LIAISON NES®

User Manual

Rev. 03
(English)

Software v1.5

For *In Vitro* Diagnostic Use

INSTRUMENT

IVD For *In Vitro D*iagnostic Use

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Document Revision History

Revision	Impacted chapter/section	Description of Change(s)
01	N/A	Initial release
02	All	Updated GUI images to align with software v1.4 Revised procedures to align with software v1.4 Revised formatting, text, and chapter/section titles for clarity and consistency Removed references to linking user ID barcodes Removed references to exporting results to USB Consolidated system-related operator instructions into a new section titled *Preparing the System* Updated LIAISON NES® trademark
	Instrument Specifications and Setup	Removed language setup instructions Added instructions for connecting to Wi-Fi and Ethernet
	Home Screen Overview	Added profile, cloud, and network icons and descriptions
	Run a Quality Control Test	Moved instructions for logging in to the system to *Preparing the System*
	Run a Test	Moved instructions for logging in to the system to *Preparing the System*
	Administrator Settings and Features	Moved instructions for logging out of the system to *Log Out and Power Off the LIAISON NES®* Removed language preferences Added *Assay Management*, *Printer Settings*, and *Generate a Support File*
	Troubleshooting	Removed errors not applicable to software v1.4 Added errors and procedures associated with software v.14
03	All	Updated GUI images to align with software v1.5 Updated LIAISON NES® trademark and Diasorin logo on instrument images Updated LIAISON NES® trademark on cartridge labels
	Preparing the System	Added Software Version Overview

Diasorin

Table of Contents

1 Preface

1.1 Conventions Used in this Manual

The LIAISON NES® User Manual uses the following text conventions.

Items marked with a highlighted arrow before the paragraph are used to draw attention to steps or critical actions that the user must follow.

	Notes include additional information or references to other sections of this manual.
Enter This Text	Web addresses are displayed using a different font color. The address may appear within a paragraph or separately. Example: www.diasorin.com
Internal Reference	References/links to sections in this manual are italicized.
Best Practice	Best practices are highlighted with special colorized text in the left-hand column. The text draws at-a-glance attention to recommended procedures and practices.

1.2 Content Disclaimers

1.2.1 Pictorial Disclaimer

Sample printouts, graphics, displays, and screens are for information and illustration purposes only and shall not be used for clinical or maintenance evaluations. Data shown in sample printouts and screens do not reflect actual patient names or test results. Assay names shown in example printouts, graphics, displays, and screens are not intended to indicate the availability of such assays, nor do they imply review, conformity assessment, or approval by any national or supranational governmental authority, including the FDA or applicable Notified Bodies in the EU.

1.2.2 Hardware Disclaimer

The LIAISON NES® hardware and software specifications are subject to change. The system images, hardware components, hardware specifications, and software versions included in the LIAISON NES® User Manual may not match the system installed on your specific instrument. Any changes or modifications to the authorized system installation have been verified as compatible with the functionality outlined in this document.

1.2.3 Table of Contents Disclaimer

Incremental manual updates may cause the Table of Contents or Index page numbering to change.

1.3 Privacy and Protection Measures

National, state, and local laws on patient data privacy, such as the HIPAA Privacy Rule, may regulate, restrict and/or prohibit the creation, use, storage, or transmission of files that contain individually identifiable health information and/or protected health information. It is strongly recommended that the users of the LIAISON NES® consult their institutional privacy officer or ethics board to understand the applicable laws and regulations. The end-user assumes all risks, responsibilities, and liabilities when creating, using, storing, or transmitting files with individually identifiable health information and/or protected health information.

The LIAISON NES® can generate analytical data that may refer to or contain the health condition of individual patients, including protected health information ("PHI"). To minimize the risks associated with disseminating such information outside of an end-user's network, the LIAISON NES® is designed to operate without generating PHI, through the use of unique alphanumeric sample identifiers ("SID") capable of use in combination with an end user's laboratory information system (if connected).

To the extent required by local privacy and data security laws and regulations, end-users are responsible for the following behavior: SIDs used with the LIAISON NES® must not refer to the patient or contain references to a patient's personal data; the end-user's laboratory information system (if connected) must be the only mechanism to match an SID with a patient and/or such patient's PHI. The end-user assumes any and all responsibility and risk for damages resulting from the failure to follow the above instructions or to take advantage of the LIAISON NES® protection measures described herein.

Diasorin's responsibilities regarding data privacy and protection measures are as follows:

a. Diasorin shall comply at all times with applicable privacy and data security laws and regulations.
b. Diasorin shall have no liability for use or disclosure of data generated using the LIAISON NES® once such data is transferred by end-users outside of the boundaries of the LIAISON NES® itself, including after such data has been written, printed, or sent to an end-user's laboratory information system (if connected).
c. Diasorin shall have no liability for use of the LIAISON NES® for any purpose for which it was not designed.

2 System and Software Introduction

The LIAISON NES® system is a novel point-of-care molecular solution from Diasorin. Patient samples can be directly loaded into innovative ready-to-use cartridges, simplifying complex laboratory workflows and producing actionable results. The smart graphical user interface (GUI) guides the user through the steps of running a test.

2.1 Intended Use

The Diasorin Molecular LIAISON NES® instrument and cartridge are used for automated extraction, amplification, and fluorometric identification of nucleic acid from a biological sample for *in vitro* diagnosis by a healthcare professional in a point-of-care or laboratory setting.

2.2 Instrument Overview

The LIAISON NES® instrument is comprised of the following:

- Touchscreen User Interface
- Status LED Indicator
- Audio Speaker
- Barcode Scanner

2.3 Software Overview

The LIAISON NES® software is a graphical user interface (GUI) application that serves as the end-user interface to the LIAISON NES® system. The software is installed on an embedded computer and provides the environment in which a user runs assays and obtains results. **Optionally, the system is capable of interfacing with a Laboratory Information System (LIS) and the Diasorin Cloud**.

2.4 Consumables Overview

The LIAISON NES® instrument can process one cartridge at a time. Cartridges are single-use only. The samples and reagents in the cartridges do not have direct contact with the instrument or with other assays running on the system. Cartridges can hold various sample volumes depending on the assay being run.

2.5 Diasorin Support

For technical service, contact Diasorin Support in the U.S. by calling 800-838-4548 or by visiting *www.diasorin.com/liaison-nes*.

3 Regulatory and Safety Considerations

3.1 Safety and Precautions

The LIAISON NES® and its related devices and accessories are designed to work safely and reliably when used in accordance with the instructions provided. All warnings and precautions mentioned in this manual should be followed to avoid unsafe actions that could result in personal injury or harm and/or damage to the system.

3.1.1 Safety Information

Read the following safety information before using the LIAISON NES®. This system contains electrical and mechanical components that, if handled improperly, are potentially harmful. In addition, biological and chemical hazards may be present during system operation. Only use the LIAISON NES® for its intended purpose in accordance with this manual. Adhere to provided warnings and standard laboratory safety practices. Retain these instructions for future reference.

Notice for Users: Any serious incident that occurs in relation to the device shall be reported to Diasorin Molecular.

3.1.2 Explanation of Product Label Symbols

The symbols listed below represent warnings, conditions, and instructions. They may indicate potential hazards or provide additional information that is necessary for safe and proper use of the LIAISON NES®. Each symbol represents a specific meaning that is internationally recognized. These symbols may appear on the product packaging and labels, on accompanying instructional materials, and in this document.

Refer to the *Glossary* for a full list of product label symbols.

Explanation of Single Word Consequences

Caution: Indicates a hazardous situation where caution is necessary. If not avoided, the situation could result in minor or moderate injury.

Warning: Indicates a hazardous situation that requires operator awareness or action. If not avoided, the situation could result in death or serious injury.

Important and Additional Information

Important Note: The user should carefully review this information before proceeding.

3.1.3 Important Safety Instruction

Hot Surfaces – Surfaces within the cartridge bay maintain temperatures up to 60°C (140°F) for a short period after use and may cause contact burns or damage to materials in contact with this area.

Biological Risks during use of device – User may be exposed to potentially infectious materials while performing the following activities:

- Handling samples and performing steps to run the test
- Cleaning spills
- Handling and disposing of waste materials
- Performing maintenance/cleaning procedures

The following information will help the user minimize the impact of this exposure:

- Always follow your institution's standard safety practices, which include wearing appropriate personal protective equipment (PPE) when handling samples and using the instrument.
- Treat all samples, reagents, and consumables (e.g. swabs, cartridges) as potentially capable of transmitting infectious agents.
- Consider all instrument surfaces or components that come in contact with samples, reagents, and consumables as potentially capable of transmitting infectious agents.

Precautions include, but are not limited to, the following:

- Observe local and national provisions, legislation, and laboratory regulations.
- Use appropriate Personal Protective Equipment (PPE), such as disposable gloves, lab coats, and eye protection.
- Avoid direct skin contact with samples, reagents, and parts of the instrument.
- Do not eat, drink, smoke, apply cosmetics, or handle contact lenses where kit reagents or human specimens are being used.
- Use appropriate personal protective equipment (PPE) for maintenance or cleaning procedures. Clean the system immediately if potentially infectious material has been spilled.

Biological Risks – User may be exposed to hazardous and infectious agents.

- After the completion of a test, the cuvette in the cartridge contains amplified samples (amplicons).
- Do not disassemble, break, pierce, or tamper with used cartridges. This may cause the amplicons to leak and cause contamination.
- Leaks from previous results can cause contamination of subsequent tests, leading to false positive results.
- Handle samples according to standard laboratory practices.

Chemical – User may be exposed to hazardous chemicals when handling cartridges.

Exposure to hazardous chemicals is minimized by following the instructions provided in the assay-specific documentation (such as Instructions for Use), product-specific labels, and product-specific safety data sheets (SDS).

In general, observe the following precautions when handling chemicals:

- Consult the safety data sheet (SDS) for safe use instructions and precautions.
- Avoid contact with skin and eyes. If contact with the material is anticipated, wear nitrile gloves, protective eyewear, and a lab coat.
- Maintain good housekeeping. Do not eat, drink, or store food and beverages in areas where chemicals are used.
- Seek immediate medical attention if irritation or signs of toxicity occur after exposure to harmful chemicals.

Warning – Handle with Care

Avoid placing the instrument near ledges. If the instrument is accidentally dropped or struck by a falling object, the touchscreen may shatter, creating sharp glass shards and jagged edges. In the event of a drop, do not directly handle broken shards; use appropriate tools and personal protective equipment (PPE) to safely clean up. Contact *Diasorin Support* for a replacement.

Do not operate the instrument or use the power adapter if it has been exposed to moisture or water.

Do not use the instrument if the instrument or its packaging is open and/or damaged.

Only use the three-pin power adapter (with a protective earth grounding) that is provided with the instrument. Use the appropriate power adapter and cable for the region. The correct power adapter and cable are required to maintain the safety and electromagnetic compatibility of the system.

Ensure that interfaces via Ethernet and USB are separated from the mains by double or reinforced insulation and present no risk of electrical shock.

Only operate the instrument for its intended use and in accordance with this User Manual and the warnings in this document. Do not operate the instrument and power adapter outside the manufacturer's specifications, as performance and protection could be impaired.

Operate the instrument on a clean, flat, stable surface away from direct sunlight. Air flow vents located on the back of the instrument must not blocked or restricted.

Do not open, disassemble, or tamper with the instrument, consumables, or other accessories, as this could result in possible injury or death.

	Dispose of any assay components that are dropped, cracked, opened, or damaged in the biohazardous waste.
	Do not move or jostle the instrument while a test is in progress.
	Do not connect OR disconnect any peripheral equipment connected to the instrument while performing a test. Peripheral equipment includes, but is not limited to, flash drives or printers.
	Do not forcibly open the instrument door. Do not apply force to the door when it is already open. Close the door gently.
	**Waste handling and disposal** – Each facility is responsible to ensure waste is disposed of in accordance with the appropriate local regulations. See the manufacturer's assay-specific documentation (such as Instructions for Use), the product-specific label, or the product-specific safety data sheet (SDS).

3.1.4 Electromagnetic Capability Safety

The LIAISON NES® system has been tested by Eurofins Electrical and Electronic Testing, Inc. and complies with the electromagnetic interference (EMI) requirements for the United States, European Union, and Canada.

Only operate the instrument for its intended use and in accordance with this User Manual and the warnings in this document. Do not operate the instrument and power adapter outside the manufacturer's specifications, as performance and protection could be impaired.

Operate the instrument on a clean, flat, stable surface away from direct sunlight. Air flow vents located on the back of the instrument must not be blocked or restricted.

Do not open, disassemble, or tamper with the instrument, consumables, or other accessories, as this could result in possible injury or death.

The LIAISON NES® was tested and found to be in compliance with the following electromagnetic compatibility (EMC) standards:

- EN 61326-1:2020 / IEC 61326-1:2020 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
- EN 61326-2-6:2020 / IEC 61326-2-6:2020 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
- IEC 60601-1-2:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

The LIAISON NES® system is intended for use in the electromagnetic environment specified below. The customer or the user of the LIAISON NES® system should ensure that it is used in such an environment.

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

Emissions Test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Class B
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

Immunity Test	Compliance Level Against IEC 60601-1-2 Edition 4.0:2014
Electrostatic discharge (ESD) IEC 61000-4-2	Contact: +/- 8 kV Air: +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 kV
Radiated Immunity Testing IEC 61000-4-3	3 V/m 80-2700 MHz 1kHz 80% am 9-28 V/m 385-6000 MHz pulse mode
Electrical fast transient/burst IEC 61000-4-4	Power Supply Lines at 100 kHz, +/- 2.0 kV Input/Output Lines at 100 kHz, +/- 1.0 kV
Surge IEC 61000-4-5	Line to Line: +/- 1.0 kV Line to ground: +/- 2.0 kV
Conducted Immunity Testing IEC 61000-4-6	3 V: 0.15 – 80 MHz 6V: In ISM Bands between 0.15MHz and 80 MHz 80 % AM at 1 kHz
Voltage dips IEC 61000-4-11	0 % UT; 0,5 cycle, At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°
Voltage interruptions IEC 61000-4-11	0 % UT; 250/300 cycle
Power frequency (60 Hz) magnetic field IEC 61000-4-8	30 A/m at 60 Hz
Proximity to Magnetic Fields IEC 61000-4-39	134.2 kHz and 13.56 MHz

- Elements of the LIAISON NES® system identified as essential and potentially susceptible to electromagnetic interference include the pump, heaters, and motors. Under excessive electromagnetic interference, the LIAISON NES® system may experience errors and abort the assay run. In this scenario, the operator will need to reboot the equipment, remove the cartridge, and dispose of the cartridge in the biohazardous waste.
- Use of this equipment stacked with other equipment is not allowed.
- Avoid using this equipment close to other equipment. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of cables other than those specified or provided could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment, constituting improper operation.

- Electromagnetic Interference (EMI):

  This equipment has been tested and found to comply with the requirements of IEC 60601-1-2 for electromagnetic compatibility. However, to help ensure optimal performance and continued safe operation, avoid placing the device in close proximity to sources of radio frequency (RF) emissions. These include, but are not limited to:

  - Mobile phones and wireless communication devices (including 5G millimeter wave)
  - RFID readers and EAS (Electronic Article Surveillance) systems
  - Wireless Power Transfer devices
  - Wireless routers and Bluetooth transmitters
  - Industrial equipment generating strong electromagnetic fields

  Maintain a minimum separation distance of 30 cm (12 inches) between the device and any RF emitter. This helps reduce the potential for electromagnetic interference and supports reliable operation in all environments. If you experience any irregularities during use, refer to *Instrument Performance Errors* for guidance.

3.2 Quality Control Overview

Each assay cartridge contains an internal control (IC) that is used to detect PCR failures and/or inhibitions. Users must perform quality control (QC) testing on the LIAISON NES® instrument. Each site should establish the frequency of QC testing based on applicable local laws, regulations, and standard good laboratory practice.

Refer to *Run a Quality Control Test* for or more details.

3.3 Service and Maintenance Overview

There are no user serviceable parts in the LIAISON NES®. Do not attempt to open or repair any system components. Contact *Diasorin Support* for assistance.

For cleaning instructions, refer to *Cleaning and Maintenance*.

3.4 Troubleshooting Overview

If an error occurs, the LIAISON NES® will display an error message with suggestions to resolve the issue. Follow the on-screen instructions to troubleshoot the issue. If the issue persists, contact *Diasorin Support* for assistance.

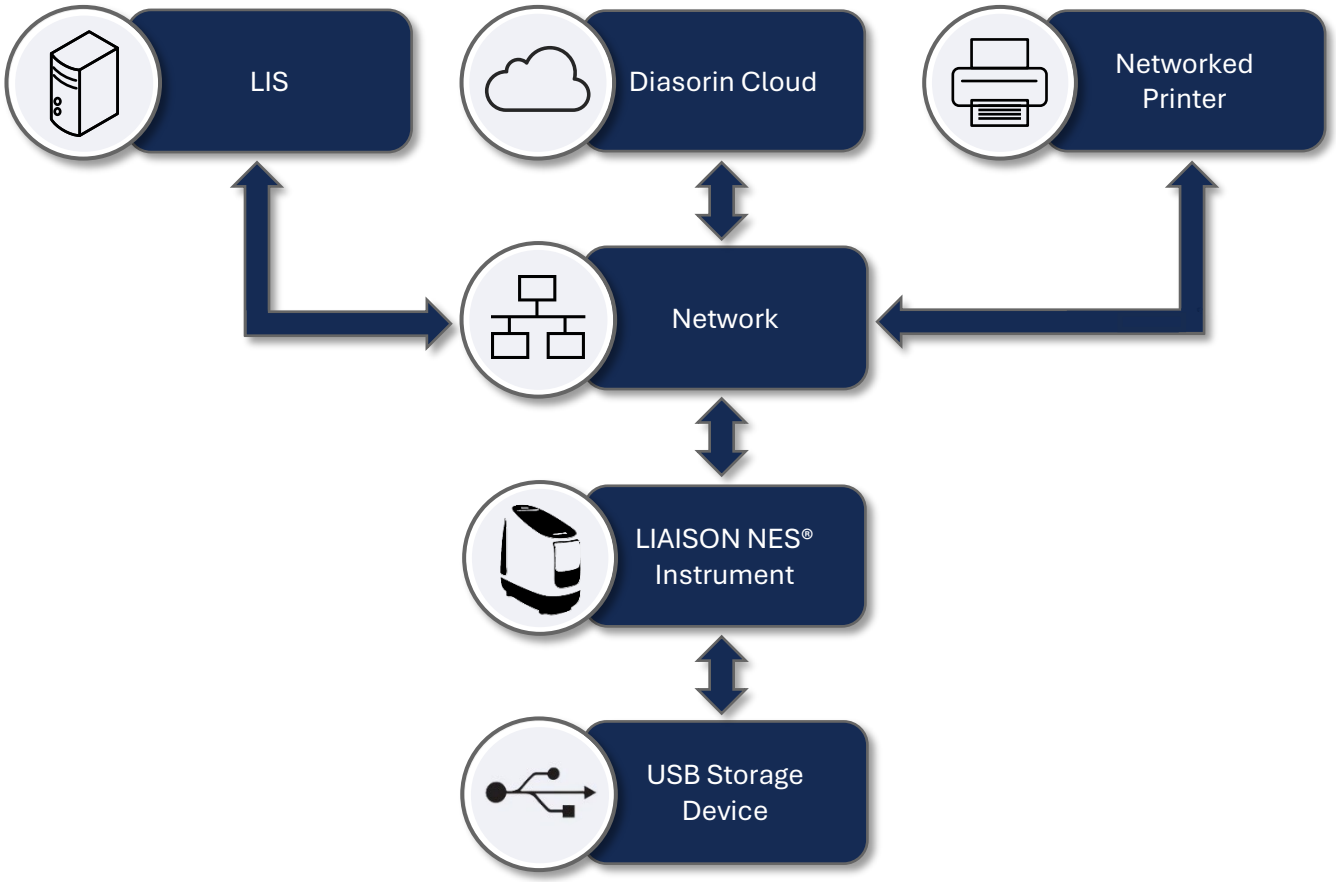
For troubleshooting information, refer to *Troubleshooting*.

4 Cybersecurity

4.1 System Connectivity Overview

The LIAISON NES® system is intended for standalone use or as part of a secure internal network. Supported, authorized connections include:

- Network printing via TCP/IP over Ethernet or Wi-Fi
- Laboratory Information System (LIS) connectivity for transmitting results
- Cloud communication for secure transmission of results and telemetry
- USB ports for controlled installation of updates and export of support files



4.2 Cybersecurity Controls and Features

The LIAISON NES® system is equipped with robust cybersecurity controls that protect critical functionality while safeguarding data integrity and infrastructure.

4.2.1 Device-Level Protections

The LIAISON NES® system includes the following features that protect critical functionality:

Feature	Description
System Integrity	The system checks the software and database integrity on startup. If data integrity has been compromised, the system disables assay functionality, and the device must be returned to Diasorin Molecular for replacement.
Firewall	The device has a network firewall that disables all ports at all times, except port 5353, which is briefly enabled for use by mDNS during printer discovery.
Process Isolation	The system software separates critical and non-critical processes. If a critical process is compromised or becomes nonfunctional, the system automatically reboots to preserve operational integrity and limit the spread of potential cybersecurity threats, ensuring continued protection of essential device functionality.
Network Independence	Network functionality is non-critical. The system can perform all essential functions without a network connection. As a result, internet outages, reduced network performance, or other network-related cybersecurity incidents do not critically impact the instrument's core functionality. For components that utilize network connectivity, the system includes mechanisms to detect and recover from network disruptions, ensuring continued reliability and data integrity.
Encryption	Software update files, assay update files, and assay files stored on the system are cryptographically signed. The instrument will not install or use any files that have been modified.

4.2.2 Built-in Cybersecurity Controls

4.2.2.1 Secure Configuration Controls

All LIAISON NES® devices are shipped with a standard factory configuration. Users can only access the graphical user interface and cannot access the operating system or file system. Operating system settings cannot be modified by users.

4.2.2.2 Software Configuration Controls

The NES operational software is protected from unauthorized changes. Software updates are available for download or provided via USB. In all cases, the update package has a secure digital signature that prevents installation of unauthorized changes. After the signature is verified, the software is installed onto a physically inaccessible nonvolatile memory device.

At system startup, the software modules are verified against a manifest with checksums to prevent execution of adulterated programs. The software bill of materials (SBOM) can be provided upon request.

4.2.2.3 Dependencies and Availability Controls

Results can be exported from the system by three methods: printing to a networked printer, transmitting to the Laboratory Information System (LIS), or transmitting to a cloud interface. Printing, LIS transmission, and cloud transmission require a functional network connection.

