

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 upated.
		4	 Adding Sample to the Labmaster LUCIA™ cassette updated (Page 13)

Contents

1.	Important information			
	1.1	Intended Use	4	
	1.2	Disclaimer	4	
	1.3	Explanation of Symbols	4	
	1.4	Labmaster LUCIA™ machine label	5	
	1.5	Safety Information	5	
	1.6	Declaration of Conformity	6	
	1.7	Warranty	6	
	1.8	Disposal of the Labmaster LUCIA™ Analyzer	7	
2.	Labn	naster LUCIA™ Analyzer	7	
	2.1	Principle	7	
	2.2	Technical Specification	8	
	2.3	Delivery, transportation and Storage	8	
	2.4	Package contents	8	
	2.5	Installation procedure	8	
3.	Grap	hical User Interface (GUI)	9	
	3.1	Operation	9	
	3.2	Login with Operator ID	9	
	3.3	Home Screen	10	
	3.4	Settings Screen	10	
	3.5	Measurement History	11	
4.	Patie	ent sample measurement	12	
5.	Qual	ity Control (QC) Measurement	14	
6.	Anal	yzer Cleaning	16	
	6.1	Start/End of Daily Use Cleaning	16	
	6.2	Spillages	16	
7.	Trou	bleshooting	16	
	7.1	Reminder Message	16	
	7.2	Warning Message	16	
	7.3	Operational Issues	17	
8.	Result Export			
	8.1	Application Function Keys	18	
	8.2	Labmaster LUCIA™ Windows Application (Windows® 7 or higher)	18	
	8.3	Labmaster LUCIA™ Android Application	20	
	8.4	Application Error Messages	22	
9.	Cont	act Information	23	

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.
- In order to obtain accurate results, LUCIA 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		WEEE; waste electrical and electronic equipment
	Date of manufacture	7	Keep dry
CE	European Conformity	类	Keep away from sunlight
	Temperature limit	Ţ	Fragile, handle with care
	Consult Instruction for Use	<u> </u>	This side up
SN	Serial Number	*	Bluetooth
IVD	<i>In vitro</i> Diagnostic Medical Device	À	Caution
REF	Catalogue number		Biohazard
	Direct current	4	Electrical hazard

1.4 Labmaster LUCIA™ machine label



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.

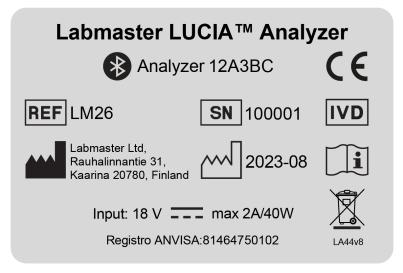


Figure 1. An example of Labmaster LUCIA™ Analyzer machine label



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

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.



- Ensure that LUCIA Analyzer is in proper working condition before operating.
 Read and follow all instructions, warnings and cautions before using the LUCIA Analyzer.
- Misuse of LUCIA Analyzer can cause harm to user and/or surroundings.
- Do NOT allow LUCIA Analyzer to come in contact with liquid. In case LUCIA Analyzer comes in contact with liquid, unplug it immediately.
- Use LUCIA Analyzer only for its intended use described in this manual.
- 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 while measuring.
- Do not use any power supply unit other than provided with LUCIA Analyzer.
- Do not use LUCIA Analyzer with any other accessories than those instructed by Labmaster Ltd.
- Do not place anything on top of LUCIA Analyzer.



- Do not use LUCIA Analyzer outdoors.
- Keep LUCIA Analyzer away from mechanical and magnetic interference. If it is suspected that performance is affected by electromagnetic interference, correct operation may be restored by increasing the distance between the equipment and the source of the interference.
- Do not use this device in proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these can interfere with proper operation.
- 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 2011/65/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

The Labmaster LUCIA™ Analyzer complies with the electromagnetic emission and immunity requirements described in the standard IEC 61326-2-6.

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

1.7 Warranty

Labmaster Ltd. offers the customer a 24-month limited warranty on a new Labmaster LUCIA™ Analyzer. The warranty period starts within 1 month of 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.



