

CUBE-S / CUBE

User Manual



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













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SYMBOLS & ABBREVIATIONS

The following symbols and abbreviations are used in the product labeling and instructions for the Eurolyser laboratory photometer.

Symbol / Abbreviation

Explanation

	Conformity marking according to the directive 2004/108/EC of the European Parliament and of the European Council
	Catalogue number / Order number
	Lot number
	Serial number
	Bluetooth
	Connection
	Power Supply / Device Readiness
	Use by
	Temperature limitations
	Relative humidity limitations
	Manufacturer
	Production date
	Sterile
	Warnings and precautions, see accompanying documents
	Operator's action
	Refer to the user's manual and follow the instructions
	Do not dispose with household waste
ERS TC	ERS Testing Cartridge

LED	Light Emitting Diode
PC	Personal Computer
ID	Identification
HIS / LIS	Hospital Information System / Laboratory Information System
AC	Alternating Current
DC	Direct Current
RFID	Radio Frequency Identification

Table 1: Product Labelling and User Manual Symbols

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INTRODUCTION

Intended use of the Eurolyser CUBE-S/CUBE Laboratory Photometer

The Eurolyser CUBE-S/CUBE Analyser consisting of the CUBE-S/CUBE Instrument laboratory photometer and the CUBE-S/CUBE Tablet PC is intended as a general purpose laboratory instrument for the quantitative determination of clinical wet chemistry parameters.

The CUBE-S/CUBE Instrument is highly compact and is designed as a point of care measuring Instrument for the ERS (Eurolyser Reagent System). It is easy to use and provides quick, reliable and accurate results.

About this user manual

This user manual will guide you through the installation, operation and maintenance of your Eurolyser CUBE-S/CUBE Instrument. The user manual also explains how the photometer works, describes the quality assurance system and assists you in troubleshooting any errors or problems. When not used according to the user manual the CUBE-S/CUBE Instrument may be influenced or damaged.

We recommend that you familiarize yourself with these instructions before operating the Eurolyser CUBE-S/CUBE Instrument. Some of the information in this user manual is marked with following symbols:



Operator's action



Warnings and precautions; see accompanying documents



Refer to the user manual or test kit package insert and follow the given instructions

Inspecting the package contents

When unpacking the CUBE-S/CUBE Analyser, check the contents against the list below and examine the components for signs of shipping damage (see illustration on the following page).

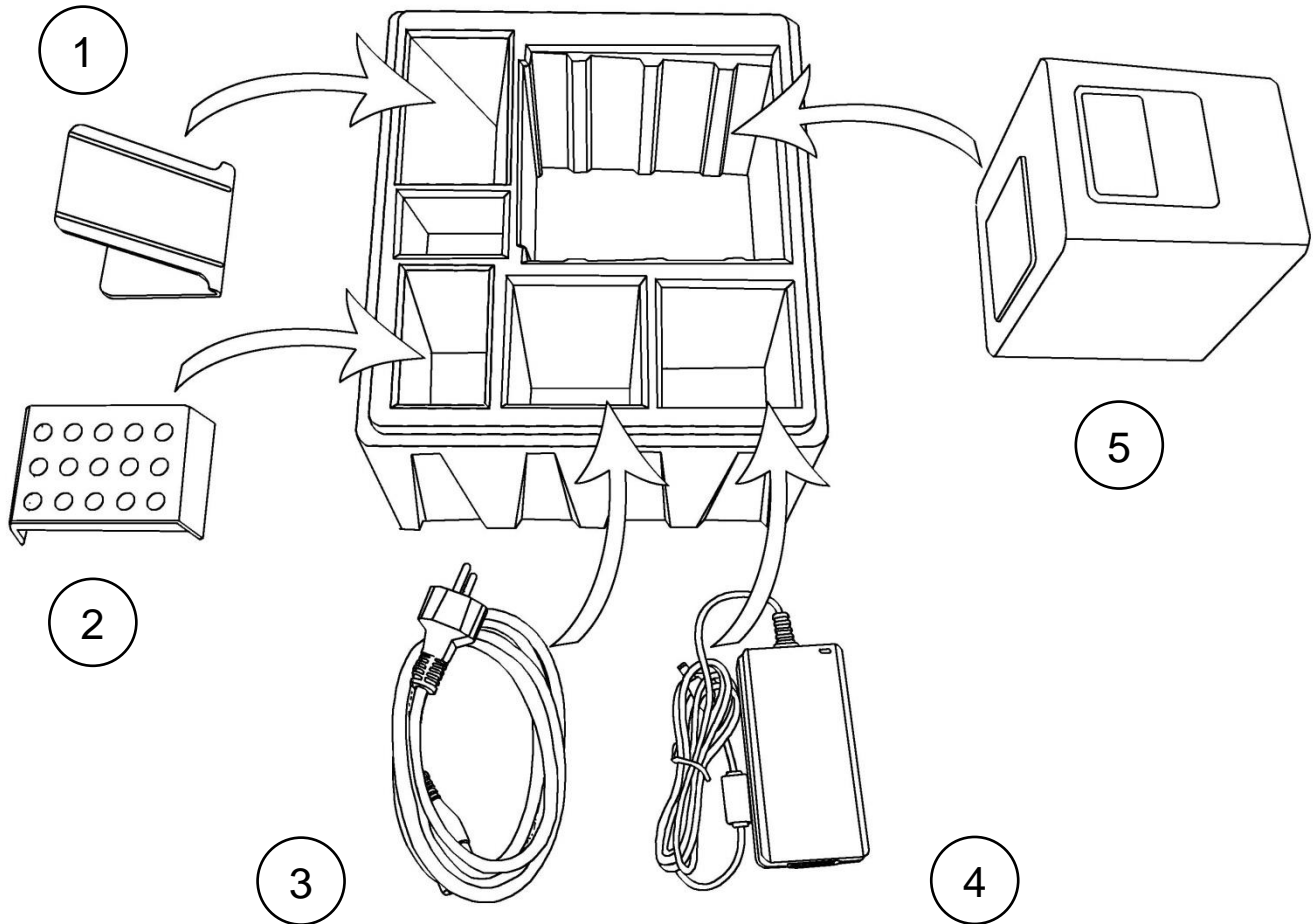
The CUBE-S/CUBE package contains:

- the Eurolyser CUBE-S/CUBE Instrument
- a main adapter
- a power cable
- this user Manual (on a CD)
- the Quick Reference
- a Test-Kit Rack
- a Tablet Stand

If any part of the package is missing or damaged, please report this to your supplier immediately. It is recommended to keep the original packaging, in case the Instrument ever needs to be transported.

CUBE-S/CUBE packaging

In case of returning the CUBE-S/CUBE Instrument to the manufacturer and/or before transporting the Instrument, please repack the CUBE-S/CUBE Instrument contents in the original packaging according to the following illustration:



1. Tablet Stand
2. Test-Kit Rack
3. Power Cable
4. Main Adapter
5. CUBE-S/CUBE Instrument

Note: In case of a necessary return of the Instrument to the manufacturer or before transport please repack the CUBE-S/CUBE Instrument contents in the original packaging according to the illustration above! Moreover, please remember to reinsert the white transport lock into the CUBE-S/CUBE Instrument door before repacking (see Transport lock on page 13)!

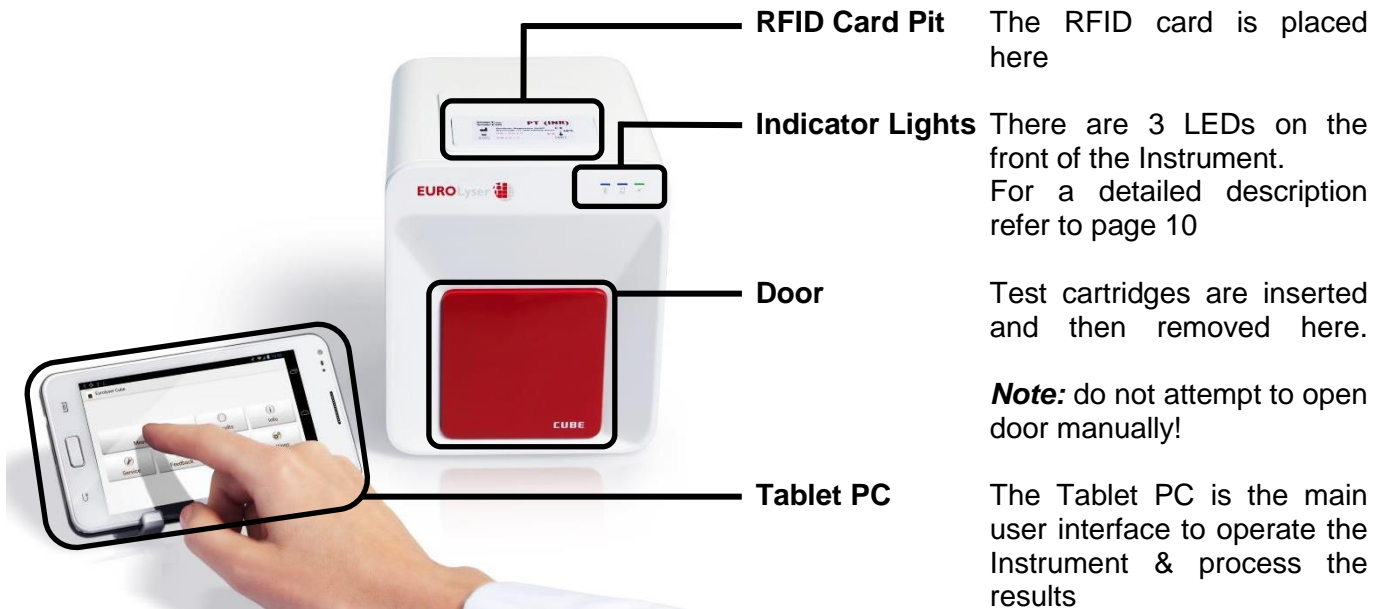
Note: The CUBE-S/CUBE Tablet PC is delivered in a separate package and must be returned in this if necessary.

