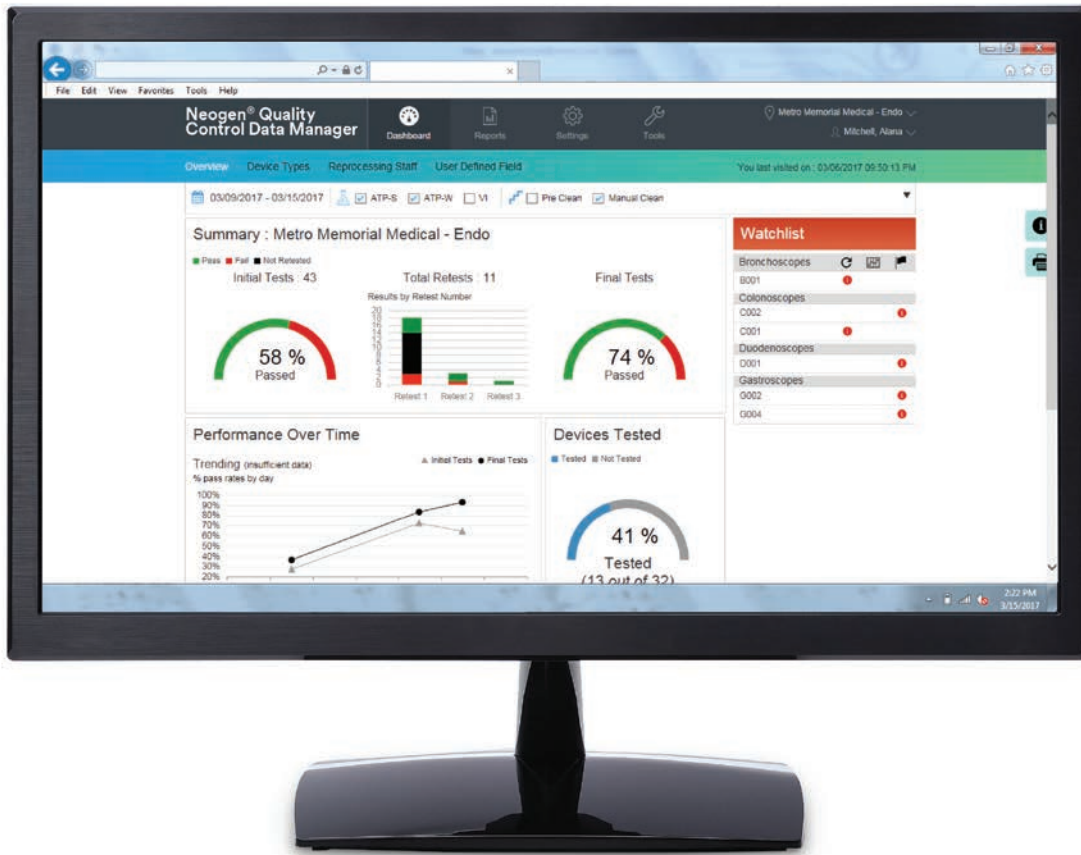




Neogen® Clean-Trace® ATP Monitoring System

Site Planning and Installation Guide

This Site Planning and Installation Guide is intended to provide information to help plan for and execute site installation for the Neogen Clean-Trace ATP Monitoring System.

- I. Planning for Space and Storage
- II. IT Requirements
- III. Monitoring Plan Development
- IV. Neogen® Quality Control Data Manager Set-up
- V. Preparing for In-Service Checklist

I. Planning for Space, Storage, and Use Conditions

When planning out space for the storage and use of the Clean-Trace ATP Cleaning Monitoring System, consider all of the system components:

For **environmental surfaces** application:

- Clean-Trace® Luminometer LX25, with dedicated power adapter and USB cable
- Clean-Trace® ATP Surface Test UXC
- PC or laptop to access internet and connect to Neogen Quality Control Data Manager

For **flexible endoscope, lumened or other surgical instrument** applications:

- Clean-Trace Luminometer LX25, with dedicated power adapter and USB cable
- Clean-Trace ATP Water Test H2O
- Clean-Trace ATP Surface Test UXC
- Clean-Trace Water Test Accessory Kit WTK
- AG-3 Endoscope Stabilizing Stand for Water Test H2O

- In addition, the facility provides additional materials – see page 3.
- PC or laptop to access internet and connect to Neogen Quality Control Data Manager

Specifications and Storage: Clean-Trace Luminometer LX25

Length: 59.27 (2.33) mm (in.)