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 Labmaster Support: support@labmaster.fi

1.8 Disposal of the Labmaster LUCIA™ Analyzer



For disposal procedure of LUCIA Analyzer, please contact Labmaster Technical Support. support@labmaster.fi



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 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).

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 need 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 :- 100-240 V AC (50/60 Hz)

Operational environment

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

Humidity:- Maximum relative humidity: 80%

Location: - Dry, clean, levelled surface away from direct sunlight, mechanical and magnetic interference

2.3 Delivery, transportation and 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

Transportation: -When transporting Labmaster LUCIA™ Analyzer, keep dry, upright and protected from mechanical shocks. Use the original analyzer box for transportation. The transportation temperature range is +2 °C to +50 °C (+35° F to +122° F).

Storage: -Store Labmaster LUCIA[™] Analyzer in dry, upright and protected from mechanical shocks. The original analyzer box should be used for storing the analyzer if needed for long term out of use. The storage temperature range is +2 °C to +50 °C (+35° F to +122° F).



Ensure the Labmaster LUCIA $^{\text{TM}}$ Analyzer is decontaminated before transportation or Storage.

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



Ensure that there is enough space at the front of the Labmaster LUCIA™ Analyzer to allow the tray to move in and out. Min:- **6 cm**

Ensure the final location of the Labmaster LUCIA™ Analyzer is dry, clean and on a level surface. The analyzer must **NOT** be placed in direct sunlight or be affected by mechanical or magnetic interference.

- i. Connect the power cable into the PSU.
- ii. Connect the PSU's output lead to the Labmaster LUCIA™ Analyzer
- iii. Plug the power input cable from PSU to the external AC power outlet.
- iv. Power on the analyzer by using the power switch at the rear of the Labmaster LUCIA™ Analyzer.
 - While powering, the Labmaster 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.
- v. The Analyzer must be powered on for 30 minutes before 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.





NOTE:- Screen images shown in this instructions for use are representative of those displayed by the system.

3.2 Login with Operator ID

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

Note:- The Operator ID should be no longer than 10 characters.

- 1. Tap on the Operator ID window. See Figure 3.
 - This will launch the virtual keyboard.
- 2. Enter Operator ID using virtual keyboard.
- 3. Tap the Accept icon 🗸 .
 - Once the operator ID is entered and accepted, the analyzer moves to the Home Screen. See Figure 4.

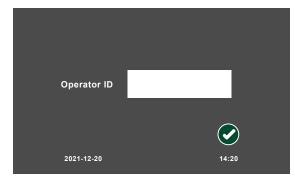


Figure 3. Operator ID Screen

3.3 Home Screen

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

- 1. Go to Settings
- 2. Patient sample measurements
- 3. Quality control measurements
- 4. View Measurement history
- 5. Change the Operator ID

2021-12-20

Figure 4. Home Screen

3.3.1. Change the Operator ID

To change the Operator ID, carry out the following procedure:

- 1. Tap on the Lock icon in the Home screen.
 - A text box will appear next to the Operator ID.
- 2. Reselect the text box.
 - This will allow the operator to edit the Operator ID using the virtual keyboard.
- 3. Enter the Operator ID and tap Accept .

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:

- 1. View Error Log.
- 2. Change Time / Date.
- 3. Change Brightness / Volume
- 4. Change Language

Analyzer ABC123 Analyzer ABC123 2021-12-20 14:25

Figure 5. Settings Screen

3.4.1. View Error Log

By tapping the Error Log icon, the information of the faulty measurement can be viewed on the error log page. See Figure 6.

 The error log enables analyzer diagnosis and tracking of unsuccessful measurements.

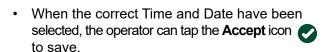


Figure 6. View Error Log Screen

3.4.2. Time and Date

By tapping on the Time and Date icon, the operator will be taken to the Time and Date screen. See Figure 6.

The time and date can be changed by selecting the corresponding arrow keys and by tapping on the calendar.



