## Issue Date: 2017-04

# **Clean-Trace™ Luminometer LX25**

**User Manual** 

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#### Important Safety Information 3M™ Clean-Trace Luminometer LX25

Please read, understand, and follow all safety information contained in these instructions prior to the use of this 3M™ Clean-Trace™ Luminometer. Retain these instructions for future reference.

### **Product Description and Intended Use:**

The 3M<sup>™</sup> Clean-Trace<sup>™</sup> Luminometer LX25 is a battery operated Luminometer utilized primarily for objective and sensitive determination of the end result of 3M<sup>™</sup> Clean-Trace<sup>™</sup> Adenosine Tri-Phosphate (ATP) tests. The Clean-Trace Luminometer LX25 power supply is provided to charge the battery.

3M has not designed nor documented the Clean-Trace Luminometer LX25 or Clean-Trace Luminometer LX25 power supply for use with other manufacturers' products, use with other manufacturers' designs, or use in any other application that has not been evaluated or documented by 3M and may lead to an unsafe condition. The Clean-Trace Luminometer LX25 is not intended to be used in potentially flammable or explosive environments. Surfaces or solutions should not be considered sterile based on results from the 3M Clean-Trace Luminometer LX25. The 3M Clean-Trace Luminometer LX25 is not intended to be used in the diagnosis of conditions in humans or animals. The user is responsible to know and follow applicable workplace regulations. Clean-Trace ATP tests, equipment, and software must be utilized by technicians that have been properly trained on the 3M™ Clean-Trace™ ATP Monitoring System according to all applicable instructions for use.

If this product is used in a manner not specified, the results provided by the product may be impaired.

#### **Explanation of Signal Word Consequences**



WARNING: Indicates a hazardous situation which, if not avoided, could result in serious injury or death



**CAUTION:** Indicates a hazardous situation which, if not avoided, could result in minor or moderate injury and/or property damage.

**NOTICE:** Indicates a situation which, if not avoided, could result in property damage.

## **Explanation of Safety Related Symbols**



Warning: Hazardous Voltage



Attention: Read Accompanying Documentation



CAUTION: Recycle 3M™ Clean-Trace
Luminometer LX25 to avoid environmental
contamination. This product contains recyclable
parts. For information on recycling, in the US
please contact 3M Health Care Service Center
at 1-800-292-6298 for additional information.
Outside of the US contact your local 3M office.



WEEE mark - This product contains electrical and electronic components and must not be disposed of using standard refuse collection. Please consult local directives for disposal of electrical and electronic equipment.



Class II: Class two insulation referred to as double insulation.



Applies to 3M Clean-Trace Luminometer LX25 Power Supply: Alternating current AC source.



Applies to 3M Clean-Trace Luminometer LX25 Power Supply: Direct current DC source.



UL NRTL mark (US and Canada electrical safety)



CE mark (conforms to applicable requirements for European Economic Area).



RCM mark (Australia electrical safety and EMC)



BC mark (California regulation for battery charging systems)



The 3M Clean-Trace Luminometer LX25 model number, which is LX25.



The 3M Clean-Trace Luminometer LX25 serial number





Efficiency: Complies to section 301 of Energy Independence and Security Act (EISA) complies with Energy Star tier.

2 (North America), ECP tier 2 (China), MEPS tier 2 (Australia), Code of Conduct (Europe)

#### **⚠** WARNING

#### • To reduce the risks associated with fire and explosion:

- Do not incinerate or dispose of battery or 3M Clean-Trace Luminometer LX25 in fire.
- Do not use or store the Clean-Trace Luminometer LX25 or power supply in potentially flammable or explosive environments. The Clean-Trace Luminometer LX25 system is not designed or categorized as "Intrinsically Safe."
- Do not use or place the Clean-Trace Luminometer LX25 on wet surfaces.

#### To reduce the risks associated with hazardous voltage and fire:

- Do not modify any part of the Clean-Trace Luminometer LX25 and power supply.
- Keep power supply visible and accessible at all times.
   The plug connected to the outlet is used to disconnect the Clean-Trace Luminometer LX25 from the main power supply.
- Do not use any power supply cord or USB cord (power supply cord) other than those specified by 3M.
- Do not allow the power supply to get wet.

