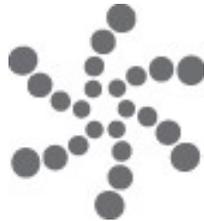


# nanōmix eLab<sup>®</sup> Analyzer

## USER MANUAL



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## **Introduction**

This User Manual contains instructions for the Nanomix eLab<sup>®</sup> Analyzer test system. To run specific tests, please refer to the product-specific documentation accompanying the assay cartridges. The analyzer and assay cartridges are sold separately.

## **Overview**

The Nanomix eLab<sup>®</sup> system consists of a handheld analyzer and an integrated, self-contained assay cartridge that performs a biochemical assay. The cartridge performs sample processing and generates a signal for detection by the analyzer to produce qualitative or quantitative test results, depending on the type of assay cartridge used. The analyzer controls fluidic and electrical elements within the cartridge, measures the electronic signals generated on the cartridge, and controls the temperature of the cartridge.

## **Parts and Accessories**

- Nanomix eLab Analyzer
- Analyzer Protection Sleeve (installed over the unit)
- Medical Power Adapter/Charger
- Medical Grade AC Power Cord
- USB Connector Cord (3ft Mini USB)

**NOTE:** All components listed above are included in the Nanomix eLab<sup>®</sup> analyzer package. Compatible assay cartridges are purchased and packaged separately.

## **Intended Use**

The Nanomix eLab<sup>®</sup> system is an in vitro diagnostic test system for the qualitative or quantitative measurement of analytes in patient specimens. The eLab system is for use in clinical laboratory or point of care (POC) settings.

## **Sample Collection**

Please refer to the product-specific information included with Nanomix eLab<sup>®</sup> cartridges for information on the sample collection for the test.

## **Compatible Assay Cartridges**

The Nanomix eLab<sup>®</sup> analyzer is designed to be used with Nanomix eLab cartridges only. Please refer to the product-specific information included with Nanomix eLab cartridges to confirm compatibility.

# **Warnings, Precautions and Limitations**

## **IMPORTANT SAFETY INSTRUCTIONS**

- DANGER – Misuse of equipment can cause electrocution, burns, fire and other HAZARDS.
- Basic safety precautions should always be taken, including all those listed below.

If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

## **READ THIS BEFORE USING THE EQUIPMENT**

- Do not place the equipment in liquid, nor put it where it could fall into liquid. If the equipment becomes wet, unplug it before touching. Water or fluids may damage the analyzer and may cause an electrical shock.
- Use the equipment only for the purpose described in the instructions for use.
- Do not use accessories which are not supplied by the manufacturer. Using the analyzer with unauthorized accessories may damage the device and void the warranty.
- Plug the equipment into an AC electrical supply outlet that is properly grounded. Use medical grade AC power cord only.
- Do not use the equipment if it is not working properly, or if there is any apparent or suspected damage including:
  - damage to the flexible supply cord or its plug;
  - damage caused by dropping the equipment; or
  - damage caused by dropping the equipment into water or splashing water onto it.
- The system should be periodically inspected for damage.
- Do not let the equipment or its flexible cord come into contact with surfaces that are too hot to touch.
- The equipment is not and cannot be sterilized. Do not bring or use the analyzer in a surgical environment requiring sterilized devices.
- Do not block air openings nor place equipment on a soft surface which might block them, and keep air openings free from lint, hair, fluff, etc.
- Do not place anything on top of the equipment.
- Unless specifically instructed to do so by the instructions for use, do not drop or put anything into any opening in the equipment
- There is no preventative maintenance or calibration performed on the eLab analyzer.
- Do not attempt to repair damaged or non-working components, including analyzer battery. Replacing the battery may cause excessive temperatures, fire, or explosion. There are no user or field serviceable components. Contact Nanomix customer support for servicing and repair.
- Any changes or modifications to the equipment not expressly approved by Nanomix may damage the system, may result in bodily harm, and will void the warranty.
- Operate and store the equipment according to the operational and storage requirements found in this User Manual.
- Never insert a cartridge that you suspect might be damaged into the analyzer. Discard any cartridges that are damaged.
- Keep the equipment out of the reach of children.
- Unauthorized modification of the system could result in a hazard.