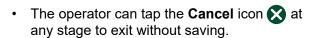




Figure 7. Time and Date Screen

3.4.3. Brightness and Volume

By tapping on the Brightness and Volume icon, the brightness can be adjusted by tapping on the slider and volume can be set to 'on' or 'off'. See Figure 8.

- When the correct Brightness and Volume have been selected, the operator can tap the Accept icon 🕢 to save.
- The operator can tap the **Return** icon **at** any stage to exit without saving.

2021-12-20

Figure 8. Brightness and Volume Screen

3.4.4. Language Options

The language can be changed by selecting the Language icon. See Figure 9.

- 1. Tap on Settings icon () in the Home Screen.
- 2. Tap on the Language Icon 🚮 at the top right of the screen.
- 3. Tap on the language required.
- 4. Tap on the Accept icon or tap the Cancel icon 🗙 to keep original language.



Figure 9. Language Options Screen

3.5 Measurement History

The Measurement History of the last 200 patient sample measurements, see Figure 10, can be accessed by selecting the history icon 📶.

- By tapping on the Individual Patient Data and then tapping the Accept icon, detailed information of the measurement is displayed. See Figure 11.
- Results can be transferred to a Windows PC or an android device via the Bluetooth application.

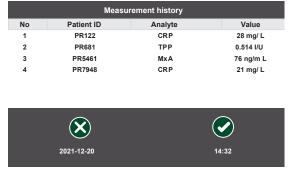


Figure 10. Measurement History Screen

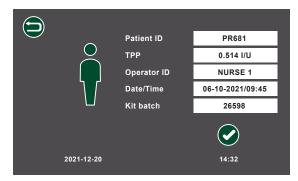


Figure 11. Detailed Patient Information Screen

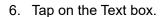
4. Patient sample measurement

- 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 3.3.1

- 2. Check that the Labmaster LUCIA™ test Kit's NFC Card and test components have the same LOT number.
- 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 (a) on the Home Screen.
 - A new page will appear. See Figure 12.
 - · 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.



- 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 screen will appear showing NFC icon. See Figure 13.
- 9. Place the NFC Card on the NFC icon on the Labmaster LUCIA™ Analyzer. See Figure 14
 - · There is a timeout limit of 30 seconds for reading the NFC Card.
- 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 15 will appear.
- 12. Slide the Labmaster LUCIA™ test cassette onto the tray. See Figure 17.



Figure 12. Patient Sample Measurement Screen



Figure 13. NFC Screen



Figure 14. NFC Card read

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 16.

- 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.

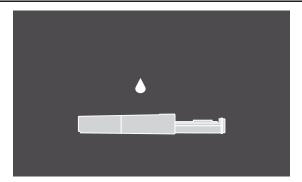


Figure 15. Load cassette screen



Figure 16. Sample application time out screen



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.
- 13. Transfer the sample to be tested to the Labmaster LUCIA™ test cassette according to the instructions of the Labmaster LUCIA™ test Kit. See Figure 18. Note: A capillary tube is used here as an example.
- 14. 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 19.

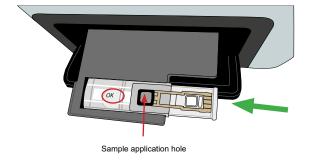


Figure 17. Labmaster LUCIA™ cassette loading

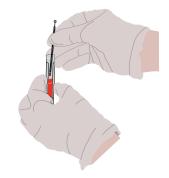


Figure 18. Sample transfer method (Capillary Tube)

- 15. Hold the tip of the sample transfer device against the membrane until the sample has spread over the entire membrane.
- 16. After adding the sample, tap the Accept icon on the sample application time out screen. See Figure 16.
 - The Labmaster LUCIA™ Analyzer will automatically proceed to the measurement stage. The tray will move in and the Measurement Timer screen in Figure 20 will appear.
 - · Once the measurement is completed, the analyte test result with the Patient ID will appear. See Figure 21.
 - · At the same time, the tray will come out with the used cassette.

