Inflammatix

Myrna™

Instrument User Manual

LBL-00057, REV A

CAUTION—Investigational device. Limited by Federal (or United States) law to investigational use.

Go to www.inflammatix.com/support for service contact information.

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1.0 HANDLING, WARNINGS, AND PRECAUTIONS

1.1 Myrna™ Instrument

1. For Investigational Use.
2. Operating Conditions: The Myrna Instrument should be used between 59°F and 86°F (15°C and 30°C), 20% to 80% relative humidity, and 0-6562 feet (0 to 2000m, 101325 Pa – 76142 Pa) elevation. Failure to do so may yield invalid results.

3. Use the Myrna Instrument only as directed.
4. The Myrna Instrument is best used in a room with adequate lighting and away from glare. Failure to do so may result in difficulty during setup and in seeing the test results on screen.
5. Place the Myrna Instrument on a level surface and do not move during operation. Failure to do so may yield invalid or inaccurate results.
6. A grounded power outlet is required for operation. In addition, a local surge protector is recommended if the installation site is not set up site-wide for surge protection.
7. Note: the internal instrument power supply specifications are as follows ~ Line 100-240 VAC, 50/60 Hz, 9A MAX
8. Do not touch or move the Myrna Instrument power cable while a test is running.
9. Do not unplug the Myrna Instrument during operation.
10. While color-blind users may be unable to differentiate the Myrna Instrument red, green, and white status lights, they can consult the light behavior and information on the screen to determine test status. When interpreting results, the user can consult the location of a colored band and the value presented.

    See Section 0: Operating the Instrument for more information

11. If a spill occurs on the Myrna Instrument or power cord, power down the instrument, unplug the unit, and wipe it down with 70% ethyl or isopropyl alcohol. Allow the Myrna Instrument or power cord to completely dry before continued use.

    The instrument exterior may also be cleaned with:

    - Quaternary ammonium and isopropyl alcohol (e.g., Super Sani-Cloth Wipes)
    - Sodium hypochlorite (5.2% household bleach) up to a 1:10 dilution. Wipe down with water afterward.

    Caution: Do not spray cleaning solution directly onto the instrument.

    See section 12.1: Cleaning the exterior for more information.

1.2 Test cartridge and sample tube

1. Store and use the test cartridge only in temperature ranges shown below. Bring cartridge up to temperature range if exposed to colder temperatures. Operating Conditions: Test cartridges should be stored and used between 59°F and 86°F (15°C and 30°C), 20% to 80% humidity, and 0-6562 feet (0 to 2000m, 101325 Pa – 76142 Pa) elevation. Failure to do so may yield invalid results. Refer to test cartridge and sample tube Instructions for Use (IFU) for more information.

2. Do not freeze test cartridges. In case of refrigeration or other exposure to cold temperatures, ensure that they are allowed to fully come to at least minimum operating temperature of 59°F (15°C) prior to use.
3. Use the test cartridge only with the correct sample tube. Discard cartridge if another tube type is accidentally inserted.
4. Do not use the test cartridge past its expiration date.
5. The test cartridge is for single use only; do not reuse.
6. Some sample tubes may be removed from their test cartridge after the test is completed. For detailed information on handling and storing these sample tubes, please refer to the specific test's Instructions for Use (IFU).
7. Always handle test cartridge and sample tubes per standard blood-borne pathogen precautions.
8. Do not invert the sample tube before cap is secured.
9. Leave test cartridges in their foil pouch until just before test.
10. Use test cartridges immediately after opening.
11. Inspect test cartridge foil pouches for any damage to packaging. Discard if damaged.
12. Check foil pouch for expiration date. Discard if expired.
13. Do not drop the test cartridge and/or sample tube. Discard if dropped.
14. Check test cartridge for any damage. Discard if damaged.
15. Check sample tube for any damage. Discard if damaged.
16. Do not shake or tilt the test cartridge after adding a sample. This may cause an inaccurate result.
17. Do not touch the cartridge components with fingers. The blisters contain caustic liquids.
18. Use only Inflammatix test cartridges. Inserting any other object can damage the instrument.
19. Dispose of test cartridge and sample tube per local regulations.

20. In the event of power failure or if the unit is unplugged for any length of time, reset the current time on the instrument before resuming operation. Failure to do this will create inaccurate patient test records.
21. If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

2.0 PERFORMANCE SPECIFICATIONS

2.1 Intended use

The Myrna Instrument is an automated *in vitro* diagnostic (IVD) device intended for use with FDA cleared or approved Inflammatix cartridges only. The Myrna Instrument is intended to be used by healthcare professionals, and exclusively with Inflammatix test cartridges.

2.2 Regulatory compliance

The Myrna Instrument is for IVD use only.

2.3 Operating Environment

All sites for the Myrna Instrument should ensure the following standards:

- A well-lit, central work area should be dedicated for instrument installation that is level and a minimum of 24 inches (60 cm) deep by 15 inches (38 cm) wide.
- Installation site does not need to be sterile, but it should be clean and dry. Work surfaces should be cleaned as needed, and surrounding floors cleaned intermittently and as needed. Due to the acute nature of the illnesses/injuries commonly treated at the installation site, frequent cleaning may be necessary. Keep the work area clean according to your facility's policies.
- The instrument, cartridges, and samples should reside in a climate-controlled environment while in operation at a range of 59°F and 86°F (15°C and 30°C). For information on test cartridge storage, refer to the respective Instructions for Use documents (IFU) for the specific test cartridge.
- Consumables (exam gloves, etc.) should be stored in an area adjacent to the instrument in cupboards, drawers, etc. Biohazardous waste containers of sufficient size to house used cartridges should be located in an adjacent area.
- Free access to power outlets in the immediate vicinity: a singe outlet for the instrument, and any additional required outlets for peripherals.
- A grounded power outlet is required for operation. In addition, a local surge protector is recommended if the installation site is not set up site-wide for surge protection.
- Note: the internal instrument power supply specifications are as follows: ~ Line 100-240 VAC, 50/60 Hz, 9A MAX
- Proximity to other instruments on the same table must be restricted to units with low vibration.

Each Myrna Instrument is packed with a power cable for the destination region. Please contact Inflammatix for a replacement if the included cable is damaged or incorrect for the region.

3.0 INTRODUCTION

3.1 Description of Inflammatix System

Description of the Myrna Instrument

The Myrna Instrument is a platform instrument that provides pneumatic, thermal, motor, and optical control to complete the steps in an assay and runs an algorithm to process the data acquired and produce the test results. An included touch screen display provides the primary method of input and, in concert with a “wizard” style interface, guides the user through the steps necessary to initiate a run. An outward facing barcode scanner acts as the primary method for entering information into the instrument software during a normal test workflow.

3.1.1 Description of the test cartridge

The cartridge is a single-use consumable that contains all of the reagents necessary for a test, as well as the fluidic channels and structures necessary to move, mix, hold, and incubate the required fluid volumes for sample preparation and analysis for a given assay. The cartridge accepts either a sample tube containing the patient sample to test, or an external quality control sample. All waste and amplified material remain sealed within the cartridges after the test is performed.

3.2 Internal controls

The internal controls that reside on the cartridge are used to ensure the integrity of a cartridge run and confirm that the results are valid. If any of the controls fail, the user is presented with an error and guided as to the appropriate next steps.

3.2.1 Assay definition file

The Assay Definition File (ADF) contains the assay-specific data needed to import a new test into the instrument software and run that test to produce the relevant results. The ADF includes the classifier module that processes the results, among other test-specific data.

3.2.2 Myrna Instrument and test cartridge integration

The Myrna Instrument and the test-specific cartridge work together as a system to process the sample. By reading the 2-D barcode label affixed to the cartridge packaging, the instrument identifies the test to be performed along with collecting other cartridge-specific identifying information. The user inserts the cartridge/sample tube assembly into the instrument to run the given test. The cartridge does not have any active electrical control mechanisms and relies on the instrument to apply the necessary pressures and external forces to complete the test. Test results are available onscreen and can be configured to be output to a local printer, or sent to an LIS/EMR for interpretation.

Full sample traceability is maintained through the 2D barcodes and results are stored on the instrument.

4.0 INITIAL SETUP

4.1 Unpacking the Instrument

Carefully open the box flaps. Lift the upper foam structure out of the box. Remove the power cord and set it aside. Remove the protective cardboard covering the instrument touchscreen. Remove and thoroughly review the instrument quick start reference guide. Carefully lift the instrument out of the polybag contained in the carton and place it on a clean, dry, level surface. Placement should allow a comfortable working height, with adequate clearance to allow ease of use. Ensure that there is a power outlet within 6 feet of the chosen installation location.

Note: The instrument weighs 45 pounds. Follow site recommendations for what an individual should lift or carry. Seek assistance as needed.

When unpacking, check the components for signs of shipping damage. Each Inflammatix package includes:

- 1 Myrna Instrument
- 1 Power supply cable
- 1 Quick Reference Guide for setup

If the package is found incomplete, please report missing items or shipping damage to your local supplier.

After completing the steps shown in Section 4.0 Initial setup, reviewing Section 11.1: Admin Best Practices is recommended.

4.2 Hardware setup

Once the instrument has been placed on the work surface, inspect the instrument housing to ensure that it is complete, intact, and undamaged. Do the same for the power cord. Document any issues and report them to your Inflammatix contact immediately.

Ensure that the rear of the instrument is not covered or blocked for proper ventilation. Plug the power cord connector into the power cable port on the back of the instrument. Plug the other end of the power cord into an available grounded outlet or surge protector.

Instrument setup is now complete.

Note: A thermal printer and test cartridges can be provided separately.

4.3 Power

4.3.1 Power On

Ensure that the power cord is properly seated in the port on the back of the instrument and plugged into a grounded outlet or surge protector.

Press and hold the power button on the left side of the instrument for a full second.

The instrument responds by illuminating the power button, initiating screen activity, and making audible sounds.

The instrument start-up sequence will typically take about 2 minutes. During this time the instrument will go through a self-test sequence in which it will verify that all of the mechanical subassemblies and cartridge interfaces are in proper working order.

Note: In cases where the instrument needs to run a virus scan, the startup can take over 10 minutes.

4.3.2 Power Off

On the display screen, press the menu button in the upper left corner to access the menu.

Select Shutdown at the bottom of the list of options. After the instrument has gone through the software shut down sequence, the screen goes dark and the power button light turns off.

Note: It will takes several seconds for the instrument to power down. Do not unplug the instrument until complete shutdown occurs.

4.4 Printers

The Myrna Instrument is compatible with the Dymo 450 and 550 series line of thermal printers. Contact your Inflammatix representative regarding printers and printing supplies.

For printer setup instructions, see 0: Report Printer Settings.

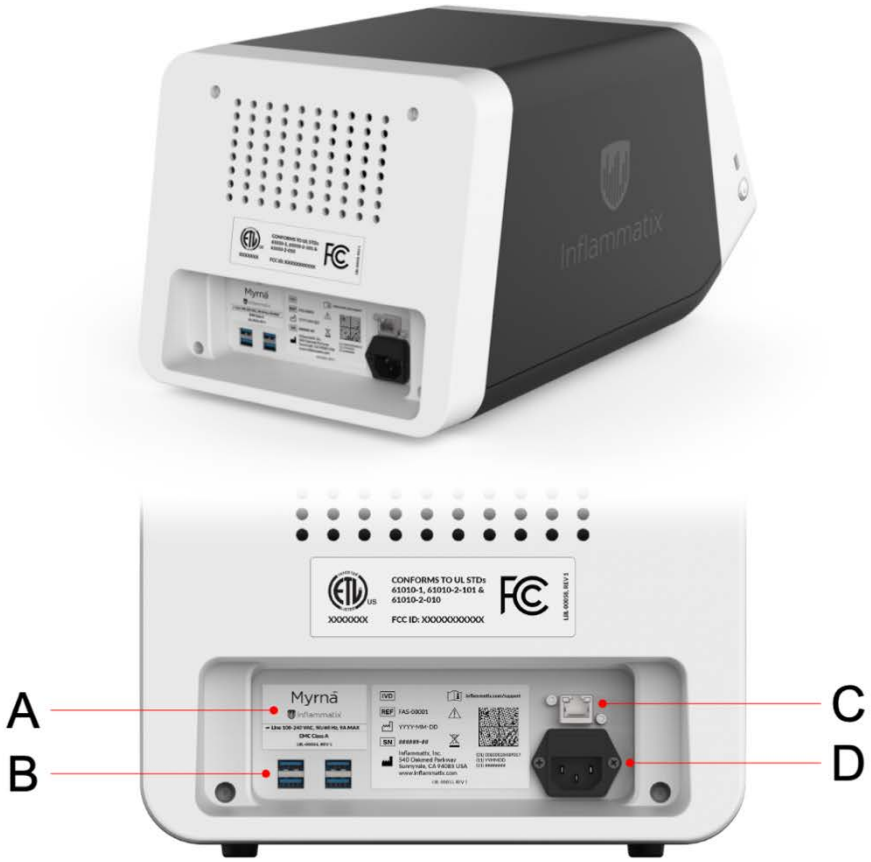
4.5 Points of interaction - front of instrument

A. Touchscreen display
B. USB port
C. Power button
D. Scanner beam window
E. Cartridge opening
F. Status light ring

Powering on: See directions previously described Section 4.3 above. Be sure to hold down the power button for a full second and wait for the startup sequence to complete.

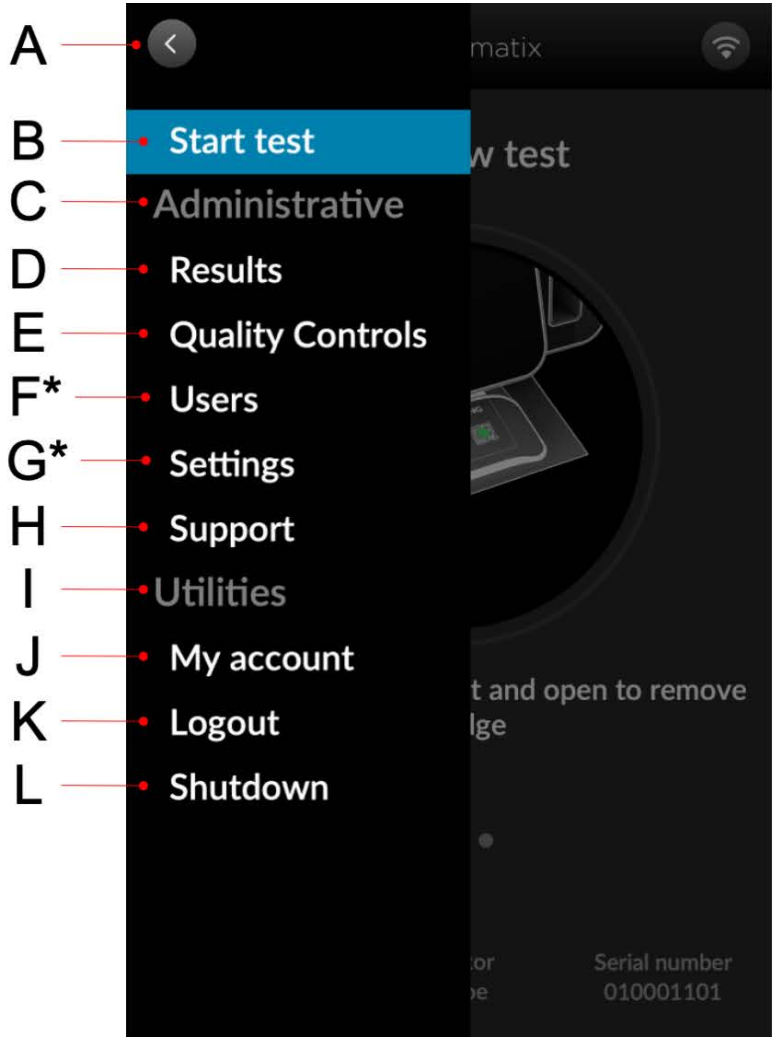
Powering off: See directions previously described Section 4.3 above. After pressing Shutdown, the screen goes dark and the power button light turns off.

4.6 Points of interaction - back of instrument



A. Product labeling
B. USB ports (4)
C. Ethernet port
D. Power cable port

4.7 Points of interaction – main menu



A. Back button collapses the menu.

   Note: Achieve this action by touching the screen anywhere outside the menu

B. Returns to the Start New Test screen

C. Administrative submenu header (not selectable)

D. Results provides access to historical results stored on the instrument.

E. Quality Controls displays the quality control access menu screen and provides an entry to the QC workflow

F. Users displays the list of users*

G. Settings provides access to a separate settings menu*

H. Support provides access to product resources and troubleshooting guidance

I. Utilities submenu header (not selectable)

J. My account provides access to changing user password and setup of email notifications

K. Logout

L. Shutdown powers the instrument down

*Available only when logged in as an administrator-level (Admin) user

In cases where the menu is unavailable due to a system process in progress, the relevant menu item will be grayed out.

4.8 Initial setup

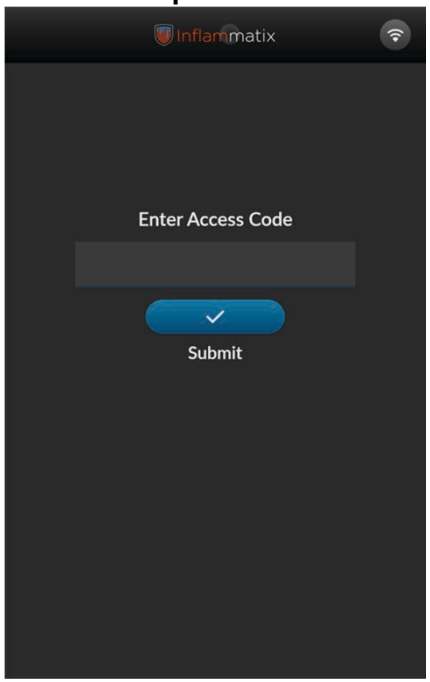


Figure 1 – Enter access code

Enter the one-time access code obtained from Inflammatix.
Note: Once used, Admin setup and password are required to access the instrument. See also Section 11.1 Admin best practices.

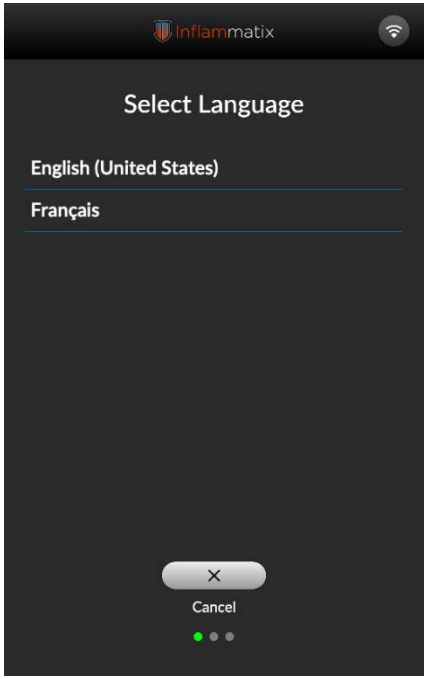


Figure 2 – Select language

Select Language from the available list.

Figure 3 – Select login method

Select Login Method for your lab facility. This setting will apply for all Operators. Password is always required for Admin Users.
The options are:

- User ID and Password
- User ID Only
- Open Access

Note: Open Access allows anyone with instrument access to run a test.

Initial setup continued

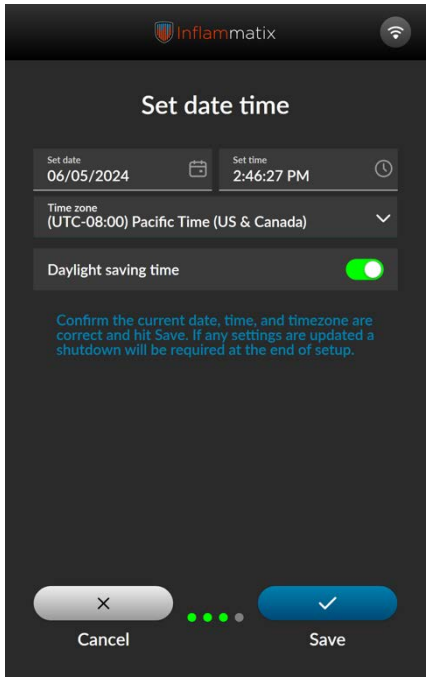


Figure 4 – Set date time

Enter local date and time.
Select the correct local time zone from the pulldown menu.
Toggle daylight savings time on as needed and select Save.
Note: changing the date and time in the future will require a system restart.

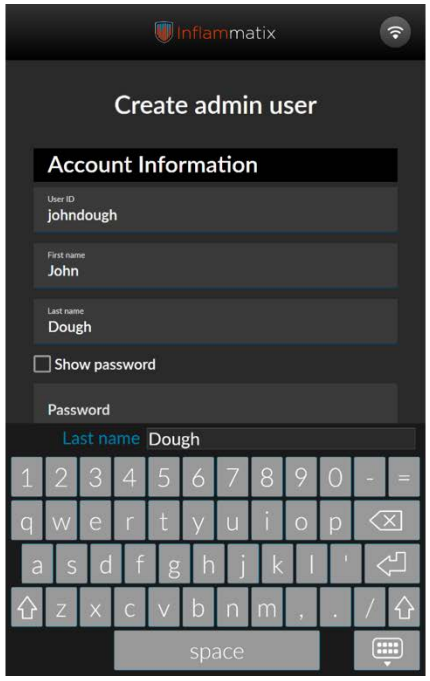


Figure 5 – Enter user data

Enter Admin User Data. The keyboard will appear when an input field is selected.
Note: The alphanumeric user ID must match any corresponding ID badge barcode exactly to be used in a typical workflow.
User ID:

- Is case sensitive
- Capital letters are not required.
- Symbols are not allowed.

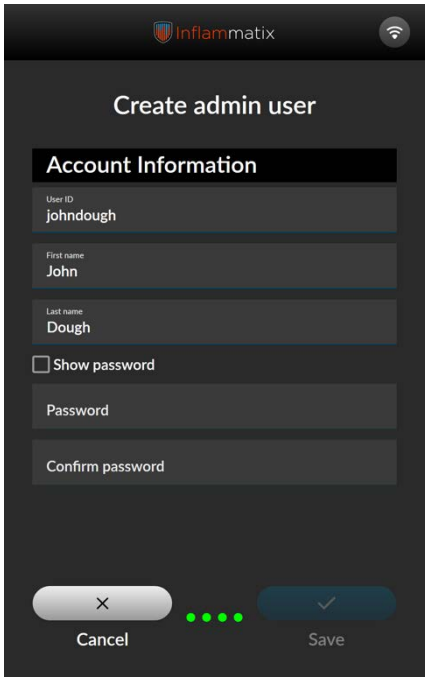


Figure 6 – Enter password

Enter password using the onscreen keyboard.
Passwords:
Must be 6-12 characters
Are case sensitive
Must have at least one of each of: upper case letter, lower case letter, number, special character (defined in the following set: !@#$%^&*)

Initial setup continued

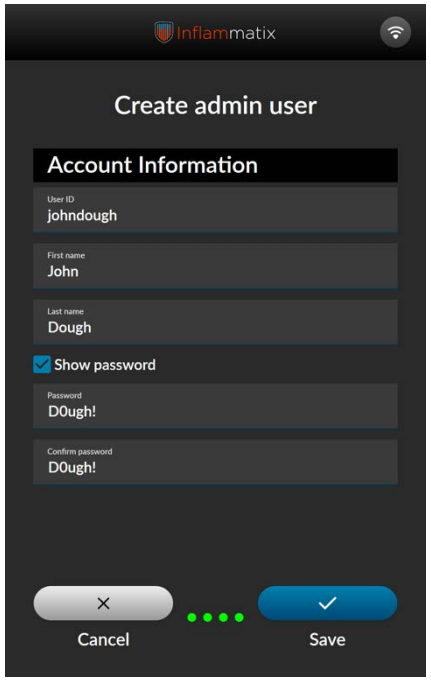


Figure 7 – Confirm password

Re-enter password to confirm.
Note: Record and save password carefully. If forgotten, contact Inflammatix support. Inflammatix recommends adding multiple Admin users to ensure access.

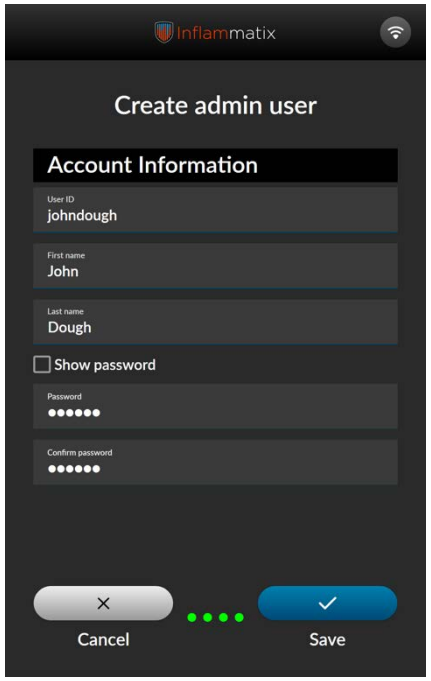


Figure 8 – Select save button

Select the Save button.

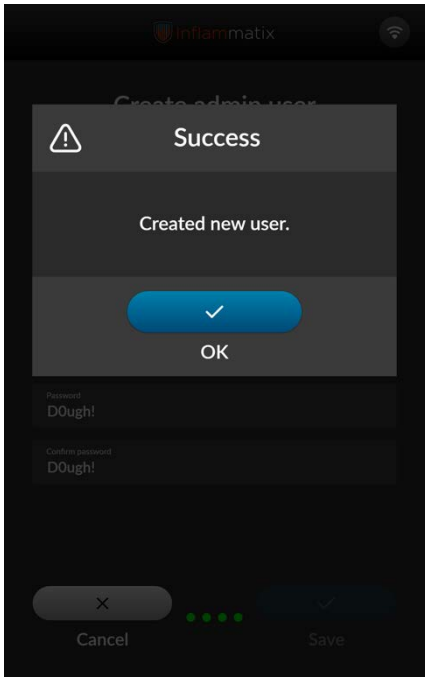


Figure 9 – Confirmation

Select the OK button. The Admin User can now perform all Myrna Instrument tests when logged in.
Inflammatix recommends reviewing section 11.1 Admin Best Practices

5.0 GENERAL SETTINGS

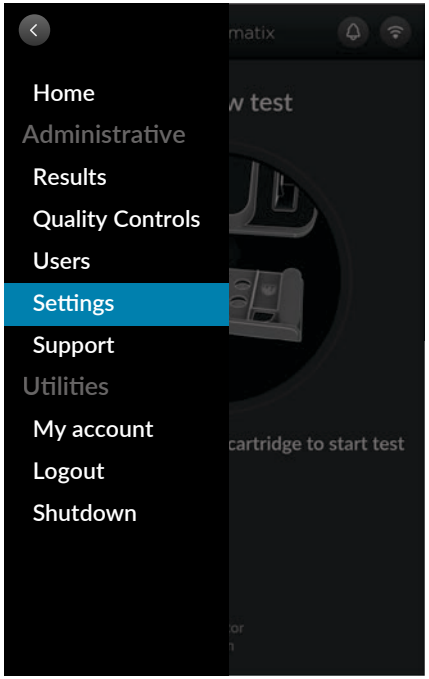


Figure 10 – Select settings

From the Admin Menu, select Settings.

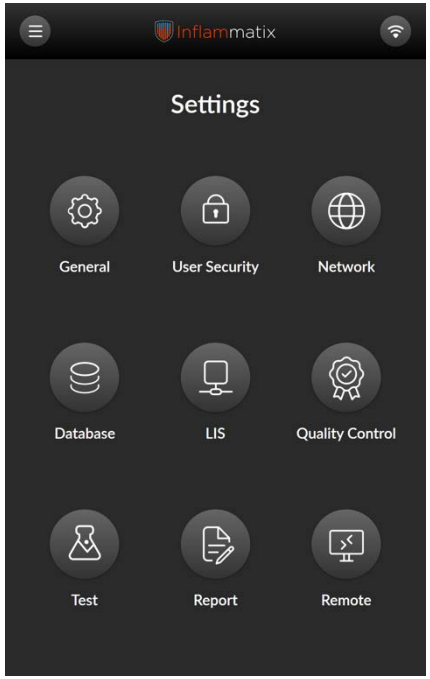


Figure 11 –Select general

From the Settings Menu, select General.

