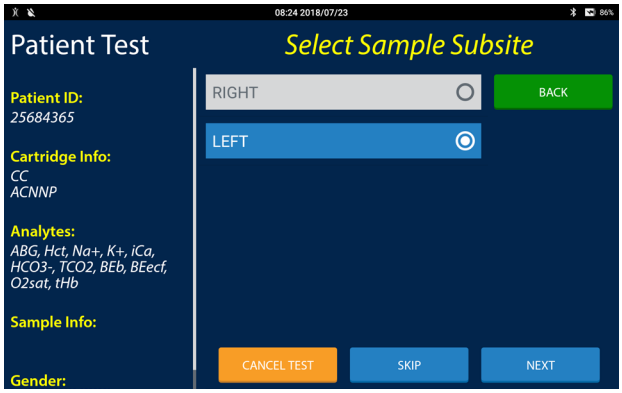
- **Sample Type:** The default sample type selections are Arterial, Venous, Mixed Venous or Capillary for Adult and Pediatric and Capillary or Cord for Neonate. Additional sample types can be added, and the default types removed, from the Analyte Ranges Menu (refer to Section 8.5). Select the correct sample type and press NEXT.



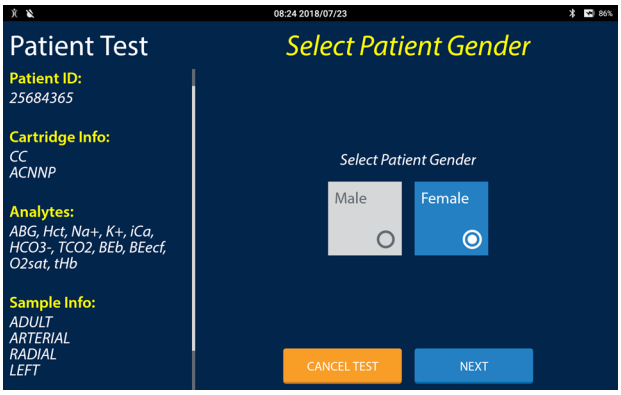
- **Sample Site:** The default sample site selections are Brachial, Radial, Femoral or Arterial Line for the Arterial sample type. There are no default sample sites for Venous, Mixed Venous, Capillary or Cord sample types. Additional sample sites can be added, and the default sites removed, from the Analyte Ranges Menu (refer to Section 8.5). Select the correct sample site and press NEXT.



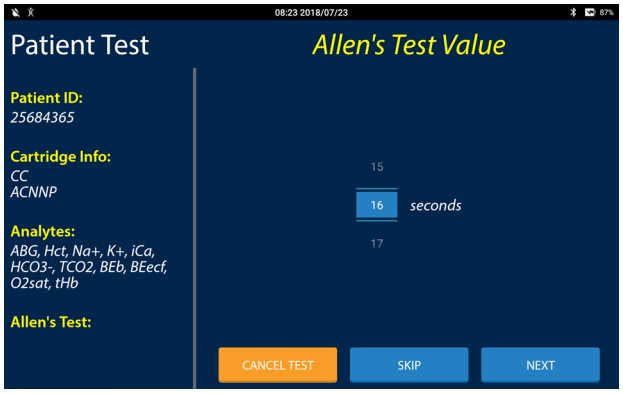
- **Sample Subsite:** The default sample subsite selections are Right or Left for the Brachial, Radial and Femoral sample sites. There are no default sample subsites for Arterial Line. Additional sample subsites can be added, and the default subsites removed, from the Analyte Ranges Menu (refer to Section 8.5). Select the correct sample subsite and press NEXT.



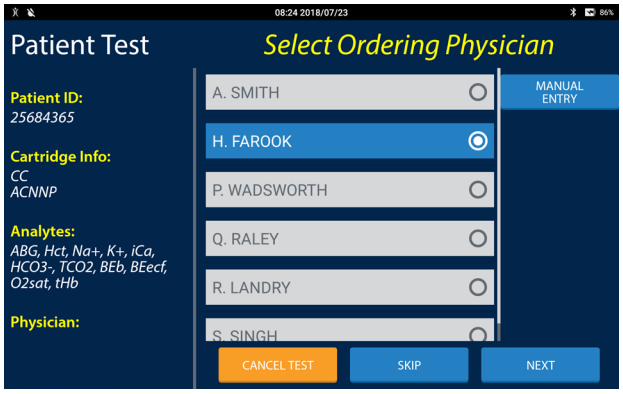
- **Patient Gender:** Select male or female (patient gender only displays if both Patient Type and Patient Specific Reference Ranges are enabled. Refer to Section 8.5) Select the correct gender and press NEXT.



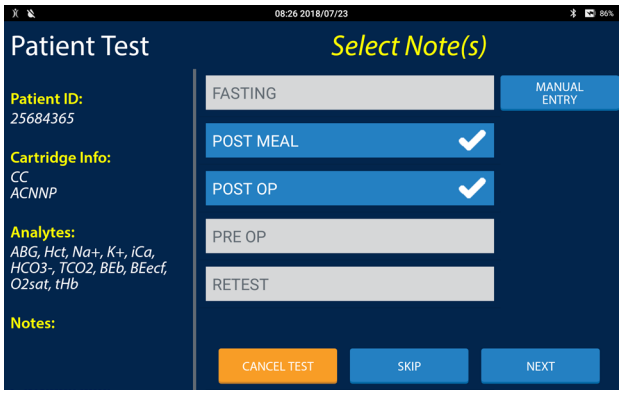
- **Allen's Test:** Select the result of the Allen's Test in seconds.
  - The number will turn red if the result is outside of the configured range for a passing Allen's Test (refer to Section 8.7)



- **Ordering Physician:** Select the ordering physician from the pre-populated list (refer to Section 8.7) or enter the physician's name manually by selecting Manual Entry if it is enabled.



- **Patient Notes:** Select the applicable notes from the pre-populated list (refer to Section 8.7) or enter notes manually by selecting Manual Entry if it is enabled.

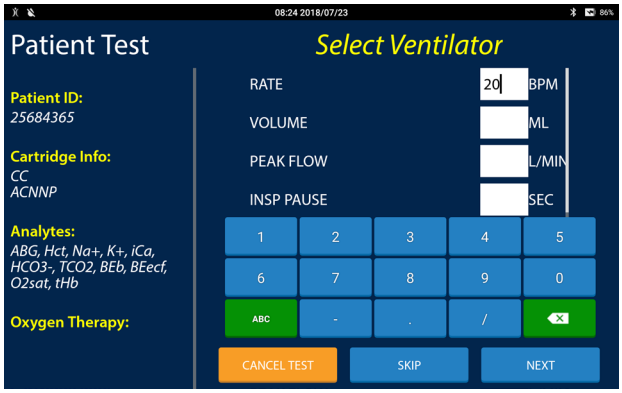


Blood Gas (BG) and Combo cartridge (CC)

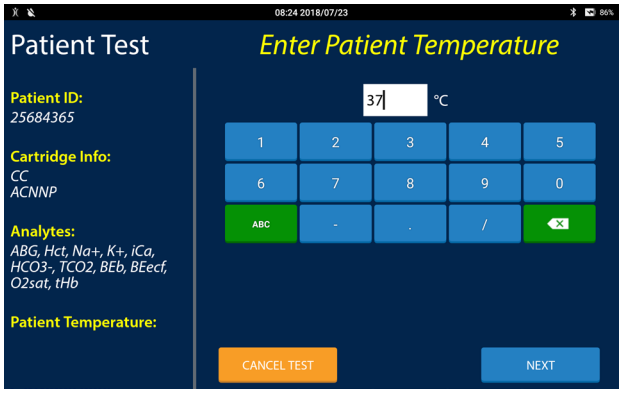
The following information may be entered for the IRMA Blood Gas (BG) and Combo (CC) cartridges:

- To enter Oxygen Therapy information:
  - If Therapy Mode is enabled in ABG Test Settings (refer to Section 8.8), select the correct ventilator and press NEXT.
  - If Device Mode is enabled in ABG Test Settings (refer to Section 8.8), select the correct oxygen therapy device and press NEXT.
  - A separate text entry area will display for each configured oxygen therapy parameter (refer to Section 8.8). Enter all of the required parameters and press NEXT.

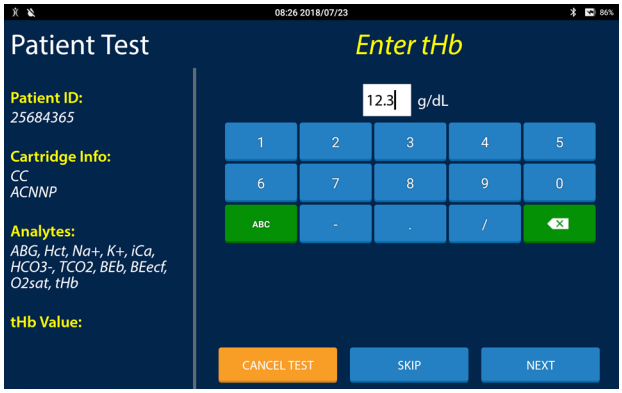
  Note: If there are more parameters than can fit above the keyboard, scroll to the screen to move the blank text entry areas up.



- **Patient Temperature:** Enter the patient's temperature. The temperature entered will be used to correct the blood gas results. Press NEXT.



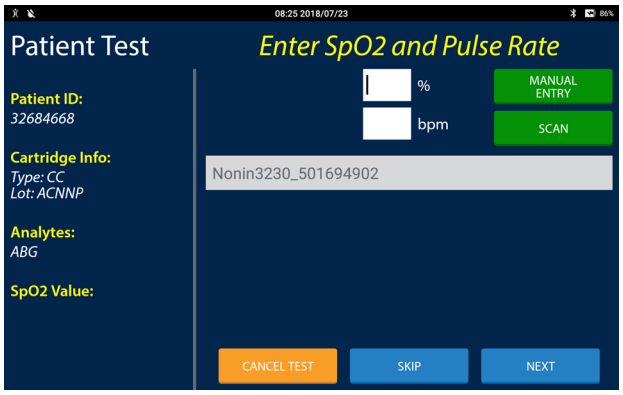
- **Hemoglobin:** Enter the patient's hemoglobin (refer to Section 8.8) for use in calculating the base excess in blood value (BEb) and press NEXT.



- **SpO_2:** Enter the patient's SpO_2 and Pulse Rate manually or select a *Bluetooth* enabled pulse oximeter (refer to Section 8.8) from the list to populate .

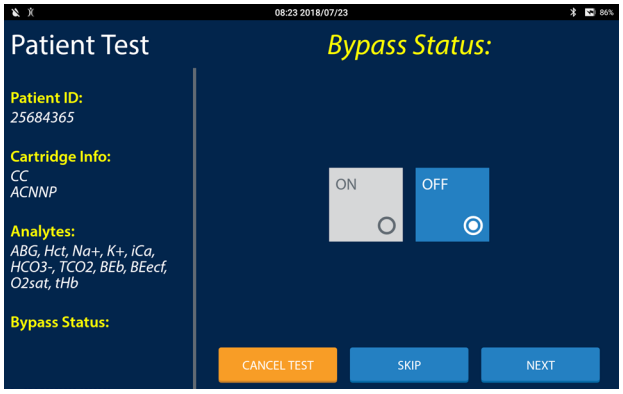
  Note: It may take several seconds for the two values to appear when automatically read from the pulse oximeter.

  - If the desired pulse oximeter is not in the list or the incorrect pulse oximeter was selected from the list, press SCAN. The list of available pulse oximeter devices will be refreshed.
  - Press NEXT.



CC and H3

- **Bypass Status:** Select On if the patient is on cardiopulmonary bypass or Off if they are not and press NEXT.
  - Selecting On will correlate the hematocrit (Hct) result using the appropriate slope and intercept values configured in Settings (refer to Section 8.7).



Section 3: Quality Control Testing

Quality Assurance (QA) can be defined as the required systems and actions to provide adequate confidence that a service, such as a point of care diagnostics program, satisfies the medical needs of the patient.[1] Quality Control (QC) is a major component of a QA program, and can be defined as the systematic process of assessing and documenting the analytical performance of an analysis system.

By design, a point of care (POC) system is intended to be used by non-laboratory clinical staff who typically do not have a background in quality control, analyzer maintenance, and calibration procedures that are inherent components of traditional laboratory analyzer QA programs. Traditional laboratory analyzer QC programs are designed to detect system problems primarily through the use of liquid controls. System problems are typically related to calibration or maintenance problems that result from the exposure of the system and sensors to multiple samples. The IRMA System was designed to eliminate problems related to calibration and maintenance.

3.1 IRMA Cartridges

The IRMA System utilizes single-use cartridges, also referred to as unit-use or disposable cartridges. Each cartridge houses miniaturized electrochemical sensors and a pre-packaged calibrant. The calibrant is manufactured and tested with NIST traceable gases and standards.

Prior to sample introduction, the sensors on each IRMA cartridge are automatically calibrated using the calibrant. Calibration of the cartridge is complete when information determined by the manufacturer for each cartridge lot (the Cal Code) is combined with measurements taken during the calibration process. The manufacturer derived Cal Code information is stored in the IRMA System memory following initial entry of a new cartridge lot, or can be entered via the barcode reader.

3.2 IRMA Quality Control

The IRMA Quality Control program consists of the following 4 elements:

1. Comprehensive, automatic, internal quality and procedural checks that continuously monitor sensor response and instrument response. The IRMA System software monitors responses throughout the calibration and sample analysis phases of a test. If an uncharacteristic response is detected during the calibration phase, the system rejects the cartridge and does not allow that cartridge to be used for sample analysis. Since sample introduction occurs after calibration, rejected cartridges do not result in the loss of the sample. If an uncharacteristic sensor response is detected during the sample analysis phase, the system suppresses that sensor and does not report an analyte result for that sensor.
2. Electronic quality control (EQC) is performed through a comprehensive diagnostic check of the edge connector, internal electronics, and cartridge interface circuitry. An EQC test simulates the electronic signals that are produced by IRMA sensors during a cartridge test. During an EQC test, an isolated region of the internal circuit board sends a range of signals through the cartridge measurement channels. The range of signals generated encompasses the entire linear range expected from blood analysis. EQC also performs a current leakage test on every edge connector pin. Signal measurements must fall within strict predetermined thresholds for the test to pass. IRMA EQC is an internal method, and does not require the use of an external device.
3. Liquid quality control (LQC) is performed to verify proper shipping and cartridge storage conditions using various liquid control solutions of known analyte concentration. Control materials are commercially available in levels corresponding to normal and abnormal clinical conditions.
4. A Temperature Quality Control, (TQC) test is performed using the IRMA Temperature Verification Cartridge to verify proper operation of the IRMA System's temperature control system and edge connector interface. Although the temperature is monitored continuously during patient testing, the TQC test allows for easy external verification.

3.3 LQC Material Handling

LQC Materials

For all IRMA cartridge types LifeHealth recommends RNA Medical Quality Controls and Linearty Kits. Ranges for RNA Medical controls may be found on the LifeHealth website (www.lifehealthmed.com) and scanned directly into the IRMA System (refer to Section 8.4). Other brands of LQC Materials may exhibit interference or matrix effects and are not supported by LifeHealth.

CC, BG and H3 Control Materials Procedure

1. Follow Directions for Use on control package insert.
2. Follow the instructions on the IRMA Tablet until the Inject Sample screen is displayed (refer to Section 3.6).
3. Use a 1 to 3 mL, non-heperanized syringe, with an 18 to 20 gauge needle.
4. Carefully snap open the control ampule.
5. Place the tip of the needle below the surface of the liquid when drawing the sample to minimize air contamination.
6. Draw approximately 1 mL of control into a 1 mL syringe. Draw all but the last of the control, being careful not to draw up air, into a 2 or 3 mL syringe.

   Note: The syringe must be kept vertical, with the needle pointing down from the time the sample is drawn until it is injected.
7. Remove the needle of the syringe.

   Note: Do not remove any bubbles before injecting the contents of the syringe into the cartridge.
8. Remove the Luer cap from the cartridge and firmly attach the syringe to the cartridge.
9. Immediately inject nearly all of the control material in the syringe following the technique in Section 2.2.

   Note: Confirm there are no bubbles visible in the cartridge flow path.
10. Continue the test as described in Section 3.6.

3.4 Quality Control Recommendations

Following method verification and establishment of liquid quality control limits, LifeHealth recommends EQC as the primary method of assessing system accuracy and precision. Since each test site may have unique requirements, each site should select and verify a quality control system that meets their needs. LifeHealth recommends that QC be performed as follows:

Run An EQC Test:

- Once per shift of patient testing on each IRMA System;
- When the IRMA System experiences a significant change in storage temperature, (e.g., movement from a cold to a hot environment);
- Whenever the performance of the IRMA System requires verification, according to facility or regulatory agency protocol.

Run Two Levels of Liquid Control:

- Before a new cartridge lot or shipment is placed into use, (following the required equilibration period) to verify proper shipping and equilibration conditions. Cartridge lot verification is not required for each IRMA System in use.

Additional Liquid Control Testing:

- Is required only if cartridges are required to go through an additional equilibration period due to temperature fluctuations of greater than 8°C (14.4°F) in the cartridge storage area. Refer to Section 1.7 for additional equilibration information.
- If cartridges are required to go through an additional equilibration period, run two levels of liquid control before placing the cartridge lot back into use.

Run A Temperature Test:

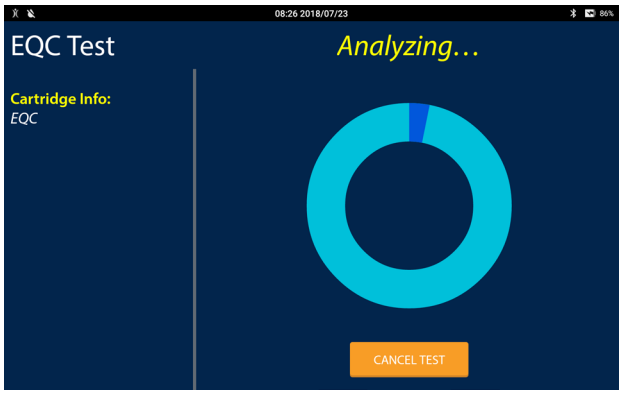
Monthly to verify that the IRMA System's temperature control system is operating properly.

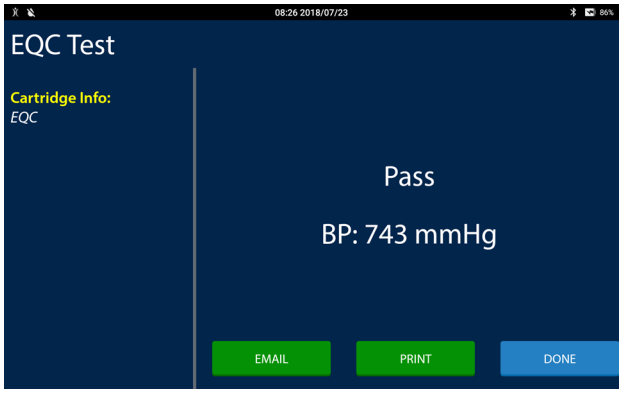
3.5 Electronic Quality Control

Electronic quality control tests are performed manually.

Performing a Manual EQC Test

1. Press the wake button on the IRMA Base.
2. From the Main Menu, select QC Test.
3. If logged into the IRMA System as a QA User, select QC Test from the QC Menu.
4. From the QC Test Menu select Perform Electronic Test.
5. When the EQC test has been completed the results screen will be displayed.
   - If the EQC test passed, Pass will be displayed along with the measured barometric pressure.
   - If the EQC test failed, Fail will be displayed along with one or more error codes and the measured barometric pressure.
6. If a hardcopy of the test results are required press the PRINT button to print the test results.
7. Press EMAIL to email the test report. See Section 2.4 for a description of the email feature.
8. Press DONE to accept the test and return to the QC Test menu.





3.6 Running an LQC Test

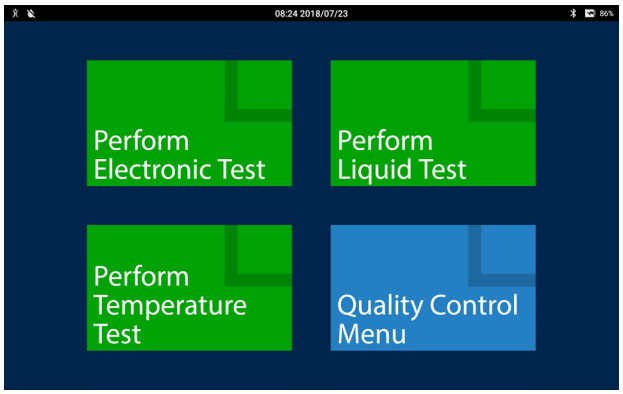
To initiate a LQC test:

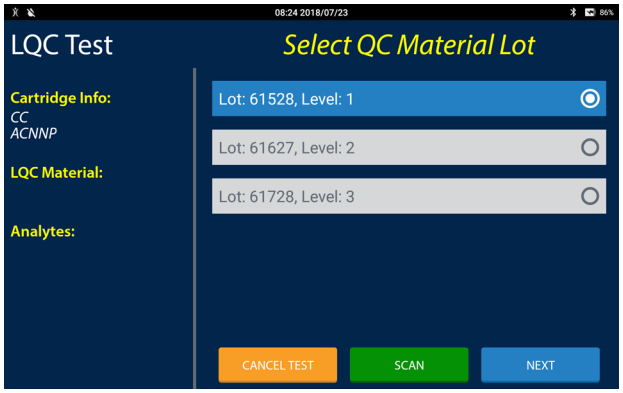
1. Press the wake button on the IRMA Base.
2. Select QC Test from the Main Menu.
3. From the QC Test menu select Perform Liquid Test.
4. Check the expiration date on the IRMA cartridge pouch label. The IRMA System will NOT allow testing if the cartridge is expired.
5. Scan the cartridge pouch label or manually enter the information by pressing MANUAL ENTRY. To enter information manually (the manual entry screens are not shown):

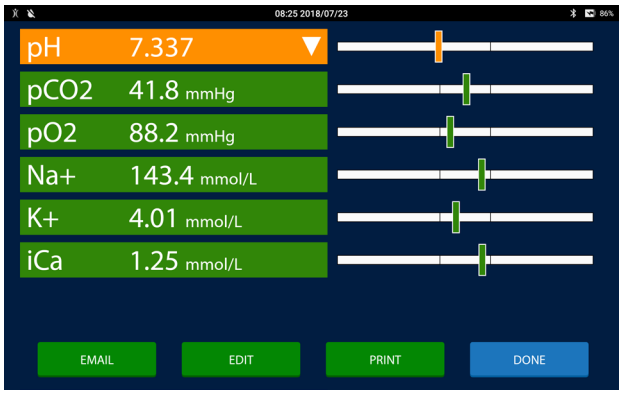
- Select the Product Type by choosing the correct IRMA cartridge type. The Select Cartridge Lot Code screen will appear next.
- A listing of available lot codes to choose from will appear. Select the correct lot code and press NEXT.
  - If the lot code does not appear select the Add New button.
  - Enter the lot code and cal code printed on the cartridge pouch label and press NEXT.

6. Select the LQC Material lot and level that corresponds to the lot and level of the liquid control solution that will be used to perform testing.
7. When the Insert Cartridge screen appears, remove the cartridge from the package.
8. Remove the protective tape from the leads on the end of the cartridge (Figure 2.5). After removing the tape, do not touch the leads. Do not remove the cartridge cap.
9. Insert the cartridge into the IRMA System within 15 minutes of opening the cartridge pouch (Figure 2.6). Discard the cartridge if not inserted into the IRMA System within 15 minutes and press CANCEL TEST.
10. When the Inject Sample screen appears, remove the Luer cap from the cartridge by twisting and lifting the cap. Inject the sample. See Section 3.3 for sample injection details.
11. Ensure that no air bubbles or calibrant gel are present in the sample path and press NEXT.

    Note: If air bubbles or calibrant gel are present in the sample path, they must be removed. See Section 2.2 for removal instructions. If the bubbles or gel cannot be removed, press CANCEL TEST, discard the IRMA cartridge, and begin again with a new IRMA cartridge.
12. The Analyzing screen will be displayed.
13. When the test is complete, the test results screen will be displayed.
14. Remove the cartridge with the collection device attached. Dispose of both in accordance with established guidelines for your facility.







Note: If the cartridge has not been removed the remove cartridge screen will be displayed.

3.7 LQC Test Results

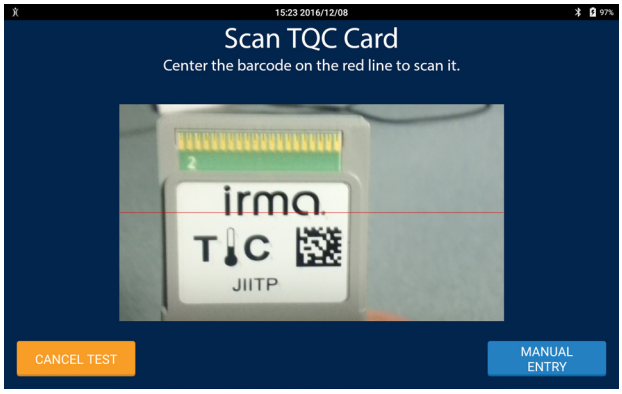
For information on how results are displayed on the test results screen refer to **Results Screen** in Section 1.10. To use the test results screen:

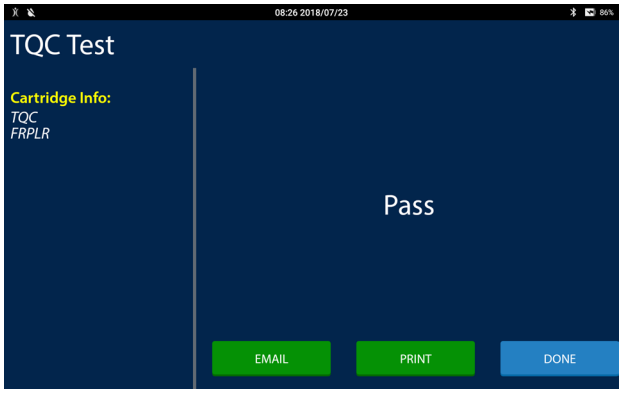
- The result graph bars will contain three sections. If the result is outside of the center (passing) section the analyte has failed LQC testing. Analytes outside of the qc range will be displayed on orange analyte buttons with either an upward pointing triangle (High) or a downward pointing triangle (Low.)
- To review information entered during the test press EDIT. All of the test record details are displayed in the test progress area. In the list of test details, only user notes, if it is Enabled, may be edited.
  - To change the user notes, press on the user notes in the list. The user notes screen will be displayed. If the information is incorrect or incomplete edit the notes.
  - Select Next or Skip.
  - Select Done to return to the test results screen.
- To print the test results press PRINT.
- To email the test results press EMAIL. See Section 2.4 for a description of the email feature.
- To accept the test and return to the Main Menu press DONE.

3.8 Temperature Quality Control

Remove the IRMA temperature verification cartridge from under the printer door. To initiate a TQC test:

1. Press the wake button on the IRMA Base.
2. From the Main Menu, select QC Test.
3. Select Perform Temperature Test.
4. Scan the barcode on the temperature verification cartridge or manually select the cartridge's calibration code by pressing MANUAL ENTRY. To enter the calibration code manually (the manual entry screens are not shown):
   - Select the calibration code from the screen that is printed below the temperature verification cartridge's barcode and press NEXT.
   - If the calibration code does not appear select the Add New button.
   - Enter the calibration code that is printed below the temperature verification cartridge's barcode and press NEXT.
   - Select the calibration code and press NEXT.
5. When the Insert Cartridge screen appears insert the temperature verification cartridge into the IRMA System.
6. The Analyzing screen will be displayed.
7. When the TQC test has been completed the results screen will be displayed.
   - If the TQC test passed, Pass will be displayed.
   - If the TQC test failed, Fail will be displayed along with one or more error codes.





8. If a hardcopy of the test results are required press the PRINT button to print the test results.
9. Press EMAIL to email the test report. See Section 2.4 for a description of the email feature.
10. Press DONE to accept the test and return to the QC Test menu.

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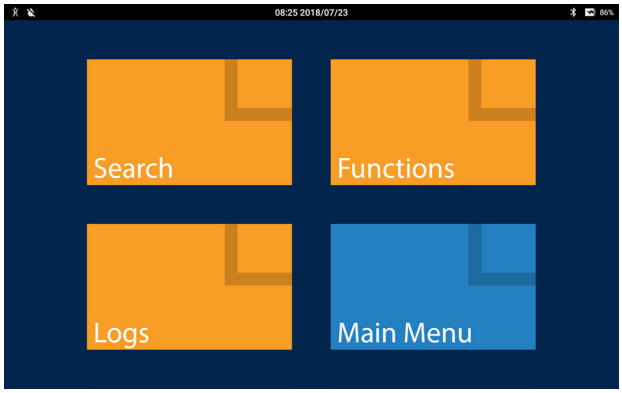
Section 4: Review

This section describes the IRMA System's data storage capabilities, the procedures to search patient and QC test results, how to access the logs and how to use the instrument functions.

4.1 Review Options Overview



IRMA System Review features are accessed through the Review menu. The features that may be accessed are controlled by the Operator ID privilege level.

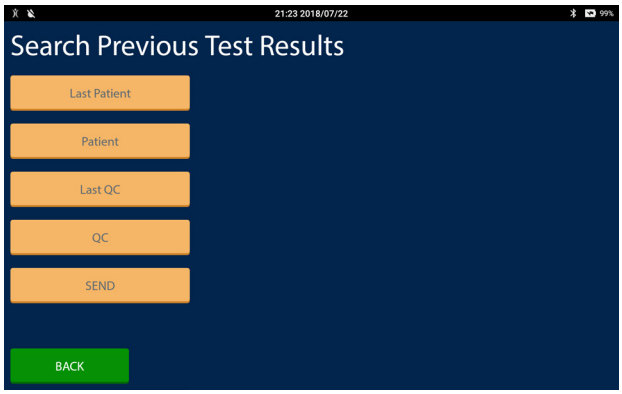
- QA Users (identified as "QA") have access to all Review features.
- Non-QA Users (identified as "User") have access to a subset of the Review Features.

Access the Review menu by selecting the Review button on the Main Menu. If the OID Required setting is configured to Disabled, the User features will be displayed. To access the QA User settings when logged into the IRMA System as a User, press the IRMA Tablet's power button to place the IRMA Tablet in sleep mode. Press the IRMA Tablet button again to wake it and then enter a QA Operator ID. The following features are available when accessing the Review menu as a QA User:

Search	Recall last patient or QC test result
	Search patient results by Date, Patient ID, or Operator ID
	Search QC results by Date or Operator ID
Logs	Access the logs
Functions	Perform a software update, veiw the About screens and save, clear and restore the database.
Main Menu	Returns to the Main Menu.