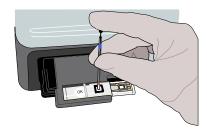


Figure 19. Sample transfer to cassette

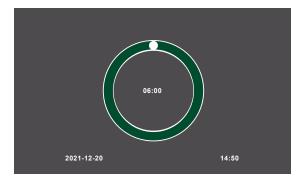


Figure 20. Measurement Timer screen

- 17. Remove the used cassette from the tray.
- 18. Tap on the Accept icon 🗸 on the patient's test result screen's pop-up window message.
 - The tray will move in into its normal position.
- 19. Tap Accept icon when the result is read on the screen in Figure 22.
- 20. Dispose the used Labmaster LUCIA™ cassette in accordance with local rules and regulations.

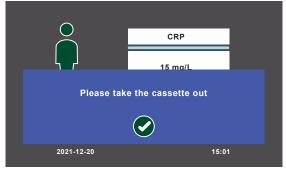


Figure 21. Pop up Message screen

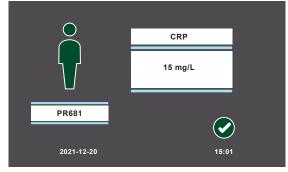


Figure 22. Patient's test result screen



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: - If the Labmaster LUCIA™ Analyzer is already operating, but the operator has been changed for the next round of measurements (i.e. next shift), the on-coming operator will be required to enter their 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.

- 1. Tap the Quality Control icon on the home screen. The QC screen will appear. See Figure 23.
- 2. Tap the QC icon again.
 - · The operator will be presented with a screen that will have options for measuring quality controls with different concentration levels. See Figure 24.
 - · By selecting any of the control sample icons, the QC measurement screen will appear. See Figure 25.
 - The Quality Control measurement icon is for running a QC test sample.
 - The View Measurement History icon 📶 allows the operator to view and have access to the previous 200 measurements in each level.



Figure 24. QC low, mid and high concentration



Figure 23. QC screen



Figure 25. QC measurement screen

NOTE: - If the operator selects a QC measurement, the measurement will follow the same transitional stages as described in section 4 with any regular sample measurements.

For each of the measurements, the operator can choose either to accept or reject the result. See Figure 26.

The operator is then directed to the comparable QC History Screen. See Figure 27.

3. To return to the Home Screen, tap Accept .

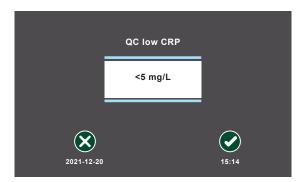


Figure 26. QC measurement screen

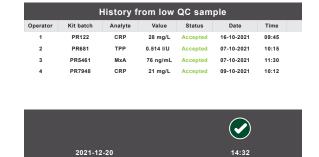


Figure 27. QC history of selected concentration screen



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

6. 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

6.1 Start/End of Daily Use Cleaning

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

6.2 Spillages

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

- Carry out the procedure in Section 6.1 Start/End of Daily Use Cleaning.
- For spillages in the tray, see Section 7.3 Operational Issues.

7. Troubleshooting

7.1 Reminder Message

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

This reminder message appears when the operator does not enter the patient ID. In order to exit the message and enter patient ID, select the accept icon and enter the ID.

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

7.2 Warning Message

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

The door was not closed properly.

The LUCIA analyzer's door was not closed properly. Check for any visible obstacles in the doorway obstructing the door from closing properly. Discard the cassette and re-measure with a new one.

Kit expired.

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

Rejected measurement/Reading NFC card failed.

Restart the LUCIA Analyzer and remeasure the sample. If warning reoccurs, contact support@labmaster.fi

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

Ensure that the device is at the operational temperature range and that the device has been exposed to an ambient temperature for at least 30 minutes. Repeat the measurement with a new cassette. Ignoring and continuing with the measurement may lead to false result. For traceability purpose, + or - will be added to the operator ID for the measurements outside of the recommended measuring temperature range.