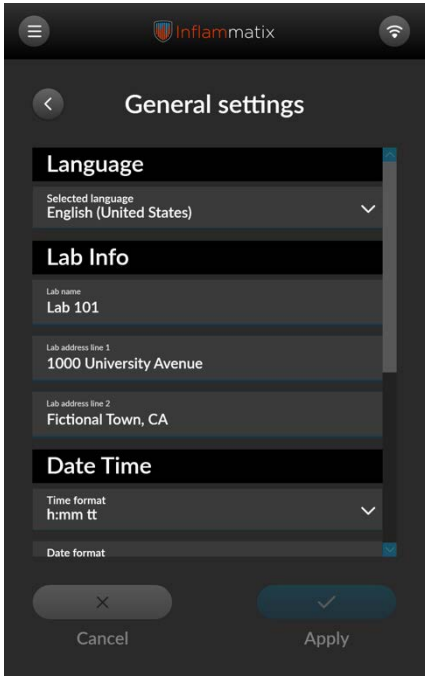


Figure 12 – Select language and enter lab info

From General settings, select the default language for the instrument.
Then select Lab info. Enter lab name and location data using the onscreen keyboard.
Scroll down to the Date/Time settings

General settings continued

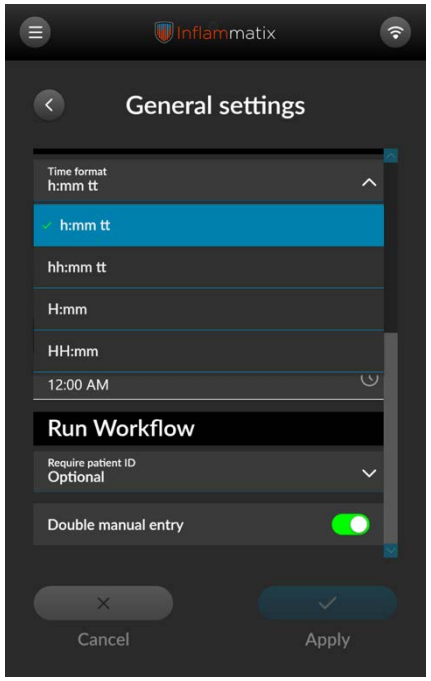


Figure 13 – Set time format

Enter the local date and time before beginning the first operation. Reset in the event of a power failure, or if the machine is unplugged for more than a brief period. From the pulldown menu, select the correct local time format. 24-hour formats do not have the tt designation, which includes am and pm.

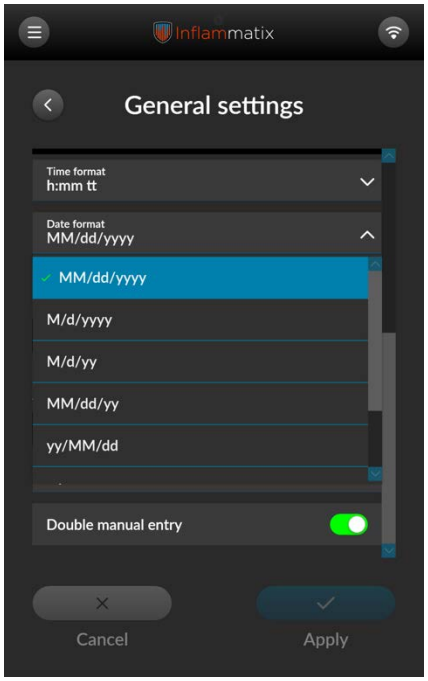


Figure 14 –Set date format

From the pulldown menu, select the correct local date format.

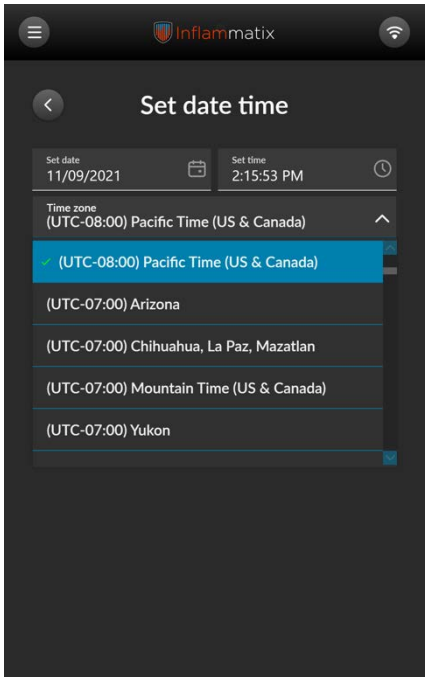


Figure 15 – Set time zone

Select the correct local time zone from the pulldown menu and select Save.

General settings continued

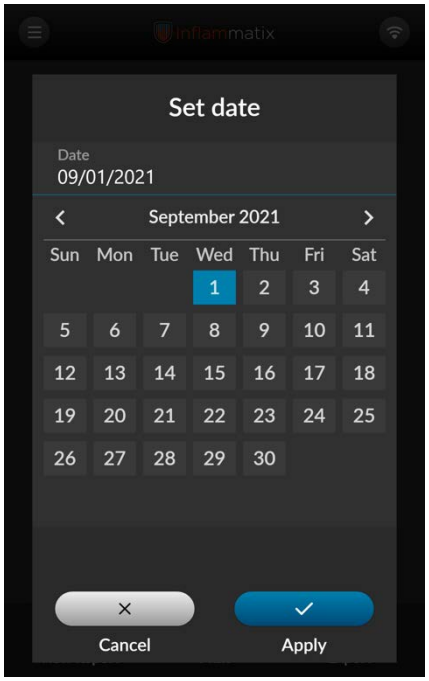


Figure 16 – Set date

Select the correct current date, then select Apply.

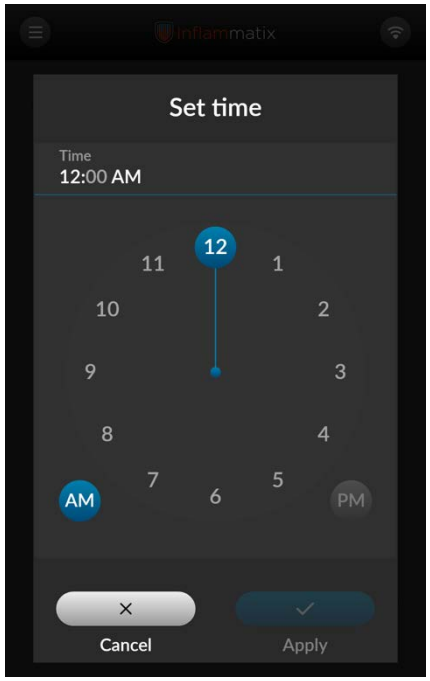


Figure 17 –Set hour

Select Hour, then Apply, then select AM or PM. If a 24-hour time format has been selected, the system will use AM and PM settings to set correctly. Use a mobile phone or other connected device as the time reference.

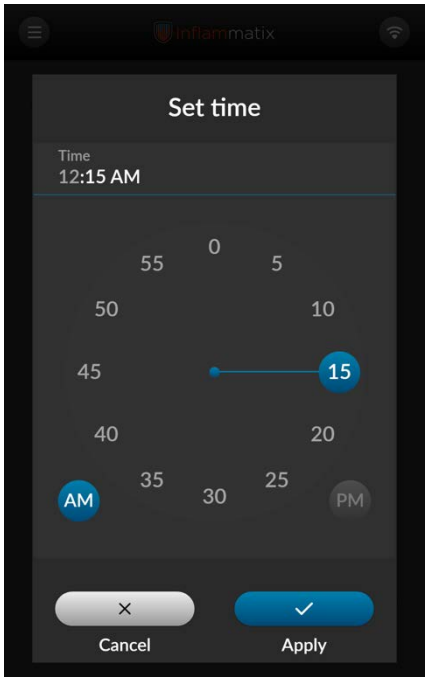


Figure 18 – Set minute

Set the correct local time in minutes.

General settings continued

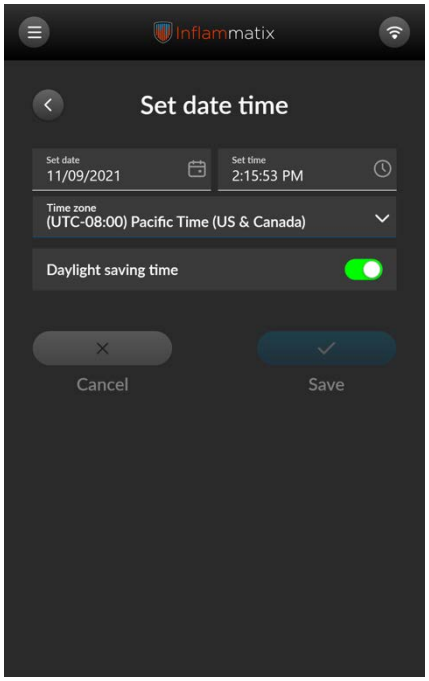


Figure 19 – Confirm date and time

Confirm correct setting of the date and time.

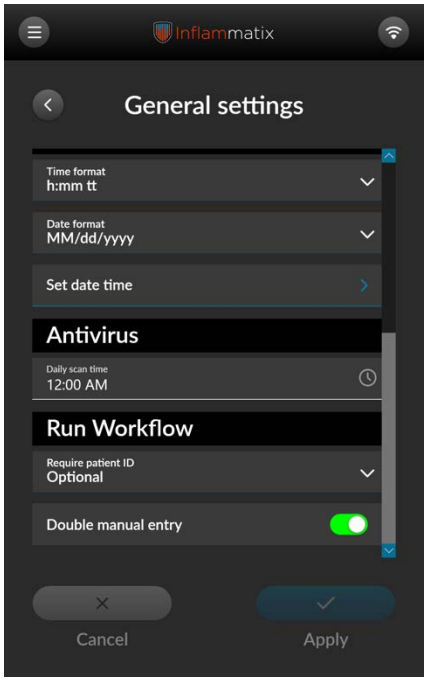


Figure 20 – Set antivirus time

Set the Antivirus hour to run the daily antivirus scan. Typically sites may set this to run at midnight to avoid overlap with busy system use periods.

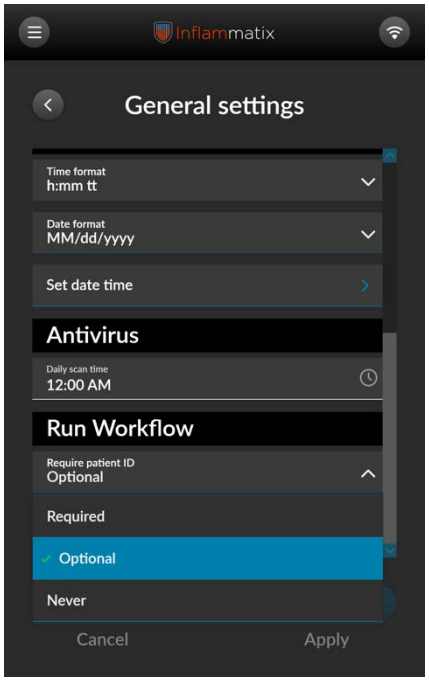


Figure 21 – Set require patient ID

Select appropriate option for Patient ID screen from the pulldown menu:

- Required
- Optional
- Never

Select optional double manual entry of Patient ID or any manually entered data per the local lab policy.

5.1 User Account types and privileges

The Instrument permits two types of user accounts to access the instrument software and tests: Operator and Admin (administrative user).

5.1.1 Operator privileges

An Operator can perform the following functions:

- Process a patient sample
- Run a quality control
- Access historical test results
- View and access features on the support page
- Edit information on their own account
- Export information about previously executed tests and other system data

5.1.2 Admin privileges

In addition to those listed above, an Admin user can perform the following functions:

- Make changes to various instrument settings
- Add and deactivate users
- Perform software upgrades as instructed by Inflammatix

Note: Users must be added individually. The Myrna instrument software does not support bulk user addition.

5.2 New user setup

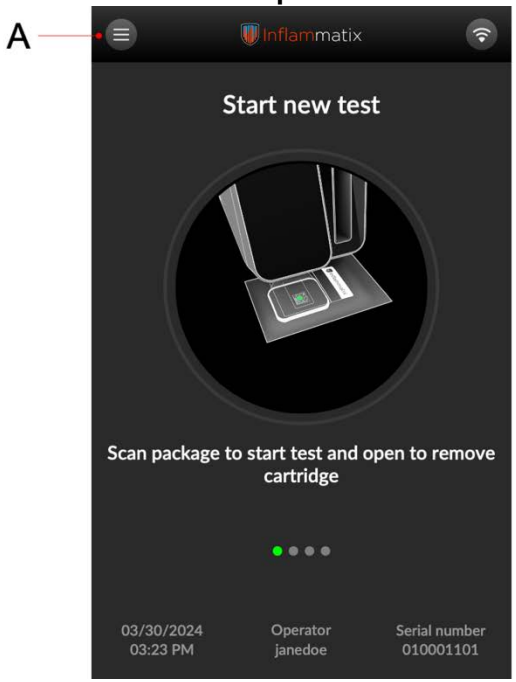


Figure 22 – Select menu button

Log in as an authorized Admin user for this instrument (not shown).
Select the menu button in upper-left corner.

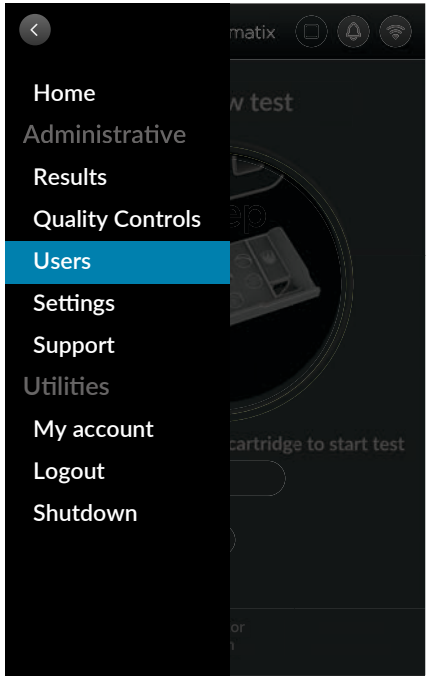


Figure 23 – Select users

Select Users from the Admin menu.

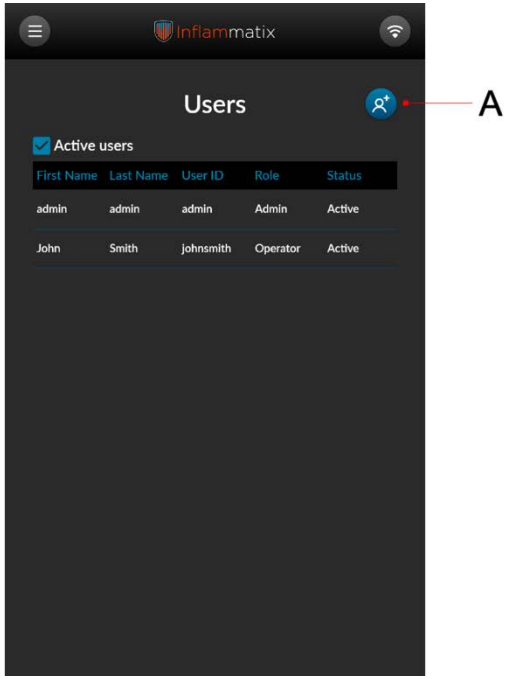


Figure 24 – Select add user button

The Users screen displays. Current active users are listed.
Select Add User by pressing the blue button in the upper-right corner.

New user setup continued

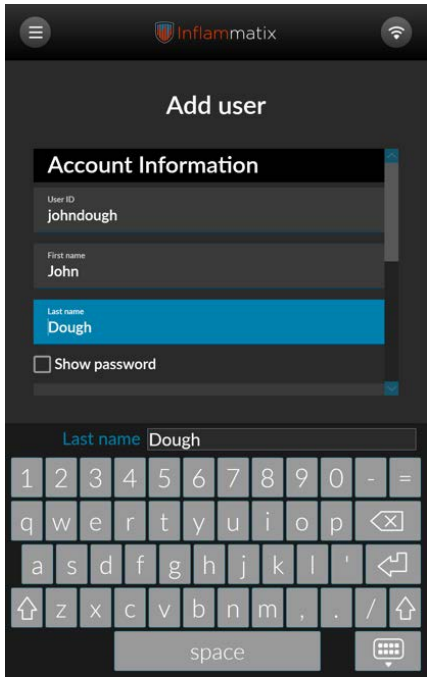


Figure 25 – Enter new user account information

Enter User data, including password, if required. Note: the user ID must match any corresponding ID badge barcode exactly to be used in a typical workflow.
Passwords:

- Must be 6-12 characters
- Are case sensitive
- Must have at least one of each of: upper case letter, lower case letter, number, special character (defined the follow set: !@#$%^&*)

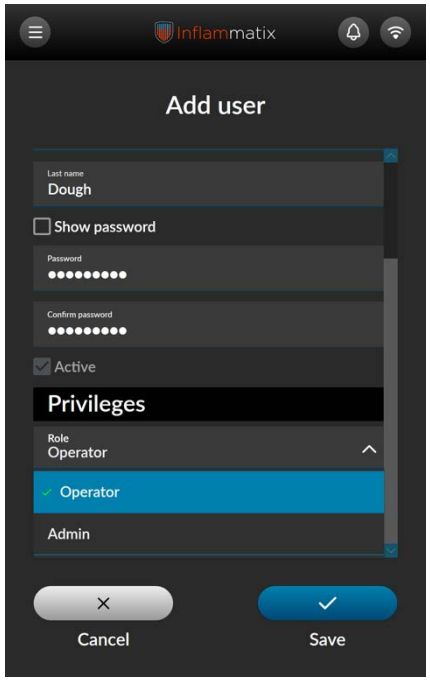


Figure 26 – Select role

Scroll to the Privileges area on the lower screen.
Under Role, select Operator or Administrator from the pull-down menu.

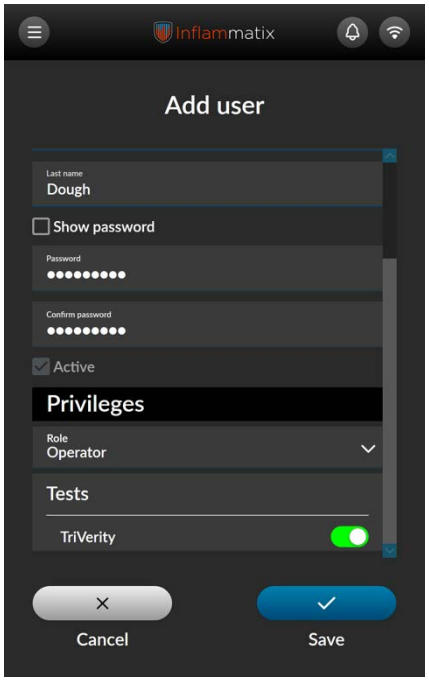


Figure 27 – Select tests

Under Tests, select from the list of available tests. Toggle the buttons. Enabled tests will display in green. Disabled tests will display in gray.

New user setup continued

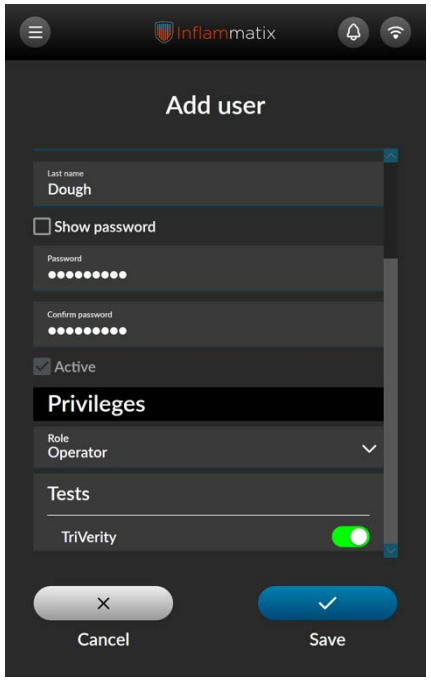


Figure 28 –Select save button

Select Save in the lower-right corner to save the User entry.

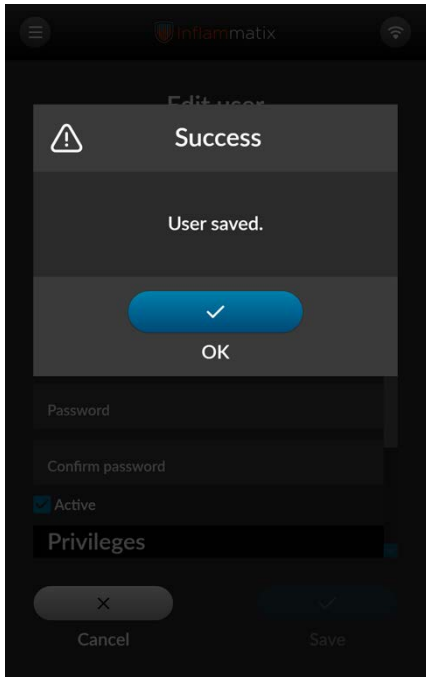


Figure 29 – User saved

A pop-up screen confirms the successfully added user and returns to the active users list.

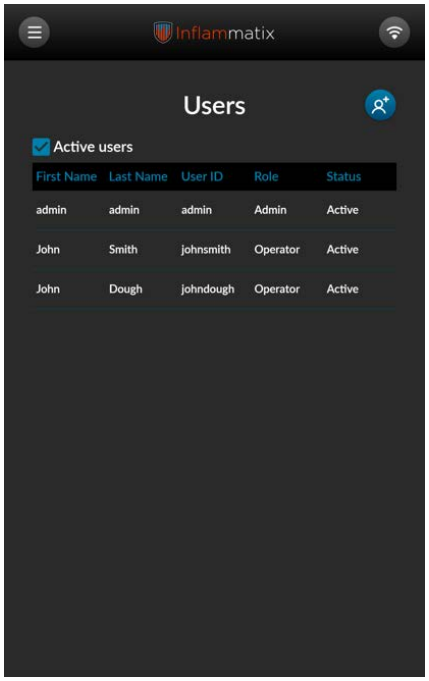


Figure 30 – Verify added user

Verify that the new User is listed under Active Users.
To add more Users, select the blue button in the upper right corner.
For newly added users, Inflammatix recommends a practice logout and login with badge or manual entry to make sure that access is understood and authorized.

5.3 Deactivating a user

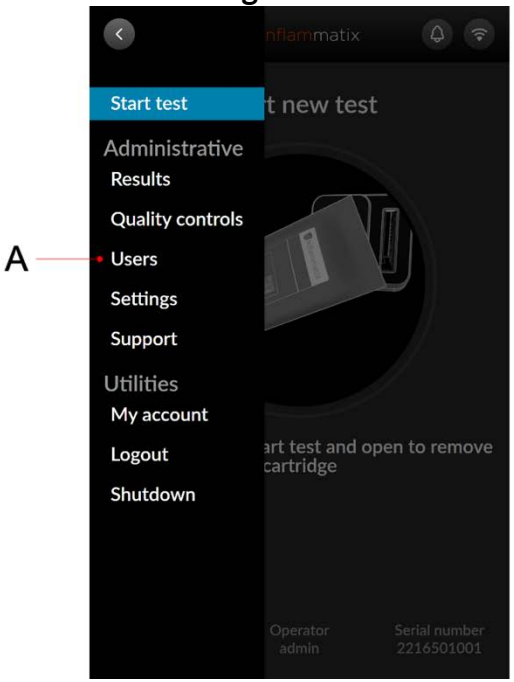


Figure 31 – Select users

Select Users from the Admin menu.

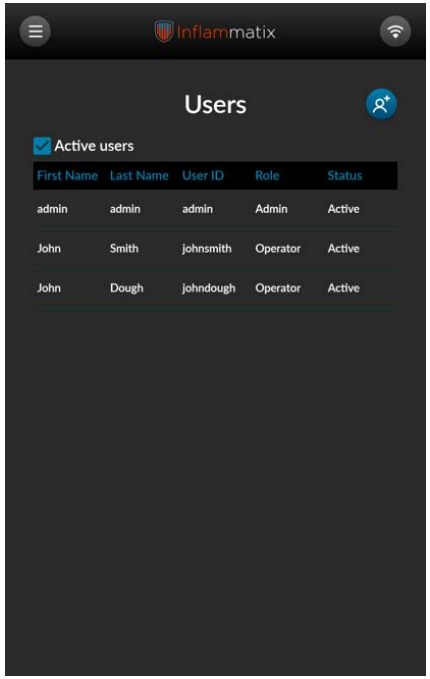


Figure 32 – Select user for deactivation

Select target user from Active Users.

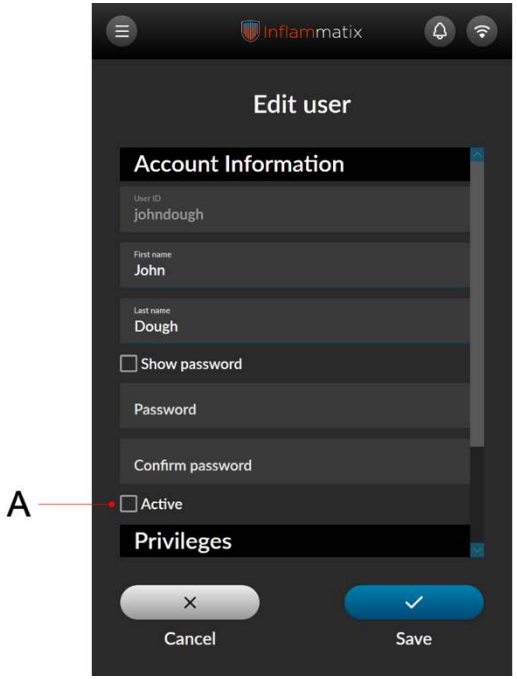


Figure 33 –Uncheck active status

Uncheck the Active box above Privileges.

Deactivating a User continued

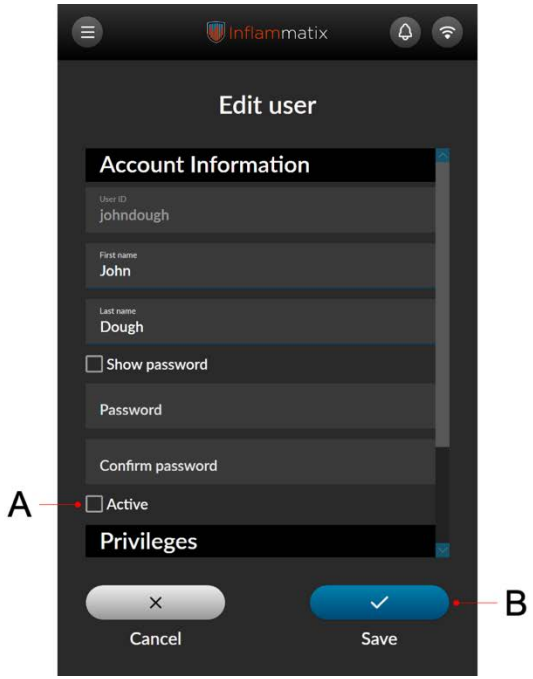


Figure 34 – Select save

Verify that the box is unchecked.
Select Save.

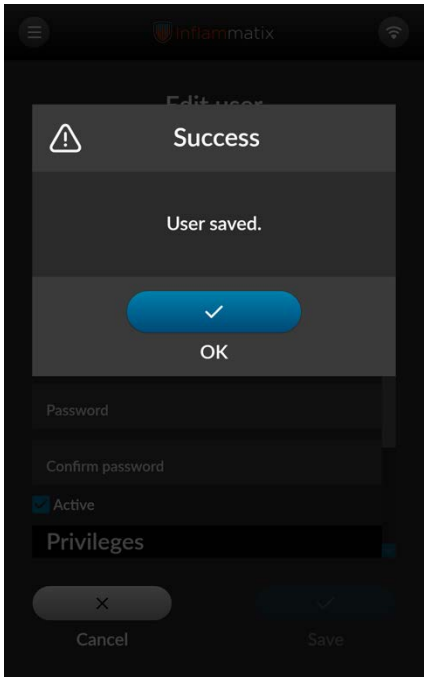


Figure 35 – User saved

A pop-up screen confirms the successful edit.

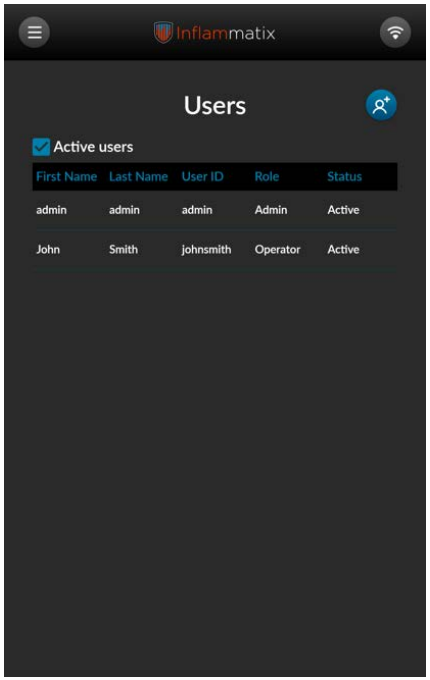


Figure 36 – Verify user deactivation

The screen then redisplays the Active User screen. Verify that the deactivated user is no longer listed.
Deactivated user ID and test records remain on the instrument, but access is now denied if attempted by the deactivated user.
Note: unchecking the Active users box displays all users, including those that have been deactivated.

5.4 User security settings

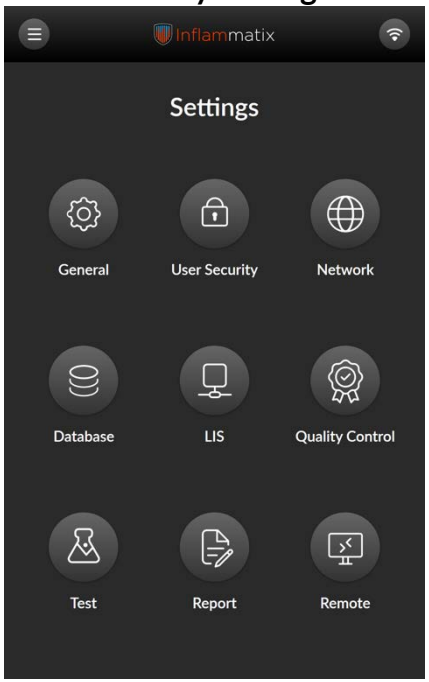


Figure 37 – Set login method

From the Admin Menu, select Settings. From the Settings Menu, select User Security.