If one of these options is unavailable, the other options can still be used. If all interfaces become unavailable due to a cyberattack or other malfunction, results are stored on the system for future export using any supported method. Additionally, any failed transmissions to the LIS or cloud due to a network interruption are automatically re-sent upon successful reconnection to the network.

4.2.3 User-enabled Cybersecurity Controls

4.2.3.1 Transport Layer Security (TLS)

To protect patient health data during transmission between the LIAISON NES® system and the Laboratory Information System (LIS), it is strongly recommended to enable Transport Layer Security (TLS) for all HL7 message exchanges. When enabled, TLS provides encryption and authentication, reducing the risk of interception or unauthorized access.

Refer to *Enable Connection to the Laboratory Information System (LIS)* for instructions on enabling Transport Layer Security (TLS).

After enabling TLS, adhere to the following recommendations to maintain secure communication between the LIS and the instrument:

- Ensure that valid digital certificates are installed on both the LIAISON NES® and LIS systems. Monitor certificate expiration dates and renew them as needed.
- Limit LIS-NES communication to trusted IP ranges or secure VPN tunnels.
- Periodically review TLS configurations to ensure compliance with current security best practices.

Important Note: Failure to implement secure communication measures may expose patient data to interception or unauthorized access.

4.3 Cybersecurity Guidance for Network Administrators

If the instrument is connected to a network, appropriate measures should be implemented to prevent unauthorized access to the device and its data. These recommendations are intended to help network administrators mitigate the risk of cyber-attacks.

4.3.1 Software Updates

The LIAISON NES® Software is delivered as a single package that includes all Diasorin proprietary software as well as off-the-shelf components used by the software. Software updates are performed by users. Software updates are delivered via the cloud or via USB. Software updates are digitally signed to prevent tampering and installation of corrupt files.

4.3.2 Security Strategy

Consider implementing a Zero Trust security strategy at your organization. The Zero Trust strategy assumes breach, verifies each request as though it originated from an uncontrolled network, and uses least privilege access to maximize network security. Details of the Zero Trust strategy can be found at *https://learn.microsoft.com/en-us/security/zero-trust/zero-trust-overview*.

4.3.3 Intrusion Detection

Implement intrusion detection systems on your network to monitor any suspicious activities or attempts at gaining unauthorized access by outside parties.

4.3.4 Vendor Security

Choose reputable vendors who prioritize security and provide updates and support for your network systems.

4.3.5 User Training

Train users and healthcare staff in cybersecurity best practices to help keep the network the instrument is a part of as secure as possible. This includes training on how to avoid phishing emails, using strong passwords on network systems, not sharing or reusing passwords, and only using USB drives that originate from a reputable source.

4.3.6 Security Testing

The network should be tested regularly to identify and proactively address any vulnerabilities that an outside attacker could use to gain access to the instrument or other networked assets.

4.3.7 Access Control

To prevent unauthorized access, limit physical access to the instrument to authorized individuals only. Additionally, ensure the device is connected only to trusted networks.

4.3.8 Logging and Auditing

Keep detailed logs of device activity and regularly review them for signs of unauthorized access or suspicious behavior.

4.3.9 User Permissions

Grant users the minimum level of network access necessary for their roles to limit potential damage from internal threats.

4.3.10 Incident Response Plan

4.3.10.1 User Network Breach

Develop and practice an incident response plan to minimize the impact of any security breach and to protect patient data.

4.3.10.2 LIAISON NES® Device Breach

In the event of system corruption due to a cyber-attack, the system will display the message “Unvalidated software, not for clinical use.” The Incident Response Plan for this scenario is as follows:

- Shut down the instrument.
- Contact *Diasorin Support*.

4.3.11 Regulatory Compliance

Ensure your network complies with relevant cybersecurity standards and regulations, such as HIPAA in the United States or GDPR in Europe.

4.3.12 Security Policies

Develop and enforce security policies for your device, including policies that address user access and acceptable use policies.

4.3.13 Interfaces and Protocols

The LIAISON NES® system contains a number of different communication and networking interfaces and protocols that are used for various purposes:

- **TCP/IP:** Networking the instrument
- **LIS:** Transmitting results and receiving orders from a networked LIS server
- **USB:** Physical USB ports on the instrument for installing updates and exporting support files
- **Cloud:** Transmitting results and telemetries of the instrument to a cloud interface

4.4 Cybersecurity Guidance for End Users

The following recommendations are intended for end users of the LIAISON NES® system as best practices to safeguard the system from cyber threats and attacks.

- Use complex passwords containing a mix of uppercase and lowercase letters, numbers, and special characters.
- Never share your password.
- Change your password periodically.
- Always log in to the system with your own user credentials.
- Always log out of the system when your work is complete.
- Only use USB drives from a trusted source.
- If you suspect a security incident or unusual behavior on the system, report it to the appropriate authorities within your organization promptly.
- For LIAISON NES® administrator users, when connecting to a network printer, only use printers on a known trusted network.

5 System Components

5.1 LIAISON NES® Front View

5.2 LAISON NES® Back View

5.3 Touchscreen

The fully colored touchscreen facilitates interaction with the device's graphical user interface (GUI). Users can select, scroll, and perform various tasks on the interface by interacting with the touchscreen. Appropriate personal protective equipment (PPE) must be worn when handling the touchscreen. Users can interact with the touchscreen tactilely, or they can use the provided stylus.

Refer to *Sound and Display Preferences* to change brightness of the screen.

5.4 Status LED Indicator

The LED strip above the touchscreen indicates the system status.

LED Indicator States:

Color	State	Indication
Green	Flashing	System initialization/Self-Check
	Solid	System ready
Blue	Progress Bar (moving from left to right)	Test run in progress
	Progress Bar + Flashing	Early result*
	Flashing	Test run is complete
Red	Solid	System error

* Available on certain assays. Refer to the assay-specific Instructions for Use (IFU) for more details.

5.5 Audio Speaker

The LIAISON NES® is equipped with an audio speaker, which notifies the user of various tasks while the system operates.

An audio tone plays in the following instances:

- When the system is powered on
- When a self-check is completed successfully
- When a test is completed successfully
- When there is an error on the instrument requiring user attention

The instrument plays a short beep tone in the following instance:

- When a barcode is scanned

5.6 Barcode Scanner

The LIAISON NES® is equipped with a barcode scanner located on the front of the device. The scanner reads both 1D and 2D barcodes and can retrieve the Patient Order, patient identification (Patient ID), and quality control (QC) information encoded in the barcodes.

The barcode scanner automatically activates and deactivates in response to movement in front of it. To manually activate the scanner, select SCAN on the home screen.

The LIAISON NES® barcode scanner supports the following 1D and 2D barcode types:

Barcode Type	Name
1D	Code 39
	Code 128*
	Codabar
	Interleaved 2 of 5
2D	QR Code
	Data Matrix
	PDF417

**Code 128 can only be used for Patient IDs*

5.7 Connectivity Ports

The LIAISON NES® includes the following connectivity ports:

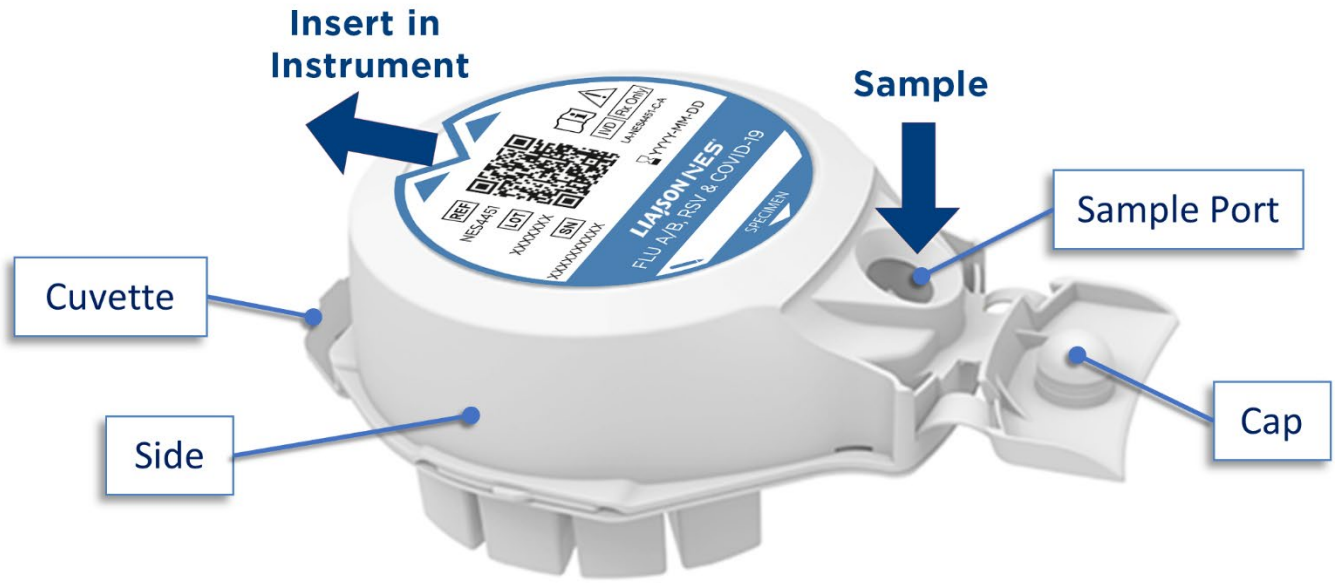
- Two USB (Type A)
- One Ethernet port

5.8 Cartridge Overview

The LIAISON NES® assay cartridge requires sample preparation before it is ready-to-use. The tubes on the underside of the cartridge contain the reagents needed to perform the test. The cartridge includes a cap that covers the sample port. Cartridges are packed and shipped with the caps slightly ajar. Before adding the sample, the cap must be fully opened. After the sample is added to the sample port, the cap must be completely closed before the cartridge can be used in testing.

The reaction occurs in the cuvette, which is the flat protruding part of the cartridge located on the back. The cuvette is the most sensitive part of the cartridge.

Caution: Do not touch, scratch, or tamper with the underside foil on the cartridge. Do not scratch or tamper with the cartridge wells and the reagents located on the bottom of the cartridge.

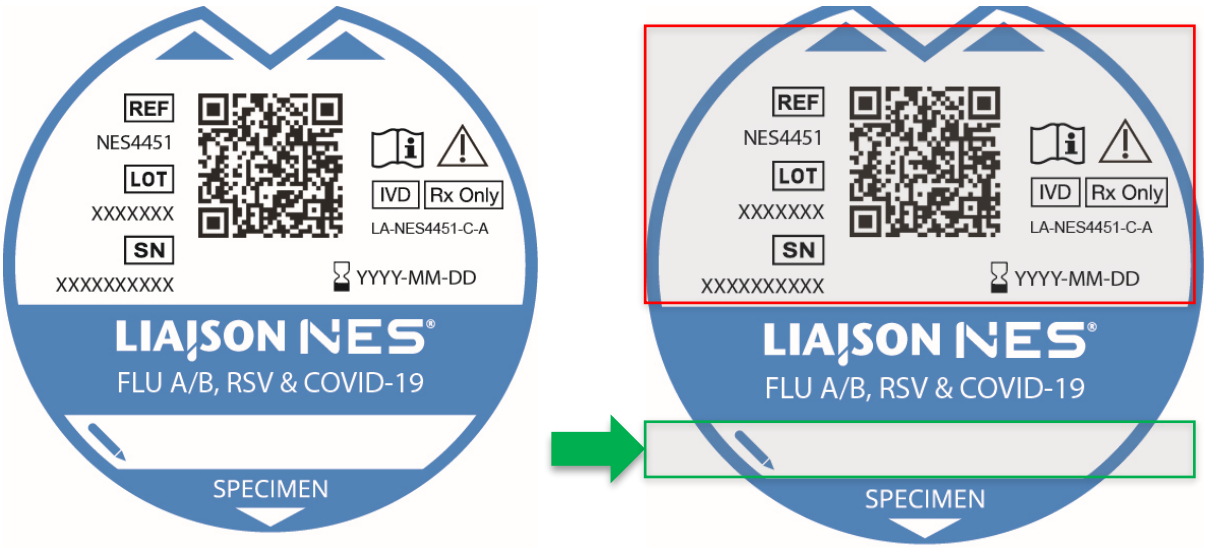


Caution: Hold the cartridge by the sides and keep the cartridge upright – do not tilt or shake.

5.8.1 Cartridge Label and Patient Identification

Each cartridge label identifies the test type and product information. The label also includes the Cartridge ID barcode, which the instrument scans internally. Do not scan the Cartridge ID barcode on the label because it is intended for internal use only.

When writing a Patient ID on the cartridge label, use the dedicated white space at the bottom of the label, indicated by the green arrow and box in the image below. Do not write in or mark the area near the Cartridge ID barcode in the center of the label, indicated by the red box. If a marking or label obscures the Cartridge ID barcode, the instrument will not recognize the cartridge after it is inserted.



Important Note: Do not scan the Cartridge ID barcode on the cartridge label. The Cartridge ID barcode is read internally by the instrument and contains only test-related information. It does not include any patient information or serve as a Patient ID.

Refer to the *Glossary* for more information on cartridge label symbols.

Caution: Do not touch, scratch, or tamper with the underside foil on the cartridge. Do not scratch or tamper with the cartridge wells and the reagents located in the bottom of the cartridge.

Important Note: For best results, keep the cartridge upright and on a flat surface during operation and storage.

5.9 Recommended Additional Equipment

5.9.1 Uninterruptible Power Supply (UPS) or Surge Protector

Diasorin recommends using an Uninterruptible Power Supply (UPS) with a rating of 900 Watts/1500VA with a 100Wh capacity for locations that have a generator to restore power in case of a power outage. For locations that do not have a backup generator, contact *Diasorin Support* to discuss recommended battery life requirements.

6 Instrument Specifications and Setup

The instrument package includes:

- LIAISON NES® Instrument
- Power Adapter
- Power Cable
- Ethernet Cable
- Accessories Box containing:
    - Touchscreen Stylus
    - Screen Wipe
    - Instrument Dust Cover

The following equipment is not included in the instrument package but is recommended for use with the LIAISON NES® system:

- Uninterruptible Power Supply (UPS) or Surge Protector

Refer to *Recommended Additional Equipment* for more information.

6.1 Site Preparation and Facilities Requirements

- Counter space: Clean, flat, level, stable surface capable of supporting the weight of the instrument
- Wall clearance: Sufficiently distanced so as not to block the exhaust fan inlet or outlet on the back of the instrument
- Electrical outlet for region-specific power cord (100-240 Volts): Within 2 meters (6 feet) of instrument

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation.

Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the LIAISON NES® system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Do not cover the instrument or block the exhaust fan inlet or outlet.

6.2 Environmental Conditions

Operating Environment	Professional Healthcare Facility
Altitude	Operation up to 2000 m (6561 ft) above mean sea level Storage up to 2000 m (6561 ft) above mean sea level
Operating Temperature	15°C to 30°C (59°F to 86°F)
Operating Humidity	20% to 80% relative humidity, non-condensing
Shipping and Storage Temperature	-20°C to 60°C (-4°F to 140°F)
Shipping and Storage Humidity	15% to 80% relative humidity, non-condensing
Pollution Degree	2

6.3 Performance Specifications

6.3.1 General System Specifications

Color Touchscreen	5.5 inches Thin Film Transistor (TFT)
Communications	Ethernet and Wi-Fi 2 x USB-A ports
Data Storage	Internal Data storage of approximately 10,000 results (including QC runs)
Dimensions	4.3 inches (width) x 9.5 inches (height) x 10.2 inches (length) 11 cm (width) x 24 cm (height) x 26 cm (length)
Weight	6.6 lbs 3.0 kg
Power adapter	24 V
Installation Category	Category 1
Sound Pressure Level	Produces sound pressure levels no greater than 62 dBA at a distance of 1 m radius when audible alerts aren't active.
Sample Volume Max	Follow the assay-specific Instructions for Use for the appropriate sample volume
British Thermal Units (BTU)	~ 82 BTU/hr while idle and ~ 680 BTU/hr max when running (Not Verified)

6.3.2 Electronic Specifications

Power adapter (Model: AQM200PS24)

Rated Input Voltage	85-264 VAC
Rated Input Frequency	47/63 Hz
Rated Output Current	8.3 Amps
Rated Output Voltage	24 Volts
Rated Output Power	200 Watts
Dimensions	2.13 inches (width) x 1.3 inches (height) x 6.6 inches (length) 5.4cm (width) x 3.3cm (height) x 16.7cm (length)
Weight	1.32 lbs (0.6 kg)
Operating Environment	As per the environmental conditions specified above
Storage Environment	As per the environmental conditions specified above

6.4 Set Up the LIAISON NES®

6.4.1 Unbox the Instrument

Caution: Read and carefully follow all the warnings and precautions included in this document.

Warning – Handle with Care

Avoid placing the instrument near ledges. If the instrument is accidentally dropped or struck by a falling object, the touchscreen may shatter, creating sharp glass shards and jagged edges. In the event of a drop, do not directly handle broken shards; use appropriate tools and personal protective equipment to safely clean up. Contact *Diasorin Support* for a replacement.

Remove the LIAISON NES® instrument from its packaging and place it on a clean, flat, and stable surface. The installation location must be free of vibrations, well-ventilated, and temperature-controlled. Ensure the space around the instrument is clear to allow ventilation through the underside and back of the instrument. Do not cover the instrument or block the exhaust fan inlet or outlet. Avoid placing the instrument in direct sunlight, near desk or table edges, under shelves, near air conditioning vents, near a source of water or moisture, or near fire hazards.

6.4.2 Connect the Power Supply

Caution: Ensure the power switch on the back of the instrument is in the "O" (OFF) position before plugging in the power adapter.

1. Connect the power cable to the power adapter input, as shown in the image below.

2. Use the output connector to connect the power adapter to the instrument. Ensure the output connector is oriented correctly before plugging it in. There is only one correct orientation, which is shown in the images below:

Orient the output connector so that the flat portion of the connector faces the exhaust fan and the center of the instrument. Carefully align the prongs of the output connector with the corresponding sockets on the power connection port.	Gently insert the output connector into the power connection port with the flat side of the connector facing toward the exhaust fan. Do not use force to insert the output connector. If there is resistance, confirm that the output connector prongs are aligned with the corresponding sockets.

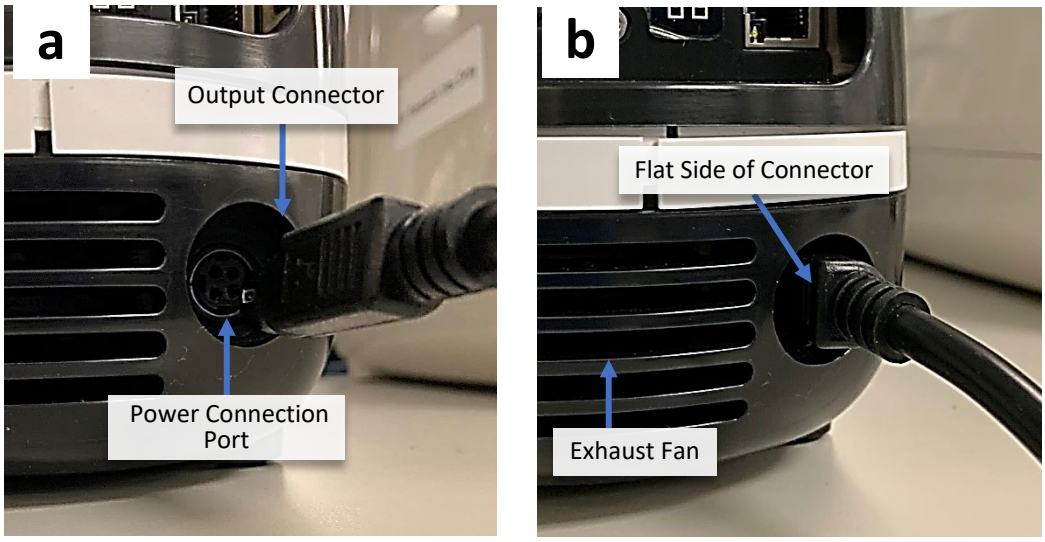


Figure 3-2 – Power Connection

3. After connecting the power adapter to the LIAISON NES®, plug the power cable into an electrical outlet.

6.4.3 Power on the LIAISON NES®

Caution: Ensure the power cable is securely connected to the instrument.

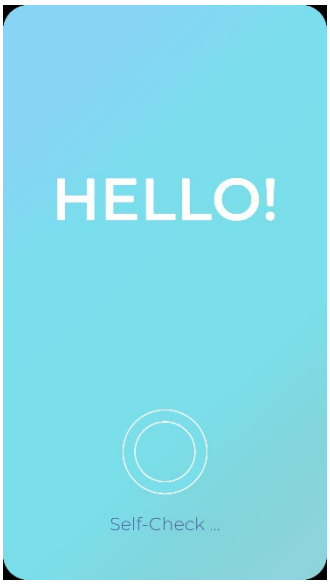
Important Note: Never disconnect the power cable or power off the instrument while the instrument is powered on.

Important Note: Do not move or power off the instrument during a self-check. Doing so may cause instrument fault or error.

Flip the power switch on the back of the instrument to the "—"(ON) position to power on the LIAISON NES® instrument. The startup sequence initializes automatically.

During startup, the LIAISON NES® system performs a self-check to verify the firmware (FW), database, and instrument functionality. The system indicates when the self-check is successful.

If the system fails any part of the self-check, an error message displays and the LED indicator above the touchscreen turns red. Refer to *Self-Check Failure During Initial Setup* if this occurs during the initial self-check.



6.4.4 Connect Systems

It is recommended that the instrument be connected to a network to enable essential functions such as time synchronization, software updates, and data transfer.

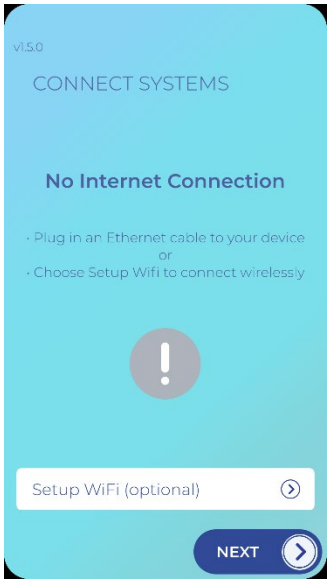
If the instrument is connected to a network, ensure the network complies with relevant cybersecurity standards and regulations, such as HIPAA in the United States or GDPR in Europe.

