

# LABMASTER LUCIA Analyzer

## Instructions for Use



## Changes Record

### Instructions for Use for Labmaster LUCIA™ Analyzer

Revision	Date of Change	Section(s)	Description of Change
8	October 2022	N/A	• Change Record added
		1.1, 1.6, 2.1, 3.4.3	• Rephrasing
		1.4	• Labmaster LUCIA™ Analyzer machine label added
		1.5	• Updated safety information as per IEC 61326-2-6:2020
		1.7	• Declaration of Conformity updated
		2.2	• Technical specifications updated
		8.2.3	• Figure 28 and 29 updated
		8.3.2	• Figure 36 updated
9	August 2023	1.4	• Manufacturing date changed from 'Year' only to 'Year - Month' format in label.
		1.4	• Figure 1 updated.
		4	• Adding Sample to the Labmaster LUCIA™ cassette updated (Page 13)
10	March 2025	1.5	• Safety Information updated
		1.6	• Declaration of Conformity updated
		1.7	• Notice on Reporting Serious Incidents added
		1.8	• Warranty information updated
		1.9	• Disposal of Labmaster™ LUCIA Analyzer updated
		2.2	• Technical Specification updated
		2.3	• Delivery, Transportation and Storage updated
		2.5	• Installation procedure updated
		3.1	• Operation icons updated
		3.2, 3.3	• Login with Operator ID, Home Screen updated
		3.4	• Analyzer settings updated
		3.4.1	• Change admin PIN added
		3.4.2	• Instructions for addition of Operators added
		3.4.2	• Instructions for removal of Operators added
		3.4.4	• Instructions for changing Operator's PIN added
		3.4.5	• Instructions for changing Operator added
		3.4.6	• Detailed view of Error Log added
		3.4.9	• Analyzer's identification added
		3.4.10	• New languages and date format added
		5	• Quality control (QC) measurement instructions updated
		6	• Factory Reset section added
		7	• Analyzer Cleaning updated
		8.1	• Reminder messages updated
		8.2	• Warning messages updated

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# 1. Important information

Thank you for choosing Labmaster LUCIA™ Products! Please read this manual thoroughly before operating the Labmaster LUCIA™ Analyzer (LM26). Follow the instructions in this manual.



















## 1.1 Intended Use

Labmaster LUCIA™ Analyzer is a semi-automated near-patient device used in *in vitro* diagnostics by healthcare professionals in professional healthcare facility environment. Labmaster LUCIA™ Analyzer is used together with Labmaster LUCIA™ test for quantitative or qualitative *in vitro* diagnostic analysis of analytes. LUCIA Analyzer measures CECL (cathodic electrochemiluminescence) signals and calculates result of analyte based on emission signals emitted from LUCIA cassettes. LUCIA tests are purchased separately.

## 1.2 Disclaimer

- Test results should never be used alone for diagnosis. The patient’s medical history, clinical examinations and other laboratory results should be taken into consideration when interpreting LUCIA test results. A clinical decision is always required.
- Use of LUCIA Analyzer is compatible only with LUCIA test manufactured by Labmaster Ltd.
- To obtain accurate results, tests should always be performed with LUCIA Analyzer at temperature range of +18 °C to +30 °C (+64 °F to +86 °F) and a maximum relative humidity of 80%.
- Avoid exposure of LUCIA Analyzer to dust, moisture or direct sunlight.
- Do not mishandle or disassemble your LUCIA Analyzer in any event.

## 1.3 Explanation of Symbols

	Manufacturer		Date of manufacture		European Conformity
	Temperature limit		Consult Instruction for Use		Serial Number
	Catalogue number		<i>In vitro</i> Diagnostic Medical Device		WEEE; waste electrical and electronic equipment
	Keep dry		Keep away from sunlight		Fragile, handle with care
	This side up		Bluetooth		Direct current
	Caution		Biohazard		Electrical hazard

## 1.4 Labmaster LUCIA™ machine label

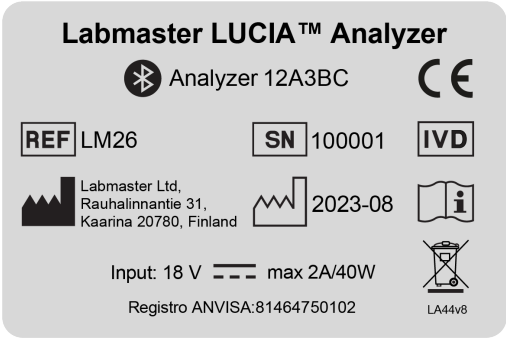
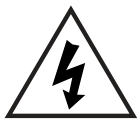


Figure 1. An example of Labmaster LUCIA™ Analyzer machine label



**NOTE:** - The Serial number, Bluetooth ID and Date of manufacture (year - month) are analyzer specific.



**Caution:** - Before the LUCIA™ Analyzer is used for the first time, operator must ensure that the electrical specification shown on the LUCIA™ Analyzer machine label is suitable for the country/region in which the analyzer will be operated. See Figure 1.

## 1.5 Safety Information



The operator should ensure they have read the Safety Information below, before using the Labmaster LUCIA™ Analyzer.

This also includes the Warnings and precautions, Health and safety Information, Disposal, Analytical precautions, Procedures and limitations referred to in the test Kit Instructions for Use.



### **WARNING: - EARTHED POWER SOCKET, POWER SUPPLY AND ACCESS TO MAINS CONNECTION**

- The LUCIA Analyzer MUST be plugged into an Earthed socket
- The LUCIA Analyzer MUST be positioned on the workbench where the operator/user has immediate access to the mains switch and socket.
- Use only the Power Supply Unit (PSU) and cables provided with LUCIA Analyzer.
- The LUCIA Analyzer is for indoor use only.



**NEVER** attempt to remove or open any parts of the LUCIA Analyzer.

- The use of a damaged or faulty LUCIA Analyzer can result in a personal injury.
- Never open LUCIA Analyzer's door/tray while measuring.



Ensure that LUCIA Analyzer is in proper working condition before operating.

- Ensure to read, understand and follow all instructions, warnings and cautions before using the LUCIA analyzer.
- Misuse of the LUCIA Analyzer can cause harm to the operator and/or surroundings.
- Only use the LUCIA Analyzer for its intended use.



Do **NOT** allow LUCIA Analyzer to come in contact with liquid. In case LUCIA Analyzer comes in contact with liquid, unplug it immediately.

- Do **NOT** place anything on top of LUCIA Analyzer.
- Keep the LUCIA Analyzer away from any mechanical or magnetic interference.

Refer to general and local Laboratory Procedures, Rules and Regulations for the correct level of Personal Protection Equipment (PPE) to wear.



### **Labmaster LUCIA™ test kit Instructions for Use**

Refer to the **LUCIA test kit Instructions for Use** for all Warnings and Cautions, Health and Safety Information, Disposal, Analytical Precautions, Procedures and Limitations.

## 1.6 Declaration of Conformity

Hereby, Labmaster Ltd. declares that LUCIA™ Analyzer and/or its components are in compliance with the RoHS directive (Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment 2015/863/EU) and with RED directive (Radio equipment directive 2014/53/EU). The full text of the EU declaration of conformity is available at the following address: [www.labmaster.fi](http://www.labmaster.fi)

The Labmaster LUCIA™ Analyzer complies with the electromagnetic emission and immunity requirements described in the standard IEC 61326-2-6. This equipment is not intended for use in residential environments and may not provide adequate protection to radio reception in such environments.