Width: 88.47 (3.48) mm (in.)

Height: 268.17 (10.56) mm (in.)

Weight: 517.83 (18.26) g (oz.)

Do not store or use the Clean-Trace Luminometer LX25 or power supply in a location exposed to steam, high humidity, dust, or strong vibration. It is recommended that the Clean-Trace Luminometer LX25 unit be stored inside a cabinet or enclosed area where it can be protected from potential liquid splashes or introduction of particulates into sensitive areas of the instrument. Cabinet storage can also help to prevent damage due to the Clean-Trace Luminometer LX25 being knocked off of work spaces.

Environmental Condition	Operating Condition
Indoor Use Only	- Only use the data connections to a computer that conforms to IEC/EN/UL/CSA 60950-1 - Keep Clean-Trace Luminometer LX25 away from liquids and high humidity when connected to the computer
Altitude	Maximum 3000 meters
Operating Temperature Range	+5°C to +40°C (+41°F to +104°F)
Relative Humidity	10–90% Non-condensing
Storage Temperature Range	-40°C to +70°C (-40°F to +158°F)
AC Voltage for power supply Mains supply voltage fluctuations up to +10% of nominal voltage Temporary overvoltages occurring on the mains supply	100–240 Volts
Frequency	50–60 Hertz
AC Current for Power Supply	300 mA
Power Supply Output Voltage	5 Volts DC
Power Supply Output Current	1.2 Amps
Neogen Clean-Trace Luminometer Input Current	850 mAMPs
Overvoltage	Category II
Pollution Degree	2

Storage Conditions: Clean-Trace ATP Tests UXC and H2O

Clean-Trace ATP Tests are sensitive to environmental conditions and it is important to properly store the products as recommended in the product labeling.

Upon receipt of the Clean-Trace Surface Test UXC or Water Test H2O, the foil pouches should be removed from the shipper box and stored at 2–8°C (36–46°F). This will require a refrigerator for storage of the Clean-Trace ATP Tests in a convenient place for operators to access. Store the ATP Tests in the pouch until time of use. For your reference, the size of the Clean-Trace ATP Test foil package is 10.5 in. by 6 in. (27 cm by 15 cm).

Clean-Trace ATP Tests can withstand short exposure times to higher temperatures, but the shelf life of the product is dependent on the TOTAL time the product is held outside the recommended storage conditions of 2–8°C (36–46°F). The enzyme quickly loses its activity when the product is exposed to temperatures >37°C (98.6°F). All precautions should be taken to minimize any risk of exposure to temperatures >37°C (98.6°F).

Shelf-Life

Clean-Trace ATP Surface Test UXC

- 10 months when stored between 2–8°C (36–46°F)
- Maximum of 28 days up to a maximum of 21°C (70°F)

Neogen® Clean-Trace® ATP Water Test H2O

- 12 months when stored between 2–8°C (36–46°F)
- Maximum of 2 months if continually stored at 21–25°C (70–77°F)

Shipping*

Clean-Trace ATP Surface Test UXC

- Maximum of 7 days up to a maximum of 30°C (86°F)
- Maximum of 2.5 days up to a maximum of 37°C (98.6°F)

Clean-Trace ATP Water Test H2O

- Maximum of 7 days up to a maximum of 25°C (77°F)
- Maximum of 1 day up to a maximum of 37°C (98.6°F)

* ATP Tests can withstand the above Shipping times and temperatures and still maintain the above stated Shelf-Life times and temperatures. For example, a Clean-Trace ATP Surface Test UXC can withstand 7 days at 30°C of shipping, followed by the remaining portion of the stated shelf life of 10 months storage at 2–8°C or 28 days at 21°C.