WARNING: Wrong packing and/or the use of inappropriate packaging can cause severe damage to the Instrument!

SYSTEM DESCRIPTION

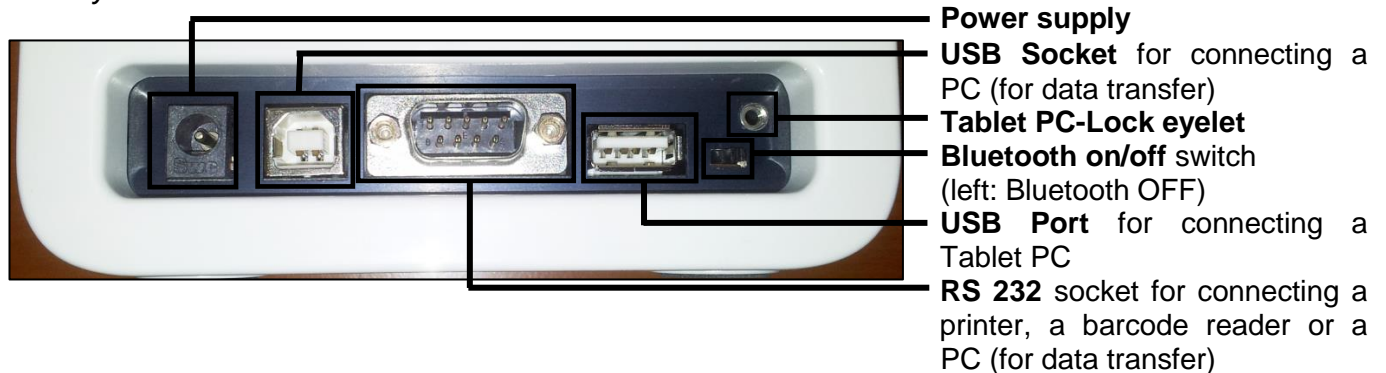
Description of the Eurolyser CUBE-S/CUBE Analyser

This section introduces the general characteristics of the Eurolyser CUBE-S/CUBE Instrument and Tablet PC.



CUBE-S/CUBE Instrument Interfaces

Eurolyser CUBE-S/CUBE Instrument Interfaces




- Do not use liquid cleaners on the Instrument or Tablet PC! Use a lint-free, slightly damp cloth only!
- Do not attempt to open the door manually


Indicator lights


Eurolyser CUBE-S/CUBE front



LEDs on the Eurolyser CUBE-S/CUBE Instrument

-  This green LED indicates the readiness of the photometer
Flashing: the Instrument is warming up and testing cannot be started yet (*Note:* this takes approximately 10 min.)
Constantly lit: the Instrument is warmed up and ready for use
Off: the Instrument is not plugged in

-  This blue LED indicates a connection to a Tablet PC
Constantly lit: a connection with a Tablet PC is established
Off: the Tablet PC is not connected


-  This blue LED indicates a Bluetooth connection to Tablet PC
Constantly lit: a connection with a Tablet PC is established
Flashing: Bluetooth is activated on the photometer but no Tablet PC is connected via Bluetooth
Off: Bluetooth is switched off

Note: The Bluetooth connection is operational with Tablet PCs with serial numbers Tb##### or higher. To keep the Tablet PC constantly powered it is recommended to use the USB cable connection.

How to handle the Eurolyser CUBE-S/CUBE Laboratory Photometer

The CUBE-S/CUBE Instrument is operated solely by means of the Tablet PC. All the basic operating steps are displayed as symbols. An overview of these symbols can be found in Table 1 (p. 3) and Table 2 (p. 12). To activate a symbol tap it with a finger.

In order to perform a test, the RFID card enclosed in the test kit must first be placed on the Instrument. This card contains all the data needed to perform the tests. No analysis can be started without the RFID test card!

The door opens automatically once a test is initiated by pressing the  button. After entering all the requested data on the Tablet PC and inserting the ERS cartridge into the slot, close the door and the testing procedure begins automatically. After the analysis is completed, the door opens automatically and the test cartridge is to be removed.

The door prevents ambient light, dust, dirt and humidity from entering the Instrument during the testing process and when the Instrument is not in use.

Please make sure the door is closed whenever the Instrument is not in use.

How the Eurolyser CUBE-S/CUBE Laboratory Photometer works

The Eurolyser CUBE-S/CUBE Instrument is an open measuring system. This means that it is able to use various reagents from multiple manufacturers. To perform a test the CUBE-S/CUBE Instrument is loaded with an ERS cartridge filled with reagents from the respective reagent manufacturers. The Instrument can process endpoint tests, kinetic tests and coagulation tests. Due to the latest LED technology used it is maintenance-free.

The Instrument is equipped with an RFID card-reader module. RFID cards are necessary for performing any testing procedures. They are included in the test kits from the respective test manufacturers and contain all the specific steps for the various tests, the lot data, as well as the calibration data. The Instrument performs the tests automatically according to that data. Numerous types of tests can be selected and performed automatically.

The sample and the reagent are automatically mixed within the Instrument. The photometer unit performs the analysis with a light diode. The absorption of light rays is measured during this process and the measured value is then converted into the test result using mathematical methods. The result is displayed on the Tablet PC. Optionally, results can be exported to an external computer or an HIS/LIS and can also be printed out using an external printer.

After the test process the door opens automatically and the ERS cartridge can be removed and discarded. After confirming the result on the Tablet PC and closing the door on the instrument the system is ready to perform the next analysis.

Manufacturer calibration

The Eurolyser CUBE-S/CUBE Instrument is manufactured according to the highest quality standards in order to yield safe and accurate testing results. Every Instrument is inspected and calibrated during the manufacturing process, using the EU-stipulated reference methods.

PICTOGRAMMS / BUTTON SYMBOLS

Tablet PC symbols and their functions

Tapping one of these symbols on the Tablet PC activates the described function.





















Symbol	Name	Function
	CUBE-S/CUBE App Icon	Starts the Eurolyser CUBE-S/CUBE app
	Browser	Opens the Web Browser on the Tablet PC
	Android Settings	Opens the Android settings menu
	Return arrow	Cancels an input OR return to the previous screen or menu
	Return to main menu	Returns directly to the main menu
	Measurement	Opens the menu for test data entries
	Results	Opens the result list screen
	CUBE-S/CUBE Settings	Opens the Configuration menu
	Edit	Opens an entry or value so it can be edited
	Confirm	Confirms the input
	Abort to main menu	Cancels an action and returns to the main menu
	Start analysis	Starts the test process
	Print	Opens the print / export / mail dialogue
	Filter	Opens the Filter Options
	Transmit	Opens the Export dialogue
	Chart	Displays the photometric data curve of a test result
	Page forward	Displays the next page
	Page backward	Displays the previous page
	Recycle bin	Opens the delete dialogue
	Synchronize	Synchronises result(s) and Instrument status with the Eurolyser servers

Table 2: CUBE-S/CUBE Tablet PC symbols

GETTING STARTED

The proper placement of the CUBE-S/CUBE Laboratory Photometer



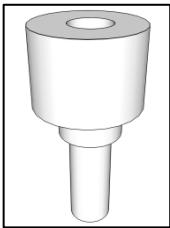
Place the Instrument on a dry, clean, stable and level surface. Make sure the Instrument has at least 10 cm of table surface and clearance on each side and that the Instrument can be easily disconnected from the power source. Allow the Instrument to acclimate to the ambient room temperature before operating it.

The Instrument can be damaged by:



- Condensing humidity and water
- Heat and large temperature fluctuations
- Direct sunlight
- Vibrations (e.g. from centrifuges and dishwashers)
- Electromagnetic radiation
- Electrostatic discharge

Transport lock



Upon first use the white transport lock is to be removed from the door of the Instrument.