The Labmaster LUCIA™ Analyzer complies with the Safety requirements for electrical in vitro diagnostic (IVD) medical equipment for measurement, control and laboratory use in the standard 61010.

The power supply for the analyzer fulfills the FCC class A requirements.

## 1.7 Notice on Reporting Serious Incidents

For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/746/EU on In vitro Diagnostic Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorized representative and to your national authority.

## 1.8 Warranty

Labmaster Ltd. offers the customer a 24-month limited warranty on a new Labmaster LUCIA™ Analyzer. The warranty period starts from dispatch.

In a situation of manufacturing defect during warranty period, Labmaster Ltd. will repair or replace the system/ components at its discretion. Contact Labmaster Support [support@labmaster.fi](mailto:support@labmaster.fi).



### Warranty Disclaimer

- In no event shall Labmaster Ltd. be liable for any consequential or incidental damages arising from the use or misuse of this product.
- The warranty will be invalidated if consumables not authorized by Labmaster Ltd. are used, or if unauthorized persons perform alterations or attempt repairs.
- The warranty does not cover consumable parts or carriage costs from the customer's address to Labmaster Ltd.
- For further information on Warranty, contact: [support@labmaster.fi](mailto:support@labmaster.fi)

## 1.9 Disposal of the Labmaster LUCIA™ Analyzer



The Labmaster LUCIA™ Analyzer **MUST** be disposed of in accordance with the Waste Electrical and Electronic Equipment Directive (WEEE Directive) which is the European Community Directive 2012/19/EU on waste electrical and electronic equipment (WEEE). For further LUCIA Analyzer disposal information, please contact Labmaster Technical Support. [support@labmaster.fi](mailto:support@labmaster.fi)

For other countries – refer to the Local Laws and Regulations



A decommissioned Labmaster LUCIA™ Analyzer must be treated as a potentially biohazardous waste.

- Disinfect the analyzer before disposing: - wipe exterior of the analyzer and the tray with 70% Iso-propanol (IPA) or ethyl alcohol. Refer to the Manufacturer's Safety Data Sheet for Health and Safety Warnings regarding IPA.
- Ensure all Patient Data is deleted from the LUCIA Analyzer before disposing. To delete Patient Data, Follow Section 6.

## 2. Labmaster LUCIA™ Analyzer

### 2.1 Principle

The Labmaster LUCIA™ Analyzer is an instrument based on cathodic electrochemiluminescence. The instrument is designed to be used only with Labmaster LUCIA™ test.

LUCIA test is based on a formation of immunochemical complex with the analyte to be measured and labelled antibody. The excess labeled antibody is washed away during an automatic step which needs no user interaction. Excitation current is supplied to the labelled complex. Resulting electrochemiluminescence is measured and the on-board microprocessor calculates the result of the analyte using a pre-programmed calibration. The result is displayed on the screen of the LUCIA Analyzer.

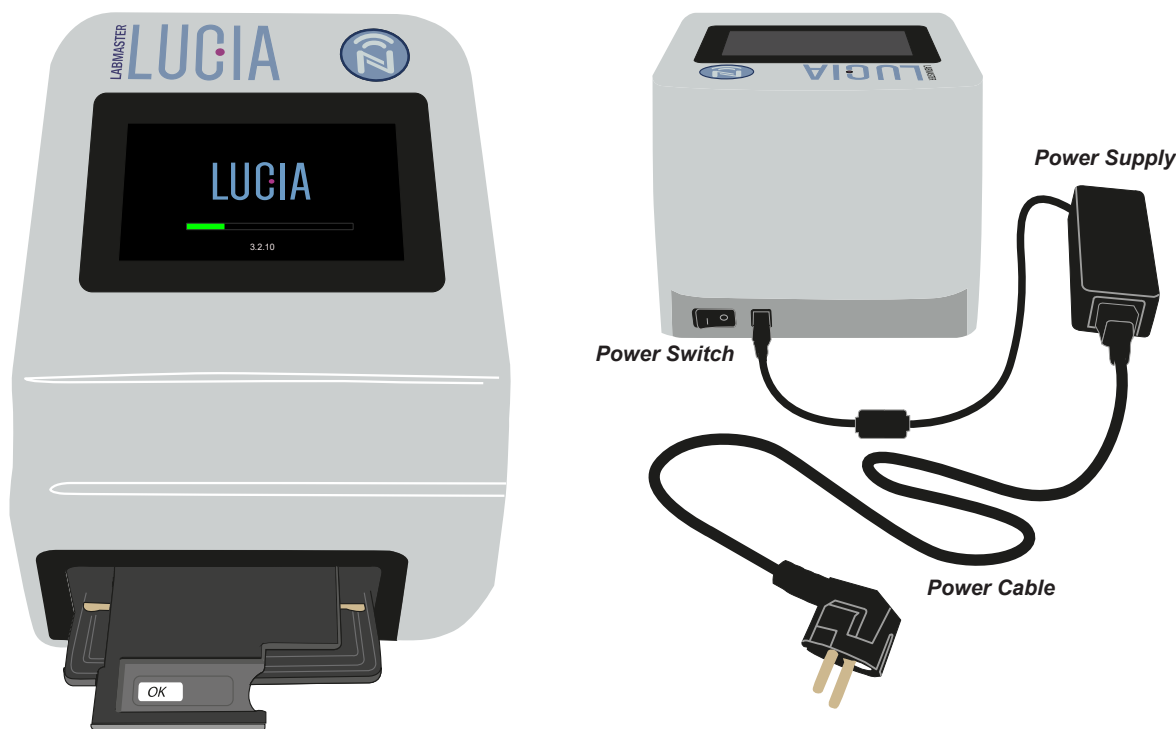


Figure 2. Labmaster LUCIA™ Analyzer

### 2.2 Technical Specification

#### Physical Description and Power Requirements

**Dimensions :** 255 mm (L) x 195 mm (W) x 160 mm (H)

**Weight :** 3.6 Kg

**Display :** 5" Touchscreen

**Power Supply Unit Input Voltage :** 100-240 V AC (50/60 Hz) +/- 10%

**Power Supply Unit Input Current :** 1A at 115 V AC and 0.5A at 230 V AC

**Power Supply Unit Output :** 18 V DC, Max 2.22 A

#### Operational environment

**Temperature :** +18 °C to +30 °C (+64 °F to +86 °F)

**Humidity :** Maximum relative humidity: 80%

**Altitude :** < 2000 m

**Location :** Dry, clean, levelled surface away from direct sunlight, dust, moisture mechanical and magnetic interference

**Pollution Degree :** 2

## 2.3 Delivery, transportation and Storage



Ensure the Labmaster LUCIA™ Analyzer is decontaminated before transportation or Storage.



### Delivery:

Inspect the analyzer for any signs of damage. If there are signs of damage to the Labmaster LUCIA™ Analyzer, contact Labmaster Technical support: [support@labmaster.fi](mailto:support@labmaster.fi)

### Transportation:

When transporting or storing Labmaster LUCIA™ Analyzer, keep dry, upright and protected from mechanical shocks.

- The original LUCIA analyzer box should be used to transport the Analyzer.
- The transportation temperature range is +2 °C to +50 °C (+35° F to +122° F).