#### • To reduce the risks associated with hazardous voltage:

- Disconnect the Clean-Trace Luminometer LX25 from the outlet or the computer before cleaning.
- Do not modify or service the Clean-Trace Luminometer LX25 or power supply. Only 3M authorized service personnel should provide service or repair.
- Do not use the Clean-Trace Luminometer LX25 or power supply if the enclosure is broken.
- Do not use a damaged power supply or damaged power supply cord.
- Replace damaged components with 3M designated replacement parts only.

#### • To reduce the risks associated with illness or infection:

- Do not use the Clean-Trace Luminometer LX25 and 3M Clean-Trace ATP Tests in the diagnosis of conditions in humans or animals.
- Do not use the Clean-Trace Luminometer LX25 and 3M Clean-Trace ATP Tests as an indication of disinfection or sterilization of surfaces or devices.

#### **↑** CAUTION

#### To reduce the risks associated with exposure to chemicals:

Always wear protective apparel while using these products.

#### • To reduce the risks associated with cross contamination:

- Always perform decontamination procedures as documented in the Clean-Trace Luminometer LX25 User Manual after each use.
- Do not use the 3M Clean-Trace Luminometer LX25 with ATP tests manufactured by companies other than 3M.
- Always perform ATP Tests within temperature use range of 15-25OC. Performing tests outside of temperature use range can result in false negative readings.
- Ensure annual recommended service and calibration of the 3M Clean-Trace Luminometer LX25 is completed through the 3M Service Center or 3M authorized service personnel.

### To reduce the risks associated with sharp objects and property damage:

Dropping of or impact to the Clean-Trace
 Luminometer LX25 may result in damage to the device or introduction of particulate into sensitive areas of the instrument.

## • To reduce the risks associated with environmental contamination:

 Always follow applicable regulations and facility policies when disposing of the Clean-Trace Luminometer LX25, power supply, and battery.

#### NOTICE

- To reduce risk of damage and ensure an accurate result with the 3M™ Clean-Trace™ Luminometer LX25:
  - Do not operate the Clean-Trace Luminometer LX25 in close proximity to strong magnetic fields.
  - Do not store or operate the Clean-Trace Luminometer LX25 at temperatures above 70°C.
  - Do not store or operate the Clean-Trace Luminometer LX25 at temperatures below -40°C as condensation may occur. The instrument should be allowed to warm to room temperature before use and a cloth or tissue should be used to wipe dry the outer surfaces.
  - Only insert 3M<sup>™</sup> Clean-Trace<sup>™</sup> ATP Tests into the Clean-Trace Luminometer LX25 chamber.
  - Do not use cleaning agents in the Clean-Trace Luminometer LX25 chamber.
  - Ensure the ATP Test is inserted into the Test sleeve and activated before inserting the Test into the Clean-Trace Luminometer LX25 chamber.
  - Do not tilt the Clean-Trace Luminometer LX25 while ATP Tests are in the chamber.

- Do not leave a used (activated) ATP Test in the Clean-Trace Luminometer LX25 chamber after the result has been read and recorded.
- Ensure annual recommended service and calibration of the Clean-Trace Luminometer LX25 is completed by the 3M Service Center or 3M authorized service personnel.
- Periodically inspect the Clean-Trace Luminometer LX25 for damage, including cracks or swelling.
- 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.
- Reference the Environmental Operating Conditions table in the Important Safety Information for Clean-Trace Luminometer LX25 in this User Manual.
- Use only 3M Clean-Trace ATP Tests and 3M accessories supplied by your local 3M sales representative or distributor.
- Do not use the Clean-Trace Luminometer LX25 if liquid or a foreign object gets inside the device.