Note: keep both the transport lock and the original packaging. In case of a defect the Instrument is to be returned in the original packaging (see p. 8) with the transport lock installed to prevent any damage during transportation!

Connecting the power supply

Eurolyser CUBE-S/CUBE Instrument Interfaces



Power supply

USB Socket for connecting a PC (for data transfer)

Tablet PC-Lock eyelet

Bluetooth on/off switch
(left: Bluetooth OFF)

USB Port for connecting a Tablet PC

RS 232 socket for connecting a printer, a barcode reader or a PC (for data transfer)



- Connect the power cable to the power supply unit.
- Insert the plug from the power supply unit into the power socket on the back of the Instrument
- Plug the power cable into the wall socket.



Always connect to the proper supply voltage. The power supply voltage must comply with the regulations cited in the technical specifications on page 40. Ensure a properly installed electrical grounding. The Instrument is to be operated only using the power supply unit provided.

The Tablet PC

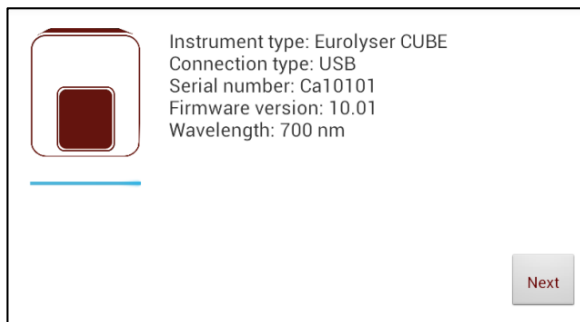
The Eurolyser CUBE-S/CUBE Instrument is operated with a Tablet PC.

Connect the Tablet PC to the USB port of the plugged-in Instrument and then turn on the Tablet PC.

An independent Tablet PC manual is delivered with the Tablet PC. It describes in detail the operating of the Tablet PC, how to manage settings and the establishing of a Bluetooth or USB connection between the CUBE-S/CUBE and the Tablet PC.

Starting & Operating the Tablet PC

1. Connection Screen



The connection screen appears upon connecting the Tablet PC with the CUBE-S/CUBE Instrument.

Tap *Next* to continue.

2. Main Menu

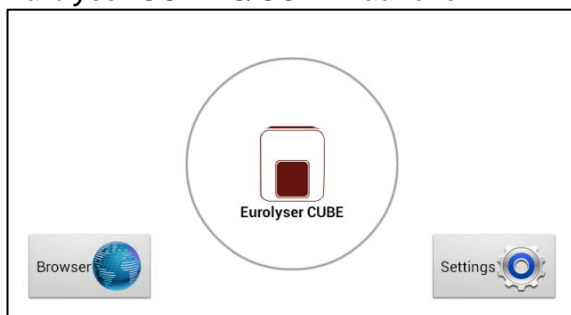


The CUBE-S/CUBE app starts and the main menu appears.

Note: while the Eurolyser CUBE-S/CUBE Instrument is warming up (indicated by the flashing green LED on the front) the "Measurement" Button is grey and inactive.

The Eurolyser CUBE-S/CUBE Launcher

Eurolyser CUBE-S/CUBE Launcher



When the Tablet PC is not connected to the Instrument or by pressing the Home Button the Eurolyser CUBE-S/CUBE Launcher appears:


Tapping *Browser* opens the Android web browser

Tapping *Eurolyser CUBE-S/CUBE* starts the CUBE-S/CUBE app

Tapping *Settings* opens the Android settings menu

Note: If the standard Android Desktop appears instead, switch the Tablet PC off, back on, select "CUBE-S/CUBE Launcher" and confirm by tapping "Always".

Changing the language of the Eurolyser CUBE-S/CUBE application

The language of the application is automatically set according to the language of the operating system of the Tablet. It can be changed by pressing the home button on the Tablet PC (the launcher appears), then pressing  to open the settings. Swipe down and select *Language and input* in the category "Personal". Tap *Language* and choose a language. Press the home button to return to the launcher.

Note: the Eurolyser CUBE-S/CUBE application supports several languages. If you choose a language in the system settings that is not supported by the CUBE-S/CUBE app English will be used.

How to switch the Eurolyser CUBE-S/CUBE Laboratory Photometer ON



The Instrument is switched on by plugging the power cable into the socket. This launches the Instrument's automatic start-up and warm-up processes. Please wait for these to be completed (approximately 10 minutes).

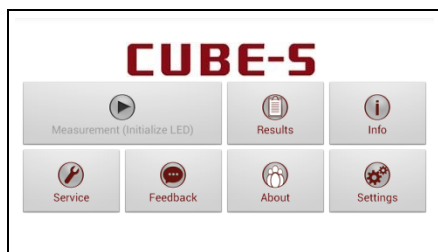
When operating the Instrument:



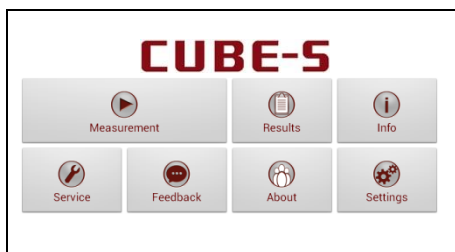
- The door protects the analysis system from dust, dirt and humidity. Empty the door's cartridge chamber after every analysis and keep it closed when the Instrument is not in use.
- The door opens automatically. Do not attempt to open the door manually!
- If an error message appears during an analysis, please consult the "Troubleshooting" section on page 38.

The automatic start-up and warm-up processes


1. Warm-up menu



2. Main Menu



The automatic start-up procedure (indicated by the flashing green LED) starts as soon as the Instrument is connected to the power supply. The Instrument is warmed up to its proper working temperature in approximately 10-15 minutes.


As soon as the initialization of the optical unit is completed, the  button turns from b/w to color and reacts to tapping. The Instrument is now operational.

CONFIGURING THE EUROLYSER CUBE-S/CUBE

You can configure your Eurolyser CUBE-S/CUBE laboratory photometer according to your needs before using it. To access the configuration menu follow these steps:

1. Start-up menu



Tap  to open the Settings menu.

2. Settings menu



Tap the setting you want to configure. Swipe down to view all available options.

All following descriptions are examples. The configuration of the Eurolyser CUBE-S/CUBE Instrument models may vary depending on the tests used.



Note: The normal values, units and sample types for a test can only be displayed if the respective test RFID card has been placed on the Instrument and read.

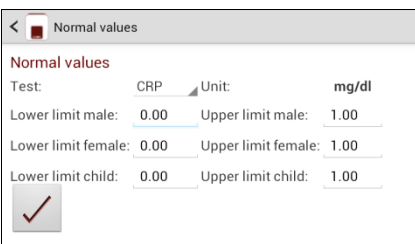
Setting normal values and limits

1. Settings menu




Tap *Normal Values* to open the Normal Values / Limits menu.

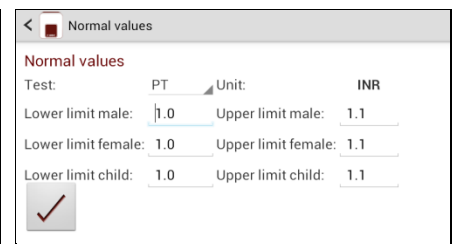
2. Normal values/limits menu, e.g. CRP




To change a limit tap the value and change it using the appearing Tablet PC keyboard.

To change the test for which the normal values are displayed tap  and select a test in the appearing drop down menu*.

2.1 Normal values/limits menu, e.g. PT



To change a limit tap the value and change it using the appearing Tablet PC keyboard.

To change the test for which the normal values are displayed tap  and select a test in the appearing drop down menu.

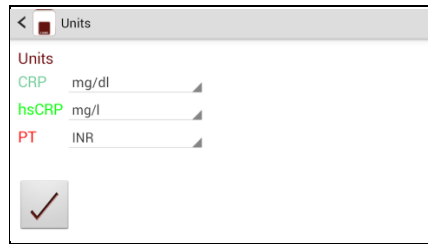
Setting units

1. Configuration menu



Tap *Units* to open the Unit selection menu.

2. Unit selection menu



Tap and select a unit in the appearing drop-down menu. Confirm the change(s) with .

Configuring inputs (Sex, Sampletype, Hematocrit, Operator)

1. Configuration menu



Tap *Input* to open the input menu.

2. Input menu



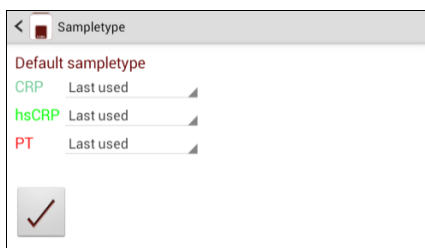
Tap a parameter and the respective menu will open. The following descriptions are provided in the order of the parameters in the Input menu.