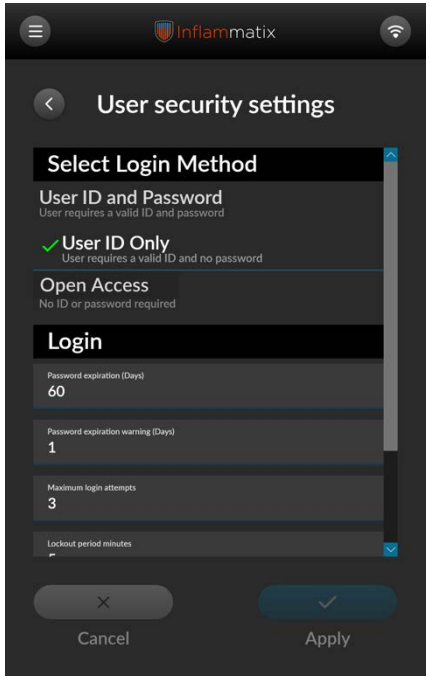


Figure 38 –Set login method

From the pulldown menu, select Login Method. This setting will apply for all Operators. Password is always required for Admin Users.

- The options are:
- User ID and Password
- User ID Only
- Open Access
- Open Access allows anyone with access to the instrument to run a test.

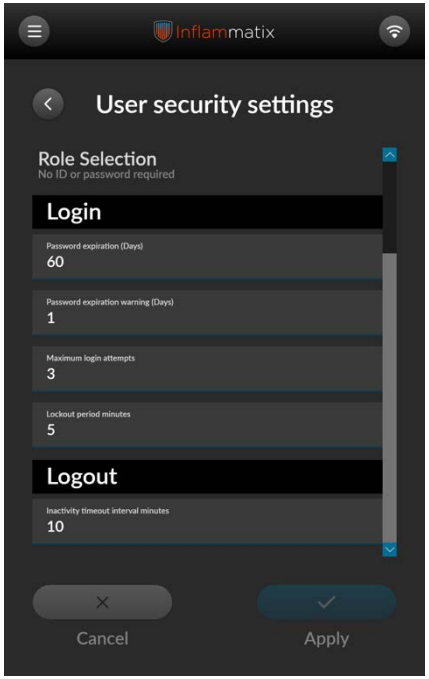


Figure 39 – Login and logout settings

From the pulldown menu, select the Automated Login and Logout functions. The options are:

- Login
- Password expiration (days)
- Password expiration warning (days)
- Maximum login attempts
- Lockout period (minutes)
- Logout

Inactivity timeout (minutes)

User security settings continued

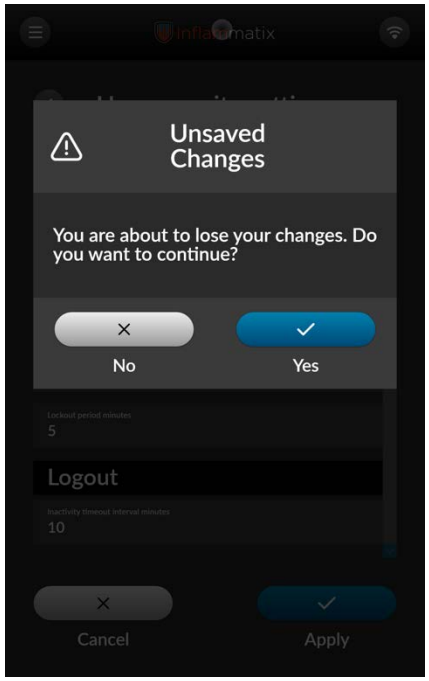


Figure 40 – Unsaved changes

Navigating away from the screen without selecting Apply alerts the user to save the data just entered.
Note: The instrument presents this screen when any data is entered but is not yet saved.

5.5 Network settings

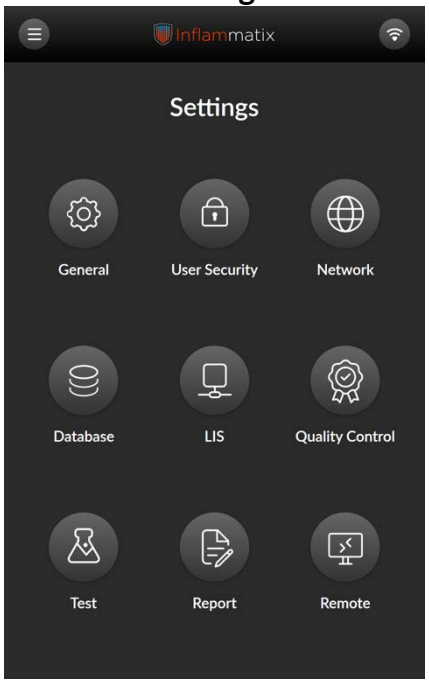


Figure 41 – Select network

From the Admin Menu, select Settings.
From the Settings Menu, select Network.

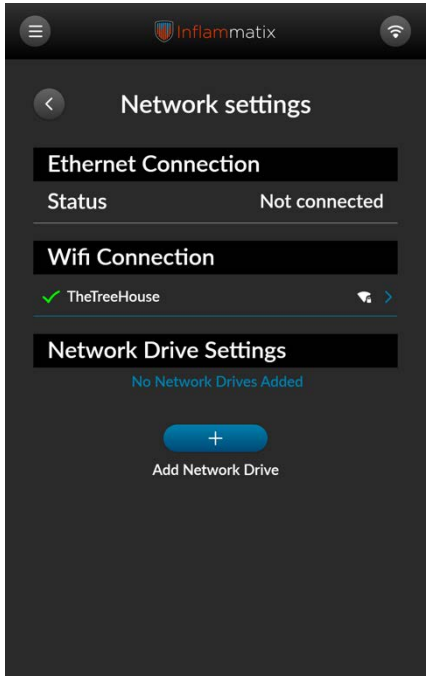


Figure 42 –Set network connection

This screen displays the current network status of the instrument.
If an ethernet cable is connected to the instrument, the screen will display connected.
If the instrument is connected via WiFi, the screen will display the connected network.

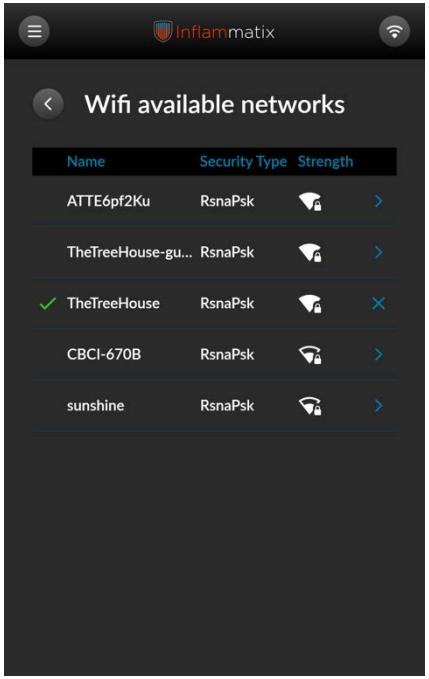


Figure 43 – Available WiFi network

This screen displays the WiFi available networks. Select the correct WiFi network for the installation site.
Inflammatix recommends use of private networks only.
All patient results on the system are encrypted.

Network settings continued

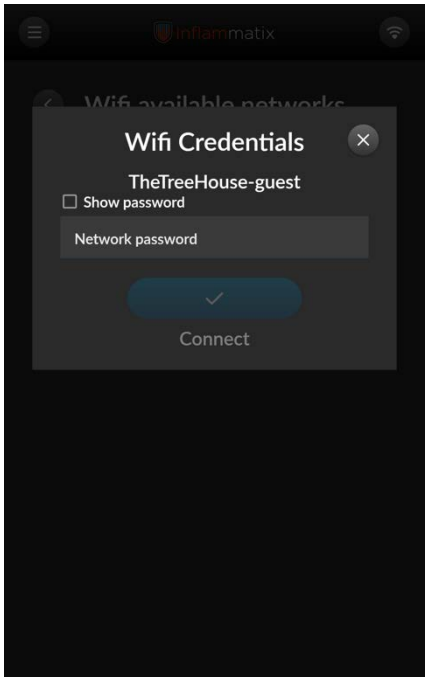


Figure 44 –WiFi credentials

Enter the correct password for the selected WiFi network.

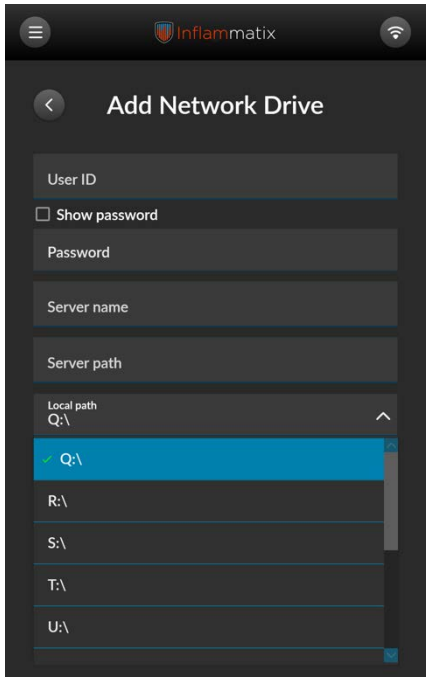


Figure 45 – Add network drive

Selecting Add Network Drive brings up the screen shown.
Select the target drive path from the list of available.

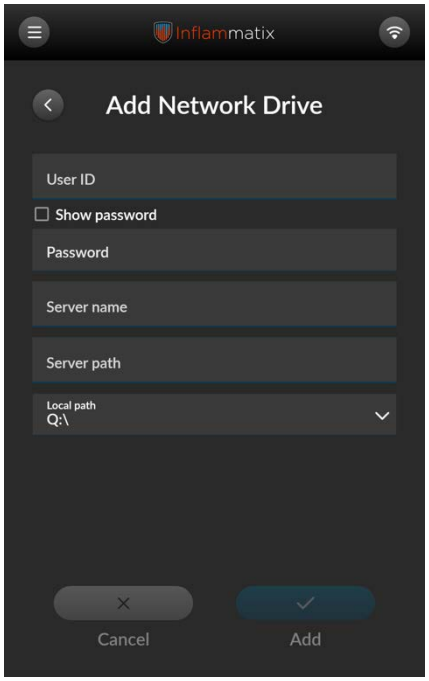


Figure 46 – Network drive password

Enter the password for the selected drive if required.
The password can be displayed by selecting the Show password check box.
Select the Add button once complete.

5.6 Database settings

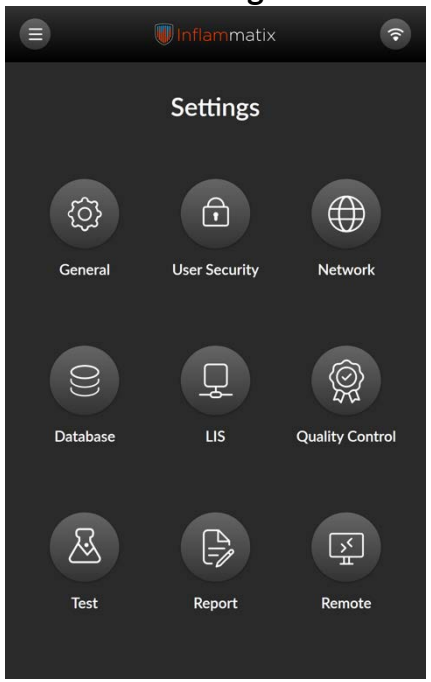


Figure 47 –Select database directory

From the Admin Menu, select Settings.
From the Settings Menu, select Database.

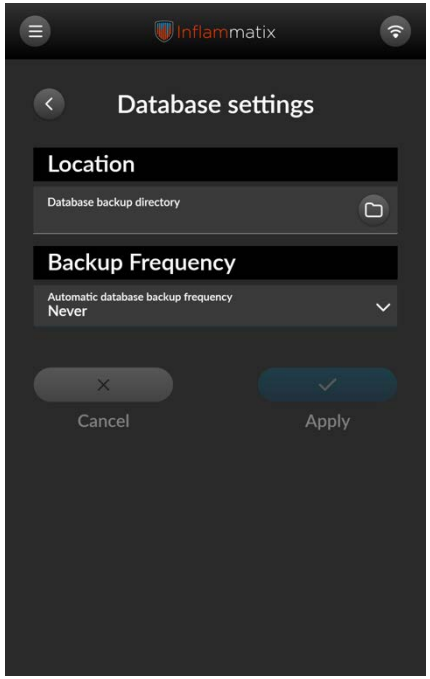


Figure 48 – Set backup directory

This screen selects a target drive, including USB, for database backup before database purge.

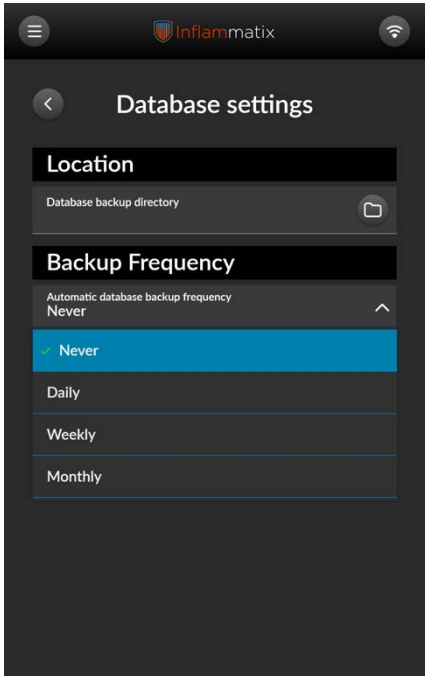


Figure 49 – Set backup frequency

This list menu selects an automated backup frequency to the selected drive.

5.7 Database settings

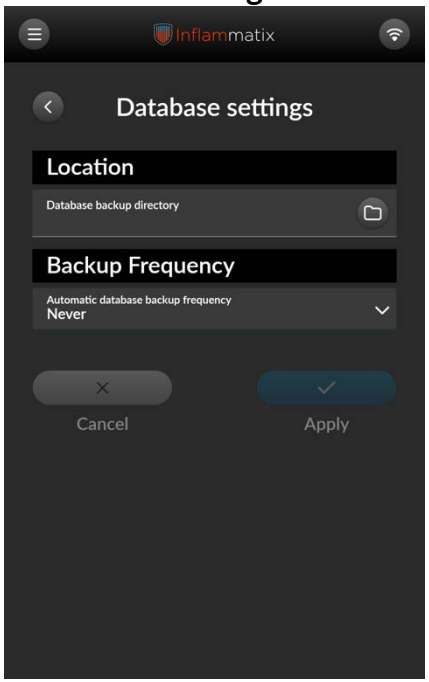


Figure 50 – Set backup directory

This screen selects a target drive, including USB, for database backup before database purge.
Note: Drives are recommended to be NTFS formatted for best performance.

5.8 LIS settings

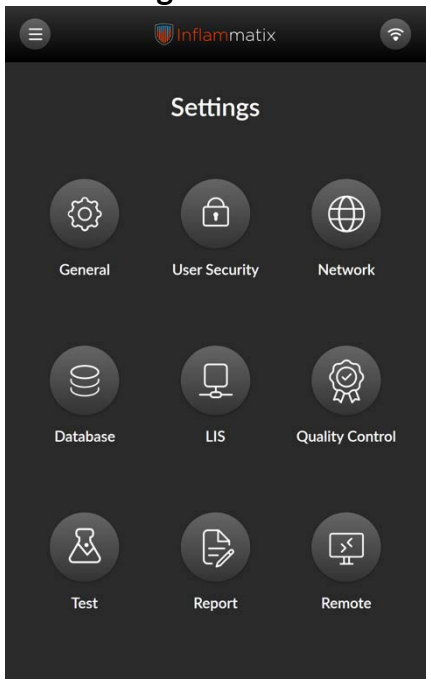


Figure 51 – Select LIS

From the Admin Menu, select Settings.
From the Settings Menu, select LIS.

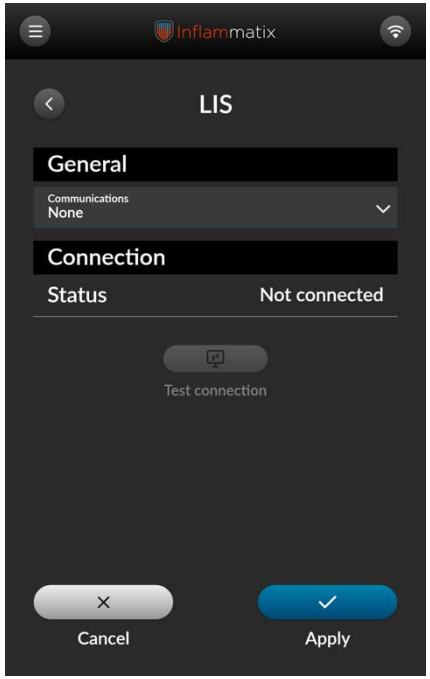


Figure 52 –Select LIS commnunications

The screen indicates the status of LIS connection.

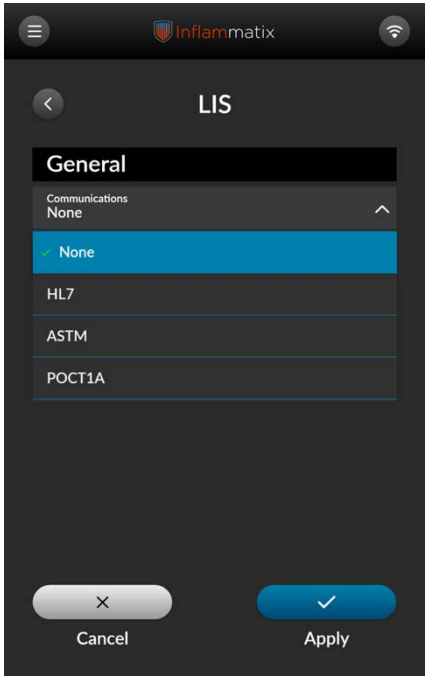


Figure 53 – Set backup frequency

Select the correct protocol for your facility LIS or other lab or hospital records database:

- HL7
- ASTM
- POCT1

Please consult your IT department for setup and further information on this setting.
Select Apply.

LIS settings continued

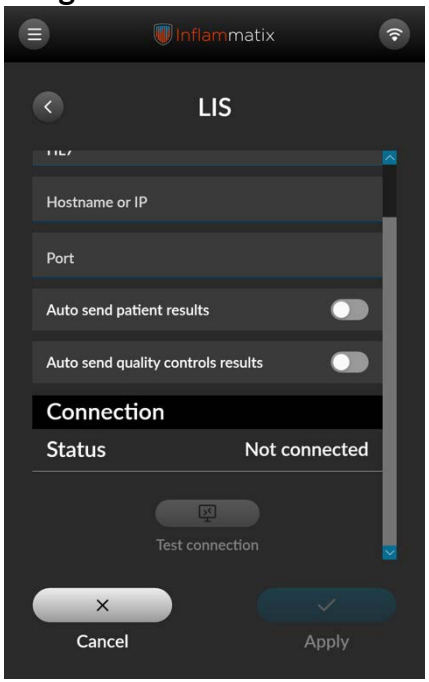


Figure 54 – Set auto send for LIS

Please consult your local IT department for the correct settings for your facility's database records management.
Toggle the correct setting for automatic send of patient and QC test results. If these are set to automatic, these buttons will be grayed out on the workflow screens, and no action is required.

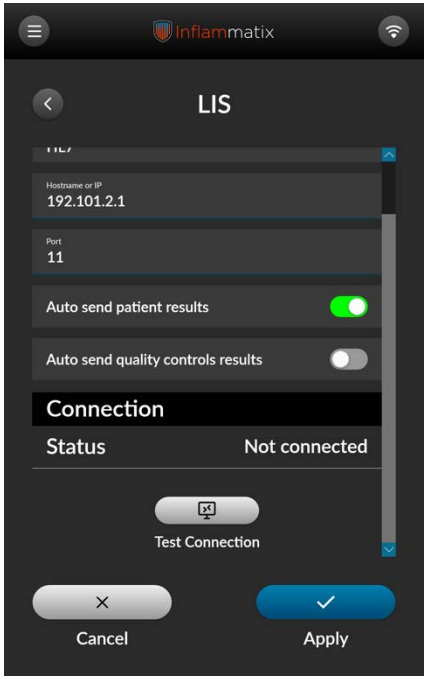


Figure 55 – Select LIS communications

Verify that all LIS settings are correct.
Note: If communications are interrupted with the LIS system for any reason including power failure, records transfers will be paused and automatically resumed when the link is restored.

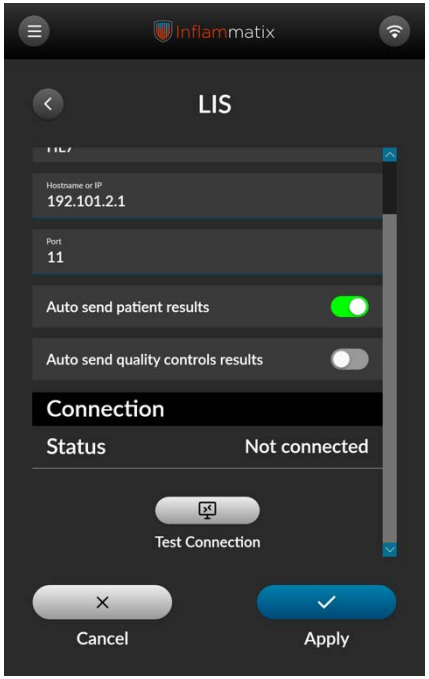


Figure 56 – Test LIS connection

LIS connection can be tested by selecting the Test connection button.

5.9 Quality control settings

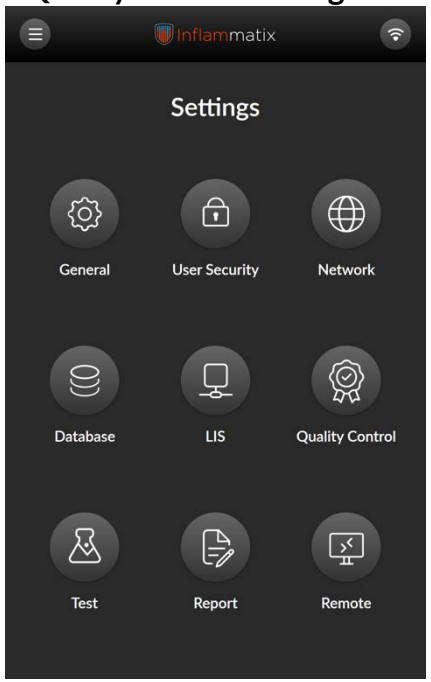


Figure 57 – Select quality control

From the Admin Menu, select Settings. From the Settings Menu, select Quality Control.

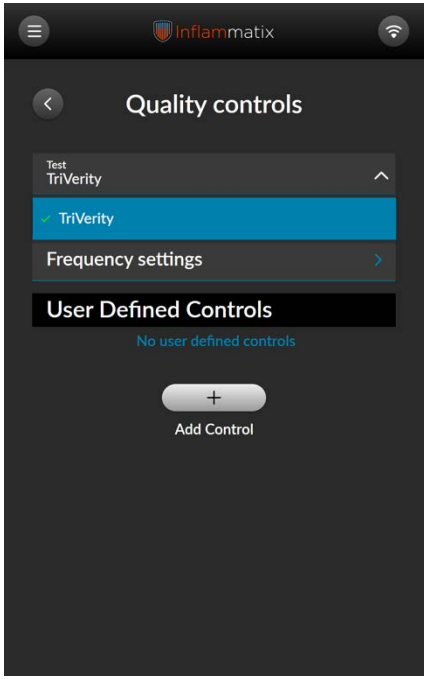


Figure 58 –Select QC test

This screen provides separate QC prompt settings for each test type.

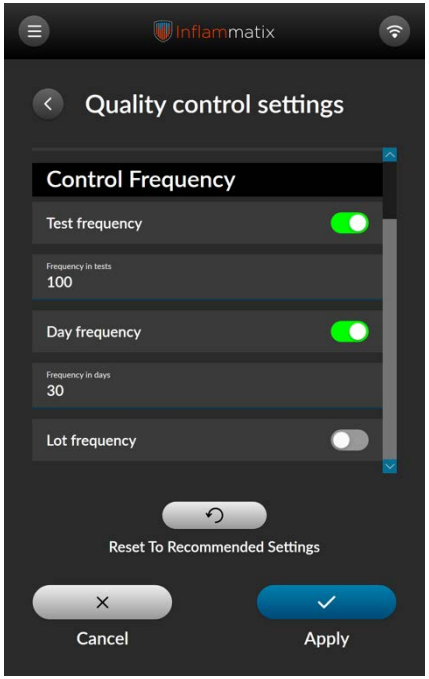


Figure 59 –Required to run test

Please follow local lab procedures for the Required test setting.
If the toggle is set to on (green) the system will prevent running of the designated test until a control test is performed.

Switching tests continued

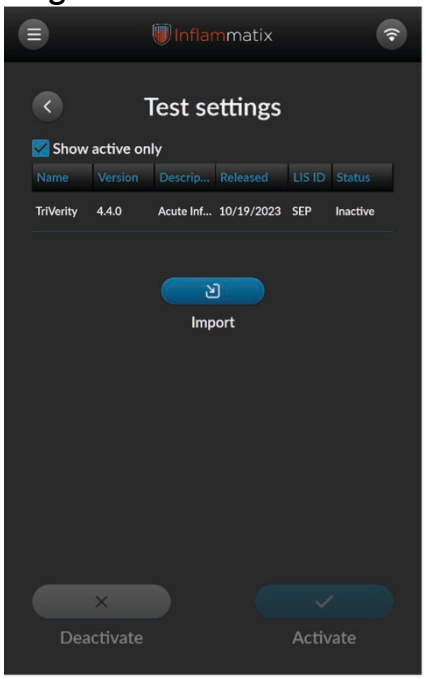


Figure 60 – Uncheck show active only

Uncheck Show active only.

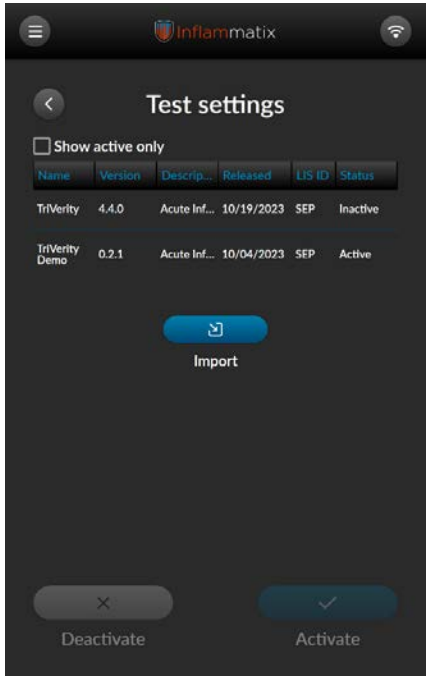


Figure 61 – View ADFs

All installed ADFs should now be shown.

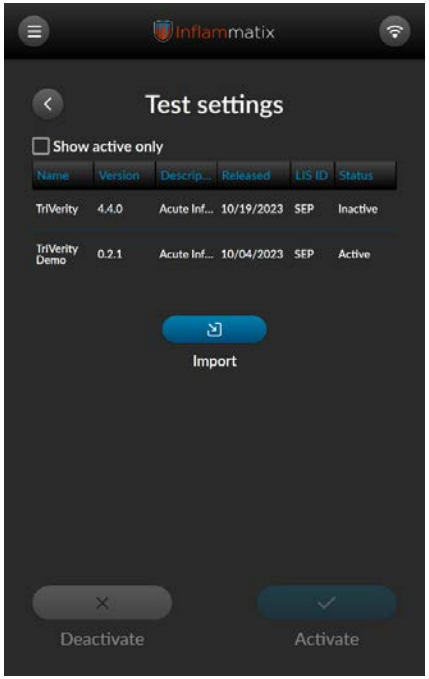


Figure 62 – Select ADF

Select the ADF that you wish to switch to.

In the example shown, the software will change from Version 4.4.0 to Version 0.2.1.

Switching tests continued

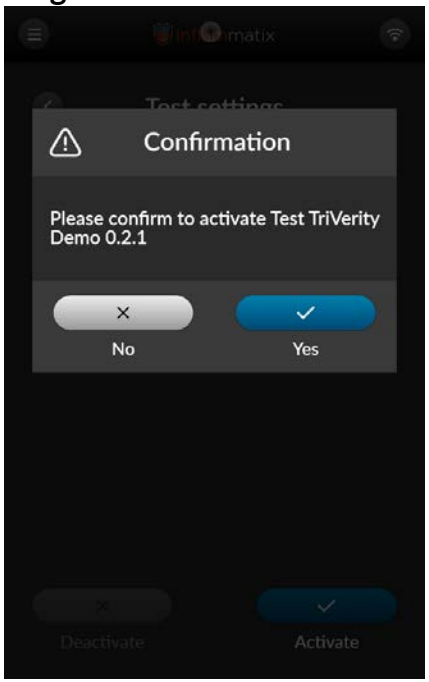


Figure 63 – Confirmation

Uncheck Show active only.