### Storage:

The storage temperature range is +2 °C to +50 °C (+35° F to +122° F).

## 2.4 Package contents

To set-up LUCIA Analyzer for the first time, unbox the contents of the package as listed below.

- Inspect the contents for any physical damage and/or missing component(s).

1. LUCIA Analyzer      2. Power Cable      3. Power Supply unit (PSU)      4. Instructions for Use (IFU)

## 2.5 Installation procedure



The LUCIA Analyzer **MUST** be positioned on a workbench where the operator/user has immediate access to the mains power switch and socket.

- Do **NOT** block access to the LUCIA Analyzer mains plug connection so that it is difficult to disconnect.
- Ensure that there is enough space at the front of the LUCIA analyzer to allow the tray to move in and out. Min: - **60 mm**
- Ensure that the final location of the LUCIA Analyzer is dry, clean and on a level surface. The LUCIA Analyzer must **NOT** be in direct sunlight and be affected by mechanical and magnetic interference.

Refer to Figure 2 for electrical connection.

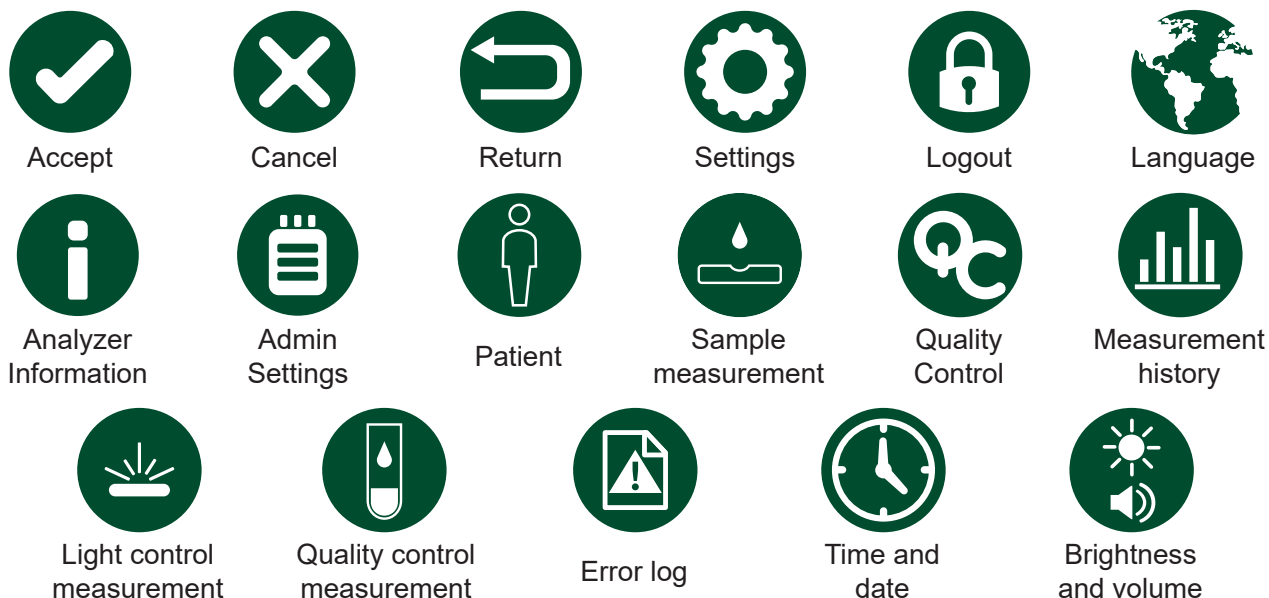
- Using the correct regional power cable, connect to the PSU.
  - Connect the PSU's output cable to the LUCIA Analyzer
  - Plug the power input cable from PSU to the external AC power outlet and turn on mains power.
  - Power on by using the power switch at the rear of the LUCIA Analyzer. See Figure 2.
- During power up, the LUCIA Analyzer will execute a series of self-check routines.
  - The tray will move out and back in.
  - Upon successful completion, the Operator ID screen will be displayed.
  - The LUCIA Analyzer must be powered on for 30 minutes before use.
- The LUCIA Analyzer is ready for use.



## 3. Graphical User Interface (GUI)

### 3.1 Operation

The Labmaster LUCIA™ Analyzer is operated with Primary Functions Icons. Each Primary Function icon is represented and controlled by corresponding keys on the touch screen. The primary function icons of the Labmaster LUCIA™ Analyzer are described below.




### 3.2 Login with Operator ID



**NOTE:** - The Labmaster LUCIA analyzer has 2 levels of users: admin operator and operator. The 'admin' has right to add, delete operators and change PIN for oneself and operators.

The Labmaster LUCIA™ Analyzer returns to the Operator ID screen after completion of automatic self-check routines. The operator will be required to enter the Operator ID and the PIN

**Note:** - The default Operator ID is 'admin' and the PIN is '0000'. Please change the admin PIN as soon as you successfully log in first time.

1. Tap on the Operator ID window. See Figure 3.
  - This will launch a virtual keyboard.
2. Enter Operator ID using virtual keyboard.
3. Similarly, enter the PIN in the PIN input box.
4. Tap the Accept icon .
  - Once the operator ID and PIN are entered and accepted, the analyzer moves to the Home Screen. See Figure 4.

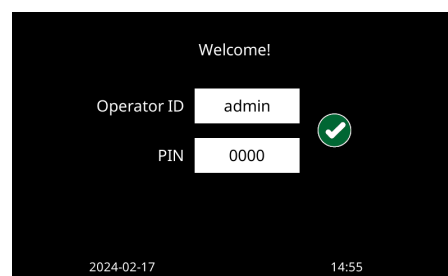


Figure 3. Login Screen

### 3.3 Home Screen

In the Home Screen, see Figure 4, the operator can perform the following:

Go to Settings	Sample measurements
Quality control measurements	View Measurement history
Change Operator login	

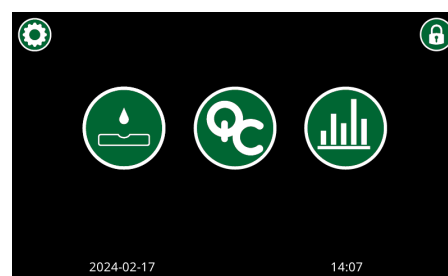



Figure 4. Home Screen

### 3.4 Settings Screen

By tapping the Settings icon  in the Home Screen, the Settings screen will appear, see Figure 5, allowing the operator to carry out the following settings:

Change PIN (admin login)	Add/delete operators (admin login)
View Bluetooth ID	View error log
Adjust time and date	Adjust brightness and volume
View analyzer information	Change Languages
Change date formats	

#### 3.4.1. Change Admin PIN

The admin PIN can be changed with admin login only. After changing the PIN, write it down and do not lose.


To change the admin PIN, follow the procedures below:

1. Log into the analyzer with Operator as 'admin' and the PIN.
2. From the 'Settings' icon, press 'admin settings'.
3. Select 'admin' from the Operator's list. Then press 'Change PIN'.
4. After pressing 'Change PIN' a warning message is displayed. Press accept to change PIN.
5. Tap on the PIN box. When the keypad opens, input the new PIN.
  - The PIN length must be between 3 to 4 digits.
6. Press OK. The PIN has changed.