3.1 Default sex menu



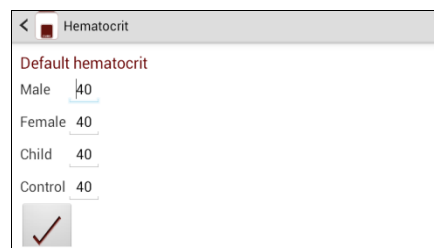
Tapping opens a drop down menu. Select which gender is to be used as the standard default. *Last used* means that the gender last used will always be selected.

3.2 Sampletype menu



Tap and a drop down menu opens, select which type of sample should be selected by default. *Last used* means the sample type last used will be selected. Confirm with . Press to cancel.

3.3a Hematocrit menu (CUBE Analyser)



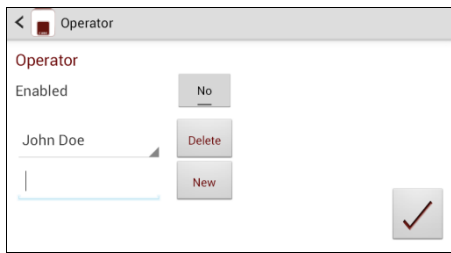
Tap a desired hematocrit value and change it using the appearing Tablet PC keyboard. Confirm the change(s) with . Press to cancel.

3.3b Hematocrit menu (CUBE-S Analyser)






Choose *HCT Auto* for an analyser-side calculation of the HCT value or *HCT Manual* for defining your own HCT values. Tap a desired hematocrit value and change it using the appearing Tablet PC keyboard. Confirm the change(s) with . Press to cancel.

3.4 Operator menu



Enable the operator mode by tapping the button.

To create a new operator, type the name in the box and then tap .

To delete an operator, tap  and select a name in the drop down menu, then tap .

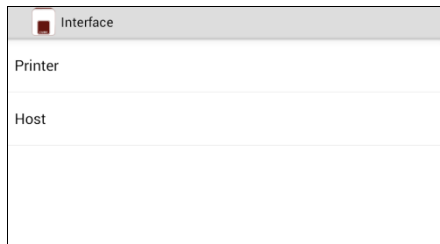
Configuring interfaces

1. Configuration menu



Tap *Interface* in the Configuration menu. The Interface menu appears.

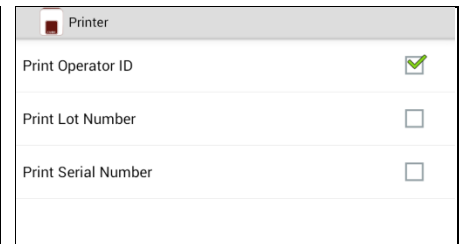
2. Interface menu



Tap an interface to configure and the respective configuration menu appears.

The following descriptions are in the order of the interfaces in the Interface menu.

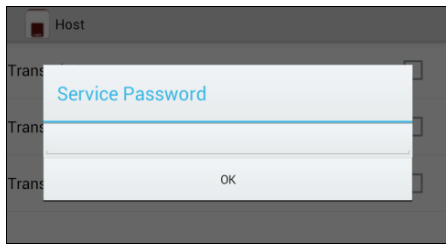
3.1 Printer configuration menu



Tap a checkbox next to an option to select or de-select it.

Note: the screenshot above is for demonstration purposes only. By default all boxes are unchecked.

3.2a Host configuration password screen



The service password is required to change interface host options. Tapping on the input field opens the Tablet PC keyboard and the password can be typed. After pressing OK on the password screen, the host configuration menu opens.

If you do not know the Service Password please contact your dealer.

3.2b Host configuration menu



Tap a checkbox next to an option to select or de-select it. Checking *Automatic transmission* allows for automatic transmission of the standard information of a measurement result after the measurement is done via USB or serial port. Operator ID, lot number and serial number are additional information that can be added to the *Automatic transmission* or standard manual transmission format.

Note: the screenshot above is for demonstration purposes only. By default all boxes are unchecked.

OPTIONAL EQUIPMENT

Printer, barcode scanner or PC

The following optional devices (not included in the standard delivery package) can be connected to the Instrument:

- An external printer – for optional test result printouts
- An external barcode scanner
- A PC – for the transfer of test data into a HIS or laboratory software

To install the printer (see “Technical specifications” section on page 40) please connect the RS232 cable to the RS232 socket at the Instrument.



Connect optional equipment only when the Instrument is switched off. Please note that attaching optional equipment (e.g. a printer) can increase the amount of leakage current. All optional equipment must be connected before such leakage current can be measured.



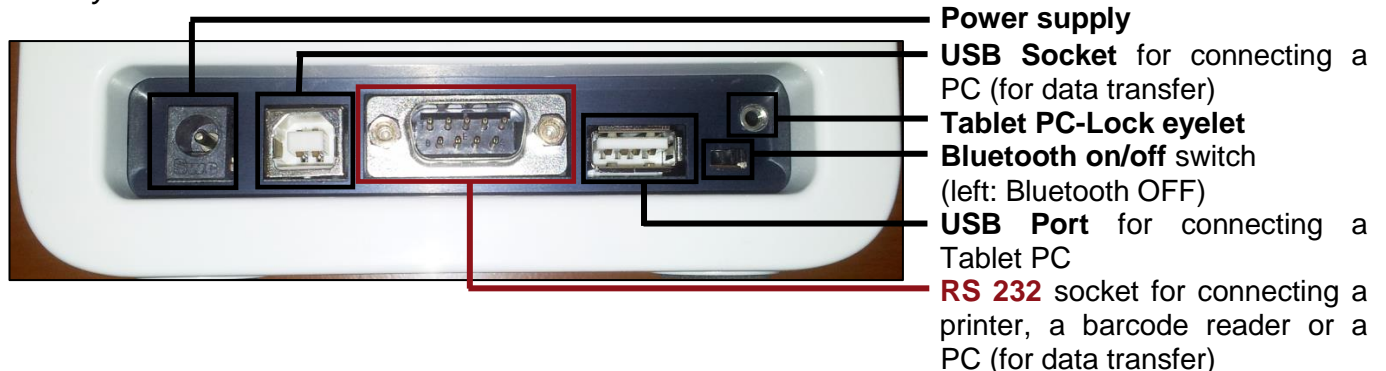
If the Instrument is not used according to the instruction manual, then the provided levels of safety will be lowered.

Connecting a barcode scanner

To install the barcode reader (see “Technical specifications” section on page 40) please connect the RS232 cable to the RS232 socket at the Instrument (see illustration below). Always connect the power supply to the barcode scanner correctly before using it.

If a printer should be installed simultaneously an adapter has to be interconnected (e.g. barcode-printer-interface-cable, Eurolyser order number: SZ0405).

Eurolyser CUBE-S/CUBE Instrument Interfaces



Using a barcode scanner to scan patient ID and/or operator information

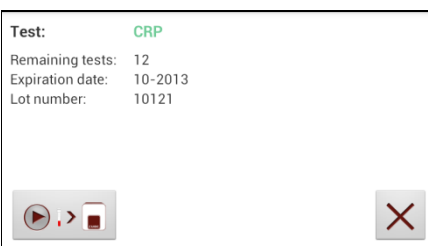
1. Main menu





Start a test by tapping .

Make sure that a RFID card is placed on the CUBE-S/CUBE Instrument.

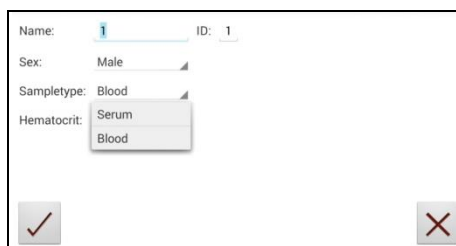
2. Test screen





The Eurolyser CUBE-S/CUBE displays the type of test and number of tests remaining on the RFID card.

Tap  to proceed to the input menu or  to exit to the main menu.

3. Input menu




Scan patient information with the barcode scanner. It will automatically be set as "ID" value.

Tap  to confirm the input or  to exit to the main menu.

4. Select operator screen*¹



On this screen an operator can now be selected by scanning the operator barcode and tapping  to continue.

If new information is scanned (i.e. the operator has not been created in the operator menu yet) a new operator will be created automatically.

5. Insert cartridge and close door



The door opens automatically. Insert the cartridge and close the door. The test procedure starts automatically.

*¹ This screen only appears if the operator input has been enabled (see 3.4 on page 17)!

How to wake the CUBE-S/CUBE Analyser up or switch it OFF



When the Tablet PC displays the main menu, the "power safe" function dims the screen. Pressing the Lock Switch will re-illuminate the display to its customary level of brightness.

It is not necessary to switch the Instrument off every day. Switching the Instrument off completely can only be done by disconnecting it from the power supply.

TEST PROCEDURES

Overview of the testing and measuring procedures

Allow the ERS test cartridge to reach room temperature before use. If the CUBE-S/CUBE Instrument has been disconnected from the power supply, plug it in soon enough for it to be at the proper operating temperature when it is needed.