## **Environmental Operating Conditions**

<b>Environmental Condition</b>	Operating Condition	Units
Indoor Use only	- Only use the data connections to a computer that conform to IEC/EN/UL/CSA 60950-1	Not applicable
	<ul> <li>Keep Clean-Trace Luminometer LX25 away from liquids and high humidity.</li> </ul>	
Altitude	3000 maximum	Meters
Operating Temperature Range	+5 to +40 (+41 to +104)	°C (°F)
Relative Humidity	10 – 90 Non-condensing	%
Storage Temperature Range	-40 to +70 (-40 to +158)	°C (°F)
AC voltage for power supply	100-240	Volts
Mains supply voltage fluctuations up to +10% of nominal voltage		
Temporary overvoltages occurring on the mains supply		
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
Input current	850	mAMPs
Overvoltage	Category II	Not applicable
Pollution Degree	2	Not applicable

#### **REGULATORY COMPLIANCE**

The CE Mark denotes compliance of the 3M<sup>™</sup> Clean-Trace<sup>™</sup> Luminometer LX25 with the following European Directives:

 R&TTE Directive 1999/5/EC – Radio and telecommunications terminal equipment directive

#### **FCC Radio Frequency Rules and Regulations**

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

**FCC Intentional Radiator Certification** 

Contains FCC ID: Z64-WL18SBMOD

This equipment contains an intentional radiator approved by the FCC under the FCC ID number shown above. This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

NO MODIFICATIONS. Modifications to this device shall not be made without the written consent of 3M Company. Unauthorized modifications may void the authority granted under Federal Communications Commission Rules permitting the operation of this device.

Industry Canada Radio Frequency Rules and Regulations CAN ICES-3 (A)/NMB-3(A): This Class A digital apparatus meets all requirements of the Canadian ICES-003.

Contains transmitter module IC ID: 451I-WL18SBMOD

Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference received, including interference that may cause undesired operation of the device.

#### **LIMITED WARRANTY**

3M Infection Prevention Division Hardware ("Hardware") includes the 3M™ Clean-Trace™ Luminometer LX25 and any associated software, on-line service and other components supplied by 3M which are described in the applicable Site Planning and Installation Guide and Operator Manuals. ("User Documentation").

#### LIMITED WARRANTY AND DISCLAIMER

3M warrants that for one year from the date of sale, that the Hardware will substantially perform in accordance with the User Documentation, THIS WARRANTY IS VOID IF: (A) THE HARDWARE HAS BEEN REPAIRED BY PERSONS NOT AUTHORIZED BY 3M; OR (B) THE HARDWARE HAS BEEN ALTERED, MODIFIED, OR MISUSED; OR (C) THE HARDWARE IS USED WITH PRODUCTS, SUPPLIES, COMPONENTS OR SOFTWARE NOT SUPPLIED BY 3M FOR USE WITH THE HARDWARE: OR (D) THE HARDWARE OR A COMPONENT IS USED FOR OTHER USES (FOR EXAMPLE USE WITH OTHER CIRCUIT BOARDS OR SOFTWARE) OR (E) THE HARDWARE HAS NOT BEEN MAINTAINED OR USED IN ACCORDANCE WITH THE USER DOCUMENTATION. UNLESS PROHIBITED BY LAW, THIS WARRANTY IS MADE IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO THE IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE, THE IMPLIED WARRANTY OF MERCHANTABILITY, OR ANY IMPLIED WARRANTY ARISING OUT OF A COURSE OF DEALING OR OF PERFORMANCE, CUSTOM OR USAGE OF TRADE. 3M DOES NOT WARRANT THAT THE SOFTWARE OR ON-LINE SERVICE WILL FUNCTION ERROR FREE.

If within one year from date of purchase, the Hardware does not conform to the express warranty set forth above, 3M's sole obligation and User's sole remedy shall be, at 3M's option: 1) to repair or replace the non-conforming component; or, 2) refund the purchase price.

#### **LIMITATION OF LIABILITY**

UNLESS PROHIBITED BY LAW, 3M WILL NOT BE LIABLE TO USER OR OTHERS FOR ANY OTHER DIRECT, INDIRECT, CONSEQUENTIAL, INCIDENTAL OR SPECIAL DAMAGES INCLUDING, FOR EXAMPLE, LOST PROFITS, BUSINESS, INVESTMENTS, OR OPPORTUNITIES EVEN IF 3M HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. The parties agree that 3M's total cumulative liability to User for direct damages for all causes shall not exceed One Hundred Dollars, or the price paid for the Hardware, whichever is higher. Some states or countries may have laws which require liability rights different from those stated above. In such state or countries, the minimum required liability terms shall apply.

Within the US, please contact the 3M Healthcare Helpline 1-800-228-3957 to request service under this warranty. Outside of the US, please contact your local 3M office to request service.