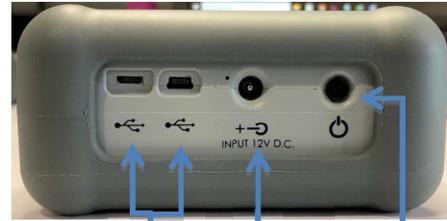
- The eLab analyzer should only be stored in compliance with specified storage environment conditions and operated within specified operational environment conditions.
- User should avoid staring directly into the LED beam of the barcode scanner.
- The eLab analyzer should not be disposed of in the regular waste system due to the internal lithium battery and potential environmental hazard. Follow local regulations for disposal and recycling of electronics components and batteries.
- Only safety-approved external data processing equipment may be connected to the device USB ports.
- Detailed information on each test is contained in the product-specific documentation, provided with the test kit. Some substances in the patient's sample and/or conditions may interfere with cartridge tests.
- **Notice of serious incident:** Any serious incident that has occurred in relation to the eLab analyzer device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.
- KEEP THESE INSTRUCTIONS

## **Power**

The eLab analyzer contains a rechargeable Lithium-ion polymer battery pack. The AC/DC power adapter provided with the eLab analyzer connects to the power supply port. The analyzer can be operated on battery or while connected to wall power. The analyzer can be connected or disconnected from wall power at any time with no effect on operation, assuming the battery is sufficiently charged to provide power.

Recharge time to 100% from a completely depleted battery is approximately 7 hours using the AC/DC power adapter.

To avoid battery depletion, users may keep and operate the eLab analyzer plugged into an electrical outlet. If using the eLab analyzer on battery power, check the battery capacity and recharge periodically as necessary.



### ***Battery Specification:***

Type: Lithium-ion polymer battery pack  
Nominal voltage: 3.7V  
Rated capacity: 9000mAh

### ***Power Adapter Specification (WSA512M):***

Power input: 100-240 VAC, 50-60 Hz  
Power output: 12 VDC, 2.5 A

## **Turning the Analyzer On and Off**

The Power button is located on the top of the analyzer.

### ***Power On:***

- To power-on the eLab analyzer, push the power button.
- The startup procedure may take approximately 25 seconds. During this time the display may flash on and off. When the startup procedure has completed the log-in screen will be shown.

### ***Power Off:***

 To power-off the eLab analyzer, tap the shutdown button on the home screen. You will be prompted to confirm the shutdown.

OR Push and hold the power button for 3 seconds.  
The analyzer will beep three times indicating that it is starting the shutdown sequence.

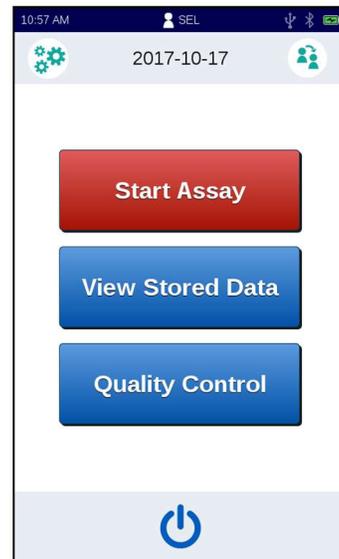
### ***Emergency forced shut down:***

- If the analyzer does not respond to either of the standard shutdown methods, push and hold the power button for 15 seconds to force a hardware shutdown. Because this does not allow a normal software shutdown process, in some cases, this may cause the unit to display an error state on restart. Cycle the unit off and on again to clear the problem.

## Navigation

The eLab analyzer has a user-friendly touchscreen that provides the user with step-by-step instructions. Navigation is simple with easy to recognize icons and screens that feature vertically scrolling lists that can be controlled by swiping the screen in the direction desired.

Icon	Description	Navigation / Action
	Home button	Return to Home screen
	Shutdown	Power off eLab analyzer
	Settings	Goes to Settings menu
	Switch user	Logs current user out and returns to Login screen
	Previous and next	Go back or forward one screen in operational sequence
	Back and forward	Go back and forth between linked screens
	Expand and collapse	Expand to view details, or collapse to hide details
	Scan mode	Switch to barcode scan entry mode
	Keyboard mode	Switch to on screen keyboard entry mode
	Filter/Search	Define a search filter for a displayed list
	Print	Print results to attached printer
	Send	Send results to Bluetooth or USB connection
	Send to USB	Send results to USB connected device
	Send to Bluetooth	Send results to Bluetooth paired device
	Pair Bluetooth	Initiate Bluetooth pairing



*Home Screen*

## Status Bar

The eLab analyzer status bar displays icons for easy reference to time, user, and battery charge as well as printer, Bluetooth and USB connectivity.