To analyse a patient sample:

- Place the provided RFID card from the test kit on the Instrument.
- Prepare a test cartridge and a patient sample according to the instructions on the test kit insert
- Enter the required patient data.
- Insert the test cartridge into the Instrument and start the analysis.
- The result will be displayed on the Tablet PC.
- The result will be saved in the Tablet PC's memory.
- If desired, export the result to an (optional) external computer, print the result with an (optional) external printer or send it via email (see p. 26)

How to run a control test:

- Place the provided RFID card from the test kit on the Instrument.
- Prepare the control serum according to the instructions on the control package insert.
- Enter the lot number instead of the patient data.
- Prepare the test just like a patient sample and start the analysis.
- The result is displayed on the Tablet PC.
- Record the result according to your laboratory's quality guidelines.
- The result will be saved in the Instrument's memory – just like a patient's results.
- If desired, export the result(s) to an (optional) external computer, print the result with an (optional) external printer or send it via email (see p. 26)
- Verify that the result lies within the mandatory limits for the control material (according to the control material's package insert).

Be sure to follow the detailed instructions for the analysis processes that are provided in the following sections and to comply with the information provided on the package insert enclosed with each testing kit.

Operating safety precautions

When operating the CUBE-S/CUBE Analyser:

- Use only your fingertips to operate the Tablet PC! Do not use pens or any other objects that may scratch or damage the screen.



- If an error message appears on the screen, please consult the “Troubleshooting” section on page 38.
- The door protects the analysis system from dust, dirt and humidity. Empty the door’s cartridge chamber after every analysis and keep it closed when the Instrument is not in use.
- The door opens automatically. Do not attempt to open the door manually!

When handling a test cartridge:



- Do not use test cartridges after their expiration date, or when the test cartridges have not been stored in accordance with the regulations
- Do not use the test cartridge if the packaging is damaged or if fluids have leaked.
- The test cartridge must reach room temperature (20-28°C; 68-82.5 °F) before use
- Use gloves when handling and disposing the test cartridges, patient samples and sample collection equipment, because they pose a potential biohazard



- Please refer to package insert provided with each test kit suitable for use with the Eurolyser CUBE-S/CUBE Instrument and follow all instructions regarding:
 - The proper temperature a cartridge must have before a test is performed
 - The exact amount of the sample volume
 - The regulations for the proper storage of the test cartridges

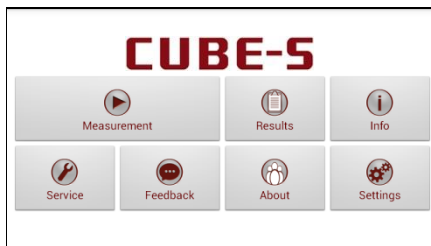
Analysing a patient sample

1. RFID card placement



Take the provided RFID card out of the test kit package and place it on the RFID card pit on top of the Instrument.

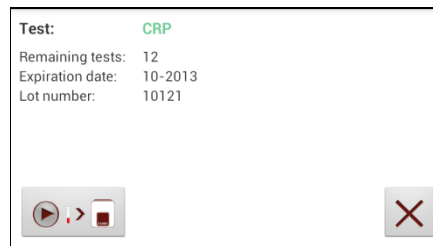
2. Main menu



Tap  in the main menu to start a measurement.


The Eurolyser CUBE-S/CUBE Instrument automatically reads the RFID card and the Test Menu appears.

3. Test screen

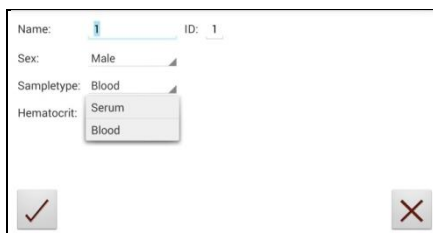


The Eurolyser CUBE-S/CUBE displays the type of test and number of tests remaining on the RFID card.


Tap  to proceed.

Tap  to return to the main menu.

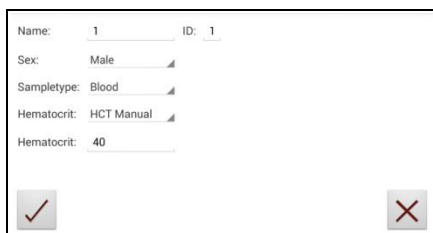
4. Input menu





Tap the desired input field (e.g. "Name"), the Tablet PC keyboard appears. Enter the information and confirm with "Done".

Next, tap  and select an entry from the drop down-menu. When using a CUBE-S/CUBE-S analyser additional options are available when selecting Hematocrit*¹.

5. Input menu Hematocrit*¹





When tapping the desired setting for hematocrit the value can be set manually when choosing *HCT Manual*. *HCT Auto* allows for automatic calculation of the HCT value by the device's software.

Tap  to confirm the input or  to return to the main menu.


6. Select operator screen*²



All saved operators will be shown in the drop down list. Tap  and select an operator or tap  to create a new operator (see 3.4 on p. 17 for details).

Tap  to confirm the input.

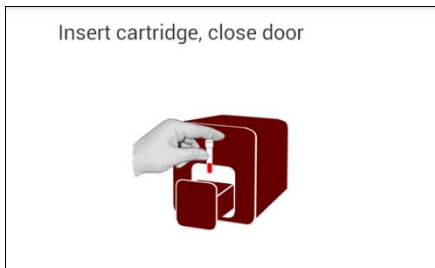
Note: when testing for the first time, you will be prompted to create an operator.

Tap  to open the operator menu (see 3.4 on p. 17 for details).

*¹ The manual input of hematocrit or automatic calculation via the input menu is only available to CUBE-S. This feature does not apply to CUBE.

*² This screen only appears if the operator input is enabled (see 3.4 on page 17)

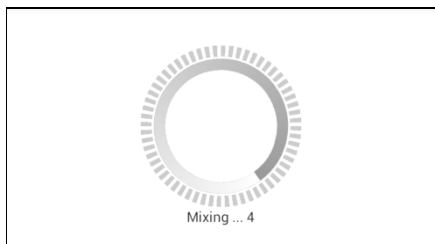
7. Insert cartridge and close door



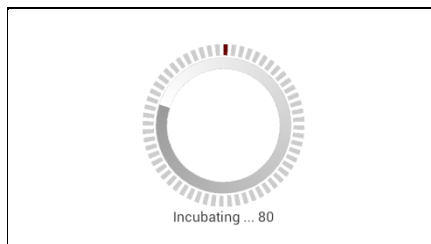
The door opens automatically. Insert the cartridge and close the door. The test procedure starts automatically.

The Instrument displays the following information during the testing process (varies by test type):

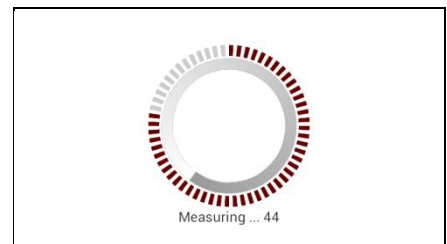
Mixing



Incubating



Measuring

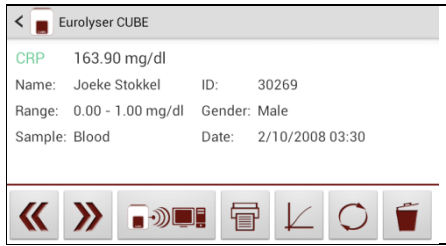


- **Be sure to handle the test cartridge according to the instructions on the package insert**
- **Be sure the test cartridge is properly sealed before inserting it into the Instrument**
- **Be sure the test cartridge is fully inserted into the proper opening in the Instrument**
- **Use ONLY manufacturer-approved test cartridges! Otherwise serious damage to the CUBE-S/CUBE photometer and/or inaccurate test results may occur**
- **Do not attempt to open the door manually!**

Viewing and processing test results

After processing a test, the result screen appears on the Tablet PC:

1. Result Screen



The test result is displayed on the Tablet PC. Use and to scroll back and forth within the results. Tap to export to a HIS/LIS or PC or send as Email.

Tap to print.

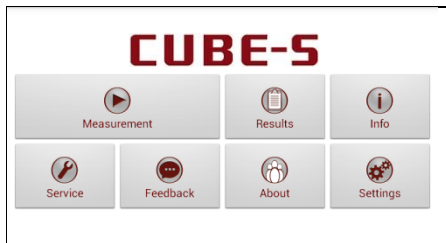
Tap to open the photometric data curve.

Tap to delete the result.

Tap to exit to the main menu.

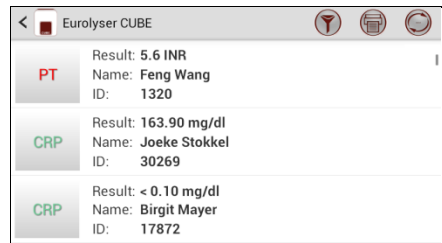
All test results are stored on the Tablet PC. They can be accessed as follows:

1. Main Menu



Tap in the main menu to open the Result List.