Best Practice	For optimal performance, connect the LIAISON NES® to the network using an Ethernet connection. To ensure backup connectivity in the event of an Ethernet failure, set up Wi-Fi as well.

6.4.4.1 Connect to Wi-Fi

To connect to Wi-Fi,

1. Select **Setup WiFi (optional)**.
2. Choose the desired network from the list of available Wi-Fi networks.
3. Enter the Wi-Fi network password, then select the blue arrow in the bottom right.
4. Select **Connect**.
5. Confirm that the connection status displays as connected to the Internet.



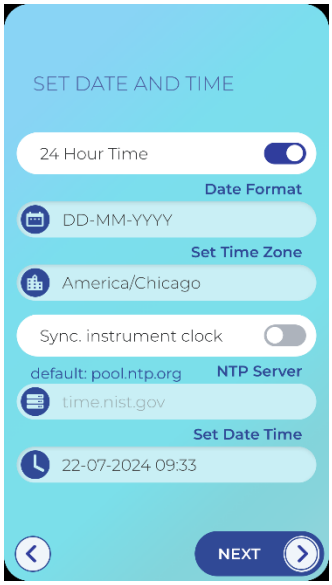
6.4.4.2 Connect to Ethernet

Use the Ethernet port on the back of the instrument and the Ethernet cable provided with the instrument to connect to Ethernet,

1. Insert one end of the Ethernet cable into the Ethernet port on the back of the instrument.
2. Insert the other end of the Ethernet cable into a secure, active Ethernet port.
3. Select **NEXT** when the connection status displays as connected to the Internet.

6.4.5 Set the Date Time Format

To set the preferred date and time format,



1. Use the **24-Hour Time** toggle switch to choose a clock format. To select the 12-hour (AM/PM) clock format, toggle the switch to the left.
2. Select the **Date Format** field and choose one of the following: **DD-MM-YYYY**, **MM-DD-YYYY**, or **YYYY-MM-DD**. Then select the back arrow.

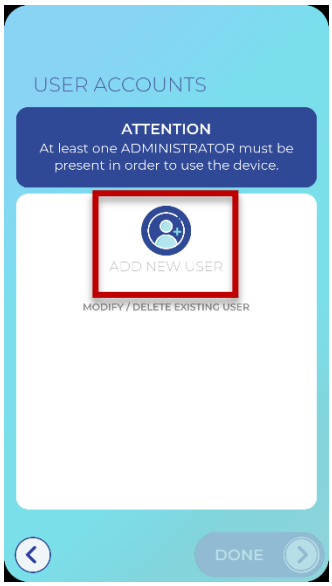
6.4.6 Set the Date and Time

Best Practice	Automatic clock synchronization is recommended for accurate timekeeping. An internet connection is required to enable automatic synchronization.

To set the date and time,

1. Select the **Set Time Zone** field and choose the appropriate time zone. Then select the back arrow.
2. To enable automatic clock synchronization, toggle the **Sync instrument clock** switch to the right. Select the **NTP Server** field and enter the Network Time Protocol (NTP) Server. Then select the back arrow.
3. To manually enter the date and time, select the **Set Date Time** field and scroll to set the current date and time. Then select the back arrow. This option is only available when Sync instrument clock is disabled.
4. Select **NEXT** to continue setting up the instrument.

6.4.7 Set up an Administrator Account



To ensure that there is always an administrator account on the LIAISON NES® instrument, create an administrator account during initial setup.

To set up an administrator account,

1. Select **ADD NEW USER**.
2. Enter the desired username, then select **NEXT**.
3. Confirm **Administrator** is selected, then select **NEXT**.
4. Enter the desired password, then select **NEXT**.
5. Reenter the password, then select **NEXT**.
6. Select **DONE.** The new user account appears under MODIFY / DELETE EXISTING USER.
7. Select **DONE** again.
8. Select **Let's Get Started** to redirect to the login screen.

Refer to *User Accounts and Login Settings* for instructions on how to change passwords, enable/disable accounts, and delete accounts. .

7 Preparing the System

7.1 Power on the LIAISON NES®

Caution: Ensure the power cable is securely connected to the instrument.

Important Note: Never disconnect the power cable or power off the instrument during a self-check or while a test is in progress.

Flip the power switch on the back of the instrument to the "—"(ON) position to power on the LIAISON NES®. The startup sequence initializes automatically.

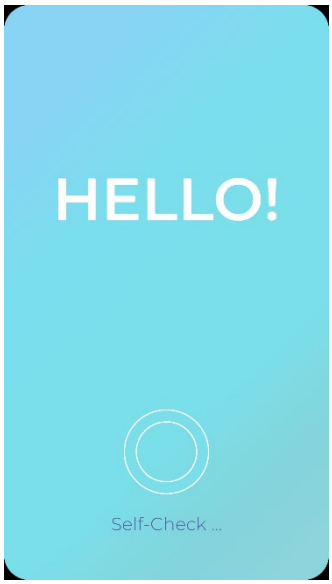
Refer to *Log Out and Power Off the LIAISON NES®* for instructions on how to safely power off the instrument.

7.2 Self-Check

Important Note: Do not move or power off the instrument during a self-check. Doing so may cause instrument fault or error.

During startup, the LIAISON NES® performs a self-check to verify the firmware (FW), database, and instrument functionality. The system indicates when the self-check is successful.

If the system fails any part of the self-check, an error message displays and the LED indicator above the touchscreen turns red. Refer to *Self-Check Failure During Startup* if this occurs.



7.3 Change Password During Login

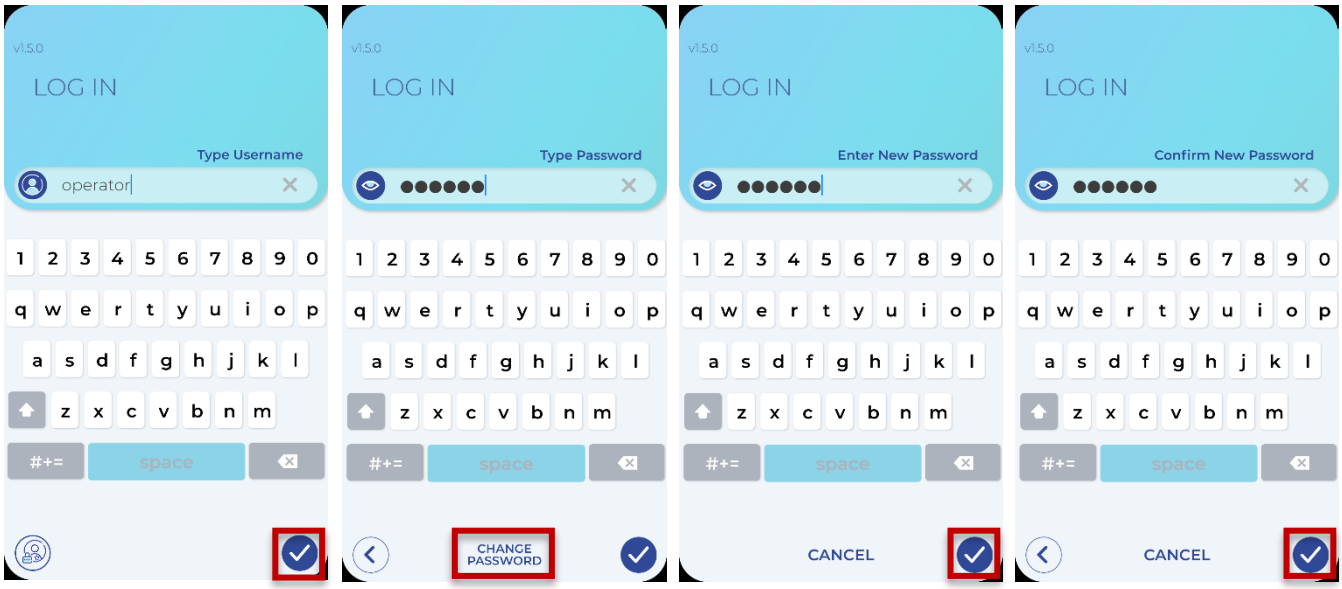
Users can change their password while logging in to the system. New users should change their password during their first login. The system also prompts users to change their password when it expires.

Best Practice	The LIAISON NES® system supports multiple user accounts. For regulatory compliance, cybersecurity, and traceability - do not share your username and password with anyone.
Best Practice	Passwords should be between 5-16 characters in length and contain a combination of letters, numbers, and symbols to create a strong, unique password.

To change your password during login,

1. Enter your username, then select the check mark.
2. Enter your current password, then select **CHANGE PASSWORD**.
3. Enter the desired new password, then select the check mark.
4. Reenter the new password, then select the check mark.

Important Note: Select the eye icon next to the typed characters to view the typed password.

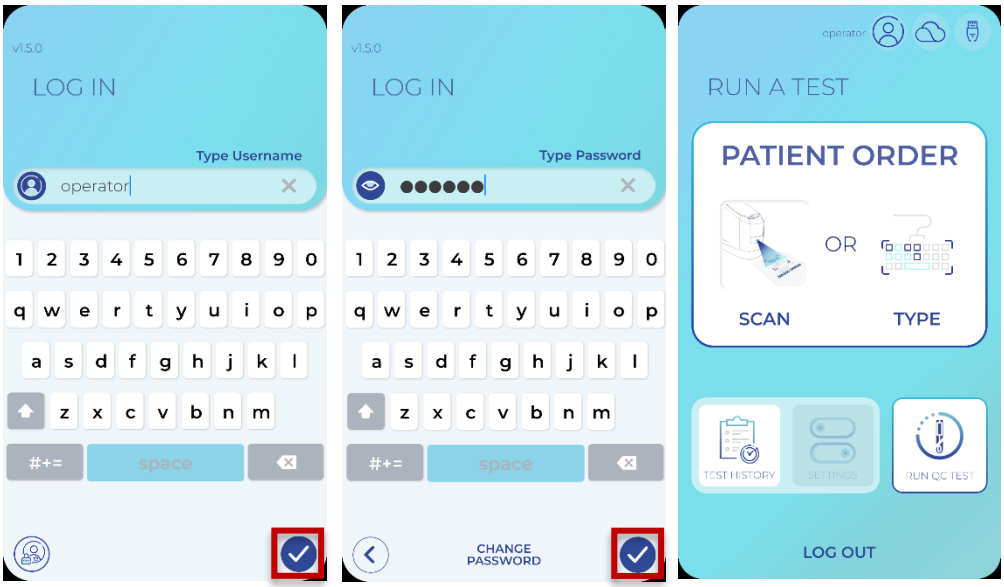


7.4 Log in to the Software

To log in to the LIAISON NES® system,

1. Enter your username, then select the check mark.
2. Enter your password, then select the check mark. The home screen displays.

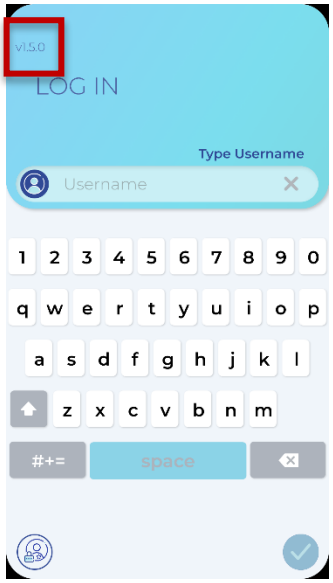
Important Note: Select the eye icon next to the typed characters to view the typed password.



7.5 Software Version Overview

The software version is displayed in the upper left corner of the login screen.

Only administrators can perform software updates.



Refer to *Software Updates* for information about updating the software.

7.6 Home Screen Overview

The LIAISON NES® home screen has the following indicators and functions.

Profile Icon: Displays the username for the user currently logged in to the system.

Cloud Icon: Indicates that the system is connected to the Cloud.

Network Icon: Indicates the active network connection type – Wi-Fi or Ethernet. Only one icon appears on the home screen based on the current connection.

NOTIFICATIONS: Select to view important notifications. This icon appears when notifications are present.

TYPE: Select to enter the Patient ID manually. Selecting this activates the on-screen keyboard.

SCAN: Select to scan the Patient Order barcode. Selecting this activates the barcode scanner. Motion also activates the barcode scanner.

TEST HISTORY: Select to view past test results (patient and quality control).

SETTINGS: Select to access the settings screen. The following options are available on the settings screen: Preferences, User Accounts and Login, Assay Management, QC Expiry Settings, Connectivity, Printer Settings, Install Update, Gen Support File, and Factory Reset. Only administrators can access the settings screen.

RUN QC TEST: Select to scan a QC barcode and initiate a quality control (QC) test. Selecting this activates the barcode scanner. Motion also activates the barcode scanner.

LOG OUT: Select to log out the current user.

8 Run a Quality Control Test

The LIAISON NES® system uses quality control (QC) tests to ensure the accuracy of test results. Each site should establish its own frequency of QC testing based on applicable local laws, regulations, and standard good laboratory practice. At a minimum, QC testing must be performed in the following instances:

- Before using a new cartridge lot
- For every new assay added to the instrument menu
- For each new lot of assays on an instrument
- Every 60 days for each lot on each instrument

It is also recommended that QC testing be performed in the following instances:

- After adding a new user to the system
- Every 30 days for each lot on each instrument

Only use QC samples and cartridges purchased from Diasorin. The QC samples and assay cartridge kits are sold and packaged separately.

Assays available for testing on the LIAISON NES® have associated Control Swab Kit(s). Control Swab Kits contain individually wrapped positive and negative control swabs. Each swab can only be used once. Upon receipt of the kit, store it according to the package labeling.

The procedures below describe the process of running a QC test on the LIAISON NES®. Complete these procedures for both the positive control and the negative control. Refer to the assay-specific Instructions for Use (IFU) for instructions on preparing a sample/cartridge.

8.1 Warnings and Precautions

	**Carefully read the assay-specific Instructions for Use (IFU) and Quick Reference Guide (QRG) before running a test.**
	Wear appropriate personal protective equipment (PPE), including gloves, when handling the cartridge and any disposable or preparatory items that may have come into contact with potentially biohazardous substances.
	Dispose of any assay components that are dropped, cracked, opened, or damaged in the biohazardous waste.
	Do not move or jostle the instrument while a test is in progress.
	Do not connect OR disconnect any peripheral equipment while a test is in progress. Peripheral equipment includes, but is not limited to, flash drives and printers.

Hold the cartridge by the sides and keep the cartridge upright – do not tilt or shake.

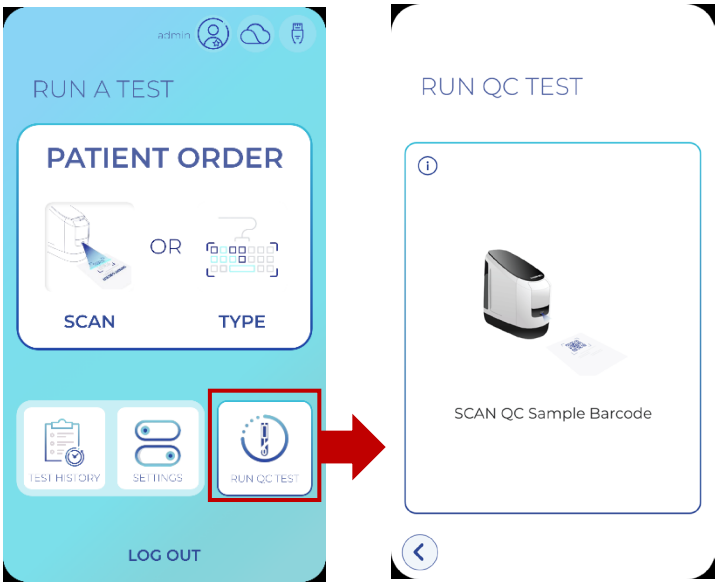
8.2 Set Up a Quality Control Test

Set up a quality control (QC) test on the LIAISON NES® by scanning the QC barcode included with the assay-specific positive or negative control.

To scan the QC barcode from the home screen,

1. Move the QC barcode in front of the barcode scanner to activate it automatically or select **RUN QC TEST** to manually activate the barcode scanner.
2. Hold the QC barcode in front of the barcode scanner. A short beep indicates the instrument scanned the barcode.

Important Note: Do not scan the Cartridge ID barcode atop the cartridge label; this barcode is read inside the instrument. Only scan Patient Order barcodes and the QC barcodes on the control sample's packaging.



8.3 Load a Cartridge and Run a Quality Control Test

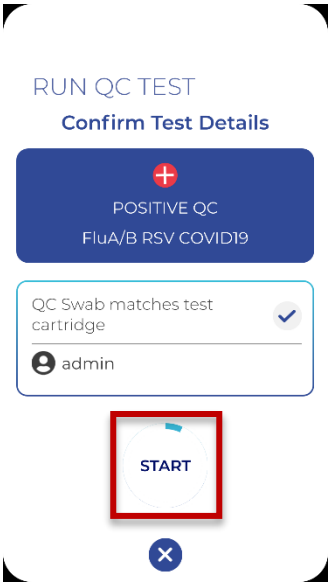
Caution: Each cartridge can only be used once. Attempting to reuse a cartridge will produce an error message.

Caution: Do not forcibly open the instrument door or apply downward force on the door while the door is open.

DOOR OPENS AUTOMATICALLY
Insert loaded Cartridge

Close Door

1. When the instrument door opens, insert the cartridge containing the quality control (QC) sample. Make sure:
   - The cartridge label faces up.
   - The two blue arrows on the label point toward the inside of the instrument.
2. Close the instrument door when prompted.
3. Review the QC test details. Check the following:
   - The QC type is correct (positive or negative).
   - The QC test type matches the intended assay.
   - The QC sample type matches the test cartridge.
4. If the QC test details are correct, select **START** or wait for the test to start automatically after 60 seconds.
5. If the QC test details are incorrect, select the blue **X** at the bottom of the screen before the 60-second review period ends to cancel the test.
   a. When the instrument door opens, remove the cartridge and dispose of it in the biohazardous waste.
   b. Close the instrument door when prompted.



8.4 Quality Control Test in Progress

While a quality control (QC) test is in progress, the time remaining and the QC test details are displayed on the touchscreen.

The LED status indicator functions as a progress bar during the test.

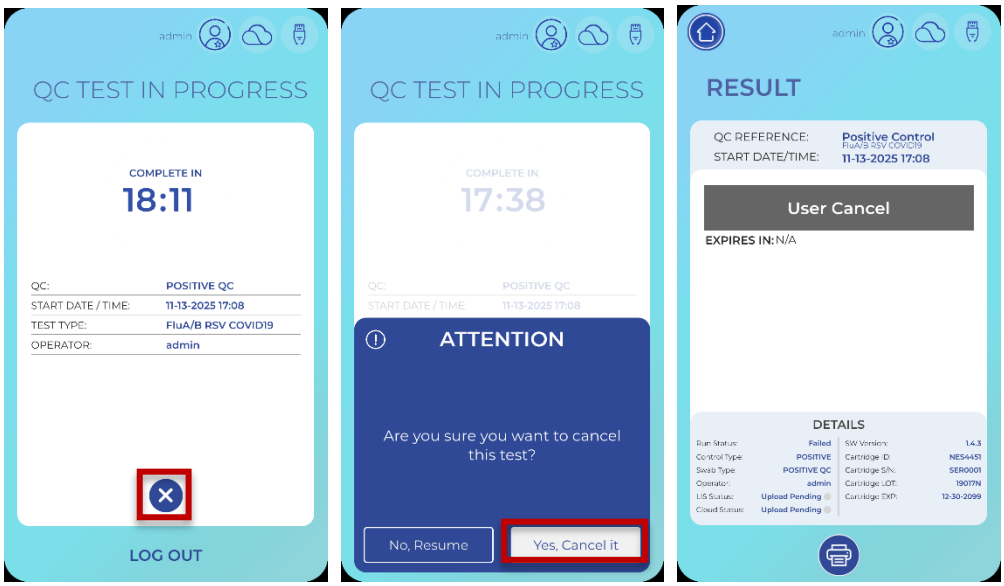
Caution: Do not move or jostle the instrument while a test is in progress.

8.5 Cancel a Quality Control Test

Important Note: Once a test is canceled, the cartridge can no longer be used.

To cancel a quality control (QC) test while the test is in progress,

1. Select the blue **X** at the bottom of the screen.
2. Select **Yes, Cancel it** in the confirmation dialog.
3. When the instrument door opens, remove the cartridge and dispose of it in the biohazardous waste.
4. Close the instrument door when prompted.



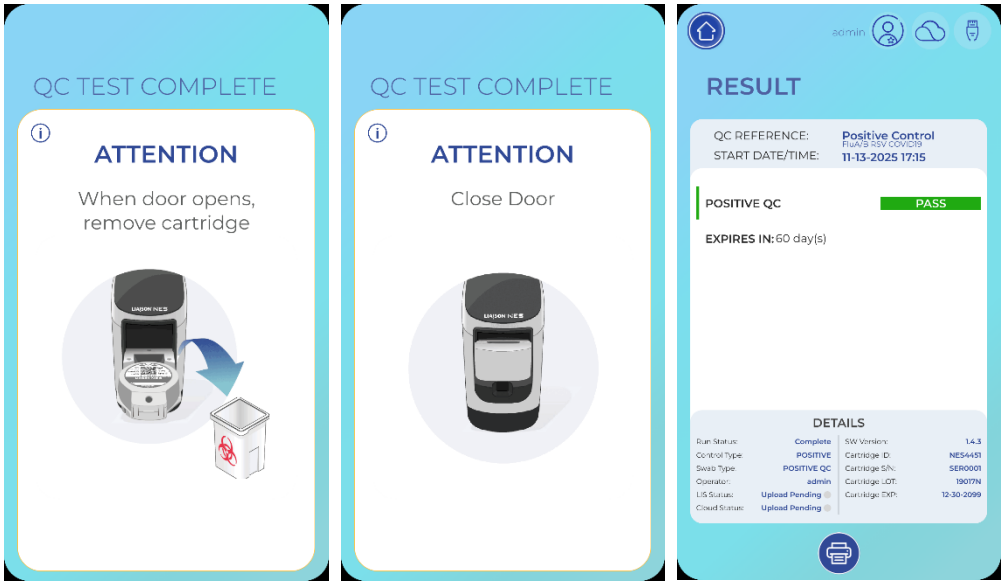
8.6 Complete a Quality Control Test and View Results

When the system finishes the quality control (QC) test, the instrument door opens automatically. To complete the QC test and view the results,

1. Remove the cartridge and dispose of it in the biohazardous waste.
2. Close the instrument door when prompted.

Upon completion of a QC test, the results are automatically displayed on the touchscreen and uploaded to the Diasorin Cloud and Laboratory Information System (LIS), if connected. Refer to the assay-specific Instructions for Use (IFU) for information on interpreting QC test results.