5.10 Importing a new test

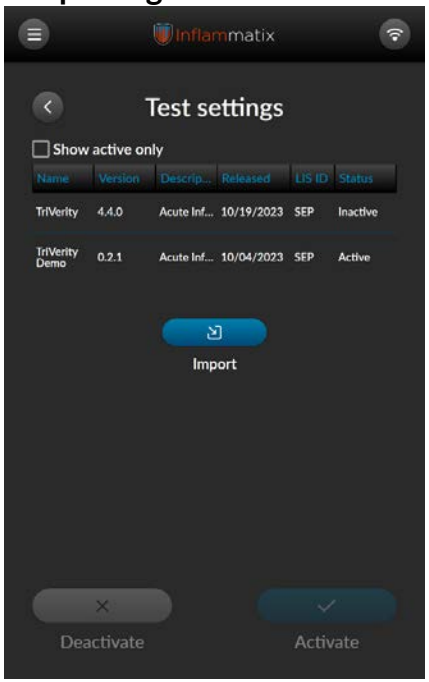


Figure 64 – Importing a new test

To import a new test, receive the updated ADF from Inflammatix and save it to a flash drive. Plug the flash drive into the instrument.

Click the blue “Import” button and navigate to the file on the flash drive using the file explorer. Select the file and confirm import of the ADF by checking that the active test is the one expected.

5.11 Report Printer Settings

To set up the printer, follow the instructions below and on the next page.

- Locate the printer adjacent to the Myrna Instrument
- Plug the USB cable into an available USB port on the back of the instrument.
- Plug the power cable into an available grounded outlet or surge protector.
- Verify that light on the front of the printer is illuminated.

When this is complete, proceed to the instructions on the following page.

Dymo LabelWriter 550

Dymo LabelWriter 550 Turbo

Dymo LabelWriter 5XL

Report printer settings continued

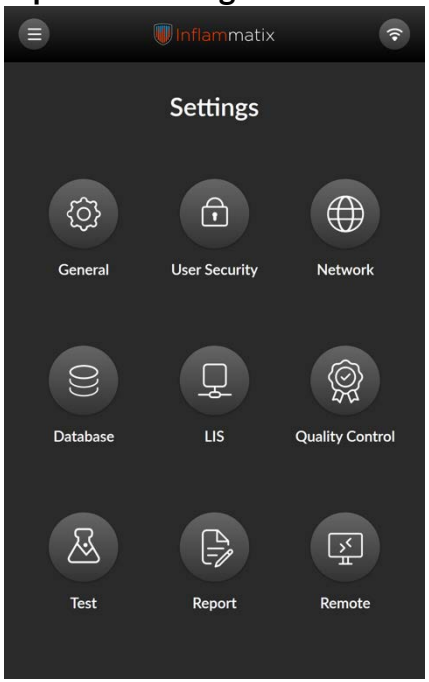


Figure 65 – Select report

From the Admin Menu, select Settings.
From the Settings Menu, select Report.

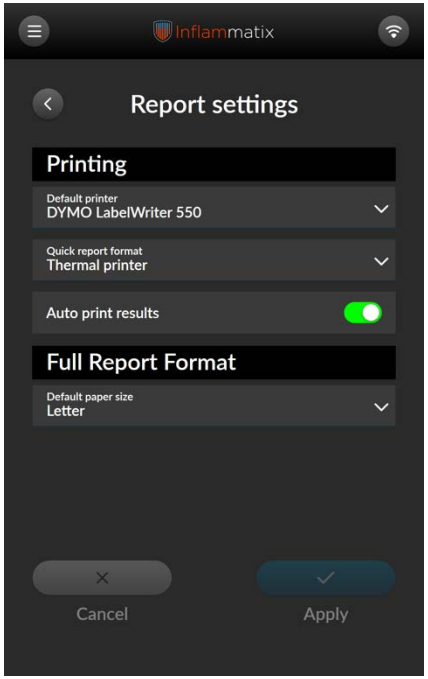


Figure 66 – Select printer

Select the correct printer from the menu. Selecting the correct model of printer is critical to being able to print reports. The correct drivers for the printer are already installed on the instrument.

5.12 Remote notifications settings

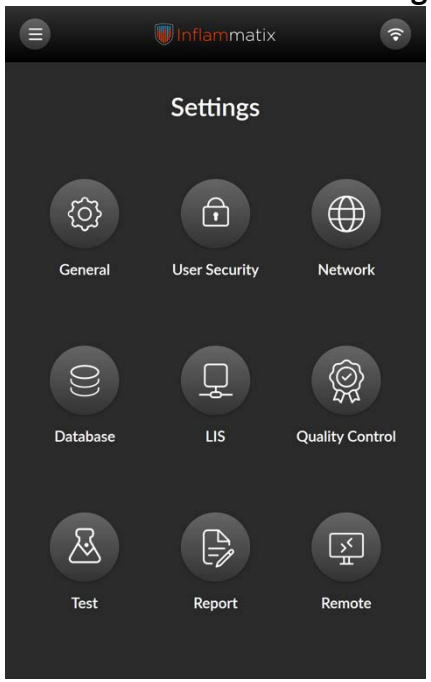


Figure 67 – Remote notifications

From the Admin Menu, select Settings. From the Settings Menu, select Remote.

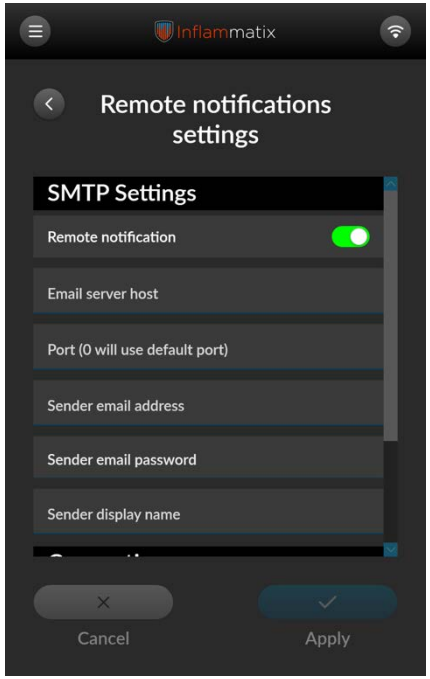


Figure 68 – Remote notifications

This screen sets up SMTP (email) communication of test results from the designated sender.

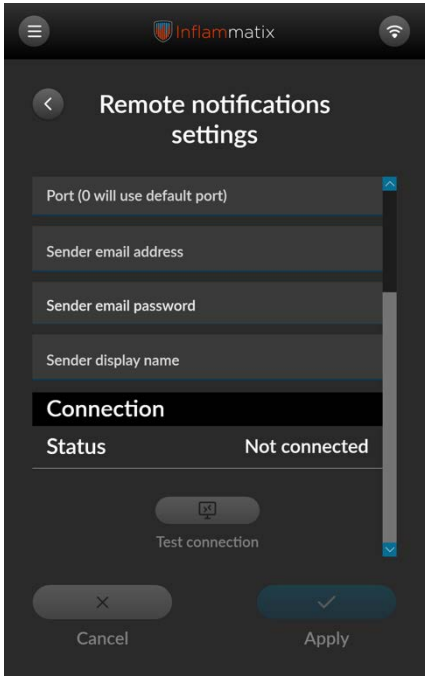
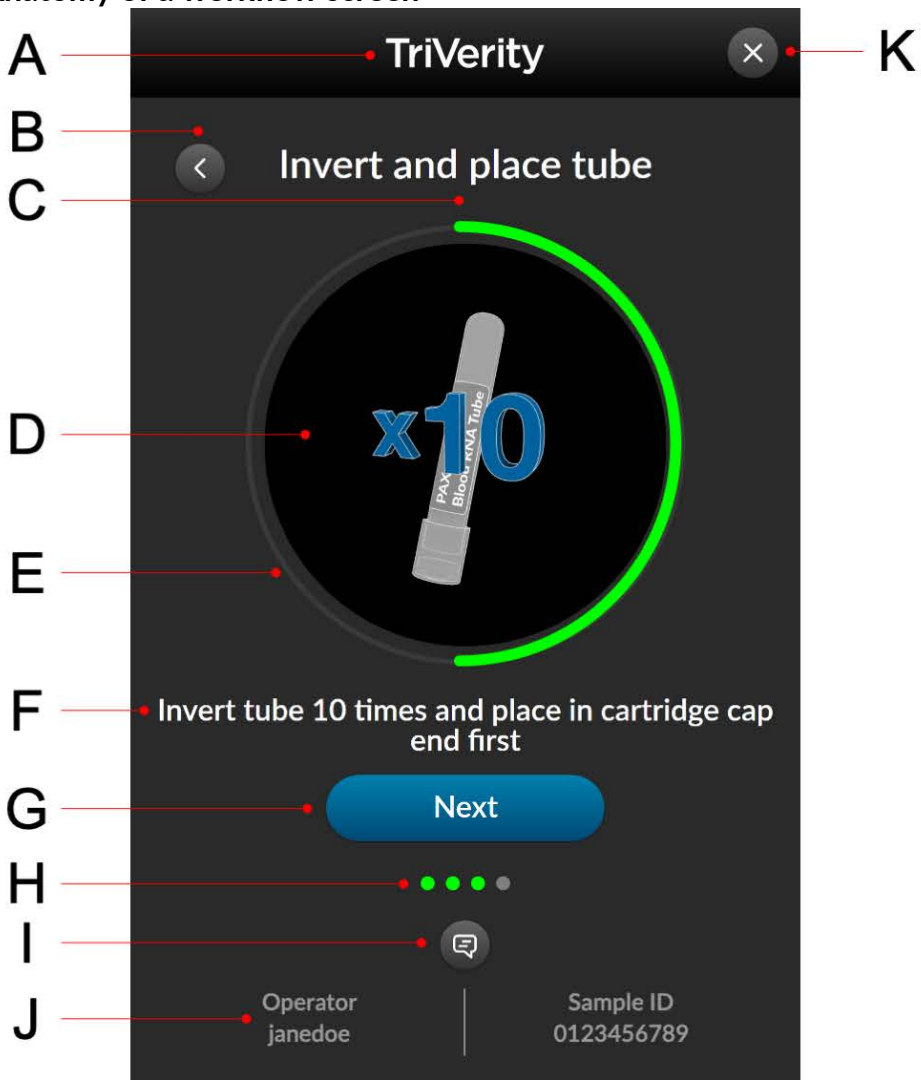


Figure 69 – Remote notifications

After populating the email information and pressing Apply, press the Test connection button to verify connection.

6.0 OPERATING THE INSTRUMENT

6.1 Anatomy of a workflow screen



The figure shown displays elements presented onscreen that work in concert to provide identification, clarification of the workflow step, and progress indication.

A. Test name (displayed after the Start New Test step)

B. Back button

C. Workflow step (primary call to action)

D. Central pane shows workflow step

E. Test step progress ring

F. Secondary detailed explanation of the workflow step

G. Command button (varies by workflow step)

H. Workflow progress indicator

I. Comment button

J. Footer displaying test-specific information as it is entered

K. Close button exits workflow

NOTE: This is a general representative screen and does not display all types of cartridges used in testing.

6.2 Lighting behavior

Instrument state	Lighting Color	Lighting Behavior	Action
Workflow walkthrough screens	White	Solid illumination	No action required.
Insert and eject cartridge	White	Quick pulsing	Intended to draw attention to the cartridge opening. Insert or remove the ejected cartridge.
Test in progress	Green	Solid illumination	No action required; test is running.
Test complete	Green	Moderate pulsing	Test is complete, review results or eject cartridge.
Test complete, but instrument idle with screen backlight off	Green	Moderate pulsing	Test is complete, review results or eject cartridge.
Error state	Red	Moderate pulsing	Follow the command on screen to resolve the error state. This includes error status codes for cartridge failure, system failure, insufficient sample, and critical errors. See Section 10.3 for more information.
Instrument idle with cartridge inserted	White	Moderate pulsing	No action required.
Instrument idle with screen backlight off	White	Solid illumination	No action required.
Menu selections other than a test	None	No illumination	No action required. Other selections include settings, support documents, etc.

Figure 70 - Status light examples

7.0 QUALITY CONTROL

7.1 Control testing purpose

The Myrna Instrument allows for quality control testing. The frequency of reminders to run a quality control test are configurable in the following manner:

- Test frequency – reminder to run a QC is triggered per every N number of tests run
- Day frequency – reminder to run a QC is triggered every N days
- Lot frequency – reminder to run QC is triggered for every new cartridge lot run

Controls should be run in accordance with local, state, and federal accrediting organizations, as applicable.

7.2 Procedure for running a quality control test

Before you run a QC test

Follow these warnings and cautions before you begin the test:

- To avoid contamination and injury, follow local cleaning standards.
- Verify that the cartridge is correct for the intended test type.
- Always handle the cartridges and sample tubes per standard blood-borne pathogen precautions, with gloves.
- Check cartridge for any damage to packaging. Discard if damaged.
- Check cartridge for expiration date. Discard if expired.

Follow these warnings and cautions during the QC test:

- Before opening cartridge and QC sample tube pouches, scan barcodes as instructed on screen.
- Disregard the barcode on the cartridge. This barcode is read automatically by the machine after insertion.
- Do not drop the sample tube and/or test cartridge. Discard if dropped.
- Do not shake or tilt the test cartridge after adding a sample. This may cause an inaccurate result.
- Do not touch the cartridge components with fingers. The blisters contain caustic liquids.

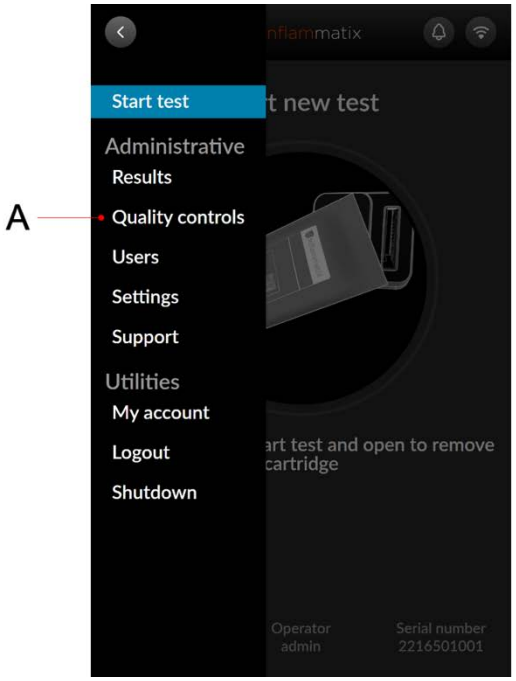


Figure 71 – Select quality controls

Select Quality Controls from the Admin User or Operator User Menus.

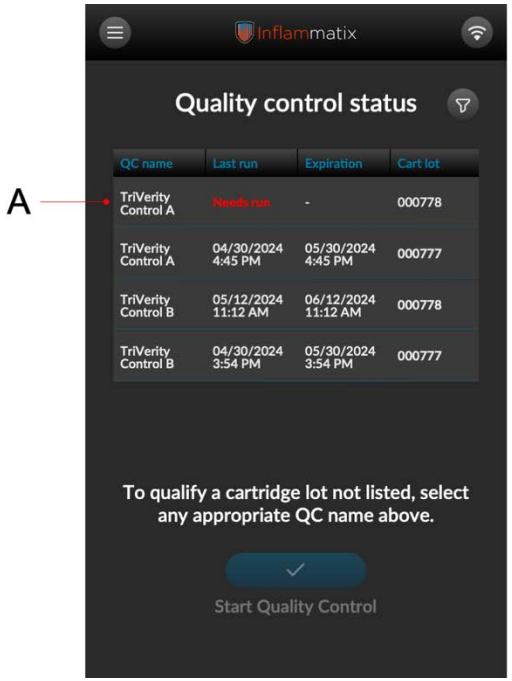


Figure 72 – Status and start quality control

Select desired quality control from the list shown.
Optional filters may be applied to the list by selecting the button in the upper-right corner.
NOTE: QCs must be pre-added in order for them to be displayed in the instrument.
Select the Start Quality Control button.

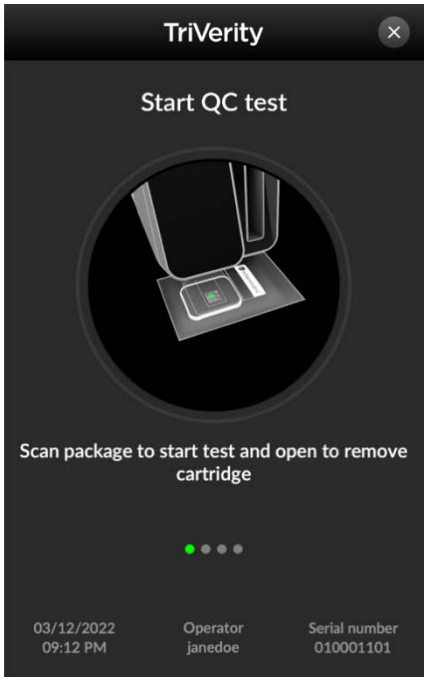


Figure 73 –Start QC test

Caution: Use correct cartridge for intended test.
Scan the cartridge foil pouch barcode. This informs the instrument of the test type.
Using the tear notch, carefully open cartridge foil pouch and remove the cartridge.
Follow the prompts on screen and prepare the external quality control as necessary.
Press the NEXT button on the instrument screen.

Procedure for running a quality control test continued

Figure 74 – Insert cartridge

When the instrument is ready, the door will open, and the solid white light will flash. Place the cartridge into the doorway of the instrument with the label side facing the screen, as shown. Gently advance the cartridge until the instrument pulls it in.

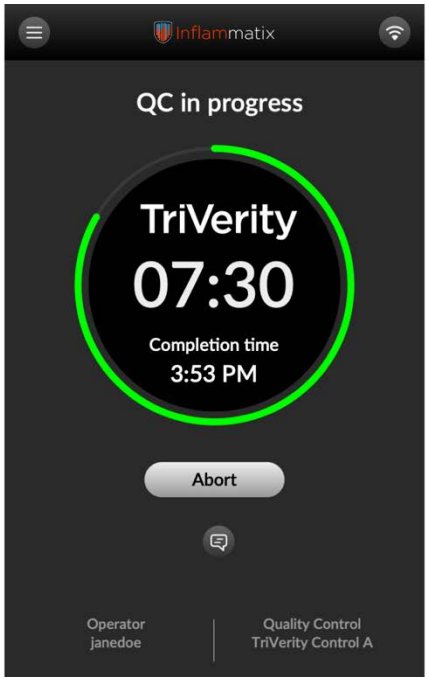


Figure 75 – QC in progress

The test process begins with the display of a countdown clock, to show progress. The door light changes to a solid green while the test is in progress.
The estimated completion time is displayed.

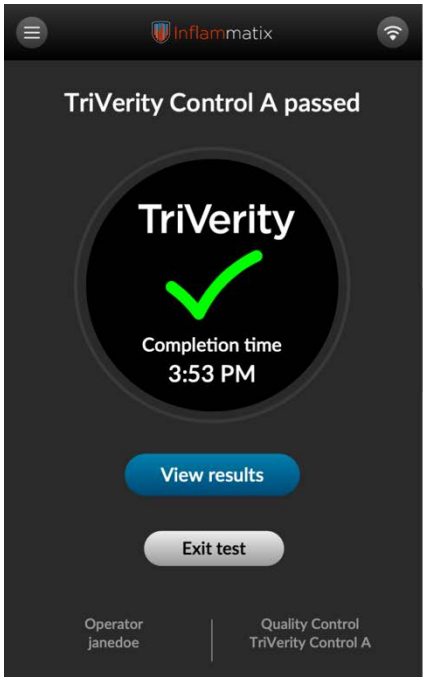


Figure 76 – QC test passed

If the test has passed, the screen displays passed. The door light pulses in green.
Select View Results or Exit Test.

Procedure for running a quality control test continued

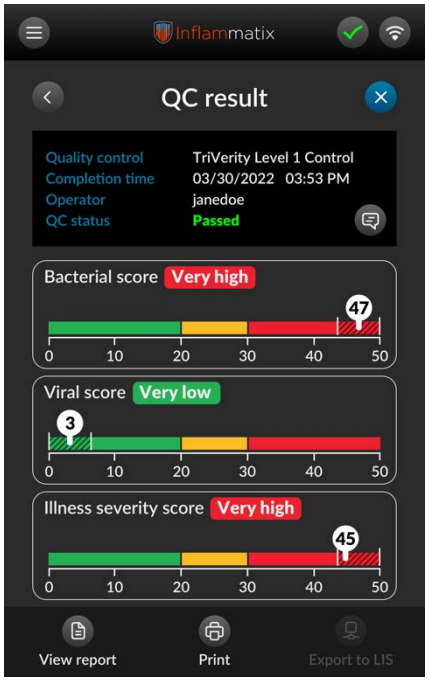


Figure 77 – View QC results

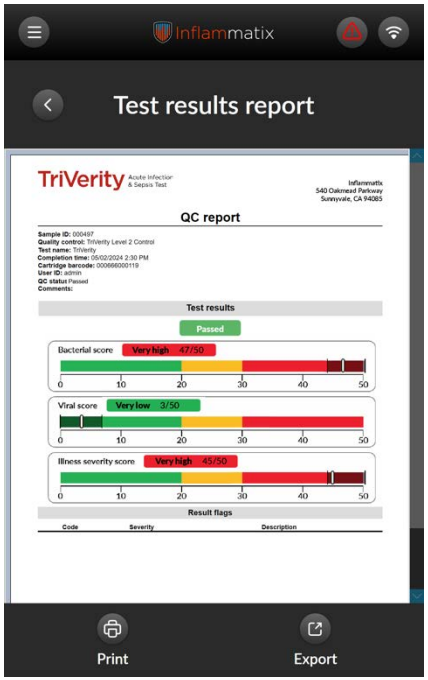


Figure 78 – View QC report

Figure 79 – Remove cartridge

The QC result screen displays. Three buttons at the bottom of the QC Result screen offer these options:

- View report
- Print
- Export to LIS (Laboratory Information System)

Note: that the Export to LIS is automatic if this button is grayed out.

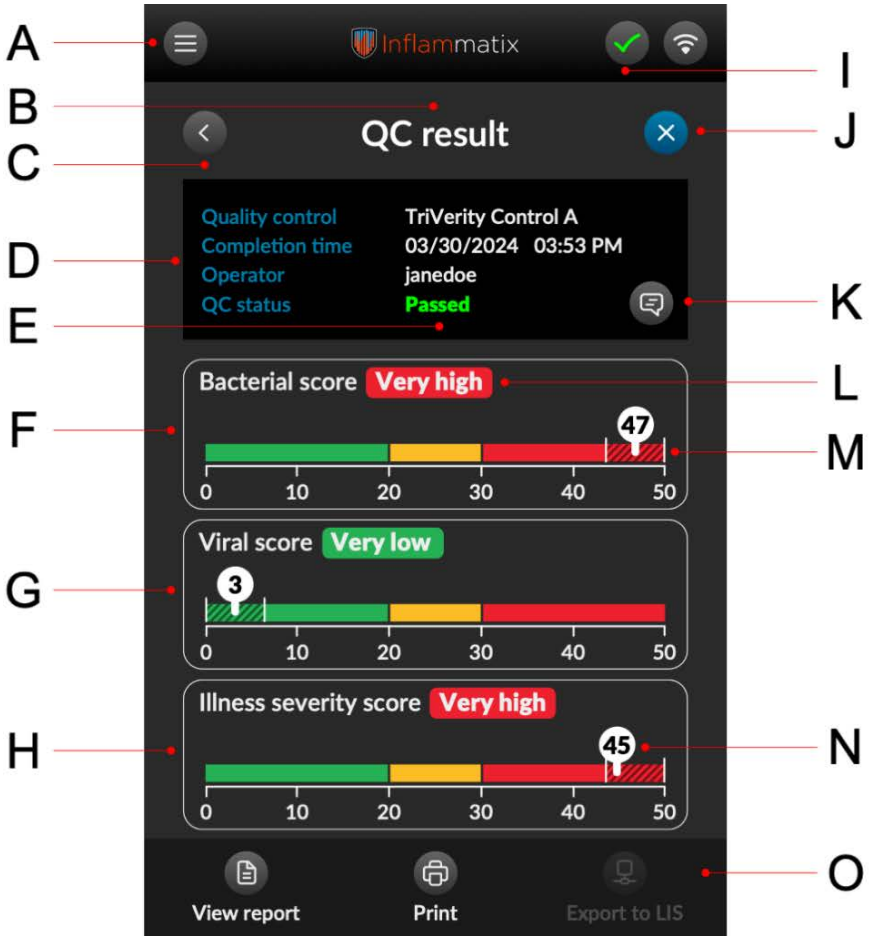
If View report is selected, it displays as shown above. Two options are offered:

- Print (to a connected thermal printer)
- Export (to a local drive or connected network)

The back button in the upper-left returns to the QC result screen.
Further information on analyzing QC results shown at the end of this section

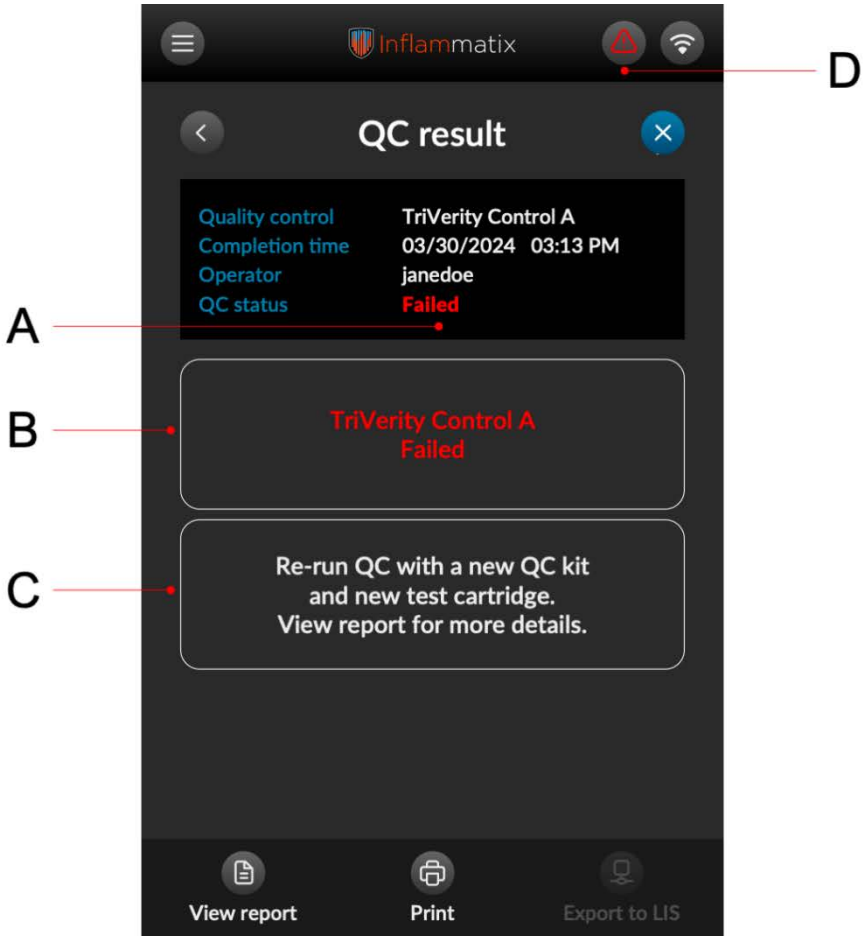
Exit test by pressing the blue X button on the upper-right corner of the QC result screen, or by pressing the back button in the upper-left corner to return to the QC test passed screen to Exit Test.
When Exit Test is selected, the light will flash white while the cartridge is ejected. Discard cartridge per laboratory procedures.

7.3 QC Results passed example



A. Return to Main Menu
B. Screen header
C. Returns to the QC Test Complete screen
D. Metadata for this QC test event
E. Status for this QC test event
F. QC test range and bacterial score
G. QC test range and viral score
H. QC range and illness severity score
I. Returns to the Test Complete screen
J. Exits the test and triggers ejection of the cartridge
K. Display any comments entered during the workflow or test
L. Result band
M. Range within which a result must fall to pass
N. Exact QC result for this range
O. Footer that includes options for results export

7.4 QC Results failed example



A. Indicates the QC status of this test

B. Indicates control type that failed for this test

C. Instructions to resolve the issue

D. Returns to the Test Complete screen

Note: A passed or failed report result is saved in the system under Results and can be retrieved and printed at any time.

7.5 Export and Print Command buttons

Icon	Label	Explanation
	View Report	Displays a report.
	Export to LIS	Exports the report to the LIS Laboratory Information System) which may be connected to the EMR (Electronic Medical Record). This is a configurable option, and this button is grayed out if set to automatic or if no LIS is connected.
	Print	Prints the test or other result to a connected thermal printer.
	Export to PDF	Exports the results report or reports in the form of a PDF to an external drive or designated network location.

7.6 Exporting a report

Test result reports can be output in a variety of different ways by using the buttons at the bottom of the test result and test result report screens.

7.7 QC Post-test procedure

For post-test procedures, refer to the respective Instructions for Use documents (IFU) for the specific test cartridge.

7.8 Setting up a user-defined control

User defined controls may also be set up and run. Follow the steps below for setting up a user defined control.

