

**LABMASTER** **LUCIA™**  
**Instructions For Use**



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# 1 Important Information

Thank you for choosing Labmaster LUCIA™ Products!

Please read this manual thoroughly before you operate the Labmaster LUCIA™ Analyzer.

Follow carefully all the instructions given in this manual.

## 1.1 Intended Use

Semi-automated Labmaster LUCIA™ Analyzer is an *in vitro* diagnostic medical device. It's a cathodic electro-chemiluminescence measuring instrument.

Labmaster LUCIA™ Test is an *in vitro* diagnostic test for the quantitative determination of the designated analyte from blood with LUCIA Analyzer by healthcare professionals. LUCIA Tests are not provided with the LUCIA Analyzer.

When interpreting LUCIA Test results, take into consideration the patient's medical history, clinical examinations and other laboratory results. Test results should never be used alone for making a diagnosis. A clinical evaluation is always required.

## 1.2 Please Additionally Note

- Use LUCIA Analyzer together with the LUCIA Test. The person carrying out the test should not arrive at any conclusion and/or should not take any decision of medical and/or therapeutic importance based on the test result without first consulting a physician.
- LUCIA Analyzer is only compatible with LUCIA Tests manufactured by Labmaster Ltd. The use of LUCIA Analyzer with immunoassay kits of other brands than LUCIA Tests will yield misleading results and is therefore prohibited.
- In order to obtain accurate results, the LUCIA Tests should always be performed in the LUCIA Analyzer in the approved environment having a temperature between +18 °C to +35 °C (+64 °F to +95 °F) and a maximum relative humidity of 80%.
- Avoid exposure of LUCIA Analyzer to dust, water (or any other liquid) or direct sunlight.
- Do not throw, shake, drop or mishandle LUCIA Analyzer.
- Do not disassemble your LUCIA Analyzer in any event.

## 1.3 Safety Information

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The user must ensure that LUCIA Analyzer functions safely and it is in proper working condition before it is being used. Make sure to read carefully through and follow all instructions, warnings and cautions before using the LUCIA Analyzer.

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Misuse of LUCIA Analyzer may cause harm to user and/or surroundings.

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Do not allow LUCIA Analyzer to get in contact with liquid in any manner. If LUCIA Analyzer becomes wet, unplug it before touching it.

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Use LUCIA Analyzer only for its intended use described in this manual.

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Never attempt to remove or open any parts of the LUCIA Analyzer casing.

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The use of a damaged or faulty LUCIA Analyzer may result in a personal injury..

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Never open the LUCIA Analyzer door while measuring.

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Use only the power supply provided with LUCIA Analyzer.

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Do not use LUCIA Analyzer with any other accessories than provided by Labmaster Ltd.

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Do not use LUCIA Analyzer if it is not working properly, or if it has suffered any damage.

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Do not place anything on the top of LUCIA Analyzer even when it is not being used.

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Do not insert anything into any openings in the LUCIA Analyzer, unless otherwise instructed.

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Do not use LUCIA Analyzer outdoors.