#### 3.4.2. Add Operators

Addition and removal of Operators can only be made through admin login.

To add or remove Operators, follow the procedures below:

1. Log into the analyzer with 'admin' and 'PIN'.
2. From the 'Settings' icon, press 'admin settings'.
3. When the Operator list screen appears, press 'Add'.
4. Insert desired 'Operator ID' and 'PIN' and press Accept .
  - The Operator ID length must be between 3 to 10 characters and the PIN length must be 3 to 4 digits.

#### 3.4.3. Remove Operators

1. Follow steps from Section 3.4.2 until step 2.
2. Next select the operator to delete. Then press 'Remove'.
  - A warning message will be displayed.
3. Press accept  to delete the operator.
  - The operator will be removed from the list.

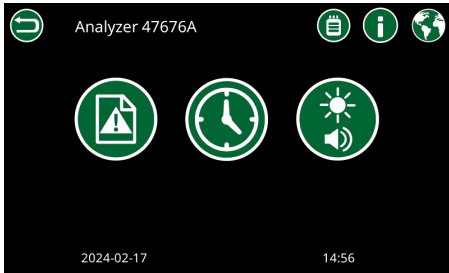


Figure 5. Settings Screen

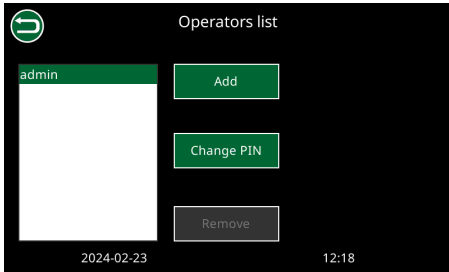


Figure 6. Operators lists

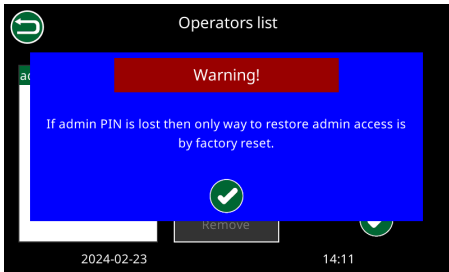


Figure 7. Warning notification for admin PIN

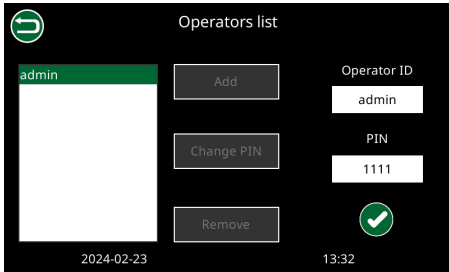


Figure 8. Changing admin PIN

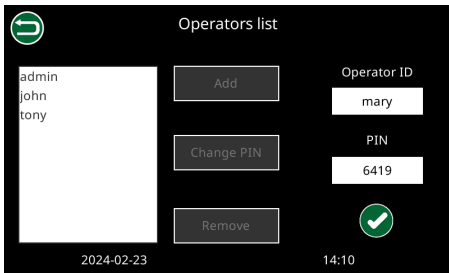


Figure 9. Adding operator

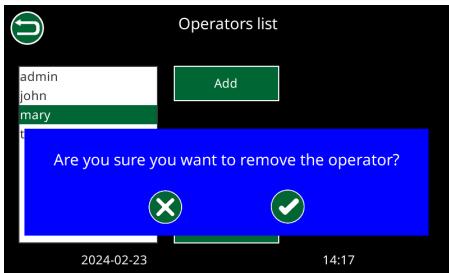



Figure 10. Removing operator

### 3.4.4. Change Operator's PIN

**Note:** - The Operator's PIN can be changed with admin log in only

1. Follow the steps from section 3.4.1.
2. Select the Operator of which the PIN is to be changed and press 'Change PIN'.
3. Enter the new PIN and press Accept .

### 3.4.5. Change Operator



1. Press the 'Lock' icon from the Home screen. A login screen will be displayed.
2. Input the 'Operator ID' and 'PIN' for login.

### 3.4.6. View Error Log



The information of faulty measurements can be viewed on the error log page. See Figure 11.

1. Click on error log icon from the settings screen.
2. A detailed error log can be accessed by pressing a particular result from the log. See Figure 12.

### 3.4.7. Adjust Time and Date

1. Tap on the Time and Date icon. See Figure 5.
2. Choose the date from the calendar and time from the HH/MM scroll bar. When the correct time and date have been selected, tap the **Accept**  to save.
3. The operator can tap the **Cancel** button  at any stage to exit without saving. See Figure 13. See section 3.4.10 to change date format.

### 3.4.8. Brightness and Volume

1. Tap on Brightness and Volume icon. See Figure 5.
2. Move the corresponding slider to adjust brightness and volume level. Tap **Accept**  button to save the setting.
3. The operator can tap the **Cancel** button  at any stage to exit without saving. See Figure 14.

### 3.4.9. View Analyzer Identification

The analyzer's information can be viewed from the Analyzer identification screen. The information includes Chip ID (MCU UID), Hardware revision, Serial number, Bluetooth ID and 2 cores software versions.

1. Tap on Device information icon  from the Settings screen.
2. Press up/down arrow to toggle between two pages.
3. Press return icon  to exit the screen.

Error log			
No.	Kit	Operator ID	Date
4	CRP	ANNA	2024-11-27
3	CRP	ANNA	2024-11-20
2	MxA	JOHN	2024-11-10
1	CRP	ANNA	2024-11-10

Figure 11. Error Log

Operator ID	ANNA
Kit	CP329
Date/time	2025-02-20 11:20
Emission	2000
Excitation	480
Reason	Excitation too low.

Figure 12. Detailed error Log

January 2025							HH	MM
Mo	Tu	We	Th	Fr	Sa	Su		
			1	2	3	4	5	
6	7	8	9	10	11	12		
13	14	15	16	17	18	19		
20	21	22	23	24	25	26		
27	28	29	30	31				

10	10
----	----

Figure 13. Adjust time and date


Brightness	Volume
------------	--------




Figure 14. Adjust brightness and volume

MCU UID	0032 004D 3339 5108 3535 3734
HW revision	2
Serial number	200010
Bluetooth ID	47676A

Figure 15. Analyzer identification screen

### 3.4.10. Language and date format

The language and date formats can be changed from the language icon .

1. Tap on language icon from the Settings screen.
2. Tap on the language to choose the desired language and press Accept .
3. Tap on date format to choose desired date format for the analyzer and press Accept .
4. Press cancel icon  to exit without saving the desired language or date format.

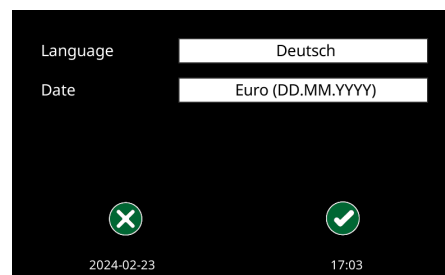




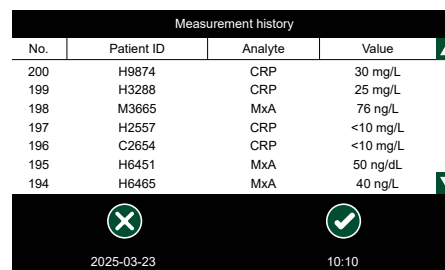


Figure 16. Language and date format

## 3.5 Measurement History

The Measurement History of the last 200 patient sample measurements can be accessed by selecting the history icon .