Important Note: The cartridge must be removed to view the results. This is a precautionary step to avoid leaving the cartridge in the instrument.



9 Run a Test

9.1 Warnings and Precautions

Carefully read the assay-specific Instructions for Use (IFU) and Quick Reference Guide (QRG) before running a test.

Wear appropriate personal protective equipment (PPE), including gloves, when handling the cartridge and any disposable or preparatory items that may have come into contact with potentially biohazardous substances.

Dispose of any assay components that are dropped, cracked, opened, or damaged in the biohazardous waste.

Do not move or jostle the instrument while a test is in progress.

Do not connect OR disconnect any peripheral equipment while a test is in progress. Peripheral equipment includes, but is not limited to, flash drives and printers.

Hold the cartridge by the sides and keep the cartridge upright – do not tilt or shake.

Refer to the assay-specific Instructions for Use (IFU) for the patient sample preparation steps.

Best Practice

Document the Patient ID in the designated white space at the bottom of the cartridge label.

Only write on or affix labels to the designated space on the cartridge label. Do not write on or affix anything near the Cartridge ID barcode. Do not scan the Cartridge ID barcode on the cartridge label.

It is strongly recommended that Patient Orders/Patient IDs not contain patient names or any of the patient's personal information. Refer to *Privacy and Protection Measures* for more information.

9.2 Set Up a Test

Set up a test on the LIAISON NES® by scanning the Patient Order barcode or by manually entering the Patient ID.

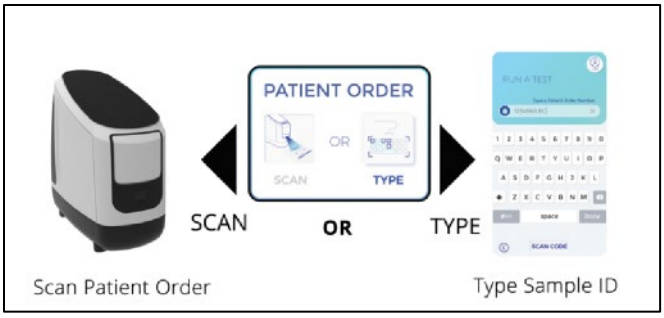
To scan the Patient Order barcode from the home screen,

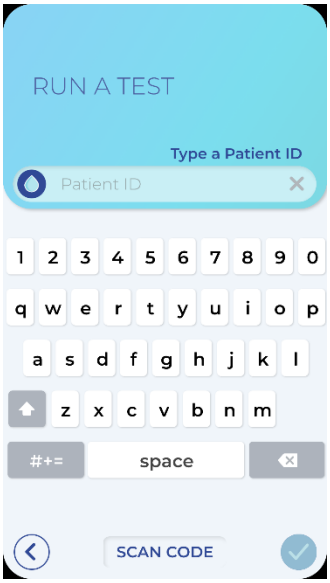
1. Move the Patient Order barcode in front of the barcode scanner to activate it automatically or select **SCAN** under PATIENT ORDER to manually activate the barcode scanner.
2. Hold the Patient Order barcode in front of the barcode scanner. A short beep indicates the instrument scanned the barcode.

To manually enter the Patient ID from the home screen,

1. Select **TYPE** under PATIENT ORDER. The on-screen keyboard displays.
2. Enter the Patient ID, then select the check mark in the bottom right.

Important Note: Do not scan the Cartridge ID barcode atop the cartridge label; this barcode is read inside the instrument. Only scan Patient Order barcodes and the QC barcodes on the control sample's packaging.





9.3 Load a Cartridge and Run a Test

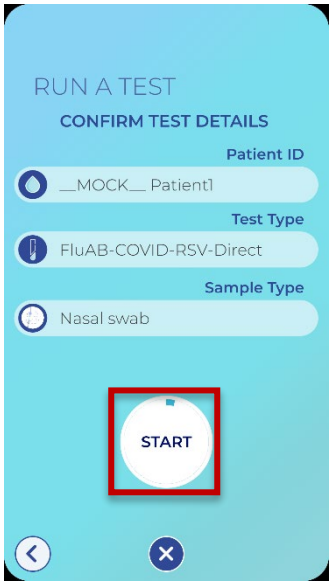
Caution: Each cartridge can only be used once. Attempting to reuse a cartridge will produce an error message.

Caution: Do not forcibly open the instrument door or apply downward force on the door while the door is open.

DOOR OPENS AUTOMATICALLY
Insert loaded Cartridge

Close Door

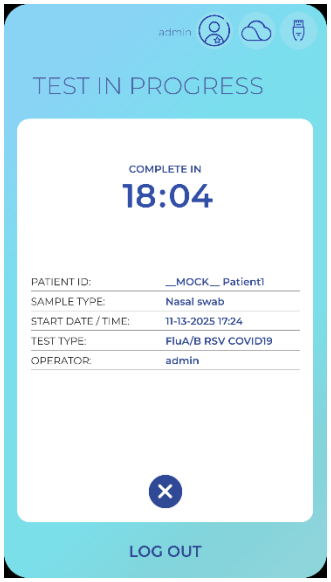
1. When the instrument door opens, insert the cartridge containing the patient sample. Make sure:
   - The cartridge label faces up.
   - The two blue arrows on the label point toward the inside of the instrument.
2. Close the instrument door when prompted.
3. Review the test details. Check the following:
   - The Patient ID is correct.
   - The Test Type matches the intended test.
   - The Sample Type matches the collection method.
4. If the test details are correct, select **START** or wait for the test to start automatically after 60 seconds.
5. If the test details are incorrect, select the blue **X** at the bottom of the screen before the 60-second review period ends to cancel the test.
   a. When the instrument door opens, remove the cartridge and dispose of it in the biohazardous waste.
   b. Close the instrument door when prompted.



9.4 Test in Progress

While a test is in progress, the time remaining and the test details are displayed on the touchscreen.

The LED status indicator functions as a progress bar during the test.



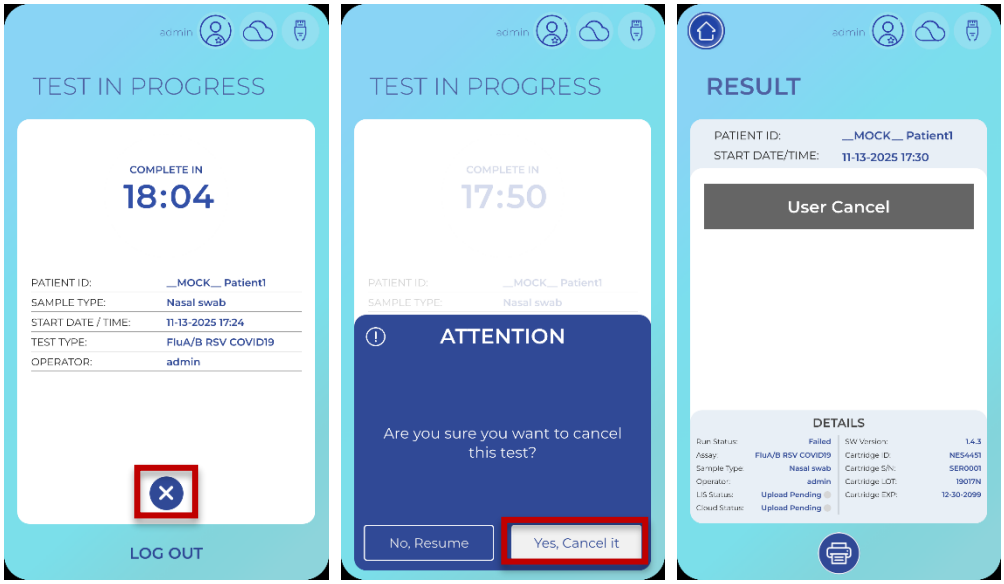
Caution: Do not move or jostle the instrument while a test is in progress.

9.5 Cancel a Test

Important Note: Once a test is canceled, the cartridge can no longer be used.

To cancel a test while the test is in progress,

1. Select the blue **X** at the bottom of the screen.
2. Select **Yes, Cancel it** in the confirmation dialog.
3. When the instrument door opens, remove the cartridge and dispose of it in the biohazardous waste.
4. Close the instrument door when prompted.



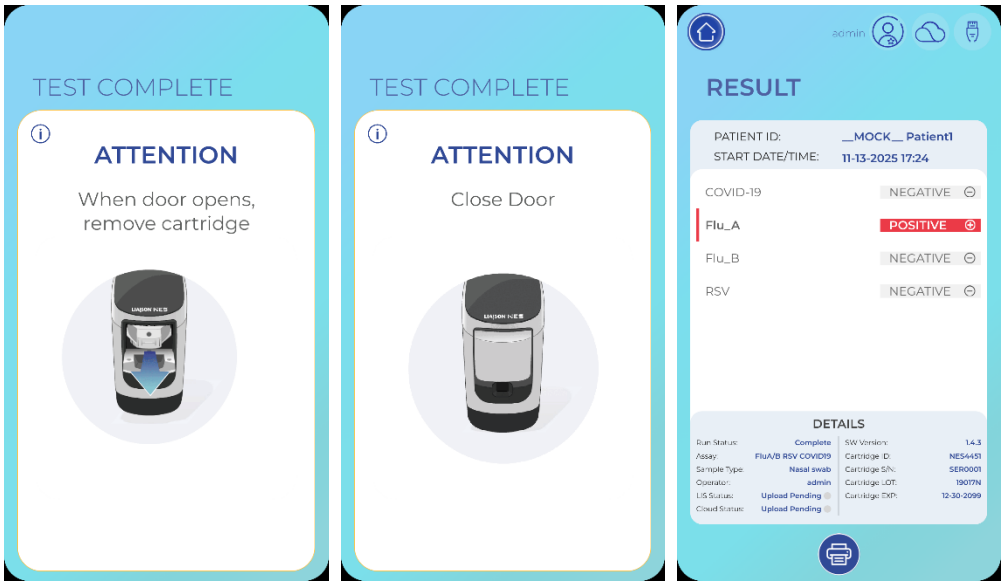
9.6 Complete a Test and View Results

When the system finishes the test, the instrument door opens automatically. To complete the test and view the results,

1. Remove the cartridge and dispose of it in the biohazardous waste.
2. Close the instrument door when prompted.

Upon completion of a test, the results are automatically displayed on the touchscreen and uploaded to the Diasorin Cloud and Laboratory Information System (LIS), if connected. Refer to the assay-specific Instructions for Use (IFU) for information on interpreting test results.

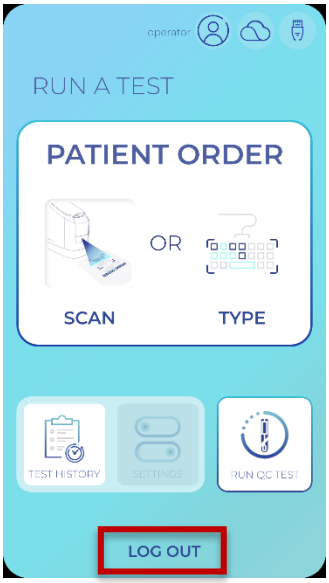
Important Note: The cartridge must be removed to view the results. This is a precautionary step to avoid leaving the cartridge in the instrument.



10 Log Out and Power Off the LIAISON NES®

10.1 Log Out of the LIAISON NES®

To log out of the LIAISON NES® from the home screen, select **LOG OUT**. The login screen displays.



10.2 Power off the LIAISON NES®

To safely power off the LIAISON NES®, ensure the following:

- No self-check is in progress. Powering off during a self-check can cause severe damage.
- All tests are complete. Powering off while a test is in progress can cause severe damage.
- Used cartridges are removed from the instrument. Leaving a used cartridge inside the instrument can cause contamination.
- The instrument door is closed.

If the criteria listed above are met, the LIAISON NES® instrument can be powered off. Flip the power switch on the back of the instrument to the “O” (OFF) position to power off the LIAISON NES®.

Best Practice	It is recommended that the LIAISON NES® instrument be powered off when it is not in use. Best practice is to power off the instrument each day at the end of work hours. If the instrument cannot be powered off daily, it should be powered off at the end of the work week.

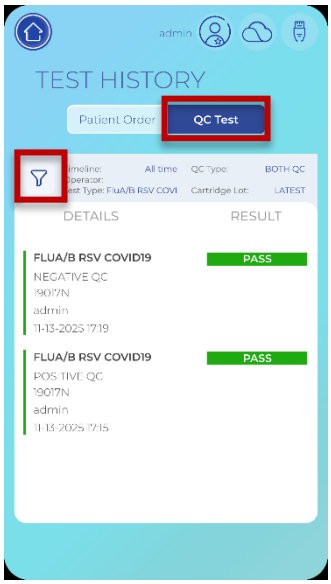
11 Test History

The LIAISON NES® system internally stores data from each test performed on the instrument. The LIAISON NES® system can store data from up to 10,000 tests simultaneously.

To access previous test data,

1. Navigate to the home screen and select **TEST HISTORY**.
2. Under TEST HISTORY, choose **Patient Order** or **QC Test**.
3. Select a test to view its results.

11.1 Filter Quality Control Test Results

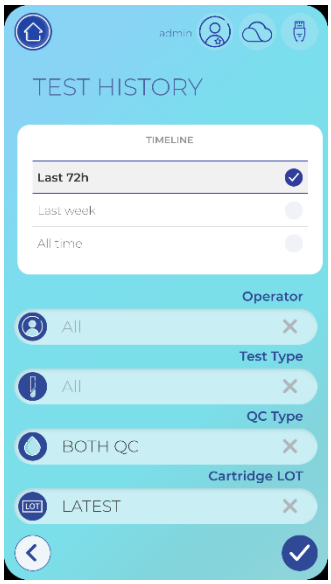


Use the filter function to specify which quality control (QC) results to display.

To filter QC test results,

1. Navigate to the home screen and select **TEST HISTORY**.
2. Select **QC Test** under TEST HISTORY.
3. Select the filter icon to view filtering options.
4. Choose the desired filter(s). Multiple filters can be applied at once.
5. Select the check mark to apply the filter(s).

11.1.1 QC Test Filters Overview



TIMELINE: Choose a timeline to filter results by the timeframe the tests were completed in. Available options include Last 72 hours, Last week, and All time.

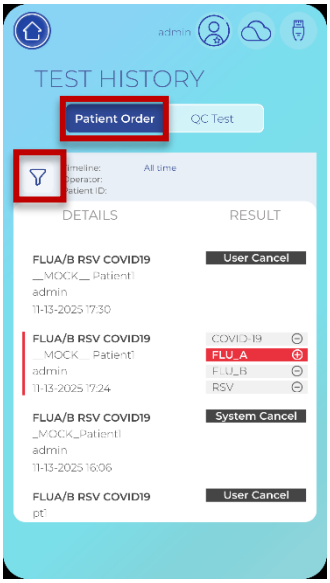
Operator: Select to filter results by the user who performed the test. Choose a user from the list or search for a specific username. This filter applies to both operator and administrator accounts.

Test Type: Select to filter results by assay type. Choose an assay from the list. All assays available on the instrument are listed as options.

QC Type: Select to filter results by quality control type. Choose a QC type from the list. Available options include POSITIVE QC, NEGATIVE QC, and BOTH QC.

Cartridge LOT: Select to filter results by cartridge lot. Choose SPECIFIC LOT to search for a particular lot or select ALL or LATEST to choose from multiple lots.

11.2 Filter Patient Order Results

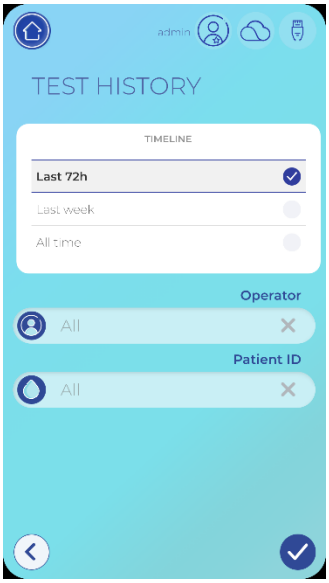


Use the filter function to specify which Patient Order results to display.

To filter Patient Order results,

1. Navigate to the home screen and select **TEST HISTORY**. Patient Order results are displayed by default.
2. Select the filter icon to view filtering options.
3. Choose the desired filter(s). Multiple filters can be applied at once.
4. Select the check mark to apply the filter(s).

11.2.1 Patient Order Test Filters Overview



TIMELINE: Choose a timeline to filter results by the timeframe the tests were completed in. Available options include Last 72 hours, Last week, and All time.

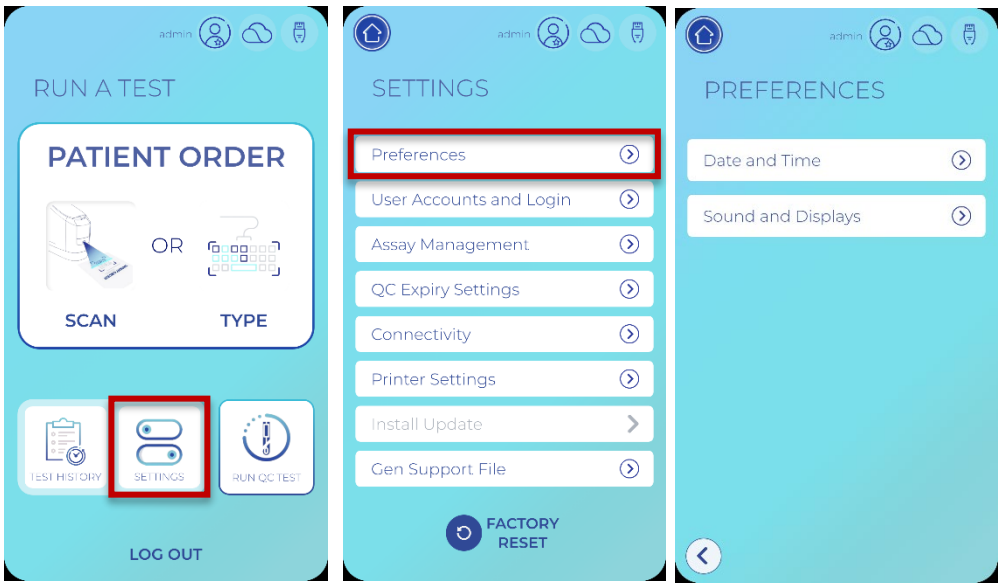
Operator: Select to filter results by the user who performed the test. Choose a user from the list or search for a specific username. This filter applies to both operator and administrator accounts.

Patient ID: Select to filter results by Patient ID. Enter the Patient ID in the Type a Patient ID field, then select the blue check mark.

12 Administrator Settings & Features

12.1 System Preferences

Administrators can configure system preferences, including date, time, sound, and display settings.



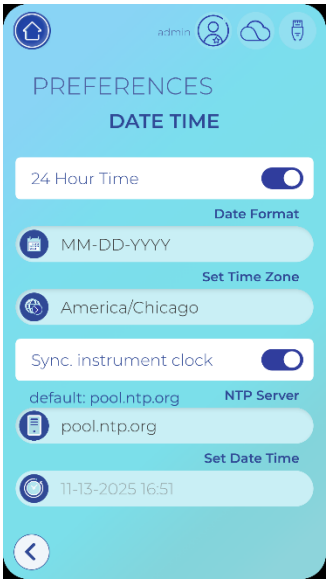
12.1.1 Date and Time Preferences

For administrator use only:

To configure the date and time settings,

1. Navigate to the home screen and select **SETTINGS**.
2. Select **Preferences**, then select **Date and Time** to view the date and time options.
3. Adjust the date and time settings as needed.

12.1.1.1 Date Time Settings Overview



24 Hour Time: Toggle to select the clock format. To use the 12-hour (AM/PM) format, toggle the switch to the left.

Date Format: Select to modify the date format. Available options include DD-MM-YYYY, MM-DD-YYYY, and YYYY-MM-DD.

Set Time Zone: Select to choose the time zone for the instrument. This option is available only when the instrument is connected to the internet. Setting the correct time zone ensures accurate timestamps for tests and logs.

Sync. Instrument clock: Toggle to enable or disable automatic synchronization of the system clock. When enabled, the instrument updates its time automatically using the selected NTP server. This option is available only when the instrument is connected to the internet.

NTP Server: Select to enter the Network Time Protocol (NTP) server used for clock synchronization. This option is available only when the instrument is connected to the internet and Sync instrument clock is enabled. A reliable NTP server keeps the instrument clock accurate.

Set Date Time: Select to manually enter the date and time. This option is available only when Sync instrument clock is disabled. Manual date and time entry is strongly discouraged because the instrument should remain connected to the internet for optimal performance, including accurate timekeeping, software updates, and data integrity.

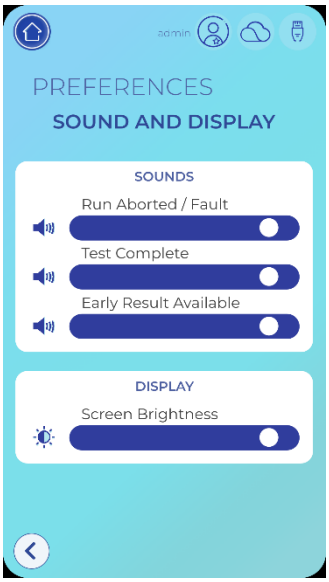
12.1.2 Sound and Display Preferences

For administrator use only:

To modify the sound and display settings,

1. Navigate to the home screen and select **SETTINGS**.
2. Select **Preferences**, then select **Sound and Displays** to view the sound and display options.
3. Use the sliders to adjust the volume and screen brightness.

12.1.2.1 Sound and Display Settings Overview



Run Aborted/Fault: Adjust the slider to change the volume of the alert tone that plays for an aborted run or fault. Move the slider to the right to increase the volume. Move the slider to the left to decrease the volume.