Icon	Description
	<p><b>Printer</b></p> <p>Indicates printer connection status.</p> <ul style="list-style-type: none"><li>• Visible but translucent if enabled but not connected.</li><li>• Solid white if enabled and connected.</li><li>• Not shown if printing is not enabled.</li></ul>
	<p><b>USB</b></p> <p>Indicates USB data sharing connection status.</p> <ul style="list-style-type: none"><li>• Visible but translucent if enabled but not connected.</li><li>• Solid white if enabled and connected.</li><li>• Not shown if USB data sharing is not enabled.</li></ul>
	<p><b>Bluetooth</b></p> <p>Indicates Bluetooth data sharing connection status.</p> <ul style="list-style-type: none"><li>• Visible but translucent if enabled but not paired.</li><li>• Solid white if enabled and paired.</li><li>• Not shown if Bluetooth data sharing is not enabled.</li></ul>
 	<p><b>Battery</b></p> <p>Shows proportionate battery level. Always visible.</p> <ul style="list-style-type: none"><li>• Charge bar is normally green, turns red if less than 15% charged.</li><li>• Outline is normally black, turns red if less than 15% charged.</li><li>• When charging, a lightning bolt is shown in the middle of the battery icon.</li></ul>

# Operations

## Start Up

- When the eLab analyzer is turned on, it will run through a boot-up sequence and a self-check.
- When the analyzer is ready for use, you will be prompted to enter a User Name.
- Use the keypad or scanner to enter a pre-configured User Name, and then tap the Next arrow.
- If the User Name is not recognized, the prompt will turn red and you will remain on the screen until a valid User Name has been entered.
- If the User Name is recognized, the Passcode screen will be shown.
- Enter your passcode and tap the Next arrow.
- If the passcode is correct, the Home screen will be shown.

## Test Procedure

**IMPORTANT:** Do not insert the cartridge into the analyzer until prompted to do so by the eLab screen.

The eLab Test Procedure should be conducted with the use of personal protective equipment.

Tap 'Start Assay' on the Home screen and follow the on-screen prompts as described in the following steps:

1. Enter a Record ID using the on-screen keyboard, and then tap the Next arrow. The barcode scanner can be used if the Record ID is available in a linear barcode format. The Record ID may not be required depending on eLab configuration selections.

**IMPORTANT:** To ensure patient privacy, do not use patient identifying information in the Record ID.

2. Scan the cartridge lot barcode.



**CAUTION:** Do not stare into the LED of the scanner.

Scanner window location



The cartridge lot barcode is located on the label of the cartridge pack.

To scan the barcode, position the barcode parallel to the eLab analyzer approximately 3-4 inches away from the scanner window so that the barcode location is illuminated by the red LED line.

When the cartridge barcode is successfully scanned, the analyzer will beep and the cartridge lot number (LXXXXXX) will appear in the text entry field. Tap the Next arrow to proceed.

**LOT** LN150500

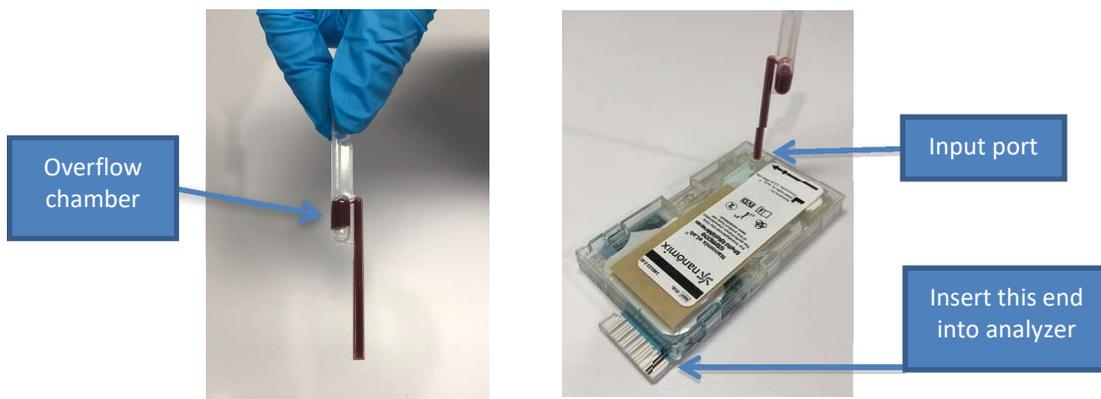
Tip: You can also use the on-screen keyboard to enter the cartridge lot number. The cartridge lot number is the string starting with 'L' shown next to the 'LOT' symbol at the top of the label.

3. Open the cartridge pack and remove the cartridge and transfer pipette.
4. Load the sample into the cartridge using the pipette provided in the cartridge pack:
  - Squeeze the top bulb of the pipette firmly before inserting into the vacutainer.
  - Slowly release pressure on bulb to fill until sample spills into the overflow chamber.
  - Insert pipette into the cartridge input port. Squeeze bulb with steady pressure to transfer sample to cartridge.

**IMPORTANT:** To avoid pulling the sample back out of cartridge, do not release pressure on the bulb until after you remove the tip from the cartridge input port.

**IMPORTANT:** Protective gloves should be worn by the operator to avoid contact of biological substances with skin surfaces. The eLab touch screen can be operated with surgical and nitrile gloves.