2. Result List Screen



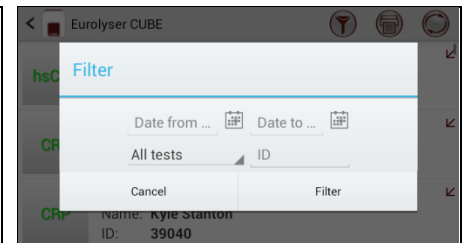
The stored results can be browsed by swiping up and down.

Tap a result to open the result screen (see above), to return to the result list from a result screen press the *Return Arrow* .

Tap to open the filter options

Tap to print, mail or export.

2.1 Filter Options



Results can be filtered by date, test type and Patient ID.

Tap to set the desired start date, to set the desired end date.

Tap to select a test type in the drop down menu (e.g. PT)

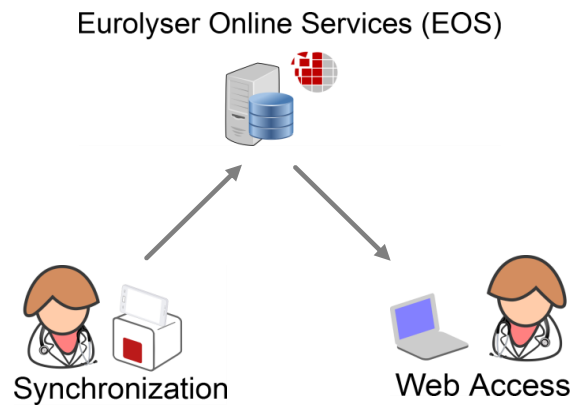
Tap to filter by patient ID



- **Whenever the transmission of the operator ID, lot number and serial number is activated in the appropriate settings menu (see p. 18) the according data will be transferred to the printer or host system automatically and will appear on the printouts and/or the computer or host system.**

Eurolyser Online Services (EOS)

The Eurolyser CUBE-S/CUBE offers the possibility to store test results on the encrypted Eurolyser Online Services (EOS) servers. Before test results can be synchronized a registration with the EOS is needed.



The feature to synchronize data from the CUBE-S/CUBE app into the EOS account can be used according to the steps described on page 27, *EOS Synchronization*.

The synchronized data can be viewed by using a web-browser on e.g. a PC or tablet. A description of the possibilities of the *EOS Web Access* and an explanation of the user interface can be found on page 31, *EOS Web Access*.



- **Sensitive data is encrypted by using industry standard cryptographic algorithms (following ENISA recommendations) directly on the instrument before transmitting data**
- **Data decryption is done on the web-browser. Eurolyser has no access to personal passwords and cannot retrieve them in case of a loss.**

EOS Synchronization

Once registered and logged in with an EOS account the synchronization is enabled.


Generally there are three possibilities of synchronizing data:

- Synchronizing all currently stored measurement results at once
- Synchronizing a single measurement result
- Synchronizing a filtered measurement result list

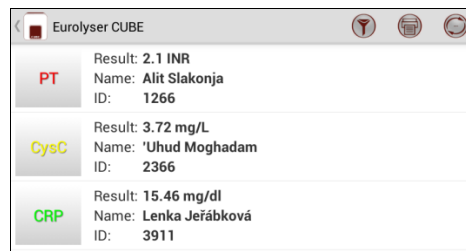
Synchronizing all test results


1. Main Menu



Tap  in the main menu to open the Result List.

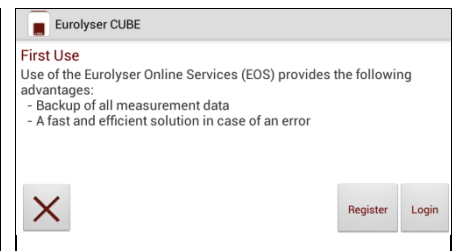
2. Result List Screen





Tap  in the upper right corner to synchronize all test results.

When not logged in with an EOS account the registration or login mask will appear.

3. EOS Registration & Login Mask



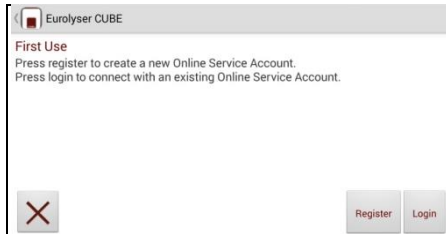
Use  to register a new EOS account or  to log in with an already existing EOS user (see Eurolyser Online Services Registration on page 29 respectively


Eurolyser Online Service Login on page 30). After a successful registration or login the results will be synchronized.

Eurolyser Online Services Registration

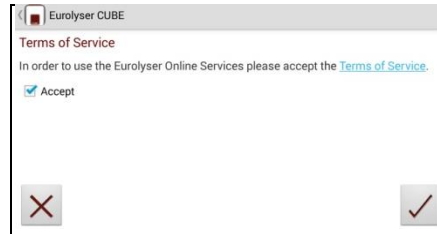
The Eurolyser CUBE-S/CUBE application asks the user to register or login to the EOS once before synchronizing. The following steps describe the process of a registration.


1. EOS Registration & Login Mask



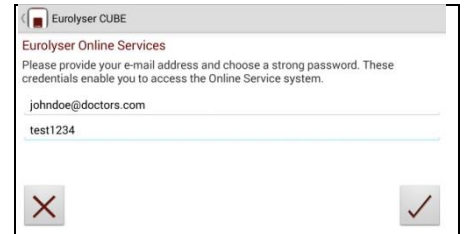
In the registration and login mask press  to open the registration screen.


2. Terms of Services



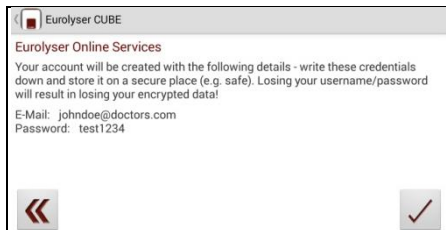
Before registering with the EOS system the terms of services need to be read and accepted. Please read through the terms of services thoroughly. The terms of services are accepted by ticking the "Accept" checkbox and pressing .


3. Registration



Register with the EOS system by providing an e-mail address and a strong and secret password. Accept the account information by pressing . The registration confirmation appears.

4. Registration Confirmation



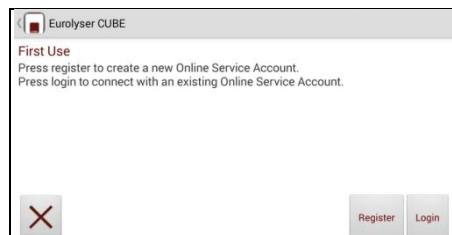
Please double check the registration details and accept by pressing . After successfully registering with the EOS system the login is done automatically at each synchronization request.



- **Do not lose the password! Eurolyser has no way to retrieve the password!**

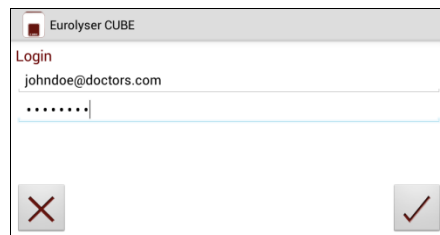
Eurolyser Online Service Login


1. EOS Registration & Login Mask



Press  to open the login mask.

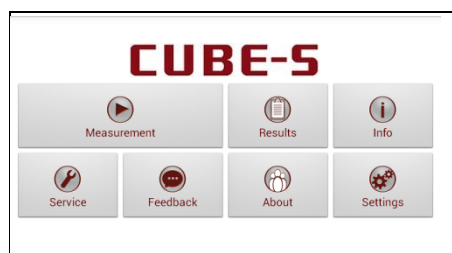
2. Login Mask




Provide your EOS account information and tap  to log in.

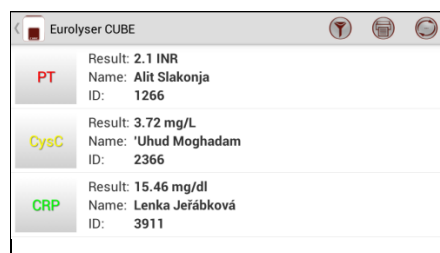
Synchronizing a single result

1. Main Menu



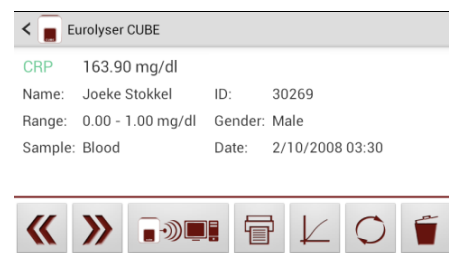
Tap  in the main menu to open the Result List.


2. Result List Screen



Tap a result to open the result detail screen.