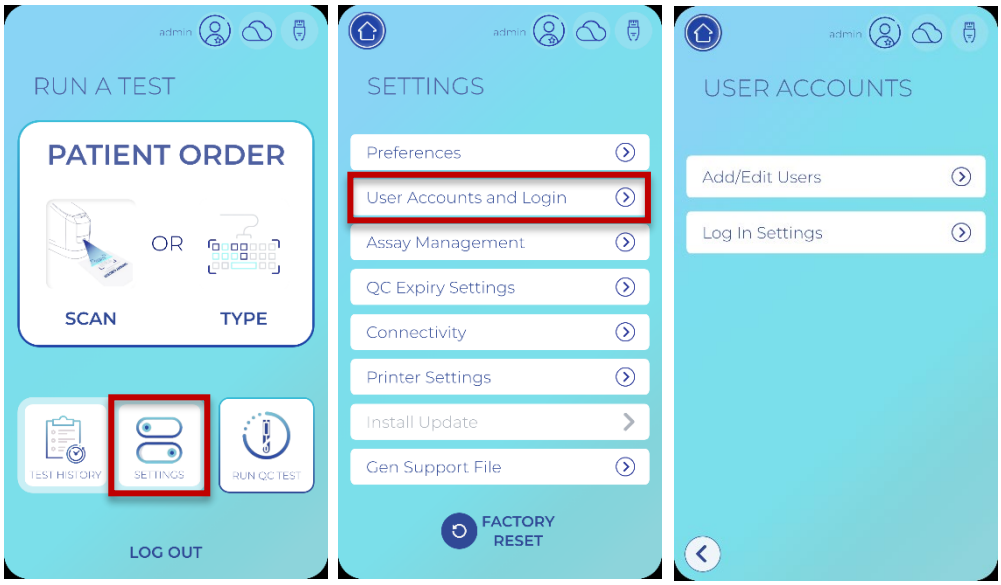
Test Complete: Adjust the slider to change the volume of the alert tone that plays when a test is completed. Move the slider to the right to increase the volume. Move the slider to the left to decrease the volume.

Early Result Available: Adjust the slider to change the volume of the alert tone that plays when an early result is available. Move the slider to the right to increase the volume. Move the slider to the left to decrease the volume.

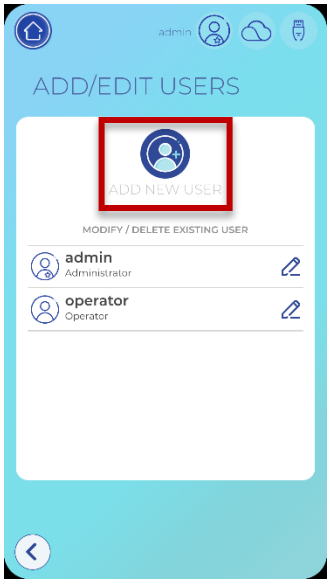
Screen Brightness: Adjust the slider to change the brightness of the display. Move the slider to the right to increase brightness. Move the slider to the left to decrease brightness.

12.2 User Accounts and Login Settings

Administrators can manage user accounts, including adding, deleting, disabling, and editing operator and administrator accounts. They can also configure login settings such as the number of allowed failed login attempts, the inactivity period before auto-logout, and the password validity period.



12.2.1 Add Users



For administrator use only:

To add a new user,

1. Navigate to the home screen and select **SETTINGS**.
2. Select **User Accounts and Login**, then select **Add/Edit Users**.
3. Select **ADD NEW USER**.
4. Enter the desired username, then select the next arrow.
5. Select **Administrator** or **Operator**, then select the next arrow.
6. Enter the desired password, then select the next arrow.
7. Reenter the password, then select the next arrow.

Important Note: Select the eye icon next to the typed characters to view the typed password.

12.2.2 Change Passwords

Best Practice

The LIAISON NES® system supports multiple user accounts. For regulatory compliance, cybersecurity, and traceability - do not share your username and password with anyone.

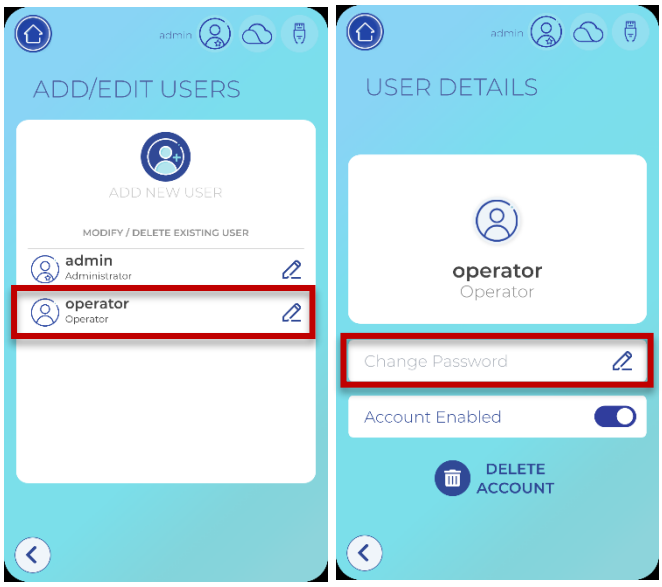
For administrator use only:

Administrators can change the passwords for operator and administrator accounts.

If an administrator has forgotten their password and no other administrator accounts exist, refer to *All Administrator Accounts Locked*.

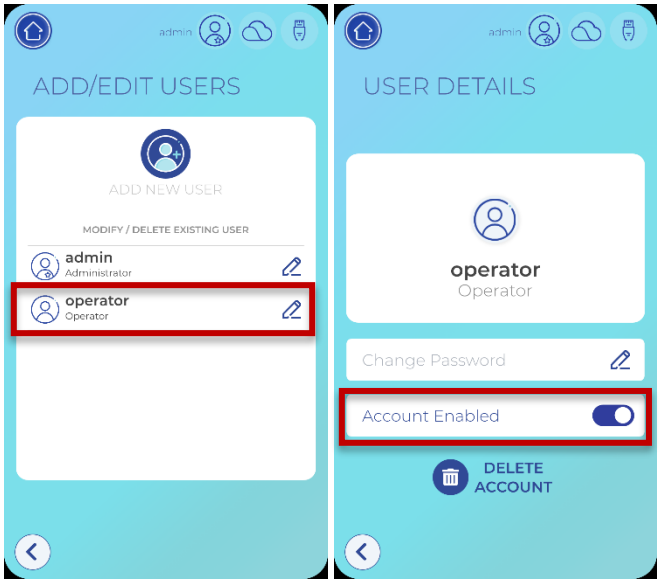
To change a user's password,

1. Navigate to the home screen and select **SETTINGS**.
2. Select **User Accounts and Login**, then select **Add/Edit Users**.
3. Select the desired user.
4. Select **Change Password**.
5. Enter the new password, then select the next arrow.
6. Reenter the new password, then select the next arrow.



Important Note: Select the eye icon next to the typed characters to view the typed password.

12.2.3 Enable/Disable Accounts

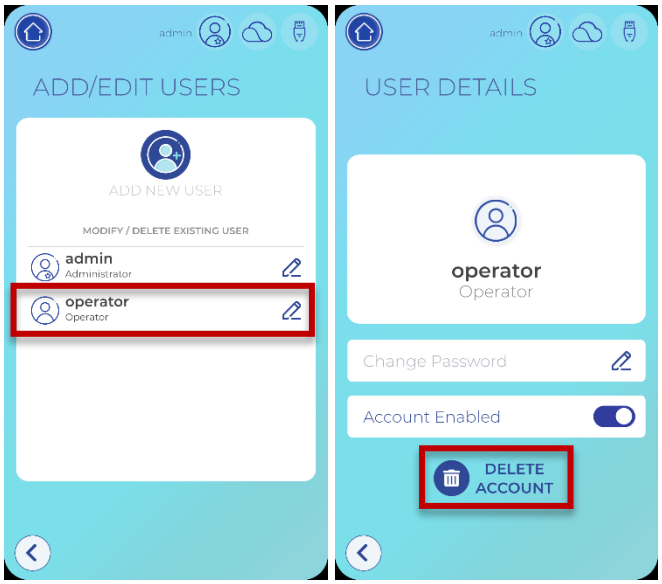


For administrator use only:

To enable or disable a user account,

1. Navigate to the home screen and select **SETTINGS**.
2. Select **User Accounts and Login**, then select **Add/Edit Users**.
3. Select the desired user.
4. Use the **Account Enabled** toggle switch to enable or disable the account.

12.2.4 Delete Accounts



For administrator use only:

To permanently delete a user account,

1. Navigate to the home screen and select **SETTINGS**.
2. Select **User Accounts and Login**, then select **Add/Edit Users**.
3. Select the desired user.
4. Select **DELETE ACCOUNT**.
5. Select **YES** in the confirmation dialog.

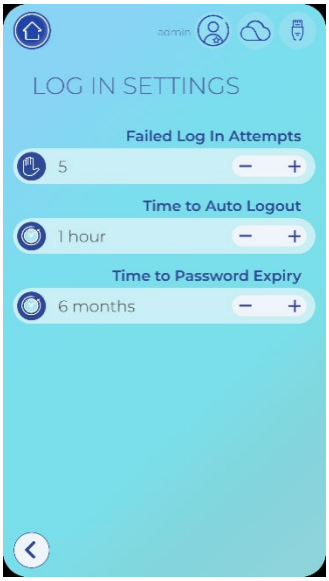
12.2.5 Configure Log in Settings

For administrator use only:

To set the number of allowed failed login attempts, the inactivity period before auto-logout, and the password validity period,

1. Navigate to the home screen and select **SETTINGS**.
2. Select **User Accounts and Login**, then select **Log In Settings**.
3. Use the -/+ buttons to edit the login settings.

12.2.5.1 Log In Settings Overview



Failed Log In Attempts: Use the -/+ buttons to set the number of login attempts allowed before a user account is locked.

Time to Auto Logout: Use the -/+ buttons to set the duration an account can remain logged in without activity. After this period, the system automatically logs out the account.

Time to Password Expiry: Use the -/+ buttons to set the duration user account passwords remain valid for. After this period, users must change their passwords.

12.3 Assay Management

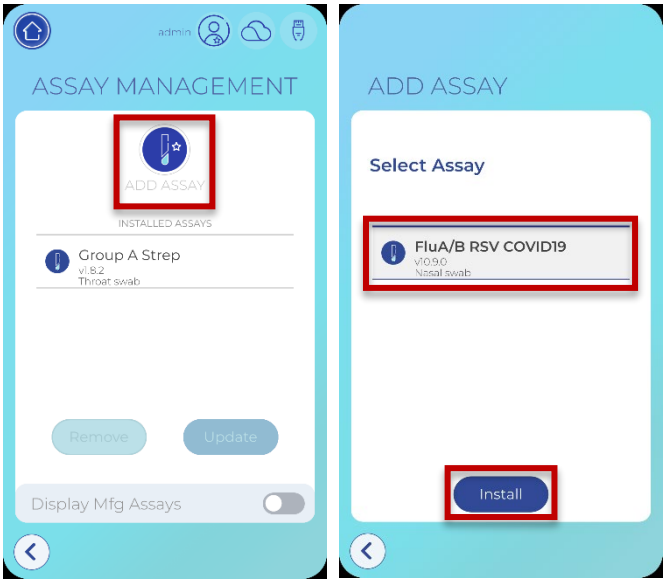
Administrators can manage assays on the instrument, including adding new assays, updating existing assays, and removing assays.

12.3.1 Add an Assay

For administrator use only:

To add an assay to the assay menu,

1. Navigate to the home screen and select **SETTINGS**.
2. Select **Assay Management**, then select **ADD ASSAY**.
3. Insert the FAT32-formatted USB drive containing the assay file into the USB port on the front of the instrument.
4. Wait for the assay to appear under Select Assay, then select it.
5. Select **Install**, then select **Yes** in the confirmation dialog. The system indicates when the assay installation is completed.
6. Select **Continue**.

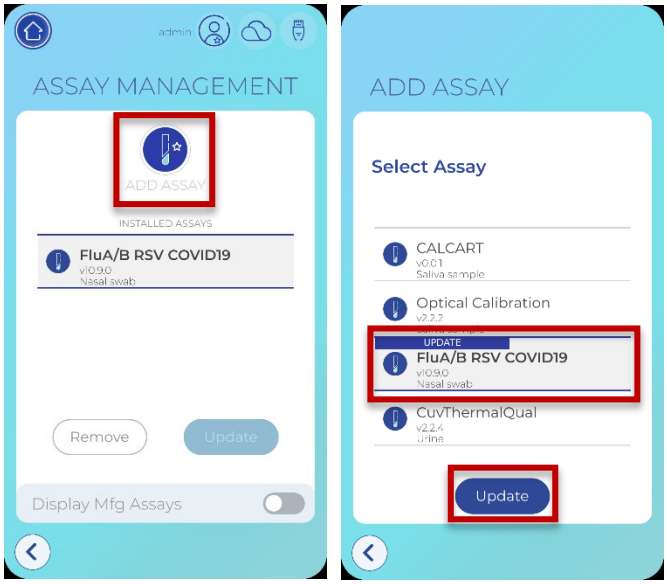


12.3.2 Update an Assay

For administrator use only:

To update an existing assay,

1. Navigate to the home screen and select **SETTINGS**.
2. Select **Assay Management**, then select **ADD ASSAY**.
3. Insert the FAT32-formatted USB drive containing the assay update file into the USB port on the front of the instrument.
4. Wait for the update ribbon to appear above the assay, then select it.
5. Select **Update**, then select **Yes** in the confirmation dialog. The system indicates when the assay update is completed.
6. Select **Continue.**

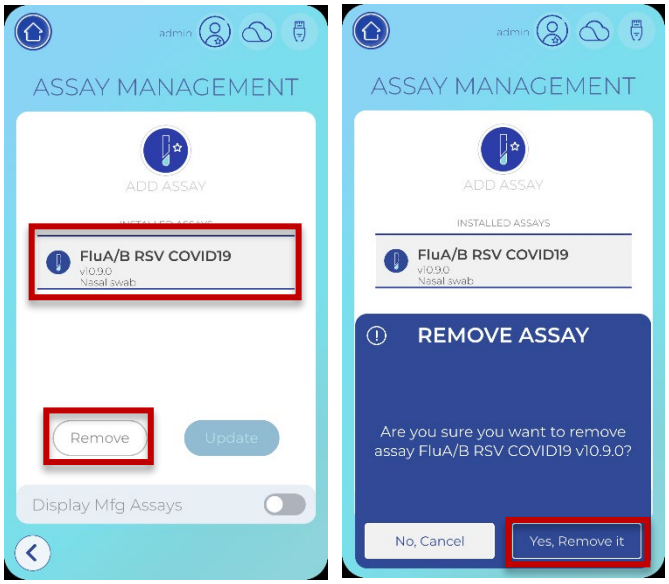


12.3.3 Remove an Assay

For administrator use only:

To remove an assay from the assay menu,

1. Navigate to the home screen and select **SETTINGS**.
2. Select **Assay Management**, then select the desired assay from the list of installed assays.
3. Select **Remove**, then select **Yes, Remove it** in the confirmation dialog. The system indicates when the assay removal is completed.
4. Select **Continue.**



12.4 Quality Control Expiration Settings

Administrators can configure the quality control (QC) expiration settings, including setting how long a QC test remains valid and when the QC expiration warnings display.

12.4.1 Quality Control Expiration Settings

For administrator use only:

To configure the quality control (QC) expiration settings,

1. Navigate to the home screen and select **SETTINGS**.
2. Select **QC EXPIRY Settings.**
3. Use the -/+ buttons to modify the quality control expiration settings.

12.4.2 QC Expiration Settings Overview

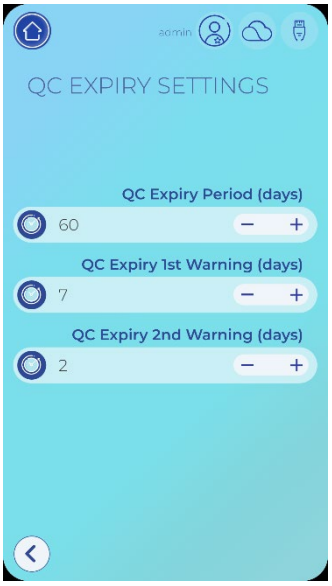
Best Practice

Set the number of days for the second QC expiration warning so it is closer to the expiration date than the first warning. For example, if the first warning is set to 7 days before expiration, set the second warning to 2 days before expiration.

QC Expiry Period (days): Use the -/+ buttons to set the duration a quality control test remains valid. After this period, a new QC test must be performed.

QC Expiry 1st Warning (days): Use the -/+ buttons to set when the first expiration warning appears. The warning displays the set number of days before the quality control test expires. For example, if seven days is selected, the warning appears seven days before expiration.

QC Expiry 2nd Warning (days): Use the -/+ buttons to set when the second expiration warning appears. The warning displays the set number of days before the quality control test expires. For example, if two days is selected, the warning appears two days before expiration.



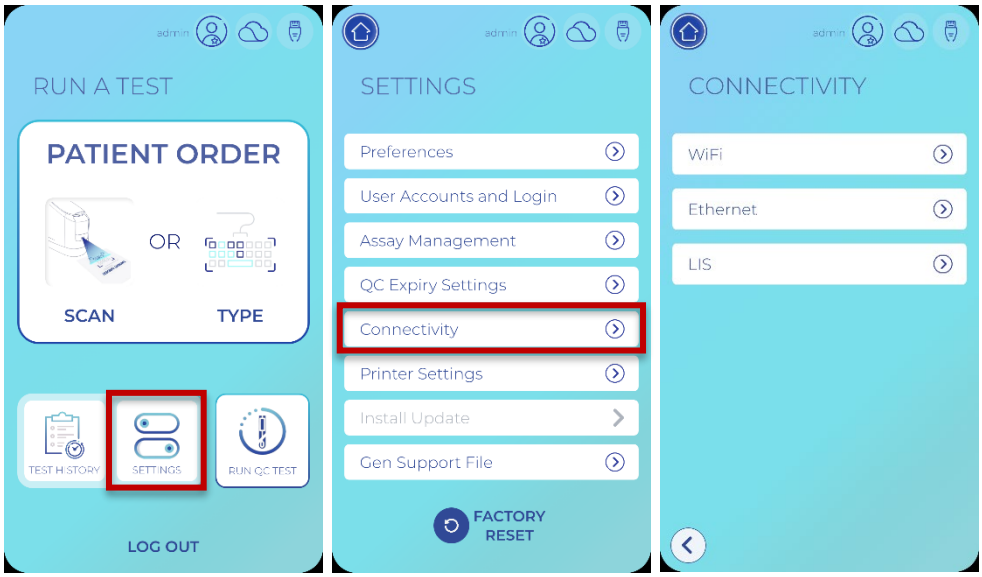
12.5 Connectivity Settings

Administrators can configure connectivity settings, including connecting the instrument to Wi-Fi networks, enabling Ethernet communication, and establishing secure connections to the Laboratory Information System (LIS). They can also view network details such as MAC address, IP settings, and connection status.

It is recommended that the instrument be connected to a network to enable essential functions such as time synchronization, software updates, and data transfer.

If the instrument is connected to a network, ensure the network complies with relevant cybersecurity standards and regulations, such as HIPAA in the United States or GDPR in Europe.

Best Practice	For optimal performance, connect the LIAISON NES® to the network using an Ethernet connection. To ensure backup connectivity in the event of an Ethernet failure, set up Wi-Fi as well.



12.5.1 Connect to Wi-Fi:

Important Note: Wi-Fi can only be enabled and connected when the Ethernet cable is unplugged.

For administrator use only:

To connect the LIAISON NES® to Wi-Fi,

1. Navigate to the home screen and select **SETTINGS**.
2. Select **Connectivity**, then select **WiFi**.
3. Toggle the **Wi-Fi** switch to the right to enable Wi-Fi connectivity.
4. Select the desired Wi-Fi network from the list of available Wi-Fi networks.
5. Enter Wi-Fi network password, then select the check mark in the bottom right. A message displays when the system connects to the Wi-Fi network.

12.5.2 Connect to Ethernet

Connect the LIAISON NES® to the Ethernet using the Ethernet port on the back of the instrument and the Ethernet cable provided with the instrument.

To connect to Ethernet,

1. Insert one end of the Ethernet cable into the Ethernet port on the back of the instrument.
2. Insert the other end of the Ethernet cable into a secure, active Ethernet port.

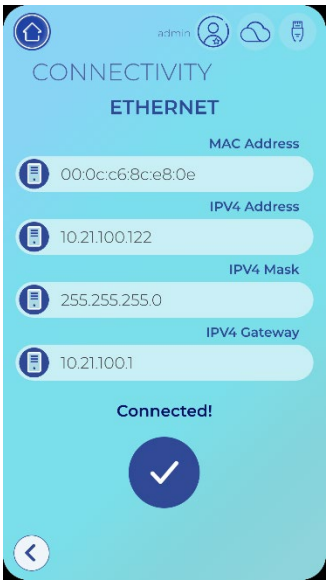
12.5.2.1 Ethernet Settings

For administrator use only:

When an active Ethernet cable is connected to the LIAISON NES® instrument, the instrument automatically connects to the internet using a Dynamic Host Configuration Protocol (DHCP). The MAC Address, IPV4 Address, IPV4, and IPV4 Gateway are automatically configured.

To view this information,

1. Navigate to the home screen and select **SETTINGS**.
2. Select **Connectivity**, then select **Ethernet**. The following information is displayed:
   - MAC Address
   - IPV4 Address
   - IPV4 Mask
   - IPV4 Gateway
   - Connection status



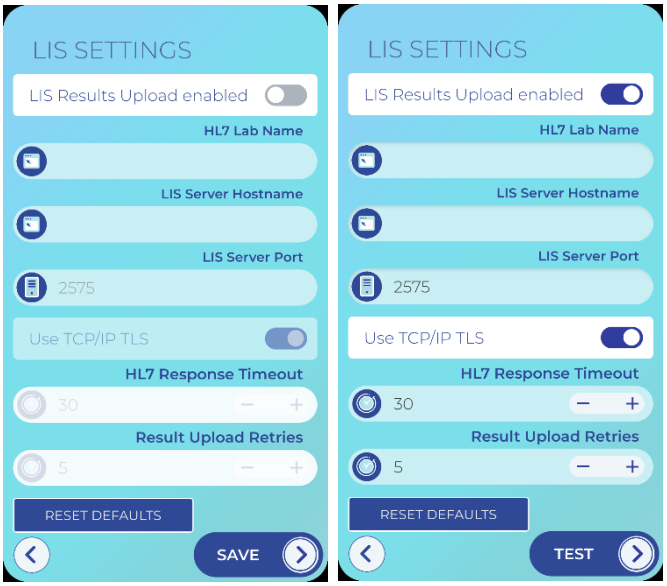
12.5.3 The Laboratory Information System (LIS)

A Laboratory Information System (LIS) is a third-party software platform designed to manage, store, and track data related to medical operations. It facilitates the flow of patient information, test results, and other essential data within the patient testing environment.

To view the LIS settings,

1. Navigate to the home screen and select **SETTINGS**.
2. Select **Connectivity**, then select **LIS**.

12.5.3.1 LIS Settings Overview



LIS Results Upload enabled: Toggle to enable or disable sending test results to the Laboratory Information System (LIS). This must be enabled to edit other LIS settings.