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## 1.4. Symbols

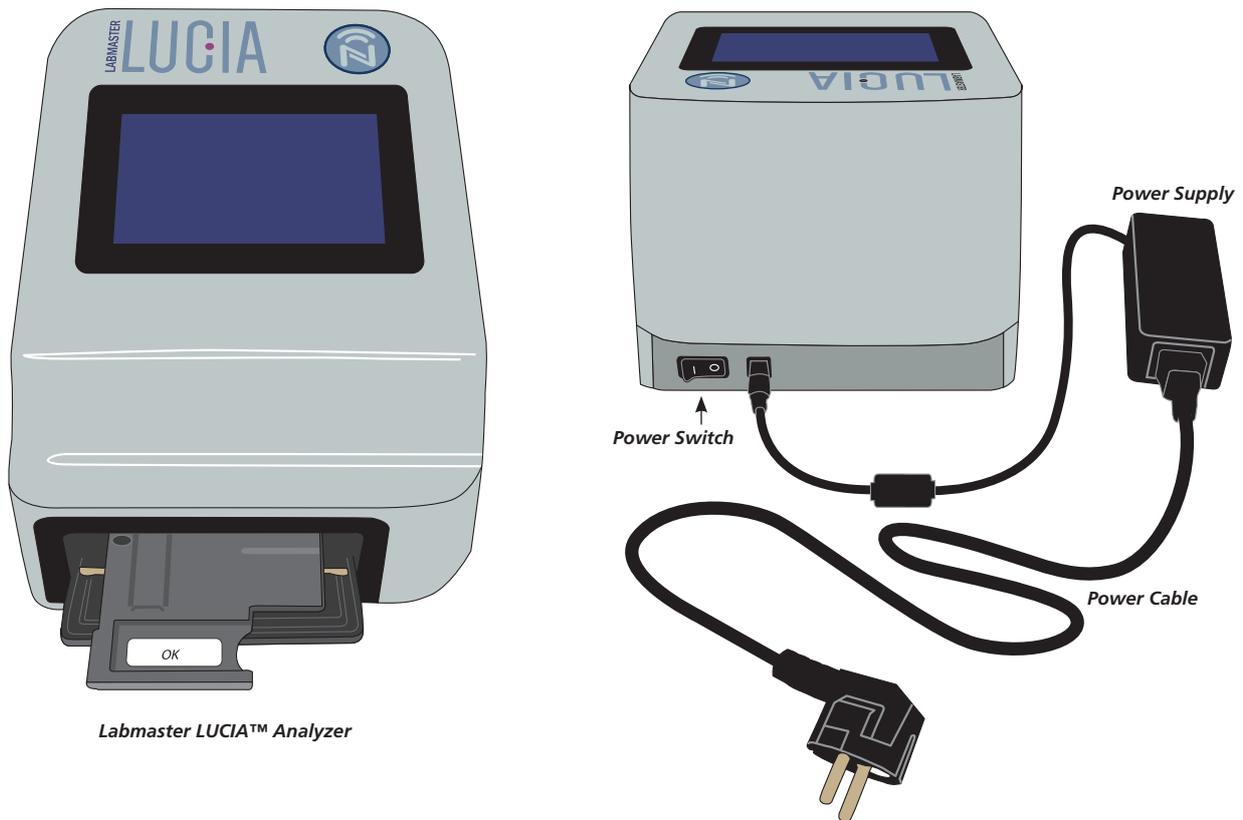
Following list explains the various symbols, related to the system and which the user will find in this LUCIA Analyzer operation manual, LUCIA product labels and packaging and the package inserts.

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	Manufacturer
	Date of manufacture
	Use by date (YYYY-MM-DD)
	Contains sufficient for <n> tests
	The CE marking
	Temperature limit
	Do not reuse
	Consult instructions for use
	REF Catalogue number
	LOT Batch code
	SN Serial number
	Direct current
	Separate collection for electrical and electronic equipment
	Keep dry
	Keep away from direct sunlight
	Handle with care
	<i>In vitro</i> -diagnostic medical device
	Bluetooth

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# 2 Labmaster LUCIA™ Analyzer



Labmaster LUCIA™ Analyzer

## 2.1. Principle

LUCIA Analyzer is a cathodic electrochemiluminescence instrument to be used only with LUCIA Test Cassettes.

LUCIA Test is based on a formation of immunochemical complex with the analyte to be measured. The complex comprises two different analyte recognizing antibodies, the other of these two being labelled with a luminescent label. The diluted sample is added into the cassette and the cassette is placed into the LUCIA Analyzer.

The sample passes through a membrane that contains the labeled analyte recognizing antibody. The analyte in the sample forms a sandwich complex with the labeled antibody and the antibody coated onto the silicon chip. The excess labeled antibody is washed away during the washing step. Labelled complex is excited with electricity. Resulting luminescence is collected and the on-board microprocessor computes the concentration of the analyte in the clinical specimen based on a pre-programmed calibration. The computed and converted result is displayed on the screen of the LUCIA Analyzer.

## 2.2 Technical Specification

### Physical description:

<b>Dimensions</b>	250 mm (L) x 185 mm (W) x 160 mm (H)
<b>Weight</b>	3.0 Kg
<b>Power supply</b>	100-240 V AC
<b>User interface</b>	5" Touchscreen with GUI (Graphical User Interface)

## Operational environment:

**Temperature** +18 °C to +35 °C

**Humidity** Maximum relative humidity 80%

**Location** Dry, clean, dust free and flat surface in an indoor setting and away from direct sunlight, mechanical vibration and magnetic fields

This device meets the EMC guideline as per EN 61326-2-6:2006.

## 2.3. Power Requirements

LUCIA Analyzer can only be operated by using the provided original power supply. Power supply can be connected to 100-240VAC (50/60Hz).