Testing Supplies & Space: Flexible Endoscope or Surgical Instrument Applications

For flexible endoscope or lumened surgical instrument applications, there are additional items that you will need to use with the Clean-Trace Water Test H2O to also consider when planning storage requirements**:

- Neogen Water Test Accessory Kit
- Sterile sample collection containers
- Sample cup holder (available from Neogen)
- 60 cc and/or 10 cc disposable syringes
- Sterile water

Next, determine where the Clean-Trace ATP testing will be completed. This is typically in the cleaning/decontamination area of the reprocessing room. Testing is often performed on a suitable counter space or a separate cart.

Facilities vary in design, so consider options for maximum space that do not interfere with other cleaning related processes.



** Refer to sampling guides, videos, and poster for more information.

II. IT Requirements and Data Security for Clean-Trace Luminometer LX25 and Neogen Quality Control Data Manager

The following IT requirements must be met in order to use the Clean-Trace Luminometer LX25 and Neogen Quality Control Data Manager. The facility IT management should be included in assessment of the Clean-Trace ATP Monitoring System to ensure the requirements can be met. This assessment should be made prior to purchase or installation of the system.

Operating System and Computer Requirements

The Clean-Trace Quality Control Data Manager web interface can be accessed via common web browsers. Supported browsers include:

- Internet Explorer
- Google Chrome®
- Microsoft Edge®
- Safari®

The Neogen® Synchronization Manager supports the following operating systems:

- Microsoft Windows® 10
- Microsoft Windows® 11

General PC Requirements

- 1 Ghz or greater processor
- 4 GB RAM
- 100 MB free disk space
- Available USB 2.0 compatible port (for Synchronization Manager)
- Minimum Display Resolution: 1366×768
- Internet Access

Network Requirements

The Clean-Trace Luminometer LX25 requires access to the Neogen hosted infrastructure via one of two methods:

- 1. Wireless (preferred):** Access to the internet via a wireless network to the Neogen hosted infrastructure. Data is communicated directly between Neogen hosted infrastructure and the Clean-Trace Luminometer LX25.

Data is automatically uploaded to the Neogen hosted infrastructure in real-time using the WiFi function on the Clean-Trace Luminometer LX25. Before the WiFi function can be used, the Clean-Trace Luminometer LX25 must first be registered to the Quality Control Data Manager software using the USB cable connection to a workstation running the Synchronization Manager Software.

In order to be able to use the wireless data transfer feature as soon as possible, work with your facility's IT department early in the set-up process to ensure that you do not have any issues connecting the Clean-Trace Luminometer LX25 to your facility's secure wireless network.

- 2. Wired Access:** Access to the internet from a local windows PC via a wired network to the Neogen hosted infrastructure. This requires use of the Neogen® Synchronization Manager software which facilitates the transfer of data between the Clean-Trace Luminometer LX25 and the Neogen hosted infrastructure via a USB connection.

Hosted Infrastructure Address: <https://qcdm.Neogen.com>

For additional assistance in connecting the Clean-Trace Luminometer LX25 to the Neogen hosted infrastructure using wireless or wired access, please refer to the "Connecting the Neogen® Clean-Trace® Luminometer LX25" section of your Neogen® QCDM Setup Guide.

Clean-Trace Luminometer LX25 Security Recommendations

Neogen recommends the following best practices to increase the security of your Clean-Trace Luminometers LX25:

- Maintain responsible physical control over the Luminometers LX25.
- Do not connect the Luminometers LX25 to public networks.
- Use of additional network controls:
 - Implement a network policy control that only allows communication between the Luminometer LX25 (media access control (MAC) Address XXX) to and from the host qcdm.Neogen.com on ports 80(TCP) and 443(TCP). In addition, the Luminometer LX25 will need to be allowed to communicate with the configured DNS server on port 53(UDP) and NTP servers on port 123(UDP).
 - Use of network segmentation for Luminometers LX25.
 - Use of NAC network controls.
- Ensure that the Luminometers LX25 are only serviced by authorized Neogen service centers.
- Report any concerning behavior regarding these products to a Neogen representative.

Hosted Data Security - Frequently Asked Questions

The following are a list of frequently asked questions to address specific questions that you or your IT department may have with regards to the Neogen Quality Control Data Manager.

Q: Where is the Neogen Quality Control Data Manager/ Clean-Trace Luminometer LX25 data hosted?