4.2 Search Test Results

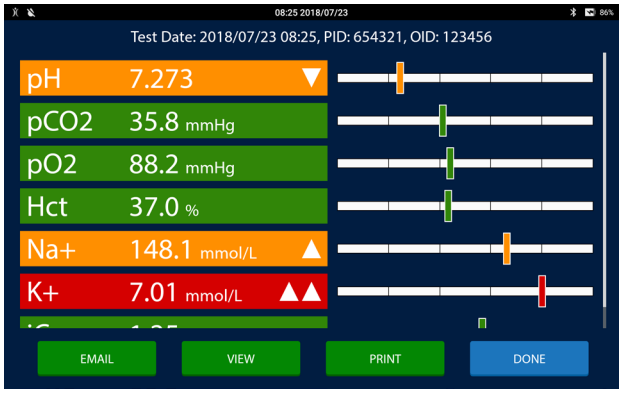
Select the Search button to access the Search Previous Test Results menu.



Last Results - Patient

To review the last patient result, select Last Patient. The results from the last patient test will appear. Refer to Section 1.10 for details on how the test results are displayed. The following options are found on the bottom of the results screen:

- **Edit:** Select Edit to change any of the test information that was entered during the test (refer to Section 2.5). The Edit screen will appear. Make any changes to the test information as described in Section 2.4.
- **View:** Select View to view the test information that was entered during the test (refer to Section 2.5). The Edit screen will appear, however, none of the test information may be changed. When finished, press DONE.
- **Print:** Select Print to send the results to the IRMA printer.
- **Email:** Select Email to email the results report. See Section 2.4 for a description of the Email feature.
- **Done:** Select Done to return to the previous screen.



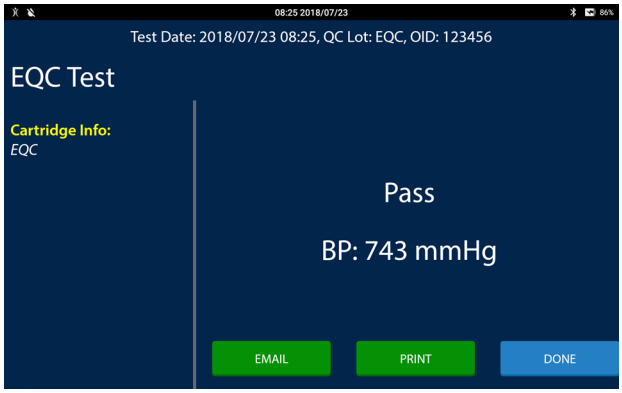
Options for Multiple Records Retrieved by the Search Function Table 4.1

Review	Selecting the Review button will display the results record by record. Press the arrow in the top right or top left of the screen to move through the records. The test information on an individual record (see Section 2.4) may be viewed by selecting the View button. Individual test results can be • Sent to the IRMA printer • Emailed
Print	Selecting the Print button will send all of the returned results to the IRMA printer. The results may be printed in English.
Send	Selecting the send button will attempt to transmit the retrieved test results to the external data manager.

Last Results - QC

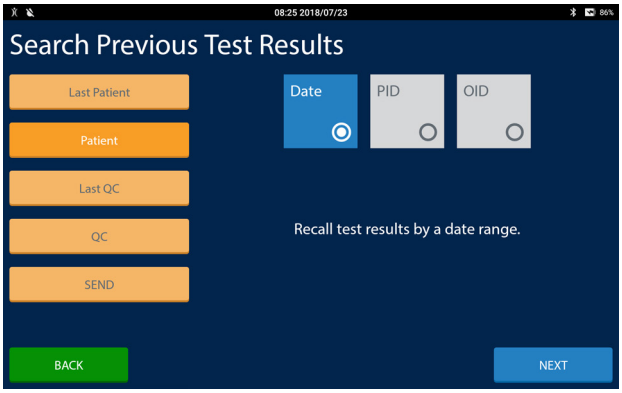
To review the last QC result, select Last QC. The last QC test (LQC, EQC or TQC) will appear. Refer to Section 3.5 for details on the EQC results screen, Section 3.7 for details on the LQC results screen and Section 3.8 for details on the TQC results screen.

- Press Email to email the QC report.See Section 2.4 for a description of the Email feature.
- Press Print to print the QC report to the IRMA LH Printer.
- Press Done to return to the main Search screen.



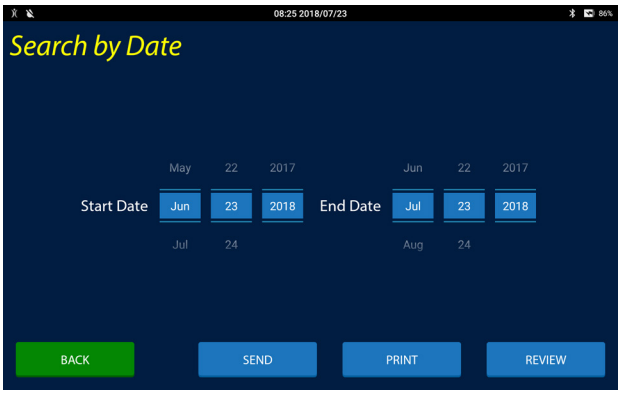
Search Patient Results

To recall patient test results select Patient from the Search Previous Test Results screen. Patient results can be recalled by Date, Patient ID (PID) or Operator ID (OID). Recalled patient results may be reviewed, sent or printed.



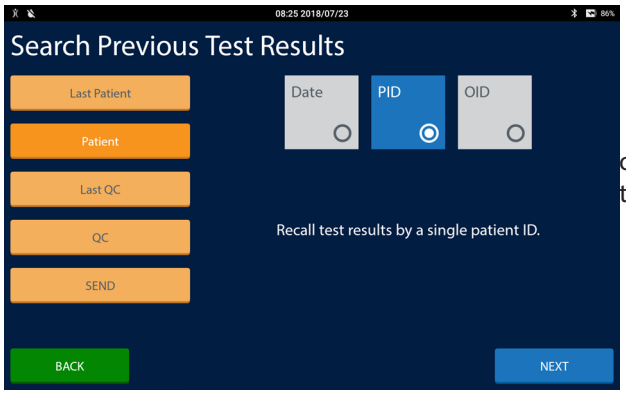
Search by Date:

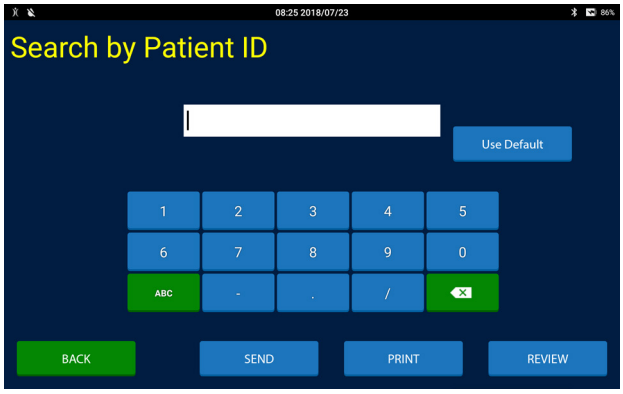
1. Select the Date button.
2. Press the NEXT button. The Search by Date screen will appear.
3. Set the Start Date and End Date for the search by using the spinners. There are three options for the patient records that will be recalled: Review, Send or Print. These options are detailed in Table 4.1. Select Back to return to the previous screen.



Search by Patient ID (PID):

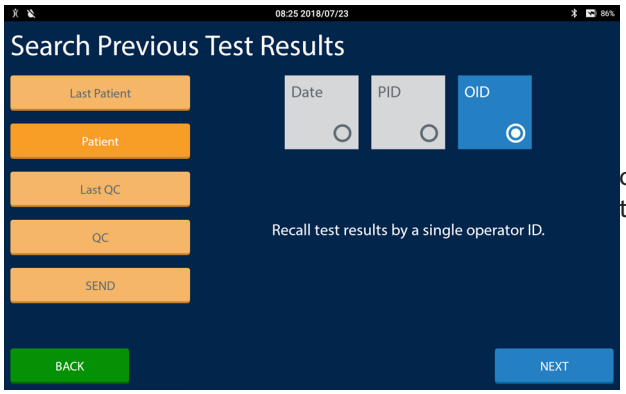
1. Select the PID button.
2. Press the NEXT button. The Search by Patient ID screen will appear.
3. Manually enter or scan the PID. There are three options for the patient records recalled: Review, Send or Print. These options are detailed in Table 4.1. Select Back return to the previous screen.

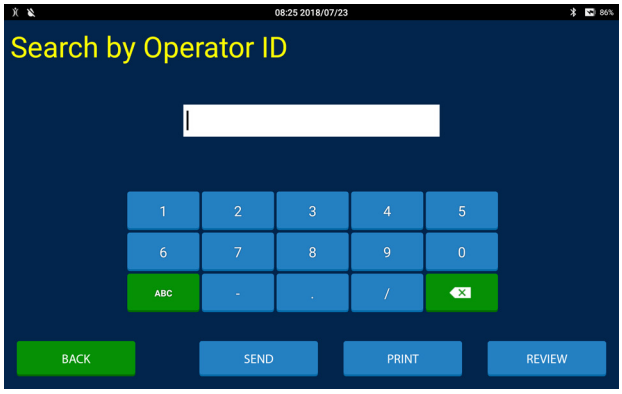




Search by Operator ID (OID):

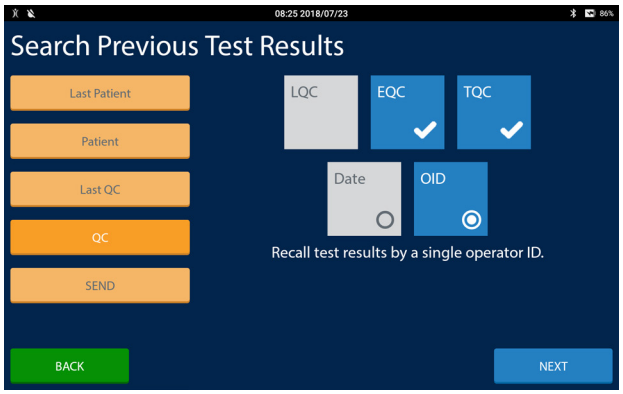
1. Select the OID button.
2. Press the NEXT button. The Search by Operator ID screen will appear.
3. Manually enter or scan the OID. There are three options for the patient records recalled: Review, Send or Print. These options are detailed in Table 4.1. Select Back return to the previous screen.





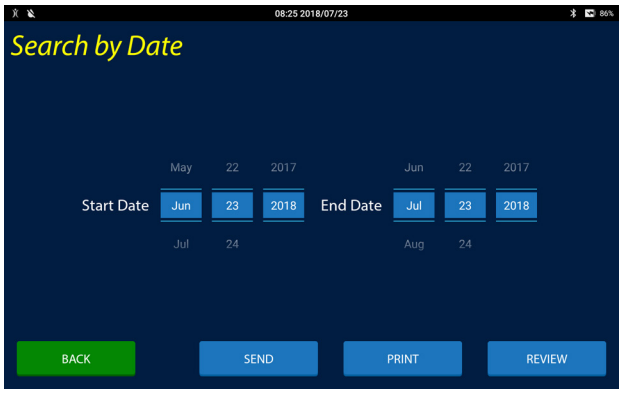
Search QC Results

Select QC from the Search Previous Test Results Menu. QC results can be searched by QC test type, Date, or Operator ID (OID). Recalled QC results may be reviewed, sent or printed.



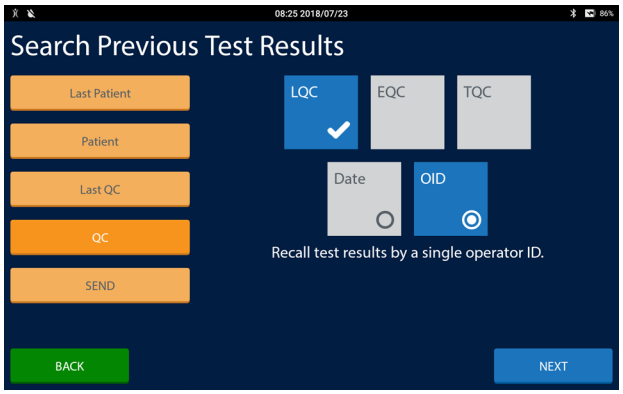
Search by QC Test Type and Date:

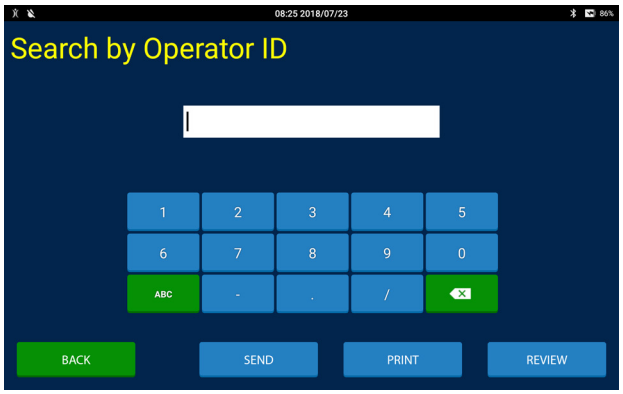
1. Select the QC test type(s).
2. Select the Date button.
3. Press the NEXT button. The Search by Date screen will appear.
4. Set the Start Date and End Date for the search by using the spinners. There are three options for the QC records recalled: Review, Send or Print. These options are detailed in Table 4.1. Select Back to return to the previous screen.



Search by QC Test Type and Operator ID (OID):

1. Select the QC test type(s).
2. Select the OID button.
3. Press the NEXT button. The Search by Operator ID screen will appear.
4. Manually enter or scan the OID. There are three options for the QC records recalled: Review, Send or Print. These options are detailed in Table 4.1. Select Back to return to the previous screen.





4.3 IRMA Functions

Select the Functions button to access the IRMA System's Functions menu.

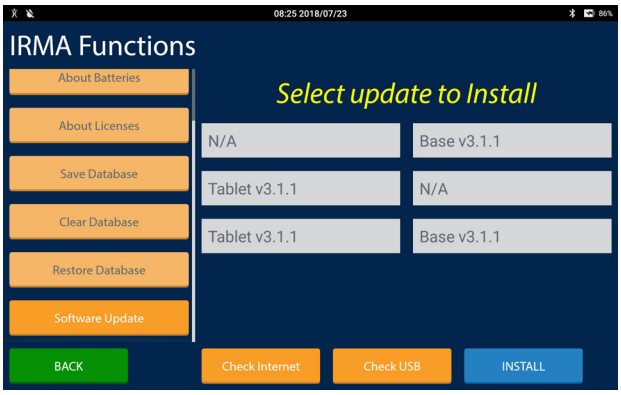
- QA Users (identified as "QA") have access to all functions menus.
- Non-QA Users (identified as "User") have access to the About screens only.

Software Update

Select Software Update from the IRMA System's Functions Menu to install new software. A list of available software updates will be displayed. The IRMA System will never automatically install software updates.

To manually download software:

- Press the CHECK INTERNET button. The IRMA System will check the LifeHealth servers for new software. The IRMA System must be connected to a network with access to the internet to check the LifeHealth servers for new software.
- Insert a USB memory device containing a software update into the IRMA Base's USB port and press the USB Button. The IRMA System will search the updates directory on the USB memory device for new software.



The software available to install will be displayed in two columns. The left column contains the IRMA Tablet software available to be installed. The right column contains the IRMA Base software available to be installed. The software will be installed as a set (IRMA Tablet software and IRMA Base software.) If the IRMA Tablet does not have a corresponding IRMA Base version of software to be installed the button in the right column will display NA. If the IRMA Base does not have a corresponding IRMA Tablet version of software to be installed the button in the left column will display NA. The most recent software will be displayed at the top of the list. The IRMA System cannot be downgraded to an older version of software. To install software:

1. Plug in the AC adapter or make sure the battery percentage is greater than 50%.

   DO NOT unplug the AC adapter or press either the IRMA Base's wake button or the IRMA Tablet's power button during the software installation process.

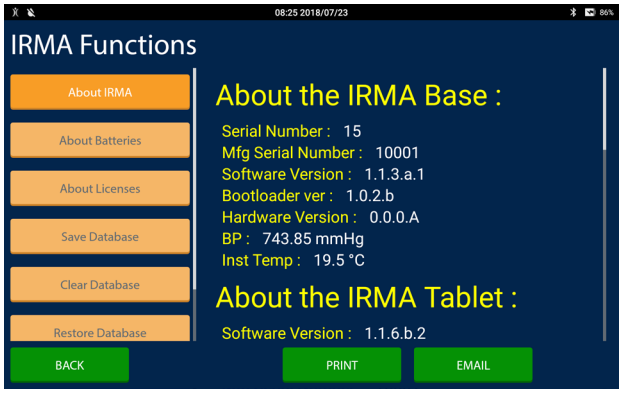
2. Select the software to be installed and press the INSTALL button.
3. IRMA Base software, if available, will be installed first. A progress dialog will be displayed during software installation.
4. If IRMA Tablet software is available it will be either an IRMA Tablet without Android update or an IRMA Tablet with Android update. The instructions for both situations follow.
5. If IRMA Tablet software without an Android update is being installed a dialog will appear asking to install the software. Press the INSTALL button.
6. A message indicating the IRMA app has been stopped will appear. Press the OK button.
7. The IRMA Tablet software installation will proceed. When the installation is completed a dialog will be displayed. Press the START button.
8. If IRMA Tablet software with an Android update is being installed a dialog will appear informing the user that the system will install and reboot. Press the INSTALL button. A reboot dialog will appear.
9. The installing system update animation screen will appear. The update may take several minutes during which the progress bar may appear to be frozen.
10. When the update is complete the tablet will reboot.
11. To verify the software installation was successful press the ABOUT IRMA button. Verify the IRMA Base and IRMA Tablet software are at the correct revisions.
12. Press the SOFTWARE UPDATE button. The buttons for the just installed software, along with any older versions of software, should no longer be displayed.

    NOTE: It is possible new software will be available in the list after a software update.

About IRMA

Select About IRMA from the IRMA System's Functions Menu to view information about the IRMA System.

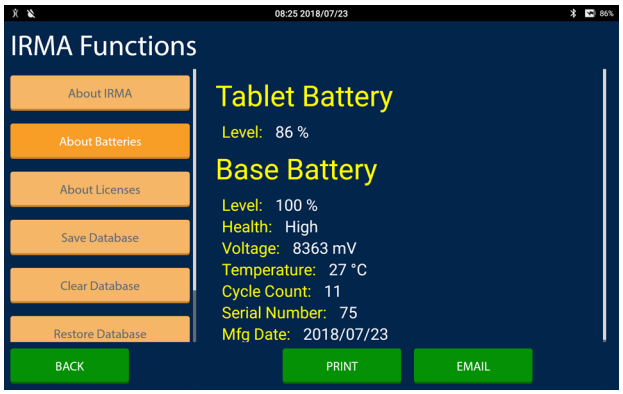
- Press BACK to return to the IRMA Functions menu.
- Press the PRINT button to print the information on the screen. The information will be printed in English.
- Press EMAIL to send the About IRMA information to Life-Health technical support.



About Batteries

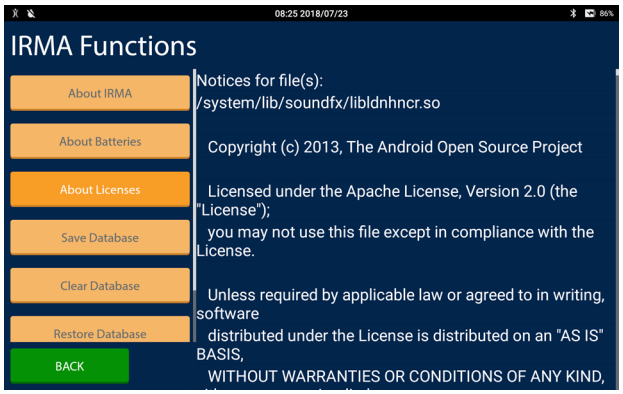
Select About Batteries from the IRMA System's Functions Menu to view information about the IRMA batteries. Press the Print button to print the information on the screen.

- Press BACK to return to the IRMA Functions menu.
- Press the PRINT button to print the information on the screen. The information will be printed in English.
- Press EMAIL to send the About IRMA information to Life-Health technical support.



About Licenses

Select About Licenses from the IRMA System's Functions Menu to view information about the open source licenses incorporated into the IRMA System software.



Save Database

To make a copy of the current database:

1. Insert a USB memory device into the IRMA Base's USB port with enough memory to hold the database.
2. Select the Save Database button from the IRMA System's Functions Menu. The IRMA Tablet will make a copy of the current database to a predefined directory on the USB memory device. In the event this database needs to be restored to the IRMA System, this directory will be used by the Restore Database function.
3. When the database has been copied, or if any errors are encountered, a message will be displayed.

Clear Database

To permanently erase all test records from the IRMA System's database:

1. Select the Clear Database button from the IRMA Sytem's Functions Menu.
2. A message will be displayed to confirm the database should be erased.
3. Press DELETE ALL. All test records will be deleted from the IRMA System's database.

Restore Database

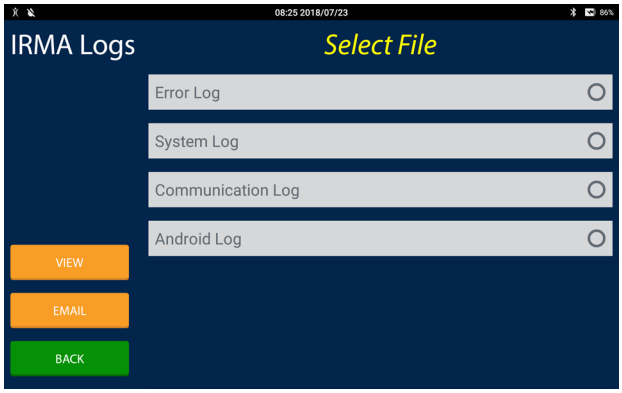
To replace the IRMA System's current database with a saved database:

1. Insert a USB memory device into the IRMA Base's USB port with a copy of the saved database to be restored.
2. Select the Restore Database button from the IRMA System's Functions Menu. The IRMA System will check the USB device for a database to restore in the predefined directory.
3. If a database is found a message will be displayed to confirm the current database should be replaced with the database on the USB memory device.
4. Press OK. A message will display when the saved database has replaced the current database.

4.4 IRMA Logs

Select the Logs button to view the IRMA System logs. Each log will have a button. The first page of the log is a title page. The most recent log entry will display at the top of the second page. The last 180 days of log entries are contained in the log.

- Press the VIEW DOCUMENT button to view the log pdf on the screen.
- Press EMAIL to send the About IRMA information to LifeHealth technical support.
- Press the DONE button to exit the log viewing screen.



Error Log

The error log captures IRMA system errors and is intended for use in troubleshooting the IRMA System by LifeHealth technical support.

System Log

The system log captures IRMA system events and is intended for use in troubleshooting the IRMA System by LifeHealth technical support.

Communications Log

The communications log captures IRMA system communication events and is intended for use in troubleshooting IRMA System communications by LifeHealth technical support.

Android Log

The Android log captures Android events and is intended for use in troubleshooting the IRMA System by LifeHealth technical support.

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Section 5: Troubleshooting

The IRMA Blood Analysis System troubleshooting information is organized to address both general and specific operating problems.

General problems are those that cannot be detected by the IRMA System's software (e.g., the IRMA System does not turn "on" or the printer does not operate).

Specific problems are those identified by the software (e.g., low battery or faulty cartridge). A screen message signals the presence of a specific operational problem or condition, and guides the user through the resolution process.

5.1 Troubleshooting General Operational Problems

Corrective actions are listed to help resolve each problem noted in this section. If the corrective actions do not resolve the problem, call your service provider for assistance.

IRMA Base or IRMA Tablet Does Not Turn On

Problem	Corrective Action(s)
The IRMA Tablet does not turn on when the base power button is pressed	1. Verify that the IRMA Tablet is correctly seated in the dock 2. Verify that the white LED on the base is on. • If it is blinking, press the power button on the base again. • If it is off, plug the AC power supply into a working outlet. Press the power button on the base. 3. If the IRMA Tablet is still not on, press and hold the IRMA Tablet power button until a screen appears.
The IRMA Tablet does not turn on when the IRMA Tablet power button is pressed.	1. Press and hold the IRMA Tablet power button until a screen appears. 2. Place the tablet in the dock 3. Press the IRMA Base wake button
The IRMA Base does not turn on when the wake button is pressed	Verify that the white LED on the base is on. • If it is blinking, press the wake button on the IRMA Base again. • If it is off, plug the AC power supply into a working power source.

Battery Problems

Problem	Corrective Action(s)
The IRMA Tablet does not charge	1. Verify that the IRMA Tablet is correctly seated in the dock and that the AC power supply is plugged into a working outlet.
The IRMA Base does not charge	1. Verify that the IRMA Base battery is installed (refer to Section 6.2) and/or that the AC power supply is plugged into a working outlet. 2. Confirm that the white LED comes on and is not blinking. 3. From the Main Menu, choose Review and then About Batteries. Check that the IRMA Base battery information is present.

Printer Problems

Problem	Corrective Action(s)
Poor print quality	1. Only use paper provided by your service provider. 2. Try a new roll of paper. Ensure that paper rolls and paper printouts are not exposed to sunlight or fluorescent light for an extended period of time.
The printer paper advances, printer sounds are heard but no print appears	1. Verify that the paper roll unwinds from the bottom of the roll. Printing is possible only on one side of the paper. Refer to Section 1.1 for more information. 2. Only use paper supplied by your service provider.
The paper does not advance	1. Open the printer compartment and check for a paper jam . 2. Ensure that the printer door is closed. You will hear an audible click as it closes. 3. Ensure that at least 1 in. (2.54 cm) of paper is showing after the printer door is shut.
The printer does not operate	1. Ensure that the printer door is closed. You will hear an audible click as it closes. 2. From the Main Menu, choose Review and then About IRMA. Check that the printer information is present. 3. If the information is not present, follow the pairing instructions in Section 8.9.

IRMA Tablet Problems

Problem	Corrective Action(s)
Cannot Connect To Base message is displayed when attempting to start a test or access an About screen.	1. Verify that the white LED on the IRMA Base is on and is solid. If the white LED is blinking press the IRMA Base's power button. Wait for the white LED to turn solid and try the IRMA Tablet again. If the white LED is off plug the base into AC power. Wait for the white LED to turn solid and try the IRMA Tablet again. 2. If the amber LED on the IRMA base is solid the IRMA Tablet and IRMA Base need to be configured. Refer to Section 8.9.
The IRMA Tablet does not respond to pressing it or the screen is blank and will not turn on.	1. Wait approximately 3 minutes for the IRMA Tablet to restart. 2. If the IRMA Tablet does not restart after waiting 3 minutes, make sure the IRMA base is plugged into AC Power, place the IRMA Tablet in the dock and wait 5 minutes. If the IRMA Tablet will not turn on contact your Service Provider.

Inconsistent Test Results

Problem	Corrective Action(s)
General	1. Verify that the cartridge has not been out of the package more than 15 minutes. 2. Verify that the cartridges have equilibrated to room temperature for the recommended time following removal from shipping cartons. See Appendix B, Section B-7 for equilibration requirements. 3. Run an EQC test to verify that the IRMA System is operating properly. 4. Run an TQC test to verify that the IRMA System is operating properly. 5. Verify the date of the IRMA System is correct.

Problem	Corrective Action(s)
Patient test results	1. Review the above corrective actions (general). 2. Draw another sample and repeat the patient test with a new cartridge. Rule out preanalytical errors. Refer to Sections 2.1 and Appendix A, Section A-2. 3. Verify that injection technique is correct. Refer to Section 2.2.
Liquid QC test results	1. Review the above corrective actions (general). 2. Verify that the temperature of the room where the IRMA Cartridges and LQC Materials are stored has not shifted. Refer to Sections 1.7 and the LQC package insert. 3. Verify that injection technique is correct. Refer to Section 2.2. 4. Review QC sample handling recommendation (refer to Section 3.3) and repeat the test with a new control ampule. 5. Verify that the IRMA Cartridges and LQC Control Material have properly equilibrated to room temperature. Refer to Sections 1.7 and the LQC package insert. 6. For pO_2 and pCO_2 results, if the storage temperature of the LQC Material is at or below 20°C (68°F) or is at or above 24°C (75°F), adjust the ranges according to the instructions on the LQC Material range sheet found at www.lifehealthmed.com.

EQC Failures

Problem	Corrective Action(s)
EQC failures	1. Repeat the EQC test. 2. Confirm that the relative humidity in the IRMA System's operating area is within specification. 3. Replace the edge connector. Run an EQC and a TQC test.

Temperature Test Failures

Problem	Corrective Action(s)
TQC test failures Figure 5.1  	1. Clean the IR sensor. Refer to Section 7.4. 2. Verify that the temperature verification cartridge used is an IRMA temperature verification cartridge and not an IRMA TRUPOINT temperature verification cartridge (see Figure 5.1). 3. Verify that the correct 5 character calibration code from the temperature verification cartridge label scanned correctly or was entered correctly (if manually entered). 4. Verify that the IRMA System and temperature verification cartridge have equilibrated to room temperature. If a TQC test fails, place the temperature verification cartridge on a tabletop and wait at least 15 minutes before retesting with the same temperature verification cartridge. Do not place the temperature verification cartridge in its holder under the printer paper door during this equilibration period. 5. Repeat the TQC test using the same temperature verification cartridge; if the TQC test fails again, use a different temperature verification cartridge (if available).

5.2 Troubleshooting Specific Operating Problems

An error screen message signals the presence of a specific operating, data entry, or screen selection problem or condition, explains its probable cause, and guides the user through the resolution process. If necessary, call your service provider for assistance.

Sensor Errors

Error Message	Reason	Corrective Action(s)
Sensor error - use new cartridge or Suppressed Result Analyte value displays "-----"	Displays upon receipt of a sensor error during testing	1. Remove and dispose of the cartridge; retest with a new cartridge. 2. Verify that the cartridges are properly equilibrated. 3. Verify that test procedures are being followed. 4. If a high rate of sensor errors persists, clean the IR sensor. Refer to Section 7.4. 5. If a high rate of sensor errors persists, run an EQC test and call your service provider for assistance.

Procedural Errors

Error Message	Reason	Corrective Action(s)
Cartridge removed prematurely	The cartridge was removed during a test or was not completely inserted	Dispose of the cartridge and retest using a new cartridge. Fully insert the cartridge and do not remove the cartridge during testing.
Time for data entry expired	Data was not completely entered within the allotted time period following cartridge insertion.	Remove and dispose of the cartridge. Retest with a new cartridge, making required entries within the allotted time period.
Sample injection time expired	Sample was not injected and/or continue was not selected within 4 minutes of the Inject Sample screen being displayed.	Remove and dispose of the cartridge. Retest with a new cartridge. Inject the sample and select continue within the required time period.
Temperature Card removed prematurely	The temperature card was removed while a temperature test was in progress.	Return to the QC Testing Menu. Repeat the temperature test and do not remove the temperature card during the test.