HL7 Lab Name: Select to enter the laboratory name assigned to the facility. This name is included in HL7 messages sent to the LIS.

LIS Server Hostname: Select to enter the network address of the LIS server. This is required for the instrument to communicate with the LIS.

LIS Server Port: Select to enter the network port used by the LIS server. This field is populated by default and cannot be blank.

Use TCP/IP TLS: Toggle to enable or disable Transport Layer Security (TLS). TLS encrypts and authenticates data sent between the instrument and the LIS. This option is enabled by default and is strongly recommended for secure transmission of patient data.

HL7 Response Timeout: Use the -/+ buttons to set the maximum duration (in seconds) the instrument waits for a response from the LIS server. If no response is received within this period, the communication attempt fails.

Result Upload Retries: Use the -/+ buttons to set the number of times the instrument will attempt to resend a result if the initial upload fails.

RESET **RESET DEFAULTS:** Select to restore all LIS settings to their default values.

SAVE/TEST: Select to save changes when LIS is disabled. When LIS is enabled, select to test the LIS connection and save changes.

12.5.4 Transport Layer Security (TLS)

To ensure patient data transmitted between the LIAISON NES® and the Laboratory Information System (LIS) is encrypted and authenticated, it is strongly recommended to enable Transport Layer Security (TLS) for all HL7 message exchanges. Administrators can enable TLS while connecting the LIAISON NES® to the LIS.

Before enabling TLS,

- Confirm the LIS supports TLS.
- Install the necessary digital certificates on both the LIAISON NES® and LIS systems.

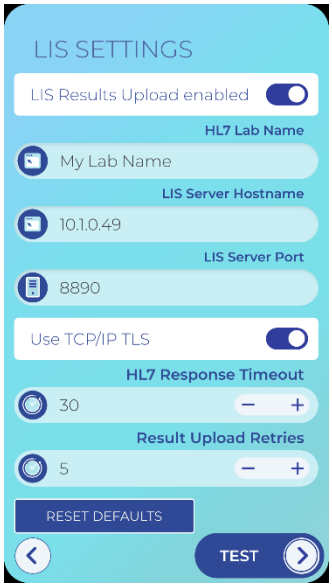
12.5.5 Enable Connection to the Laboratory Information System (LIS)

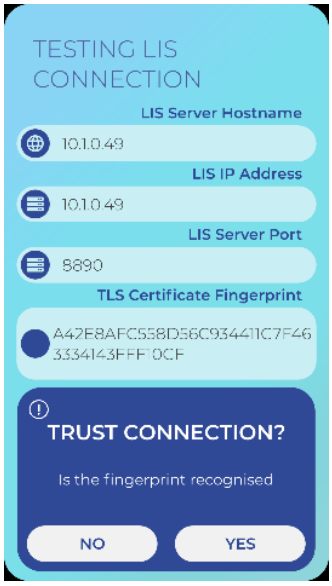
Only administrators can connect the LIAISON NES® to the Laboratory Information System (LIS). Before connecting the LIAISON NES® to the LIS, verify that administrative users have network access to connect to the facility's secure network.

To enable Transport Layer Security (TLS) and connect to the LIS, follow the steps below.

Warning: Diasorin strongly recommends enabling Transport Layer Security (TLS) whenever possible to maintain compliance with cybersecurity best practices and regulatory expectations. If TLS is not enabled, patient data may be transmitted in clear text, increasing the risk of unauthorized access.

1. Navigate to the home screen and select **SETTINGS**.
2. Select **Connectivity**, then select **LIS**.
3. Toggle the **LIS Results Upload enabled** switch to the right to allow results to upload to the LIS. Enabling this also unlocks the other fields for editing.
4. Select the **HL7 Lab Name** field, enter the lab name assigned to the facility, then select the check mark.
5. Select the **LIS Server Hostname** field, enter the network address of the target LIS server, then select the check mark.
6. Select the **LIS Server Port** field, enter the network port used by the LIS server, then select the check mark.
7. Confirm the **TCP/IP TLS** toggle switch is toggled to the right. TLS is enabled by default.



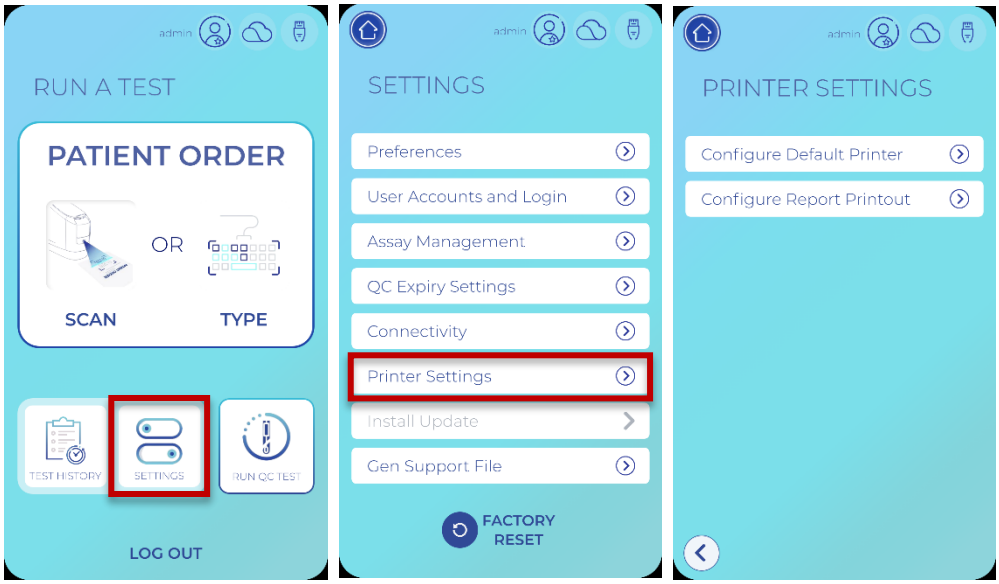


8. Select **TEST** in the bottom right to save changes and test the LIS connection.
9. Review the LIS Server Hostname, LIS IP Address, LIS Server Port, and TLS Certificate Fingerprint.
10. If the fingerprint is recognized and the information is correct, select **YES**.
11. Select **OK** to finish connecting the LIS.

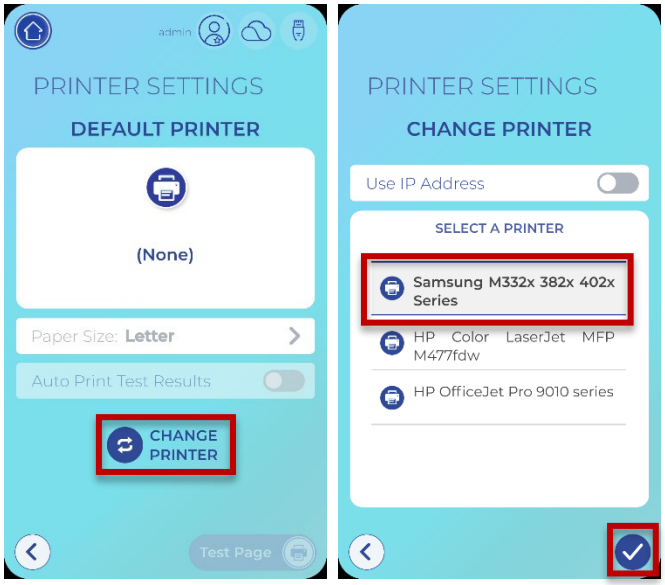
The LIS connection does not need to be tested or configured each time the instrument is powered on. Once the LIAISON NES® is connected to the LIS, the system automatically uses the configured settings for future connections.

12.6 Printer Settings

Administrators can add printers to the LIAISON NES® via the network or the printer's IP address. After adding a printer, administrators can print test pages to confirm functionality. They can also customize the information included on printed reports, such as the store or lab name, address, email, phone number, and website.



12.6.1 Add a Networked Printer

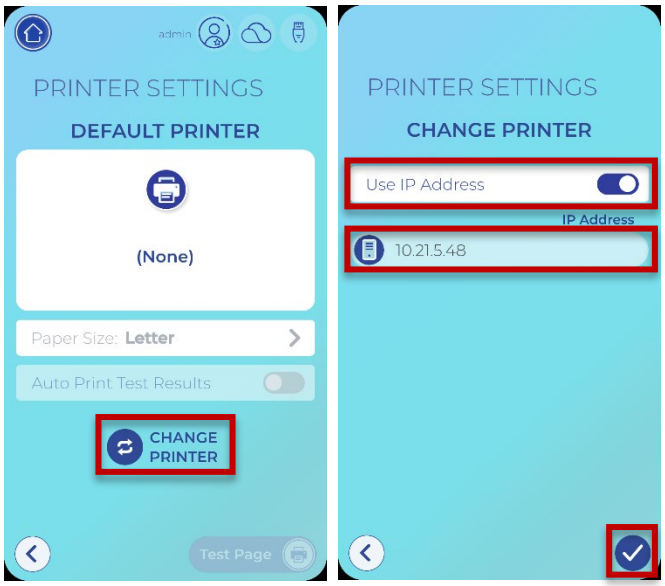


For administrator use only:

To add a printer through the network,

1. Navigate to the home screen and select **SETTINGS**.
2. Select **Printer Settings**, then select **Configure Default Printer**.
3. Select **CHANGE PRINTER**.
4. Choose a printer from the list, then select the check mark. A message displays indicating whether the printer is set up successfully.
5. Select the check mark to return to the printer settings screen. If the printer is not set up successfully, select the back arrow, then add the printer using its IP address.

12.6.2 Add a Printer Using its IP address

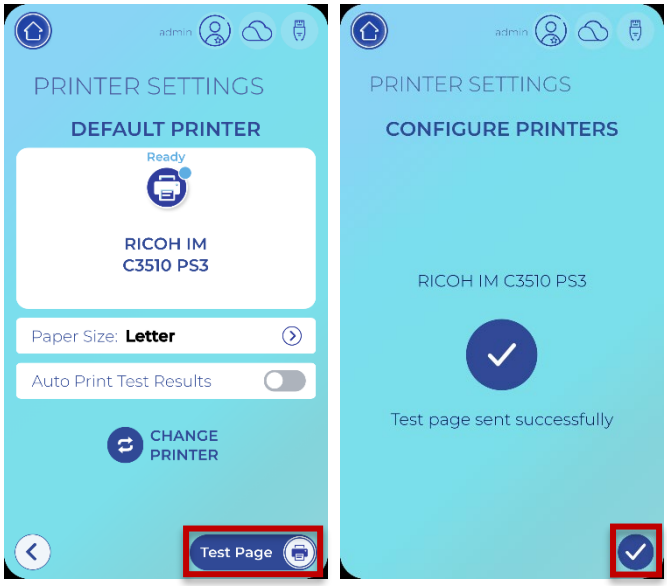


For administrator use only:

To add a printer using its IP address,

1. Navigate to the home screen and select **SETTINGS**.
2. Select **Printer Settings**, then select **Configure Default Printer**.
3. Select **CHANGE PRINTER**.
4. Toggle the **Use IP Address** switch to the right to enable connecting by IP address.
5. Select the **IP Address** field.
6. Enter the IP address for the desired printer, then select the check mark.
7. Select the check mark again. A message displays indicating whether the printer is set up successfully.
8. Select the check mark to return to the printer settings screen.

12.6.3 Print a Test Page

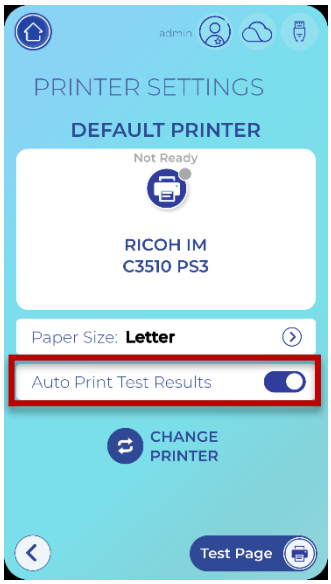


For administrator use only:

To print a test page to the default printer,

1. Navigate to the home screen and select **SETTINGS**.
2. Select **Printer Settings**, then select **Configure Default Printer**.
3. Select **Test Page**. A message displays indicating whether the test page prints successfully.
4. Select the check mark to return to the printer settings screen.

12.6.4 Enable Auto Print Results



For administrator use only:

To enable automatic printing of test results when a test completes,

1. Navigate to the home screen and select **SETTINGS**.
2. Select **Printer Settings**, then select **Configure Default Printer**.
3. Toggle the **Auto Print Test Results** switch to the right.

12.6.5 Configure the Report Printout

Test results are documented in a report that can printed via the default printer. Administrators can define the facility-identifying information included in the report.

For administrator use only:

To customize the test report,

1. Navigate to the home screen and select **SETTINGS**.
2. Select **Printer Settings**, then select **Configure Report Printout.**
3. Use the on-screen keyboard to define the information included in the report.

12.6.5.1 Report Printout Settings Overview

Store/Lab Name: Select to edit the store/lab name included in the report.

Store/Lab Address: Select to edit the address included in the report.

Email: Select to edit the email address included in the report.

Phone Number: Select to edit the phone number included in the report.

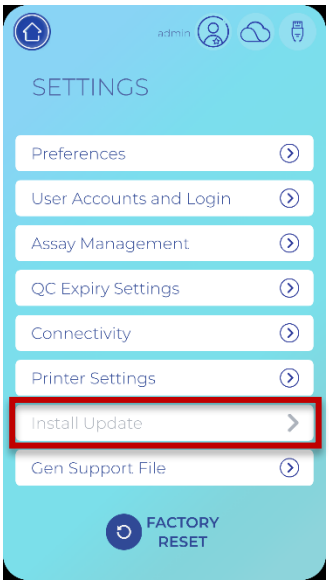
Website: Select to edit the website included in the report.

12.7 Software Updates

If the LIAISON NES® is connected to the internet and the cloud, the system displays a notification on the home screen when a software update becomes available. If the update is critical, the instrument may restrict the use of new lots or new assay files until the update is completed.

If the LIAISON NES® is not connected to the internet or the cloud, an off-instrument notification is sent when a software update becomes available. Administrators can then download and install the update via USB.

Only administrators can perform software updates. Test results remain stored on the instrument during the update process and after updating to a new software version.



12.7.1 Install a Software Update on a LIAISON NES® with Internet and Cloud Connection

To install a software update on a LIAISON NES® instrument that is connected to the internet and the cloud,

1. Navigate to the home screen and select **SETTINGS**.
2. Select **Install Update** to start the download and installation process. Once installation begins, the instrument will not be useable.
3. Select **Continue** to restart the instrument after the installation has completed.

12.7.2 Install a Software Update on a LIAISON NES® without Internet or Cloud Connection

To install a software update on a LIAISON NES® instrument that is not connected to the internet or the cloud,

1. Download the software update onto a FAT32-formatted USB drive.
2. Insert the FAT32-formatted USB drive containing the software update into the USB port on the front of the instrument.
3. Navigate to the home screen and select **SETTINGS**.
4. Select **Install Update** to start the download and installation process. Once installation begins, the instrument will not be useable.
5. Select **Continue** to restart the instrument after the installation has completed.

12.8 Custom Barcoded Test Orders

To simplify workflow, the LIAISON NES® system is capable of reading customized test orders that include the Patient ID and the test ordered for the Patient ID. This feature helps mitigate user errors associated with running an incorrect or unintentional combination of sample and assay panel. When a custom test order is scanned on the instrument, the instrument reads and matches the test ordered with the cartridge inserted.

When setting up custom test barcodes for the LIAISON NES®, only use barcodes with the following format:

ORD^[Patient ID]^[Cartridge ID]

- "ORD" is a fixed 3-character string to identify the barcode as a Test Order.
- "Patient ID" is an alphanumeric string of 1-20 characters used to identify the patient.
- "Cartridge ID" is an alphanumeric string of 1- 10 characters used to identify the test.
- "^" is the field separator character.

Example:

ORD^PATIENT123456^COVIDFLU01

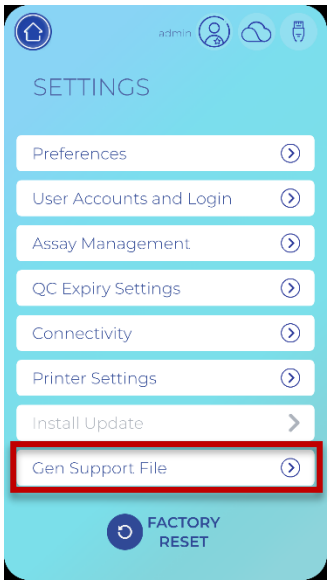
12.9 Generate a Support File

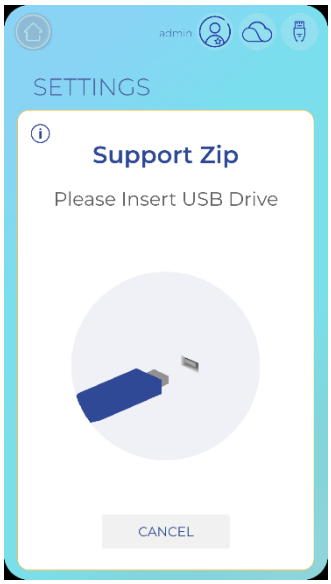
For administrator use only:

Administrators can generate a support file to send to Diasorin for technical support troubleshooting.

To generate a support file,

1. Navigate to the home screen and select **SETTINGS**.
2. Select **Gen Support File**.
3. Insert a FAT32-formatted USB drive into the USB port on the front of the instrument. A message displays while the support file is being generated.
4. Remove the USB drive when prompted.
5. Select **CONTINUE**.





12.10 Reset to Factory Settings

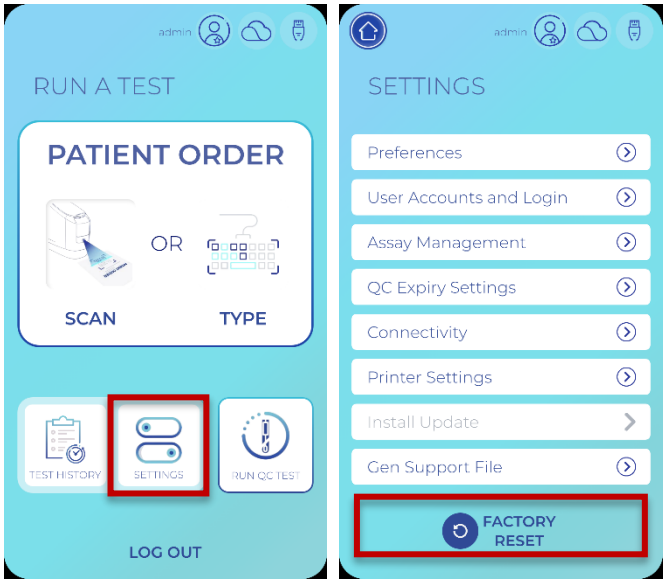
Important Note: Do not move the instrument or power off the instrument during a self-check, as doing so may cause instrument fault or error.

For administrator use only:

Administrators can use the factory reset feature to restore the LIAISON NES® instrument to its initial authenticated configuration.

To reset to factory settings,

1. Navigate to the home screen and select **SETTINGS**.
2. Select **FACTORY RESET**.
3. Select **Yes** in the confirmation dialog. Do not power off the instrument while it is resetting.
4. The instrument restarts automatically after resetting. Wait for the self-check to complete before powering off the instrument or logging in to the system.

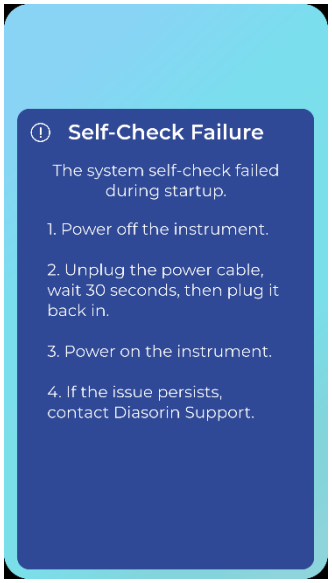


13 Troubleshooting

WARNING: Do not open the instrument housing. There are no parts that can be serviced by the user.

Troubleshooting Index

13.1 Startup and Self-Check Errors



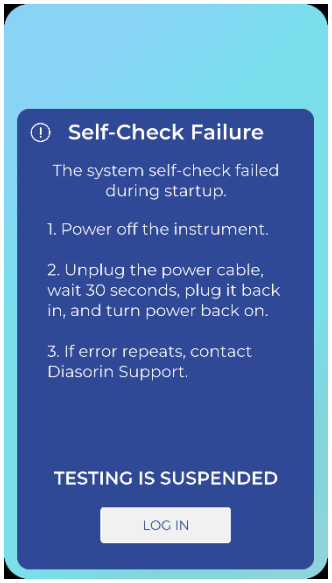
13.1.1 Self-Check Failure During Initial Setup

A warning dialog displays if a self-check fails during the initial instrument setup.

To resolve this issue, follow the on-screen instructions.

If the issue is not resolved, contact *Diasorin Support* for assistance.

13.1.2 Self-Check Failure During Startup



A warning dialog displays if a self-check fails during the startup sequence. Do not resume testing until this issue is resolved.

To resolve this issue, follow the on-screen instructions.

If the issue is not resolved, contact *Diasorin Support* for assistance.

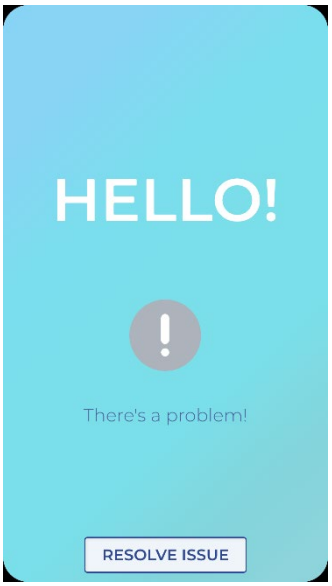
13.1.2.1 Accessing Test History

If the issue is not resolved, test results stored in the test history can still be accessed.

To access the test history,

1. Select **LOG IN.**
2. Enter your username, then select the check mark.
3. Enter your password, then select the check mark.
4. Select **TEST HISTORY**.