A: The data is hosted in Amazon Web Services (AWS) hosting facilities (USA). AWS provides data security, redundancy, disaster recovery, and infrastructure maintenance (See AWS Data Center Controls <https://aws.amazon.com/compliance/data-center/controls/>).

Q: How is the data transmitted between customer computers and the Neogen servers?

A: Data between customer computers and Neogen servers is encrypted via TLS 1.2.

Q: How is the data stored on the servers?

A: Data is housed within secure data centers. Sensitive data is encrypted at rest. Access to data is restricted to trained and authorized staff. Access is controlled via “division of responsibility” processes.

Q: What security measures are in place to keep the data from each customer separate and how you ensure that each customer will only have access to their own data?

A: Each customer is set up in the system as a new “Organization”. The system is designed to segregate the data such that a user can only see data for the organization (or related organizations as defined by a parent-child relationship) that they are using. We carry out extensive testing to ensure that only the correct data is displayed to a user.

Q: Who at Neogen would have access to this data, and how do you ensure that the data would only be accessed for valid purposes?

A: Qualified and trained IT personnel have access for support purposes. All activities carried out via the website are logged by the application. All access to servers requires multi-factor authentication and strong passwords.

Q: How are changes to the system managed?

A: All changes to the system are carried out via our change management process which follows a robust re-verification and re-validation process.

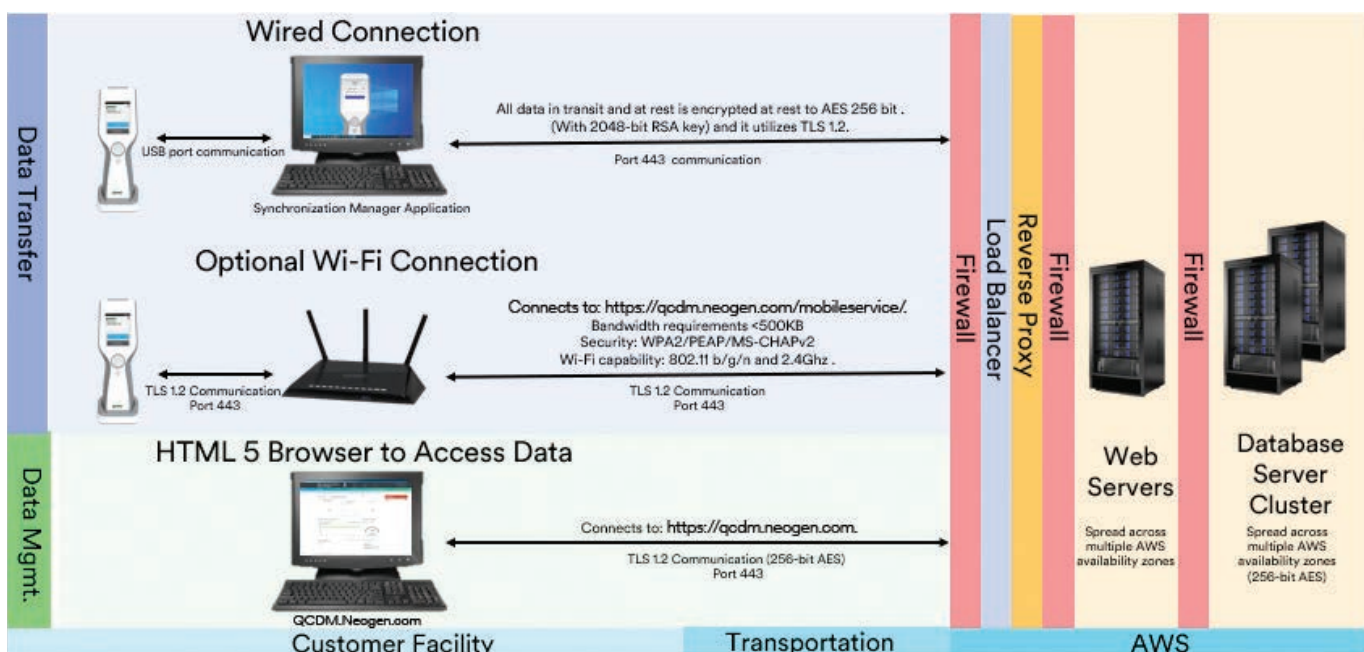
Q: How is the data protected from malicious software attacks?