1. Tap on measurement history icon from main screen. See Figure 4.
2. A measurement history screen is displayed. See Figure 17.
3. For detailed measurement history of any particular result, click on the desired result and press Accept  button.
4. To exit the screen, press return  button from the detailed results. Next press cancel  button from the measurement history screen.



Measurement history			
No.	Patient ID	Analyte	Value
200	H9874	CRP	30 mg/L
199	H3288	CRP	25 mg/L
198	M3665	MxA	76 mg/L
197	H2557	CRP	<10 mg/L
196	C2654	CRP	<10 mg/L
195	H6451	MxA	50 ng/dL
194	H6465	MxA	40 ng/L

Figure 17. Measurement history

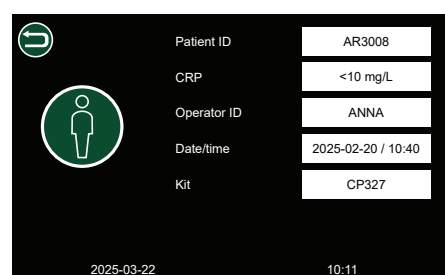


Figure 18. Detailed measurement result





**NOTE:** - Results can be transferred to a Windows PC via the Bluetooth application.

## 4. Patient sample measurement

1. Turn on Labmaster LUCIA™ Analyzer 30 minutes before use.
  - If the Labmaster LUCIA™ Analyzer has already been turned on for more than 30 minutes, measurements can be started immediately.
  - Follow the Labmaster LUCIA™ test Kit instructions for analyte specific instructions.



**NOTE:** - If the Labmaster LUCIA™ Analyzer needs “Operator ID” change, follow step 3.4.5

2. Check that the Labmaster LUCIA™ test Kit's NFC Card and test components have the same batch number.
3. Collect and prepare the sample to be tested according to the Labmaster LUCIA™ test Kit Instructions.
4. Unwrap the Labmaster LUCIA™ cassette from the sealed pouch.
5. Select the Patient Sample icon  on the Home Screen.
  - A new page will appear. See Figure 19.
  - The operator will then be prompted to enter the Patient ID.
  - The operator can tap the Cancel icon  at any stage to exit without saving.

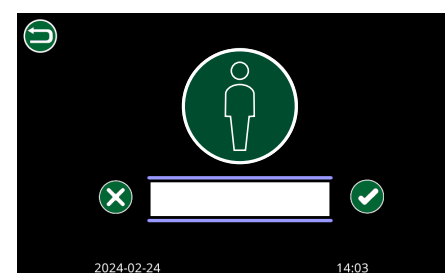


Figure 19. Patient measurement screen


6. Tap on the Text box.
  - The virtual keyboard will appear.
7. Enter the Patient ID.
  - To edit the Patient ID, re-select the ID text box.
8. Once the correct Patient ID has been entered, tap the Accept icon .
  - The NFC reading screen will appear. See Figure 20.
9. Place the NFC Card on the NFC icon on the Labmaster LUCIA™ Analyzer. See Figure 21.



Figure 20. NFC reading screen

**Note: - There is a timeout limit of 30 seconds for reading the NFC Card. Repeat from section 1 if timeout is triggered.**

10. After a successful read, place the NFC card back into the corresponding Labmaster LUCIA™ test Kit box.
11. Upon successfully reading of the NFC Card, the tray from the analyzer will come out and the screen in Figure 22 will appear.
12. Slide the Labmaster LUCIA™ test cassette onto the tray. See Figure 24.



Figure 21. NFC Card read

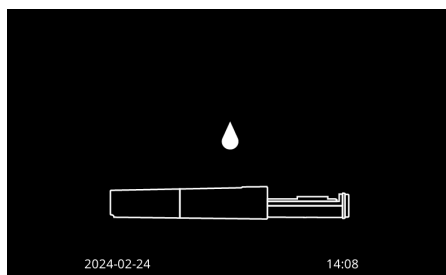


Figure 22. Patient measurement screen

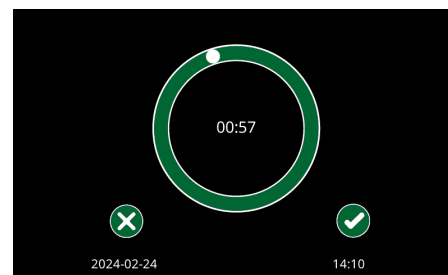


Figure 23. Patient measurement screen



#### Adding Sample to the Labmaster LUCIA™ cassette

As soon as the NFC card is read, the Labmaster LUCIA™ cassette should be placed onto the tray and apply the sample within **1 MINUTE**. See Figure 23.

- Application of the sample to the cassette starts the chemical reaction for the assay. Accept icon starts the measurement process.
- Tap accept icon immediately after sample application.
- If the accept icon is not tapped within 1 minute the measurement process is terminated and the tray will close.
  - If sample was not applied within 1 minute and the accept icon was not tapped: enter the patient ID again and read the NFC card and apply the sample to the same cassette.
  - If only some of the sample was applied within 1minute and the accept icon was not tapped: take a new cassette, enter patient Id again and read the NFC card and apply the same sample to the cassette.



#### Labmaster LUCIA™ test cassette

The Labmaster LUCIA™ test cassette must be used immediately after removal from its packaging.

- When the Labmaster LUCIA™ test cassette is loaded correctly onto the tray, the OK text (highlighted in red oval) can be seen under the Labmaster LUCIA™ test cassette with a sample application hole facing upwards.
- If the **OK** text is not visible, the Labmaster LUCIA™ test cassette has been wrongly loaded onto the tray. Remove the Labmaster LUCIA™ test cassette and re-load correctly.

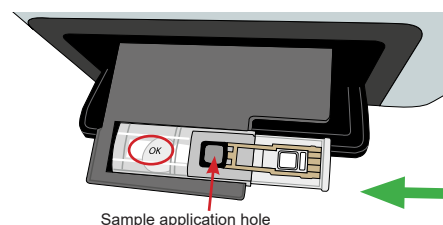


Figure 24. LUCIA cassette loading

- Transfer the sample to be tested to the Labmaster LUCIA™ test cassette according to the instructions of the Labmaster LUCIA™ test Kit. **Note:** A capillary tube is used here as an example.
- Place the tip of the sample transfer device into the sample application hole of the Labmaster LUCIA™ cassette so that it contacts the membrane. See Figure 26.
- Hold the tip of the sample transfer device against the membrane until the sample has spread over the entire membrane.
- After adding the sample, tap the Accept icon on the sample application time out screen. See Figure 23.

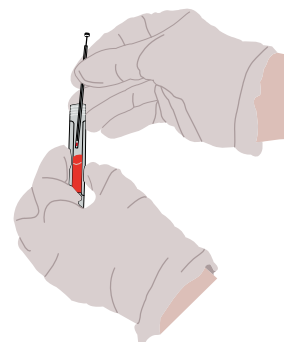


Figure 25. Sample transfer method (Capillary Tube)

- The Labmaster LUCIA™ Analyzer will automatically proceed to the measurement stage. The tray will move in and the Measurement Timer screen in Figure 27 will appear.
- Once the measurement is completed, the tray will come out and the analyte test result with the Patient ID will appear. See Figure 28.
- After pressing Accept , a pop-up notification will appear. See Figure 29.