13.1.3 Problem During Startup

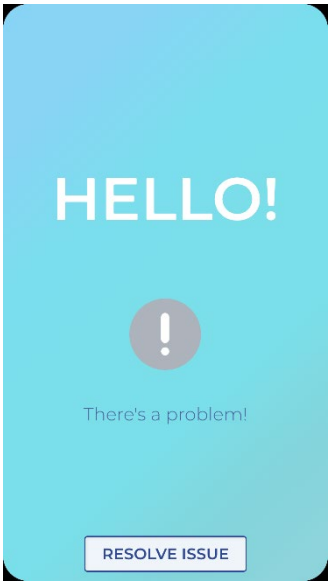


A warning dialog displays if there is a problem during startup.

To resolve this issue, select **RESOLVE ISSUE**. The LIAISON NES® will attempt to fix the problem.

If the instrument cannot resolve the issue, contact *Diasorin Support* for assistance.

13.1.4 Cartridge Detected During Startup



A warning dialog displays if a cartridge is detected during startup.

CAUTION: Wear gloves to handle the cartridge. Discard the cartridge in the biohazardous waste.

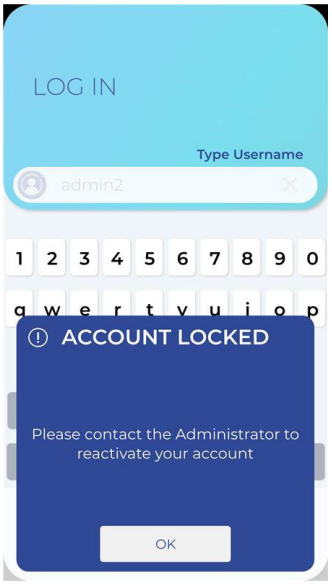
To resolve this issue,

1. Select **RESOLVE ISSUE**. If another warning dialog displays stating that the door is not opening correctly, refer to *Door Fails to Open During Cartridge Recovery.*
2. When the instrument door opens, remove the cartridge and dispose of it in the biohazardous waste.
3. Close the instrument door when prompted to continue the self-check.

If the issue is not resolved, contact *Diasorin Support* for assistance.

13.2 Account Access Errors

13.2.1 Account Disabled



Disabled accounts cannot log in to the LIAISON NES® system. A warning dialog displays if a disabled account's username is entered on the login screen.

To resolve this issue,

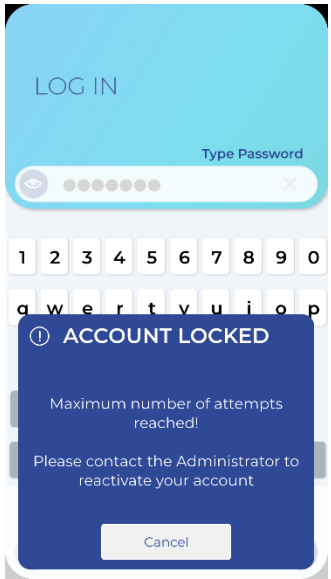
1. Select **OK** in the dialog.
2. Notify an administrator. Only administrators can re-enable accounts.

For administrator use only:

To re-enable an account from the home screen,

1. Select **SETTINGS.**
2. Select **User Accounts and Login**, then select **Add/Edit Users**.
3. Choose the desired user from the list.
4. Toggle the **Account Enabled** switch to the right to enable the account.

13.2.2 Account Locked Due to Failed Password Attempts



If an incorrect password is entered too many times, the account is locked. A warning dialog displays if an account is locked due to the number of password attempts. Administrators can reactivate locked operator and administrator accounts.

To resolve this issue,

1. Select **Cancel** in the dialog.
2. Notify an administrator. Only administrators can reset passwords for locked accounts.

If all administrator accounts are locked, refer to *All Administrator Accounts Locked.*

For administrator use only:

To reset the password for a locked account from the home screen,

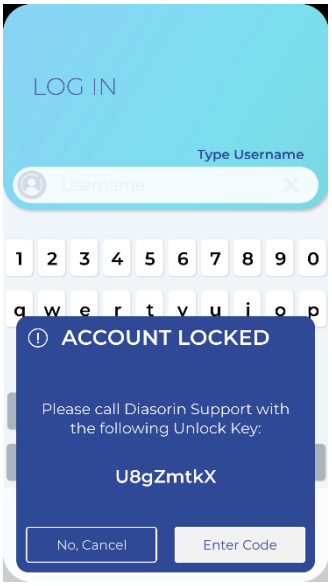
1. Select **SETTINGS.**
2. Select **User Accounts and Login**, then select **Add/Edit Users**.
3. Choose the desired user from the list.
4. Select **Change Password**.
5. Enter the new password, then select the next arrow.
6. Reenter the new password, then select the next arrow.

The user should change their password upon their next login for security.

Refer to *Change Password During Login* for instructions on changing passwords upon login.

13.2.3 All Administrator Accounts Locked

If an incorrect password is entered too many times, the account is locked. A warning dialog displays if an account is locked due to the number of password attempts.

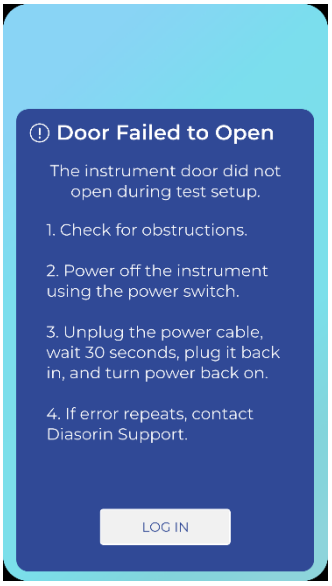


If all administrator accounts are locked,

1. Select the locked user icon at the bottom left of the login screen. An unlock key code displays.
2. Use the unlock key code to retrieve the reset code via the cloud.
3. Select **Enter Code**.
4. Enter the reset code, then select the check mark.
5. Select an administrator account to unlock.
6. Enter a new password for the account, then select the next arrow.
7. Re-enter the new password, then select the next arrow.

13.3 Door Operation Errors

13.3.1 Door Fails to Open During Test Setup



A warning dialog displays if a problem with the door is detected while setting up a test. Do not resume testing until this issue is resolved.

To resolve this issue, check if there is an obstruction blocking the door from opening. If the door is obstructed,

1. Remove the obstruction.
2. Follow the on-screen instructions.

If the issue is not resolved, or if this warning displays when the door is not blocked, contact *Diasorin Support* for assistance.

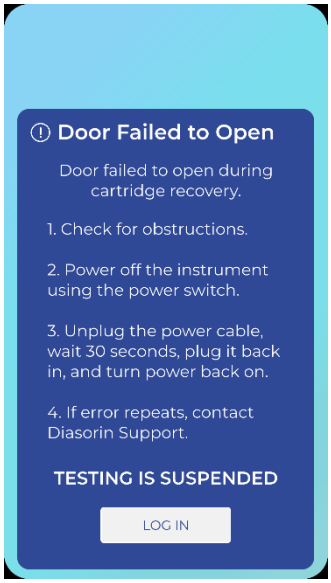
13.3.1.1 Accessing Test History

If the issue is not resolved, test results stored in the test history can still be accessed.

To access the test history,

1. Select **LOG IN.**
2. Enter your username, then select the check mark.
3. Enter your password, then select the check mark.
4. Select **TEST HISTORY**.

13.3.2 Door Fails to Open During Cartridge Recovery



CAUTION: Do not forcibly open the instrument door or apply downward force on the door while the door is open.

CAUTION: Wear gloves when handling the cartridge. Discard the cartridge in the biohazardous waste.

A warning dialog displays if a problem with the door is detected while the instrument is releasing a cartridge to resolve a startup error. Do not resume testing until this issue is resolved.

To resolve this issue, check if there is an obstruction blocking the door from opening. If the door is obstructed,

1. Remove the obstruction.
2. Follow the on-screen instructions.

If the issue is not resolved, or if this warning displays when the door is not blocked, contact *Diasorin Support* for assistance.

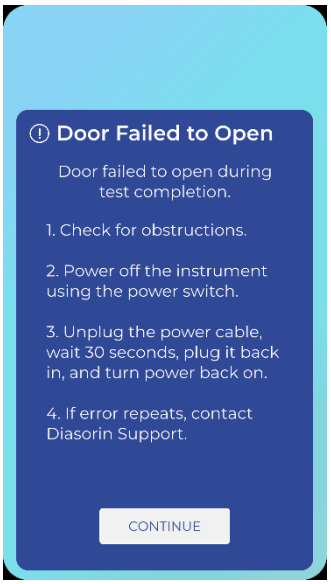
13.3.2.1 Accessing Test History

If the issue is not resolved, test results stored in the test history can still be accessed.

To access the test history,

1. Select **LOG IN.**
2. Enter your username, then select the check mark.
3. Enter your password, then select the check mark.
4. Select **TEST HISTORY**.

13.3.3 Door Does Fails to Open During Test Completion



CAUTION: Do not forcibly open the instrument door or apply downward force on the door while the door is open.

CAUTION: Wear gloves when handling the cartridge. Discard the cartridge in the biohazardous waste.

A warning dialog displays if a problem with the door is detected when a test is completed. Do not resume testing until this issue is resolved.

To resolve this issue, check if there is an obstruction blocking the door from opening. If the door is obstructed,

1. Remove the obstruction.
2. Follow the on-screen instructions.

If the issue is not resolved, or if this warning displays when the door is not blocked, contact *Diasorin Support* for assistance.

13.3.4 Door Does Not Close

CAUTION: Do not forcibly open the instrument door or apply downward force on the door while the door is open.

CAUTION: Wear gloves when handling the cartridge. Discard the cartridge in the biohazardous waste.

If the instrument door does not close, or if resistance is encountered when closing the door, confirm the following:

- The cartridge is oriented correctly, with the cartridge label facing upward and the two blue arrows on the label pointing toward the inside of the instrument.
- The cartridge cap is closed.
- The cartridge is fully inserted into the instrument.
- There are no obstructions inside the cartridge bay.

If the issue is not resolved,

1. Dispose of the cartridge in the biohazardous waste.
2. Contact *Diasorin Support* for assistance.

13.3.5 Door Does Not Latch When Closed

CAUTION: Do not forcibly open the instrument door or apply downward force on the door while the door is open.

CAUTION: Wear gloves when handling the cartridge. Discard the cartridge in the biohazardous waste.

If the instrument door closes completely but does not latch automatically, confirm the following:

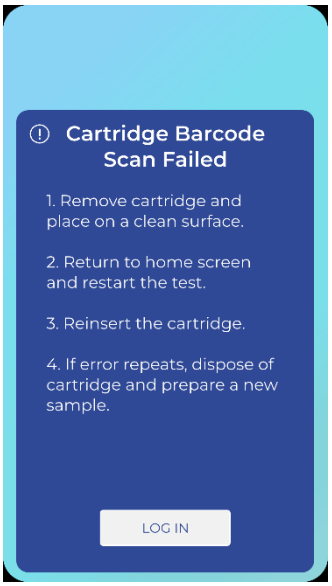
- The cartridge is oriented correctly, with the cartridge label facing upward and the two blue arrows on the label pointing toward the inside of the instrument.
- The cartridge cap is closed.
- The cartridge is fully inserted into the instrument.
- There are no obstructions inside the cartridge bay.

If the issue is not resolved,

1. Dispose of the cartridge in the biohazardous waste.
2. Contact *Diasorin Support* for assistance.

13.4 Cartridge Errors

13.4.1 Cartridge Barcode Scan Failed



A warning dialog displays if the instrument fails to internally scan the Cartridge ID barcode.

CAUTION: Wear gloves when handling the cartridge. Discard the cartridge in the biohazardous waste.

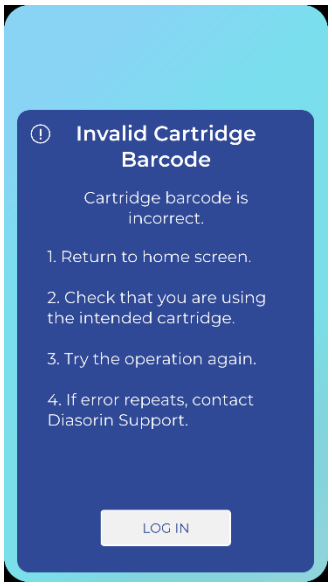
To resolve this issue, follow the on-screen instructions.

If the issue is not resolved, confirm the following:

- The Cartridge ID barcode on the cartridge's label is clearly visible.
- The Cartridge ID barcode on the cartridge's label is not damaged or defaced.

If the problem persists, contact *Diasorin Support* for assistance.

13.4.2 Invalid Cartridge Barcode



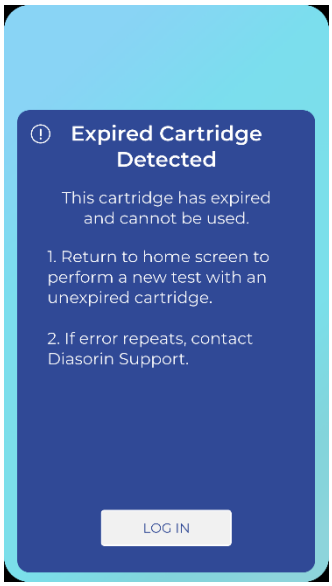
A warning dialog displays if the instrument detects an invalid cartridge barcode.

CAUTION: Wear gloves when handling the cartridge. Discard the cartridge in the biohazardous waste.

To resolve this issue, follow the on-screen instructions.

If the issue is not resolved, contact *Diasorin Support* for assistance.

13.4.3 Expired Cartridge Detected



Expired cartridges cannot be used on the LIAISON NES® system. A warning dialog displays if an expired cartridge is detected.

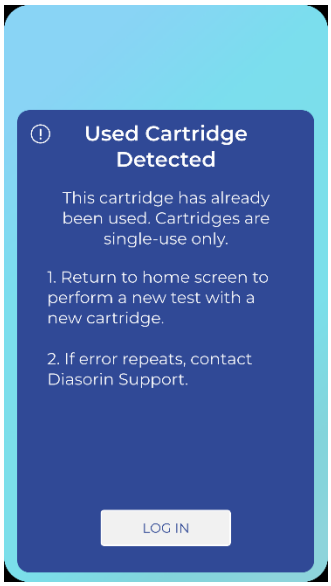
CAUTION: Wear gloves when handling the cartridge. Discard the cartridge in the biohazardous waste.

To resolve this issue, follow the on-screen instructions.

Before running a test with a new cartridge lot, perform a positive and negative quality control (QC) test.

If this warning displays when the cartridge has not expired, contact *Diasorin Support* for assistance.

13.4.4 Used Cartridge Detected



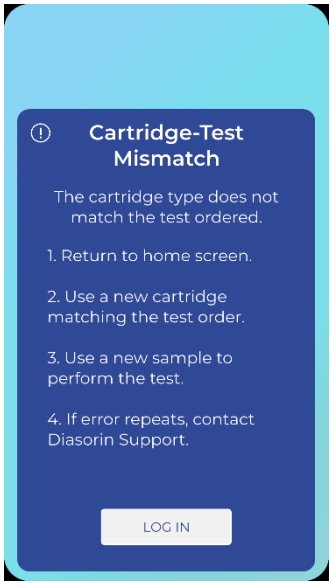
Cartridges are single-use only. Do not reuse cartridges. Reinsertion or reuse of a cartridge is not allowed. A warning dialog displays if the instrument detects that a used cartridge has been inserted.

CAUTION: Wear gloves when handling the cartridge. Discard the cartridge in the biohazardous waste.

To resolve this issue, follow the on-screen instructions.

If this warning displays when the cartridge hasn't been used or if the problem persists, contact *Diasorin Support* for assistance.

13.4.5 Cartridge-Test Mismatch



Make sure the test ordered matches the cartridge type used. A warning dialog displays if the test ordered doesn't match the cartridge type inserted. For example, this warning displays if the test is ordered for a respiratory panel of targets, but the cartridge inserted detects non-respiratory targets or a different test panel.

CAUTION: Wear gloves when handling the cartridge. Discard the cartridge in the biohazardous waste.

To resolve this issue, follow the on-screen instructions.

If the issue is not resolved, contact *Diasorin Support* for assistance.

13.4.6 Cartridge Cannot Be Removed

A warning dialog displays if the instrument cannot release a cartridge. Do not resume testing until this issue is resolved.

CAUTION: Wear gloves when handling the cartridge. Discard the cartridge in the biohazardous waste.

To resolve this issue, follow the on-screen instructions.

If the issue is not resolved, contact *Diasorin Support* for assistance.

13.4.6.1 Accessing Test History

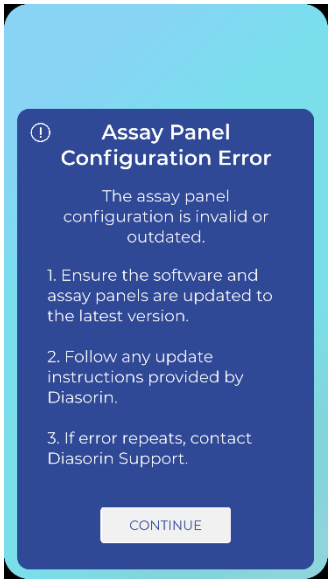
If the issue is not resolved, test results stored in the test history can still be accessed.

To access the test history,

1. Select **LOG IN.**
2. Enter your username, then select the check mark.
3. Enter your password, then select the check mark.
4. Select **TEST HISTORY**.

13.5 Assay Errors

13.5.1 Assay Panel Configuration Error



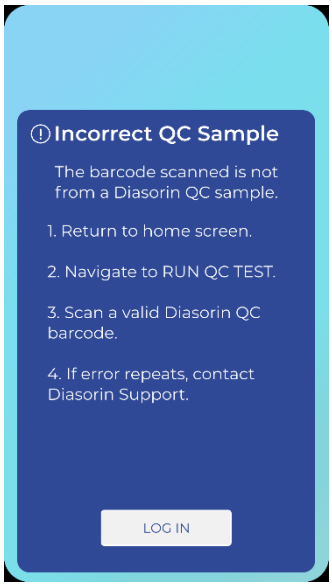
A warning dialog displays if the assay panel configuration is invalid or outdated.

To resolve this issue, follow the on-screen instructions.

If the issue is not resolved, contact *Diasorin Support* for assistance.

13.6 Quality Control Errors

13.6.1 Incorrect Quality Control Sample

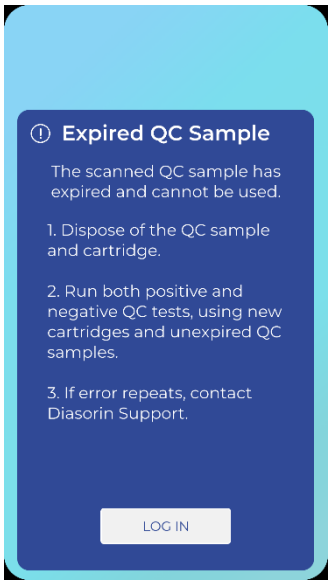


A warning dialog displays if the barcode scanned during quality control (QC) test setup is not from a QC sample. Ensure the correct barcode is scanned when setting up a QC test. QC materials must be purchased from Diasorin. Other samples cannot be used for QC testing.

To resolve this issue, follow the on-screen instructions.

If the problem persists when the correct QC barcode is scanned, contact *Diasorin Support* for assistance.

13.6.2 Expired Quality Control Sample

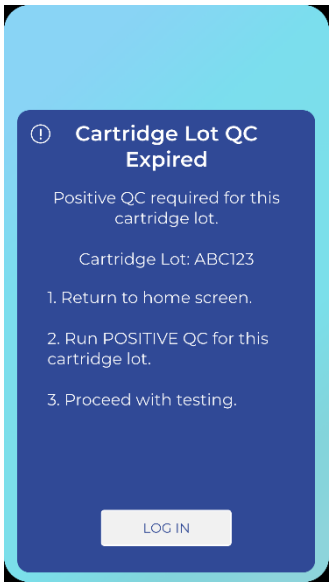


Expired quality control (QC) samples cannot be used on the LIAISON NES® system. A warning dialog displays if an expired QC sample is detected.

To resolve this issue, follow the on-screen instructions.

If the QC materials have not expired and this error message displays, contact *Diasorin Support* for assistance.

13.6.3 Cartridge Lot Positive Quality Control Expired

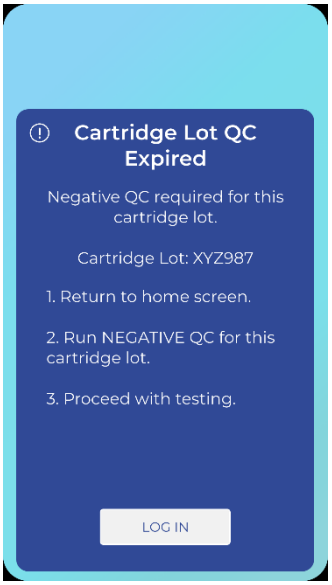


A warning dialog displays if the positive quality control (QC) for the cartridge lot has expired.

To resolve this issue, follow the on-screen instructions.

If the positive QC for the cartridge lot has not expired and this error message displays, contact *Diasorin Support* for assistance.

13.6.4 Cartridge Lot Negative Quality Control Expired

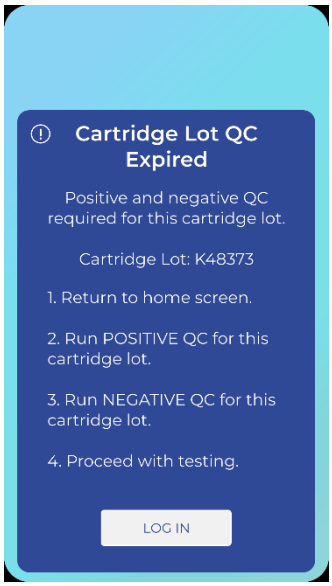


A warning dialog displays if the negative quality control (QC) for the cartridge lot has expired.

To resolve this issue, follow the on-screen instructions.

If the negative QC for the cartridge lot has not expired and this error message displays, contact *Diasorin Support* for assistance.

13.6.5 Cartridge Lot Quality Controls Expired



A warning dialog displays if both the positive and negative quality controls for the cartridge lot have expired.

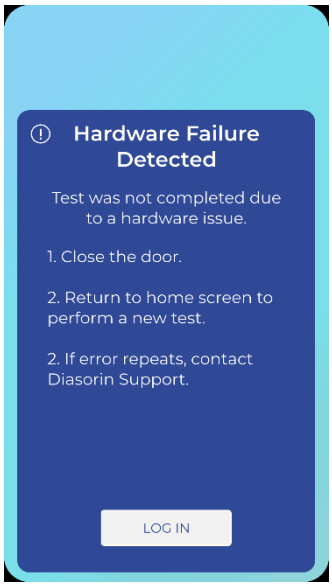
To resolve this issue, follow the on-screen instructions.