7.3 Operational Issues

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

Indication	Probable cause	Corrective action
Liquid droplets on the tray.	Leakage of the cassette.	Blot the liquid into soft paper or cloth.
No power in LUCIA Analyzer.	Power and / or connection failure.	 Confirm that the electrical outlet is on. If it is not on, switch it on. Turn the LUCIA Analyzer on. Disconnect and firmly reconnect the power cable.
No test results.	Computational difficulty.	 Restart the LUCIA Analyzer and remeasure. If the problem reoccurs, contact support@labmaster.fi.
Failure of opening and closure of door.	Power and / or connection failure. Mechanical malfunction.	 Switch off the power and restart LUCIA Analyzer. If the problem reoccurs, contact support@labmaster.fi.
Tray with cassette stuck inside LUCIA Analyzer	Mechanical malfunction or misplaced cassette.	 Switch off the power and restart LUCIA Analyzer. Repeat the measurement using a new LUCIA cassette. If the problem reoccurs, contact support@labmaster.fi.
Abnormal noise from LUCIA Analyzer.	Mechanical malfunction or misplaced cassette.	 Restart LUCIA Analyzer. Repeat the measurement using a new LUCIA cassette. If the problem reoccurs, contact support@labmaster.fi.
LUCIA Analyzer screen flashing.	Electrical / GUI problem.	 Restart your LUCIA Analyzer. If the problem reoccurs, contact support@labmaster.fi.
LUCIA Analyzer screen freezing.	Hardware error.	 Restart LUCIA Analyzer. (If there was a LUCIA cassette inside LUCIAAnalyzer, take it out during the series of self-check routines as the tray will be automatically exposed.) Repeat the measurement using a new LUCIA cassette. If the problem reoccurs, support@labmaster.fi.

8. Result Export



Results from the LUCIA Analyzer can be exported to a Windows® PC by the LUCIA Analyzer Windows application. For Android devices, this is done by the means of an Android application.

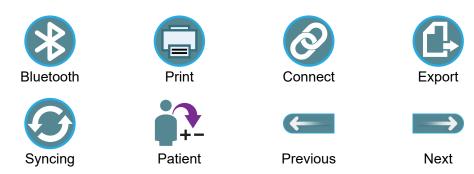
- All communications are by Bluetooth® Version 4 or higher short-range wireless technology.
- The installation and operation of these applications are described in this section.



DISCLAIMER: - The Windows PC and Android applications are not qualified as *in vitro* diagnostic medical device software as per Regulation (EU) 2017/746

8.1 Application Function Keys

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



8.2 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.

8.2.1. 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.

8.2.2. 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.

8.2.3. 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 28.



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



Figure 28. Labmaster LUCIA™ Analyzer Windows Application Home screen

- 2. Tap the correct analyzer from the drop-down menu and tap the connect button. See Figure 29.
 - The PC application will attempt to connect to the analyzer.
 - The drop-down menu will turn green when connected. See Figure 30.

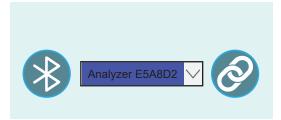


Figure 29. Drop Down Menu



Figure 30. Successful Connection



If the Labmaster LUCIA™ Analyzer is not available in drop-down menu, follow the procedure in the section 8.2.2 to pair the PC and the LUCIA Analyzer.

- 3. Tap the Synchronize icon to import data from connected LUCIA™ Analyzer. See Figure 31.
 - Syncing with Analyzer followed by 'Bluetooth ID' will be displayed above drop-down menu. See Figure 31.
 - After the application is successfully the Syncing Complete! Device Disconnected! message will be displayed and the result table will be updated.

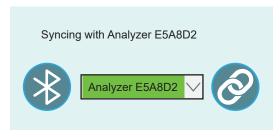


Figure 31. Syncing with Labmaster LUCIA™ Analyzer

8.2.4. Data Handling and Printing

- 1. To retrieve a detailed view of a specific result, tap on the specific patient data. See Figure 31.
 - 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 32.
- 4. Tap on the Export icon at the bottom right corner to export all the data in .csv format.