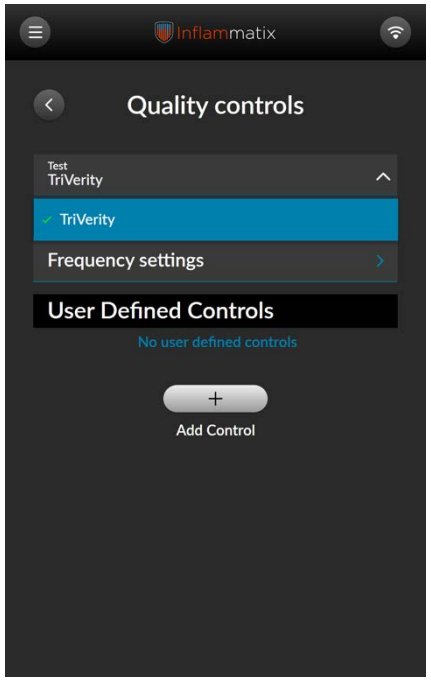


Figure 80 – Select test only

From the Quality Controls settings page, select the Add Control button under User Defined Controls.

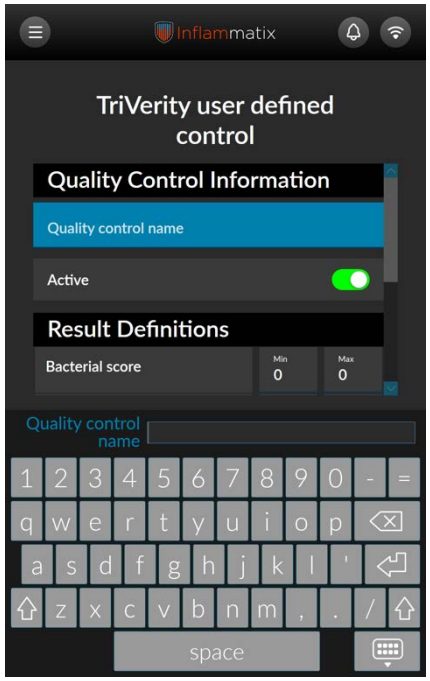


Figure 81 –List all tests

Specify a name for the control in the top text entry field.

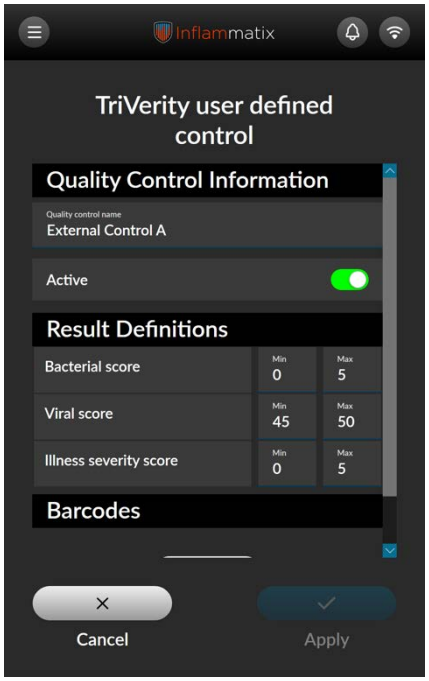


Figure 82 –List all tests

Set the control to active.
Under Results Definition, define the ranges within which a score must fall to qualify as passing.

Setting up user defined control continued

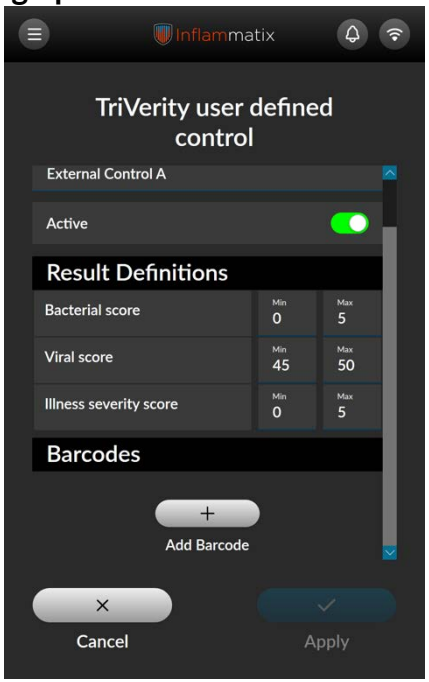


Figure 83 – Select test only

Press the Add Barcode button to enter a barcode either manually or by scanning it with the front facing instrument barcode scanner.

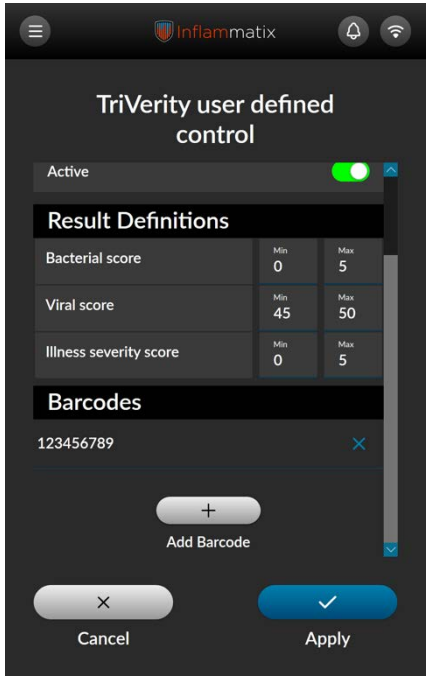


Figure 84 –List all tests

Press apply once all of the necessary fields have been populated.

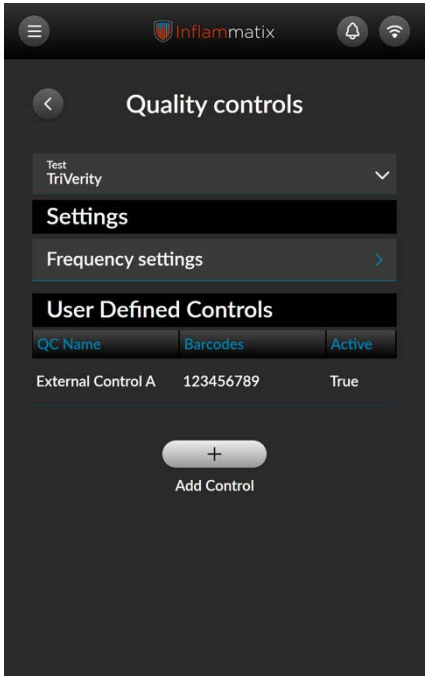


Figure 85 –List all tests

The user defined control should now be listed on the Quality controls settings screen under User Defined Controls.

8.0 RUNNING A PATIENT TEST

8.1 Sample collection

Follow the collection procedure for the applicable sample tube. This can be found in the sample tube IFU or Inflammatix test IFU.

Ensure the sample is properly mixed and if any time has passed, take the necessary steps to resuspend the RNA in the sample tube.

Caution: Make sure that the sample collection tube matches the cartridge type for the selected test.

8.2 Procedure for running a patient test

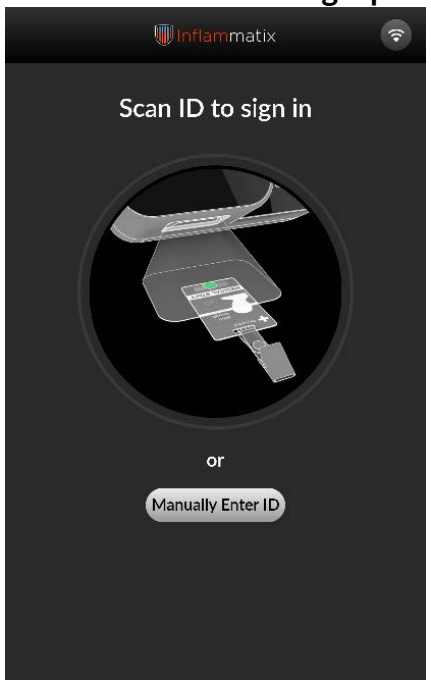


Figure 86 – Scan ID to sign in

Scan or manually enter User ID and password, if required.

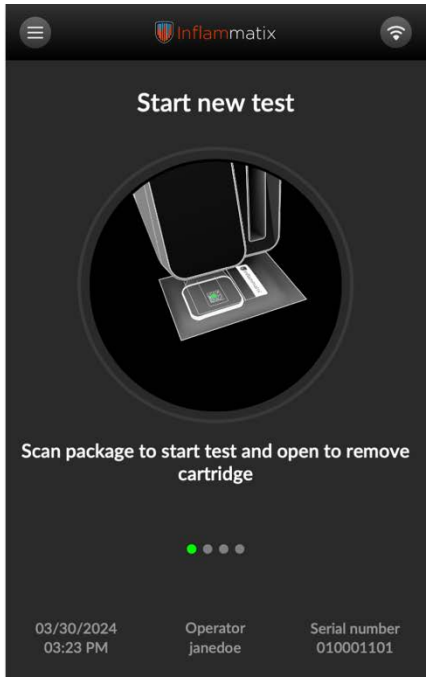


Figure 87 – Scan cartridge pouch barcode

Caution: Check the test cartridge foil pouch expiration date and for any damage to packaging. Discard if expired or damaged.
Scan the cartridge foil pouch barcode. This informs the instrument of the test type.
Using the tear notch, carefully open cartridge foil pouch and remove the cartridge. Use immediately after opening.

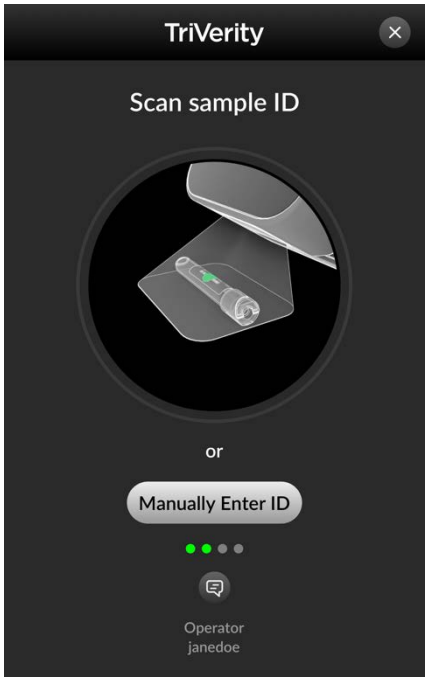


Figure 88 – Scan sample ID

Caution: Check test cartridge and sample tube for damage. Discard if damaged.
Scan the sample ID as shown above, or manually enter the sample ID as shown on the following page.

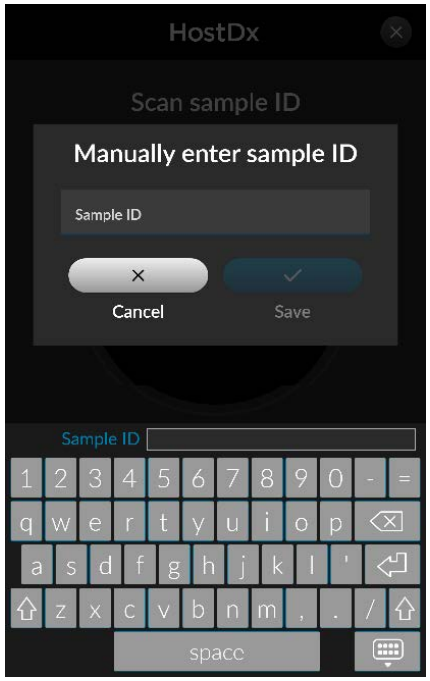


Figure 89 – Manually enter sample ID

Manually enter Sample ID.

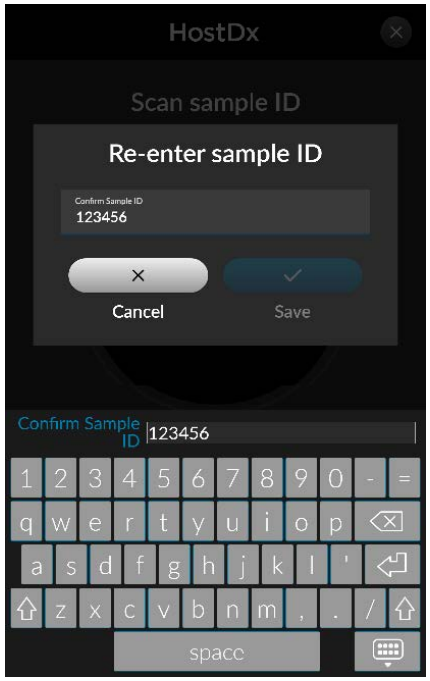


Figure 90 – Confirm sample ID

Manually re-enter sample ID if required.

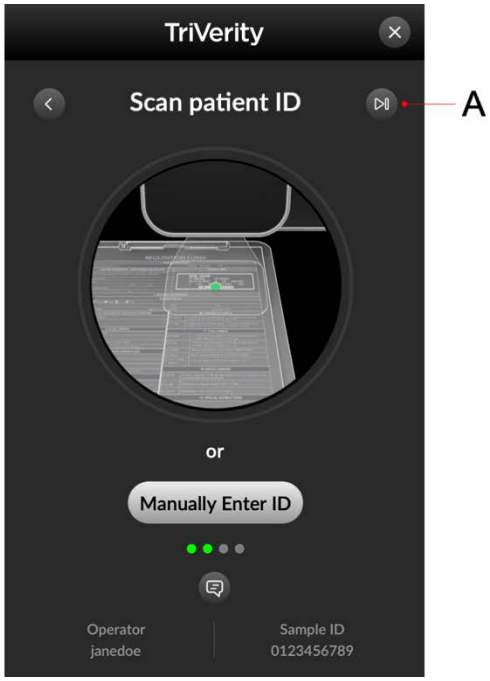


Figure 91 – Scan patient ID (optional)

Scan or manually enter the optional Patient ID if your system requires it.
To skip this step, press the skip button in the upper-right corner.
If the instrument is configured not include this workflow step, this screen will not appear.

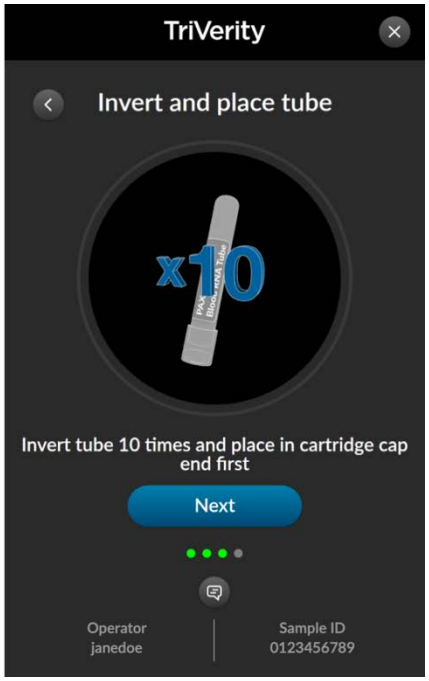


Figure 92 –Invert sample 10 times

Figure 93 – Place tube in cartridge

Figure 94 – Place cartridge in instrument

Caution: Inversion must be repeated immediately before the test is to be performed if there is a delay or sample is re-used.
Gently invert the sample tube 10 times as shown above. The image below shows one inversion.

Caution: Do not shake or tilt the test cartridge after inverting and tube placement.
Caution: Avoid touching the cartridge components with fingers. Blisters contain caustic liquids.
Insert the sample tube into the cartridge cap side first, until a click is heard and felt.

When the instrument is ready, the door will open, and the status light will change from solid white to flashing. Place the test cartridge into the doorway of the instrument with the label side facing the screen.
Note: Only insert the cartridge that has been scanned by the Myrna Instrument in Step 2 of the test workflow.

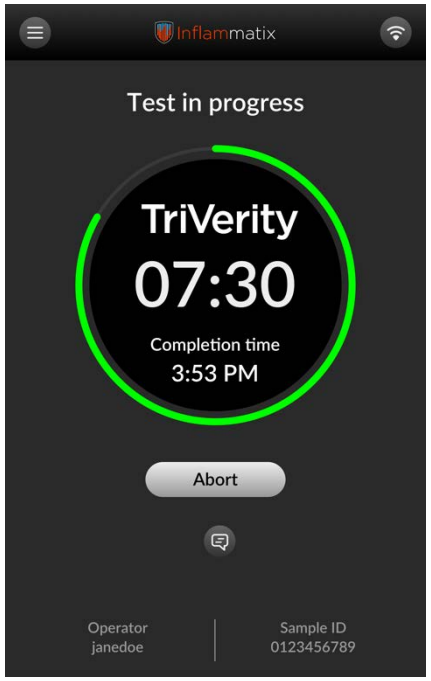


Figure 95 – Test in progress

The test process begins with display of a countdown clock to show progress. The instrument light displays solid green.
The estimated completion time is displayed.
The automated testing progress continues.

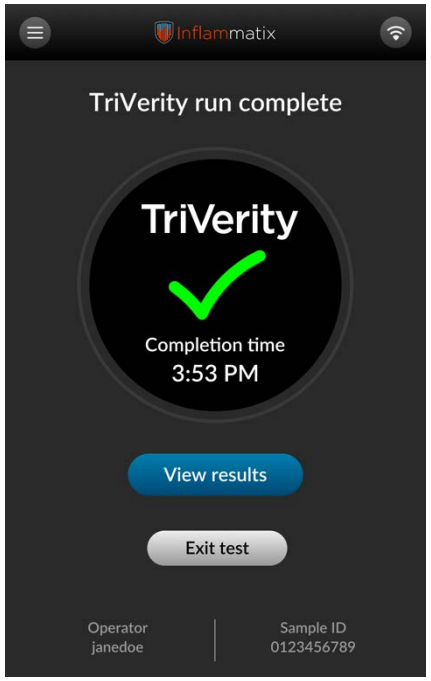


Figure 96 –Test complete

When the test is complete, the screen displays a green check mark. The instrument green light pulses to signify test complete.
Select View Results.

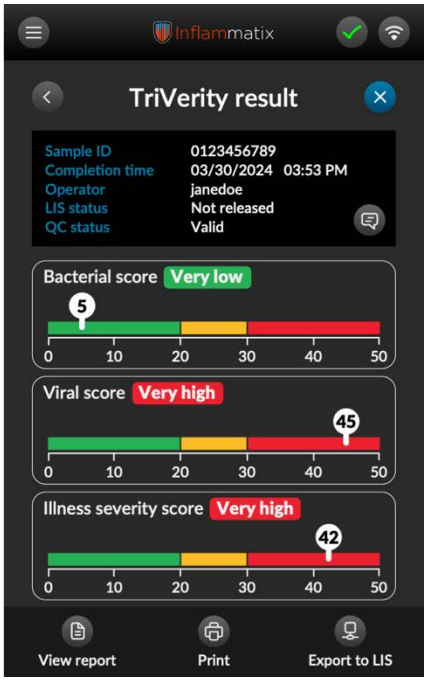


Figure 97 – View results

Three buttons at the bottom of the Result screen offer these options:

- View report
- Print
- Export to LIS (Laboratory Information System)

Note: Export to LIS is automatic if this button is grayed out.
For further information on interpreting test results, see Section 8.3

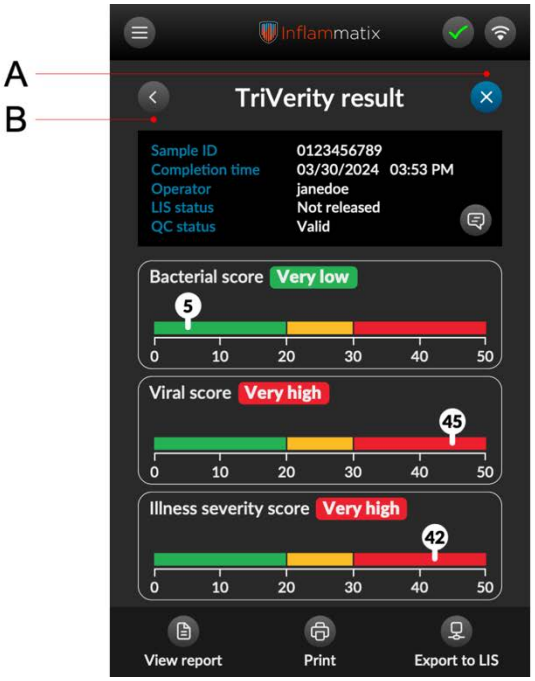


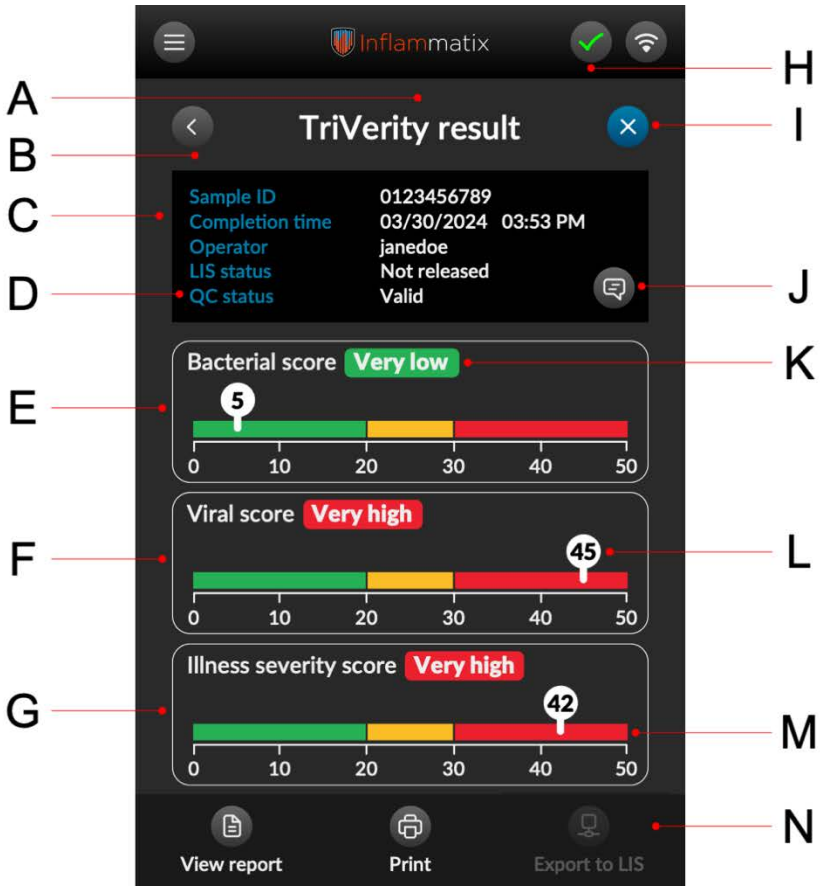
Figure 98 – Select to exit test

Figure 99 – Remove cartridge

Exit test by:
Pressing the blue X button in the upper-right corner or
Pressing the arrow button in the upper-left corner to return to Test Complete (Figure 96), then select Exit Test.

When Exit Test is selected, the light pulses white while the cartridge is ejected. Gently remove the cartridge. The light returns to static white.
Discard cartridge per laboratory biohazard procedures.

8.3 Interpreting results example



A. Test results screen header
B. Returns to the Test Complete screen
C. Metadata for this test event
D. Quality control status
E. Bacterial range, bands, and score
F. Viral range, bands, and score
G. Illness severity range, bands, and score
H. Returns to the Test Complete screen
I. Exits the test and triggers ejection of the cartridge
J. Displays any comments entered during the workflow or test
K. Result band
L. Range of five (5) interpretation bands within which a score will fall
M. Exact score for this result
N. Footer that includes options for results export. If the rightmost button is selected, the results export to the LIS system. If Export to LIS is automatic, or LIS is not connected for any reason, this button is grayed out.

Note: This report result is saved in the system under Results and can be retrieved and printed until a records purge is performed.

8.4 Post-test procedure

For post-test procedures, refer to the respective Instructions for Use documents (IFU) for the specific test cartridge or sample tube.

9.0 CYBERSECURITY

9.1 Cybersecurity guidance for the Myrna Instrument

The Myrna Instrument can operate as a standalone device or within a networked environment. Approved, secure network transmissions include:

- Transmitting test results to a laboratory information system (LIS)
- Connecting to a data management web portal

The Myrna Instrument incorporates comprehensive cybersecurity controls integrated into the pre-configured computer operating system. Inflammatix ensures that the computer is free from malicious software before delivery. The software runs on a secure operating system in a locked-down mode configured to prevent unauthorized access. The internal data drive uses encryption to protect information at rest. Antivirus scanning happens automatically at regular intervals and following particular system events.

Test results are processed by secure software modules designed to ensure data integrity and confidentiality through the use of encryption during data transmission.

The Myrna Instrument uses user accounts with restricted privileges for routine operations. Administrative privileges are required for configuration changes and are protected by enhanced security measures. Users must have appropriate credentials and access permissions to make any changes.

Only authorized software configuration parameters, as described in the user documentation, should be modified.

For detailed information on user setup and password requirements, see section 0: New User Setup.

9.2 Interoperability

9.2.1 Interfaces

The following is a list of network ports and other interfaces that enable the Myrna Instrument to receive and/or send data. These interfaces are secured to ensure data integrity and protect against unauthorized access:

- USB Ports: Interfaces with USB 2.0 devices. Security measures include automatic scanning of connected devices for malware and restrictions on the types of USB devices that can be used.
- Ethernet Port (802.3): Secure wired network connection with encryption to protect data in transit.
- WiFi Antenna (802.11): Supports secure wireless network connections with WPA3 encryption to ensure data integrity and confidentiality.

All other ports are locked down and otherwise inaccessible.

9.2.2 External peripherals

The Myrna Instrument is designed to interface with external peripherals such as barcode scanners, keyboards, and printers via USB. Each peripheral connection is monitored for security threats, and users are advised to connect only trusted devices (e.g., Datalogic Gryphon external barcode scanner, Dymo 450 and 550 series thermal printers). Any new peripherals must be approved and tested by Inflammatix to ensure compatibility and security.

9.2.3 Data Import and Export

- Importing Data: New test Assay Definition Files (ADFs) can be imported via USB or secure connected network drive. There are five (5) external USB ports on the instrument enclosure, all of which are secured with anti-virus scanning and encryption.
- Exporting Data: Information about previously executed tests and other system data can be exported via USB, Ethernet connection, or WiFi. Data export is secured with encryption to ensure confidentiality and integrity.

9.2.4 Software Integration

The Instrument software integrates with external health systems through the Laboratory Information System (LIS). Connections are secured and can be established via Ethernet or WiFi, using encrypted protocols.

9.2.5 Communication Protocols

The Instrument supports the following communication protocols with the LIS:

- HL7 v2
- ASTM LIS01-A and ASTM LIS2-2A
- POCT1 (POCT01-A2)

Consult your IT department for setup and assistance in selecting the appropriate protocol for your facility's LIS or other lab or hospital records database.

9.2.6 Security and Updates

- Security Measures: All data transfers are encrypted. Regular security audits are conducted to ensure compliance with cybersecurity standards.
- Firmware and Software Updates: The device firmware and software are regularly updated to ensure compatibility and security. Users are notified of updates and provided with instructions for secure installation.

9.2.7 Incident Handling

In case of any security incidents related to interoperability, such as detection of malware on a connected peripheral, users should immediately disconnect the device and contact technical support. Detailed logs of all interoperability events are maintained for audit purposes.

9.2.8 Compatibility

The instrument should only be used with the specified medical devices and peripherals listed above. Do not connect it to other medical or non-

medical devices not listed in this manual. Compatibility testing is performed to ensure seamless integration with approved devices and peripherals.

9.3 Shared responsibility for security

Ensuring the security of medical devices is a collective responsibility involving healthcare facilities, patients, healthcare providers, and manufacturers. Users must secure their networks and implement appropriate protection measures to safeguard against viruses, unauthorized access, alterations, manipulations, and data breaches. Regular training and updates on cybersecurity best practices should be provided to all users.

For access to the Software Bill of Materials (SBOM) associated with this product, please contact Inflammatix support.

9.4 Best practices for maintaining integrity

To maintain the integrity of the Myrna Instrument:

- Avoid using personal computer media (e.g., USB devices).
- Ensure that any computer media used is scanned and free of malicious software.
- Exercise caution when transferring computer media between instruments.
- Only install software provided or recommended by Inflammatix.

For field deployment, software upgrade packages are distributed via secured methods. The integrity of these updates is verified through multiple security checks built into the upgrade process and instrument software.

9.5 Response to Anomalous Conditions

The Myrna Instrument is designed to respond effectively when anomalous conditions or security events are detected. The device includes mechanisms for:

- Lockout Notifications: Users are immediately notified if the system is locked out due to too many failed login attempts. The system will log these incidents and provide guidance on how to regain access.
- Data Integrity Checks: Continuous monitoring and integrity checks are performed to ensure data has not been compromised. If any anomalies are detected, the system will alert the user and log the incident for further analysis.
- Software and ADF File Integrity: Assay Definition Files are scanned with anti-virus software prior to importing into the system. If an anomalous condition is detected, the files are rejected, and users are notified. The system logs these events for auditing purposes.
- WiFi connection limitations: The Myrna Instrument will only permit connections to WiFi networks that meet specified security protocols (e.g., WPA3). Any attempt to connect to an insecure network is blocked, and the user is notified.
- Incident Logging and Reporting: All security events and anomalous conditions are logged with detailed information to support auditing and review. These logs are accessible to authorized personnel.
- User Guidance: Users are provided with clear instructions on the steps to take when receiving notifications of anomalous conditions, including contacting support and checking system logs.
- Regular Updates and Patches: The device is regularly updated with the latest software patches to address newly discovered vulnerabilities. Users are notified of these updates by Inflammatix and required to install them.