**DO NOT** re-use the pipette. Dispose used pipette as biological waste.



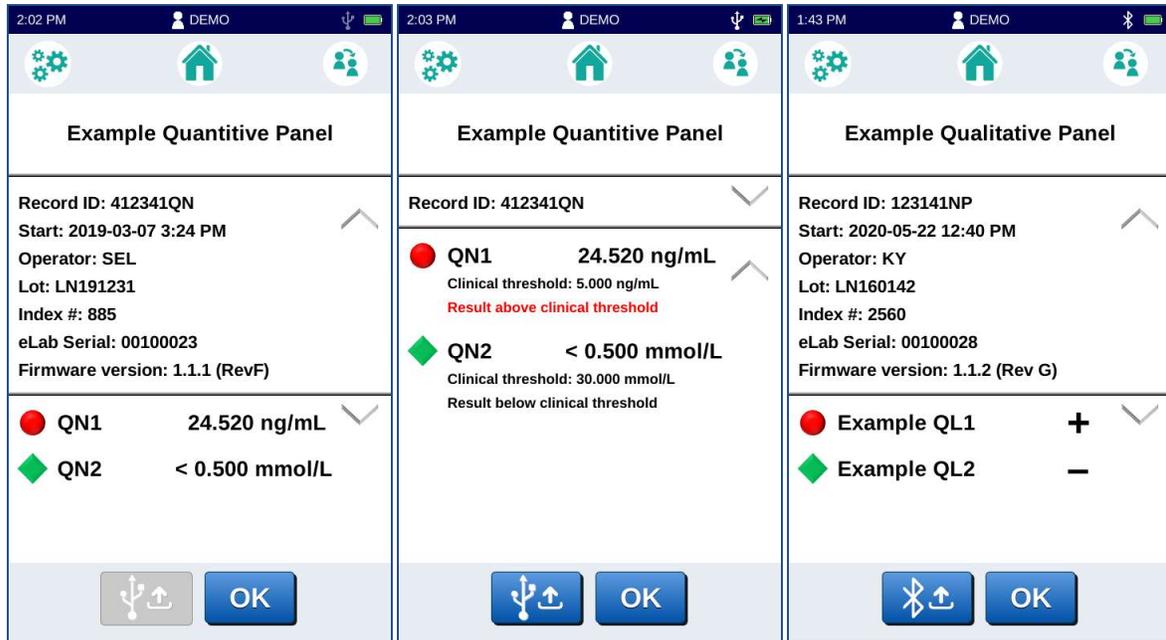
**NOTE:** Do not turn the cartridge upside down or shake after sample is inserted.

5. Insert cartridge into the eLab analyzer until it clicks into place.
6. The analyzer will detect the cartridge insertion and display a confirmation screen containing:
  - Record ID
  - Lot
7. Tap 'Yes' on the touch screen to run the assay.
 

**IMPORTANT:** Insert the cartridge and start the test immediately after transferring the sample to the cartridge.
8. During the test, the time remaining will be displayed and updated on the analyzer screen.
9. The analyzer can be moved if needed during the assay process. Motion and vibration do not affect assay performance.
10. When the test is complete, the analyzer will beep three times, and the result will be displayed on the screen. The result is automatically stored on the analyzer's internal SD card and can be accessed through 'View Stored Data' on the Home screen.
11. Remove the cartridge and follow proper disposal procedures.
12. Tap the OK button or the Home icon to go back to the Home screen.

## Test Results Display

- Test results will appear on the screen as soon as the analyzer completes the assay. Refer to the product-specific information included with the cartridge for details on the assay results for the cartridge used.
- The Expand and Collapse arrows can be used to see more or less information.



- If highlighting has been enabled using Configuration Manager, a green or red symbol will be shown next to the analyte name:

◆	Result is within defined limits
●	Result is outside defined limits

- Other test result information:

Record ID	Record identifier as entered on screen when assay started
Start	Date and time of assay start
Operator	User logged in at the time of the assay
Lot	Cartridge lot number
Sample Type	Selected sample type, or "N/A" if not applicable to this assay type
Index #	Index number of this test on the specific analyzer
eLab Serial	Serial number of the eLab analyzer
Firmware version	Firmware version at the time of the assay

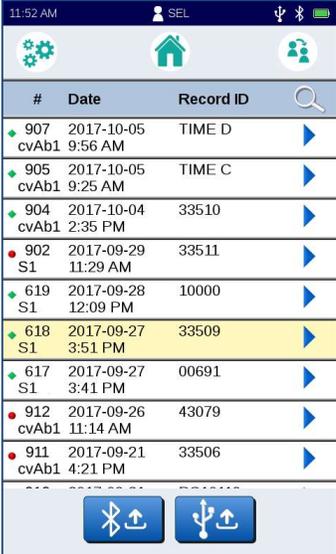
- Test results can be shared through a Bluetooth or USB connection if enabled and connected. If sharing is enabled but no device is connected, the sharing button will be shown disabled, as in the left image above.
- Test results can be printed if a USB printer has been enabled and connected.
- Tap 'OK' when done. You will be prompted to remove the cartridge (if you have not already done so) then returned to the Home screen.