Entry Errors

Error Message	Reason	Corrective Action(s)
The lot is invalid	The incorrect lot or cal code was entered.	Enter the correct cartridge lot and cal code for the selected IRMA cartridge type.
The lot is invalid	The lot or the cal code text entry are had too few characters.	Enter the correct cartridge lot and cal code for the selected IRMA cartridge type.
XXX length needs to be between X and XX	The entry had too many or too few characters. Some features, such as Patient ID, can be configured to require the entry of a specific number of characters.	Note the entry length requirements displayed on the screen. Press OK and enter a valid number of characters.

Invalid Format-Enter value in format X.XXX - X.XXX	The format of an entry was invalid.	Note the entry format requirements displayed on the screen. Select Ok and enter the value in a valid format.
The entered range is invalid	The value entered was outside of the entry range.	Press OK and enter a value within the entry range.

Temperature Errors

Error Message	Reason	Corrective Action(s)
Cartridge out of temperature range	The cartridge temperature was outside of the acceptable temperature operating range (12° to 30°C / 54° to 86°F).	Remove and dispose of the cartridge; re-test with a new cartridge within temperature operating range.
Analyzer out of temperature range	The IRMA Analyzer temperature was outside of the acceptable temperature operating range (12° to 30°C / 54° to 86°F).	Allow it to equilibrate at a temperature within the temperature operating range for at least 30 minutes before resuming testing.

Analyzer Problems

Error Message	Reason	Corrective Action(s)
Instrument Error - Error Code 6XXX.	Hardware fault during power-on or the IRMA System experienced an unrecoverable system failure.	Contact your service provider.

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Section 6: IRMA Component Replacement

This chapter describes the procedures to replace the following components:

- Edge connector
- IRMA Base battery
- Printer door
- Printer
- Dock
- IRMA Tablet

6.1 Replacing the Edge Connector

1. Clean the IRMA System as described in Section 7.
2. Open the printer door and remove the IRMA tool. Close the printer door.
3. Remove the IRMA Tablet from the dock to view instructions, if desired.
4. Close the dock and position the IRMA System with the bottom of the IRMA Base facing up and the handle away from you.
5. Locate screws #6 and #7. Loosen the screws until they turn easily (Figure 6.1).
6. Placing your hand over the screws, turn the IRMA System over until the screws fall into your hand. Keep the screws close by.
7. Place the IRMA System IRMA Base down and open the dock. Grasping the edges of the edge connector cover, pull it straight up and set the cover close by (Figure 6.2).
8. Use the IRMA tool to loosen the two outside screws that hold the edge connector (Figure 6.3). Do not loosen the two smaller screws on the top of the edge connector. Continue to loosen the outside screws until they almost fall out. Lift the edge connector out. If it does not come out, loosen the outside screws until the edge connector lifts out easily.
9. The removed edge connector should be considered a potential biohazard and should be disposed of accordingly.
10. Remove the outside screws from the edge connector and keep nearby.
11. When handling the new edge connector, **do not touch the metal portions** of the connector and handle only by the plastic (Figure 6.4).
12. Carefully pick up the new edge connector, holding it on the plastic end portion by the smaller screws. Put the screws into the outside holes.
13. Line up the screws with the screw holes in the base. Guide the edge connector down until it is seated in place. There are alignment pins on the base of the edge connector that help align it. Firmly tighten the screws.

Figure 6.1

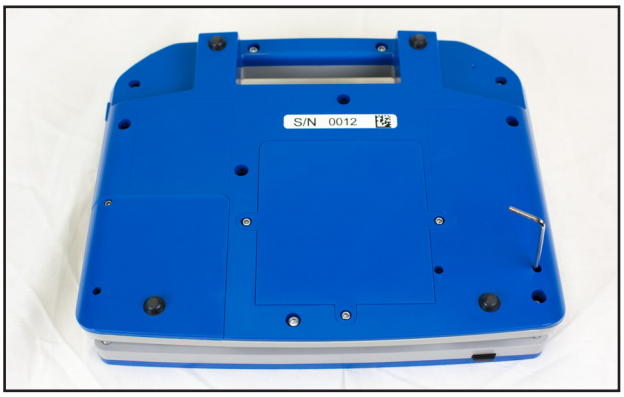


Figure 6.2

Figure 6.3

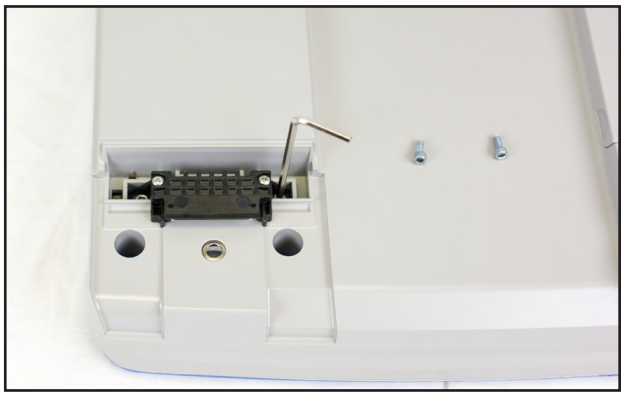


Figure 6.4

14. Replace the edge connector cover. Close the dock. Turn the IRMA System over so that the bottom of the IRMA base is facing up.
15. Replace screws #6 and #7. Firmly tighten the screws.
16. Turn the IRMA System over so that the IRMA Base is down and the dock is up. Open the dock and insert the IRMA Tablet if it was removed. Press the IRMA Base's wake button, if necessary, to wake the IRMA Base and the IRMA Tablet.
17. Run an EQC test and TQC test (refer to Section 3.4 and Section 3.5).

6.2 Replacing the IRMA Base Battery

1. Clean the analyzer as described in Section 7.
2. Open the printer door and remove the IRMA tool. Close the printer door.
3. Remove the IRMA Tablet from the dock to view instructions, if desired.
4. Close the dock and position the IRMA System with the bottom of the IRMA Base facing up and the handle away from you.
5. Locate screws #3, #4, and #5 on the battery cover door.
6. Use the IRMA tool to remove the screws. Keep them close by (Figure 6.5).
7. Remove the battery door cover (Figure 6.6). Pressing on the back middle edge of the cover may help to pop up the front edge, making it easier to remove.
8. Remove the old battery by grasping the tab and sliding the battery towards you (Figure 6.7). Lift it out.
9. Insert the new battery by lining up the groves in the battery and battery compartment. The metal connectors in the battery line up with the pins in the back of the battery compartment. Gently slide the battery in place until it stops.
10. Line up the three tabs on the battery cover's edge (the edge with no screw holes) with the three slots in the battery compartment. Place the back edge of the cover in first and then the front edge.
11. Replace the three screws with the IRMA tool and firmly tighten each one.
12. Turn over the IRMA System so that the IRMA Base is down and the dock is up. Open the dock and insert the IRMA Tablet if it was removed. Replace the IRMA Tool and close the printer door.
13. Connect the AC power supply to the IRMA Base. The IRMA System will power on.
14. On the IRMA Tablet select the Review option from the Main Menu.
15. Select the About Batteries button and verify the new base battery is recognized.
16. Run an EQC test and TQC test (refer to Section 3.5 and Section 3.7).

Figure 6.5

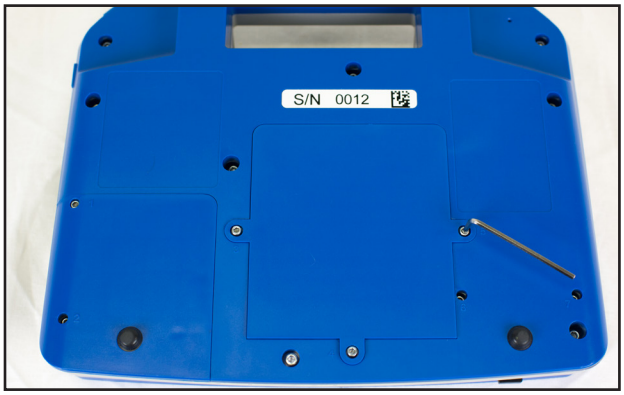


Figure 6.6

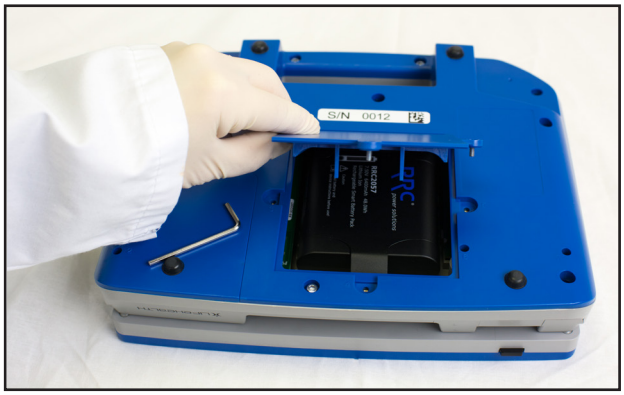
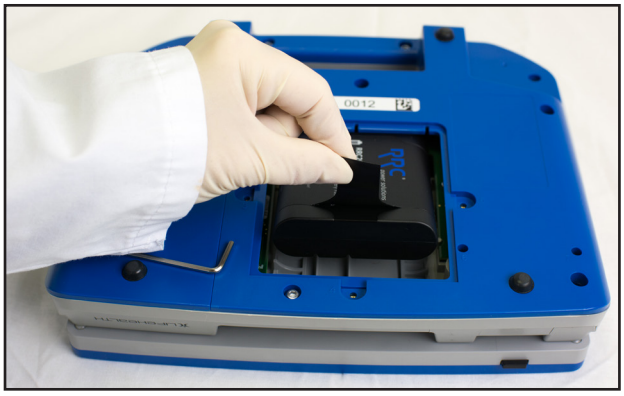


Figure 6.7

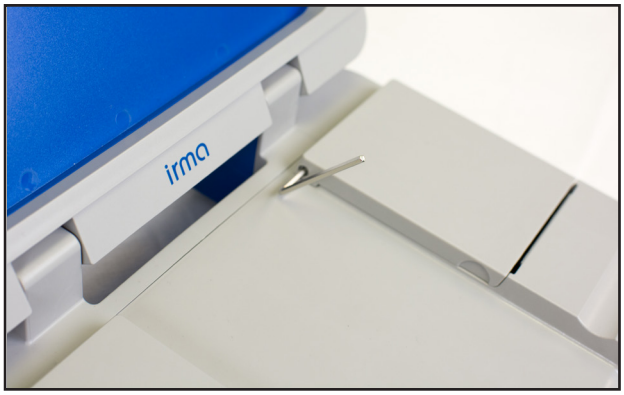


6.3 Replacing the Printer Door

1. Clean the analyzer as described in Section 7.
2. Open the printer door so that it is at a 90° angle to the IRMA Base.

3. Remove the IRMA tool.
4. Remove the platen roller from the printer door by gently pulling it straight out. Place it close by.
5. Loosen the screws at the rear of the printer door. There is one on the right hand side and one on the left hand side. Loosen until you can easily pull the door up and remove it (Figure 6.8).
6. Remove the screws and the metal bushings from the old door and place them in the new door.
7. Holding the new door at a 90° angle to the attachment bar on the base, raise it above the attachment bar and lower it in place. Using the IRMA tool, firmly tighten the screws .
8. Replace the platen roller. The white gear should be on the left side when viewed from the front of the platen. The platen should loosely fit once snapped in. If it is rigidly held, it may be positioned incorrectly left to right. Close the printer door leaving about 1 inch (2.5 cm) of paper showing.

Figure 6.8



6.4 Replacing the Printer Module

1. Clean the analyzer as described in Section 7.
2. Remove the IRMA Tablet from the dock to view instructions, if desired.
3. Disconnect the AC power supply from the IRMA Base.
4. Remove the battery as described in Section 6.2.
5. Open the printer door so that it is at a 90° angle. Remove the paper roll, IRMA tool, and temperature verication cartridge. DO NOT close the printer door.
6. Place the dock at a 90° angle to the IRMA Base. Place the IRMA System on its left side.
7. With the bottom of the base facing you, use the IRMA tool to remove screws #1 and #2 (Figure 6.9). Set them near by.
8. Gently pull out the printer.
9. When placing the new printer, do not touch any of the electronic components. Holding the new printer by the plastic sides, line up the tabs protruding from the straight edge of the printer with the slots in the base (Figure 6.10). Place the tabs in the slots and gently seat the printer. Holding the printer, place the screws in the base of the printer and tighten firmly.
10. Replace the battery as described in Section 6.2.
11. Place the IRMA System IRMA Base down. Place the printer paper roll in the depressed paper compartment with the paper unrolling from the bottom of the roll. Unroll the paper leaving about 1 inch (2.5 cm) of paper showing.
12. Replace the IRMA Tool and temperature verification cartridge and close the printer door.
13. Insert the IRMA Tablet into the dock if it was removed. Connect the AC power supply to the IRMA Base. The IRMA System will power on.
14. The new printer needs to be configured with the IRMA Tablet. Wake the IRMA Tablet if needed and pair the IRMA Tablet with the IRMA Base as described in Section 8.9.

Figure 6.9

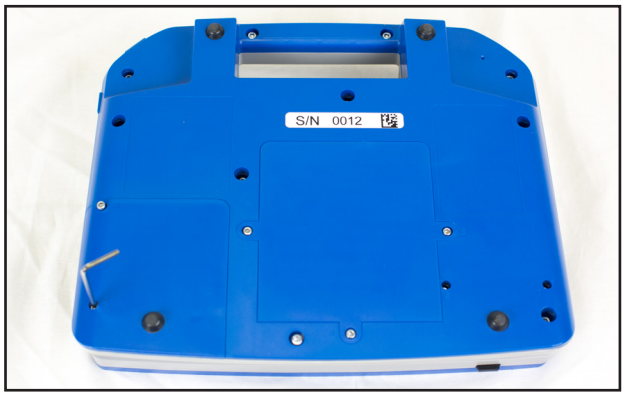
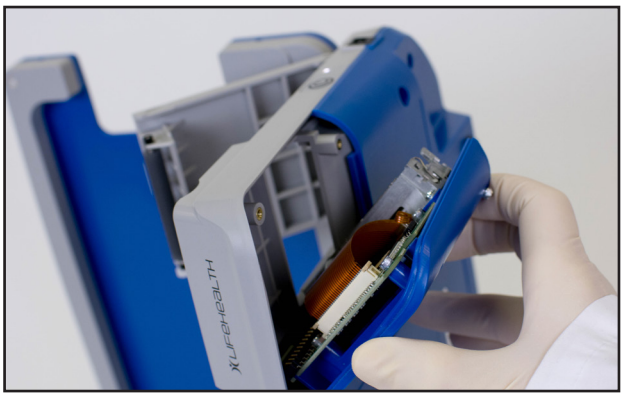


Figure 6.10



6.5 Replacing the Dock

Figure 6.11

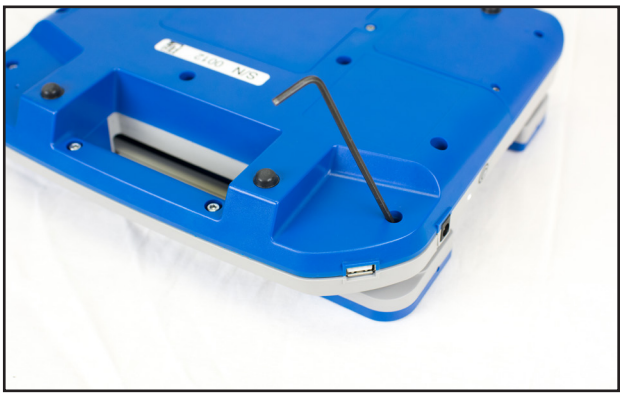


Figure 6.12

1. Clean the analyzer as described in Section 7.
2. The tool needed to install a new dock is included in the new dock packaging.
3. Disconnect the AC power supply from the IRMA Base.
4. Remove the battery as described in section 6.2.
5. Close the dock and position the IRMA System with the bottom of the IRMA base facing up and the handle facing towards you.
6. Remove the four screws under the handle with the dock tool (Figure 6.11). To completely remove the screws it may be necessary to turn the IRMA Base over so that the screws fall out. Keep the screws close by.
7. Position the IRMA System so that the bottom of the IRMA base is down, the dock is on top, and the handle is facing away from you.
8. Open the dock so that it is at a 90° angle to the IRMA Analyzer base. Remove the dock by pulling it straight up. **Do not touch the exposed electronic components inside the IRMA Base.**
9. To replace the new dock on the IRMA Base, hold the dock with the IRMA Tablet compartment facing you and the two tabs at the bottom facing downwards. The tabs match the slots in the IRMA Base (Figure 6.12). Gently place the new dock tabs over the slots in the IRMA Base and seat the dock on the IRMA Base.
10. Replace the battery as described in Section 6.2.
11. Close the dock. Turn the IRMA System over so that the bottom of the IRMA System is facing up and the handle is facing towards you. Replace the four screws and firmly tighten each one.
12. Turn over the IRMA System so that the dock is up. Open the dock and insert the IRMA Tablet.
13. Connect the AC power supply to the IRMA Base. The IRMA System will power on.
14. Verify the charging icon (see Section 1.10) is displayed in the status bar.

6.6 Replacing the IRMA Tablet

Figure 6.13

1. Clean the analyzer as described in Section 7.
2. Insert the new IRMA Tablet in the dock (Figure 6.13).
3. On the IRMA Tablet select the Settings option from the Main Menu.
4. Pair the IRMA Tablet with the IRMA Base as described in Section 8.9.
5. If the IRMA Base has an integrated printer, pair the IRMA Tablet with the IRMA Printer as described in Section 8.9.
6. Run an EQC test (refer to Section 3.4) to verify the connection with the IRMA Base.
7. Print the EQC test to verify the connection with the IRMA Printer.
8. Plug the AC power supply into the IRMA Base.
9. Verify the charging icon (see Section 1.10) is displayed in the status bar.

Section 7. Cleaning the IRMA Blood Analysis System

This chapter discussed the appropriate cleaning solutions to use and how to clean the IRMA System.

7.1 Cleaning Solutions

Use only the following cleaning solutions with a soft cloth:

- Isopropyl alcohol
- 10% household bleach in water solution
- Quaternary ammonium compounds

7.2 Cleaning the IRMA Tablet

Immediately wipe any spilled liquid off of the IRMA Tablet. Clean the tablet using a soft cloth dampened with any of the cleaning solutions listed in 7.1.

7.3 Cleaning the IRMA Base

Wipe the base with a soft cloth dampened with any of the cleaning solutions listed in 7.1. Do not spray cleaning solutions into the edge connector, printer compartment, power connection or USB port. When cleaning the dock with the IRMA Tablet removed, be careful not to damage the connector pins that are located on the inside, top-left, corner of the dock. These pins are used to charge the IRMA Tablet and connect the USB interface.

7.4 Cleaning the Infrared Sensor

Examine the infrared (IR) sensor surface daily for dirt or contamination. Clean the sensor surface as needed using a swab moistened with any of the cleaning solutions listed in 7.1 as shown in Figure 7.1. The glass surface of the probe should appear shiny and reflective when clean. Allow the IR sensor to dry completely before testing.

Figure 7.1

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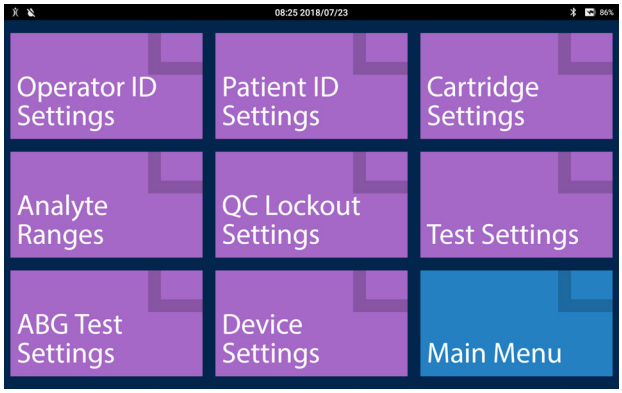
Section 8: IRMA System Settings

This chapter provides instructions for configuring the IRMA Blood Analyzer System settings.

8.1 Settings Options Overview



IRMA System settings are configured through the Settings menu. The settings that may be configured are controlled by the User ID privilege level.

- QA Users (identified as "QA") have access to all system settings menus.
- Non-QA Users (identified as "User") have access to a subset of the Device Settings menu.

Access the Settings menu by selecting the Settings button on the Main Menu. If the OID Required setting is configured to Disabled, the enter OID screen will be displayed. To access the QA User settings when logged into the IRMA System as a User, press the IRMA Tablet's power button to place the IRMA Tablet in sleep mode. Press the IRMA Tablet button again to wake it and then enter a QA User id. The following options are displayed when accessing the Settings menu as a QA User:

Note: The IRMA System comes with a default QA User: 123456. It is recommended a new QA User be added to the IRMA System and the default QA User deleted.

Operator ID Settings	Configure Operator number IDs, privileges, passwords, scanning parameters, and printing options.
Patient ID Settings	Configure the Patient ID if required and how the Patient ID is entered.
Cartridge Settings	Configure Cartridge Lots and LQC materials.
Analyte Ranges	Configure Patient Types, Reference Ranges & Reportable Ranges.
QC Lockout Settings	Configure the EQC lockout schedule.
Test Settings	Configure settings used during cartridge testing and Hct Bypass Correlation.
ABG Test Settings	Configure settings used during blood gas tests.
Device Settings	Configure IRMA Tablet settings and pair the IRMA Tablet to the IRMA Base and printer.
Main Menu	Returns to the Main Menu.

On each Settings submenu button, the current setting is displayed in small type on the second line, if applicable. For example, if an option of disabled or enabled is available and the user has chosen enabled, this will be displayed in small type on the submenu button.

For most setting options a change to the configuration is immediately saved, therefore no SAVE or DONE button will be displayed. For settings that require the operator to save the configuration a SAVE, DONE or SET button along with a CANCEL button will be displayed.

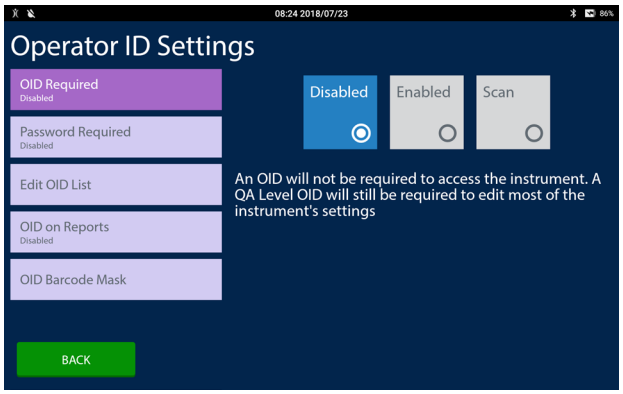
8.2 Operator ID Settings

The IRMA Analyzer can maintain 2,000 Operator IDs (OIDs). Each ID can be from 1 to 30 alpha-numeric characters in length. To access the Operator ID submenus select the Operator ID Settings button from the Settings menu.

OID Required

To configure if the IRMA System will require an OID to be accessed select the OID Required button. There are three options for OID:

- **Disabled**: An OID will not be required to access the instrument. A QA level OID will still be required to edit most of the instrument's settings.
- **Enabled**: An OID will be required to access the instrument. Using the on-screen keyboard will be the default method of entry.
- **Scan**: An OID will be required to access the instrument. Scanning a barcode will be the default method of entry.

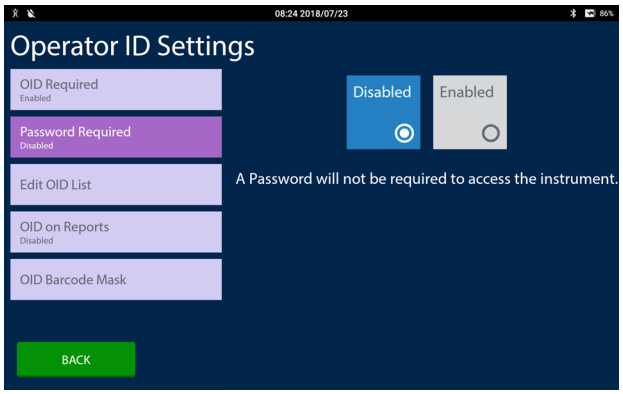


Password Required

To configure if the IRMA System will require a password to be accessed select the Password Required button. There are two options for Password:

- **Disabled**: A password will not be required to access the instrument.
- **Enabled**: A password will be required to access the instrument using the keyboard method of entry. Enter the passwords for the OID list by selecting Edit OID list.

  Note: If Password Required is Enabled and a password is not created for an OID prior to the IRMA Tablet entering sleep mode that OID will not be allowed access to the IRMA System.



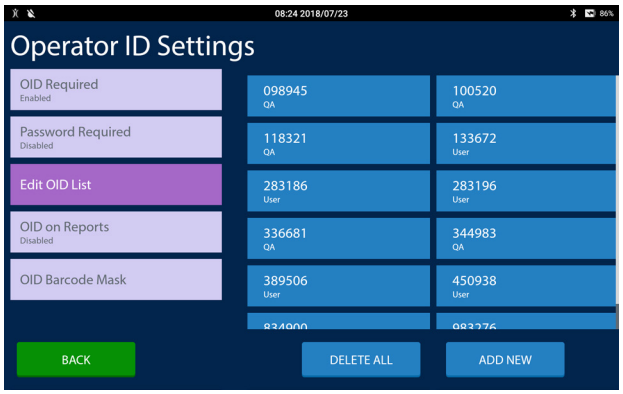
Edit OID List

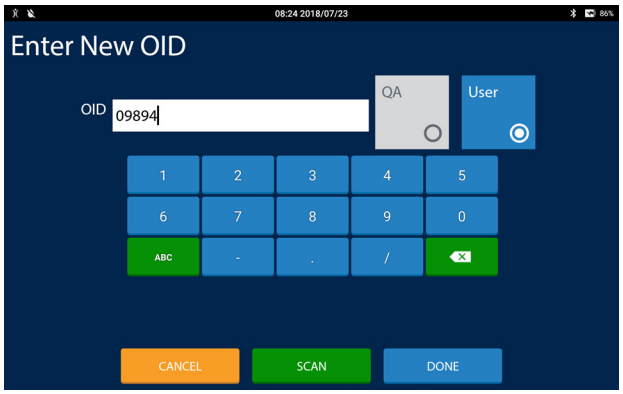
To add, edit and delete OIDs from the IRMA System select the Edit OID List button.

- To add a new OID to the list press the ADD NEW button.
  - Press the SCAN button to enter the OID using the barcode reader.
  - If the OID will be entered manually use the keyboard to enter the OID. Pressing the green ABC button will display the alpha keyboard.
  - If the Password Required setting is configured to Enabled, enter the password.
  - Select a privilege level for the OID.
  - Press the DONE button to save the OID to the OID list.

  Note: Passwords must be numeric.
- To delete an OID select the button of the OID to be deleted. The Edit OID screen will appear. Press DELETE.
- To delete all OIDs, select the Delete All button that appears on the bottom of the screen. A confirmation message will appear. Press DELETE ALL.

  Note: One QA User OID will be left in the list so that Set-

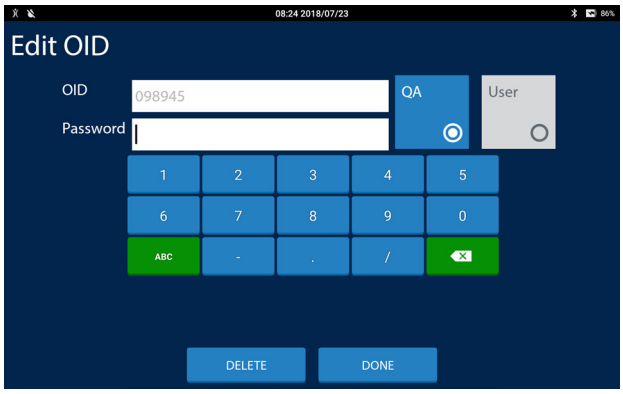




tings may still be accessed.

- To edit the properties of an existing OID select the OID button from the list.
  - The OID cannot be edited.
  - The privilege level of the user (QA or User) can be changed by selecting the desired level.
  - The password (if enabled) can be edited by using the back key and adding the new password.
  - Press DONE when finished.

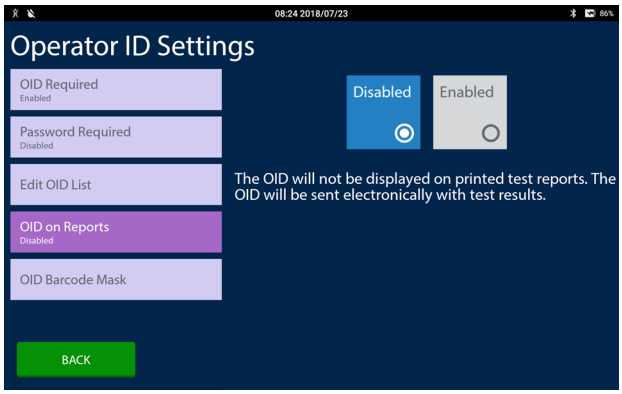
Note: To edit the OID, delete the OID and add the correct OID to the list.



OID on Reports

To configure if the IRMA System will include the OID on printed test reports select the OID on Reports button. There are two options for OID on Reports.

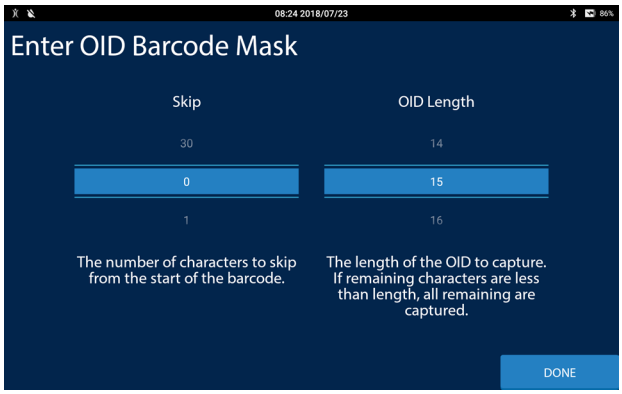
- **Disabled**: The OID will not be included on printed test reports.
- **Enabled**: The OID will be included on printed test reports.



OID Barcode Mask

If operators will be accessing the IRMA System by scanning a barcode, and the barcode includes characters that are not part of the OID, select the OID Barcode Mask button. To configure the OID barcode mask:

- **Skip:** The number of characters at the start of the barcode to ignore.
- **OID Length:** The number of characters in an OID.
  - **Example 1:** The barcode on an employee badge contains an OID that is seven characters long followed by additional data. Skip would be set to 0 and OID Length would be set to 7.