## 2.4. Package Contents

To set-up LUCIA Analyzer for the first-time use, unpack the contents of the package as listed below. Inspect the contents for any physical damage and/or missing component(s).

1. Labmaster LUCIA™ Analyzer
2. Power Cable
3. Power Supply

## 2.5. Installation Procedure



Before using the LUCIA Analyzer, make sure you have read the warning and cautionary statements described in the Safety Information (section 1.3) of this manual.

1. Connect the power supply to the LUCIA Analyzer.
2. Plug-in the power supply into a power outlet.
3. Do not block the front space of the LUCIA Analyzer as the sample tray will automatically be exposed at this point.
4. Turn the power switch behind the LUCIA Analyzer 'On'. LUCIA Analyzer will execute a self-test routine. Upon successful completion, the main screen is displayed. (**Note!** The actual content of the display text may differ depending on the specification and customer requirements.)
5. LUCIA Analyzer is now ready for use. See section 3.3.1 for switching the language.

## 2.6. Maintenance, Service and Disposal

The user must ensure that LUCIA Analyzer is only used with the power supply delivered with the instrument.

### 2.6.1. Return Procedure / Disposal

If the LUCIA Analyzer is not working for whatever reason, contact Labmaster Ltd. for consultation.

### 2.6.2. Transportation and Storage

The original shipping container should be used to ship or transport LUCIA Analyzer. The same container is also recommended for storing LUCIA Analyzer if unused.

When transporting or storing LUCIA Analyzer, keep it dry in upright position and protect it from mechanical shocks.

# 3 Graphical User Interface (GUI)

## 3.1. Operation

The operation of LUCIA Analyzer is based on primary functions; each of which can be represented and controlled by a specific corresponding key on the touch screen residing on the front panel of the LUCIA Analyzer. Once the power is turned ON, the system will automatically check its operations (system check).

Each of these primary functions of LUCIA Analyzer will be described below.

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## 3.2. Function Keys

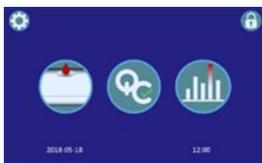
The function keys for the graphical user interface are listed below



Lock icon  
Go to operator ID writing  
by clicking this button



Operator ID screen



Main screen



Accept icon



Cancel icon



Settings icon  
Go to settings selecting  
this icon



Change language to English



Change language to Finnish



Back button, move back to  
main screen by clicking this  
button



View error log



Change date and time



Change brightness and volume



Measure a patient sample



Measure a quality control sample



View measurement history



Maintenance icon



Choose low, medium or high concentration QC sample



Measure a QC sample

### 3.3. Settings

By pressing settings icon on the left upper corner of the main screen the following set of icons can be accessed

- Language
- Error log
- Time / Date
- Light / Volume



#### 3.3.1. Language

Language can be selected by clicking the flag on the upper right corner.



#### 3.3.2. Error Log

The information of a faulty cassette can be viewed. The error log enables device diagnosis and tracking of unsuccessful cassettes.

No	Cassette	Operator	Time	Date	EXIC	EMIS
1	280219A201	SD	11:00	17.05.2018	8	80
2	280219A18	SD	9:00	17.05.2018	10538	25

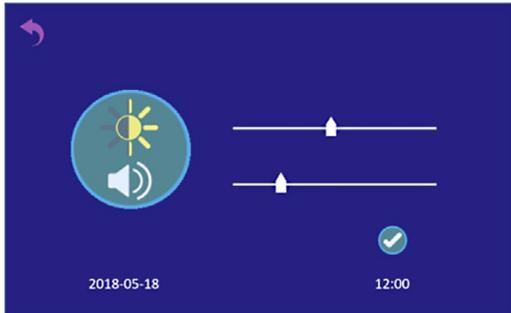
#### 3.3.3. Date and Time

Date and time can be selected by clicking the arrows right and left or up and down. Press accept icon to save the date and time or cancel to exit without saving.



### 3.3.4. Volume and Brightness

Volume and brightness can be adjusted by sliding the slider as shown in the picture below. Press accept icon to save or cancel without saving.



### 3.4. Operator ID

By pressing lock icon on the right upper corner of the main screen the following operator ID screen will be open and operator is prompted to write the operator ID.