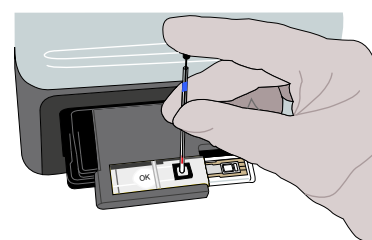


Figure 26. Sample transfer to cassette

- Remove the used cassette from the tray.
- Tap on the Accept icon on pop-up window message.
  - The tray will move in into its normal position.
- Tap Accept icon when the result is read on the screen in Figure 29.
- Dispose the used Labmaster LUCIA™ cassette in accordance with local rules and regulations.

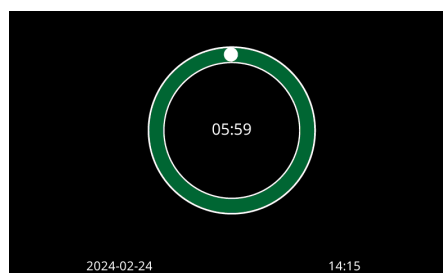


Figure 27. Patient measurement screen

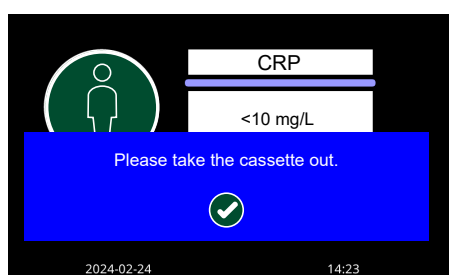


Figure 28. Patient's result screen

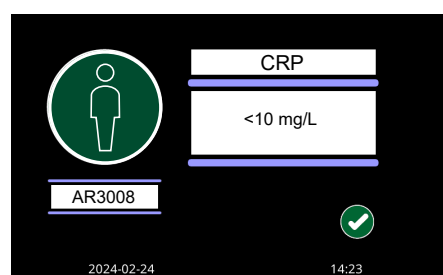


Figure 29. Pop up notification



**Note:** - Once all daily measurements are completed, ensure that the cassette is removed from the tray.

## 5. Quality Control (QC) Measurement

The Labmaster LUCIA™ Analyzer is factory calibrated.

- Turn on the Labmaster LUCIA™ Analyzer 30 minutes before use.
- Follow the Labmaster LUCIA™ test kit instructions for analyte specific quality assurance.



**NOTE:** - Remember to login with your own operator ID.



**CAUTION:** - Light Control Measurement Icon

Light control measurement on the QC screen is used for verifying the functionality of the analyzer and is used only by personnel authorized by Labmaster Ltd.

### 5.1 Quality control measurement

1. Tap the Quality Control icon on the home screen. The QC screen will appear. See Figure 30.
2. Tap the Quality control measurement icon again .
  - A new screen will appear where the Operator needs to input Sample ID. See Figure 31.
3. Follow steps 6 to 19 from Chapter 4.

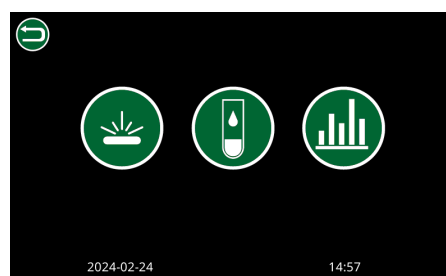


Figure 30. Quality control screen

### 5.2 Quality control measurement history

1. Go to Quality Control screen from Home screen.
2. Tap View Measurement History icon . See Figure 30.
  - All the QC measurement history will be displayed. See Figure 32.
3. To view individual detailed results, select the desired measurement and press Accept . See Figure 32.
4. To return to the Home Screen, press return followed by cancel in the QC measurement history screen.

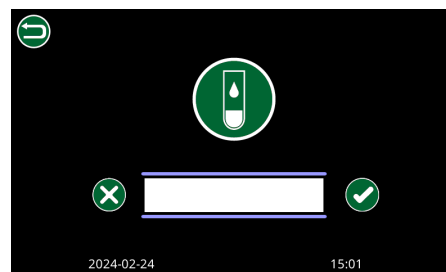


Figure 31. Quality control measurement

QC history			
No.	Sample ID	Analyte	Value
3	S2257	MxA	50 ng/L
2	T3652	MxA	30 ng/dL
1	LMH775	CRP	<10 mg/L



Figure 32. QC measurement history

Sample ID	LMH775
CRP	<10 mg/L
Operator ID	ANNA
Date/time	2025-02-19 / 11:32
Kit	CP652

Figure 33. Detailed QC measurement result



**Note:** - Once all daily measurements are completed, ensure that the cassette is removed from the tray.




## 6. Factory Reset

If the measurement history needs to be removed or the admin PIN is forgotten, the only way to reset the PIN is through a factory reset. The factory reset requires an analyzer specific factory reset NFC card. This card can be requested on demand from Labmaster Ltd.



**Note:** - The factory reset NFC card will delete all the Operators, measurement history from sample measurement and QC measurement. The brightness and volume level will also be restored to default.

Follow the steps below for the factory reset:

1. Restart the analyzer. On the log in screen, tap the 'Analyzer specific factory reset NFC card' provided by Labmaster Ltd. The following screen will appear. See Figure 34.
2. Enter the PIN provided for the NFC card and press Accept . When the PIN is correct, the analyzer will proceed with factory reset. See Figure 35.

**Note:** - After a successful factory reset, the analyzer will notify to restart the analyzer.

3. Restart the analyzer by powering 'OFF' then 'ON' the switch.
4. Log in with default admin login. Operator: 'admin' and PIN: '0000'.



Figure 34. Factory reset screen

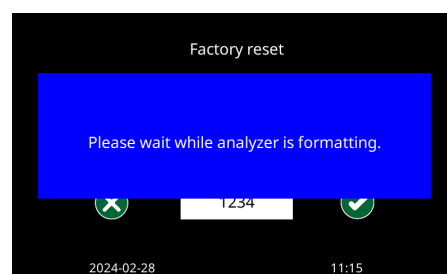


Figure 35. Factory resetting an analyzer

## 7. Analyzer Cleaning



### **WARNING: - ELECTRICAL HAZARD**

Ensure that the device is powered down and the mains electrical switch is set to off and the mains plug removed from electrical supply or PSU before cleaning.



Ensure that the Labmaster LUCIA™ Analyzer is decontaminated before transportation or Storage.

### 7.1 Cleaning

1. Ensure the device is switched off and the power cable is removed.
2. Moisten a Lint Free Cloth with 70% Iso-propanol (IPA) and wipe all external surfaces. Allow to dry.
3. Plug the power cable in and Power on.

### 7.2 Spillages

Ensure any spillages are removed and the area affected cleaned immediately.

1. Carry out the procedure in Section 7.1 Cleaning.
2. For spillages in the tray, see Section 8.3 Operational Issues.



## 8. Troubleshooting

### 8.1 Reminder Message

The following reminder messages appear on the screen during the measurements.

#### Invalid operator ID or PIN

This reminder message appears when the operator ID or PIN does not match during login. The message will disappear in 3 seconds and the log in screen will appear again.