  - **Example 2:** The barcode on an employee badge contains an eight character code for the cafeteria followed by a nine character OID. Skip would be set to 8 and OID Length would be set to 9.
  - **Example 3:** The barcode on an employee badge contains fifteen characters followed by an OID that contains seven to nine characters. There is nothing after the OID. Skip would be set to 15 and OID Length would be set to 9. Note: This is the only case where an OID barcode mask may be used with a variable length OID.

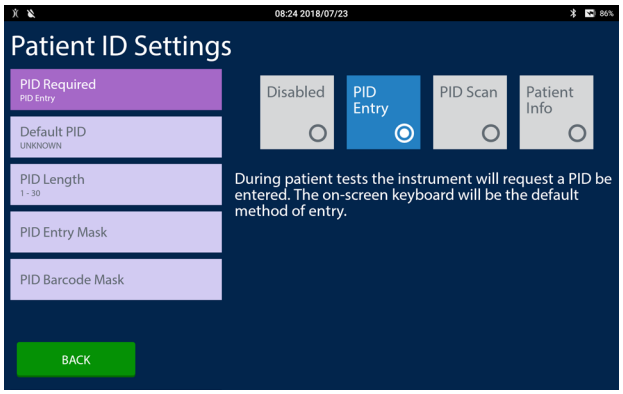
8.3 Patient ID Settings

The IRMA System may be configured to require the operator to enter a Patient ID (PID) or patient demographic information. To access the Patient ID submenus select the Patient ID Settings button from the Settings menu.

PID Required

To configure if the IRMA System will require the operator to enter a PID during patient tests select the PID Required button. There are 4 options for PID Required:

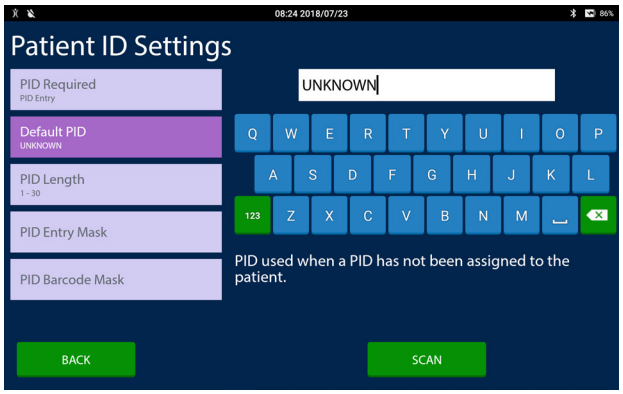
- **Disabled**: A PID will not be requested during a test.
- **PID Entry**: A PID will be required to run a patient test. The defualt method of PID entry will be the on-screen keyboard.
- **PID Scan**: A PID will be required to run a patient test. Scanning a barcode will be the defult method of entry.
- **Patient Info:** The patient name and date of birth will be required instead of a PID.



Default PID

If PID Entry or Patient Info is configured for the PID Required setting, the operator will have the option to use a default PID. To configure the default PID select the Default PID button.

- To scan the PID to use as a default, press the SCAN button.
- If the PID to use as a default will be entered manually, use the keyboard to enter the PID.

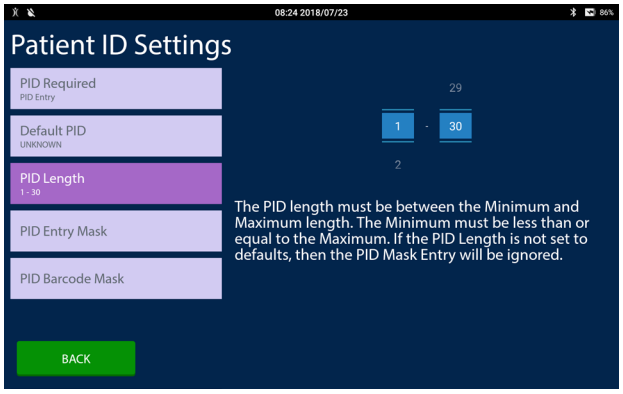


PID Length

To configure a minimum and maximum length for the PID select the PID Length button. Configuring a length for the PID will force the operator to enter a PID greater than or equal to the specified minimum number of characters and less than or equal to the specified maximum number of characters.

- Use the first spinner control to set the mimimum length of the PID.
- Use the second spinner control to set the maximum length of the PID.

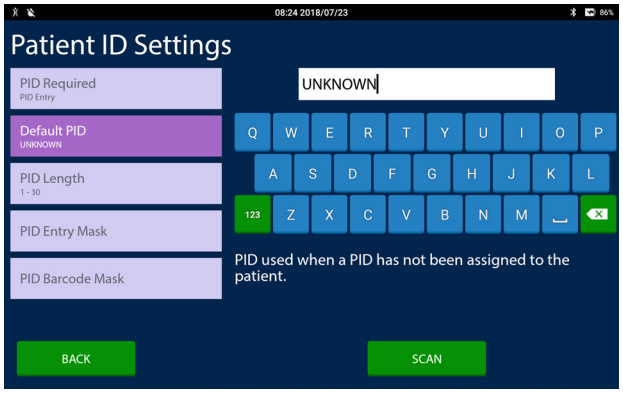
  Note: If either the PID minimum or maximum length are set to anything but their defaults, the PID Entry Mask will be ignored.



PID Entry Mask

If the PID will always be the same length, and will always match the same pattern, select the PID Entry Mask button. Configuring a PID Entry Mask will force the operator to enter or scan a PID that matches the configured mask. Enter an A, N or C for each position in the PID. To not use a mask delete all of the characters in the text entry area.

- **A:** Requires either a letter or numeral be entered.
- **N:** Requires a numeral be entered.
- **C:** Requires a letter be entered.
- **Example:** if a PID starts with two characters representing



a hospital department that may be either a letter or numeral followed by a six number identifier and finished with a single letter to indicate if they are inpatient or outpatient, the mask would be: AANNNNNNC.

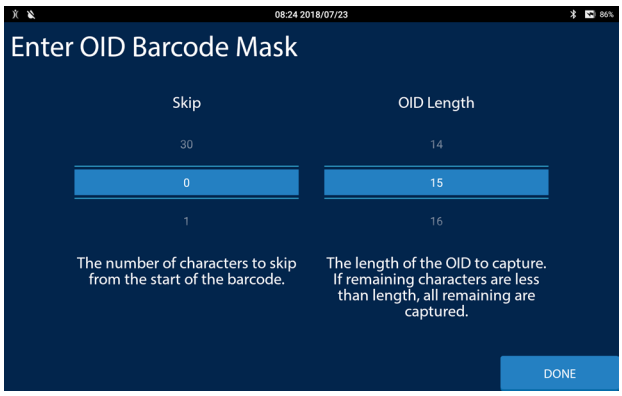
- Where AA is the two character department code.
- Where NNNNNN is the six number identifier.
- Where C is the single letter in-patient or out-patient indicator.

Note: If PIDs may be different lengths, the PID Entry Mask feature should not be used.

PID Barcode Mask

If operators will be entering PIDs by scanning a barcode, and the barcode includes characters that are not part of the PID, select the PID Barcode Mask button. To configure the PID barcode mask:

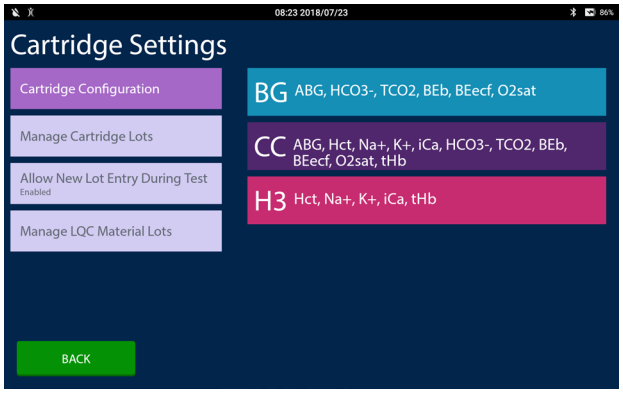
- **Skip:** The number of characters at the start of the barcode to ignore.
- **PID Length:** The number of characters in a PID.



8.4 Cartridge Settings

The IRMA System may be configured to only allow testing with certain cartridge types and the analytes reported on a cartridge type may also be restricted. Quality control materials for use in liquid quality control testing are configured here as well. To access the Cartridge Settings submenus select the Cartridge Settings button from the Settings menu.

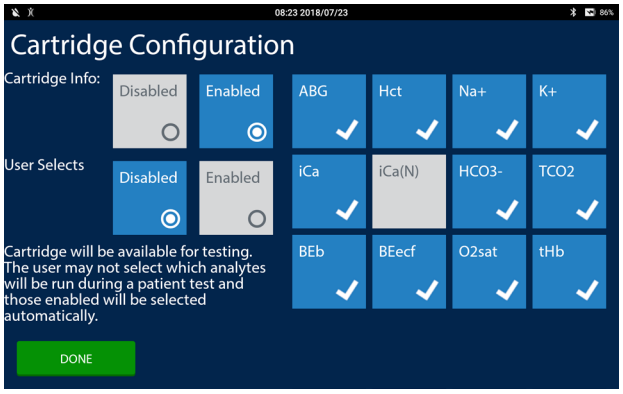
Cartridge Configuration



To restrict the IRMA cartridge types available for patient testing or to restrict the analytes reported with a patient test, select the Cartridge Configuration button. Each IRMA cartridge type will appear as a different colored ribbon. The ribbon will contain a list of selected analytes, User Selects or Disabled. For each cartridge type, the QA User can specify if the cartridge will be available for patient testing and if so, what analytes will be reported or if the operator may select which analytes to report at the start of a test. The options menus are the same for each cartridge type. The CC cartridge will be used as an example to illustrate the options available.

Select the CC ribbon. There are two options for Product Type:

- **Disabled:** The CC cartridge will not be available for testing.
- **Enabled:** The CC cartridge will will be available testing.



There are two options for User Selects:

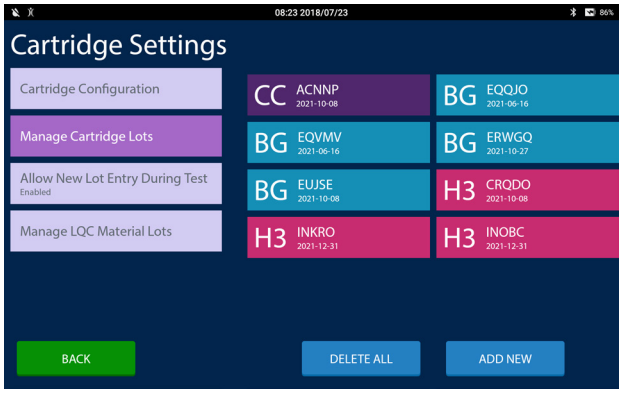
- **Disabled:** If the CC cartridge is selected for patient testing, the user will not be able to select which analytes will be reported.
- **Enabled:** If the CC cartridge is selected for patient testing, the user will select which analytes are reported.

To select which analytes will be reported if User Selects is disabled:

- If an analyte is to be reported, and the analyte box is grey, select the analyte box. It will appear blue with a check mark in the box.
- If an analyte is to not be reported, and the analyte box is blue, select the analyte box. It will appear grey without a check mark in the box.

Note: At least one reported analyte must be selected for testing.

Manage Cartridge Lots



To add or delete IRMA cartridge lots select the Manage Cartridge Lots button. All of the unexpired IRMA cartridge lots enabled for the IRMA System will appear.

- To delete an individual lot, select the lot. A confirmation message will appear. Press DELETE.
- To delete all lots, select the Delete All button that appears on the bottom of the screen. A confirmation message will appear. Press DELETE ALL.
- To add a new Lot Code, select the Add New button.
  - Scan the 2D barcode on the pouch label of the IRMA cartrige.

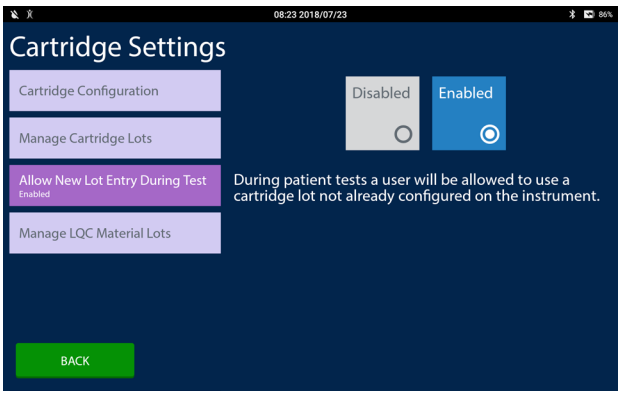
Note: If Allow New Lot Entry During Testing is set to disabled, this is the only method of adding IRMA cartridge lots to the IRMA System without running a test as a QA User.

Add New Lot Entry During Testing

To allow Users to add new IRMA cartridge lots to the IRMA System during a test select the Allow New Lot Entry During Test button. There are two options for Allow New Lot Entry During Testing:

- **Disabled:** During testing, a User will only be allowed to use IRMA cartridge lots already configured on the IRMA System.
- **Enabled:** During testing, a User will be able to add a new IRMA cartridge lot to the IRMA System by scanning the 2D barcode on the cartridge pouch label.

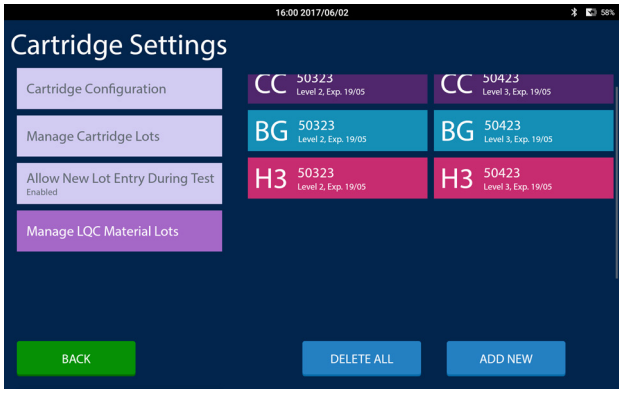
  Note: A QA User may always enter a new IRMA cartridge lot to the IRMA System during a test.

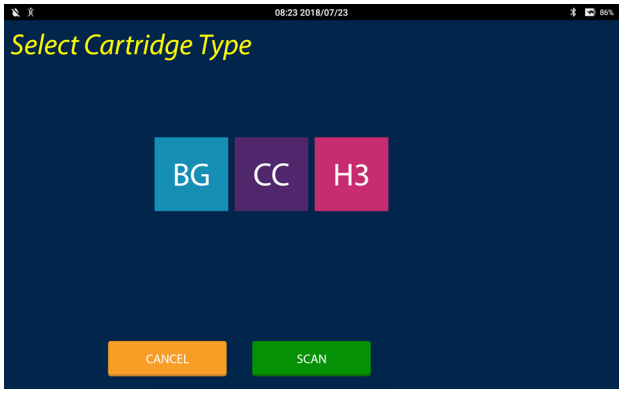


Manage LQC Material Lots

To add or delete a LQC material select the Manage LQC Material Lots button. The LQC material lots that have been configured will appear.

- To delete an individual lot, select the lot. A confirmation message will appear. Press DELETE.
- To delete all lots, select the Delete All button that appears on the bottom of the screen. A confirmation message will appear. Press DELETE ALL.
- To add a new LQC material lot, select the Add New button.
  - Scan the barcode for the desired level from the LifeHealth quality control sheet.
  - To add a lot manually, press the MANUAL ENTRY button.
  - Select the IRMA cartridge type button.

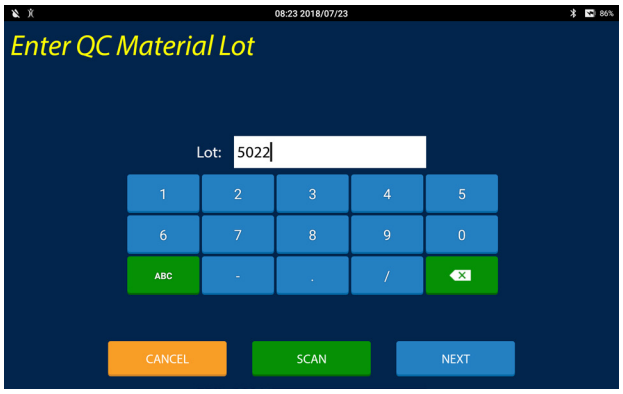


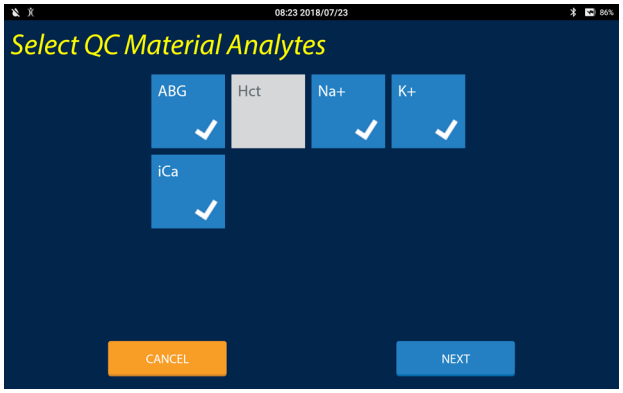


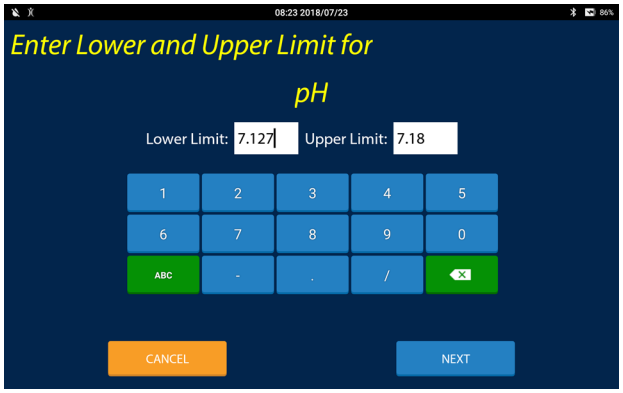
- Enter the LQC Material Lot using the on-screen keyboard. When finished press the NEXT button.
- Select the Lot Level and the expiration month and year using the spinner controls. When finished press the NEXT button.
- Select the analytes for which a range will be configured. When finished press the NEXT button.
- For each analyte enter the lower and upper limit for the analyte. When finished entering an analyte range press the NEXT button.
- After the last analyte range is entered the Manage LQC Material Lots screen will be displayed.

Note: LQC Materials may be used until 23:59 on the last day of the month in which they expire.

Note: LQC materials may not be edited. To edit a LQC material delete it and then add the correct LQC material information.







8.5 Analyte Ranges

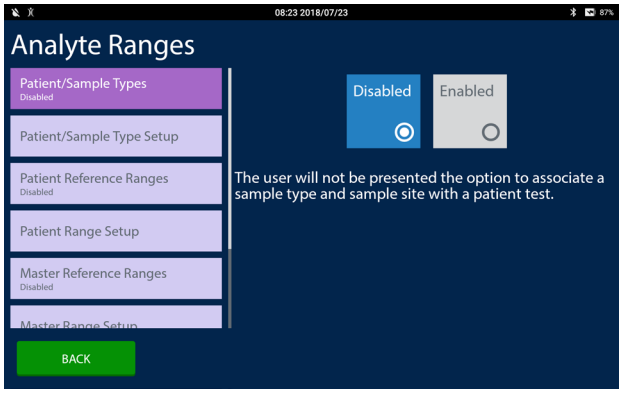
The IRMA System may be configured to associate a patient type, sample type and draw site with the patient test record and to evaluate patient test results against various ranges. To access the Analyte Ranges submenus select the Analyte Ranges button from the Settings menu.

Patient/Sample Type

To have a patient type, sample type and sample draw site associated with the patient test record select the Patient/Sample Types button. There are two options for Patient and Sample Type:

- **Disabled:** During a patient test, the user will not have the option to associate patient and sample information with the patient test record.
- **Enabled:** During a patient test, the user will have the option to associate patient and sample information with the patient test record.

  Note: Patient Specific Reference Ranges do not have to be enabled to use Patient and Sample Type.



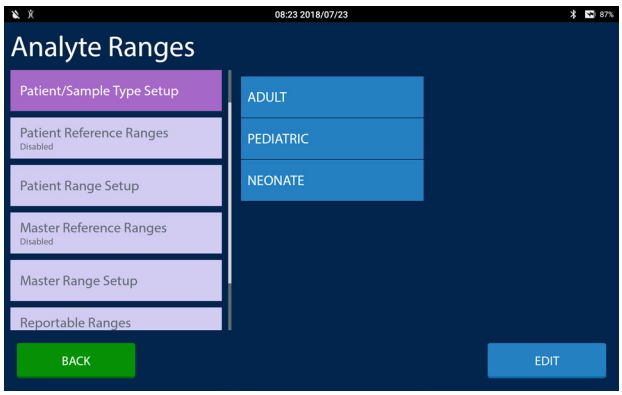
Patient/Sample Type Setup

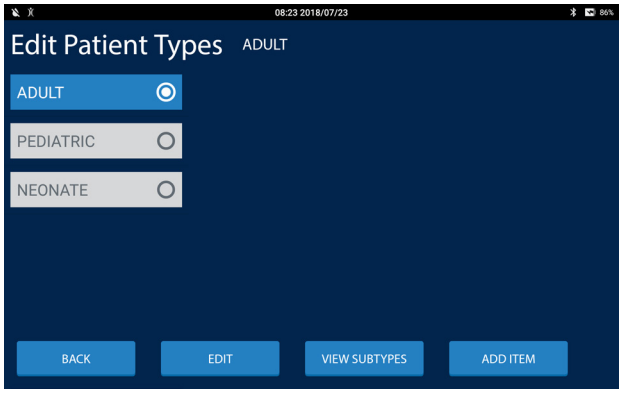
The IRMA System may be configured with up to six patient types. Each patient type may be configured with up to six independent sample types. Each sample type may be configured with up to ten indepenent sample sites. Each sample site may be configured with up to four independent sample sub-sites. The IRMA System is pre-configured with common patient and sample types for Adult, Pediatric and Neonatal patients.

To configure the patient and sample information select the Patient/Sample Type Setup button. The patient types configured for the IRMA System will display. Selecting a patient type button will display the sample types configured for that patient type. The method of viewing, adding, editing and deleting is identical for patient type, sample type, sample site and sample sub-site. Select the Edit button to view, add, delete or modify patient and sample information.

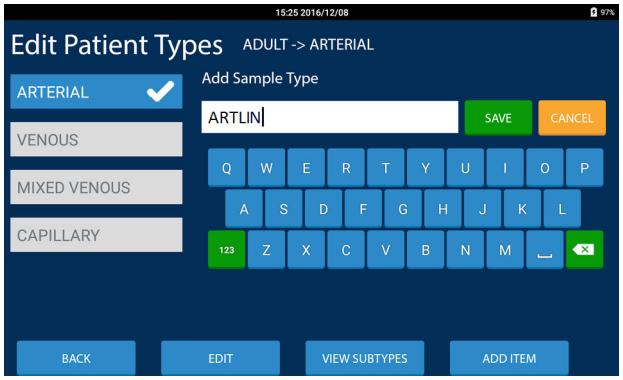
- **Edit:** Select a type from the list and press the EDIT button. Modify the type's name using the on-screen keyboard and press the SAVE button to save the changes or press the CANCEL button to not save any changes.
- **Delete:** Select a type from the list and press the EDIT button. Remove all of the characters from the text area and press the SAVE button. A message will appear confirming the deletion. Press DELETE to delete the type.
- **Add:** Select the ADD ITEM button and enter the name of the new type. Press the SAVE button to add the new item or press the CANCEL button to not add the new item.

  Note: The Add Item button will not be available if the maximum number of types has been reached. Delete a type to make space available for a new type.
- **View Subtypes:** Select a type from the list of type buttons and press the VIEW SUBTYPES button to view, add, edit or delete the next sub-type.





- Selecting View Subtypes for a patient type will display the sample types configured for that patient type.
- Selecting View Subtypes for a sample type will display the sample sites configured for that sample type.
- Selecting View Subtypes for a sample site will display the sample sub-sites configured for the sample site.
- There is no View Subtype button for sample sub-sites.

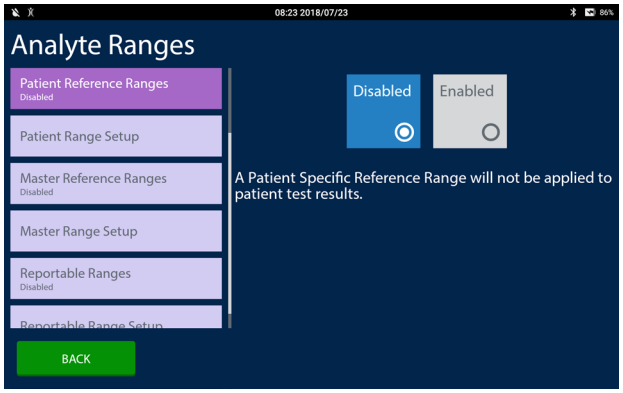


Patient Specific Reference Range

To configure the IRMA System to evaluate patient test results against reference ranges based on the patient and sample type select the Patient Reference Ranges button. There are two options for Patient Specific Reference Range:

- **Disabled:** Patient test results will not be evaluated against the corresponding Patient Specific Reference Range.
- **Enabled:** Patient test results will be evaluated against the corresponding Patient Specific Reference Range when defined.

Note: Patient specific reference ranges may only be configured for the established Patient and Sample types.



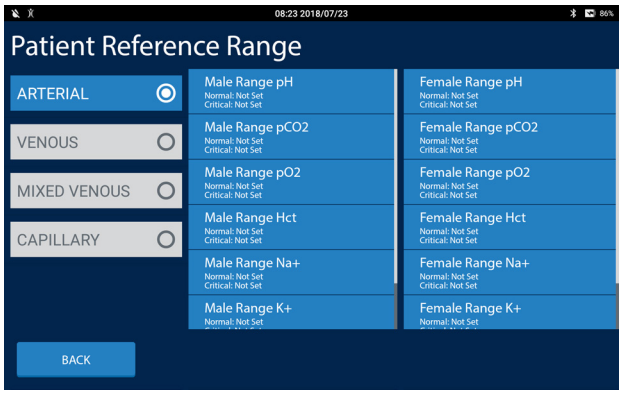
Patient Reference Range

There must be at least one patient type and sample type established in the IRMA System in order to configure a patient specific reference range and Patient/Sample Type MUST be Enabled. For each patient type-sample type combination there is one set of reference ranges for female and one set for male.

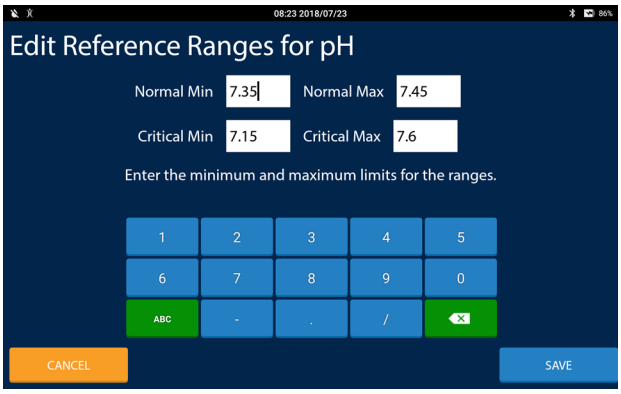
Note: The patient's sex must be entered during a patient test when the Patient Specific Reference Range setting is configured to enabled.

To configure patient specific reference ranges select the Patient Range Setup button. The patient types established for the IRMA System will be displayed. To configure a patient specific reference range:

- Select a patient type button. The sample types for the patient type will be displayed.
- Select a sample type button. For each analyte two buttons will be displayed: one for female and one for male.



To configure the reference range for a specific analyte:

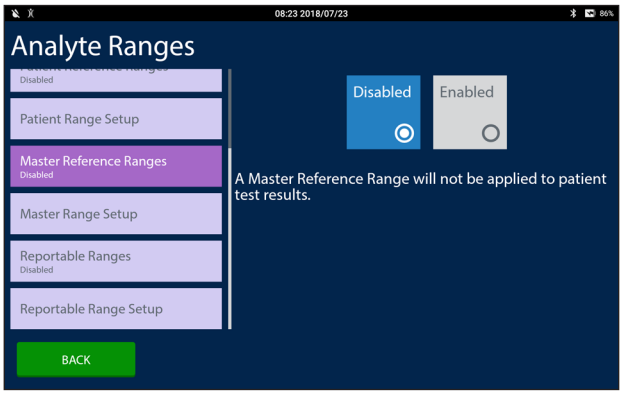


- Press a reference range button.
- Enter the minimum and maximum value for the normal range and for the critical range using the on-screen keyboard.
  - If a minimum value is entered there must be a corresponding maximum value and vice versa.
  - The minimum value must be less than the maximum value.
  - If only a single range is entered, the test results will be evaluated against a single range.
- To delete a reference range set the minimum and maximum value to blank.
- Press the SAVE button to save the range. The list of reference range buttons is displayed.

Note: If the reference range for an analyte is common to many patient populations and sample types, configure Master Reference Ranges to Enabled and configure the analyte in the master reference range and leave it blank in the patient specific reference ranges. For example, if the range for an analyte is the same in venous and arterial samples, for all patient types, but is different in capillary samples, the analyte could be configured in the capillary reference ranges and left blank in the arterial and venous reference ranges.When a capillary test is performed, its results will be evaluated against the specific capillary reference range. When an arterial or venous test is performed, its results will be evaluated against the single master reference range.

Master Reference Range

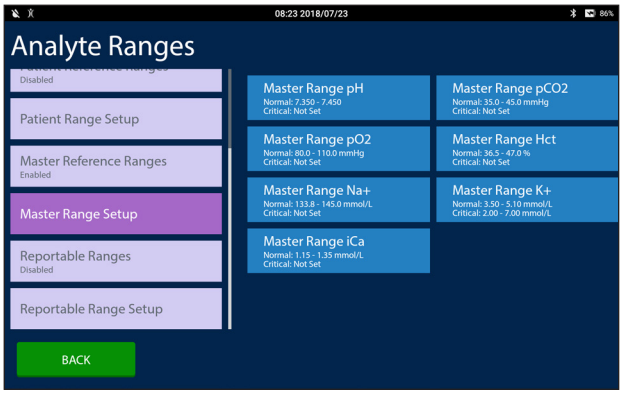
To configure the IRMA System to evaluate patient test results against a single master reference range select the Master Reference Ranges button.There are two options for Master Reference Ranges:



- **Disabled:** Patient test results will not be evaluated against the Master Reference Range.
- **Enabled:** Patient test results will be evaluated against the Master Reference Range when the Patient Specific Reference Range is configured to disabled or if there is no range defined in the corresponding Patient Specific Reference Range.