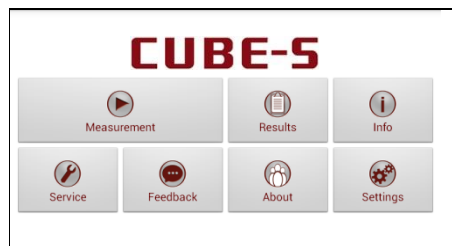
3. Result Detail Screen




Tap  to synchronize the result currently viewed.

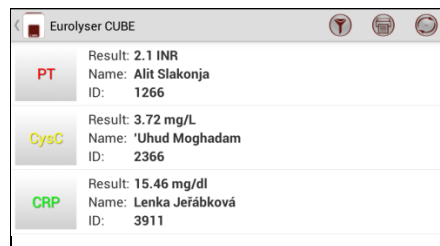
Synchronizing a filtered result list


1. Main Menu



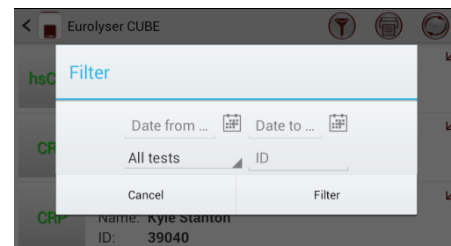
Tap  in the main menu to open the Result List.

2. Login Mask



Tap  to open the filter options.


3. Filter Options



Set a filter according to 2.1 Filter Options on page 26

4. Filtered Result List (e.g. CRP)



Tap  in the upper right corner to synchronize the filtered test results.

EOS Web Access

Once results have been synchronized into the users EOS account they can be viewed independently with a web-browser using a personal computer, tablet or smartphone.

The web application can be accessed by navigating to the following URL:

<http://eos.eurolyser.com>



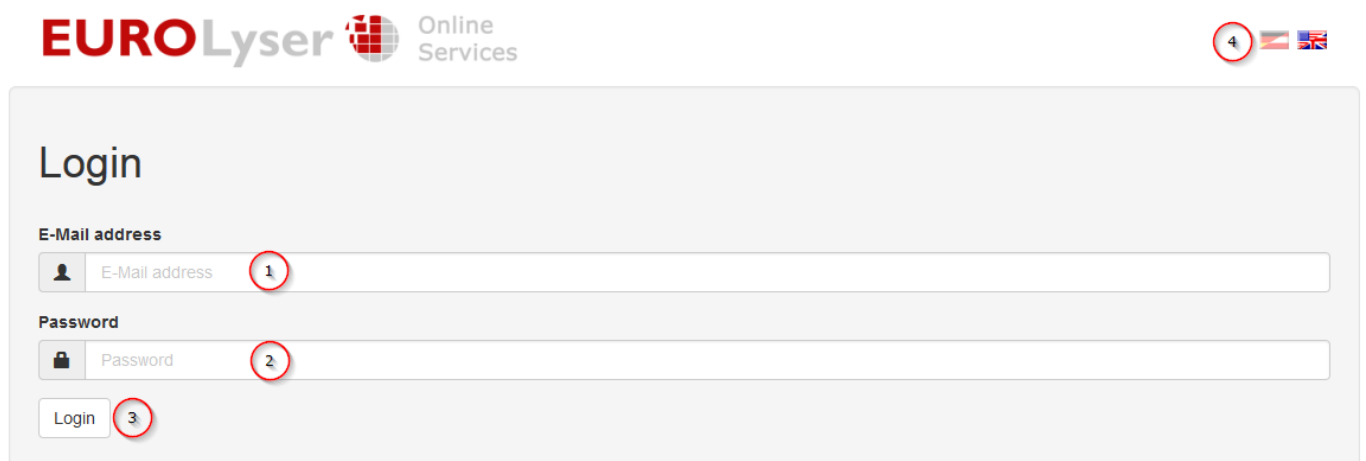
Recommended web-browsers

Web browsers that are recommended to use for accessing the EOS Web Access are shown in the table below. It is not recommended to use a browser which is not listed.

- | | |
|---------|--|
| Windows | <ul style="list-style-type: none">• Internet Explorer 10 or higher• Mozilla Firefox 24 or higher• Google Chrome 33 or higher |
| Linux | <ul style="list-style-type: none">• Mozilla Firefox 24 or higher |
| Mac | <ul style="list-style-type: none">• Mozilla Firefox 24 or higher |

Always use the most recent version of a browser to make sure that the latest security updates are applied. Older browsers might not provide all functions and features correctly in the EOS Web Access.

Login Mask

A screenshot of the login interface for the EOS Web Access. At the top left is the "EUROLyser" logo with a globe icon and the text "Online Services". At the top right is a language switch icon with a circled "4" and flags for Germany and the UK. The main area is titled "Login" and contains three input fields: "E-Mail address" with a circled "1", "Password" with a circled "2", and a "Login" button with a circled "3".

- (1) Email address which has been used for registration on the App
- (2) Password which has been used for registration on the App
- (3) Button to perform login after filling email address and password
- (4) Possible language switch

QUALITY CONTROL

A quality control program should be performed on a regular basis to verify the Eurolyser CUBE-S/CUBE Instrument is working properly and providing reliable results. Data integrity can only be assured when controls and GCLP practices are used routinely. The frequency of performing QC differs from laboratory to laboratory; please comply with your national quality control regulations.

Choosing quality control (QC) materials

The authorized manufacturers of the CUBE-S/CUBE test cartridges also supply control materials. These control kits contain control materials, which allow you to assess the measuring accuracy of the Instrument.

Ensure the measuring methods are compatible with the Eurolyser CUBE-S/CUBE Instrument before using QC kits from other suppliers.

The measuring methods are listed on the test cartridge's package insert.

Handling the QC control materials



Please refer to the package insert provided with each control kit for detailed instructions on storage and handling of control materials.

Follow the instructions in the "Analysing a patient sample" sections (starting on p. 24) on how to properly perform a control test. The measured values must be within the range of target values specified on the control vial label or in the control package insert. If the control results fall within the specified range, the testing of patient samples may begin.

If one or more controls tested are outside the specified control range:

- Verify that the control materials have been stored according to the directions and that the expiration date has not passed
- Verify that the handling and testing procedures were performed according to the directions on the package insert
- Repeat the control test, using a new control from the same lot

If one or more control results are still outside the specified range:

- Perform a test using a control from a new lot.



If all instructions have been followed but control results are still not within range please contact your local Eurolyser supplier for assistance before proceeding on testing any patient samples.

Frequency of QC testing

Control testing is recommended when:

- a new shipment of test kits is about to be used.
- a new lot is about to be used.
- if it's possible that the test cartridges have not been properly stored.
- if an unexpected patient result is obtained.
- when new personnel is being trained to use the equipment .
- if local regulations require more frequent control testing than described above, then the number of control tests performed must comply with these regulations.

CORRELATION

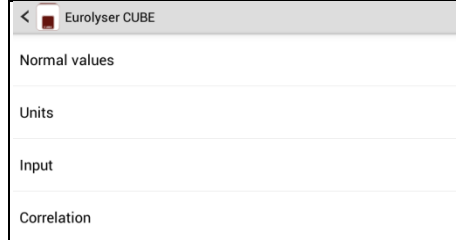
Performing a parameter correlation adjustment

1. Start-up Menu



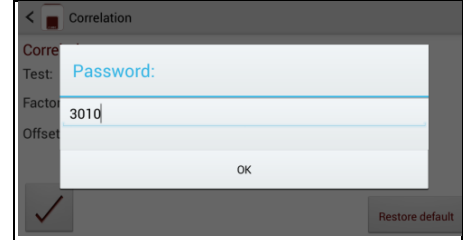
Tap *Settings* to open the settings menu.

2. Settings menu



Tap *Correlation* to open the correlation menu.



3.1 Password mask



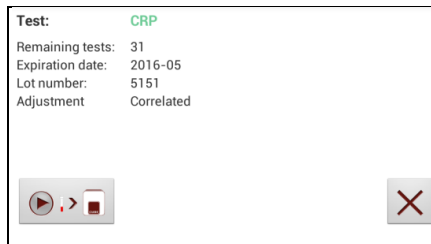
Enter the password. The default setting is 3010.

4. Correlation menu



Tapping  opens a drop down menu. Select which parameter is to be adjusted. Enter the factor and the offset accordingly and tap  to accept the new correlation settings.

5. Test Screen



An active correlation adjustment is marked by *Correlated* as seen in the test screen when starting a measurement process.