- Role-Based Access Control: The system employs role-based access control to ensure that only authorized users can access specific functions and data, enhancing overall security.
- Fail-Safe Mechanisms: The Myrna Instrument includes fail-safe mechanisms to ensure it remains in a safe and secure state during and after detecting anomalous conditions.

9.6 Additional Support

For more information on supported network configurations and cybersecurity risk management, including Assay Definition File (ADF) and software updates, please contact Inflammatix customer technical support. The Inflammatix technical support team is available to assist with any security-related inquiries and provide guidance on best practices for maintaining the security and integrity of the Myrna Instrument.

10.0 SUPPORT

This section comprises management and support tasks, including results management, error reporting, and system maintenance tasks.

10.1 Results management

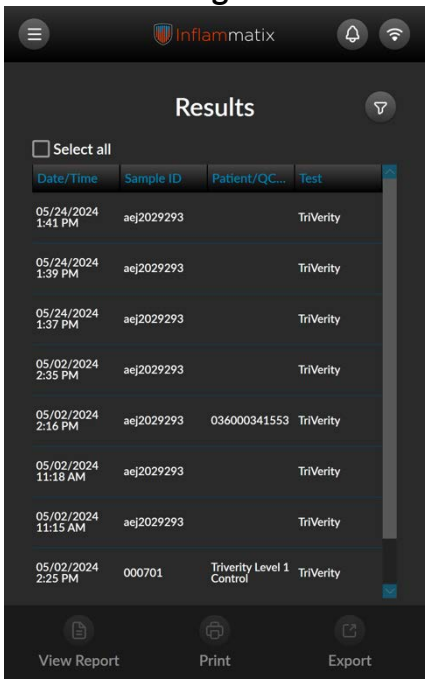


Figure 100 – List all results

Select Results from the Main Menu. Results will be listed by date by default.

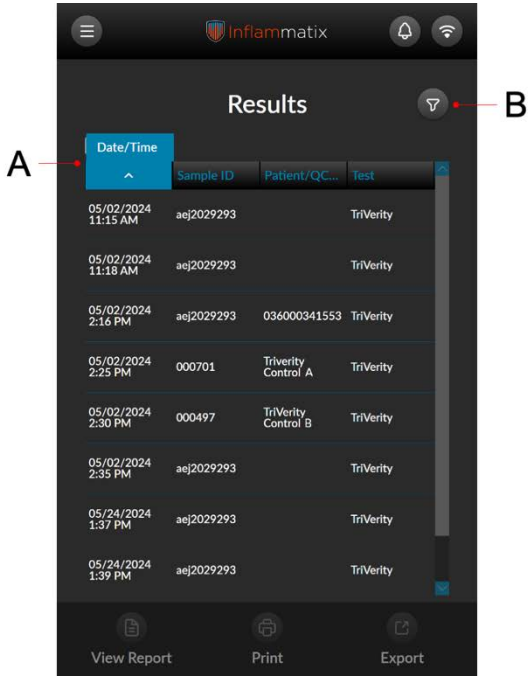


Figure 101 – Date and time selection

Select the desired header to reorder the list accordingly.
Select the filter button in the upper right to display a pop-up displaying filter choices.

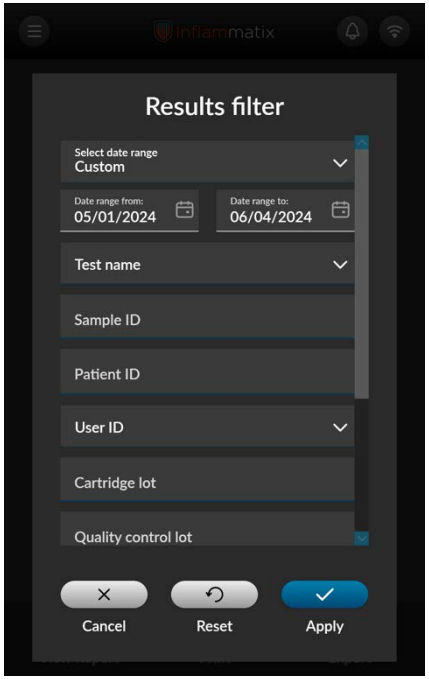


Figure 102 – Select date range

Select the start and end date range for the report from the pop-up screen. This changes the range of the results list shown.

Results management continued

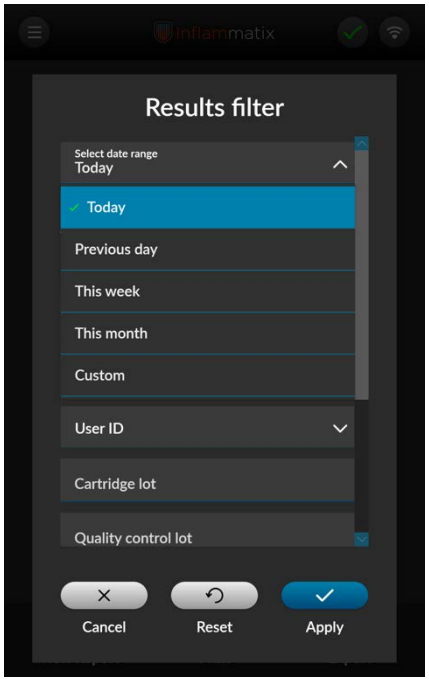


Figure 103 – Select date parameters

Customize the date range by selecting the desired option and pushing the Apply button.

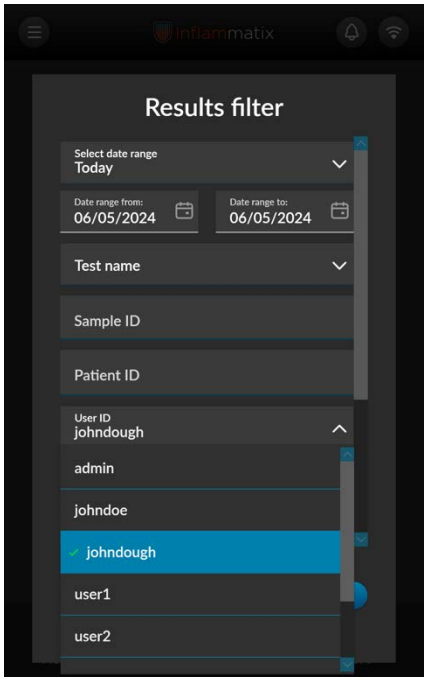


Figure 104 – Select by user

Select from other filter operations from the pulldown menu.

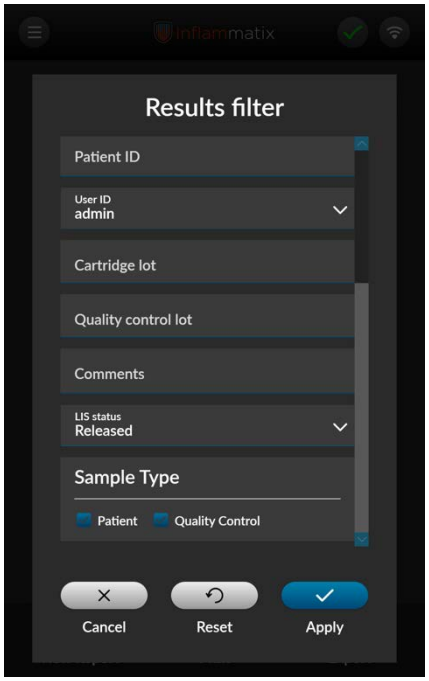
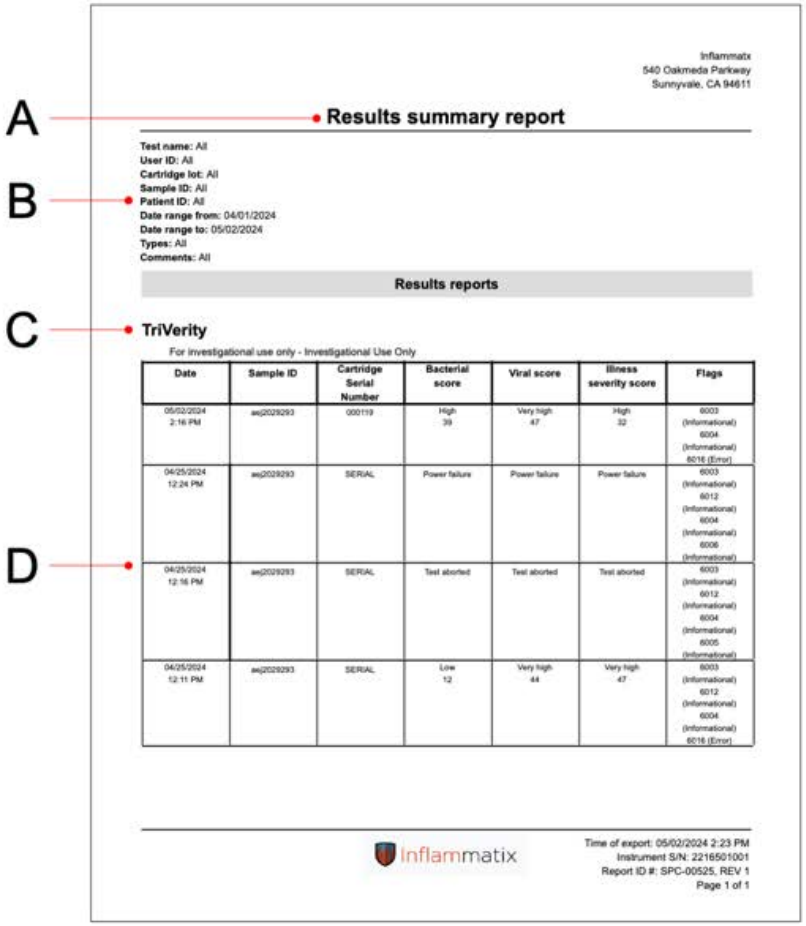


Figure 105 – Select by other parameters

Select other parameters including:

- Cartridge lot
- Quality control lot
- Comments
- LIS upload status
- Sample Type

10.2 Results summary report example



A. Title of Report

B. Report Parameters listing
   - Test name
   - User ID
   - Cartridge lot
   - Sample ID
   - Patient ID
   - Comments
   - Date range from/to
   - Test types

C. Test Type

D. Summary details including
   - Date
   - Sample ID
   - Patient ID
   - Bacterial Score
   - Viral Score
   - Illness Severity Score

   Note: Each test type will be listed in a separate table, with appropriate headings and details.

10.3 Errors and Prompts

Various errors may manifest during interaction with the instrument. These errors may include use-related errors, sub-optimal environmental conditions, or hardware and/or software faults that occur during system use.

The touchscreen display provides indication of the cause and instructions on how to take the appropriate actions to reach a resolution. In some cases, the appropriate action may simply be to wait while the instrument performs a functional test to identify the origin of an error that prevented a run from completing successfully.

Although errors may vary in level of severity and specific type, they are presented to the user in the same manner through the graphical user interface. Errors that arise may require the following actions:

A. Re-start the test with a new cartridge.
B. Reboot the system to start a test.
C. Reboot the system and re-start the test with a new cartridge.
D. Insufficient RNA - check IFU for instructions.
E. Wait for the instrument to be ready before running the next test.
F. Contact customer support.

This section provides some examples of informational pop-ups, warning pop-ups, and errors that may be seen on the Myrna Instrument. Message contents vary depending on the situation triggering the pop-up or error.

Error conditions are identified by a red light ring on the instrument. Most errors can be resolved by an Operator or Admin. Follow the on-screen prompts. If errors persist contact Inflammatix for assistance.

Please follow local standard procedures.

10.4 Informational & warning pop-up alert examples

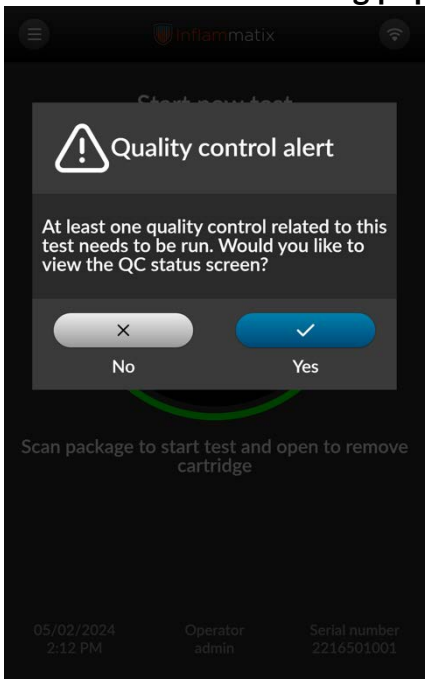


Figure 106 – Troubleshooting parameters

This alert warns that the quality control status for this test is invalid.
Unless the QC is performed, the test will report QC status as Invalid.
This is a configurable option in Settings.

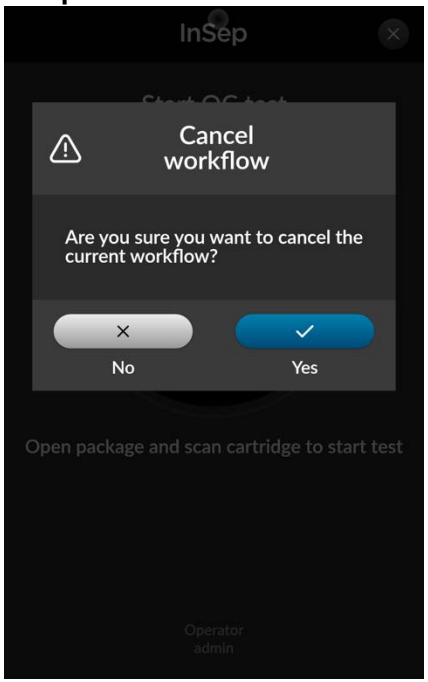


Figure 107 – Cancel workflow

This alert asks the user to confirm that they do want to cancel the current workflow.

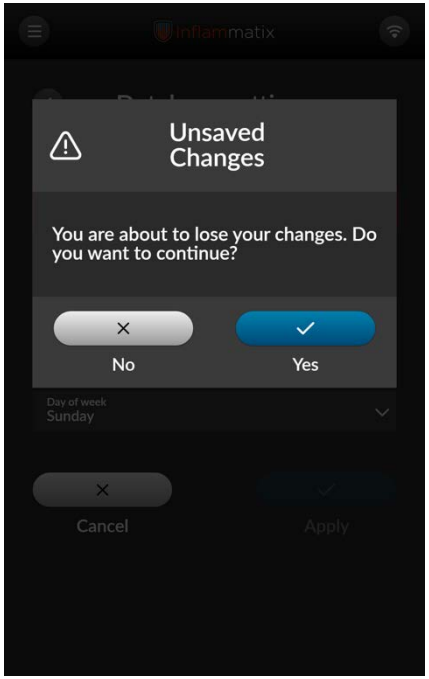


Figure 108 – Unsaved changes alert

This alert warns that data will be lost if not saved.

10.5 Cartridge failure errors

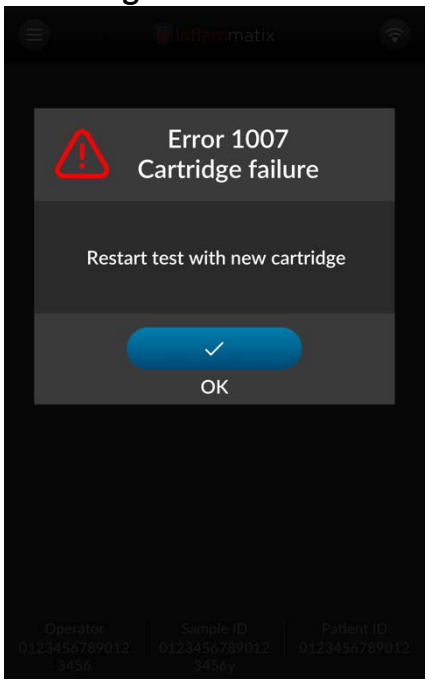


Figure 109 – Cartridge failure

The test has been interrupted and the cartridge has failed. Restart the test with a new cartridge.

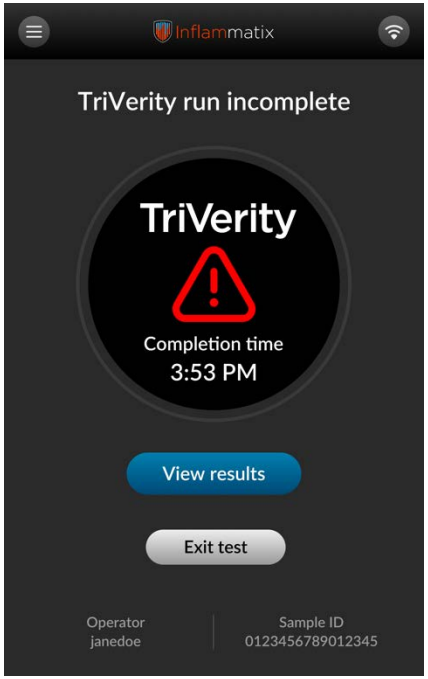


Figure 110 – Test run incomplete

When the test is incomplete, the screen shown above displays.
The red light pulses to signify an incomplete test.
Select View Results for further information.

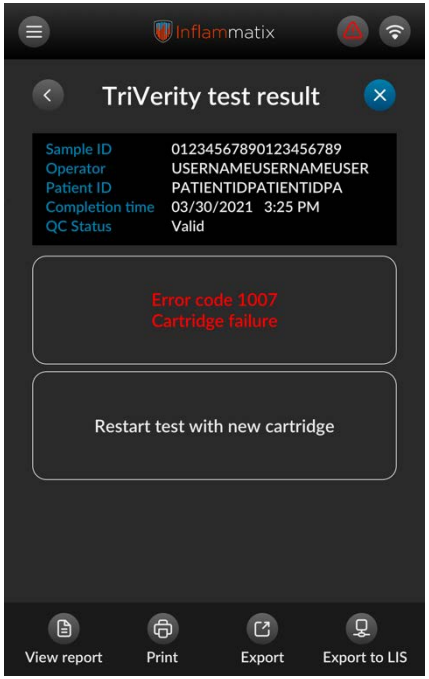
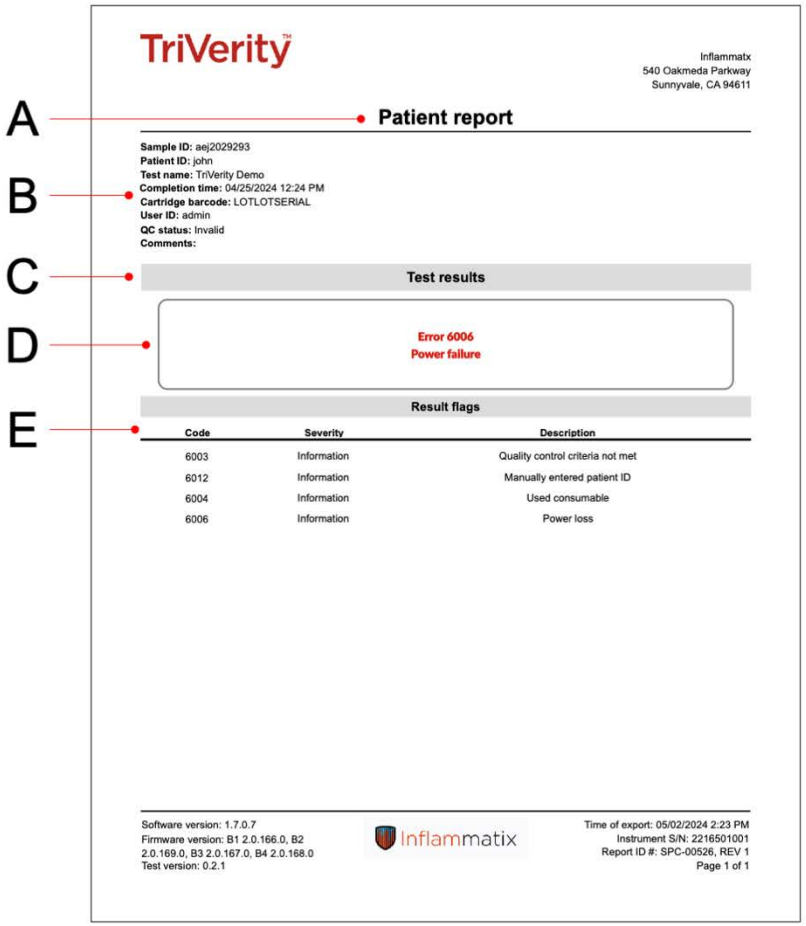


Figure 111 – Test result from incomplete

Follow the onscreen instructions and test with a new cartridge. If the error repeats with a new cartridge, contact Inflammatix support.

Sample Error Report



A. Title of Report
B. Report Parameters listing
    - Sample ID
    - Patient ID
    - Test Name
    - Completion time
    - Cartridge barcode
    - User ID
    - QC Status
    - Comments
C. Report Header
D. Error Number and name
E. Result flags including
    - Code
    - Severity
    - Description

10.6 System failure errors

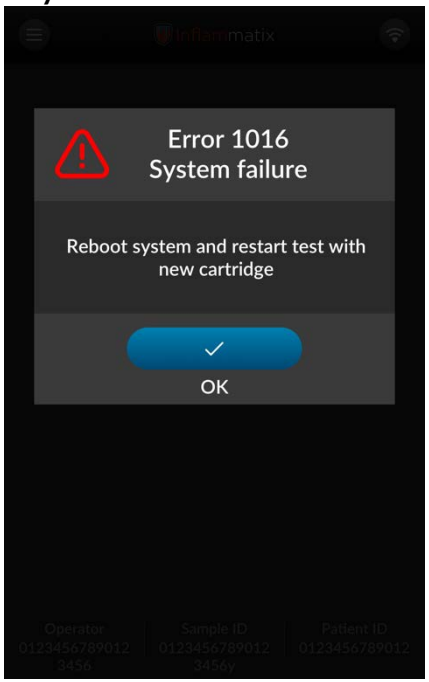


Figure 112 – System failure

When the test is incomplete, this screen displays.
Reboot the system by shutting down the software. The instrument will automatically power off. Wait a minimum of 30 seconds. Press the power button to start instrument. This software will automatically come back up.
After reboot, run a new test with a new cartridge.

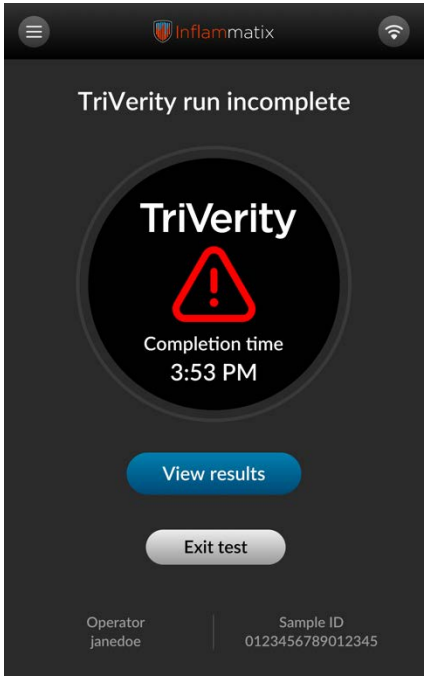


Figure 113 – Test run incomplete

When the OK button is pressed, this screen displays.
The red light ring pulses to signify an incomplete test.
Select View Results for further information.

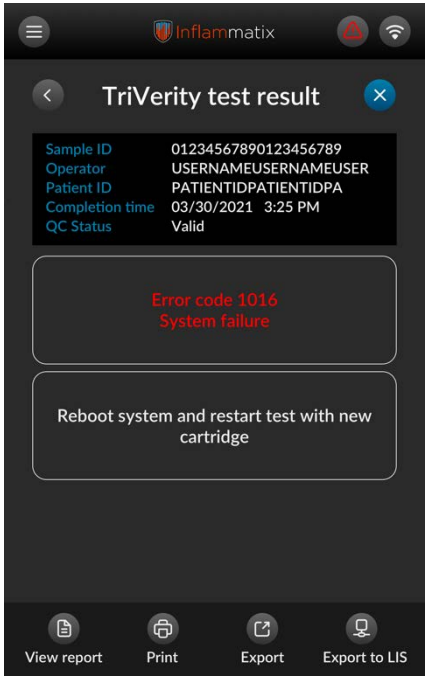


Figure 114 – System failure result

This error means that an instrument failure has occurred, and that the system needs to be rebooted.
After reboot, run a new test with a new cartridge. If the error repeats with a new cartridge, reboot again and run a QC control test for this test type. If it does not pass the QC test, follow lab procedure to contact Inflammatix support.

10.7 Test aborted errors

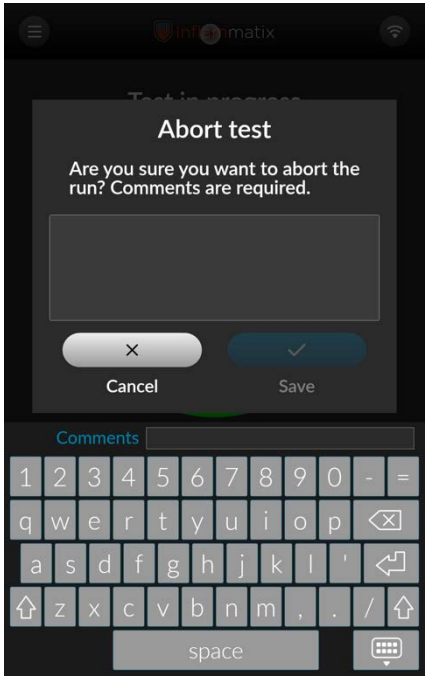


Figure 115 – Abort test comments

This alert asks for confirmation that the user wants to abort the test. Comments on the cause of the abort are required to proceed.

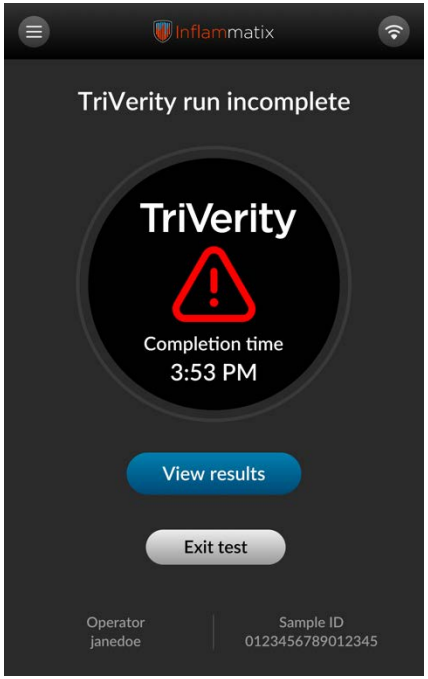


Figure 116 – Test incomplete

This error means that the test was aborted. Select View results for further information.
When the test is aborted, the incomplete test screen displays.
Select View Results.

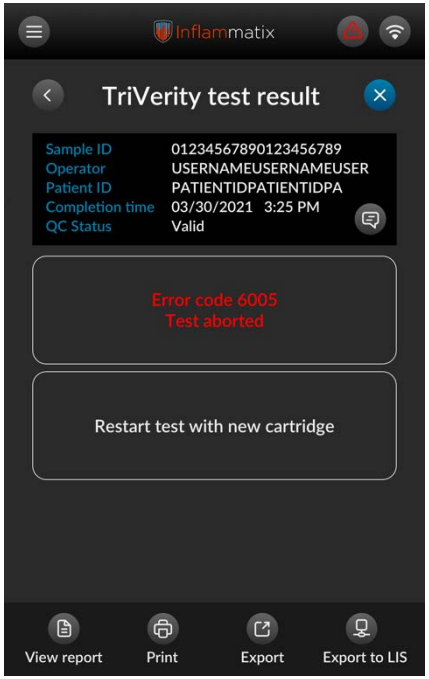


Figure 117 – Test aborted result

This error means that the test was aborted.
Run a new test with a new cartridge if results for the patient sample are desired.

10.8 Power failure errors

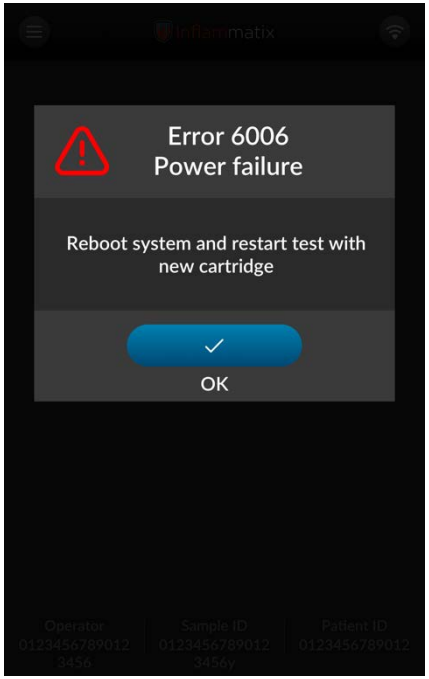


Figure 118 – Power failure

When the test is incomplete, this screen displays.
Reboot the system by shutting down the software. The instrument will automatically power off. Wait a minimum of 30 seconds. Press the power button to start the instrument. This software will automatically come back up.
After reboot, run a new test with a new cartridge.