## Viewing Stored Results

- Tap 'View Stored Data' on the Home screen main menu.
- Results are listed with the most recent results at the top of the list.

Flick the list up or down to see more records.

- Tap the blue Forward arrow next to the test to see the test record details.
  - If Bluetooth or USB data transfer has been enabled, the displayed record can be sent from the details screen.
  - If a printer is configured, the record can be printed from the details screen.
- Tap the Home icon to go back to the Home screen.
- If Bluetooth or USB data transfer has been enabled, an associated send button will appear at the bottom of the list.



#	Date	Record ID	
907 cvAb1	2017-10-05 9:56 AM	TIME D	▶
905 cvAb1	2017-10-05 9:25 AM	TIME C	▶
904 cvAb1	2017-10-04 2:35 PM	33510	▶
902 S1	2017-09-29 11:29 AM	33511	▶
619 S1	2017-09-28 12:09 PM	10000	▶
618 S1	2017-09-27 3:51 PM	33509	▶
617 S1	2017-09-27 3:41 PM	00691	▶
912 cvAb1	2017-09-26 11:14 AM	43079	▶
911 cvAb1	2017-09-21 4:21 PM	33506	▶

**NOTE:** All records in the current list will be sent. You can define a filter to limit the list to a specified subset before sending.

## Defining Filters in View Stored Results

- Tap the Filter / Search magnifying glass icon in the list header bar.
- Define the filter by tapping the Forward button on the desired parameter and selecting or entering the associated value. Tap 'OK' to apply the defined filters to the list.
- The filtered list will be indicated by a green header.
- To clear the filters, tap the filter icon and use the 'Clear Filter' button.

## Quality Control

- Refer to the product-specific documentation provided with the cartridges for information on appropriate control samples.
- Select 'Quality Control' from the Home screen to reach the Quality Control main menu.
- Select 'Start Control Assay' and follow the prompts to run a control sample.
- Select 'View Stored Results' to view stored control results.

**NOTE:** Test results for controls and regular assays draw from one set of index numbers even though the results for controls and regular assays are stored in two separate lists.

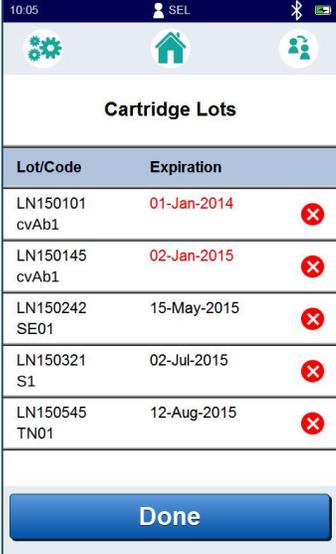


# Cartridge Lot Management

- The eLab analyzer must have a cartridge lot file for each lot of cartridges to be run on the analyzer.
- Information for cartridge lot files currently on the analyzer can be viewed in 'Manage Cartridge Lots'. The list is sorted by soonest expiration date (top) to the latest expiration date. Lots that are expired are shown with red expiration date.
- Lot files can be deleted by selecting the red (X) icon next to the lot.
- New cartridge lot files can be transferred to the eLab analyzer using the eLab Lot Manager application installed on a host computer.