Master Reference Range Setup

To configure the master reference range select the Master Range Setup button. For each analyte one button will be displayed. To configure the master reference range for a specific analyte:



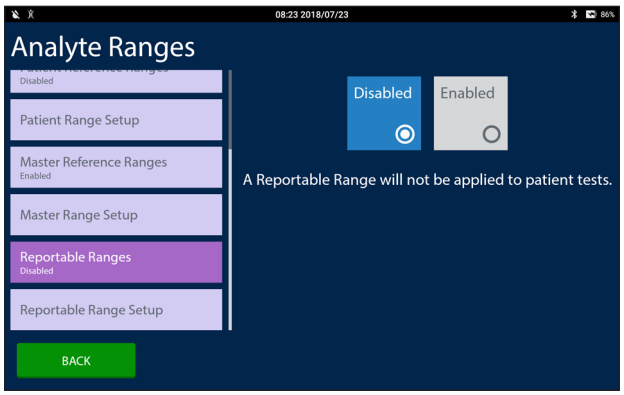
- Press the analyte's master reference range button.
- Enter the minimum and maximum value for the normal range and for the critical range using the on-screen keyboard.
  - If a minimum value is entered there must be a corresponding maximum value and vice versa.
  - The minimum value must be less than the maximum value.
  - If only a single range is entered, the test results will be evaluated against a single range.
- To delete a reference range set the minimum and maximum value to blank.
- Press the SAVE button to save the range. The list of master reference range buttons is displayed.

Note: An analyte's reference range, patient specific and master, must be inside the analytes's reportable range.

Reportable Ranges

To configure the IRMA System to evaluate patient test results against a reportable range select the Reportable Ranges button. There are two options for Reportable Ranges:

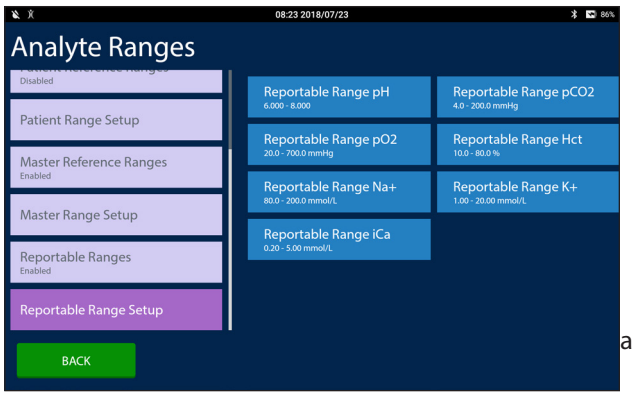
- **Disabled:** Patient test results will not be evaluated against the Reportable Range.
- **Enabled:** Patient test results will be evaluated against the Reportable Range.



Reportable Range Setup

To configure the reportable range select the Reportable Range Setup button. For each analyte one button will be displayed. By default the reportable ranges are configured to the IRMA System's machine ranges. A test result outside of the IRMA System machine range is reported as suppressed. To configure the reportable range for a specific analyte:

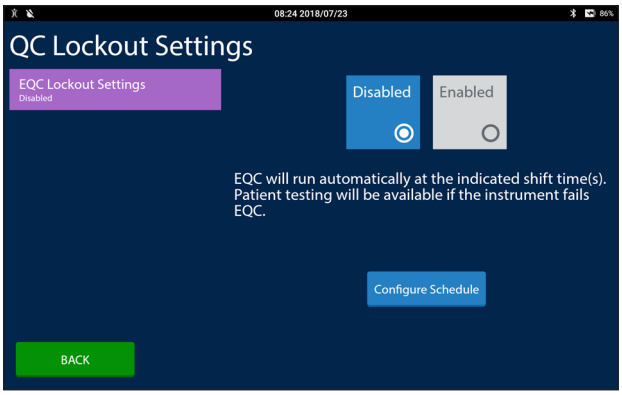
- Press the analyte's reportable range button.
- Enter the minimum and maximum value for the range using the on-screen keyboard.
  - If a minimum value is entered there must be corresponding maximum value and vice versa.
  - The minimum value must be less than the maximum value.
  - If only a single range is entered, the test results will evaluated against a single range.
- To reset a reportable range to the machine range clear the reportable range.
- Press the SAVE button to save the range. The list of reportable range buttons is displayed.



8.6 QC Lockout Settings

The IRMA System may be configured to prohibit testing if certain EQC testing has not been successfully performed. EQC lockout will prohibit patient and LQC testing. To access the QC Lockout Settings submenus select the QC Lockout Settings button from the Settings menu.

EQC Lockout Settings

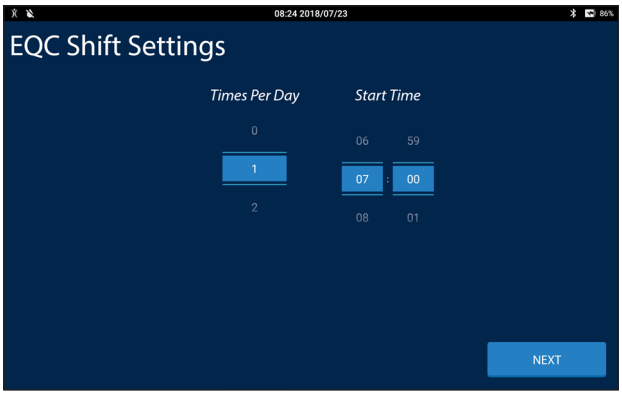


To prohibit testing on the IRMA System if the most recent EQC test failed select the EQC Lockout Settings button. There are two options for configuring EQC lockout:

- **Disabled:** A failed EQC test will not prohibit patient and LQC testing on the IRMA System.
- **Enabled:** If the last EQC test performed failed, or an EQC test was not performed for the current shift, patient and LQC testing will be prohibited until a passing EQC test is performed.

  Note: Auto-EQC tests will always be performed according to the EQC test schedule whether EQC Lockout is configured to Disabled or Enabled.

To configure the EQC test schedule press the Configure Schedule button. There are two schedule settings to configure:

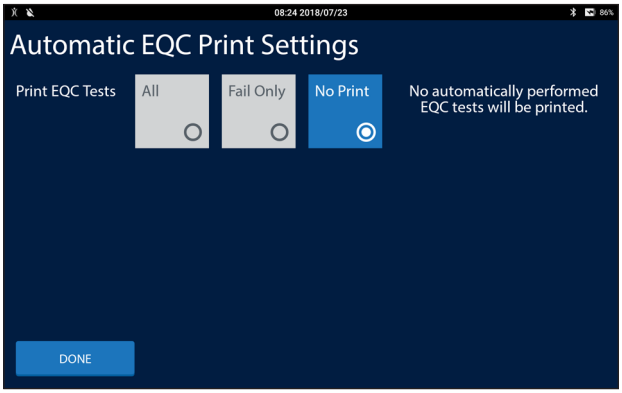


- **Times per Day:** The number of times each day a successful EQC test must be performed. The times per day is also referred to as the number of shifts. For example, if times per day is set to three, there will be three eight-hour shifts.
- **Start Time:** The time by which shift schedules are set. For example, if the start time is set to 07:00 and there are three shifts, the shift times will be 07:00 - 14:59, 15:00 - 22:59 and 23:00 - 06:59. If the start time is set to 15:00 and there are two shifts, the shift times will be 03:00 - 14:59 and 15:00 - 02:59.
- When the number of shifts and start time are configured press the NEXT button.

  Note: The IRMA System will attempt to start an EQC test at the start of a shift if no other test is being performed. It is recommended that shift schedules are timed so that they begin at least fifteen minutes before regular testing commences on the IRMA System.

  Note: If a patient or LQC test is started just prior to the start of a new shift, the test will be allowed to complete before lockout is enforced.

There are three options for configuring whether or not Auto-EQC tests are printed:



- **All:** All Auto-EQC tests will automatically be printed.
- **Fail Only:** Only Auto-EQC tests that fail will be automatically printed.
- **No Print:** Auto-EQC tests will not be automatically printed.
- When the print setting has been configured press the DONE button.

  Note: EQC tests are performed by the IRMA Base. The IRMA Base will attempt to wake the IRMA Tablet when an Auto-EQC test is started. If the IRMA Base cannot connect to the IRMA Tablet, the EQC test will be performed, but it will not be printed automatically.

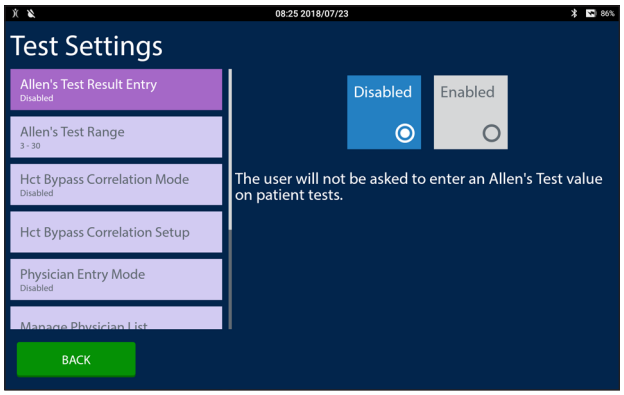
8.7 Test Settings

Test Setting options configure the screens displayed to the operator for all patient tests unless otherwise noted. To access the Test Settings submenus select the Test Settings button from the Settings menu.

Allen's Test Result Entry

To associate the result of an Allen's Test with a patient test record select the Allen's Test Result Entry button. There are two options for associating the value of an Allen's test with a patient test record:

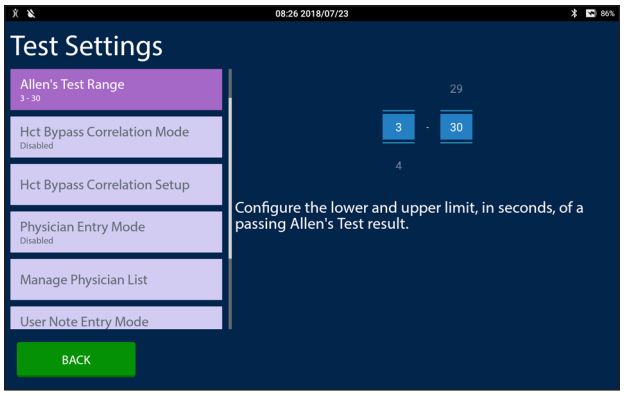
- **Disabled:** The operator will not be presented with an option to associate the value of an Allen's test with a patient test record.
- **Enabled:** The operator will be presented with an option to associate the value of an Allen's test with a patient test record.



Allen's Test Range

To configure the passing range for an Allen's Test result select the Allen's Test Range button. A lower number of seconds and an upper number of seconds are used to define the range for an Allen's Test.

- Set the first spinner to configure the lower limit of an Allen's Test.
- Set the second spinner to configure the upper limit of an Allen's Test.
- The lower limit must be less than the upper limit.

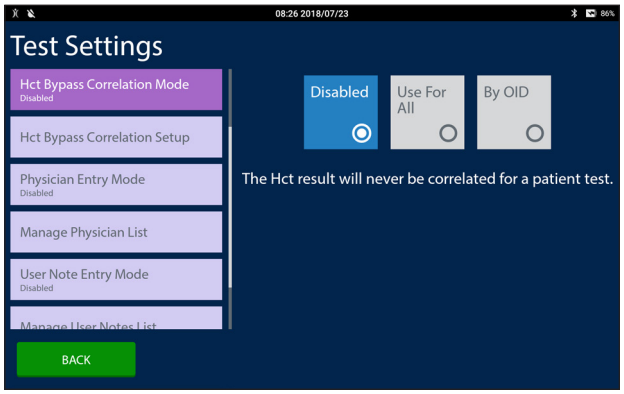


When performing a patient test the operator will have the opportunity to associate the result of an Allen's Test with the patient test record using a single spinner control. Values less than the lower number and values greater than the upper number will be colored red on the spinner control. Values greater than or equal to the lower number and values less than or equal to the upper number will be colored white on the spinner control.

Hct Bypass Correlation Mode

To adjust the hematocrit result for patients on cardiopulmonary bypass select the Hct Bypass Correlation Mode button. When the operator select On Bypass during a patient test the hematocrit result will be adjusted based on the configured slope and intercept. There are three options for configuring Hct Bypass Correlation:

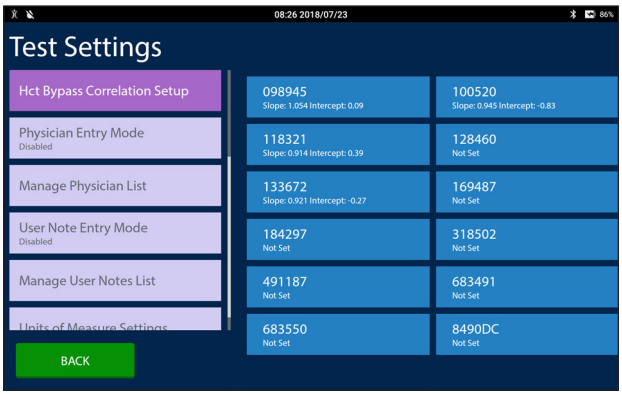
- **Disabled:** Hct results will never be correlated.
- **Use For All:** When performing a patient test reporting hematocrit (Hct) the operator must select whether or not the patient is on cardiopulmonary bypass. If the operator selects On Bypass, a single slope and intercept will be used to adjust the hematocrit result.



- **By OID:** When performing a patient test reporting hematocrit (Hct) the operator must select whether or not the patient is on cardiopulmonary bypass. If the operator selects On Bypass, the slope and intercept defined for the OID logged into the IRMA System will be used to adjust the hematocrit result. If the OID Required setting is configured to Disabled, or if a slope and intercept are not configured for the OID, the hematocrit result will not be adjusted.

Note: Hematocrit results that have correlation applied appear with a heart symbol on the results screen.

Hct Bypass Correlation Setup

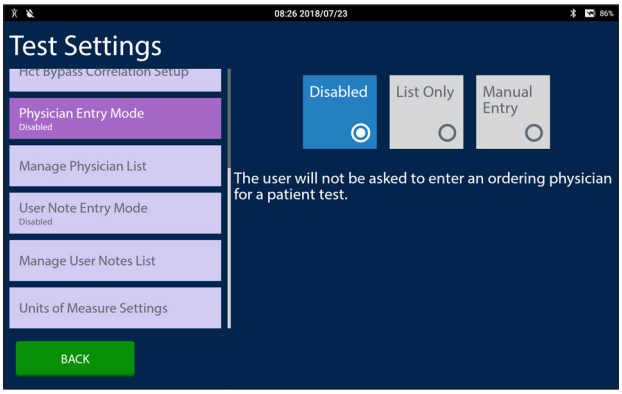


To configure the slope and intercept for all OIDs or for individual OIDs select the Hct Bypass Correlation Setup button.

- If Hct Bypass Correlation Mode is configured to Use For All, a single correlation button will be displayed.
- If Hct Bypass Correlation Mode is configured to By OID a correlation button for each OID configured in the IRMA System will be displayed.
- Select a correlation button to display the Edit Bypass Correlation screen.
  - Enter or edit the Slope and the Intercept using the on-screen keyboard. If the slope and intercept are blank the hematocrit result will not be adjusted.
  - Press the DONE button to save the changes.
  - Press the CANCEL button to exit without saving changes.

Note: Instructions for establishing a slope and intercept are located at the end of this section.

Physician Entry Mode

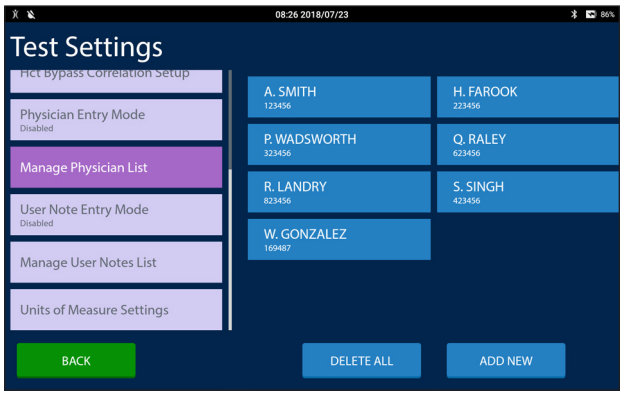


To configure the IRMA System to associate an ordering physician with the patient test record select the Physician Entry Mode button. There are three options for associating a physician name with a patient test record:

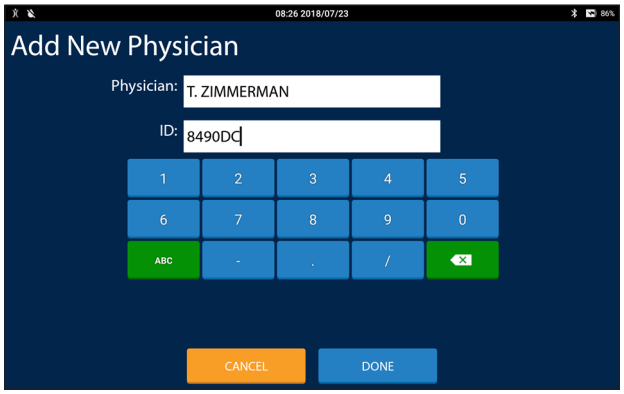
- **Disabled:** The operator will not be presented with an option to associate the name of the ordering physician during a patient test record.
- **List Only:** The operator will be presented with the option to associate the name of the ordering physician during a patient test record from the pre-configured list.
- **Manual Entry:** The operator will be presented with the option to associate the name of the ordering physician during a patient test record from the pre-configured list or by entering a name manually using the on-screen keyboard or by scanning a barcode.

Manage Physician List

To view, add, edit or delete a name from the physician list select the Manage Physician List button. A list of the configured physicians is displayed.



- To add a new physician to the list press the ADD NEW button that appears at the bottom of the screen.
  - Enter a name in the Physician text entry area using the on-screen keyboard. The name may not be blank and the name may not be a duplicate of an existing name.
  - Entry of an ID is optional. If an ID is entered it may not be a duplicate of an existing ID. When patient test records are transferred electronically the physician name and id will be transferred in the electronic record. The physician id will not be displayed on IRMA System reports.
  - Press the DONE button to save the physician name to the list.

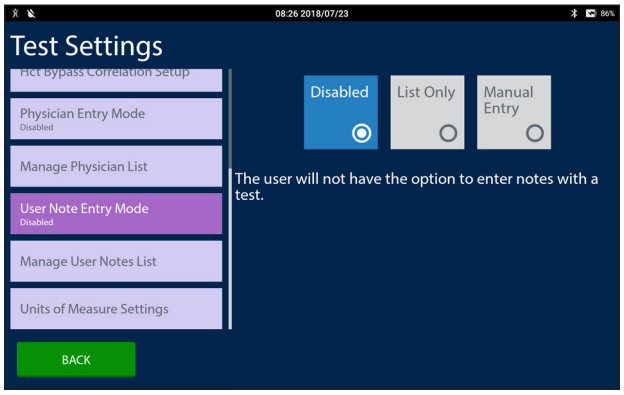


- To edit the ID associated with a physician name select the physician name from the list.
  - Edit the ID using the on-screen keyboard. The changed ID may not be a duplicate of an existing ID.
  - The physician name may not be changed. To change the name of a physician delete the physician from the list and then add a new physician.

- To delete an individual physician from the list select the physician to be deleted.
  - Select the Delete button. A confirmation message will appear. Press DELETE.
- To clear the entire list, select the Delete All button that appears on the bottom of the screen.
  - A confirmation message will appear. Press DELETE ALL.

User Note Entry Mode

To allow user notes to be associate with test records select the User Note Entry Mode button. There are three options for associating a user note with a test record:

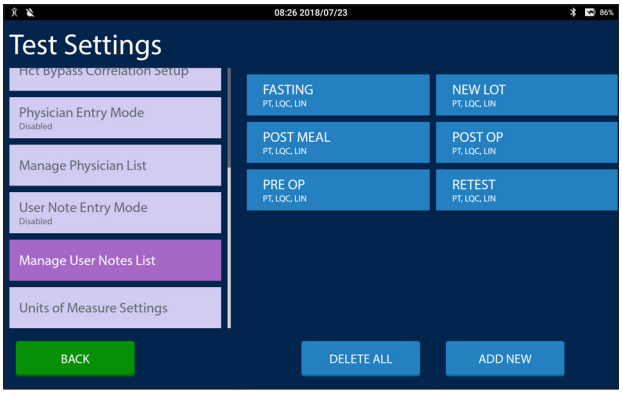


- **Disabled:** The operator may not associate notes with a test record.
- **List Only:** The operator may only associate pre-configured notes with a test record.
- **Manual Entry:** The operator may associate pre-configured notes with a test record or the operator may associate free text notes with a test record.

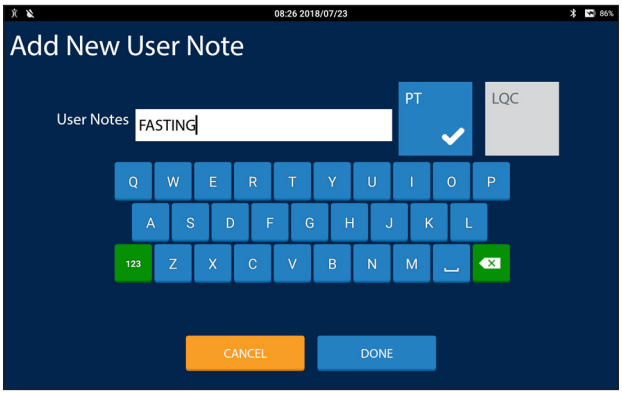
  User Notes created by the operator during a test are not added to the pre-configured list of notes.

Manage User Notes List

To view, add, edit or delete a user note from the user note list select the Manage User Notes List button. A list of the configured user notes is displayed.



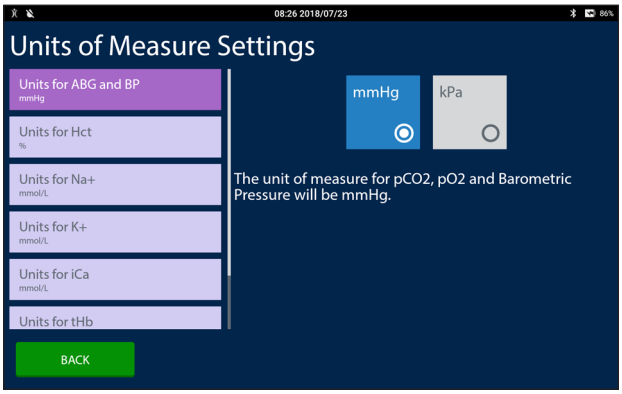
- To add a new user note to the list press the ADD NEW button that appears at the bottom of the screen.
  - Enter a unique note in the text entry area using the on-screen keyboard. The note may not be blank and the note may not be a duplicate of an existing note.
  - Select PT and/or LQC. If PT is selected the user note will be available to associate with patient tests. If LQC is selected the user note will be available to associate with LQC tests.
  - Press the DONE button to save the note to the list.
- To edit the PT/LQC designation of a user note select the user note from the list.
  - Select or de-select the PT and/or LQC button.
  - Press the DONE button to save the changes.
- To delete an individual user note from the list select the user note to be deleted.
  - Select the Delete button. A confirmation message will appear. Press DELETE.
- To clear the entire list, select the Delete All button that appears on the bottom of the screen.
  - A confirmation message will appear. Press DELETE ALL.



Units of Measure Settings

To configure the units of measure reported for an analyte, the unit of measure for temperature, and to configure whether to report BUN as BUN or Urea, select the Units of Measure Settings button. A list containing each analyte and the unit of measure currently configured for it will be displayed in a single column. To configure the unit of measure for an analyte select the analytes unit button.

- Two or more radio buttons will be displayed. Select the desired unit of measure.



Calculating Slope and Intercept for Hct Bypass Correlation

1. Configure Hct Bypass Correlation Mode to Disabled.
2. Verify the reference analyzer is properly maintained prior to the start of data collection to ensure accurate correlation.
3. Obtain at least 20 split-sample hematocrit results from at least 5 patients on cardiopulmonary bypass.

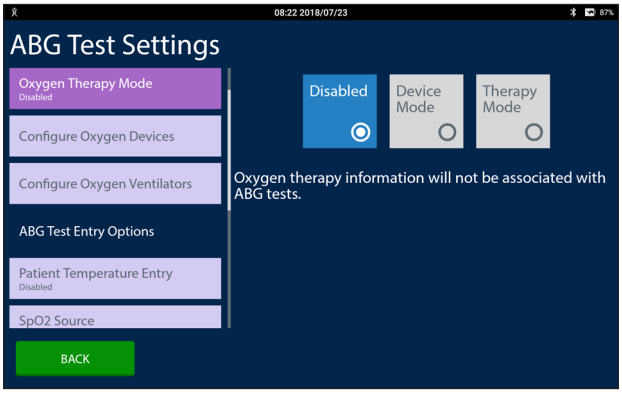
   ONLY USE SAMPLES COLLECTED FROM PATIENTS ON BYPASS; PRE- AND POST- BYPASS SAMPLES MUST BE EXCLUDED.

   IF HCT BYPASS WILL BE CONFIGURED BY OID A SEPARATE SET OF 20 SAMPLES MUST BE COLLECTED FOR EACH OPERATOR.
4. Graph the reference analyzer results against the IRMA System results for each set of values. Make the reference analyzer results the Y (dependent) variable; make the IRMA System results the X (independent) variable.
5. Perform a linear regression analysis on the results.
6. Delete any data points that are more than 3 standard deviations from the regression line. Replace them with data acquired from additional split-sample analyses and redetermine the regression line.
7. The slope and intercept values of the regression line are the slope and intercept to be entered in the IRMA System in the Hct Bypass Correlation Setup feature.

8.8 ABG Test Settings

The ABG Test Settings configure IRMA System settings for blood gas testing (the CC and BG IRMA cartridge types.) These settings include associating oxygen therapy information with the test record, correcting ABG values for patient temperature, associating a measured SpO_2 value with the test record and the formulas to use when calculating base excess, the source of hemoglobin used in the base excess calculation and the formula to use for temperature correcting pO_2. To access the ABG Test Settings submenus select the ABG Test Settings button from the Settings menu.

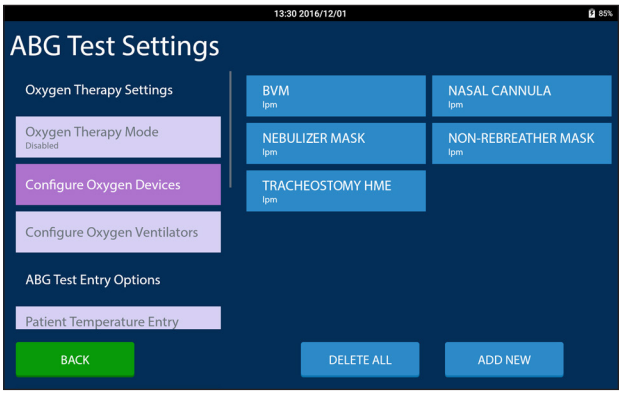
Oxygen Therapy Mode



To associate oxygen therapy information from a ventilator or other therapy device select the Oxygen Therapy Mode button. There are three options for associating oxygen theapy information with the patient test record:

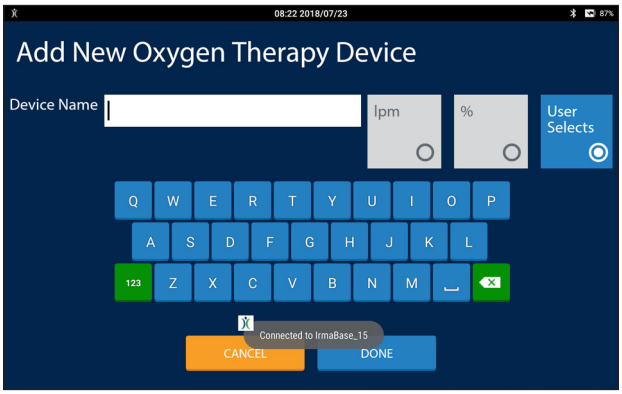
- **Disabled:** The operator will not be presented with an option to associate oxygen therapy information with a patient test record.
- **Device Mode:** The operator will be presented with a list of configured oxygen devices and a room air option. Each of the devices in the list are configured for a single oxygen therapy value.
- **Therapy Mode:** The operator will be presented with a list of configured ventilators and a room air option. Each of the ventilators in the list are configured for the entry of up to twenty oxygen therapy values.

Configure Oxygen Devices

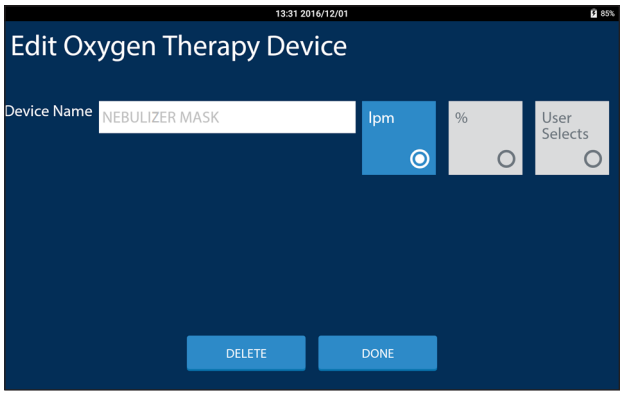


To view, add, edit or delete an oxygen device from the oxygen device list select the Configure Oxygen Devices button. A list of the configured oxygen devices is displayed.

- To add a new device to the list press the ADD NEW button that appears at the bottom of the screen.
  - Enter a unique oxygen device name in the Device Name text entry area using the on-screen keyboard. The name may not be blank and the name may not be a duplicate of an existing oxygen device.
  - Select a unit of measure radio button. The lpm selection will associate lpm (liters per minute) with the value entered by the operator. The % selection will associate % (percent) with the value entered by the operator. User Selects will allow the operator to choose from lpm or % during the test.
  - Press the DONE button to save the oxygen device to the list.
- To edit the unit of measure associated with an oxygen device from the list select the oxygen device.
  - Select the unit of measure radio button. Press the DONE button to save and exit.
  - The oxygen device name may not be changed. To change the name of an oxygen device delete the oxygen device from the list and then add a new one.



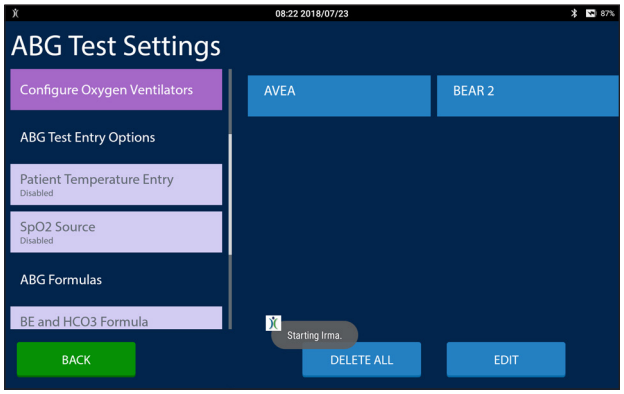
- To delete an individual oxygen device from the list select the oxygen device to be deleted.
  - Select the Delete button. A confirmation message will appear. Press DELETE.
- To clear the entire list, select the Delete All button that appears on the bottom of the screen.
  - A confirmation message will appear. Press DELETE ALL.