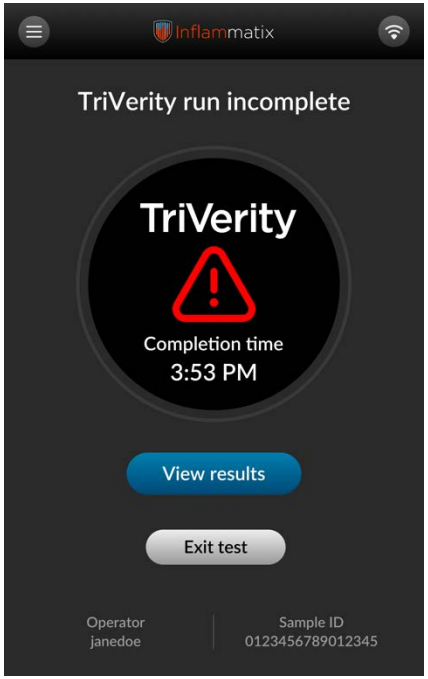


Figure 119 – Test incomplete

When the OK button is pressed, this screen displays.
The red light ring pulses to signify an incomplete test.
Select View Results for further information.

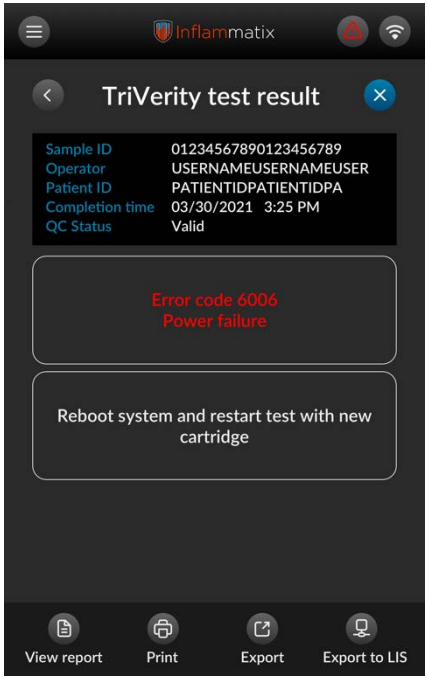


Figure 120 – Test incomplete result

This error means that an instrument failure has occurred, and that the system needs to be rebooted.
After reboot, run a new test with a new cartridge. If the error repeats with a new cartridge, reboot again and run a QC control test for this test type. If it does not pass the QC test, follow lab procedure to contact Inflammatix support.

10.9 Insufficient RNA errors

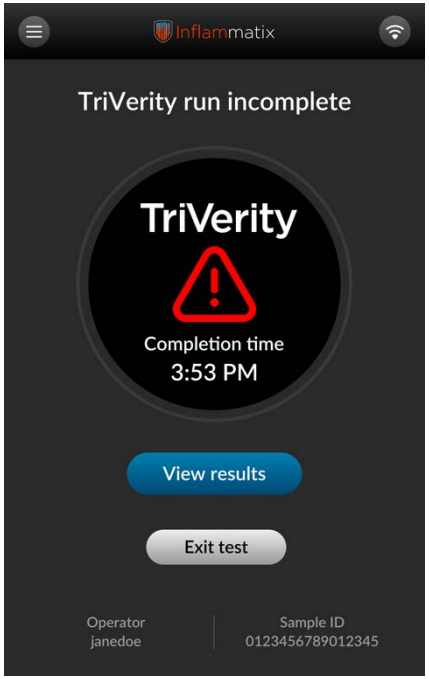


Figure 121 – Test incomplete

If the amount of RNA in the patient sample was insufficient for the test to provide accurate results, test is incomplete screen displays.
The red light ring pulses to signify an incomplete test.
Select View Results for further information.

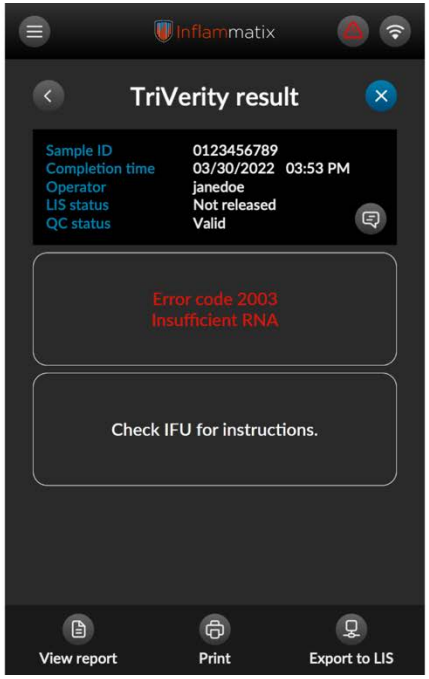


Figure 122 – Insufficient sample result

The amount of RNA in the patient sample was insufficient for the test to provide accurate results.
Refer to test Instructions for Use (IFU) for instructions on how to proceed.

10.10 Critical errors

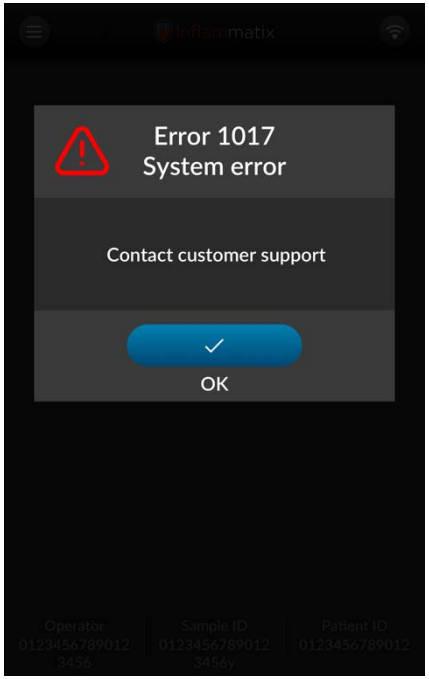


Figure 123 – Abort test comments

This error pop-up is a critical indication of malfunction.
Contact Inflammatix customer support as soon as possible for further guidance. See Section 9.4 for more information.

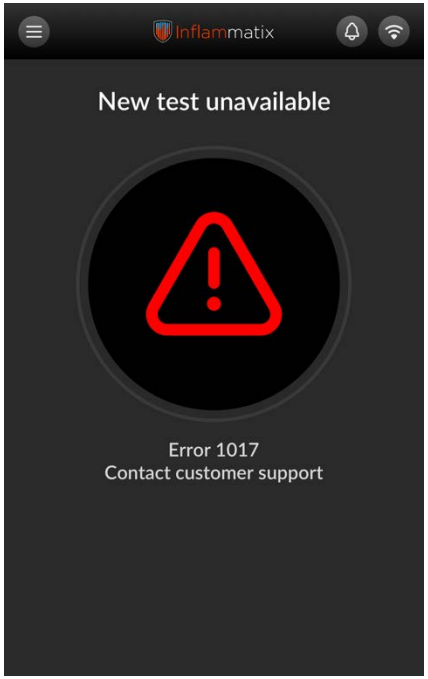


Figure 124 – New test unavailable

No more tests can be run until the issue is resolved.
Note: Access to results, reports, and other parts of the user interface remain available.

10.11 Product resources and help videos

The instrument provides a support page with help videos and options to export, import, or purge system information. Follow the illustrated steps to access support.

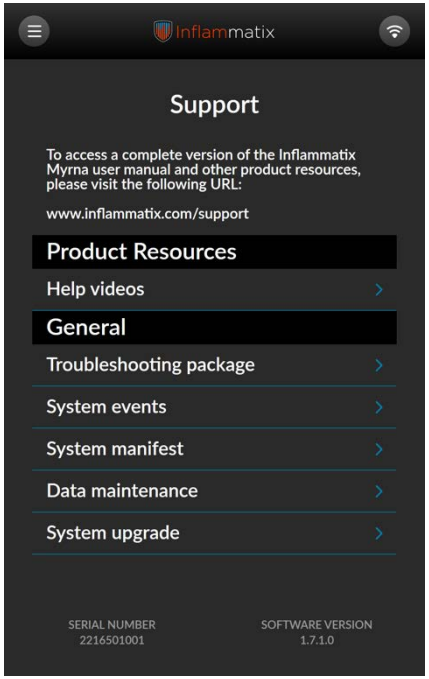


Figure 125 – Support menu

This screen is accessed by selecting Support from the main menu and lists the options and resources for support.

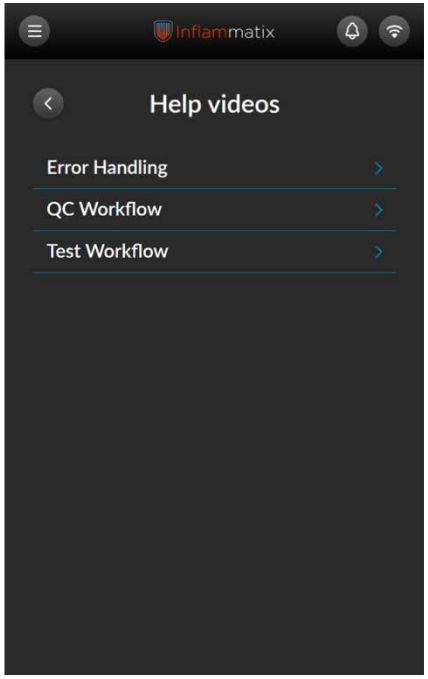


Figure 126 – Help videos

This screen lists the available videos for the instrument and tests installed on the system.
Selecting the video starts playing it.

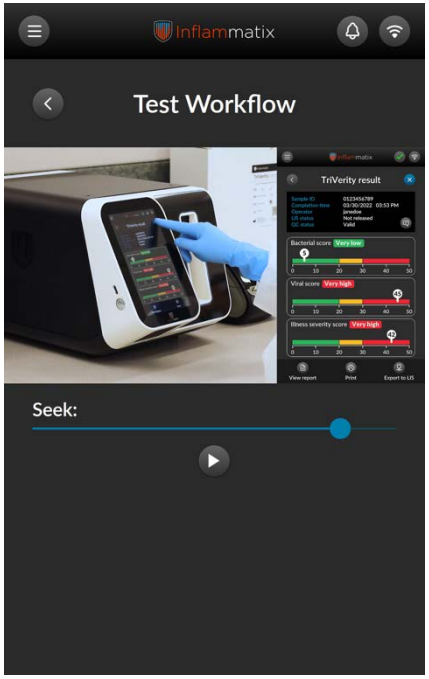


Figure 127 – Workflow video

The selected video displays. The video is controlled via the slider bar and button control.

10.12 Troubleshooting package

The troubleshooting package is a data set collected per parameters entered by the user.

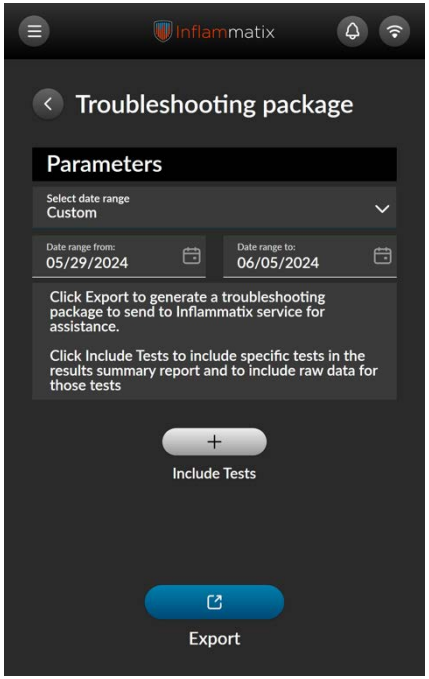


Figure 128 – Troubleshooting parameters

The troubleshooting package is a data set collected per parameters entered by the user. The package is exported to an external drive for Inflammatix to analyze system problems.
Select the Include Tests button to select a range of reports.

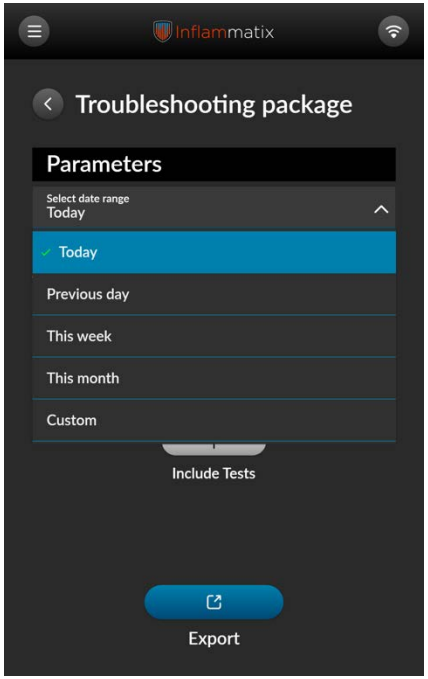


Figure 129 – Select date range

Select from the list of onscreen date ranges for test inclusion in the data as needed.

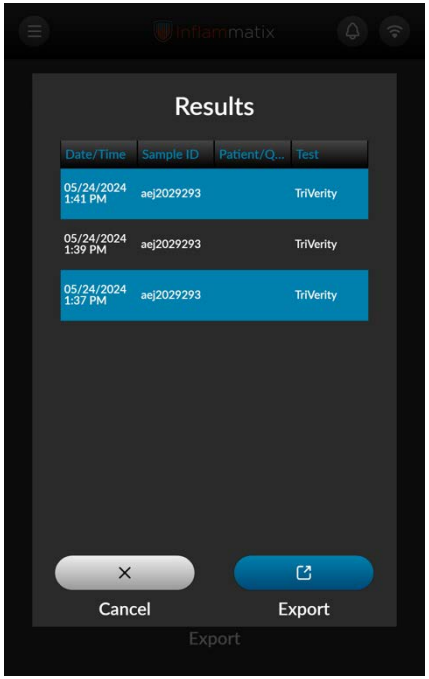


Figure 130 – Select Results for Export

Specify a connected network drive or insert USB drive into any available USB port on the instrument. Select listed tests for export, then press the Export button. The file will be copied to the USB flash drive or other connected drive.

10.13 Troubleshooting package export technical considerations

Employing a network drive for exporting a troubleshooting package is recommended. Using a connected network drive for this purpose will dramatically reduce time to export.

If using a USB drive for troubleshooting package export or other operations, Inflammatix suggests using a drive of sufficient size to ensure ample capacity for file capture.

Note: Exporting time for a troubleshooting packages that includes images can be lengthy - 5 minutes or more in some cases.

10.14 System Events

The instrument keeps a log of all runs for laboratory traceability and inquiry. System events can be access by following the steps depicted and described.

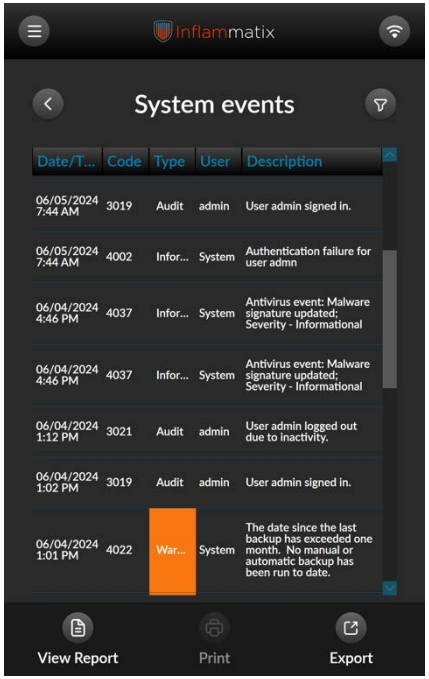


Figure 131 – System events

The System screen displays a list of recent system events.
View report displays the unfiltered list of system events. Use the filter button to apply filters.

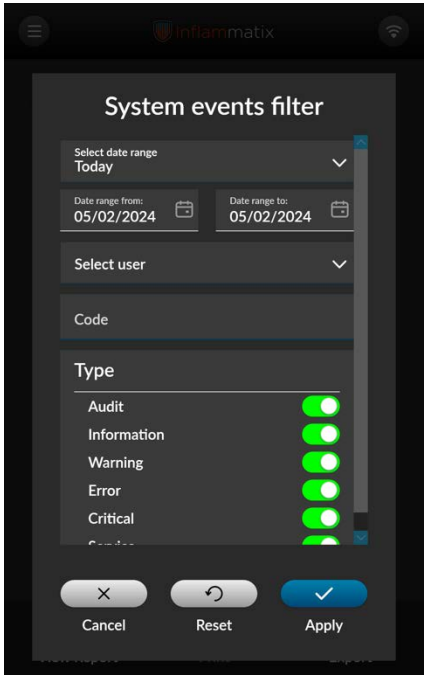


Figure 132 –Events date filter

The filter pop-up screen applies the selected filters to the list of System events.

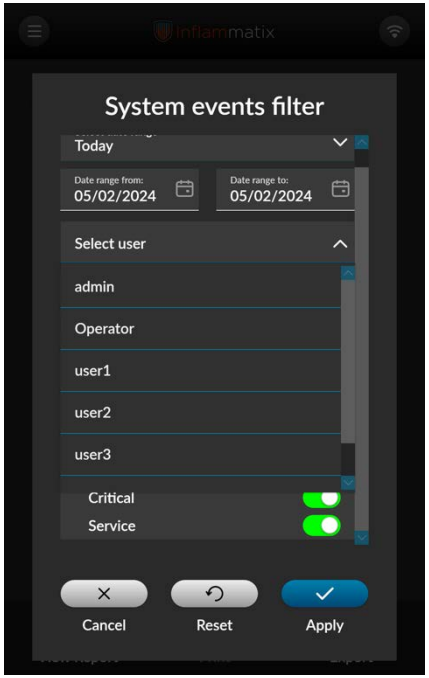


Figure 133 – Events user filter

System events can be filtered by user.

System events continued

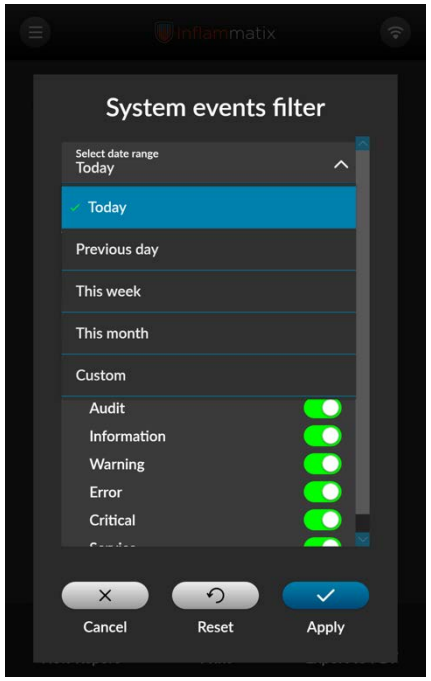


Figure 134 –Events date filter

System events can be filtered by date range.

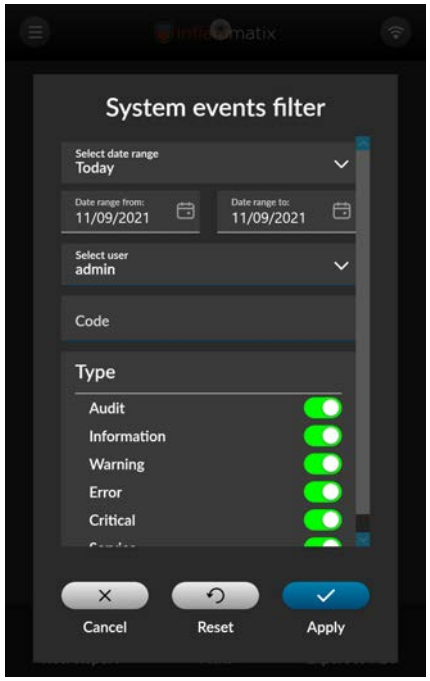


Figure 135 – Events user filter

Other options include the event code. Types may also be selected, which include:

- Audit
- Information
- Warning
- Error
- Critical (error)
- Service (error)

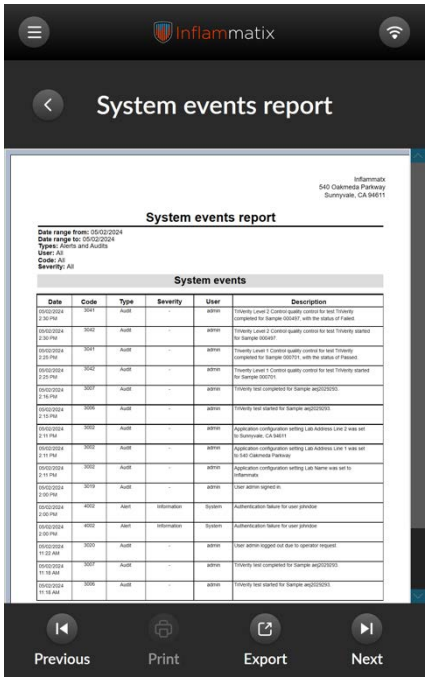
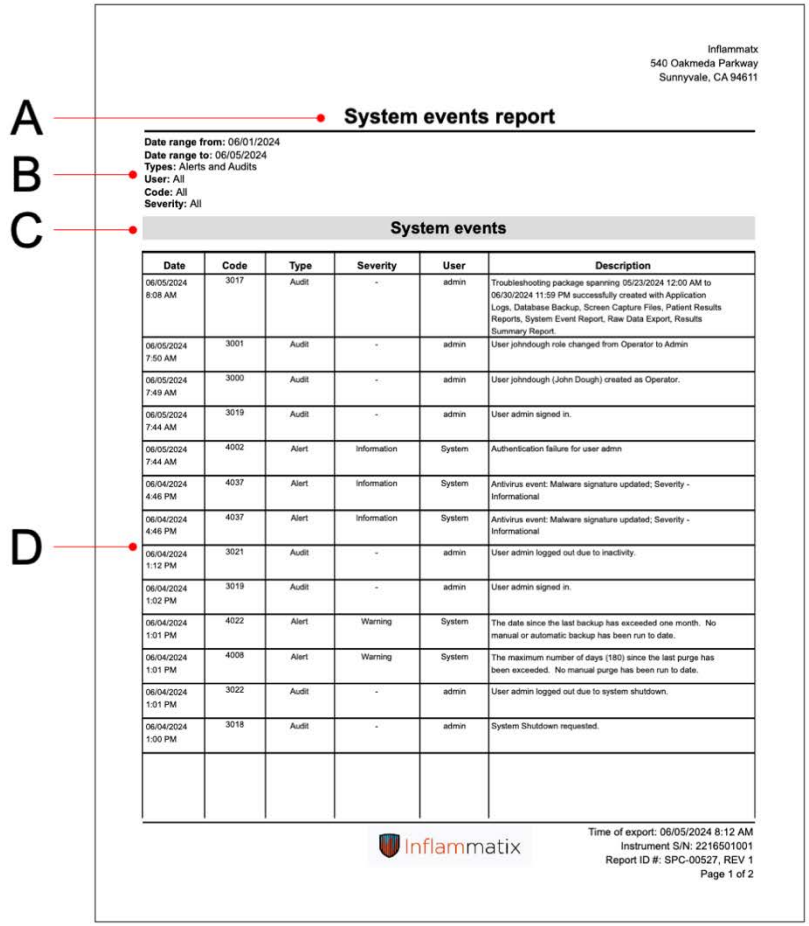


Figure 136 – System events report

After applying results, pressing the View Report button displays the filtered events report.

10.15 Systems events report example



Inflammatx
540 Oakmeda Parkway
Sunnyvale, CA 94611

A → **System events report**

Date range from: 06/01/2024
Date range to: 06/05/2024
B → **Types:** Alerts and Audits
User: All
Code: All
Severity: All

C → **System events**

Date	Code	Type	Severity	User	Description
06/05/2024 8:08 AM	3017	Audit	-	admin	Troubleshooting package spanning 05/23/2024 12:00 AM to 06/30/2024 11:59 PM successfully created with Application Logs, Database Backup, Screen Capture Files, Patient Results Reports, System Event Report, Raw Data Export, Results Summary Report.
06/05/2024 7:50 AM	3001	Audit	-	admin	User johndough role changed from Operator to Admin
06/05/2024 7:49 AM	3000	Audit	-	admin	User johndough (John Dough) created as Operator.
06/05/2024 7:44 AM	3019	Audit	-	admin	User admin signed in.
06/05/2024 7:44 AM	4002	Alert	Information	System	Authentication failure for user admn
06/04/2024 4:46 PM	4037	Alert	Information	System	Antivirus event: Malware signature updated; Severity - Informational
06/04/2024 4:46 PM	4037	Alert	Information	System	Antivirus event: Malware signature updated; Severity - Informational
06/04/2024 1:12 PM	3021	Audit	-	admin	User admin logged out due to inactivity.
06/04/2024 1:02 PM	3019	Audit	-	admin	User admin signed in.
06/04/2024 1:01 PM	4022	Alert	Warning	System	The date since the last backup has exceeded one month. No manual or automatic backup has been run to date.
06/04/2024 1:01 PM	4008	Alert	Warning	System	The maximum number of days (180) since the last purge has been exceeded. No manual purge has been run to date.
06/04/2024 1:01 PM	3022	Audit	-	admin	User admin logged out due to system shutdown.
06/04/2024 1:00 PM	3018	Audit	-	admin	System Shutdown requested.

D →

Inflammatix

Time of export: 06/05/2024 8:12 AM
Instrument S/N: 2216501001
Report ID #: SPC-00527, REV 1
Page 1 of 2

A. Title of Report
B. Test Parameters listing
   - Date Range From/To
   - Types
   - User ID
   - Code
   - Severity
C. Report Header
D. Summary Details including
   - Date
   - Code
   - Type
   - Severity
   - User
   - Description

   Note: Use the report filters to isolate Type and Severity. For example, all critical errors can be selected in filters.

10.16 System manifest

The system manifest displays the software and instrument firmware versions.

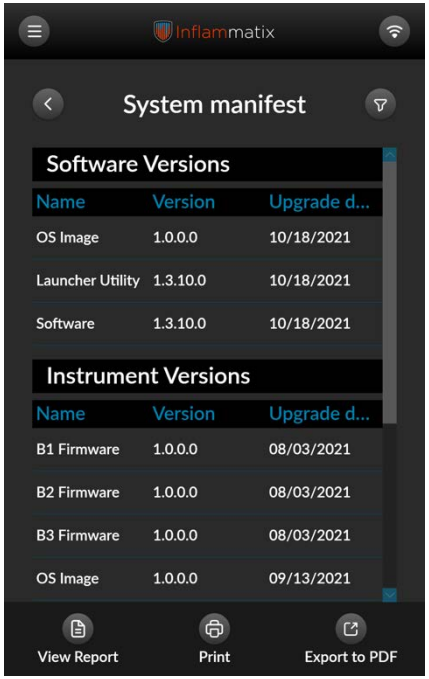


Figure 137 – System manifest versions

The System manifest screen displays the software and instrument firmware versions.
The instrument data collected in the System Manifest Report is not deleted when the data is purged.
General statistics from the results are also retained, but not individual results.

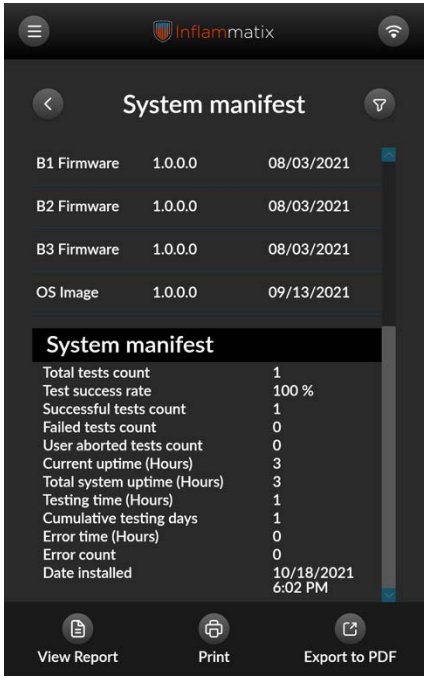


Figure 138 – Test totals

The lower portion of the System manifest displays the statistics of the instrument, with Total tests and a breakdown of test success and other data.

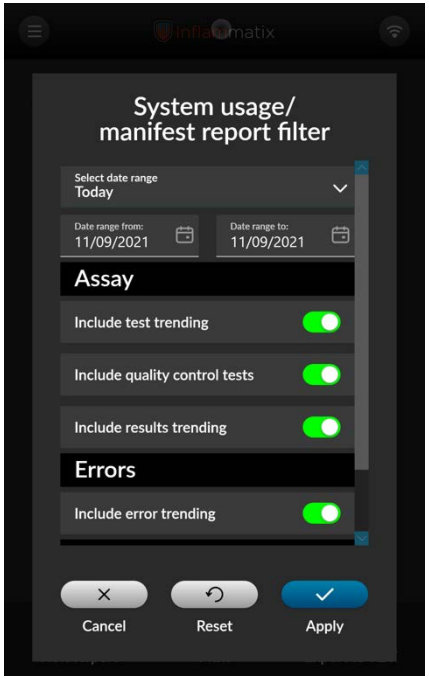


Figure 139 – Assay and errors filter

This pop-up screen displays optional assay and error filters for the System Manifest report. These filters are temporary for the purpose of forming a more focused report.