## Operating the Clean-Trace Luminometer LX25

### **User Responsibility**

Users are responsible for familiarizing themselves with product instructions and information. When selecting a test method it is important to recognize that external factors such as sampling methods, testing protocols, sample preparation, handling and laboratory technique may influence results.

It is the user's responsibility in selecting any test method, environmental surface or medical device to evaluate a sufficient number of samples to satisfy the user that the chosen test method meets the user's criteria.

It is also the user's responsibility to determine that any test methods and results meet its customers' and suppliers' requirements.



#### Clean-Trace Luminometer LX25 Design and Components

- 1. Power On/Off button
- 2. Cursor control buttons
- 3. Touch screen
- 4. USB/Power port
- 5. ATP Test Chamber
- 6. Base
- 7. Kick Stand
- 8. Power cord and adapters

## **Battery Usage and Maintenance**

The Clean-Trace Luminometer LX25 has an internal rechargeable lithium ion battery.

#### Charging the battery

- Select and attach the charger adapter to the power cord that is appropriate for power in your country.
- Connect the power cord to the Clean-Trace Luminometer LX25.
- Connect the power cord to a power outlet.
- The battery becomes fully charged in approximately 3 hours using the power supply.
   If charging via PC connection, time to fully charge is approximately 5 hours.
- To monitor the charge status, turn on the Clean-Trace Luminometer LX25. A lightning bolt appears in the battery level indicator icon (Figure 1).

#### When the battery is charged

- Disconnect the power cord from the power outlet.
- Unplug the power cord from the Clean-Trace Luminometer LX25.



Figure 1

Figure 2

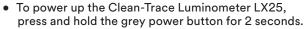
Using the battery level indicator

- The battery level indicator is located in the upper right corner of the screen.
- When a Clean-Trace Luminometer LX25 is on, the indicator shows the remaining battery level.
- In Figure 2, the indicator shows the battery is fully charged
- As the battery charge decreases, the blue segment of the indicator becomes smaller.
- When the battery level is less than 10%, the indicator becomes red, signifying the battery should be recharged.

#### Managing the battery

- During typical use the battery provides up to eight hours of charge capacity.
- As the battery ages, it will provide less than eight hours of charge capacity.
- The battery must be charged when the indicator is red, indicating less than 10% charge capacity
- The battery does not need to be fully discharged before recharging.
- When storing a Clean-Trace Luminometer LX25 for more than a month, the battery level should be at 50% or less charge. Do not store a Clean-Trace Luminometer LX25 with a fully discharged battery because the battery may lose the ability to be recharged.
- Battery replacement is recommended after two years of normal use or if the battery has been misused, or if the Clean-Trace Luminometer LX25 is overheating or its shape is distorted. Battery replacement is performed by 3M Health Care Service Center or authorized 3M Service Provider. See Care and Maintenance.

#### Power On/Off/Sleep Mode





 To power off the Clean-Trace Luminometer LX25, press and hold the grey power button for 2 seconds. Accept prompts to shut down Clean-Trace Luminometer LX25.



- You can force the Clean-Trace Luminometer LX25 to power off by holding the grey power button down for 20 seconds.
- The Clean-Trace Luminometer LX25 will automatically power itself off after 2 hours of inactivity or if the battery charge is 5% of remaining life. It is recommended to keep the device charging when not in use.
- The Clean-Trace Luminometer LX25 will go into 'Sleep Mode' after 1-30 minutes of inactivity.
  - To customize the time until sleep mode starts go to the 'Screen Timeout' screen which is found in the Settings menu.
  - To exit sleep mode, press the "Up" cursor control button.



- Sleep Mode vs. Power Off: The screen is blank for Sleep Mode and when the device is Powered Off.
  - When you encounter a device with a blank screen, first press the Up button, this will bring it out of Sleep Mode.
  - If the device does not respond to this, it is likely Powered Off. Hold the Power Button for 2 seconds to power on the device.

## Inserting a Clean-Trace ATP Test UXC or H2O into the Clean-Trace Luminometer LX25

- Press the rocker cap to open the test chamber (1).
- Insert an activated Clean-Trace ATP Test UXC or H2O (2).
- The Test handle should be visible at the top of the chamber (3).
- After the reading is complete, press the rocker cap to open the test chamber and remove the ATP Test UXC or H2O.