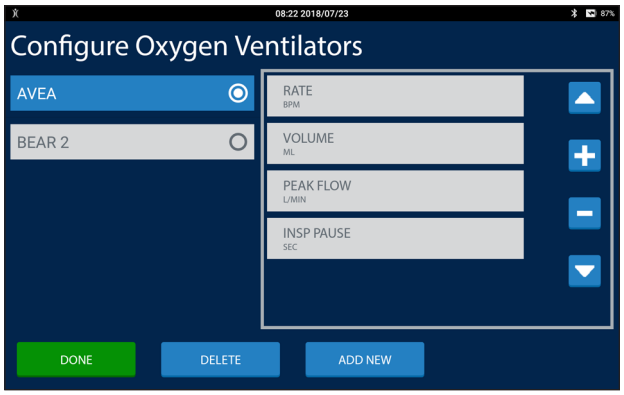


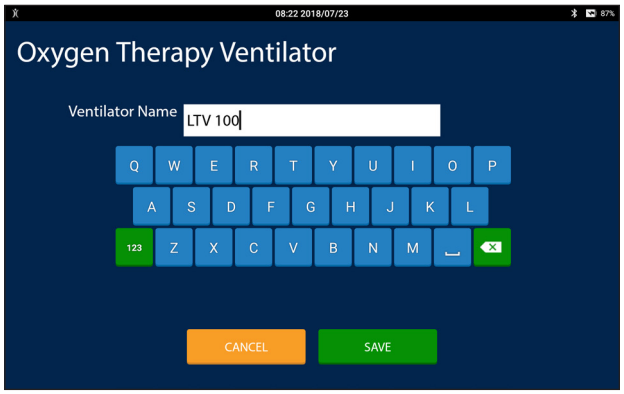
Configure Oxygen Ventilators

To view, add, edit or delete a ventilator from the ventilator list select the Configure Oxygen Ventilators button. A list of the configured ventilators is displayed.

- To add a new ventilator to the list press the EDIT button that appears on the bottom of the screen. From the Configure Oxygen Ventilators screen press the ADD NEW button.
  - On the Oxygen Therapy Ventilator screen enter a unique ventilator name using the on-screen keyboard in the Ventilator Name text entry area. Press the SAVE button.
  - From the Configure Oxygen Ventilators screen select the newly created ventilator button from the list of ventilators.
  - To add a new ventilator setting to the ventilator press the + button. Enter a unique, non-blank setting name in the Setting Name text entry area using the on-screen keyboard. Enter the setting's unit of measure in the Units of Measure text entry area using the on-screen keyboard. The unit of measure may be blank.



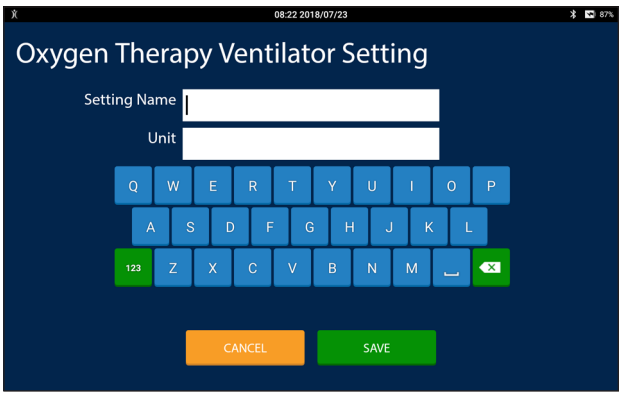




- To move the setting up in the list first select the setting to move and then press the UP ARROW button.

NOTE: The order of the settings in the list will be the order the settings are presented to the operator during a patient test.

- To move the setting down in the list first select the setting to move and then press the DOWN ARROW button.
- To delete a setting from the list first select the setting to delete and then press the - button. A confirmation message will be displayed. Press DELETE.



A ventilator setting may not be edited. To edit a ventilator setting delete it from the list and then add the correct setting.

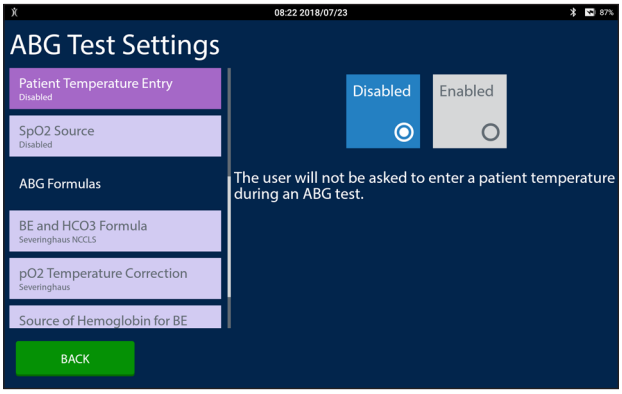
The Delete button at the bottom of the Configure Oxygen Ventilators screen is to delete the ventilator and all of its settings and not to delete a single ventilator setting.

- To delete an individual ventilator from the list press the Edit button.
  - Select the ventilator button from the list. Select the Delete button that appears on the bottom of the screen. A confirmation message will appear. Press DELETE.
- To clear the entire list, select the Delete All button that appears on the bottom of the screen.
  - A confirmation message will appear. Press DELETE ALL.

Patient Temperature Entry

To adjust patient ABG results select the Patient Temperature Entry button. There are two options for adjusting patient ABG values for temperature during a patient test:

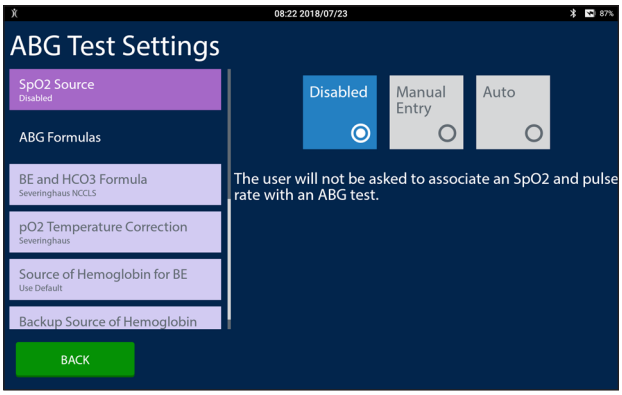
- **Disabled:** The operator will not be presented with an option to enter a patient temperature.
- **Enabled:** The operator will be presented with an option to enter a patient temperature.



SpO2 Source

To associate a measured SpO_2 value and pulse rate with a patient test record select the SpO2 Source button. There are three options for associating a measured SpO_2 value with the patient test record:

- **Disabled:** The operator will not be presented with an option to associate a measured SpO_2 value with a patient test record.
- **Manual Entry:** The operator may enter a measured SpO_2 value and pulse rate using the on-screen numeric keyboard.
- **Auto:** The instrument will discover any compatible *Bluetooth* enabled pulse oximeters and display them in a list for the operator to select. The SpO_2 and pulse rate will be read automatically from the pulse oximeter and displayed on the screen for the operator to confirm. The operator will also have the option to manually enter a measured SpO_2 value and pulse rate using the on-screen numeric keyboard.

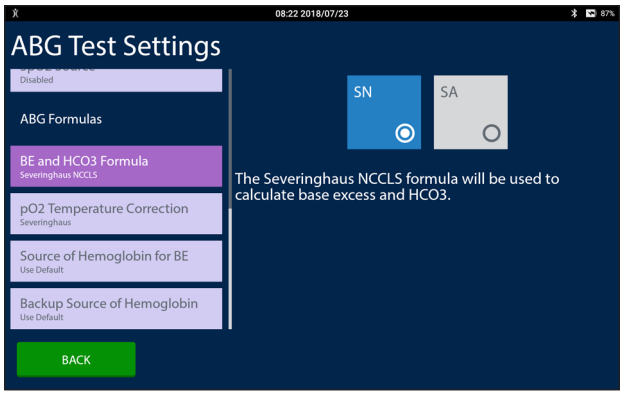


Note: To obtain a compatible *Bluetooth* enabled pulse oximeter or to obtain the list of compatible *Bluetooth* enabled pulse oximeters please contact your service provider.

BE and HCO3 Formula

To set the formula for calculating the base excess and HCO_3 reported for a patient test select the BE and HCO3 Formula button. There are two options for the BE and HCO_3 formula:

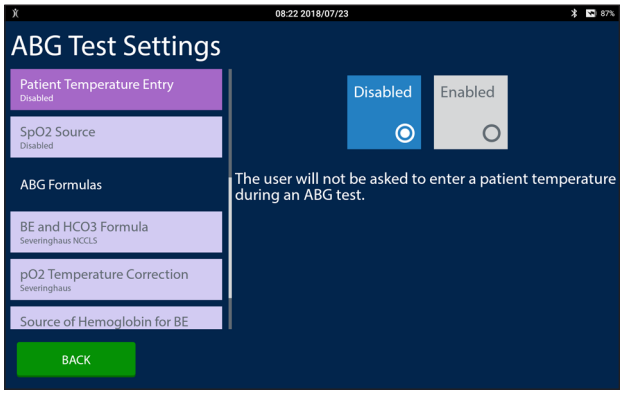
- **SN:** The Severinghaus NCCLS formula will be used to calculate the base excess and HCO_3 values reported with a patient test.
- **SA:** The Siggaard-Andersen formula will be used to calculate the base excess and HCO_3 values reported with a patient test.



pO2 Temperature Correction

To set the formula for adjusting the patient pO_2 result when a patient temperature is entered by the operator during a patient test select the pO2 Temperature Correction button. There are two options for the pO_2 correction formula:

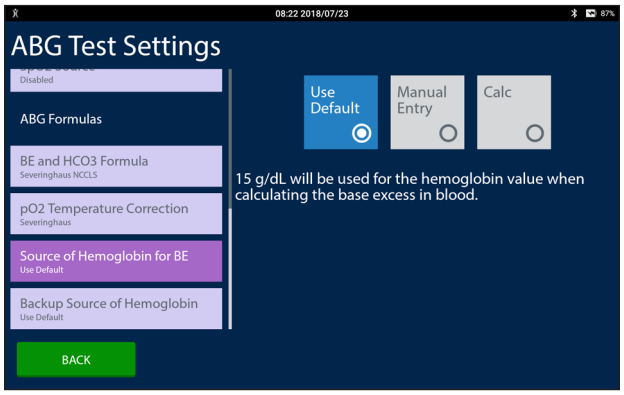
- **Severinghaus:** The Severinghaus formula will be used to calculate the temperature corrected pO_2 result reported with a patient test.
- **Kelman-Nunn:** The Kelman-Nunn formula will be used to calculate the temperature corrected pO_2 result reported with a patient test.



Source of Hemoglobin for BE

To set the source for the hemoglobin value used in calculating the base excess in blood (BEb) select the Source of Hemoglobin for BE button. There are three options for Source of Hemoglobin for BE:

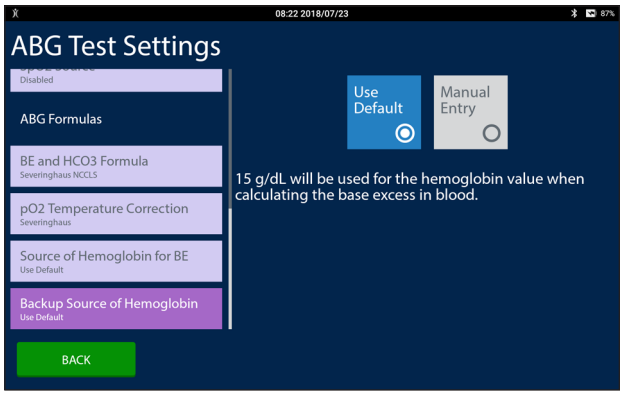
- **Use Default:** 15 g/dL will be used for the hemoglobin value when calculating the base excess in blood.
- **Manual Entry:** The operator will be prompted to enter a hemoglobin value to use in the base excess in blood calculation.
- **Calc:** The hemoglobin value calculated by the IRMA System will be used in the base excess in blood calculation.



Backup Source of Hemoglobin

To set the source for the hemoglobin value used in calculating the base excess in blood when the Source of Hemoglobin for BE setting is configured to Calc and a hemoglobin cannot be calculated by the IRMA System select the Backup Source of Hemoglobin button. There are two options for the Backup Source of Hemoglobin:

- **Use Default:** 15 g/dL will be used for the hemoglobin value when calculating the base excess in blood.
- **Manual Entry:** The operator will be prompted to enter a hemoglobin value to use in the base excess in blood calculation.

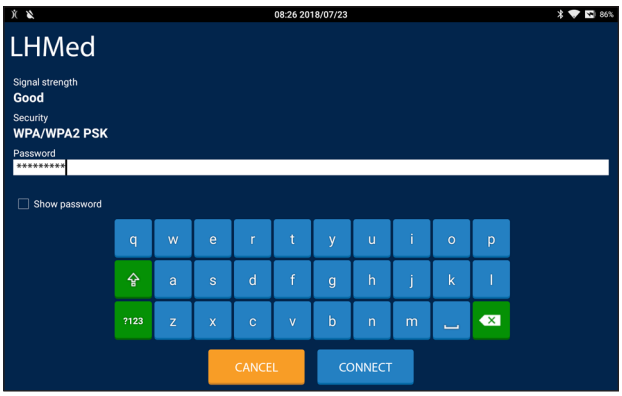


8.9 Device Settings

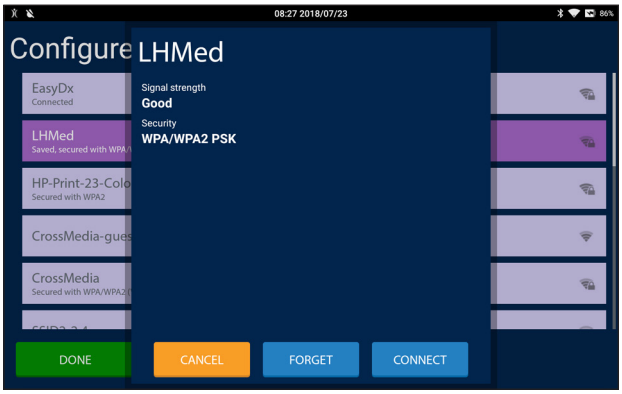
All of the non-test configuration settings for the IRMA System are contained in Device Settings. To access the Device Settings submenus select the Device Settings button from the Settings menu.

Configure Wifi

The IRMA System may be connected to a wireless network. To connect to a wireless network select the Configure WiFi button. The IRMA Tablet will scan for available wireless networks.



- To connect to a wireless network select the network ribbon from the list.
  - If the wireless network does not require a password to join the IRMA System will obtain an IP address and join the network.
  - If the wireless network requires a password a screen for entering the password will be displayed.
  - To show the password as it is entered, select the Show password checkbox.
  - To enter text in the password text entry area touch the text entry area. A cursor will appear. Use the on-screen keyboard to enter text.
  - To change between lowercase and uppercase press the green UP ARROW button.
  - To enter symbols press the ?123 button to display the numeric and symbol keyboard. To view additional symbols press the green UP ARROW button.
  - Once the password has been entered press the CONNECT button. The IRMA Tablet will attempt to obtain an IP address and join the wireless network.
- To disconnect from a wireless network select the network from the list.
  - A dialog containg the network's characteristics will display.
  - Press the FORGET button to disconnect from the network.
- If the desired wireless network does not display in the list press the RESCAN button. Pressing the Rescan button forces the IRMA Tablet to perform a new search for wireless networks.
- If a SSID is required to join the wireless network, and it was not an option on the connect to a wireless network screen, press the SSID button.



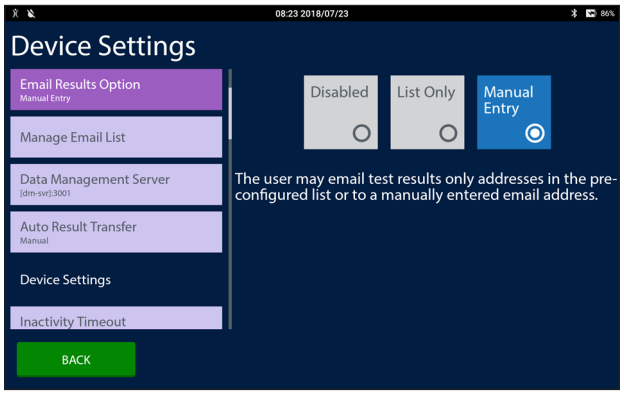
Note: The IRMA System only enables the Wifi and connects to the network when checking for updates or transferring data.

Note: The IRMA System cannot connect to a wireless network that requires the installation of a certificate.

Note: There is no configuration for using the wired Ethernet adapter. To use the wired Ethernet adapter simply plug the USB-Ethernet adapter supplied with the IRMA System into the IRMA Base's USB port and then plug a network cable into the USB-Ethernet adapter. The IRMA System is only compatible with DHCP and only connects to the network when checking for updates or transferring data.

Email Results Option

The EMAIL button will always appear for each log generated by the IRMA Logs feature and on the About IRMA and About Batteries screen. Displaying the EMAIL button on the test results screen is configurable.

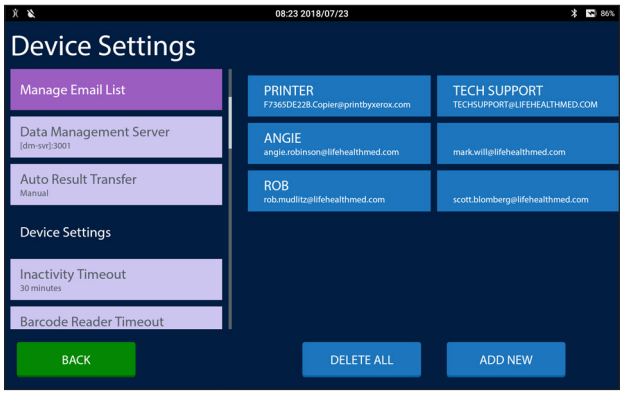


- **Disabled:** The EMAIL button will not appear on the test result screen.
- **List Only:** The EMAIL button will appear on the test result screen and the user must select an email address from the list.
- **Manual Entry:** The EMAIL button will appear on the test result screen and the user may select an email address from the list or manually enter one. A manually entered email address will not be added to the Email List.

Note: The IRMA System must connect to a network with Internet access in order to send email. The IRMA System cannot receive emails.

Manage Email List

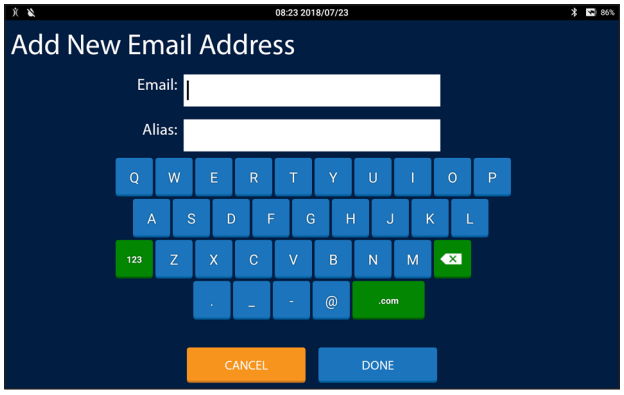
To add, edit and delete email addresses from the IRMA System select the Manage Email List button.



- To add a new email address to the list press the ADD NEW button.
  - Use the keyboard to enter the email address and optionally an alias. Pressing the green 123 button will display the numeric keyboard.

  Note: The alias will appear in the list of email addresses when the EMAIL button is selected from a test results screen. If the alias is blank the email address will appear.

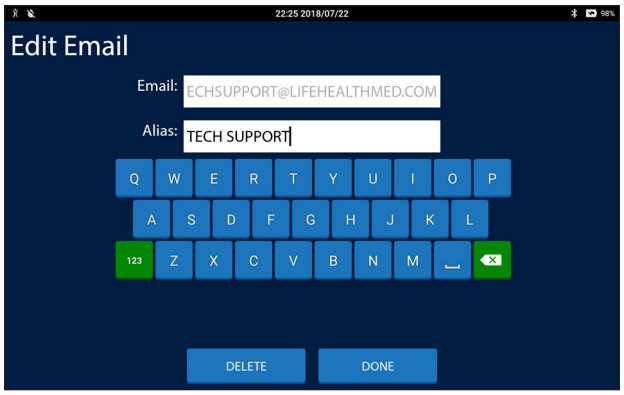
  - Press the DONE button to save the OID to the OID list.
  - Press the CANCEL button to return to the Manage Email List screen without saving the entry.



- To delete an email address select the button of the email address to be deleted. The Edit Email screen will appear. Press DELETE.
- To delete the complete list of email addresses, select the Delete All button that appears on the bottom of the screen. A confirmation message will appear. Press DELETE ALL.

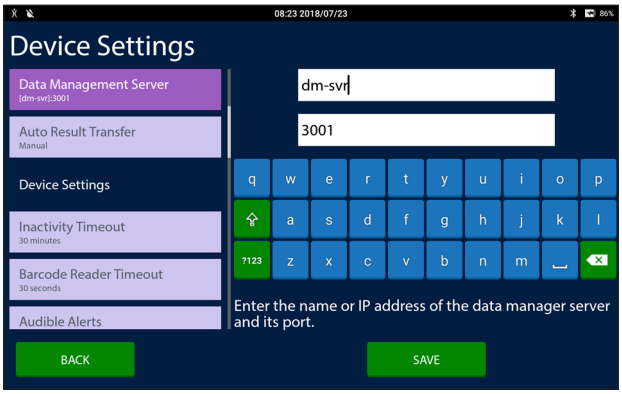
Note: Test reports will be sent as a PDF attachment to the email. Many laser and inkjet printers support printing PDF documents emailed to them as attachments. Please consult your printer's documentation for more information on whether or not it supports this feature.

Note: The email address generated by the IRMA LH includes do not reply. This may trigger your email system to route the email to the junk or spam folder.



Data Management Server

The IRMA System may be configured to transmit test results using the POCT1-A protocol to an external data management system. To configure the address of the data management system's server select the Data Management Server button.

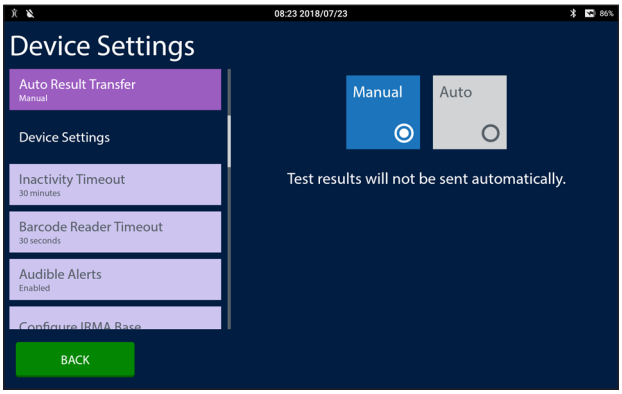


- Enter the server's name or IP address in the top text box.
  - Use the keyboard to enter the server's. Pressing the green 123 button will display the numeric keyboard.

  Note: Any entry in the address text box will enable the SEND button.
- Enter the port on which the data management system is listening in the bottom text box.
- Press the SAVE button.

Auto Result Transfer

When a Data Management Server address is configured test results may be transferred to the external data management system automatically when a test completes. To configure the automatic transfer of test results select the Auto Result Transfer button.

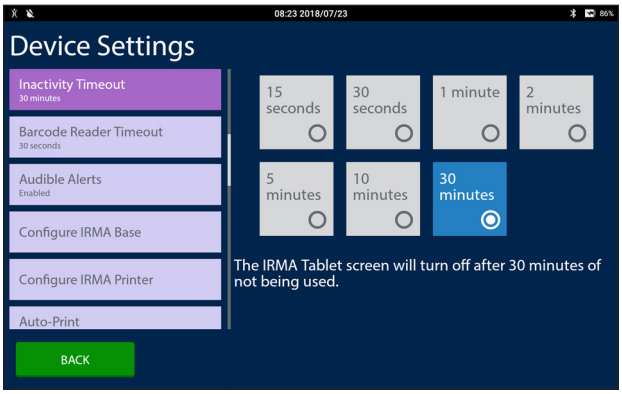


- **Manual:** Test results will not be sent automatically. Test results may still be transferred from the Search feature in the Functions menu.
- **Auto:** Test results will be sent when a test completes.

  Note: When configured to Auto the IRMA System will attempt to send any unsent test results upon the completion of a test. If the attempt to send is unsuccessful the current test result, and any unsent test results, will be sent upon the completion of the next test.

Inactivity Timeout

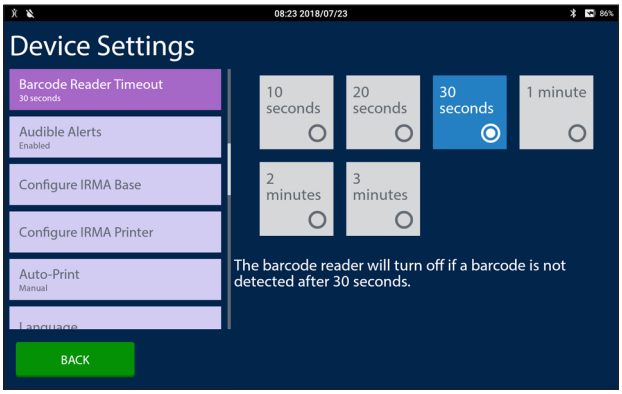
To set the amount of time the IRMA Tablet may be inactive before entering sleep mode select the Inactivity Timeout button.



- Select radio button corresponding to the desired timeout period.

Barcode Reader Timeout

To set the amount of time the IRMA Tablet's barcode reader may be active without detecting a barcode select the Barcode Reader Timeout button.

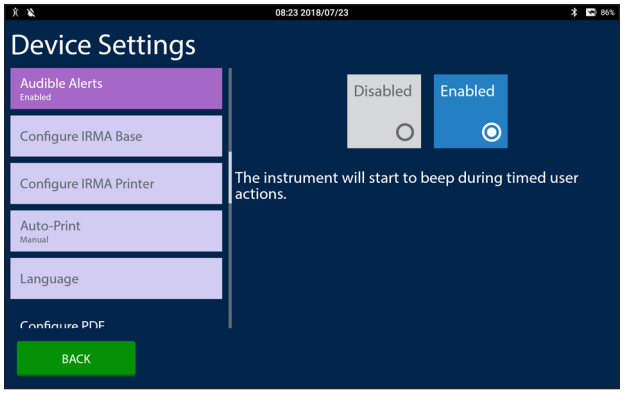


- Select radio button corresponding to the desired timeout period.

Audible Alerts

To configure the IRMA System to beep halfway through a timed operator action select the Audible Alerts button. There are two options for Audible Alerts:

- **Disabled:** The IRMA System will not beep during a timed task.
- **Enabled:** Halfway through a timed task the IRMA System will beep every five seconds.



Configure IRMA Base

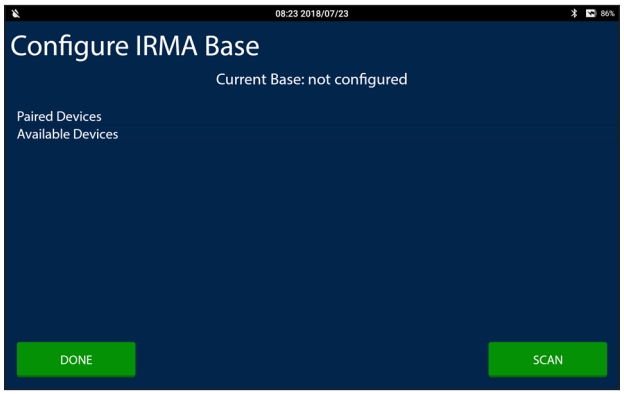
To assign an IRMA Tablet to an IRMA Base select the Configure IRMA Base button. Near the top of the Configure IRMA Base screen will be displayed Current Base: and the serial number of the IRMA Base assigned to the IRMA Tablet. If not configured is displayed instead of an IRMA Base serial number than the IRMA Tablet is not assigned to an IRMA Base.

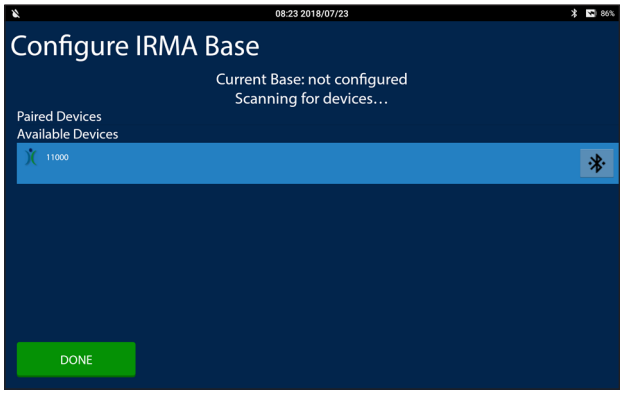
To assign an IRMA Base:

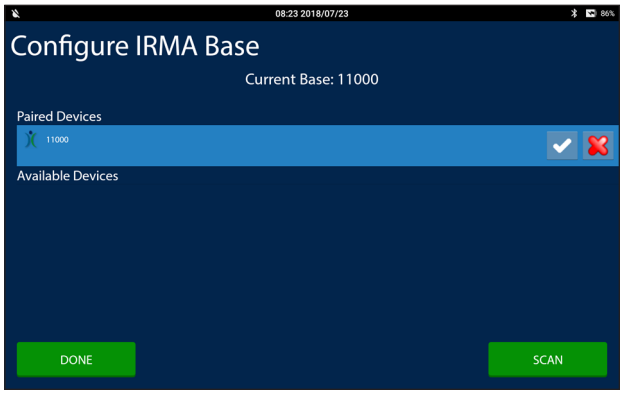
1. Turn on the IRMA Base. The IRMA Base is on when the white LED next to the Wake Button is solid white. To turn the IRMA Base on:
   - Plug in the AC Power Supply, or
   - Press the Wake button on the IRMA Base.
2. With the IRMA Base on, press the IRMA Base's Wake button three times. The white LED on the IRMA Base will blink once. If it does not blink once press the button again. Wait for the white LED to blink a second time. Press the IRMA Base's Wake button three times. The white LED will start blinking. The amber LED will turn on and not blink.

   Note: The IRMA Base will stay in pairing mode for two minutes.
3. On the IRMA Tablet, press the SCAN button. A blue ribbon will appear for each IRMA Base detected. Each ribbon will contain the serial number of the IRMA and a button with a Bluetooth Connect icon (refer to Section 1.10.)
4. Press the BLUETOOTH CONNECT button. A button with a red X will appear in the ribbon. If the red X button does not appear within three seconds press the BLUETOOTH CONNECT button again.
5. A pairing message will appear. Continue to wait until the Set Default message appears. Press the SET DEFAULT button.
6. When the IRMA Tablet is paired with the selected IRMA Base, the serial number of the IRMA Base will appear near the top of the screen next to Current Base: and a white check mark button will appear on the selected base ribbon.
7. If the pairing is unssuccessful, press the DONE button to return to the Device Settings screen. Press and hold the power button on the IRMA Tablet until the Reboot or Power Off dialog appears. Select Reboot. Then repeat this process from step 1.