By touching the textbox for operator ID in the middle, a hidden keyboard will appear on the screen. To edit the operator ID, retouch the ID textbox again to display the hidden keyboard.

Once you have typed in the operator ID, continue by selecting the accept icon on the right.

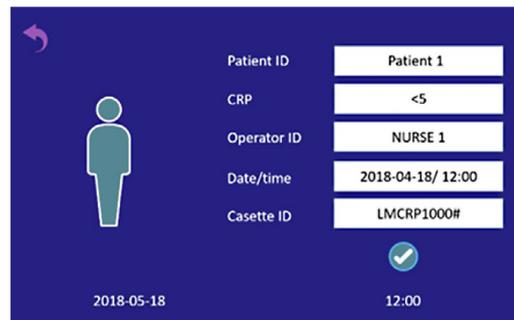
### 3.5. Measurement History



At any point, the history files can be accessed by using the history view icon and the last 100 patient sample measurements or 100 QC measurements can be seen.

Measurement History			
No	Patient ID	Analyte	Value
1	122345-123C	CRP	<5 mg/l
2	122346-123D	CRP	8 mg/l
3	122347-123E	CRP	20 mg/l
4	122348-123F	CRP	6 mg/l
5	122349-123G	CRP	8 mg/l
6	122350-123H	CRP	>200 mg/l
7	122351-123I	CRP	15 mg/l
8	122345-123C	CRP	<5 mg/l

By selecting the patient data and accepting it, a detailed information of measurement is displayed. The cancel icon returns the instrument to the main screen.



Results can be transferred via Bluetooth. Special program for PC and Android device is necessary.

# 4 Patient Sample Measurement

Prior to start, the test set up (the LUCIA Tests and LUCIA Analyzer) should always be first exposed to an ambient temperature for at least 30 minutes just before performing the actual test.

Note: If the LUCIA Analyzer is already turned 'ON' but the operator has been changed, the new operator needs to write his/her operator ID by clicking the lock icon.

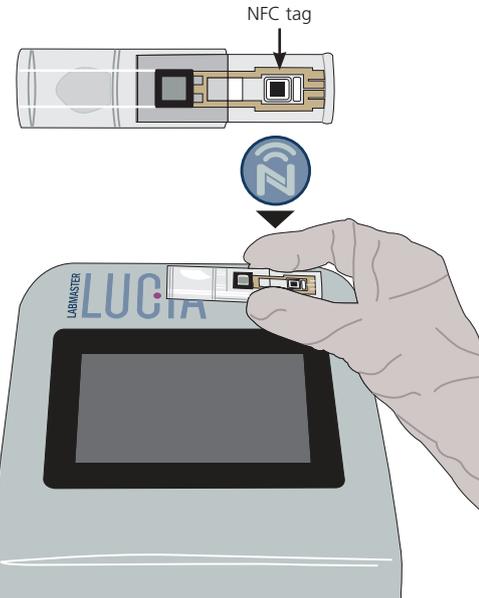


## 4.1. Patient Sample Measurement

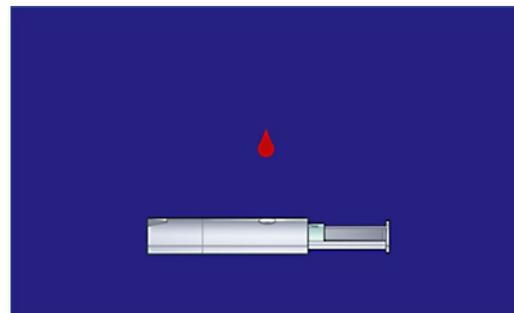
1. Follow the instructions of **LUCIA Test Kit Insert**.
2. Collect and prepare a sample.
3. Unwrap the LUCIA Cassette from the sealed pouch.
4. Select the patient sample icon on the left from the main screen. A new page will open and the operator is prompted to write the patient ID.