System manifest continued

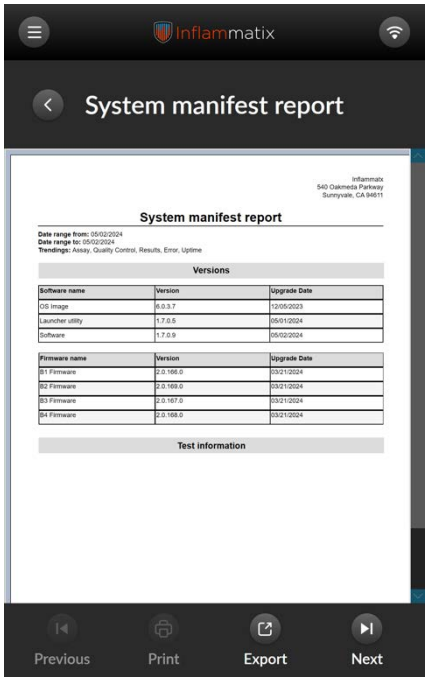
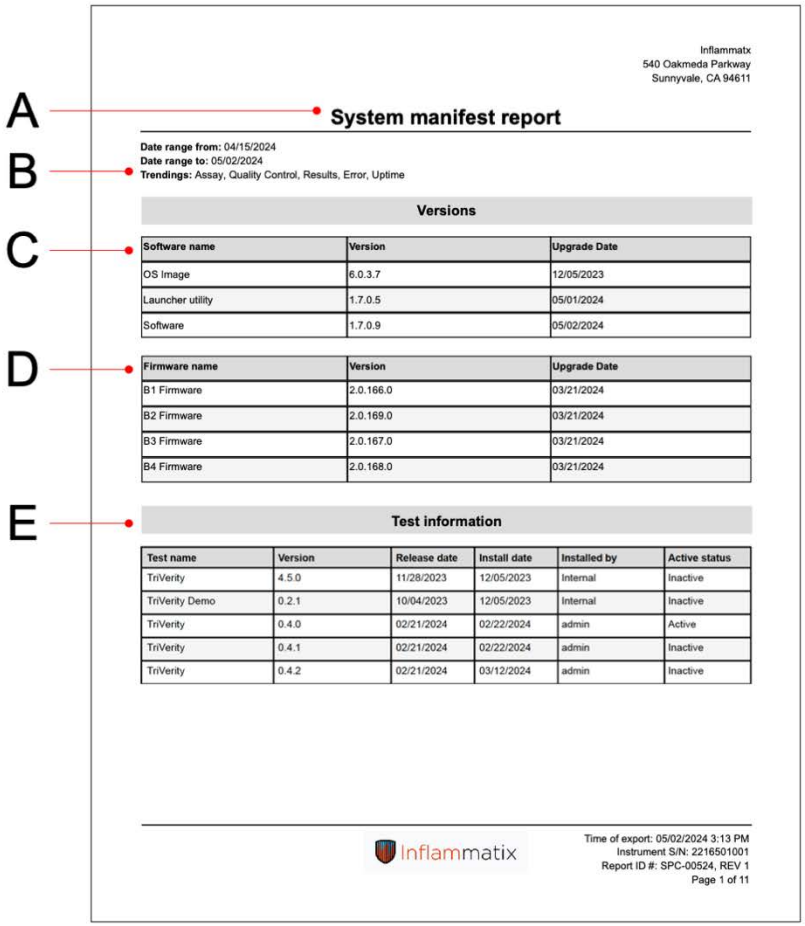


Figure 140 – System manifest report

Pressing the View Report button displays the System Manifest report with any applied filters.
For System Manifest Report examples and diagrams see the following pages.

System manifest report - page 1



Inflammatx
540 Oakmeda Parkway
Sunnyvale, CA 94611

System manifest report

Date range from: 04/15/2024
Date range to: 05/02/2024
Trendings: Assay, Quality Control, Results, Error, Uptime

Versions

Software name	Version	Upgrade Date
OS Image	6.0.3.7	12/05/2023
Launcher utility	1.7.0.5	05/01/2024
Software	1.7.0.9	05/02/2024

Firmware name	Version	Upgrade Date
B1 Firmware	2.0.166.0	03/21/2024
B2 Firmware	2.0.169.0	03/21/2024
B3 Firmware	2.0.167.0	03/21/2024
B4 Firmware	2.0.168.0	03/21/2024

Test information

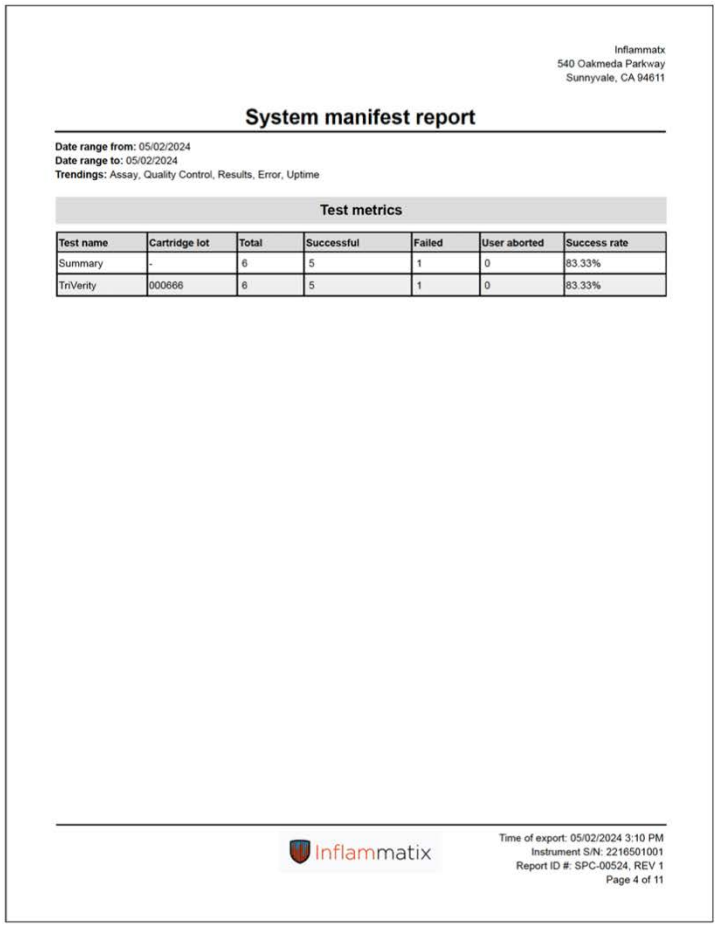
Test name	Version	Release date	Install date	Installed by	Active status
TriVerity	4.5.0	11/28/2023	12/05/2023	Internal	Inactive
TriVerity Demo	0.2.1	10/04/2023	12/05/2023	Internal	Inactive
TriVerity	0.4.0	02/21/2024	02/22/2024	admin	Active
TriVerity	0.4.1	02/21/2024	02/22/2024	admin	Inactive
TriVerity	0.4.2	02/21/2024	03/12/2024	admin	Inactive

Inflammatix

Time of export: 05/02/2024 3:13 PM
Instrument S/N: 2216501001
Report ID #: SPC-00524, REV 1
Page 1 of 11

A. Title of Report
B. Report Parameters listing
    - Date Range From/To
    - Trending events
C. Software Version list
D. Firmware Version list
E. Installed test list

System manifest report - page 2



Inflammatx
540 Oakmeda Parkway
Sunnyvale, CA 94611

System manifest report

Date range from: 05/02/2024
Date range to: 05/02/2024
Trendings: Assay, Quality Control, Results, Error, Uptime

Test metrics

Test name	Cartridge lot	Total	Successful	Failed	User aborted	Success rate
Summary	-	6	5	1	0	83.33%
TriVerity	000666	6	5	1	0	83.33%

Inflammatix

Time of export: 05/02/2024 3:10 PM
Instrument S/N: 2216501001
Report ID #: SPC-00524, REV 1
Page 4 of 11

Instrument use metrics including:

- Total test count
- Failed test count
- User aborted test count
- Current uptime (Hours)
- Total system uptime (Hours)
- Testing time (Hours)
- Cumulative testing days
- Error time
- Error count
- Date installed

Other metrics displayed in this report:

- Test metrics listed by test name
- Error metrics listed by error code
- Test trends chart by date
- Test results chart by test type, score type, and date
- Test results by test type, score type and date
- Test results by test type, score type, and date
- Error trends and counts by date
- System status by date

10.17 Data maintenance - purging

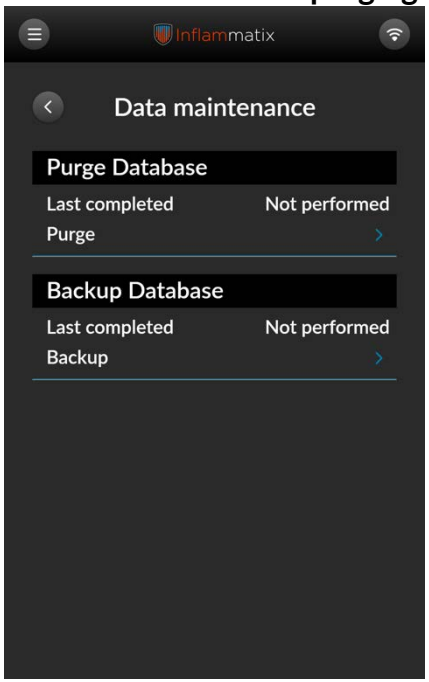


Figure 141 – Database maintenance

The system database becomes full of test records over time, and the system will send an alert to purge.
The default setting for purge is every six months, with the default purge date set to records older than 1 year.
To perform a database purge, select the appropriate Purge Database field on the Data maintenance screen.

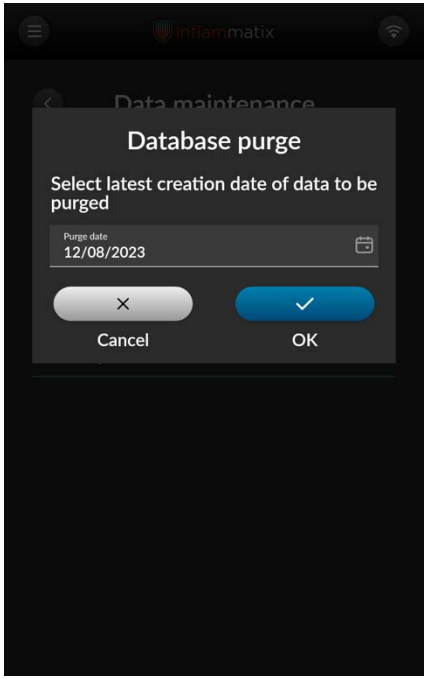


Figure 142 – Database purge

Select the latest date for the database purge. All data marked with an earlier date will be purged.
A purge data on a schedule appropriate for your facility's circumstance.
Inflammatix recommends purging records every 6 months at minimum. If a purge is not done before 6 months, a warning pop-up will be presented informing of future instrument function limitation.

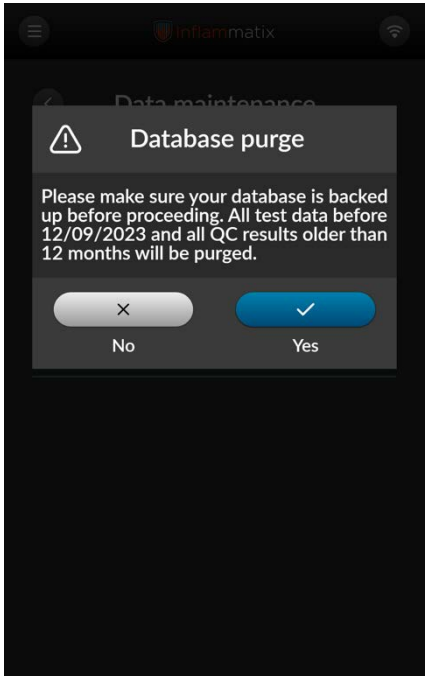


Figure 143 – Database purge warning

A confirmation pop-up screen window presents. A purge will be performed based on the specified date for test results, but also for audits, alerts, and QC data older than 1 year.
Note: The system will retain statistics from test results but will purge individual patient results.

10.18 Data maintenance – backup

Inflammatix strongly recommends performing regular database backups to ensure the retention of test information, system configurations, and settings stored on the Myrna Instrument. These backups are crucial for maintaining data integrity and enabling the restoration of internal device configurations in the event of data loss or system failure.

To perform a backup:

- Schedule Regular Backups: Set up automatic or manual backups at regular intervals (e.g., daily, weekly) to ensure up-to-date information is always available.
- Secure Storage: Store backups in a secure location to protect against data loss due to physical damage or cyber threats.
- Verification: Inflammatix can verify the integrity of the backup files as needed to ensure they are complete and free from corruption.
- Restoration: In the event of data loss or system failure, Inflammatix will use the backup files to restore the system to its previous state. Only an authorized and authenticated Inflammatix representative has the ability to restore the device configuration to a previous state.

For additional instructions on performing backups and restoring data, contact Inflammatix customer support at **www.inflammatix.com/support**.

Data maintenance - backup continued

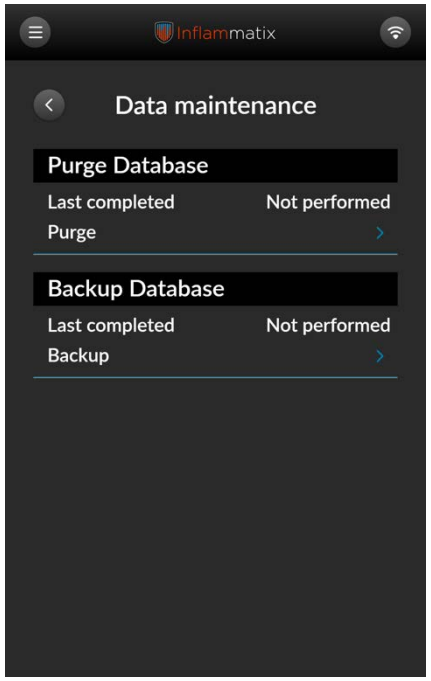


Figure 144 – Backup database

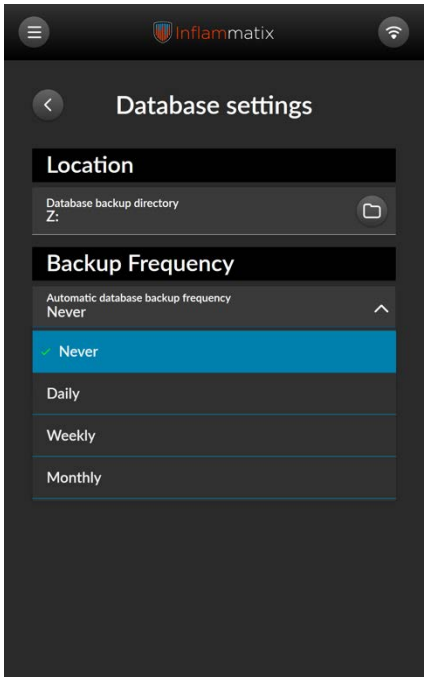


Figure 145 – Perform backup

It is recommended to perform periodic database backups. This is accomplished by selecting the Backup Database.

Select the desired drive location and confirm. Backups may be saved to a hard drive or flash drive via USB, or to a networked drive mapped via Settings.
Select the desired backup frequency and confirm.
A confirmation screen will provide confirmation of successful completion of database backup.

Perform a database backup on a schedule appropriate for your facility's circumstance. The instrument will prompt for a purge after 6 months as a default. Inflammatix recommends performing a backup at this time at minimum.

10.19 System upgrade

To perform a software upgrade follow the steps despited and described below.

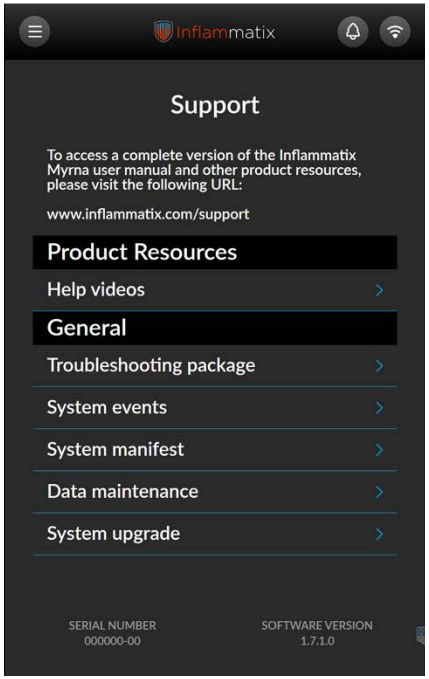


Figure 146 – System upgrade

Select the System Upgrade option from the Support menu.

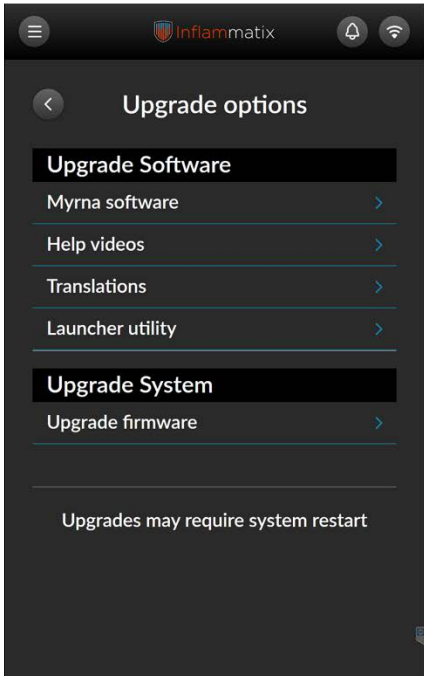


Figure 147 – Upgrade

Plug in a flash drive with the upgrade file provided by Inflammatix support. Select the type of upgrade desired from the following options:

- Myrna software
- Help videos
- Translations
- Launcher utility
- Firmware

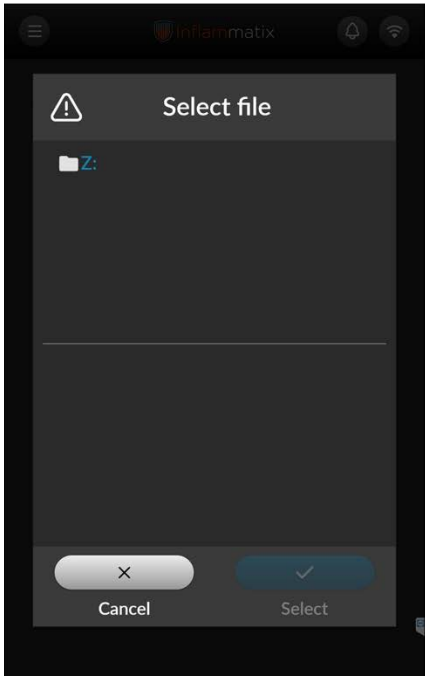


Figure 148 – Select file and import

Follow the on-screen prompts to complete the upgrade.

NOTE: a restart of the instrument may be required.

11.0 ADMIN

11.1 Admin best practices

Inflammatix recommends the following list of tasks for best upkeep and operations, to be performed by Administrators.

Read Section 1, Handling, Cautions and Warnings, carefully and thoroughly.

11.1.1 Set up two or more administrators

Set up at least two administrative users, to ensure access if a password is forgotten.

The system can be set up for Open Access. Setting up all users with ID and password access will save the user ID alongside the test records associated with that user.

11.1.2 Purge patient results data regularly

Purge data on a schedule appropriate for your facility's circumstance. The instrument will prompt for a purge after 6 months as a default. If data is not automatically saved to a LIS or other patient data network, backup files from the deletion date via USB and securely archive the data. It is best to perform backup and purge when the database is approaching 80% capacity. Individual records are deleted during a purge, but the instrument will retain non-identified test statistics.

11.1.3 Set up reports in advance

Each report type has instructions for setup in this document. Inflammatix recommends setting up these parameters upon installation to save time and confusion when a report is needed.

11.1.4 QC setup and frequency

If your facility recommends quality control tests be run, QCs can be set up in the system via Settings, and run via the QC Panel in the Menu. An Admin user may select how often and under what conditions users will be prompted to run a quality control that has been added via the QC Settings.

11.1.5 Set up LIS

Set up the connection to LIS or other network with support from your facility's IT department. Contact your distributor if an error or problem disrupts workflow and cannot be quickly resolved.

11.2 Power interruption

In the event of a sudden power interruption, check the accuracy of the instrument's current date and time in the lower-left corner of the login or start new test screen.

The instrument time will need to be reset to current time whenever power is suddenly interrupted, or if the unit is unplugged for more than a brief period. Failure to do so may result in erroneous test records.

Power interruption

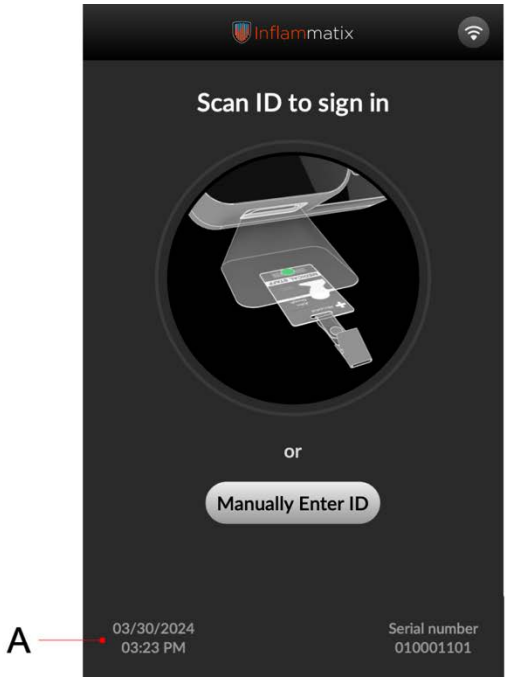


Figure 149 – Date time display

When the instrument is shut down but not unplugged, the instrument retains the date and time. If the instrument is unplugged or power is interrupted for an extended period, the date and time must be reset in settings.
Check the date/time in the lower-left corner of the screen.

12.0 MAINTENANCE

The Myrna Instrument does not require regular or preventative maintenance by users. It performs multiple functional and operational tests to guarantee proper performance. Periodically, the instrument will automatically run a self-maintenance procedure.

12.1 Cleaning the exterior

As needed, use a soft cloth sprayed or soaked with an ethanol solution 70% (v/v) in H2O to wipe the exterior surface of the Myrna Instrument. Use care around openings in the instrument enclosure such as connector ports.

The instrument may also be cleaned with:

- Quaternary ammonium and isopropyl alcohol (e.g., Super Sani-Cloth Wipes)
- Sodium hypochlorite (5.2% household bleach) up to a 1:10 dilution. Wipe down with water afterward.

Caution: Do not spray cleaning solution directly onto the instrument.

Caution: Wipe the exterior of the instrument only; do not attempt to clean the interior of the instrument.

Caution: Do not mix quaternary ammonium with sodium hypochlorite (bleach); doing so can result in can result in injury.

If a hazardous material spill occurs in the adjacent area, follow site recommendations or do the following:

Soak up material with a disposable absorbent pad. Wipe the contaminated area and materials with 10% bleach. Wipe down the surface so that it is saturated with the 10% bleach solution and let it rest for at least 5 minutes. Once a minimum of 5 minutes has passed, spray the area with 70% ethyl or isopropyl alcohol and wipe down the surface. Dispose of affected single-use materials such as the absorbent pad, medical gloves, test tube holder, and test cartridges. Discard affected single-use materials according to the Institution's standard practices.

If a spill occurs within the instrument, contact support.

Before using any cleaning or decontamination methods (except those recommended by the manufacturer), users should confirm with the manufacturer that the proposed method will not damage the equipment.

Note: instrument exterior surfaces (powder coated aluminum, soda-lime glass, and ABS) have been chosen to be able to withstand cleaning agents.

13.0 SERVICE

13.1 Servicing

In case of instrument malfunction, please reach out to your Inflammatix contact. Service and repair must be performed by authorized and qualified personnel. Should instrument software or components approach end of life/support, Inflammatix will contact customers as needed to ensure device integrity. Refer to inflammatix.com/support for regional service contact info.

13.2 Warranty

The Inflammatix Warranty for the Myrna Instrument covers defects in materials or manufacturing for a period of twelve months from the date of delivery. Inflammatix agrees to repair or replace the instrument if it becomes inoperative due to the failure of any internal parts. The warranty does not cover damage caused by use not in accordance to instructions. Any customer modification to the instrument will render the warranty null and void.

13.3 Instrument return procedure

To return an instrument from within the United States, please follow these steps:

- Visit the Customer Support Webpage for detailed return instructions and to initiate the return process, visit our customer support webpage at: inflammatix.com/support.
- Contact Your Local Sales Representative or Authorized Distributor: If you prefer, you can also contact your local sales representative or an authorized distributor for assistance with the return process. They will provide you with the necessary instructions and support.

Please ensure that you have the instrument's serial number and your purchase information available when contacting support. Proper packaging and shipping instructions will be provided to ensure the safe return of the instrument.

13.4 Decommissioning, disposal, and recycling of the instrument

Ensure all data is purged from the instrument before disposal – see section 10.17. Contact Inflammatix support for secure disposal instructions.

The Myrna Instrument is classified as WEEE (Waste Electrical and Electronic Equipment), and it should be recycled as electrical equipment waste.

14.0 TECHNICAL SPECIFICATIONS

14.1 Instrument Specifications

Dimensions	20.00” (5.10cm) L x 11.50” (2.92cm) W x 10.50” (2.67cm) H
Weight	44 lb (19.96 kg)
Display	LCD screen with backlight and touch panel Resolution: 1200 x 1920 pixels Active Area: 4.24” x 6.78” (10.76cm x 17.22cm)
Capacity of result records	10K+
Capacity of operator list	unlimited
SW Update	Via USB flash drive or network drive
Communication Interface	USB (interface with USB 2.0 devices) Ethernet port (802.3) WiFi (802.11) HL7 v2 ASTM LIS01-A and ASTM LIS2-2A POCT1A (POCT01-A2)

14.2 Operating Conditions

Operational Temperature	59-86°F (15°-30°C)
Humidity	20-80%
Elevation	0-6562 feet (0 to 2000m, 101325 Pa – 76142 Pa)
Cartridge Temperature	Per specific test cartridge

14.3 Power Supply

Max Power	320W
Frequency	a.c.~50-60Hz

14.4 EMC standards

Internal power supply	~ Line 100-240 VAC, 50/60 Hz, 9A MAX
Pollution degree	2
Wireless technology	802.11 ac/a/b/g/n
Operating frequency	2.4 GHz and 5 GHz
Effective range	125 to 200 ft
Quality of service	adheres to methodologies described by the 802.11e QoS enhancement (WMM) standard
Cybersecurity	The Myrna Instrument will only allow connection to secured networks. See Section 0: Cybersecurity for more information.
Note: Ensure a minimum separation distance of 30 cm (approximately 1 foot) between the Myrna Instrument and other wireless devices operating in the 2.4 GHz and 5 GHz frequency bands to minimize potential interference.	

The Myrna Instrument has been rigorously tested and conforms to the IEC 61010 standard, specifically IEC 61010-1:2010, which outlines Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use. Additionally, the Instrument complies with the following UL standards:

- UL 61010-1: Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use – Part 1: General Requirements
- UL 61010-2-101: Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use – Part 2-101: Particular Requirements for In Vitro Diagnostic (IVD) Medical Equipment
- UL 61010-2-010: Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use – Part 2-010: Particular Requirements for Laboratory Equipment for the Heating of Materials

15.0 REGULATORY COMPLIANCE

The Myrna Instrument is designed and manufactured in accordance with the requirements of the U.S. Food and Drug Administration (FDA) for in vitro diagnostic medical devices. This device has been reviewed and cleared by the FDA under [insert 510(k) number here]. It meets all applicable regulations and standards as mandated by the FDA, ensuring its safety, efficacy, and performance for its intended use in the United States.

Please note that this device is not approved for use in regions outside the jurisdiction of the FDA. It has not been evaluated for compliance with regulatory requirements in other countries or regions.

16.0 SYMBOLS AND ABBREVIATIONS

16.1 Gallery of Icons

Icon	Explanation	Icon	Explanation
	menu		skip
	wifi		complete/success
	alert/alarm		report
	comment		print
	close/exit		export
	back		network/LIS

16.2 Symbols and abbreviations

Symbol/Abbreviation	Explanation	Symbol/Abbreviation	Explanation
IVD	In vitro diagnostic medical device		Warnings and precautions
REF	Catalogue number		Consult eIFU
LOT	Lot number	**LIS**	Laboratory information system
SN	Serial number	**EMR**	Electronic medical record
	Operating temperature range	**POCT1**	Point-of-Care Connectivity; Approved Standard
	Operating humidity range	**HL7**	Health Level Seven
	Operating pressure range	**ASTM**	American Society for Testing and Materials
	Single use only	**DHCP**	Dynamic host configuration protocol
	Waste electrical and electronic equipment (WEEE)	**IP**	Internet protocol
	Manufacturer	**ADF**	Assay definition file
	Date of manufacture		

16.3 Inflammatix quality and contact information

The design, development, and manufacturing of the Myrna Instrument is in accordance with the Inflammatix Quality Management System. Inflammatix is an ISO-13485 certified company.

For further detailed information on technical specifications, detection methods, and available tests and accessories for your Myrna Instrument, reach out to your Inflammatix contact.

Inflammatix contact information

540 Oakmead Pkwy

Sunnyvale, CA 94085

(650) 443-3030