#### Patient ID/Sample ID has not been entered

This reminder message appears when the operator does not enter the patient ID (in patient sample measurement) / sample ID (in QC measurement) during the start of the measurement. To exit the message, press Accept button.

#### Please take the cassette out.

This reminder message appears after the measurement cycle is complete and tray with cassette is out. Take the cassette out and select "Accept" button to exit the message.

#### Operator ID already exists

While adding a new operator, if the admin inputs the ID that already exists, then this message will be displayed. Try again with different Operator ID.

#### Chip erase successful.

This message appears when the factory reset is successful.

#### Factory reset will clear all data from the device, including measurements and operators.

This is a reminder message for the outcome of the factory reset.

#### Enter PIN to continue

To move forward with the factory reset, a correct PIN should be entered.

#### Please wait while the analyzer is formatting.

This reminder message occurs during the factory reset phase. The operator does not need to do anything.

#### Analyzer has been formatted. Please restart the device.

This reminder message occurs when the analyzer has been successfully formatted. The operator is advised to restart the analyzer.

### 8.2 Warning Message

The following warning messages appear on the screen depending on the issues related to the measurements.

#### Kit is expired.

LUCIA Test kit has expired. Remeasure the sample with a valid batch of LUCIA test components.

#### Rejected measurement. Excitation too high/Excitation too low.

The excitation value is out of defined range for the test analyte. Check the cassette and measure with a new cassette again.

#### Light leakage detected.

Excess light is detected by the analyzer during the start of the measurement. Ensure that there is no visible obstacle in the doorway. Restart the analyzer and measure again with a new cassette.

#### Temperature of the device is colder/warmer than allowed. This may affect the results.

This warning appears when the temperature of the measurement chamber in the analyzer is less than +18° C or greater than +30° C. Ensure that the temperature is within the operational temperature range.

#### Technical problem reading the NFC card

This warning message occurs when the analyzer can not read the NFC card due to technical issue. Retry to read the card again. If the problem exists, restart the analyzer and try again.

#### NFC Card could not be read.

This warning message occurs when the NFC card could not be read by the analyzer. To overcome the issue, retry to read again by starting the measurement. Restart the analyzer and try again if needed.

#### Invalid NFC card.

The analyzer only reads the authorized NFC card issued by Labmaster Ltd. Ensure that the NFC card is not corrupt and is issued by Labmaster Ltd.

#### Invalid operator ID/PIN

This warning message occurs when the admin leaves the 'Operator' or 'PIN' field empty. Ensure that the Operator ID and PIN length are within the acceptable criteria.

#### Are you sure you want to remove the operator?

This warning message occurs while removing an operator.

#### Warning. If admin PIN is lost then only way to restore admin access is by factory reset

This warning message occurs when the admin changes the login PIN.

#### Are you sure you want to format the device memory?

This warning message occurs as the final warning during factory reset.

#### Analyzer will log out soon if OK button is not pressed.

The analyzer will automatically log out the operator after 10 minutes of inactivity when it is in the Home screen. To avoid the log out, the Operator can press at any part in the screen.

#### Technical problem with motors, please restart the device.

This warning occurs when the analyzer fails to perform self-check during the start up. In case of its occurrence, please restart the device again.

## 8.3 Operational Issues

In case of operational issues, refer to the following table for corrective measures:

Indication	Probable cause	Corrective action
No power in LUCIA Analyzer.	Power and / or connection failure.	<ul style="list-style-type: none"><li>• Confirm functioning electrical outlet.</li><li>• Turn the LUCIA Analyzer on.</li><li>• Disconnect and firmly reconnect the power cable</li></ul>

Indication	Probable cause	Corrective action
Liquid droplets on the tray.	Leakage of the cassette.	<ul style="list-style-type: none"> <li>Blot the liquid into soft paper or cloth.</li> </ul>
No test results.	Computational difficulty.	<ul style="list-style-type: none"> <li>Restart the LUCIA Analyzer and remeasure.</li> <li>If the problem reoccurs, contact <a href="mailto:support@labmaster.fi">support@labmaster.fi</a>.</li> </ul>
Failure of opening and closure of door.	Power and / or connection failure. Mechanical malfunction.	<ul style="list-style-type: none"> <li>Switch off the power and restart LUCIA Analyzer.</li> <li>If the problem reoccurs, contact <a href="mailto:support@labmaster.fi">support@labmaster.fi</a>.</li> </ul>
Tray with cassette stuck inside LUCIA Analyzer	Mechanical malfunction or misplaced cassette.	<ul style="list-style-type: none"> <li>Switch off the power and restart LUCIA Analyzer.</li> <li>Repeat the measurement using a new LUCIA cassette.</li> <li>If the problem reoccurs, contact <a href="mailto:support@labmaster.fi">support@labmaster.fi</a>.</li> </ul>
Abnormal noise from LUCIA Analyzer.	Mechanical malfunction or misplaced cassette.	<ul style="list-style-type: none"> <li>Restart LUCIA Analyzer.</li> <li>Repeat the measurement using a new LUCIA cassette.</li> <li>If the problem reoccurs, contact <a href="mailto:support@labmaster.fi">support@labmaster.fi</a>.</li> </ul>
LUCIA Analyzer screen flashing.	Electrical / GUI problem.	<ul style="list-style-type: none"> <li>Restart your LUCIA Analyzer.</li> <li>If the problem reoccurs, contact <a href="mailto:support@labmaster.fi">support@labmaster.fi</a>.</li> </ul>
LUCIA Analyzer screen freezing.	Hardware error.	<ul style="list-style-type: none"> <li>Restart LUCIA Analyzer. (If there is a cassette inside the analyzer, take it out during the series of self-check routines as the tray will be automatically exposed.)</li> <li>Repeat the measurement with a new cassette.</li> <li>If the problem reoccurs, <a href="mailto:support@labmaster.fi">support@labmaster.fi</a>.</li> </ul>

## 9. Result Export



Results from the LUCIA Analyzer can be exported to a Windows® PC by the LUCIA Analyzer Windows application.

- All communications are by Bluetooth® Version 4 or higher short-range wireless technology.
- The installation and operation of these applications are described in this section.

### 9.1 Application Function Keys

The Labmaster LUCIA™ Analyzer Windows application is based on the functionality described by their corresponding function keys in the application. These function keys are listed below.



Bluetooth



Print



Connect



Export



Syncing



Patient



Previous



Next


### 9.2 Labmaster LUCIA™ Windows Application (Windows® 7 or higher)

The LUCIA Analyzer Windows application enables to export results from LUCIA Analyzer to the Windows PC via Bluetooth. The application can be downloaded from Labmaster's official website.

### 9.2.1. Windows Application Installation

1. Download the Labmaster LUCIA™ Analyzer Windows application to your PC.
2. Extract the zipped file and double-click LUCIA™ Setup.
3. Follow the application installation instruction to install the application on device.

### 9.2.2. Pairing with Labmaster LUCIA™ Analyzer

1. Go to Bluetooth & other devices in PC.
2. Click Add Bluetooth or another device.
3. Select Bluetooth.
4. Click on the LUCIA™ Analyzer Bluetooth device name you want to pair with. The Bluetooth ID can be found from “settings”  screen or the plate label under the analyzer.
5. Click Connect on the prompted message.
  - In LUCIA™ Analyzer, the same code will be prompted.
6. Tap the Accept icon to accept the connection.
  - If connection is not accepted within 20 seconds, timeout will occur.