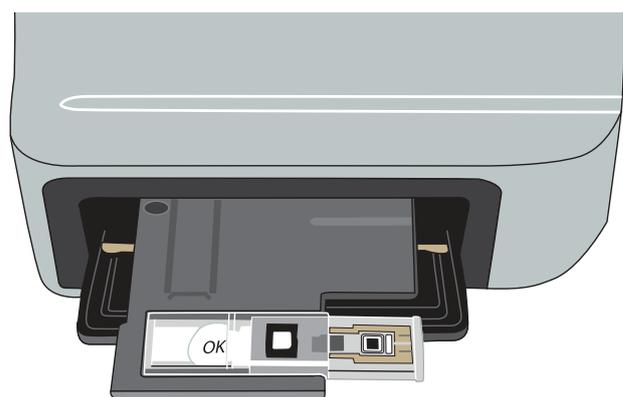
5. By touching the textbox for patient ID in the middle, a hidden keyboard will appear on the screen. To edit the patient ID, the hidden keyboard can be revisited again by retouching the ID textbox.
6. Once you have typed in the patient ID of the sample, continue by selecting the accept icon on the right (or cancel on the left).
7. Press accept, the following screen for reading NFC tag appears and indicates that the cassette needs to be placed on the NFC reader which is located on the device with NFC logo on it. There is a timeout of 30 seconds for reading the NFC.



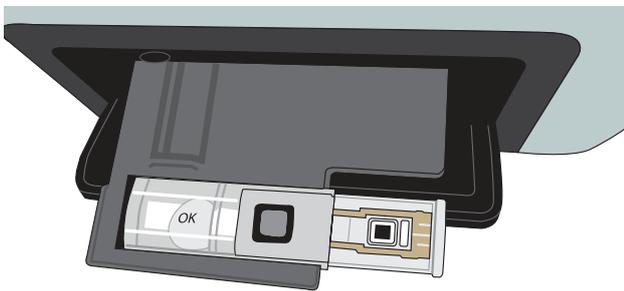
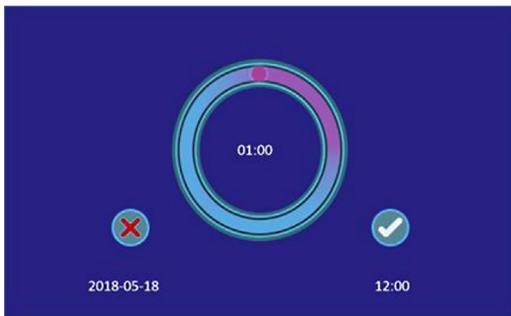
8. Upon successfully reading the tag, the following screen appears and indicates that the LUCIA Cassette can be placed onto the tray.



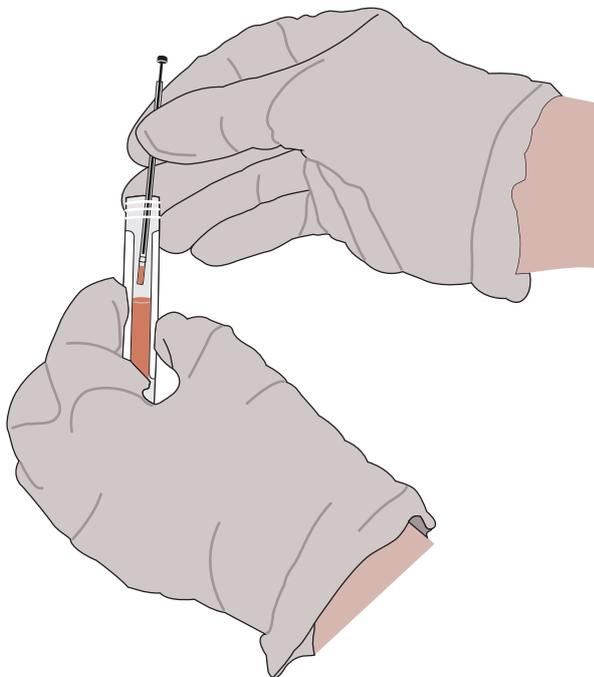
9. The cassette is placed correctly on a tray when OK text can be seen under the cassette and when sample application hole is facing upwards. If OK text can not be seen, the cassette is placed on a tray backwards.



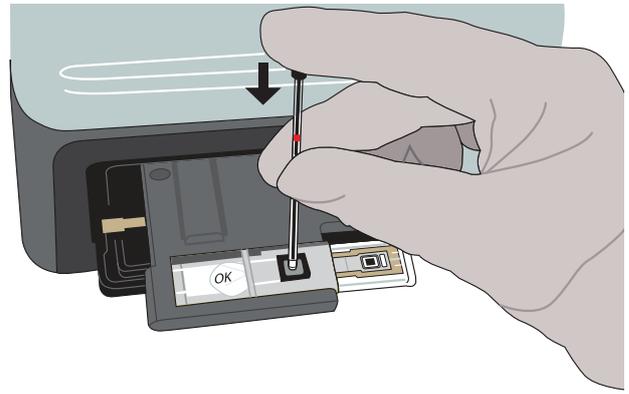
10. The following screen is a timeout screen and allows you to insert the LUCIA Cassette onto the sample tray and apply the sample within a 1-minute time frame.