OR

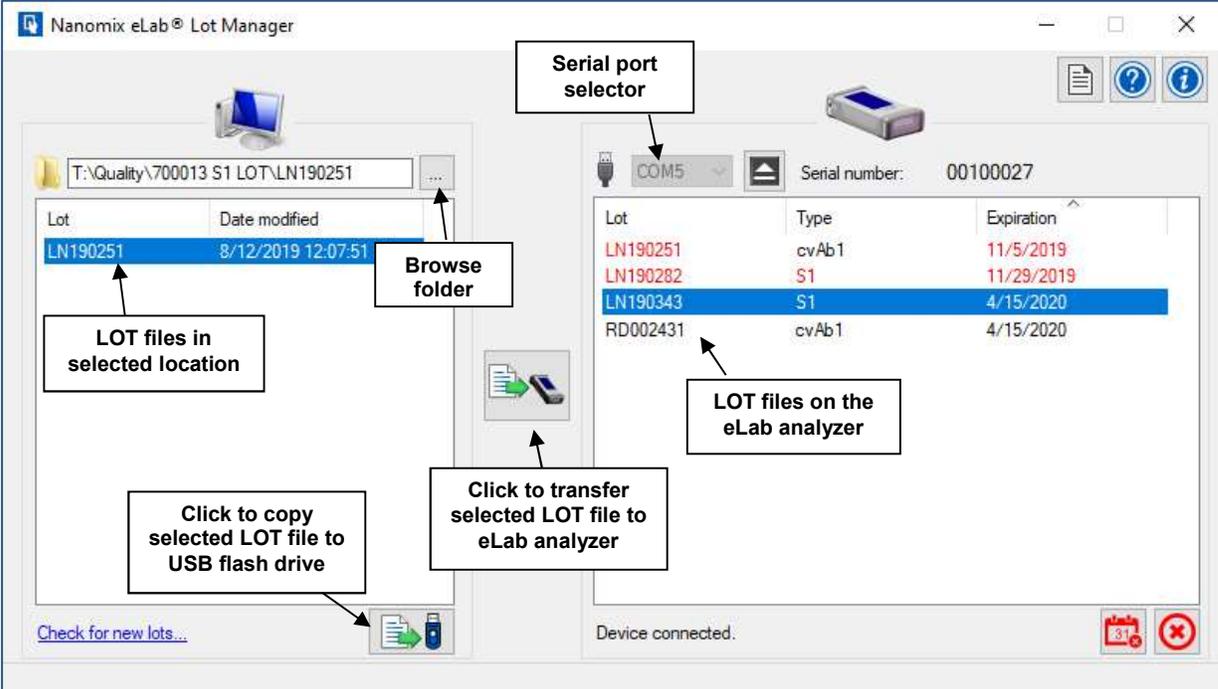
- A cartridge lot file can also be installed by attaching a pre-configured USB flash drive to the analyzer micro-USB serial port (an adapter may be required). You will be prompted to confirm installation of the lot file.



Lot/Code	Expiration	
LN150101 cvAb1	01-Jan-2014	X
LN150145 cvAb1	02-Jan-2015	X
LN150242 SE01	15-May-2015	X
LN150321 S1	02-Jul-2015	X
LN150545 TN01	12-Aug-2015	X

## Connecting to eLab Lot Manager

1. Open the eLab Lot Manager Application on the host computer.
2. Connect the eLab analyzer to a USB serial port on the host computer using the provided USB cable.
3. If prompted, select the correct serial port and click the 'Connect' button.
4. The connected eLab serial number will be displayed and a list of the lot files on the device will be displayed in the window. The list can be sorted by clicking on the column header.
5. Lot files can be deleted from the eLab analyzer through Lot Manager as well. Select the lot, then click the delete (X) button below the list. To delete all expired lots use the delete expired button (calendar with an X).



Serial port selector

Browse folder

LOT files in selected location

Click to copy selected LOT file to USB flash drive

Click to transfer selected LOT file to eLab analyzer

LOT files on the eLab analyzer

Lot	Type	Expiration
LN190251	cvAb1	11/5/2019
LN190282	S1	11/29/2019
LN190343	S1	4/15/2020
RD002431	cvAb1	4/15/2020

## ***Adding Lot Files to the eLab Analyzer with Lot Manager***

1. Use the browse folder button to select the folder where the lot files are saved.  
**Tip:** You can also type in the folder name with auto-complete assistance.
2. Select the lot file from the displayed list of lot files (files with the .LOT extension).
3. Click the Transfer button.
4. Confirm the transfer of the lot file.
5. The lot file will be transferred, then appear in the analyzer lot list.
6. When you are finished downloading lot files, click the eject button next to the serial port selector to close the connection and allow normal operation to resume on the eLab analyzer.

## ***Using a USB Flash Drive for Lot File Installation***

If it is not convenient to connect the analyzer to a PC in order to install a lot file, you can use Lot Manager to save the lot file to a USB flash drive, and then attach the USB flash drive to the analyzer to install the lot file.

1. Plug in a USB flash drive to the PC.
2. Run Lot Manager and select the lot file from the list of lot files on the PC.
3. Click the Save to USB button under the list.
4. Confirm the USB flash drive in the pop-up window and click OK. Note that only one lot file can be loaded on the flash drive for automatic installation. If a prior lot file is found on the drive, it will be deleted.
5. Detach the USB flash drive from the PC, and attach it to the micro (not mini) USB port of the analyzer. An adapter can be used to convert from standard to micro USB.
6. The analyzer will recognize that a USB flash drive has been attached and look for a lot file. If a lot file is found, the lot number will be shown on screen for you to confirm installation.

## ***Getting Cartridge Lot Files***

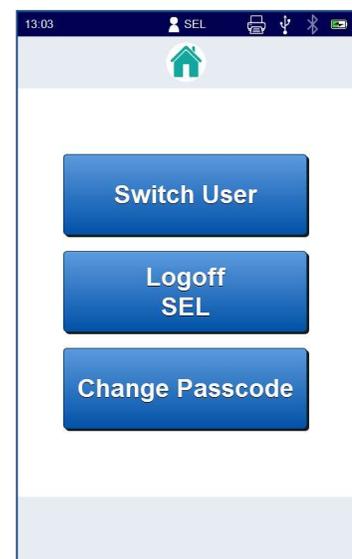
Cartridge lot files may be downloaded from the support page at [www.nano.com](http://www.nano.com) with a valid login. Click the [Check for new lots...](#) hyperlink in Lot Manager to open the support login page in an Internet browser window.