- If an ATP Test UXC or H2O remains in the Clean-Trace Luminometer LX25 chamber for more than 30 seconds, the Swab Sensor notifies with an audible tone.
- Keep the Clean-Trace Luminometer LX25 upright
  whenever a test device is in the chamber, to ensure
  accurate results and avoid spillage of reagents, which
  could damage the sensitive components of the instrument.
- If the Clean-Trace Luminometer LX25 is held at greater than 68 degrees from vertical when a test is in the chamber, a message notifies the user that the Clean-Trace Luminometer LX25 is in the incorrect position for testing and to use a more vertical position when testing.
  - Tap "OK" then hold the Clean-Trace Luminometer LX25 in a vertical position and repeat the measurement.

#### How to Perform a Quick Test

A quick test is performed under circumstances where results are not uploaded to the Quality Control Data Manager (e.g. training, demonstrations, no access to Quality Control Data Manager).

## To perform a Quick Test

- Power on the Clean-Trace Luminometer LX25.
- After successful completion of System Diagnostics this landing screen with appear:
- Log in is not required to perform a Quick Test.
- Tap "Quick Test"
- Follow the Clean-Trace ATP Test UXC or H2O Instructions for Use to collect the sample, activate the ATP Test and insert into the Clean-Trace Luminometer LX25.
- Clean-Trace ~ Luminometer LX25 Log In Quick Test
- Tap "Start" to take a measurement.
- Remove the ATP Test UXC or H2O after the measurement is complete.
- All results should be recorded.
  - Only the last 20 Quick Tests are saved on the Clean-Trace Luminometer LX25.
  - The results of a quick test are not saved to the Quality Control Data Manager.

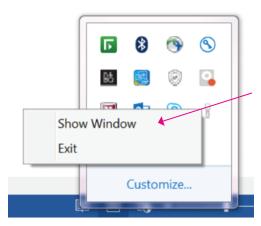
## Communicating with the 3M Quality Control Data Manger (QCDM)

Before the Clean-Trace Luminometer LX25 can be used with the Quality Control Data Manager (QCDM) it must first be synchronized to the facility's QCDM organization.

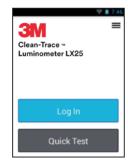
To register the Clean-Trace Luminometer LX25, the facility account must be linked to the facility's organization and the 3M™ Synchronization Manager Software installed on a workstation (desktop/laptop). Registration cannot be performed using the Clean-Trace Luminometer LX25 Wi-Fi function.

# Register a Clean-Trace Luminometer LX25 to an Organization on QCDM

1. Find the Synchronization Manager icon in system tray, right click on the icon and choose "Show window".



- 2. Power up the Clean-Trace Luminometer LX25 and launch the app if not already launched.
  - Follow the steps in the set-up menus for language, date, time and time zone.
  - b. Skip Wi-Fi set up.
  - c. Wait for diagnostics to complete.
  - d. When the landing screen appears STOP remain on landing screen DO NOT LOG IN.



- Using the USB cable provided, connect the Clean-Trace Luminometer LX25 to the workstation running the Synchronization Manager software.
- 4. After a short period, a red, spinning circle appears on the Clean-Trace Luminometer LX25 screen, indicating your Clean-Trace Luminometer LX25 is connected to the Synchronization Manager Software.



- 5. On the workstation, log into Synchronization Manager Software.
- Select the "Register" button on the workstation Synchronization Manager Software.



 Start the Synchronization on the workstation Synchronization Manger Software.



8. Wait for synchronization to complete.



- 9. Unplug the USB cord from the Clean-Trace Luminometer LX25.
- 10. The Clean-Trace Luminometer LX25 is now ready for use.

## **Routine Synchronization**

- 1. Power on Clean-Trace Luminometer LX25.
- 2. Wait for diagnostics to complete.

 When the landing page appears-STOP – remain on landing page – DO NOT LOG IN.



- Connect the Clean-Trace Luminometer LX25 to the workstation running the Synchronization Manager Software using the USB cable.
- After a short period, a red, spinning circle will appear on the Clean-Trace Luminometer LX25 indicating the Clean-Trace Luminometer LX25 is connected to the Synchronization Manager.