   Note: The white LED on the IRMA Base must be blinking and the amber LED on the IRMA Base must be solid when the SCAN button is pressed on the IRMA Tablet.





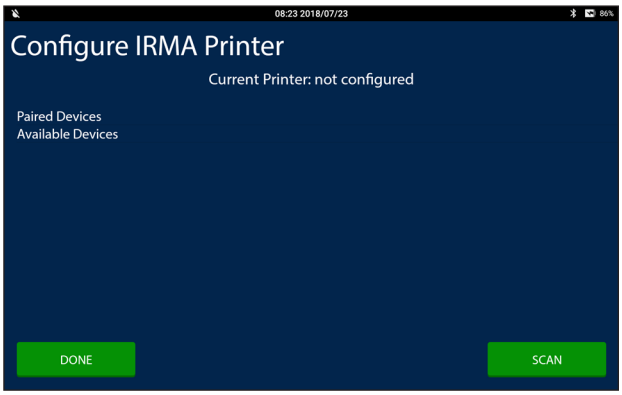


Configure IRMA Printer

To assign an IRMA Tablet to an IRMA Printer select the Configure IRMA Printer button.

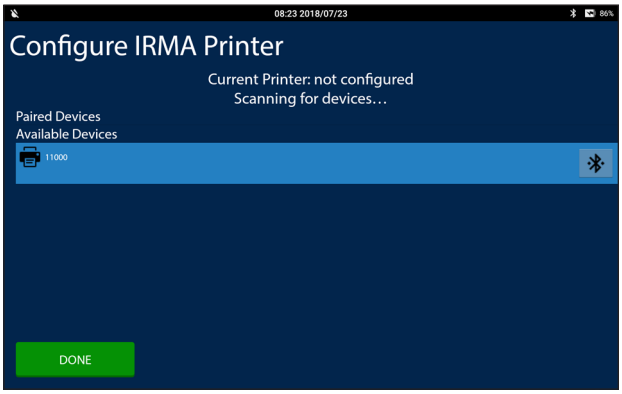
Note: The IRMA Tablet must be assigned to an IRMA Base in order to assign the IRMA Base's printer to the IRMA Tablet.

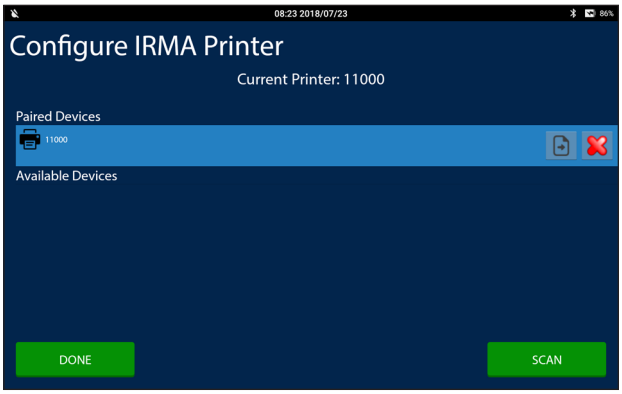
Near the top of the Configure IRMA Printer screen will be displayed Current Printer: and the serial number of the IRMA Printer assigned to the IRMA Tablet. The IRMA Printer and the IRMA Base should have the same serial number. If not configured is displayed instead of an IRMA Printer serial number than the IRMA Tablet is not assigned to an IRMA Printer.



To assign an IRMA Printer:

1. Turn on the IRMA Base. The IRMA Base is on when the white LED next to the Wake Button is solid white. To turn the IRMA Base on:
   - Plug in the AC Power Supply, or
   - Press the Wake button.
2. With the IRMA Base on, press the SCAN button on the IRMA Tablet.
3. A blue ribbon will appear for each IRMA Printer detected. Each ribbon will contain the serial number of the IRMA Printer and a button with a Bluetooth Connect icon (refer to Section 1.10.)
4. Press the BLUETOOTH CONNECT button. A button with a red X will appear in the ribbon. If the red X button does not appear within three seconds press the BLUETOOTH CONNECT button again.
5. A pairing message will appear. Continue to wait until the Set Default message appears. Press the SET DEFAULT button.
6. When the IRMA Tablet is paired with the selected IRMA Printer, the serial number of the IRMA Printer will appear near the top of the screen next to Current Printer: and a white check mark button will appear on the selected base ribbon.
7. If the pairing is unssuccessful, press the DONE button to return to the Device Settings screen. Then repeat this process from step 1.



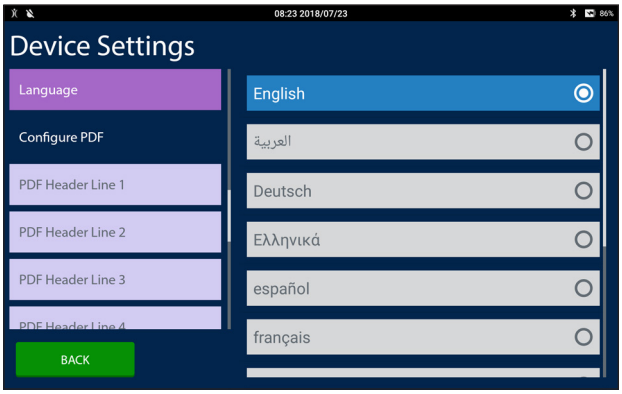


Language

To change the language and number format of the IRMA System select the Language button.

- Select the desired language button from the list.

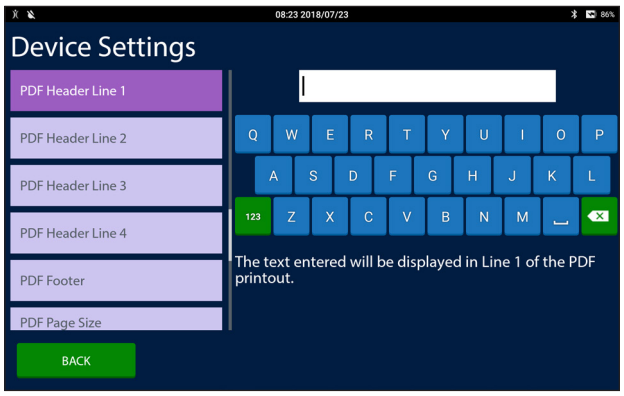
Note: Once the language is selected the IRMA System will display all translated text, including the Setting, Device Settings and Language buttons and the IRMA System User Manual, in the selected language. In the eventuality that the the IRMA System is inadvertantly switched to another language access the User Manual from the LifeHealth website and use the screenshots in it to find the Language button. The order and placement of the buttons will not change with the language, although they will be placed on either the left or right hand side of the screen based on the language selected.



PDF Report Header and Footer

To configure the header and footer included in PDF documents select one of the five PDF Header or Footer buttons.

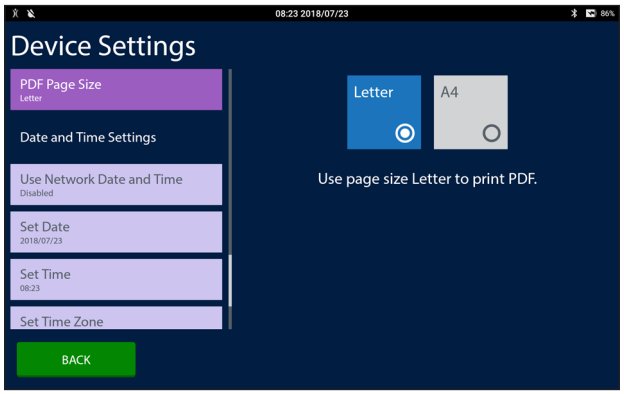
- Use the keyboard to enter text in the text box. The entered text will be displayed in the corresponding line of the PDF report. Pressing the 123 button will display the numeric keyboard.



PDF Page Size

To the page size of PDF documents select the PDF Format Size button.

- **Letter:** PDF documents will be formatted for 8.5 x11 inch paper.
- **A4:** PDF documents will be formatted for A4-sized paper.

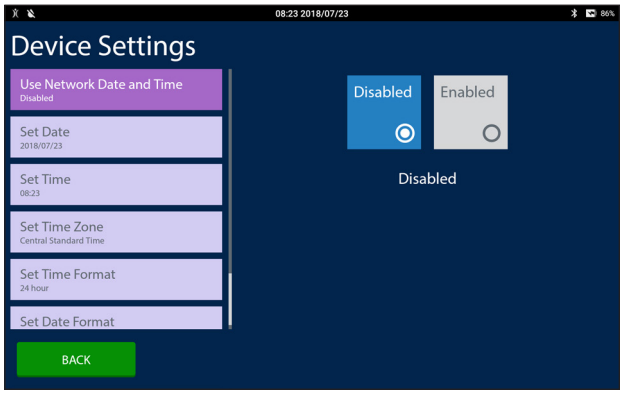


Use Network Date and Time

To configure the IRMA System to automatically adjust its date and time to the network's date and time select the Use Network Date and Time button. There are two options for configuring the whether or not to use the network's date and time:

- **Disabled:** The IRMA System will use its own internally stored and calculated date and time.
- **Enabled:** The IRMA System will attempt to find the network time server and automatically adjust its date and time.

  Note: The IRMA System must have WiFi enabled and be connected to a network, or have the USB-Ethernet adapater plugged into the USB port and a network cable connected for this feature to function properly.

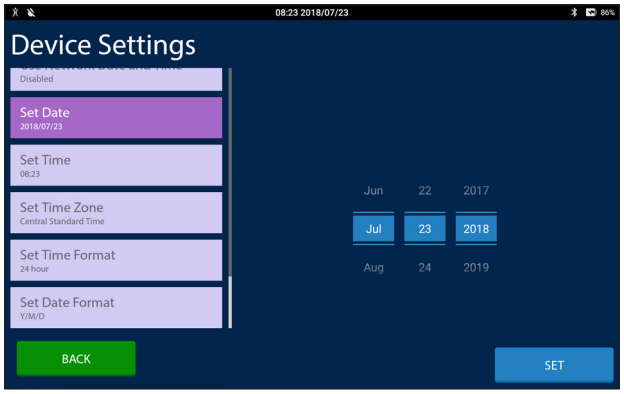


Set Date

To manually set the IRMA System's date select the Set Date button.

- Set the first spinner control to the current month.
- Set the second spinner control to the current date.
- Set the third spinner control to the current year.
- Press the SET button.

  Note: This feature is disabled if Use Network Date and Time is configured to Enabled.

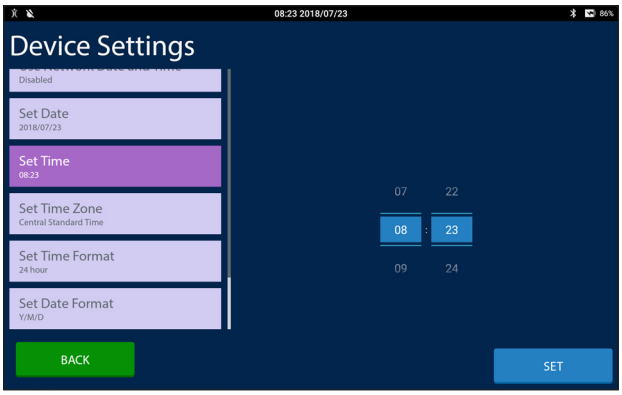


Set Time

To manually set the IRMA System's time select the Set Time button.

- Set the first spinner control to the current hour.
- Set the second spinner control to the current minute.
- If the IRMA System is configured to 12-hour time set the AM/PM spinner to the appropriate value.
- Press the Set button.

  Note: This feature is disabled if Use Network Date and Time is configured to Enabled.

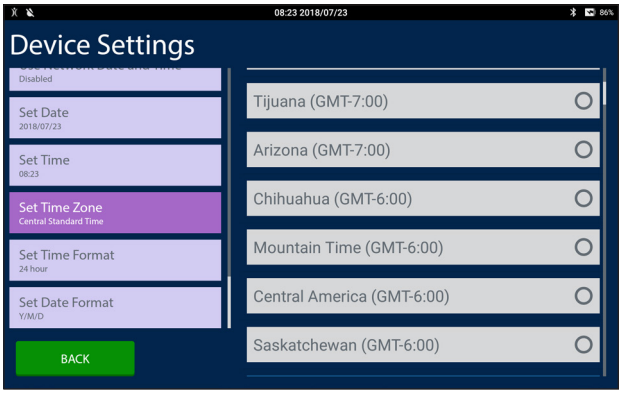


Set Time Zone

To change the time zone select the Set Time Zone button.

- Select the correct time zone from the list.

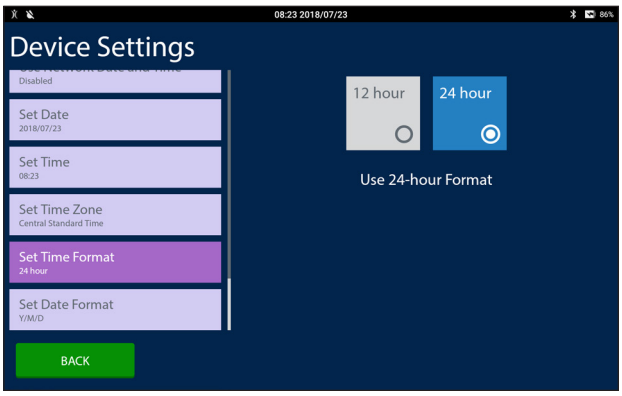
  Note: The time zone is used to determine whether or not the IRMA System automatically adjusts for day light savings time.



Set Time Format

To configure the IRMA System to use either a 24-hour or a 12-hour formatted time select the Set Time Format button. There are two options for Set Time Format:

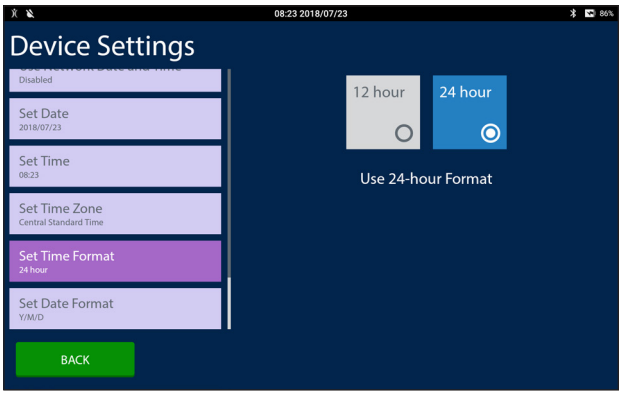
- **12 hour:** The IRMA System will display the time on a 12-hour scale.
- **24 hour:** The IRMA System will display the time on a 24-hour scale.



Set Date Format

To configure the manner in which the IRMA System formats dates select the Set Date Format button. There are three options for Set Date Format:

- **M/D/Y:** The IRMA System will display the date in Month/Day/Year order.
- **D/M/Y:** The IRMA System will display the date in Day/Month/Year order.
- **Y/M/D:** The IRMA System will display the date in Year/Month/Day order.



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Appendix A: Limitations and Safety Precautions

This appendix describes the limitations of the IRMA Blood Analysis System.

A.1 Limitations

Measurements on the IRMA System are accurate and precise, as shown in Appendix D, Performance Characteristics. However, sources of error can arise from improper collection and handling of blood specimens (pre-analytical errors) and certain physiological conditions.

A.2 Common Sources of Sampling Errors

The IRMA System was designed to eliminate many pre-analytical errors associated with testing delays, sample storage, and processing. Analysis errors can arise from improper collection or handling of blood specimens. These errors can be related to phlebotomy technique, heparin type and concentration, speed of syringe fill, inadequate sample mixing, improper storage of sample, and delays in analysis. The CLSI standards are excellent references for sample collection and handling.[1, 2, 3]

The following sources of sampling error should be considered anytime test results are inconsistent with the patient's condition or a previously established trend:

Pre-Analytical Error

- The sample was not analyzed promptly after collection. Glycolysis by leukocytes, platelets, and reticulocytes may cause pCO_2 and ionized calcium values to increase, and pH and pO_2 values to decrease.[4]
- The sample was not collected anaerobically, resulting in room air contamination. pH, pCO_2, pO_2, and ionized calcium values may change due to exposure to room air.[4]
- A sample was improperly stored.
  - Samples chilled prior to analysis may result in falsely elevated potassium values due to potassium leakage from erythrocytes and other cells.[4]
  - Samples for pH and blood gases were not analyzed within 5 minutes of collection, and were stored at room temperature, resulting in value changes.
- Delayed tourniquet release during venipuncture can result in falsely elevated potassium values or dilution effects.
- Hemolysis during sample collection can result in falsely elevated potassium values.
- The sample was drawn in a syringe that is not compatible with the IRMA System. See Section 2, Syringe Requirements.
- The sample was not well-mixed prior to sample analysis.
- The sample was not injected forcefully enough to displace the calibrant.
- Insufficient sample amount.
- Improper injection technique introduced bubbles into the sample path; bubbles were not displaced from the sample path prior to analysis phase.

Effects of Physiological Conditions on Test Results

- Blood from patients receiving certain therapeutic treatments, or with certain physiological conditions, can interfere with the performance of blood sensors. Refer to standard documents such as "Effects of Diseases on Clinical Laboratory Tests"[5] for more information.
- Accuracy of conductivity-based hematocrit measurements are dependent on a specific range of white blood cell count and total protein concentration[6]. Total protein levels may be low in patients on cardiopulmonary bypass, potentially affecting the conductivity of the sample, and therefore, the hematocrit results.[7] When a patient comes off cardiopulmonary bypass, they may still be hemodiluted. Each facility should establish protocols to determine when a patient should be considered to no longer be hemodiluted.
- The calculated total hemoglobin (tHb) is based on assumptions which may not apply to some physiological conditions.[8,9]
- The calculated parameters for TCO_2, $HCO3^-$, BEb, BEecf, tHb, and O_2Sat are based on assumptions which may not apply to some physiological conditions.[5]

- The IRMA System measures electrolyte ion activity, and automatically adjusts electrolyte results to be consistent with results from indirect methods.[10] This adjustment is valid only for an assumed activity coefficient and a typical concentration of plasma water.[9]

A.3 Interferences

Interference studies were based on CLSI document EP7 (3rd edition) and CLSI document EP37 (1st edition.) Serum or whole blood was spiked with potentially interfering substances and tested using the CC cartridge reporting all analytes (pH, pCO_2, pO_2, Na+, K+, iCa and Hct.) The concentrations tested and the observed effects are shown in Table A.1 below.

Table A.1

Interfering Substance	Concentration	Expected Effect
Acetaminophen	1.03 mmol/L	No significant difference in results in comparison to control results.
Acetylsalicylate	167 µmol/L	No significant difference in results in comparison to control results.
Ammonium	151 µmol/L	No significant difference in results in comparison to control results.
Ascorbic Acid	298 µmol/L	No significant difference in results in comparison to control results.
Bicarbonate	28.9 mmol/L	No significant difference in results in comparison to control results.
Bilirubin-Conjugated*	684 µmol/L	No significant difference in results in comparison to control results.
Bilirubin-Unconjugated*	684 µmol/L	No significant difference in results in comparison to control results.
Bromide	37.5 mmol/L	pH: No significant difference in results in comparison to control results.
		pCO_2: Bromide exhibits no significant effect up to 18.8 mmol/L at a pCO2 of 33.9 mmHg. At 37.5 mmol/L bromide was shown to bias the pCO2 measurement by -5.8 mmHg.
		pO_2: Bromide exhibits effects on pO2 at all measured levels from 9.4 mmol/L to 37.5 mmol/L at a pO2 of 88.7 mmHg. At 37.5 mmol/L bromide was shown to bias the pO2 measurement by +112 mmHg.
		Na+: Bromide exhibits no significant effect up to 9.4 mmol/L at a sodium concentration of 140 mmol/L. At 37.5 mmol/L bromide was shown to bias the sodium measurement by +10.2 mmol/L
		K+: No significant difference in results in comparison to control results.
		iCa: Bromide exhibits no effect up to 9.4 mmol/L at an ionized calcium concentration of 1.14 mmol/L. At 37.5 mmol/L bromide was shown to bias the ionized calcium measurement by +0.63 mmol/L
		Hct: Bromide exhibits an effect on hematocrit at all tested concentrations from 9.4 to 37.5 mmol/L at a packed cell volume (PCV) of 36.2%. At 37.5 mmol/L bromide was shown to bias the hematocrit measurement by -12.0%.
Calcium Chloride	4.5 mmol/L	No significant difference in results in comparison to control results.
Cholesterol	10.3 mmol/L	No significant difference in results in comparison to control results.
Cysteine	920 µmol/L	No significant difference in results in comparison to control results.
Ethanol	130 mmol/L	No significant difference in results in comparison to control results.
γ-Globulins*	7.5 g/dL	No significant difference in results in comparison to control results.
Halothane	3.95 mmol/L	No significant difference in results in comparison to control results.
Hematocrit	20%	No significant difference in results in comparison to control results.
Hematocrit	60%	No significant difference in results in comparison to control results.
Li-Heparin	3300 Units/L	No significant difference in results in comparison to control results.
ß-Hyroxybutyrate	20 mmol/L	No significant difference in results in comparison to control results.
Ibuprofen	1.06 mmol/L	No significant difference in results in comparison to control results.
Iodide	37.5 mmol/L	No significant difference in results in comparison to control results.
Lactate	10 mmol/L	No significant difference in results in comparison to control results.
Lipids*	Baseline + 1500 mg/dL	No significant difference in results in comparison to control results.
Lithium	3.2 mmol/L	No significant difference in results in comparison to control results.
Oxalate	90 µmol/L	No significant difference in results in comparison to control results.

Interfering Substance	Concentration	Expected Effect
PCO_2	104 mmHg CO_2 via Tonometry	No significant difference in results in comparison to control results.
Potassium Chloride	7 mmol/L	No significant difference in results in comparison to control results.
pH	pH 7.6 via Tonometry	No significant difference in results in comparison to control results.
Phosphate	3.9 mmol/L	No significant difference in results in comparison to control results.
Propofol	269 µmol/L	No significant difference in results in comparison to control results.
Salicylic Acid	207 µmol/L	No significant difference in results in comparison to control results.
Sodium Chloride	180 mmol/L	No significant difference in results in comparison to control results.
Uric Acid	1.4 mmol/L	No significant difference in results in comparison to control results.

* denotes use of plasma in lieu of whole blood

A.4 Safety Precautions for Blood Handling

- Use generally accepted techniques for collecting and handling blood.
- Both the cartridge and the collection device should be considered biohazardous waste and disposed of in accordance with established guidelines for your facility.
- The collection device and cartridge may have to be separated before disposal if small medical waste containers are used.

A.5 Other Safety Precautions

- Do not immerse the IRMA Analyzer, AC power supply, or IRMA Tablet in water or any other liquid.
- Use only the battery specified in Section B.1 with the IRMA Analyzer.
- Do not operate the AC power supply if the power cord or plug is damaged.
- Prevent liquid cleaning solution from entering the IRMA Analyzer battery or printer compartment.
- If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

A.6 References

1. Clinical Laboratory Standards Institute (CLSI): Procedures for the Collection of Arterial Blood Samples, Document GP43-A4, (2004).
2. Clinical Laboratory Standards Institute(CLSI): Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture, Document GP41-A6, (2004).
3. Clinical Laboratory Standards Institute (CLSI): Protection of Laboratory Workers from Occupationally Acquired Infections, Document M29-A4, (2014).
4. Burtis, C.A., Ashwood, E.R., and Bruns, D.E., eds., Tietz Fundamentals of Clinical Chemistry, 6th ed., Elsevier Saunders, Philadelphia, PA (2004).
5. Young, D.S., "Effects of diseases on clinical laboratory tests", Clinical Chemistry 1980, 6:4.
6. McMahon et. al., " A Comparison of Conductivity-Based Hematocrit Determinations With Conventional Laboratory Methods in Autologous Blood Transfusions", ANESTH ANALG, 1990;71:541-4.
7. Riley JB, Burgess BM, Smith CA, Crowley JC, Soronen SW: "In vitro measurement of the accuracy of a new patient side blood gas, pH, hematocrit and electrolyte monitor", J Extra Corpor Technol 19(3):322-329, 1987.
8. McPherson, R.A. and Pincus, M.R, eds., Henry's Clinical Diagnosis and Management by Laboratory Methods, 22nd ed., Elsevier Saunders, Philadelphia, PA (2011).
9. Oesch et. al., "Ion-Selective Electrodes for Clinical Use", Clinical Chemistry, 1986, vol 32, no 8, p.1448
10. Maas et. al., "Ion Selective Electrodes for Sodium and Potassium: A New Problem of What is Measured and What Should be Reported", Clinical Chemistry, Vol 31, no. 3, 1985 p 482.

Appendix B: Specifications and Cartridge Information

This appendix includes the IRMA System specifications and IRMA cartridge information.

B.1 IRMA System Specifications

Table B.1

IRMA System	
Operating Temperature	12 - 30°C (54-86°F)
Cartridge Measurement Temperature	37°C
System Shipping/Storage Temperature	0 - 50°C
Operating Relative Humidity	5 - 85% (non-condensing)
Operating Barometric Pressure	350 - 900 mmHg (measured by onboard barometers)
Analysis Time	30 to 120 seconds after sample injection depending on parameters
Water Ingress	IPX0
Compliance	See Section B3

IRMA Cartridge	
Dimensions	2.6 x 1.3 x 0.6 inches, 66 x 33 x 15.24 mm
Weight	5 - 7 oz., 15 - 21 g
Sample Size	0.125 - 3.0 mL

IRMA Base	
Dimensions	10.3 x 9.0 x 2.7 inches 261.6 x 228.6 x 68.6 mm
Weight (Without IRMA Tablet installed)	53 oz, 3.5 lbs 1500 g
Operation	AC Power Supply or Battery
DC Input	12 VDC, 5.0 Amps
Ports	1 USB 2.0
Bluetooth	V2.1 + EDR Class 2
Wireless Frequency Range & Power	2402 - 2480 MHz, 2mW
Modulation Type	FHSS, GFSK, P/4 DQPSK, 8DPSK
Security	Secure Simple Pairing (SSP); 128-bit encryption
Compliance FCC	Contains FCC ID: QOQWT12 Contains IC: 5123A-BGTWT12A

IRMA Base Battery	
Model	RRC2057 Lithium Ion
Time to Recharge	< 7 hours
Capacity	7.5 V, 6400 mAH
Compliance:	UL2054, IEC62133, UN38.3

Table B.1 Continued

IRMA Tablet	
Dimensions	9.9 x 0.7 x 5.8 inches 251.5 x 18 x 147 mm
Weight	20 oz. 570 g
DC Input (from Base):	5 VDC, 2 Amps
Model	Nvidia, Shield K1 Tablet
Display	8 inch, 1920 x 1200 touch HD display
Wireless	802.11n 2x2 MIMO 2.4 GHz and 5GHz Wi-Fi, Bluetooth 4.0 LE
Wireless Frequency Ranges & Power	2402 - 2480 MHz, 2.412 - 2.462 GHz, 5.180 - 5.240 GHz & 5.745 - 5.825 GHz, 252mW
Modulation Type	CCK, OFDM, FHSS
Security	WPA/WPA2
Battery	3.8 V, 5100 mAH
Compliance FCC	FCC ID: VOB-P1761WX (P/N 940-81761-2500-xxx WIFI). CONTAINS FCC ID: VOB-E1729 (P/N 940-81761-2500-xxx LTE)

IRMA AC/DC Converter	
Model	SLPower Electronics, ME60A1203F01
Dimensions	4.2 x 2.6 x 1.3 inches 106.7 x 66 x 33 mm
Weight	14.3 oz. 400 g
Input	100 - 240 VAC, 1.5 Amps, 50 - 60 Hz
Output	12 VDC, 5 Amps
Compliance EMC	UL/EN/IEC60601-1-2, 4th edition, EN55011/CISPR11, FCC Part 15.109 Class B Conducted & Radiated Emissions
Compliance Safety	IEC 60601-1(ed.3) for Safety
CB Scheme	E302267-D1010-1-CB issued on 2015-10-02
Energy Compliance	DoE Efficiency Level VI
Power Cord	IEC 320 C13

B.2 Device Disposal - At End of Useful Life

The IRMA System and accessories may be returned to LifeHealth. Lithium ion (Li-ion) batteries should be disposed of in accordance with the local, state, or federal regulations where they are used. Contact your local government for disposal practices in your area. Recycling options available in your local area should be considered when disposing of this product or batteries may be returned to LifeHealth for recycling. Comply with international shipping regulations for lithium batteries.

B.3 Directives, Safety, Emissions, and Immunity

The IRMA System complies with the following directives, safety standards and requirements:

Table B.2

Document Identifier	Document Description
2011/65/EU	RoHS Directive
2014/30/EU	EMC Directive
2014/35/EU	Low Voltage Directive
2014/53/EU	RED Directive

Table B.2 Continued

Document Identifier	Document Description
EN 61326-1:2013 IEC 61326-1:2012	Electrical equipment for the measurement, control and Laboratory use - EMC Requirements, Part 1: General Requirements
EN 55011:2009 +A1:2010 (CISPR 11:2009/a1:2010)	Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement
IEC 61010-1:2010	Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 1: General Requirements
IEC 61010-2-010:2014	Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials.
EN 60950-1:2006 + A11:2009 + A1:2010 + A12:2011	Information Technology Equipment - Safety - Part 1: General Requirements
EN 62311:2008	Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0 Hz - 300 GHz)
EN 300 328-1 V2.1.1	Wideband Transmission Systems: Data transmission equipment operating in the 2.4 GHz ISM band and using wide band modulation techniques; Harmonized Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU
EN 300 440-1 V1.6.1	Electromagnetic compatibility and Radio spectrum Matters (ERM); Short range devices; Radio equipment to be used in the 1 GHz to 40 GHz frequency range; Part 1: Technical characteristics and test methods
EN 300 440-2 V1.4.1	Electromagnetic compatibility and Radio spectrum Matters (ERM); Short range devices; Radio equipment to be used in the 1 GHz to 40 GHz frequency range; Part 2: Harmonized EN covering essential requirements of article 3.2 of the R&TTE Directive
EN 301 489-1 V1.9.2	Electromagnetic compatibility and Radio spectrum Matters (ERM); Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common Technical Requirements
EN 301 489-3 V1.5.1	Electromagnetic compatibility and Radio spectrum Matters (ERM); Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 3: Specific conditions for Short-Range Devices (SRD) operating on frequencies between 9 kHz and 246 GHz
EN 301 489-17 V2.1.1	Electromagnetic compatibility and Radio spectrum Matters (ERM); Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems
EN 301 893 V2.1.1	5 GHz RLAN; Harmonized Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU
ICES-001, Issue 4:2006	Industrial, Scientific and Medical (ISM) Radio Frequency Generators
FCC Part 15 Subpart B	Radio Frequency Devices
FCC 47 CFR Part 2 Subpart J	Equipment Authorization Procedures. Section 2.1093 Radiofrequency Radiation Exposure Evaluation: Portable Devices.
VCCI V-3/2015.04	Voluntary Control Council for Interference by Information Technology Equipment
ANSI C63.27:2017	American National Standard for Evaluation of Wireless Coexistence as per AAMI TIR69:2017, Risk management of radio-frequency wireless coexistence for medical devices and systems.