A: Neogen’s use of Amazon Web Services to host this application provides for industry-leading safeguards to monitor, detect, and protect against malicious software attacks. In addition, infrastructure is regularly updated with the latest patches.

Q: How are backups secured and how often are they performed?

A: Backups are performed daily and stored securely.

Hosted Data Infrastructure - Network Architecture



Hosted Data Security - Network Data Flow

Data for the Clean-Trace system is stored on the luminometer and/or the server depending on its classification. The following data categories are all stored on the LX25 device, stored on the service, encrypted in transit and encrypted at rest.

Username

First Name

Last Name

PIN

Organization Name

Areas/Device Types

Rooms/Devices

Test Plans

Test Points

Test Point Results

User Defined Fields

Note: No patient data is stored by the system. The First Name, Last Name & Username fields are representative of the users of the system if populated by the customer.

III. Monitoring Plan Development and Implementation

All three applications require a monitoring plan to be developed in advance of set-up in the Neogen Quality Control Data Manager. Regardless of the application, there are a number of steps involved in the successful implementation of a monitoring plan:

1. Design a test plan and determine test points
2. Identify Pass/Fail thresholds
3. Determine frequency of testing
4. Establish meaningful metrics
5. Track, trend and regularly review test result data

For more detailed information, the following documents are available from Clean-Trace ATP Monitoring system support and can be found at Neogen.com/cleantrace.

- Endoscope Reprocessing Implementation Guide
- Surgical Instrument Reprocessing Implementation Guide
- Environmental Surfaces Implementation Guide

IV. Neogen Quality Control Data Manager Set-up

Steps to set up the Neogen Quality Control Data Manager:

1. After purchasing the Clean-Trace ATP Monitoring System, your Neogen representative will request some information to allow access and set-up of the facility in the Quality Control Data Manager. This is a good time to start working with your IT department so they can take the necessary steps to get ready for connecting the Clean-Trace Luminometer LX25 to your facility's secured wireless network.
2. After your Neogen representative submits the request for your QCDM set-up, your organization will be activated for access to the Quality Control Data Manager. An email will be sent providing instructions, a link and access codes to login to the Quality Control Data Manager, along with instructions for downloading the Sync Manager. The Sync Manager is needed to register the Clean-Trace Luminometer LX25 to an organization before it can be used with the Quality Control Data Manager.
3. Leverage the Quality Control Data Manager Set-up Guide to set up monitoring plan and facility information in the Quality Control Data Manager.

V. Site Set-up and Preparing for In-Service Checklist

This checklist helps ensure the site is ready to be trained and in-serviced on the system. Review the check-list to make sure that all these items have been completed before scheduling any in-servicing appointments with Neogen.

Supplies and Storage

Refrigeration for Clean-Trace ATP UXC and H2O test swabs	☐
Safe place to store Clean-Trace Luminometer LX25 unit(s) and power cords	☐
Cabinet, bins or carts for additional sampling accessories	☐
Testing space in reprocessing area, if applicable	☐
Secure all necessary supplies - Clean-Trace ATP Tests - Clean-Trace Luminometer LX25 - PPE - Water test accessories (including Clean-Trace Water Test Accessory Kit WTK, endoscope sampling stand, sample containers, syringes)	☐

IT Requirements

Consult with your IT department to establish Wi-Fi accessibility	☐
Download the Sync Manager on PCs for USB data synchronization capability	☐

Monitoring Plan

Review the Clean-Trace Implementation Guides and determine your monitoring plan	☐
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Quality Control Data Manager (QCDM) set-up

Provide info to your Neogen representative to request Quality Control Data Manager set-up	☐
Look out for your Quality Control Data Manager welcome email and set up your unique password	☐
Review the QCDM Set-up Guide and start setting up your organization in QCDM, contact Neogen for assistance	☐
Register and sync Clean-Trace Luminometer LX25 units to your organization in QCDM	☐

Training

Utilize Neogen training materials to begin introductory training with your team prior to in-service	☐
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All boxes checked? You're ready to go!
Contact Neogen to schedule your in-service to get started.



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