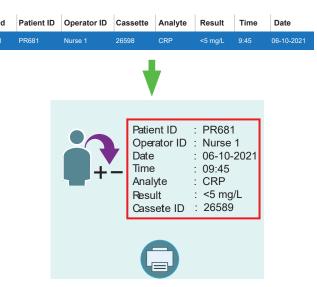


Figure 32. Retrieve a detailed view of a specific patient result

8.3 Labmaster LUCIA™ Android Application

The Labmaster LUCIA™ Analyzer Android Application allows the operator to save, print and export results from LUCIA™ Analyzer to android devices via Bluetooth.

Labmaster LUCIA™ android application can be found in Google Play Store or by scanning the QR code in Figure 33.

8.3.1. Pairing with Labmaster LUCIA™ Analyzer

- 1. Go to Settings.
- 2. Select Bluetooth.
- 3. Select Scan for devices.
- Select the Labmaster LUCIA™ Analyzer's Bluetooth device name you want to pair with.
- 5. Select Connect on the prompted message.
 - In LUCIA Analyzer, the same code will be prompted.
- 6. Select the Accept icon to accept the connection.



Figure 33. Labmaster LUCIA™ Android Application QR Code

8.3.2. Android Application Use

- 1. Open the application.
 - If Bluetooth is off, the application will prompt the operator with a message to turn on the device's Bluetooth.
 - Tap allow to turn on the Bluetooth. See Figure 34.
- 2. When installing the application for the first time, tap Allow to access the Android device as shown in Figure 35.
- After successfully launching the application, tap the Bluetooth icon to connect to your LUCIA Analyzer.



Figure 34. Allow LUCIA Analyzer to Turn on Bluetooth



Figure 35. Allow LUCIA Analyzer to Access to Device

- 4. From the drop-down list, tap the correct analyzer to connect to. See Figure 36.
- 5. Tap the Sync icon to import data from the connected analyzer. See Figure 37.
- 6. During syncing, Analyzer syncing in progress will be shown on the analyzer screen.

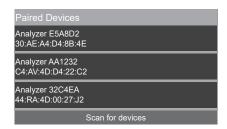


Figure 36. Select a Device/Analyzer to connect

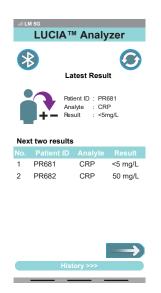


Figure 37. Android Application Main Screen



NOTE: - After data is synced successfully, a message will be displayed on the application and the Bluetooth will be disconnected automatically.

8.3.3. Data Handling and Printing

The Home screen will display the result of the latest measurement and two prior measurements simultaneously. See Figure 38.

- 1. Tap on the applicable result to view.
 - The complete patient result will be displayed.
 - Any measurement history of that particular patient stored in the device will also be displayed.
- 2. To view the next two results in the home screen, tap the **NEXT** icon. See Figure 39.
- 3. To view the previous two results in the home screen, tap the PREVIOUS icon. See Figure 39.
- 4. To view all the results, tap 'History' as shown in Figure 39.

Print or save particular result

- 5. Choose a particular result and tap print icon 📋 to print or save the result.
- 6. Follow the instructions shown on the smart phone.
 - You can save the data in your phone in pdf format or print it if printer is available.
- 7. To print the result, tap the printer from the drop-down menu. To export in pdf format, select save as pdf.
- 8. Follow the instructions on the smart phone.







Figure 38. Patient Results Saving



Figure 39. Previous and next Icons

Save whole result history

- 9. To export all the results, tap 'History' in the home screen. Next tap "Export" and enter the name for the file and tap "OK".
 - · A message "File is successfully saved" will be displayed. The data will be saved in the internal storage of your android device in folder named "Lucia".

8.4 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/Android 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.

9. Contact Information



Labmaster Ltd

Rauhalinnantie 31 20780 KAARINA, FINLAND

www.labmaster.fi info@labmaster.fi

Labmaster Sales

Email. sales@labmaster.fi Tel. +358 22 760 555

Labmaster Technical Support

Email: support@labmaster.fi



Labmaster Ltd.
Rauhalinnantie 31, 20780 KAARINA FINLAND
Tel. +358 22 760 555
Email. info@labmaster.fi

www.labmaster.fi