If the positive and negative quality controls for a cartridge lot have not expired and this error message displays, contact *Diasorin Support* for assistance.

13.7 Instrument Performance Errors

13.7.1 Hardware Failure Detected During a Test

A warning dialog displays if a hardware failure occurs during a test.



CAUTION: Wear gloves when handling the cartridge. Discard the cartridge in biohazardous waste.

To resolve this issue, follow the on-screen instructions.

If the issue is not resolved, contact *Diasorin Support* for assistance.

13.7.2 Instrument Shuts Down or Reboots while Idle

Important Note: Do not move the instrument or power off the instrument during a self-check, as doing so may cause instrument fault or error.

If the instrument loses power or reboots while idle and not during a test, ensure the power supply is safe and there are no power surges or excursions. Confirm the wall outlet is powered on and the circuit breaker has not tripped.

If the wall power is functioning correctly, to resolve this issue:

1. Flip the power switch to power off the instrument.
2. Unplug the power cable from the outlet.
3. **Wait at least 30 seconds**.
4. Confirm the power cable is securely connected to the power adapter and that the power adapter is securely connected to the instrument.
5. Plug the power cable into the outlet.
6. Flip the power switch to power on the instrument and wait for the self-check to complete.

If the self-check completes successfully, the instrument can be used normally.

If the self-check fails or if the instrument does not power on, contact *Diasorin Support* for assistance.

Best Practice

It is recommended that the LIAISON NES® instrument be powered off when it is not in use. The best practice is to power off the instrument each day at the end of work hours. If the instrument can't be powered off daily, it should be powered off at the end of the work week.

13.7.3 Instrument Shuts Down or Reboots During a Test

If the instrument loses power or reboots while running a test, ensure the power supply is safe and there are no power surges or excursions. Confirm the wall plug is powered on and the circuit breaker has not tripped.

CAUTION: Wear gloves when handling the cartridge. Discard the cartridge in biohazardous waste.

Important Note: Do not move the instrument or power off the instrument during a self-check, as doing so may cause instrument fault or error.

If the wall power is functioning correctly, to resolve this issue:

1. Flip the power switch to power off the instrument.
2. Unplug the power cable from the outlet.
3. **Wait at least 30 seconds**.
4. Confirm the power cable is securely connected to the power adapter and that the power adapter is securely connected to the instrument.
5. Plug the power cable into the outlet.
6. Flip the power switch to power on the instrument.
7. A warning dialog displays on the startup screen.
8. Select **RESOLVE ISSUE**.
9. When the instrument door opens, remove the cartridge and dispose of it in the biohazardous waste.
10. Close the door when prompted to continue the self-check.

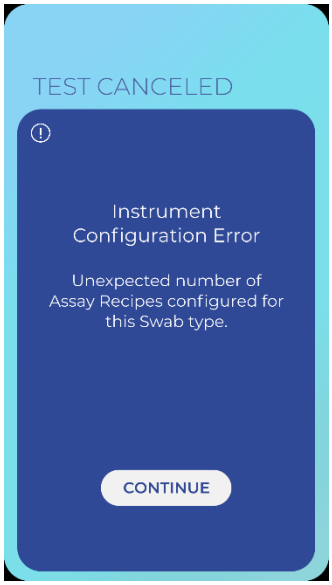
If the self-check completes successfully, the instrument can be used normally.

If the self-check fails or if the instrument does not power on, contact *Diasorin Support* for assistance.

13.7.4 Instrument Configuration Error

A warning dialog displays if the instrument is not configured correctly. Ensure the software and assay panels are updated to the latest version. When a new update is communicated, follow the steps provided by Diasorin.

If the issue persists or the update is not received, contact *Diasorin Support* for assistance.



13.7.5 Instrument Touchscreen Unresponsive

Important Note: Do not move the instrument or power off the instrument during a self-check, as doing so may cause instrument fault or error.

If the LIAISON NES® touchscreen is not responding, follow the steps below to resolve the issue:

1. Flip the power switch to power off the instrument.
2. Unplug the power cable from the outlet.
3. **Wait at least 30 seconds.**
4. Confirm the power cable is securely connected to the power adapter and that the power adapter is securely connected to the instrument.
5. Plug the power cable into the outlet.
6. Flip the power switch to power on the instrument and wait for the self-check to complete.

If the issue is not resolved or if the problem persists, contact *Diasorin Support* for assistance.

13.7.6 Barcode Scanner Does Not Scan

Important Note: Do not move the instrument or power off the instrument during a self-check, as doing so may cause instrument fault or error.

If the barcode scanner is not working correctly, check the following:

- Ensure the light turns on when motion is detected in front of the barcode scanner.
- Ensure the barcode format is correct.
- Ensure the barcode scanner window is free of dirt, debris, and obstructions.

Refer to *Instrument Specifications and Setup* for information on the location of the barcode scanner and acceptable barcode formats.

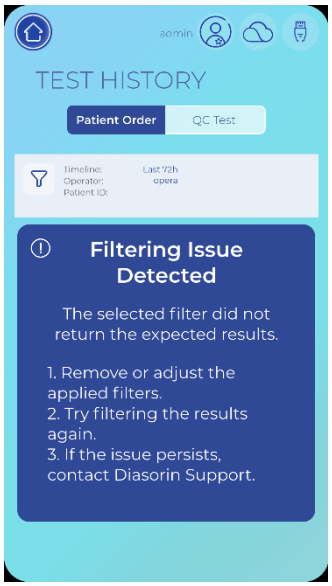
If the problem persists,

1. Flip the power switch to power off the instrument.
2. Unplug the power cable from the outlet.
3. **Wait at least 30 seconds**.
4. Confirm the power cable is securely connected to the power adapter and that the power adapter is securely connected to the instrument.
5. Plug the power cable into the outlet.
6. Flip the power switch to power on the instrument and wait for the self-check to complete.

If the issue is not resolved or if the problem persists, contact *Diasorin Support* for assistance.

13.8 Result Filtering Errors

13.8.1 Filtering Issue Detected

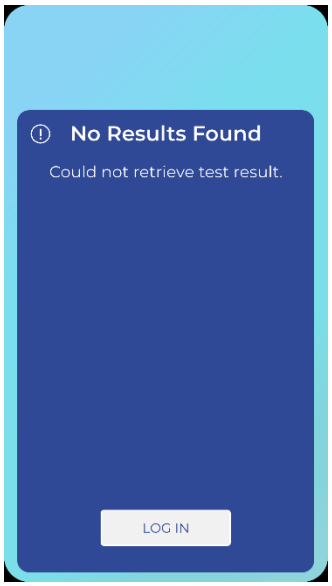


A warning dialog displays if the selected filter does not show the expected results.

To resolve this issue, follow the on-screen instructions.

If the issue is not resolved, contact *Diasorin Support* for assistance.

13.8.2 No Results Found



A warning dialog displays if the system cannot retrieve the requested results.

To resolve this issue, remove or modify the applied filters, then try filtering the results again.

If the issue is not resolved or if the problem persists, contact *Diasorin Support* for assistance.

14 Cleaning and Maintenance

To ensure proper performance of the LIAISON NES®, follow the cleaning and maintenance schedule below.

Frequency	Recommended Cleaning and Maintenance
Daily Inspection	Visually inspect the protective casing of the instrument. Discontinue use and contact *Diasorin Support* if there is noticeable damage. Check that the area around the instrument is clean and clear of obstructions. Check that the vents (back side of the instrument) are free of dust and debris.
Daily Cleaning	Follow the instructions below to clean all external surfaces with a bleach-free disinfecting wipe.

Best Practice

Wear personal protective equipment (PPE), including, but not limited to, latex-free gloves, a lab coat, and protective eyewear. All used materials should be considered biohazardous and disposed of properly.

CAUTION: Ensure that the instrument is powered off before conducting any cleaning or maintenance operations.

Warning: Never attempt to clean the internal parts of the instrument, including the cartridge bay, with any detergents or solvents. Failure to adhere to this warning could seriously damage the instrument.

Warning: Adhere to your site's decontamination procedures if there is possible contamination or spillage on or around the instrument.

Warning: Never use bleach to clean the instrument's touchscreen. Failure to adhere to this warning could impact screen clarity and functionality.

Required Cleaning Materials

- Bleach-free disinfectant wipe with at least 0.184% n-alkyl dimethyl benzyl ammonium chloride and 0.184% n-alkyl dimethyl ethyl benzyl ammonium chloride, such as Clorox® Disinfecting Wipes or equivalent.
- Paper towels
- Water

Cleaning Instructions

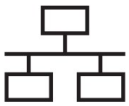
1. **Power off** – Turn off the instrument using the power switch.
2. **Disinfect** – Wipe all exterior surfaces with a bleach-free disinfectant wipe (e.g., Clorox® Disinfecting Wipes or equivalent), following the manufacturer's recommended contact time. Do not use bleach-based or abrasive cleaners.
3. **Wipe** – Use a paper towel dampened with water to wipe all exterior surfaces, including the touchscreen. Discard after use.
4. **Dry** – Use a paper towel to remove any remaining moisture. Discard after use.

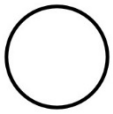
15 Glossary

Symbol	Title	Standard	Reference Number	Description
	Manufacturer	ISO 15223-1: Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied	5.1.1	Indicates the medical device manufacturer
	Date of manufacture	ISO 15223-1: Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied	5.1.3	Indicates the date when the medical device was manufactured
	Use-by date	ISO 15223-1: Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied	5.1.4	Indicates the date after which the medical device is not to be used
	Batch code	ISO 15223-1: Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied	5.1.5	Indicates the manufacturer's batch code so that the batch or lot can be identified

Symbol	Title	Standard	Reference Number	Description
	Catalogue number	ISO 15223-1: Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied	5.1.6	Indicates the manufacturer's catalogue number so that the medical device can be identified
	Serial number	ISO 15223-1: Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied	5.1.7	Indicates the manufacturer's serial number so that a specific medical device can be identified
	Keep dry	ISO 15223-1: Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied	5.3.4	Indicates a medical device that needs to be protected from moisture
	Temperature limit	ISO 15223-1: Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied	5.3.7	Indicates the temperature limits to which the medical device can be safely exposed
	Biological risks	ISO 15223-1: Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied	5.4.1	Indicates that there are potential biological risks associated with the medical device

Symbol	Title	Standard	Reference Number	Description
	Consult instructions for use or consult electronic instructions for use	ISO 15223-1: Medical Devices- Symbols to be used with medical device labels, labelling and information to be supplied	5.4.3	Indicates the need for the user to consult the Instructions for Use
	Caution	ISO 15223-1: Medical Devices- Symbols to be used with medical device labels, labelling and information to be supplied	5.4.4	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences
	In vitro diagnostic medical device	ISO 15223-1: Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied	5.5.1	Indicates a medical device that is intended to be used as an in vitro diagnostic medical device
	Warning: Hot Surface Label	ISO 7010 – Graphical symbols – Safety colours and safety signs – Registered safety signs	W017	Indicates a warning to avoid coming into contact with a hot surface
	Warning: Electricity	ISO 7010 – Graphical symbols – Safety colours and safety signs – Registered safety signs	W012	Indicates a warning to avoid coming into contact with electricity

Symbol	Title	Standard	Reference Number	Description
	Warning: Crushing of hands	ISO 7010 – Graphical symbols – Safety colours and safety signs – Registered safety signs	W024	Indicates a warning to avoid injury to hands when in the vicinity of equipment with closing mechanical parts
	This way up	ISO 7000 – Graphical symbols for use on equipment – Registered symbols	0623	Indicates correct upright position of the transport package
	Fragile; Handle with care	ISO 7000 – Graphical symbols for use on equipment – Registered symbols	0621	Indicates that the contents of the transport package are fragile and the package shall be handled with care.
	Universal Serial Bus (USB), port / plug	ISO 7000 – Graphical symbols for use on equipment – Registered symbols	3650	Indicates the device is plugged in or compatible with a USB port
	Computer network	IEC 60417 – Graphical Symbols for Use on Equipment	5988	Indicates the computer network or connecting terminals of the computer network (e.g., Wired Ethernet)
	“ON” (power)	IEC 60417 – Graphical Symbols for Use on Equipment	5007	Indicates connection to the mains (by use of the power switch) to connect the device to its source of electrical power

Symbol	Title	Standard	Reference Number	Description
	"OFF" (power)	IEC 60417 – Graphical Symbols for Use on Equipment	5008	Indicates disconnection from the mains (by use of the power switch) to separate the device from its source of electrical power
	Waste Electrical and Electronic Equipment (WEEE)	IEC 60417 – Graphical Symbols for Use on Equipment	6414	Indicates the separate collection for waste electrical and electronic equipment (WEEE) is required

*Note that this symbol is not yet part of an ISO standard.

16 Country Notes

16.1 USA and Canada

Manufactured for Diasorin Molecular LLC
11331 Valley View St, Cypress, CA 90630, United States
For Customer Service in US and Canada call toll free: 1-800-838-4548, option 1

17 Administrator's Guide for Network Configuration and Cloud Communication

For Network Administrator Use Only. Not Applicable to Users.

This chapter outlines the networking requirements for connecting a LIAISON NES® instrument to the cloud. It covers essential networking components, including Dynamic Host Configuration Protocol (DHCP) configuration, Ethernet cable connection, and Wi-Fi support features. Additionally, a troubleshooting section is provided to assist administrators in resolving common connectivity issues.

After the LIAISON NES® has been set up on a sanitized work surface and powered on, an 'active' Ethernet cable should be plugged in to the back of the instrument. Physical network connectivity can be verified by status lights on the instrument's ethernet port.

The instrument is designed to connect automatically to Microsoft Azure hosted Diasorin Cloud services.

Occasionally a facility's firewall or network security may block access or disallow full functionality.

In this event, please use this chapter to assist in your cloud communication efforts.

17.1 Networking Requirements:

17.1.1 DHCP Configuration:

Ensure that the site hosting the LIAISON NES® employs a network connection method (Wi-Fi, Ethernet) compatible with the instrument, and that the connection provides Dynamic Host Configuration Protocol (DHCP) services that will automatically assign an IP address to the device.

17.1.2 Ethernet Connection:

The LIAISON NES® instrument includes an Ethernet port, allowing for a reliable and secure wired connection to your local network infrastructure. While an Ethernet connection provides optimal stability and high-speed data transfer, it is not mandatory for regular operation or for using Laboratory Information System (LIS) and cloud functionalities.

17.1.3 Wi-Fi Connection:

The LIAISON NES® instrument supports Wi-Fi connectivity (2.4GHz 802.11n and 5GHz 802.11ac), providing flexibility in network deployment and device placement. Although Ethernet connections typically offer enhanced security, stability, and speed, the NES instrument can fully operate using Wi-Fi alone. When both Ethernet and Wi-Fi are active, the instrument automatically prioritizes the Ethernet connection. Supported Wi-Fi security protocols include WPA2-PSK and WPA3-SAE.

17.2 Troubleshooting:

17.2.1 Connectivity Issues:

Ensure the local network is actively providing Dynamic Host Configuration Protocol (DHCP) services.

If the LIAISON NES® instrument fails to connect to the network, first ensure that the Ethernet cable is securely plugged into both the instrument and the network switch/router. Verify that the status lights are active on the Ethernet port on the instrument.

Verify that the network port on the switch/router is operational by testing it with another device.

Check the DHCP settings on the instrument to confirm that it is configured to obtain an IP address automatically. If necessary, restart the DHCP service.

The instrument's Ethernet MAC address can be viewed in **Home > Settings > Connectivity > Ethernet**. This address can help IT diagnose routing and DHCP IP address assignment issues.

17.2.2 Azure:

17.2.2.1 Azure Endpoints:

- Azure endpoints are accessed via port 443 (HTTPS)

  IOT Hub
  *.azure-devices.net

For firewall and DNS requirements related to these endpoints, refer to *Firewall / DNS – Domain Whitelisting*.

Refer to https://learn.microsoft.com/en-us/azure/iot-hub/iot-hub-devguide-endpoints

17.2.2.2 Azure Storage:

Azure storage

*.core.windows.net

Refer to https://learn.microsoft.com/en-us/azure/storage/common/storage-account-overview

17.2.2.3 IOT device provisioning:

global.azure-devices-provisioning.net

Refer to https://learn.microsoft.com/en-us/azure/iot-hub/iot-hub-devguide-endpoints

17.2.3 Wi-Fi Connectivity Problems:

If connecting via Wi-Fi, ensure that the instrument is within range of the wireless access point and that the correct SSID (network name) and password are entered.

Check for any Wi-Fi interference from other devices or sources and relocate the instrument if necessary to improve signal strength.

Verify that Wi-Fi is enabled in the LIAISON NES® instrument settings. The instrument's Wi-Fi setting(s) can be viewed via **Home > Settings > Connectivity > Wi-Fi**.

Reboot the instrument if needed.

17.2.4 Network Firewall

If the LIAISON NES® instrument is unable to communicate with the cloud server, check the network firewall settings to ensure that outgoing traffic from the instrument is not being blocked.

Important Note: To ensure seamless cloud communication for your LIAISON NES® instrument, certain network configurations and firewall settings must be adjusted. This section outlines the necessary steps and configurations required to enable cloud communication.

Verify Firewall Settings:

Configure firewall rules to allow HTTPS (port 443) outbound from the instrument to global.azure-devices-provisioning.net, *.azure-devices.net, and *.core.windows.net.

Configure firewall rules to allow the necessary ports and protocols for cloud connectivity. To enable cloud communication, verify the following settings (ports):

- Port 443: This port is used for HTTPS file requests and must be open.
- Port 8883: This port is typically used for secure Message Queuing Telemetry Transport (MQTT) communication and must also be open.

Verify Instrument Settings

Ensure the **Sync. Instrument clock** option is enabled under the instrument **SETTINGS**.

This tool uses the Network Time Protocol (NTP), connecting to the server specified on the date time settings screen:

- The NTP suite implements NTP v4 (https://www.qnx.com/developers/docs/7.0.0/index.html#com.qnx.doc.neutrino.sys_arch/topic/tcpip_NTP.html)
- It uses User Datagram Protocol (UDP) on network port 123 (https://datatracker.ietf.org/doc/html/rfc5905)

17.2.4.1 Firewall – Open Ports

To ensure connectivity between the LIAISON NES® instrument and cloud services, verify that the following outbound ports are open on the facility's firewall:

- TCP 443 (HTTPS) – required for secure web communication and file requests.
- TCP 8883 (MQTT) – required for secure Message Queuing Telemetry Transport communication.
- UDP 123 (NTP) – required for time synchronization using Network Time Protocol.

17.2.4.2 Firewall / DNS – Domain Whitelisting

For successful cloud connectivity, whitelist the following domains and their subdomains:

- *.iot.diasorin.com

- *.blob.core.windows.net
- *.azure-devices.net
- *.cloudapp.azure.com
- global.azure-devices-provisioning.net

DNS/Firewall policy requirements:

- Disable “fully qualified domains required” if this policy is enforced.
- Allow subdomains up to 10 levels below the qualified domain.

17.2.4.3 Test Network Connectivity

It's essential to verify that the network selections are reachable and viable. You can use tools like telnet from a PC on the device network to test connectivity, paying attention to the endpoint URLs listed below.

List of Required Accessible URLs

The following URLs must be accessible to the LIAISON NES® instrument for successful cloud communication:

- *.iot.diasorin.com,
- *.blob.core.windows.net,
- *.azure-devices.net,
- *.cloudapp.azure.com

Steps for Verification:

1. **Check Firewall Settings:** Ensure that ports 443 and 8883 are open on your network firewall.
2. **Use Telnet for Connectivity Testing:**
   - Open a command prompt on a PC connected to the same network as the LIAISON NES® instrument.
   - Use the telnet command to test connectivity to each URL on port 443. For example:

     ```
     Copy code
     telnet dsriotdevneust.blob.core.windows.net 443
     telnet api-dev.iot.diasorin.com 443
     ```

   - If telnet is not installed, you may need to enable it via the Control Panel (Windows) or use an alternative method such as curl or ping to check basic connectivity.

17.2.4.4 Time Synchronization Configuration

Proper time synchronization is essential for the accurate functioning and data logging of your diagnostic lab instrument. This section details the options available for time synchronization and guides you on how to configure and troubleshoot the time settings.

17.2.4.5 Time Synchronization Options

You have two options for setting the time on your diagnostic lab instrument:

1. **Default Time Server (Preferred)**
2. **Manual Time Set by Operator**

1. Default Time Server

Using a default time server is the recommended method for ensuring accurate time synchronization. This option requires an internet connection to synchronize the local time of the instrument with a time server.

Configuration Steps:

1. **Event Form is Blocked:**
   - Ensure that the event form is not blocked by your firewall or network security settings.
2. **Local Time Server Preference:**
   - Configure the instrument to prefer a local time server, if available. This can help reduce latency and improve synchronization accuracy.
3. **Entry Box/Input Field:**
   - Use the input field to enter the time server details. Note that the input field may truncate long server addresses. Ensure that the correct and full server details are entered.
4. **Server Accessibility**:
   - Verify that the instrument can reach the time server. You may need to manually implement the time server settings. Consult your network administrator for installation instructions if the server cannot be accessed directly.
5. **Connection Indicator:**
   - Check the connection status of the time server using the Red/Green LED indicator on the instrument. Green indicates a successful connection, while Red indicates a disconnection.

2. Manual Time Set by Operator

If the default time server method is not feasible, you can manually set the time on the instrument. This method is less preferred due to the potential for time drift, which can affect cloud communication and data accuracy.

Configuration Steps:

1. **User Notification:**
   - Notify the user when the time is set manually. Regular checks and adjustments may be necessary to maintain accuracy.
2. **Time Drift:**
   - Be aware that time drift can occur with manual settings. If the time becomes too inaccurate, cloud services such as Azure may cease communication with the instrument. Regularly compare the instrument's time with the local standard time and adjust as necessary.
3. **Geolocation Connection:**
   - Ensure that the instrument’s location and time zone settings are correct if using geolocation services to assist with time synchronization.
4. **Manual Time Entry:**
   - Access the time setting interface on the instrument and enter the correct local time manually. Ensure an internet connection is available for the initial setup.
5. **Consequence/Risk:**
   - Understand that inaccurate time settings can lead to issues such as partial or incorrect .JSON files. Regular maintenance and time checks are essential to mitigate this risk.

17.2.5 Network Infrastructure Issues:

If all troubleshooting steps fail, export a support zip from the instrument and forward it to *Diasorin Support*. The cloud services automatically generate connectivity diagnostic data on failure to connect. *Diasorin Support* can review and communicate the information to your IT to help diagnose the connection issue.