## **Switch User, Log-off and Change Password**

Tap the Switch User icon to change which user is logged in, log off or change your passcode.

- To switch user, select the 'Switch User' button. The current operator will be logged-off and the screen will display the Log-in screen.
- To log-off, select the 'Logoff' button.
- To change passcode, select 'Change Passcode'. Follow the screen prompts to:
  - Enter current passcode
  - Enter new passcode (minimum 4 digits)
  - Confirm new passcode

**NOTE:** If the current user has administrator access, a passcode is required (passcode cannot be disabled for administrators).



## **Cleaning and Disinfecting**

The eLab analyzer should be wiped with 10% bleach solution, then wiped dry with a clean cloth.

**NOTE:** The eLab analyzer cannot be submerged in liquid.

## **Errors and Troubleshooting**

The eLab analyzer will display an error screen with the warning triangle shown here when an error occurs. The following actions may be taken when the error codes are displayed.



<b>Error Code</b>	<b>Troubleshooting Action</b>
258 286 513 771 260 287 515 772 272 290 520 773 275 291 581 774 277 294 584 851 278 295 609 852 280 296 610 1031 282 297 611 283 298 768 284 299 769 285 770	Shut down eLab analyzer. After the analyzer is fully powered down, wait 10 seconds and restart. When analyzer is ready, try another cartridge.
263 264	Plug analyzer in to wall power. These warning codes indicate that the battery charge is getting low.
512 531 539 625 514 534 577 641 521 536 578 522 537 579 530 538 580	Try another cartridge
640	If sample is a control material, confirm assay is run through Quality Control menu. Otherwise, try another cartridge.
517 524 518 535	Try another cartridge, with extra attention to sample load technique
593 594	Try another cartridge. If problem persists, contact support.
257 265 853 259 292 1025 261 293 1026 262 519	Contact support
267 289 562 849 288 561 848 850	Confirm assay module and cartridge lot installed properly, and try again. If problem persists, contact support.
1024	Remove cartridge and try again.
1028	Indicates a corrupted file. Reinstall firmware using Configuration Manager.
1029	Indicates a corrupted file. Reinstall lot code. If problem persists, reinstall assay module using Configuration Manager.
1030	Indicates a corrupted file. Reinstall assay module using Configuration Manager.

For error codes not listed above or for further assistance, please login to the support page at [www.nano.com](http://www.nano.com).

## Settings

To access settings on the eLab analyzer, tap the Settings icon.

<b>About</b>	Select the Forward arrow next to 'About' to view the About screen.
<b>Date &amp; Time</b>	Select the Forward arrow next to 'Date & Time' to modify: <ul style="list-style-type: none"><li>▪ Current Date</li><li>▪ Current Time</li><li>▪ Time Zone</li><li>▪ Date Format</li><li>▪ Time Format</li></ul>
<b>USB Printer</b>	On/Off switch enables or disables the USB Printer function. Select the Forward arrow next to 'USB Printer' to set up printer function and automatic printing.
<b>USB Data Sharing</b>	On/Off switch enables or disables the USB Data Sharing. Select the Forward arrow next to 'USB Data Sharing' to set up automatic sharing, send buttons (where USB data sharing will be enabled) and data format.  USB data can be transferred as simple text or XML. Refer to document 140102 Nanomix eLab Analyzer Data Sharing for more details. This document can be downloaded from the support page at nano.com with a valid login.
<b>Bluetooth Data Sharing</b>	On/Off switch enables or disables the Bluetooth Data Sharing. Select the Forward arrow next to 'Bluetooth Data Sharing' to set up automatic sharing, send buttons (where Bluetooth data sharing will be enabled) and data format.  Bluetooth data can be transferred as simple text or XML. Refer to document 140102 Nanomix eLab Analyzer Data Sharing for more details. This document can be downloaded from the support page at nano.com with a valid login.
<b>Bluetooth Pairing</b>	Bluetooth Pairing becomes enabled when Bluetooth Data Sharing is enabled. Current pairing will be displayed. Select the Forward arrow next to 'Bluetooth Pairing' to add, change or delete pairing to a Bluetooth enabled device running a compatible application.  Refer to document 140102 Nanomix eLab Analyzer Data Sharing for more details. This document can be downloaded from the support page at nano.com with a valid login.
<b>Language</b>	Select the Forward arrow next to 'Language' to select language and decimal separator format.
<b>Power Management</b>	Select the Forward arrow next to 'Power Management' to select inactivity time before auto power off.
<b>Self Test</b>	Select the Forward arrow next to 'Self Test' to run a device self test.