### 9.2.3. PC Application Use

1. Search Labmaster LUCIA™ Application in your PC and open the application.
  - The application starts with Home screen as shown in Figure 36.



**NOTE:** - The Labmaster LUCIA™ Analyzer must be on the Home screen for proper functioning of Bluetooth communication.

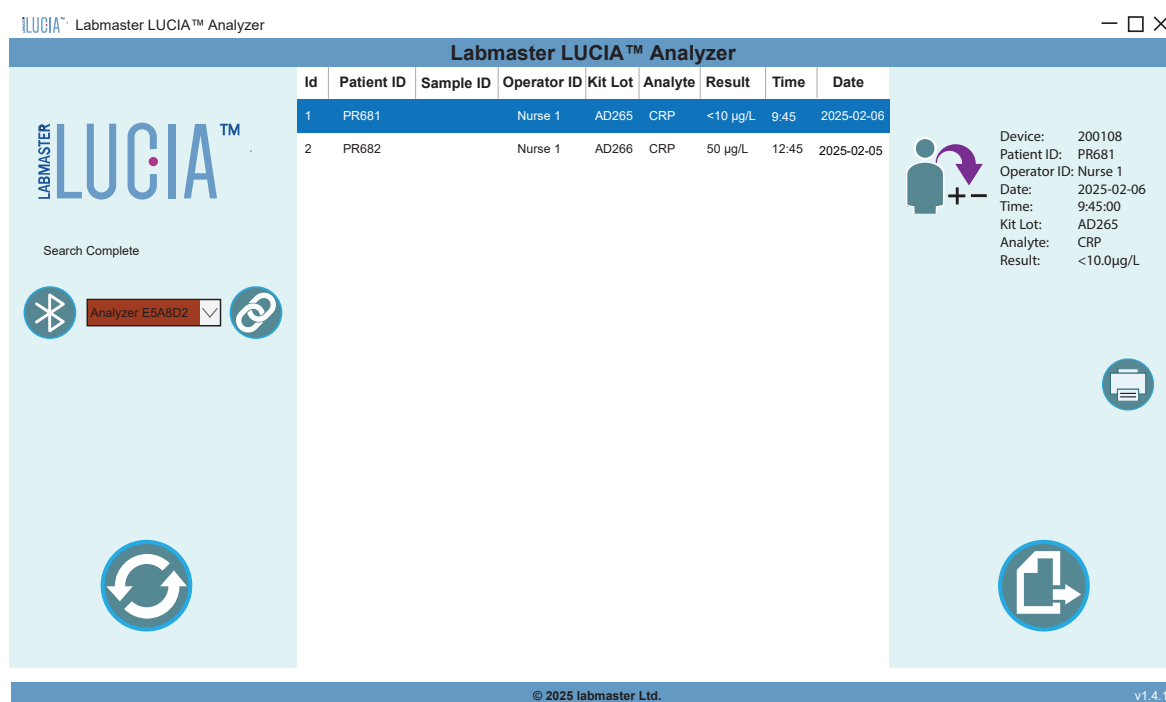


Figure 36. Labmaster LUCIA™ Analyzer Windows Application Home screen

2. Tap the correct analyzer from the drop-down menu and tap the connect button. See Figure 37.
  - The PC application will attempt to connect to the analyzer.
  - The drop-down menu will turn green when connected. See Figure 38.

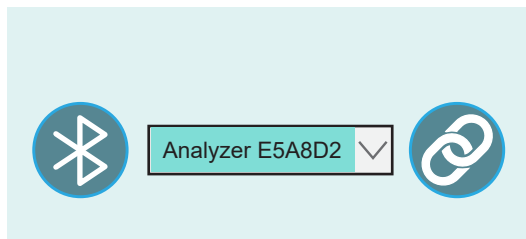


Figure 37. Drop Down Menu

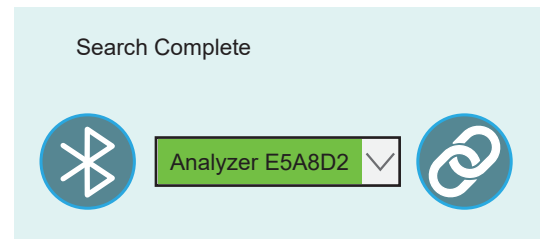



Figure 38. Successful Connection



If the Labmaster LUCIA™ Analyzer is not available in drop-down menu, follow the procedure in the section 9.2.2 to pair the PC and the LUCIA Analyzer.

3. Tap the Synchronize icon  to import data from connected LUCIA™ Analyzer. See Figure 36.
  - **Syncing with Analyzer** followed by 'Bluetooth ID' will be displayed above drop-down menu. See Figure 39.
  - After the application is successfully synced, the **Syncing Complete! Device Disconnected!** message will be displayed and the result table will be updated.

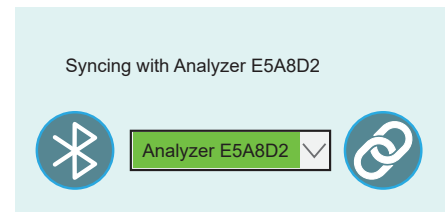


Figure 39. Analyzer syncing in progress

#### 9.2.4. Data Handling and Printing

1. To retrieve a detailed view of a specific result, tap on the specific patient data. See Figure 40.
  - This will highlight the entire patient data row.
  - The detailed information is shown on the right side of the window. See red box.
2. To print a specific patient's data, tap on the patient's data that you require to print out.
3. Tap on the Print icon. See Figure 40.
4. Tap on the Export icon at the bottom right corner to export all the data in .csv format.

Id	Patient ID	Operator ID	Cassette	Analyte	Result	Time	Date
1	PR681	Nurse 1	26588	CRP	<5 mg/L	9:45	06-10-2021
2	PR682	Nurse 1	26610	CRP	50 mg/L	12:45	08-10-2021

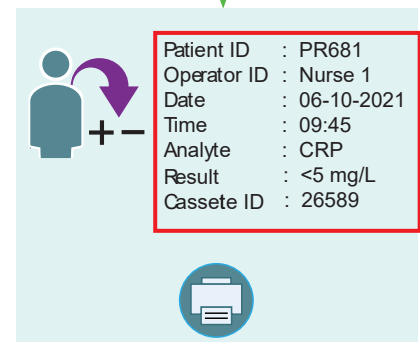


Figure 40. Retrieve a detailed view of a specific patient result

### 9.3 Application Error Messages

The following error messages may appear on the screen during result export.

#### Device not found

This error message appears if there is not any paired LUCIA analyzer available.

#### Bluetooth turned off

Bluetooth in your PC is turned off. Please turn on and try again.

#### Bluetooth already connected

Application is already connected to the LUCIA analyzer.

#### Timeout

Desired action is not completed in given time.

#### Can not connect

Application is not able to connect to the LUCIA Analyzer.

#### Make sure the device is in Home screen

This error message appears if the LUCIA analyzer is not in the Home screen. Please return to the Home screen in the analyzer.

#### Data not available to export

This error message appears if there is not any patient data available. Please sync with the LUCIA Analyzer.

#### Something went wrong. Please try again later

Desired action is not completed. Please try the action again.

## 10. Contact Information

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●●● *medical devices*





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