- 6. On the workstation, log into Synchronization Manager Software.
- Select the "Start Synchronization" button on the workstation Synchronization Manager Software.



 Start the Synchronization on the workstation Synchronization Manager Software.



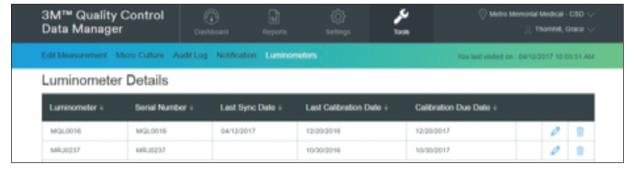
9. Wait for synchronization to complete.

#### **De-registration**

## How to Deregister a Clean-Trace Luminometer LX25

- 1. Log into facility organization on the QCDM website.
- 2. Click "Tools" from the ribbon at top of screen.
- 3. Click "Luminometers".

- 4. Find the Clean-Trace Luminometer LX25 with the correct serial number in list, click on the trash can icon.
- The Clean-Trace Luminometer LX25 will no longer be displayed in list and is now de-registered.



### Wi-Fi Set up

#### Wi-Fi Connection

Data is automatically uploaded to the QCDM in real-time using the Wi-Fi function on the Clean-Trace Luminometer LX25.

Before the Wi-Fi function can be used, the Clean-Trace Luminometer LX25 must first be registered to the QCDM using the USB cable connection to a workstation running the Synchronization Manager Software.

#### Set up Wi-Fi

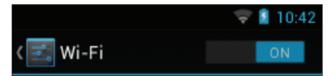
 Tap the "hamburger menu" in the upper right-hand corner of the Home screen.



- Tap "Settings"
- Tap "Wi-Fi Settings"



 Turn on Wi-Fi by sliding the indicator from "OFF" to read "ON"



- Select the appropriate Wi-Fi network and enter security credentials if required.
  - Security credentials are stored in the Clean-Trace Luminometer LX25.
  - Authentication takes place each time the Clean-Trace Luminometer LX25 is turned on and Wi-Fi is enabled.
- Tap "Done"
- Return to the "Settings" menu by tapping the Wi-Fi network icon in the upper left hand corner of the screen.
- Exit the "Settings" screen by tapping the < button in the upper left corner of the screen.

## Verifying Data Upload to QCDM

 When connected to Wi-Fi, test results will automatically be uploaded to QCDM. A "Link" icon will appear after successful upload. An unsuccessful upload will result in a triangle.



 If using the Synchronization Manager Software to upload results, refer to section on "Routine Synchronization of Results" in this document. All results will be marked with a triangle until LX25 results are synchronized and data is uploaded to the QCDM software.

### **Application Workflow**

Before access to the workflow screens is available, an organization hierarchy must be set up in QCDM, and the Clean-Trace Luminometer LX25 must be registered to a QCDM organization.

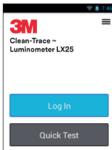
Workflows are application specific. There are applications available for assessing the cleanliness of flexible endoscopes, environmental surfaces and surgical instruments.

## **Starting the Audit**

- Power up the Clean-Trace Luminometer LX25.
- After power up the Clean-Trace Luminometer LX25 will run a device diagnostic.



 After the diagnostic is complete a landing screen appears.
 Tap "Log In"



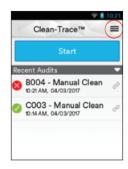
 If the organization is part of a multi-hospital set up, select desired organization from the drop-down menu then select user.



- Enter PIN
  - O An initial user and PIN can be found in the Welcome Letter emailed to the facility when the organization was first set up. A User name and PIN is established for each operator of the Clean-Trace Luminometer LX25. The User can change the assigned User and PIN the first time logging onto the Clean-Trace Luminometer LX25.



- Shows recent audits
- Use the arrow in the gray bar to toggle between a list of "Recent audits" and "Recent failed audits"



The 3M<sup>™</sup>Clean-Trace<sup>™</sup> Luminometer LX25 has a unique workflow for each application. Please choose the appropriate application and follow the screen prompts. All available application workflow are outlined below.