Additional custom settings for the analyzer user interface are set using the Configuration Manager accessory application.

## User Access to Settings

Access to Settings is limited according to User Category.

Setting	User Category			
	Administrators	Power Users	Operators	Basic Users
About	Yes	Yes	Yes	No <sup>1</sup>
Date & Time	Yes	Yes	No	No
USB Printer	Yes	Yes	Extra Option <sup>2</sup>	No
USB Data Sharing	Yes	Yes	No	No
Bluetooth Data Sharing	Yes	Yes	No	No
Bluetooth Pairing	Yes	Yes	Extra Option <sup>2</sup>	No
Language	Yes	No	No	No
Power Management	Yes	No	No	No
Self Test	Yes	Yes	No	No

### NOTES

- 1 Settings not available for Basic Users
- 2 Settings defined in Configuration Manager define whether these screens are enabled for Operator

## Administration and Configuration

The eLab analyzer can be configured using the Nanomix eLab Configuration Manager application running on a host computer.

Configuration Manager communicates to the eLab analyzer over a USB serial cable connection. To connect to the host computer, the analyzer must be powered on.

When Configuration Manager connects, the user will be locked out of other device operations. When the configuration session is complete, the analyzer returns to normal operation with the new settings in effect.

The Abort button may be used to abort the connection in case of failure. It will reboot the analyzer and return to normal operation.

### Configuration Manager functions:

- Adding and deleting users
- Defining global configuration settings
- Updating cartridge configurations
- Updating firmware

The help button on the main Configuration Manager screen displays online help, explaining all functions.



## **Technical Specifications**

<b>Size</b>	
<b>eLab analyzer (with sleeve)</b>	4.7 x 8.7 x 2.3 in (12 x 22 x 6 cm)
<b>Charger</b>	3.4 x 2.7 x 2.0 in (8.6 x 7 x 5 cm)

<b>Weight</b>	
<b>eLab analyzer (with sleeve)</b>	2.8 lbs. (1.3 kg)
<b>Charger</b>	0.5 lbs. (0.2 kg)

<b>Operational Requirements</b>	
<b>Temperature</b>	10-35°C
<b>Humidity</b>	10 to 80% RH
<b>Atmospheric Pressure</b>	101 kPa to 69.7 kPa

<b>Storage Requirements</b>	
<b>Temperature</b>	0-50°C
<b>Humidity</b>	10 to 90% RH
<b>Atmospheric Pressure</b>	101 kPa to 69.7 kPa

**NOTE:** The eLab analyzer must be stored per the storage requirements above while not in use to maintain the integrity of the device. The eLab analyzer must be used in conditions per the operational requirements above to ensure proper device function and accurate results.

## Symbol Definition

<b>Symbol</b>	<b>Meaning</b>
	Consult User Manual
	Catalog/model number
	Serial number
	For in-vitro diagnostic use only
	Lot code
	Manufacturer
	Date of Manufacture
	CE Mark
	Expiration date
	Temperature limitation: Store at 2 to 8°C
	Temperature limitation: Operate at 10 to 35°C
	Humidity limitation: Operate at 10 to 80% relative humidity (RH), non-condensing
	Atmospheric pressure: Operate at 69.7kPa to 101kPa
	Non-ionizing electromagnetic radiation
	Hazardous Waste Dispose of in accordance with local regulations
	Direct Current
	Biological Hazard

## **References**

1. IEC 61010-1: 2017, Ed 3.1, Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements
2. IEC 61010-2: Safety requirements for electrical equipment for measurement, control and laboratory use Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
3. IEC 61326-1:2012 2nd edition Electrical equipment for measurement, control and laboratory use – EMC requirements
4. IEC 62304: 2006 Medical Device Software –Software Life Cycle Processes
5. ISTA 2A:2006 Packaged Products 150 lb (68 kg) or less
6. WEEE Directive – 2002/96/EC
7. RoHS Directive – 2011/65/EU
8. FDA CDRH, January 11, 2002 “General Principles of Software Validation”; Final Guidance for Industry and FDA Staff
9. ISO 13485:2016 Medical devices Quality management systems Requirements for regulatory purposes
10. ISO 15223-1:2021, Medical devices - Symbols to be used with information to be supplied by the manufacturer— Part 1: General requirement
11. ISO 18113-1:2011 – In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) – Part 1: Terms, definitions and general requirement
12. Regulation (EU) 2017/746 of the European Parliament and of the Council on 5 April 2017 on In Vitro Diagnostic Medical Devices
13. UN 38.3- Battery transport

## **Support**

For customer support, visit the support portal at [www.nano.com](http://www.nano.com)

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