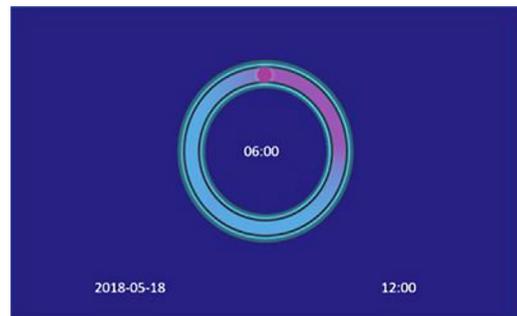
11. Transfer the sample according to instructions of the Labmaster LUCIA™ Test to the cassette. (The capillary tube is used in the examples of the pictures.)



12. Place the tip of the sample transfer device into the sample application hole of the cassette so that it lightly contacts the membrane. Hold the tip of the sample transfer device gently against the membrane until the sample has spread on the entire membrane.



13. After adding the sample, click accept icon. LUCIA Analyzer will automatically proceed to measurement and the following screen appears.



**Note!**

**Tray will immediately close automatically once the measurement starts!**

14. Once the measurement is finished, the name of the analyte, test result and patient ID will appear.



15. Once the daily measurements are done make sure that no cassette is left on the sample tray of the LUCIA Analyzer. There is no need to switch the power off.



## 4.2. Quality Control (QC) Measurement

Both the LUCIA Analyzer and LUCIA Test are factory calibrated. It is recommended to use commercial controls for quality assurance. Commercial controls should be handled according to the instruction of use provided with the controls. The user sets the limit values for the controls.

Prior to start, the test set up (the LUCIA Tests and LUCIA Analyzer) should always be first exposed to an ambient temperature for at least 30 minutes just before performing the actual test.

1. Select the quality control icon in the middle of the main screen.

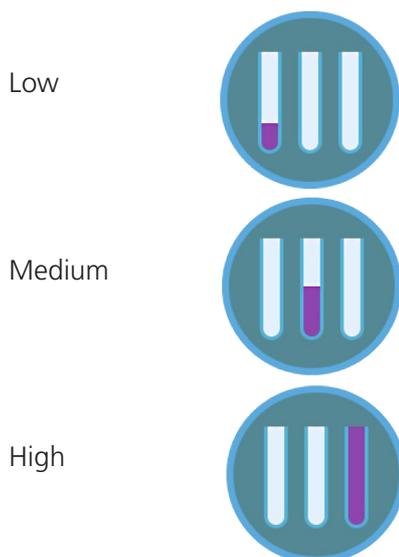


2. A following screen will open, and the operator is prompted to select the QC (on the right).

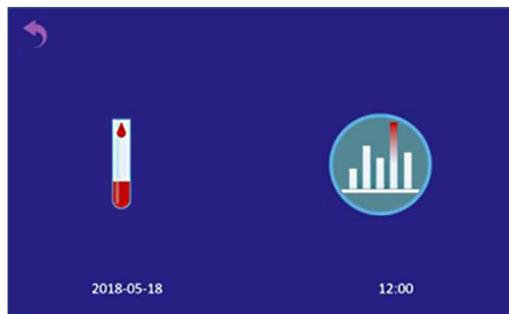
3. The maintenance icon (on the left) is for verifying the functionality of the analyzer and used only by the serviceman.



By pressing the QC icon, the following options for measuring quality controls with different concentration levels will appear:

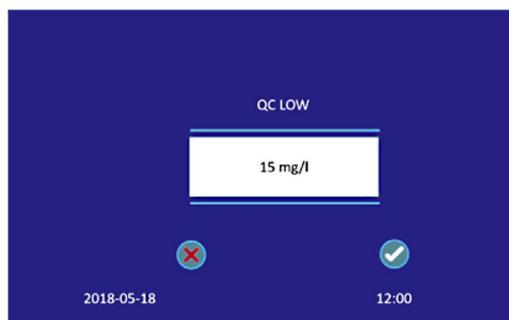


4. By selecting any of the control sample icons the following QC main screen will appear. The icon on the left (test tube) is for running a QC test sample whereas the history view icon on the right allows you to access the previous measurements.