- 1. Flexible Endoscope Workflow
- 2. Environmental Surfaces Workflow
- 3. Surgical Instrument Workflow

## 1. Flexible Endoscope Workflow

 From the Home screen tap "Start" to begin new test or select a recent failed audit for retest



Select device type

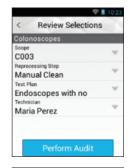


• Select Device. This is the serial number or other unique identifier.

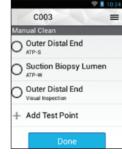


• Select "Reprocessing Step"

- Review selections
  - o Select technician.
  - o Can change device, reprocessing step and test plan
  - o Tap "Perform Audit"

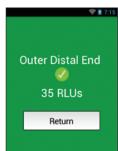


· Select test point

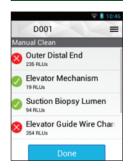


- Review selections
- Insert ATP Test
- Press "Begin Measurement" and wait until blue "Reading Result" screen disappears then press "Return"





 Repeat process until all test points have been tested. Press "Done".



#### 2. Environmental Surfaces Workflow

 From Home screen tap "Start" to begin new test or select a recent failed audit for retest



Select Area



Select Room



- Review Selections
  - Can change Room number, test plan
  - Select Housekeeper and Isolation room option
  - o Tap "Perform Audit"



• Choose test point



- Insert ATP Test UXC or H2O
- Press "Begin Measurement" and wait until blue "Reading Result" screen disappears then press "Return"



 Repeat process until all test points have been tested. Press "Done".



### 3. Surgical Instrument Workflow

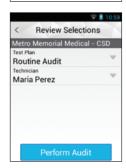
• From Home screen select "Start"



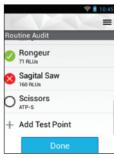
 From select "Test Plan" screen, select "Routine Audit"



 Review selections then select "Perform audit"



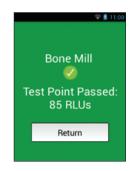
• Select instrument



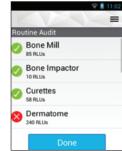
• Review selection



- Insert ATP Test UXC or H2O
- Press "Begin Measurement" and wait until blue "Reading Result" screen disappears then press "Return"



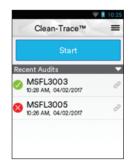
 Repeat process until all test points have been tested. Press "Done".



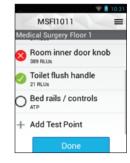
## **Performing a Retest**

To retest a failed test point:

 From the home screen, select the audit that requires retesting; marked with a red "X".



 Select the test point that requires retesting; marked with a red "X".



- Follow the prompts and select any additional test points if required.
- Complete the retest
- Select "Done"
- All retest data is recorded on the Clean-Trace Luminometer LX25 and in QCDM.

#### **Administrative Functions**

## **Accessing administrative functions**

To access administrative functions, tap the "hamburger" menu at the top, right-hand corner of the Home screen.

- Settings allow access to administrative functions
- Force Sync initiates a synchronization between the Clean-Trace Luminometer LX25 and the Quality Control Data Manager software.
- Quick Test see instructions located under "Operating the Clean-Trace Luminometer LX25"
- System Diagnostics tap to initiate device diagnostic test.



## Settings menu

- Settings Menu Functions (detail)
  - Wi-Fi Settings turn Wi-Fi on/ off, set up network
  - Server settings select or change server connection
  - O Screen brightness increase or decrease screen brightness
  - Screen timeout choose length of time before screen goes to sleep
  - o Date set current date
  - o Time set current time
  - o Time Zone choose time zone
  - o Language choose language
  - About lists app, firmware, service versions, LX25 serial number and calibration due date
  - Restart restarts Clean-Trace Luminometer LX25



## Troubleshooting

This section is intended to help solve problems that may be encountered when using the Clean-Trace Luminometer LX25. Contact 3M or your local 3M distributor for more information.