Wireless QoS & Range Requirements

QoS: None. Best-effort delivery service is sufficient.

Range: 20 meters line of site.

Wireless Security Recommendations

It is recommended that the IRMA System only be connected to networks employing the WPA or WPA2 protocol.

Simplified DoC

Hereby, EasyDx, Inc. doing business as LifeHealth, declares that the radio equipment type, a Bluetooth module and a 802.11a/b/g/n WLAN + BT, is in compliance with Directive 2014/53/EU. The full text of the EU declaration of conformity is availabe at the following address: www.lifehealthmed.com.

Warnings and Precautions:

- Do not use this instrument in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these may interfere with proper operation.
- Degree of Safety of Application in the Presence of Flammable Anesthetic Mixture With Air, Oxygen or Nitrous Oxide: The IRMA System is not approved for use in oxygen enriched atmospheres.
- It is LifeHealth's responsibility to provide electromagnetic compatibility information to the customer or users. It is the user's responsibility to ensure that a compatible electromagnetic environment for the instrument can be maintained so that the device will perform as intended.
- The electromagnetic environment should be evaluated prior to operation of the IRMA System.
- Use of the IRMA System in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets, etc.) may cause damaging electrostatic discharges that may cause erroneous results.
- Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner.
- If this device is to be operated in the 5.15 - 5.25 GHz frequency range, it is restricted to indoor environments only.

B.4 Symbol Definition

Definitions for the symbols that appear on the IRMA product labels are shown in Table B.3.

Table B.3

Symbol	Title	Description	Standard:Section Number
REF	Catalog Number	Indicates the manufacturer's catalogue number so that the medical device can be identified	ISO15223-1-2012:5.1.6
IVD	In vitro diagnostic medical device	Indicates a medical device that is intended to be used as an in vitro diagnostic medical device	ISO15223-1-2012:5.5.1
FC	This device complies with Part 15 of the Federal Communication Commission rules	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	See Table B.1 for FCC references
⚠	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself	ISO15223-1-2012:5.4.4
	Manufacturer	Indicates the medical device manufacturer	ISO15223-1-2012:5.1.1
	Symbol for the marking of electrical and electronic equipment	The symbol indicating separate collection for electrical and electronic equipment consists of the crossed-out wheelie bin	2012/19/EU:Annex IX
TÜV	TUV Certification Symbol	This product underwent electrical performance testing by TUV	Licensed by TUV America
EC REP	Authorized representative in the european community	Indicates the authorized representative in the European community	ISO15223-1-2012:5.1.2

Symbol	Title	Description	Standard:Section Number
TQC	Temperature Cartridge	Package label for the IRMA LH temperature verification cartridge, used when performing a TQC test	NA
CE	CE Marking	European commission declaration of conformity	93/68/EEC:8.0
- +	Polarity of DC power connector	To identify the positive and negative connections (the polarity) of a d.c. power supply	IEC60417/ ISO7000:5926
	Temperature Limit	Indicates the temperature limits to which the medical device can be safely exposed	ISO15223-1-2012:5.3.7

B.5 Patents

The IRMA Blood Analysis System is manufactured under one or more of the following patents: 5,232,667, 6,066,243 and 9,825,384.

The IRMA cartridges are manufactured under one or more of the following patents: 5,223,433; 5,325,853; 5,384,031; 5,781,024; D351,913; 5,968,329.

Other patents are pending.

B.6 Cartridge/Analyte Configurations

The IRMA cartridges are available in the following analyte configurations:

Table B.4

Cartridge	Measured	Calculated
BG	pH, pCO_2, pO_2	HCO_3^-, TCO_2, BEb, BEecf, O_2Sat
CC	pH, pCO_2, pO_2, Hct, Na^+, K^+, iCa	HCO_3^-, TCO_2, BEb, BEecf, O_2Sat, tHb, iCa(N)
H3	Hct, Na^+, K^+, iCa	tHb

B.7 Cartridge Storage and Equilibration Times

Following removal from their shipping container, the IRMA cartridges must equilibrate to their storage environment prior to use (refer to Section 1.7). Equilibration times depend on the product type as follows:

Table B.5

Cartridge	Equilibration Time (Hours)	Storage Temperature	Warm-up Time (Minutes)*
BG	72	15 - 30°C (59 - 86°F)	None
CC	72	15 - 30°C (59 - 86°F)	None
H3	1	15 - 30°C (59 - 86°F)	None

B.8 Reportable Ranges

The default reportable ranges* for each parameter are shown in Table B.6.

Table B.6

Parameter	Measured	Parameter	Calculated
pH	6.000 - 8.000 pH units	HCO_3^-	0 - 99.9 mmol/L
pCO_2	4.0 - 200.0 mmHg (0.53 - 26.66 kPa)	TCO_2	0 - 99.9 mmol/L
pO_2	20.0 - 700.0 mmHg (2.67 - 93.33 kPa)	Beb	±99.9 mmol/L
Hct	10.0 - 80.0 % (.100 - .800 SI)	Beecf	±99.9 mmol/L
Na^+	80.0 - 200.0 (mmol/L , mEq/L)	O_2Sat	0 - 100%
K^+	1.00 - 20.00 (mmol/L , mEq/L)	tHb	3.4 - 27.2 g/dL (2.1 - 16.9 mmol/L)

Table B.6 continued

Parameter	Measured	Parameter	Calculated
iCa	0.20 - 5.00 mmol/L (0.80 - 20.04 mg/dL; 0.40 - 10.00 mEq/L)	iCa(N)	0.20 - 5.00 mmol/L (0.80 - 20.04 mg/dL; 0.40 - 10.00 mEq/L)

B.9 Display Resolution

The display resolution* for each parameter is shown in Table B.7.

Table B.7

Parameter	Measured	Parameter	Calculated
pH	0.001 **pH units**	HCO_3^-	0.1 **mmol/L**
pCO_2	0.1 **mmHg** (0.01 kPa)	TCO_2	0.1 **mmol/L**
pO_2	0.1 **mmHg** (0.01 kPa)	Beb	0.1 **mmol/L**
Hct	0.1**%** (0.001 SI)	Beecf	0.1 **mmol/L**
Na^+	0.1 (**mmol/L** , mEq/L)	O_2Sat	0.1%
K^+	0.01 (**mmol/L** , mEq/L)	tHb	0.1 (**mmol/L** , g/dL)
iCa	0.01 (**mmol/L** , mEq/L, mg/dL)	iCa(N)	0.1 (**mmol/L** , mEq/L, mg/dL)

* Default display units are bolded.

B.10 Correlation Factor Limits

Refer to Section 8.7 for a description of the correlation feature and instructions. Correlation factors must be within the limits shown in Table B.8.

Table B.8

Parameter	Slope	Intercept
Hematocrit	0 to 10.000	-999.00 to +999.00 (%) -9.9900 to +9.9900 SI

B.11 Reference Values

While published values represent the general population, each laboratory should establish its own "normal" values which reflect the local patient population and equipment used at the site. The following published ranges should only serve as a guide.[1,2]

Table B.9

Measured Parameter	Reference Range	Notes
pH	7.35-7.45 (arterial)[1] 7.32-7.43 (venous)[1]	
pCO_2	35-48 mmHg/4.7-6.4 kPa (arterial)[1] 41-55 mmHg/5.5-7.3 kPa (venous)[1]	
pO_2	83-108 mmHg/11.1-14.4 kPa (arterial)[1]	
Na^+	136-145 mmol/L or mEq/L[1]	
K^+	3.5-5.1 mmol/L or mEq/L[1]	
iCa	1.15-1.27 mmol/L (2.30-2.54 mEq/L) (4.60-5.08 mg/dL)[1]	
Hematocrit	32-42% (2-6 years); 33-45% (6-14 years)[1] 39-51% (adult male); 35-47% (adult female)[1]	

Table B.9

Calculated Parameter	Reference Range	Notes
HCO_3^-	22-26 mmol/L (arterial)[1]; 21-28 mmol/L (venous)[3]	
TCO_2	19-24 mmol/L (arterial)[1]; 22-29 mmol/L (venous) [3]	

Table B.9 continued

Calculated Parameter	Reference Range	Notes
BE	(-2) - (+3) mmol/L (arterial or venous)[1]	
O_2Sat	94-98% (arterial)[1]; 60-85% (venous)[2]	
tHb	11.0-14.5 g/dL or 6.9-9.1 mmol/L (2-9 years)[1] 12.0-15.0 g/dL or 7.5-9.4 mmol/L (9-12 years)[1] 11.7-17.4 g/dL or 7.4-10.9 mmol/L (12-74 years, male)[1] 11.5-16.1 g/dL or 7.2-10.1 mmol/L (12-74 years, female)[1]	

B.12 Wireless Coexistence

The minimum distance from a Bluetooth transmitter is shown in Table B.10

Table B.10

Transmitter Power	Distance from IRMA Tablet	Distance from IRMA Base
100 mW	9.06 inches (230 mm)	3.94 inches (100 mm)
10 mW	2.76 inches (70 mm)	1.18 inches (30 mm)

B.13 References

1. Tietz NW, Clinical Guide to Laboratory Tests, 4th ed., 1995.
2. Wallach J, Interpretation of Diagnostic Tests - A Handbook Synopsis of Laboratory Medicine, 3rd ed., 1978.
3. Tietz NW, Fundamentals of Clinical Chemistry, 5th ed., 2001.
4. Coresh J, Astor B, Greene T, Eknoyan G, Levey A, Prevalence of chronic kidney disease and decreased kidney function in the adult US population: Third national health and nutrition examination survey. Am J of Kidney Disease, 41 (1) 1-12.

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Appendix C: Principles of Operation

This appendix describes the measurement technology of the IRMA Blood Analysis System.

C.1 Measurement Technology

The IRMA System utilizes potentiometric, amperometric, and conductimetric measurement methodologies to measure the analyte concentration in whole blood as described below:

Table C.1

Sensor	Measurement Technology
Reference	Silver/silver chloride electrode
pH, pCO_2, Na^+, K^+, iCa	Potentiometric measurement utilizing ion specific electrode (ISE) technology[12]
pO_2	Amperometric measurement based on the principles of the Clark electrode[11]
Hematocrit	Conductimetric measurement

Potentiometric Measurements

The IRMA potentiometric sensors generate a voltage which is related to ion concentration according to the Nernst equation:

$E = E° + S \log (C1/C2)$

- E is the voltage generated
- E° is a constant for the sensor
- S is the sensitivity of the sensor
- C1 and C2 are the ion activities outside and inside the sensor membrane.

Amperometric Measurements

The IRMA System amperometric sensors generate a current which is related to analyte concentration according to the relationship:

$i = S (C) + B$

- i is the current generated
- C is the analyte concentration or partial pressure of the test sample
- B is the current generated in the absence of the analyte

Conductimetric Measurements

The IRMA System determines hematocrit based on electrical conductivity, which is related to hematocrit in whole blood:

$\% \text{ hematocrit} = f (1 / \Omega)$

- Ω = sample resistance
- Conductivity = $1 / \Omega$

C.2 Calculated Parameters

Other parameters can be calculated by the IRMA System based on the measured values of a blood sample. Refer to Appendix B, Table B- 8 for the list of calculated parameters reported by the IRMA System. The following equations are used to calculate each of the parameters:

Bicarbonate [1,9]

Two formulas are available for the calculation of bicarbonate: Severinghaus/NCCLS or Siggaard-Andersen. Refer to Section 8.8 for instructions on formula selection.

- Severinghaus/NCCLS formula is based on the Henderson Hasselbach equation: $[HCO3^-] = 0.0307 \times pCO_2 \times 10^{(pH-6.1)}$
- Siggaard-Andersen formula: $[HCO3^-] = 0.230 \times pCO_2 \times \text{antilog}(pH-pKp)$ where $pKp = 6.125-\lg\{1 + \text{antilog}(pH-8.7)\}$

Total Carbon Dioxide [1,9]

Total carbon dioxide, [TCO_2], is the sum of bicarbonate and dissolved CO_2: $TCO_2 = [H_2CO_3] + [HCO3^-]$

- Severinghaus/NCCLS Bicarbonate formula: $[H_2CO_3] = 0.0307 \times pCO_2$ or $TCO_2 = 0.0307 \times pCO_2 + [HCO3^-]$
- Siggaard-Andersen Bicarbonate formula: $[H_2CO_3] = 0.230 \times pCO_2$ or $TCO_2 = 0.230 \times pCO_2 + [HCO3^-]$

Base Excess of Blood [2,10]

Base excess of blood (BEb), also called in vitro or actual base excess, is the difference in concentration of strong base in whole blood and in the same blood titrated with strong acid or base to pH=7.40/pCO_2=5.33kPa at 37°C.

Two formulas are available for the calculation of base excess: Severinghaus/NCCLS or Siggaard-Andersen. Refer to Section 8.8 for instructions on formula selection.

- Severinghaus/NCCLS formula: $BEb = (1-0.014 \times Hb)\,[HCO3^- - 24.8 + (1.43 \times Hb + 7.7)(pH-7.4)]$ where Hb is the hemoglobin value entered
- Siggaard-Andersen formula: $BEb = 0.5\left(\frac{8a'-0.919}{a'}\right) + 0.5\left[\left(\frac{0.919-8a'}{a'}\right)^2 - 4\left(\frac{24.47- HCO3^- \{5.33\}}{a'}\right)\right]^{1/2}$
  - $a' = 0.00404 + 0.000425 \times Hb$
  - $HCO3^-\,(5.33) = 0.230 \times 5.33 \times \text{antilog}[(pH(st) - 6.161) / 0.9524]$
  - $pH(st) = pH + lg(5.33 / pCO_2) \times [pH(Hb) - pH] / [lg(pCO_2\,(Hb)) - lg(7.5006 \times pCO_2)]$
  - $pH(Hb) = 0.0406 \times Hb + 5.980 - 1.920 \times \text{antilog}(-0.16169 \times Hb)$
  - $lg(pCO_2\,(Hb)) = -0.017674 \times Hb + 3.4046 + 2.12 \times \text{antilog}(-0.15158 \times Hb)$

Base Excess of Extracellular Fluid [4,9]

Base excess of extracellular fluid (BEecf), also called in vivo base excess, or standard base excess, is a quantity that reflects only the non-respiratory component of pH disturbances. Two formulas are available for the calculation of base excess: Severinghaus/NCCLS or Siggaard-Andersen. Refer to Section 8.8 for instructions on formula selection.

- Severinghaus/NCCLS formula: $BEecf = [HCO3^-] - 24.8 + 16.2(pH - 7.4)$
- Siggaard-Andersen formula: BEecf = BEb for Hb = 3 mmol/L

Oxygen Saturation [5]

Oxygen saturation (O_2Sat) is the amount of oxyhemoglobin in a solution expressed as a fraction of the total amount of hemoglobin able to bind oxygen (oxyhemoglobin plus deoxyhemoglobin). The IRMA System calculates oxygen saturation from a measured pO_2 and an assumed oxyhemoglobin dissociation curve. These results differ significantly from direct measurement. Clinically significant errors can result from incorporation of this calculated value in further calculations, such as shunt fraction, or by assuming that the value obtained is equivalent to the oxyhemoglobin fraction.

$$O_2Sat = \frac{100\,[(pO_2')^4 - 67.07(pO_2')^3 + 2121(pO_2')^2 - 8532 \times pO_2']}{[(pO_2')^4 - 67.07(pO_2')^3 + 2396(pO_2')^2 - 31350 \times pO_2' + 936000]}$$

where $pO_2' = pO_2 \times 10^{[0.48(pH - 7.4)]}$

Total Hemoglobin

Total Hemoglobin (tHb) is estimated from % hematocrit using the following equation:

tHb (g/dL) = % Hct x MCHC /100

- MCHC, Mean Corpuscular Hemoglobin Concentration, is assumed to be 34 g/dL.
- $tHb(mmol/L) = \frac{tHb(g/dL)}{1.6114}$

pH Normalized Ionized Calcium

pH Normalized iCa results can be reported for pH values between 7.2 and 7.6. pH Normalized iCa results represent the iCa result normalized to a pH value of 7.400 using the following equation: iCa(N) = iCa(1 - [0.53 x (7.4 - pH)])

Patient Temperature Correction [5,6, 7,8]

Patient temperature can be entered into the IRMA System if it deviates from 37°C. The measured pH and blood gas values are recalculated at the input temperature (T) using either the Severinghaus or Kelman-Nunn equation. Refer to Section 8.8 for instructions on formula selection.

$pH_{(T)} = pH_{(37°C)} - 0.0147(T-37) + 0.0065(7.40 - pH_{(37°C)})(T-37)$

$pCO_{2(T)} = pCO_{2(37°C)} \times 10^{(0.019\{T-37\})}$

Severinghaus pO_2 equation:

- $pO_{2Final} = pO_2 * 10^{\left\{\left[\frac{5.49*10^{-11}*pO_2^{3.88}+0.071}{9.72*10^{-9}*pO_2^{3.88}+2.30}\right](\Delta\,Temp)\right\}}$
- Δ Temp is T-37°

Kelman-Nunn pO_2 equation: $pO_{2Final} = pO_2 \times 10^{[\{0.0052 + 0.027(1-10^{\wedge}-0.13(100-O_2Sat))\}(\Delta\,Temp)]}$

- Δ Temp is T-37°

C.3 References

1. National Committee for Clinical Laboratory Standards (NCCLS): Vol. 14 No. 11, Section 5.5 (C12-A, 9/94), equations 6, 7, 9.
2. National Committee for Clinical Laboratory Standards (NCCLS): Vol. 14 No. 11, Section 5.9 (C12-A, 9/94), equation 15.
3. National Committee for Clinical Laboratory Standards (NCCLS): Vol. 14 No. 11, Section 5.8 (C12-A, 9/94), equation 14.
4. Burnett and Noonan, Clinical Chemistry, 20/12, 1499-1506 (1974).
5. National Committee for Clinical Laboratory Standards (NCCLS): Vol. 14 No. 11, Section 6.0 (C12-A, 9/94), equation 23.
6. National Committee for Clinical Laboratory Standards (NCCLS): Vol. 14 No. 11, Section 6.0 (C12-A, 9/94), equation 24.
7. National Committee for Clinical Laboratory Standards (NCCLS): Vol. 14 No. 11, Section 6.0 (C12-A, 9/94), equation 25.
8. Kelman GR, Nunn JF, J Appl Physiol 1966; Vol. 21, 1484-1490.
9. Siggaard-Andersen O., Wimberley P.D., Fogh-Andersen N., Gothgen I.H., "Measured and Derived Quantities with Modern pH and Blood Gas Equipment: Calculation Algorithms with 54 Equations", in Scandinavian Journal of Clinical & Laboratory Investigation, 48: Suppl 189:7-15.
10. Siggaard-Andersen O., The Acid-Base Status of the Blood, 4th ed., 1974.
11. Malley WJ, Clinical Blood Gases-Application and Noninvasive Alternatives, 1st ed., 1990.
12. Anderson SC, Cockayne S, Clinical Chemistry-Concepts and Applications, 1st ed., 1993.

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Appendix D: Performance Characteristics

This appendix describes the accuracy and precision of the IRMA Blood Analysis System. Results shown below are a sampling of the findings of performance testing. Greater details are available upon request.

D.1 Accuracy

CLSI Document, EP09-A3: Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline-Third Edition, was utilized. Whole blood samples were measured internally using an IRMA LH analyzer and an IRMA TRU-POINT analyzer. In order to increase the tested range 20% of samples were altered by blood gas tonometry, spiking with electrolytes, or changing plasma concentration. The following table shows statistics for each parameter:

Table D.1

Analyte	Tested (Reportable) Range	Number of Samples	Passing - Bablock Regression		Bland-Altman Distribution Results	
			Slope	Intercept	$S_{y.x}$ Std Error of Mean	Mean Bias
pH	7.073 - 7.660 (6.000 - 8.000)	40	1.046	-0.335	0.005	0.006
pCO_2 mmHg	14.5 - 111.1 (4.0 - 200.0)	40	1.038	-1.999	0.380	-0.023
pO_2 mmHg	39.0 - 210.1 (20.0 - 700.0)	40	1.003	-0.129	0.735	0.193
Sodium (Na^+) mmol/L	90.6 - 149.2 (80.0 - 200.0)	40	0.988	0.950	0.315	-0.145
Potassium (K^+) mmol/L	1.17 - 13.57 (1.00 - 20.00)	40	0.988	0.033	0.036	-0.054
Ionized Calcium (iCa) mmol/L	1.23 - 4.18 (0.20 - 5.00)	40	1.022	-0.040	0.016	0.018
Hematocrit (Hct) %	10.6 - 68.7 (10.0 - 80.0)	40	1.048	-2.490	0.303	0.743

D.2 Precision

In accordance with CLSI EP05-A3: Evaluation of Precision of Quantitative Measurement Methods; Approved Guideline-Third Edition, reproducibility was evaluated using the Multi-site protocol, 3 x 5 x 5 (3 sites, 5 days, 5 replicates per day). One site was LifeHealth, the other two sites were external sites. Analysis was performed using two way ANOVA.

Samples consisted of three levels of aqueous quality control solution for all analytes (QC623 Level 1, Level 2 and Level 3 manufactured by RNA Medical, Devens, Massachusetts) with the exception of hematocrit which had 2 levels (QC900 Level 1 and 2 manufactured by RNA Medical, Devens, Massachusetts).

Estimates of variance are expressed as SD and %CV for repeatability, within-laboratory, and reproducibility.

Table D.2

Analyte	Number of Samples	Mean	Repeatability		Within Lab Precision		Reproducibility	
			SD	%CV	SD	%CV	SD	%CV
Level 1								
pH	75	7.157	0.007	0.092	0.007	0.094	0.007	0.094
pCO_2 mmHg	75	75.6	1.154	1.527	1.221	1.616	1.231	1.629
pO_2 mmHg	75	72.3	3.572	4.939	3.894	5.383	3.894	5.383
Sodium (Na^+) mmol/L	75	114.4	0.725	0.634	0.727	0.636	0.729	0.637
Potassium (K^+) mmol/L	75	2.00	0.013	0.674	0.014	0.680	0.014	0.688
Ionized Calcium (iCa) mmol/L	75	1.40	0.015	1.040	0.015	1.102	0.015	1.102
Hematocrit (Hct) %	75	23.7	0.364	1.533	0.364	1.533	0.407	1.715

Analyte	Number of Samples	Mean	Repeatability		Within Lab Precision		Reproducibility	
			SD	%CV	SD	%CV	SD	%CV
Level 2								
pH	75	7.432	0.008	0.108	0.008	0.108	0.008	0.111
pCO_2 mmHg	75	44.0	1.007	2.290	1.027	2.336	1.060	2.412
pO_2 mmHg	75	112.0	4.004	3.575	4.004	3.575	4.012	3.582
Sodium (Na^+) mmol/L	75	135.8	1.036	0.763	1.058	0.779	1.092	0.804
Potassium (K^+) mmol/L	75	4.44	0.035	0.779	0.035	0.779	0.037	0.833
Ionized Calcium (iCa) mmol/L	75	1.09	0.011	0.986	0.011	1.055	0.011	1.055
Hematocrit (Hct) %	75	47.0	0.250	0.532	0.250	0.532	0.316	0.673
Level 3								
pH	75	7.650	0.007	0.094	0.007	0.094	0.007	0.094
pCO_2 mmHg	75	21.2	0.578	2.726	0.594	2.805	0.599	2.828
pO_2 mmHg	75	159.3	4.476	2.810	4.553	2.858	4.715	2.960
Sodium (Na^+) mmol/L	75	163.2	0.952	0.583	1.044	0.640	1.055	0.647
Potassium (K^+) mmol/L	75	6.40	0.037	0.576	0.040	0.629	0.040	0.629
Ionized Calcium (iCa) mmol/L	75	0.49	0.005	1.026	0.005	1.104	0.006	1.196

D.3 Linearity

Using CLSI EP06-A: Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline, data was collected using commercially available linearity solutions (CVC123 manufactured by RNA Medical, Devens, MA). Three (3) sites (one internal and two external) ran 5 levels in quadruplicate of linearity material for all analytes. Data points considered to be outliers were evaluated visually and statistically, as per CLSI EP06-A, and removed.

pH, pCO2, pO2 showed no significant non-linear coefficients. Na, K, Ca++, and Hct did show significant non-linear coefficients, but the differences between the higher order and linear models was within allowable error limits.

The results were as follows:

Table D.3

Analyte	Slope	Intercept	R^2	Reference Range
pH	0.996	0.035	0.999	6.845 - 7.862
pCO_2 mmHg	1.019	-0.803	0.997	11.9 - 99.4
pO_2 mmHg	1.06	-13.09	0.991	40.8 - 467.4
Sodium (Na^+) mmol/L	0.975	2.369	0.999	89.5 - 168.8
Potassium (K^+) mmol/L	1.017	-0.065	0.999	1.68 - 10.62
Ionized Calcium (iCa) mmol/L	0.975	0.016	1.000	0.48 - 2.71
Hematocrit (Hct) %	1.033	-0.600	1.000	18.2 - 59.6

Appendix E: Default Settings

This section describes factory default settings for the IRMA Blood Analysis System.

Default Settings

Refer to Section 8 for instructions on establishing IRMA System settings. The factory settings are listed below:

Table E.1

Category	Default Setting
Operator ID Settings	
• OID Required	Disabled
• Password Required	Disabled
• Edit OID List	123456
• OID on Reports	Disabled
• OID Barcode Mask	Skip: 30; OID Length 30
Patient ID Settings	
• PID Required	Disabled
• Default PID	UNKNOWN
• PID Length	1 - 30
• PID Entry Mask	None Configured
• PID Barcode Mask	None Configured
Cartridge Settings	
• Cartridge Configuration	
- BG	ABG, HCO3-, TCO2, BEb, BEecf, O2Sat
- CC	ABG, Hct, Na+, K+, iCa, HCO3-, TCO2, BEb, BEecf, O2Sat, tHb
- H3	Hct, Na+, K+, iCa, tHb
• Manage Cartridge Lots	None Configured
• Allow New Lot Entry During Testing	Enabled
• Manage LQC Material Lots	None Configured
Analyte Ranges	
• Patient/Sample Types	Disabled
• Patient/Sample Type Setup	
- Patient Type	Adult
- Sample Type	Arterial
	• Brachial, Radial, Femoral
	- Right, Left
	• Arterial Line
- Sample Type	Venous, Mixed Venous, Capillary
- Patient Type	Pediatric
- Sample Type	Arterial
	• Brachial, Radial, Femoral
	- Right, Left
	• Arterial Line
- Sample Type	Venous, Mixed Venous, Capillary
- Patient Type	Neonate

Settings Table E.1 Continued

Category	Default Setting
- Sample Types	Capillary, Cord
• Patient Reference Ranges	Disabled
• Patient Range Setup	None Configured
• Master Reference Ranges	Disabled
• Master Range Setup	None Configured
• Reportable Ranges	Disabled
• Reportable Range Setup	Refer to Appendix B, Table B-6
QC Lockout Settings	
• EQC Lockout Settings	DIsabled
- EQC Schedule	Shifts: 3; Start Time 07:00
- Print EQC Tests	No Print
Test Settings	
• Allen's Test Result Entry	Disabled
• Allen's Test Range	3 - 30
• Hct Bypass Correlation Mode	Disabled
• Hct Bypass Correlation Setup	All OIDs: Slope 1.000; Intercept 0.00
• Physician Entry Mode	Disabled
• Manage Physician List	None Configured
• User Note Entry	Disabled
• Manage User Notes List	None Configured
• Units of Measure Settings	Refer to Appendix B, Table B-7
ABG Test Settings	
• Oxygen Therapy Mode	Disabled
• Configure Oxygen Devices	None Configured
• Configure Oxygen Ventilators	None Configured
• Patient Temperature Entry	Disabled
• SpO2 Source	Disabled
• BE and HCO3 Formula	Severinghaus NCCLS
• pO2 Temperature Correction	Severinghaus
• Source of Hemoglobin for BE	Use Default
• Backup Source of Hemoglobin	Use Default
Device Settings	
• Configure WiFi	No Networks Configured
• Email Results Option	Disabled
• Manage Email List	No Email Addresses Configured
• Data Management Server	No Server Address Configured Port 3001
• Auto Result Transfer	Manual
• Inactivity Timeout	2 minutes
• Barcode Reader Timeout	30 seconds
• Audible Alerts	Enabled
• Configure IRMA Base	IRMA Tablet arrives paired with the IRMA Base

Category	Default Setting
• Congfigure IRMA Printer	IRMA Tablet arrives paired with the IRMA Printer
• Language	English
• PDF Header Line 1	Blank
• PDF Header Line 2	Blank
• PDF Header Line 3	Blank
• PDF Header Line 4	Blank
• PDF Footer	Blank
• PDF Page Size	Letter
• Use Network Date and Time	Disabled
• Set Date	Current date at manufacturer's facility
• Set Time	Current time at manufacturer's facility
• Set Time Zone	Central Standard Time
• Set Time Format	24 hour
• Set Date Format	Y/M/D

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Appendix F: Warranty

This Appendix contains warranty information.

F.1 Limited Warranty

EasyDx, Inc., dba LifeHealth ("the Company") warrants the IRMA Base, AC power supply, IRMA Tablet, and temperature verification card to be free from defects in material and workmanship under normal use and service for a period of two (2) years after date of shipment and subject to the following terms and conditions. The IRMA Tablet glass and cartridge edge connector are excluded from this warranty coverage.

Claims of defects in material or workmanship must be reported to the Company and the product returned to the Company, transportation prepaid, within the warranty period.

If found by the Company's inspection to be defective in material or workmanship, the IRMA Base, AC power supply, IRMA Tablet, and temperature verification card will either be repaired or replaced, at the Company's election, free of charge, and returned to the purchaser, transportation prepaid. If inspection by the Company does not disclose any defect in material or workmanship, the Company's regular repair or replacement charges will apply.

Improper use of or service to, or the defacing or altering of, the IRMA Base, AC power supply, IRMA Tablet, or temperature verification card will void this warranty.

F.2 Limitation of Remedies

The remedy of repair or replacement, provided in this written warranty, shall be the exclusive remedy of the purchaser for any defect in the product of the Company. Any purchaser of a LifeHealth product agrees that LifeHealth will not be liable for any other expenses, including, but not limited to, incidental or consequential damages and loss.

All obligations of the Company shall terminate two years after the date of the original shipment.

F.3 Warranty Disclaimer

Every LifeHealth product carries an express, written limited warranty, which is the only warranty, express or implied, of any LifeHealth product.

LifeHealth disclaims all other warranties, including implied warranties of merchantability or fitness.

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