5. If a running a QC test sample icon has been selected, the measurement will follow the same transitional stages as presented in section 4.1 with any regular sample measurements.

6. For each of the measurements one can choose either to accept or reject the result where after the operator is directed to the comparable QC history screen.



QC History from Low

No	Operator	CRP	STATUS	Date	Time
1	NURSE1	15	Accepted	18.05.2018	11:00
2	NURSE2	14	Rejected	18.05.2018	10:00
3	NURSE3	11	Rejected	17.05.2018	09:00
4	NURSE4	20	Accepted	16.05.2018	11:00

7. By selecting the accept icon from the QC history, a detailed view of the measurement appears whereas by choosing the cancel icon, the instrument returns to the main screen.

8. Once the daily measurements are done make sure that no cassette is left on the sample tray of LUCIA Analyzer. There is no need to switch the power off.

## 4.3. Troubleshooting



### 4.3.1. Error Messages

The following error messages may appear on the screen depending on the issues related to measurement.

#### **Please enter patient ID.**

If no patient ID is entered then the error message shown in picture above appears. Pressing accept icon will exit the error message and the patient ID must be entered.

#### **Rejected measurement / Reading NFC tag failed.**

Restart the LUCIA Analyzer and remeasure the sample with a new cassette. If error reoccurs, contact Labmaster Ltd. technical assistance.

#### **No cassette. Please try again.**

Check that there was a cassette inside the analyzer during the measurement. If not, remeasure the sample with a new cassette.

#### **The lid hasn't closed properly.**

Switch off the power and restart the LUCIA Analyzer and check that the lid closes properly. If error reoccurs, contact Labmaster Ltd. technical assistance.

#### **Cassette expired.**

LUCIA Cassette has expired. Remeasure the sample with a valid batch of LUCIA Cassette.

#### **Cassette already used.**

The Cassette has already been used or NFC tag has been read but measurement has not taken place in within a 1-minute time frame. Repeat the measurement with a new LUCIA Cassette.

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

Check that the device is stored in the correct temperature and that the device has been exposed to an ambient temperature for at least 30 minutes. Repeat the measurement with a new LUCIA Cassette.

#### **Please take the cassette out.**

The already used cassette has been forgotten inside the LUCIA Analyzer. Take it out.

In case of operational problems the following table of corrective measures might be helpful.

Symptom	Probable cause	Corrective action
Liquid droplets on a tray.	Leakage of the cassette.	Blot the liquid into the soft paper or cloth.
No power; LUCIA Analyzer screen is blank.	Power and / or connection failure.	Confirm that the electrical outlet is ON. Switch it ON if is not. Turn the LUCIA Analyzer ON. Disconnect and firmly reconnect the power cable.
No test result.	Computational difficulty.	Restart the LUCIA Analyzer and remeasure. If the problem reoccurs, contact the Labmaster Ltd. Technical Assistance.
The door for the Cassette tray fails to open / close.	Power and / or connection failure. Mechanical mal-function.	Switch off the power and restart LUCIA Analyzer. If the problem reoccurs, contact Labmaster Ltd. Technical Assistance.
Cassette stuck inside, the door does not open and the tray is inside.	Mechanical mal-function or misplaced cassette.	Switch off the power and restart LUCIA Analyzer. Repeat the measurement using a new LUCIA Cassette. If the problem reoccurs, contact the Labmaster Ltd. Technical Assistance.
Extra sound heard during the LUCIA Cassette movement.	Mechanical mal-function or misplaced Cassette.	Repeat the measurement using a new LUCIA Cassette. Restart LUCIA Analyzer. If the problem reoccurs, contact the Labmaster Ltd. Technical Assistance.
LUCIA Analyzer screen problem (flashing, etc.).	Electrical / GUI problem.	Restart LUCIA Analyzer before the next measurement. If the problem reoccurs, contact the Labmaster Ltd. Technical Assistance.
LUCIA Analyzer screen problem (freezing).	Hardware error.	Restart LUCIA Analyzer. (If there was a LUCIA Cassette inside LUCIA Analyzer, take it out during the series of self-checking routines as the sample tray will be automatically exposed.) Repeat the measurement using a new LUCIA Cassette. If the problem reoccurs, contact the Labmaster Ltd. Technical Assistance.



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