Problem	Probable Cause	Remedy
Diagnostic Check Failed	Chamber Door is open	Close the chamber door and retry the Diagnostic Check
	Operating Clean-Trace Luminometer LX25 out of correct temperature range	Operate the Clean-Trace Luminometer LX25 between 5°C and 40°C. Retry the Diagnostic Check.
	ATP Test UXC or H2O left in ATP test chamber	Remove the ATP Test UXC or H2O from the test chamber and retry the Diagnostic Check.
		If the Diagnostic Check fails after a retry, contact 3M or your local distributor.
Battery Low	Battery needs to be charged	Connect the power cord cable to the Clean-Trace Luminometer LX25 and connect the cord to a power outlet to recharge the battery.
Chamber Door Open	Chamber door was open while attempting to start the reading process	Close the chamber door after inserting a Clean-Trace ATP Test UXC or H2O and before starting the reading process.
No Swab Detected		Insert a Clean-Trace ATP Test UXC or H2O.
Instrument temperature is not within normal operating range	Instrument temperature is >40°C or <5°C	Use the Clean-Trace Luminometer LX25 at ambient temperature between 5°C and 40°C. If the problem persists, contact 3M or your local distributor.
Swab Left in Chamber		The Clean-Trace Luminometer LX25 has a sensor to determine if a Clean-Trace ATP Test UXC or H2O has been left in the chamber for more than 30 seconds following the completion of a measurement. If this situation is detected, the instrument will display a "Swab Left In Chamber" error message on the screen and provide an audible beep to remind the user to remove the Test following the measurement.
No Display	Battery fully discharged	Recharge the battery.
	Clean-Trace Luminometer LX25 is in Sleep Mode or has been turned off.	Press the "Up" button on the cursor control to wake from sleep mode. If no response, press the "Power" button for 3 seconds to turn on the Clean-Trace Luminometer LX25.
	Instrument malfunction	Contact 3M or your local distributor.
Results Lower than Expected	Sample / reagent problem	Check to ensure correct sample technique was used and ATP Test UXC or H2O activation was followed according to Clean-Trace ATP Test instructions for use. Verify with known positive samples such as a 3M Positive Control Test.
	Instrument malfunction	Contact 3M or your local distributor.
Results Higher than Expected	Direct sunlight or static discharge can cause ATP Test to phosphoresce and cause high readings	After exposure to sunlight or static discharge an immediate repeat reading is 50% of the first reading, if this is the cause of the higher than expected results. Subsequent readings become incrementally lower and finally return to normal.
		Avoid exposing ATP Test UXC or H2O to direct sunlight or static discharge.
Other Errors		Turn off the Clean-Trace Luminometer LX25 and power back on again.
		2. Retry ATP Test UXC or H2O using the Clean-Trace Luminometer LX25.
		3. If the problem persists, contact 3M or your local distributor.

#### **Cleaning and Decontamination**

Clean and low-level disinfect the Clean-Trace Luminometer LX25 immediately if any spills occur or you suspect contamination or after use in a room under contact precautions.

If any liquid is spilled inside the ATP Test chamber, do NOT attempt to clean inside the test chamber itself. Contact your 3M Health Care Service Center or local representative immediately.

Clean and disinfect the external surfaces of the Clean-Trace Luminometer LX25 once per day at a minimum.

Cleaning and Disinfecting the External Surfaces:

- Power down the Clean-Trace Luminometer LX25 and disconnect the USB/Power cable.
- Using a disposable towel lightly dampened with disinfectant, gently wipe the outer surfaces of the Clean-Trace Luminometer LX25. Make sure the towel used is just damp not dripping.
- 3. When cleaning the Clean-Trace Luminometer LX25 avoid the USB cable connection on the side of the Clean-Trace Luminometer LX25.
- 4. Rinse disinfectant from Clean-Trace Luminometer LX25 by repeating the procedure (2-3) using another disposable towel slightly dampened with distilled or deionized water.
- 5. Allow Clean-Trace Luminometer LX25 to dry for at least 1 hour.
- Do NOT reconnect the USB/Power cable until the Clean-Trace Luminometer LX25 has been allowed to dry.

The following disinfectants may be used to clean and disinfect the Clean-Trace Luminometer LX25.

- Sodium Hypochlorite (chlorine bleach) (up to .8% concentrations)
- Quaternary Ammonium Compounds (contains ammonium chlorides, Isopropyl Alcohol, and/or Ethanol)

#### **Contact Us**

For questions or additional information on the 3M™ Clean-Trace ™ Luminometer LX25 call the Clean-Trace Helpline at 1-800-228-3957.

Made in U.S.A. for

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