CLEANING INSTRUCTIONS

Cleaning the touch display of the Tablet PC

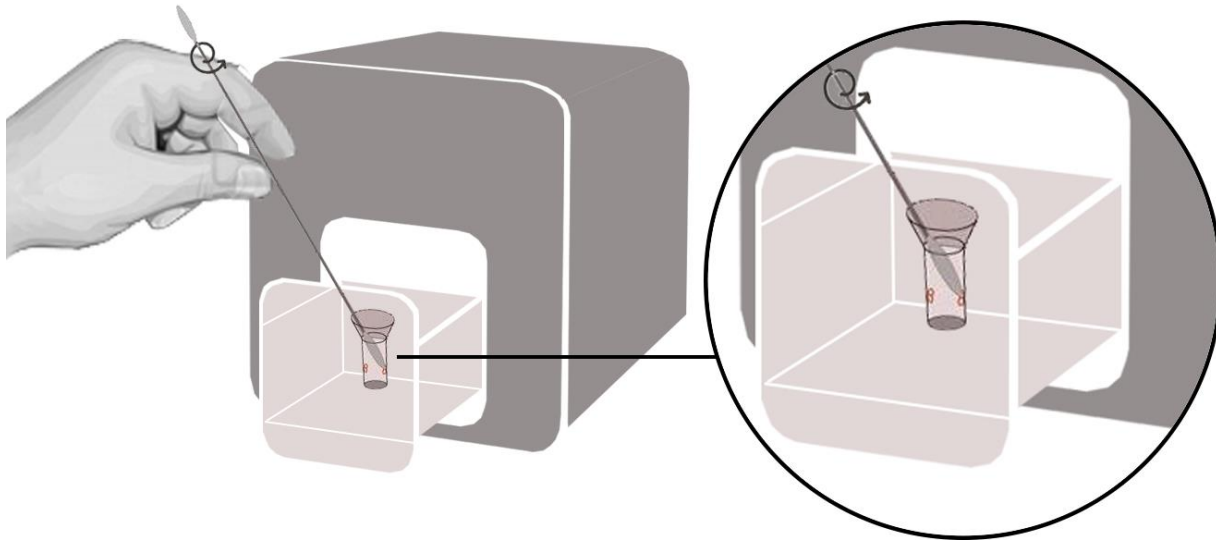
Clean the touch display of the Tablet PC with a clean, lint-free cloth moistened with water.



Do not use any other liquid except water when cleaning the Tablet PC!
To avoid damage do not spill too much water on the Tablet PC!

Cleaning the Door & Cartridge Area

Clean the door with a clean, lint-free cloth moistened with isopropyl alcohol. Wipe down the surface.
The cartridge area may be cleaned with a cotton swab moistened with isopropyl alcohol.



Cleaning the Exterior



Do not clean the surface of the Tablet PC with isopropyl alcohol!

The surface of the Eurolyser CUBE-S/CUBE Instrument should be cleaned with a clean, lint-free cloth only moistened with isopropyl alcohol. Wipe down the exposed surfaces.

EXTERNAL INTERFACE DESCRIPTION

Serial Interface

Interface signals

Pin	Signal
1	
2	TxD
3	RxD
4	
5	GND
6	
7	
8	
9	

Interface parameters

Parameter	Value
Baud rate	9600
Data bits	8
Parity	None
Stop bits	1

Data format

Data is transmitted in blocks of data sets.

One data set contains the data from one analysis.

Data sets consist of data fields.

A data field consists of an identifier (7 characters) and its respective value or text.

Data fields are concluded with one carriage return and line feed.

Data sets are concluded with three carriage returns and line feeds.

Data Fields

Identifier	Format	Example	Remarks
Name:	Text	Name: John Doe	
ID:	Text	ID: 1234	
Sex:	Male/Female/Child/Control	Sex: Male	
Sample:	Serum/Blood	Sample:Blood	Optional
HCT:	Value	HCT: 40	Optional
Testname:	Value and unit	CRP: 2.48 mg/dl	
Calculatedname:	Value and unit	eAG: 100 mg/dl	Optional
Range:	Value - Value	Range: 0.00 - 1.00	Optional
Time:	hh:mm	Time: 14:44	
Date:	dd-mm-yyyy	Date: 08-02-2007	
Operat:	Text	Operat:Max Muster	Optional
Lot No:	Value	Lot No:4111	Optional
Ser No:	Value	Ser No:Ba00001	Optional

USB Interface

The USB interface emulates the serial interface.

ERROR INFORMATION AND TROUBLESHOOTING

Error messages and possible causes

Error message	Cause	Correction
Invalid card	A wrong, defective or expired RFID card; A defective RFID module;	Use a new test kit. Contact your dealer.
Tests expired	The test cartridge has passed its expiration date.	Use a cartridge from a new test kit that has not expired.
Door blocked	The test cartridge is blocking the door because the cartridge has not been inserted completely or the cuvette has not been capped firmly enough.	Reposition the test cartridge or tighten the cap on the cuvette.
Wrong cap Missing cap Missing cartridge	The wrong ERS cap is being used or the ERS cap is missing or the cartridge is missing or an already used cartridge is inserted.	Use the correct ERS cartridge and cap.
Bolt blocked	The test cartridge blocks the bolt because the wrong ERS cap is being used.	Use the correct ERS cartridge and cap.
Measurement overflow	The photometric measurement value lies outside the measuring range (e.g. a cold cartridge has been used).	Repeat the test using a new cartridge.
Blank error	The photometric measurement value is outside the measuring range (without the cartridge).	Repeat the test after restarting the Instrument.
Temperature error	The temperature is outside the range.	Repeat the test after restarting the Instrument.
Wrong samplotype?	The wrong sample type has possibly been selected.	Select the correct sample type.
Linearity error	The reaction of kinetic test is not linear (e.g. if a cold cartridge has been used, if wrong samplotype was set, if wrong samplevolume was used or if a cartridge with integrated capillary was not used correctly).	Repeat the test using a new sample and a new cartridge.
Mix error	Instrument fails to perform test due to possible hardware error.	Please contact your local dealer.
Coagulation error	Coagulation can not be measured.	Repeat the test using a new cartridge.
Sample volume error	The provided sample volume is not correct (e.g. pipetting error).	Repeat the test using a new cartridge with correct sample volume.
Cartridge temperature error	The cartridges' temperature is too low for a proper test.	Repeat the test and refer to the package inserts for proper cartridge use.

Service information

If the problem persists after the corrective actions are taken, contact your local CUBE-S/CUBE Instrument dealer for technical assistance.

Before asking for assistance, please have the following information ready:

- the serial number of your CUBE-S/CUBE Instrument
- the test type
- the test lot number
- the control lot number
- the control results obtained so far
- a description of the problem, including any of the CUBE-S/CUBE's error messages

TECHNICAL SPECIFICATIONS

Eurolyser CUBE-S/CUBE Instrument

Photometer resolution	0.0001 ABS
Reproducibility	<1.5% CV at 1 OD
Linearity	0.1000 – 3.0000 OD better than +/- 1.5% and +/- 0.01 OD
Temperature control	Electrical temperature control of the photometer unit to 37°C +/- 2°C
Fuse	2.5 A, self-healing
Dimensions	160 x 135 x 145 mm (H x W x D)
Weight	2.2 kg (unpacked)
Communications interface	RS232, USB, Bluetooth
Tolerance conditions:	Work space: 20 - 28°C; relative humidity: 10 – 85% Transport/Storage: 0 - 50°C; relative humidity: 5 – 85%
Work surface:	A dry, clean, level surface. Avoid direct sunlight.
Power usage:	12V DC, 2A

Power supply

Manufacturer	Globtek
Type	GTM21097-5012
Mains adapter	A separate AC to DC mains adapter with double insulation
Input	90-264V AC, 47-63 Hz
Output	12V DC, 4.17A
Power usage	Max. 30 VA

Options

Thermo printer	Seiko DPU-414
Interface	Serial
Mains adapter	100-240 VAC

Barcode reader (scanner)	Datalogic Touch65	Datalogic Heron D130	Honeywell Voyager 1200g
Reading area	63 mm	2 ~ 27 cm (20 mils)	3.8 ~ 13.2 cm (5 mils)
Max. resolution	0.10 mm (4 mils)	0.10 mm (4 mils)	0.09 mm (3.5 mils)
Mains adapter	100-240 VAC	100-240 VAC	100-240 VAC

DECLARATION OF CONFORMITY



The Eurolyser CUBE-S/CUBE Analyser consisting of the CUBE-S/CUBE Instrument and the CUBE-S/CUBE Tablet PC is in conformity with the directive **2004/108/EC** of the European Parliament and the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC.

The standards

“EN 13612:2002 - Performance evaluation of in vitro diagnostic medical devices”,

“IEC 61010-1:2001 - Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements“,

“IEC 61010-2-101:2002 - Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment“,

and the standards referenced below were taken in consideration:

EN 55011:2009 Class B;

EN 61000-4-2:2009;

EN 61000-4-3:2009;

EN 61000-4-4:2009;

EN 61000-4-5:2009;

EN 61000-4-6:2009;

EN 61000-4-11:2009;

EN 61326-1:2006-05-01;

ISO 14971:2007-10-01.

SHUT DOWN AND WASTE MANAGEMENT

Before shutting down the CUBE-S/CUBE Instrument for the purpose of a repair or disposal it is necessary to ensure that there is no cartridge left within the CUBE-S/CUBE Instrument. For the purpose of delivering the CUBE-S/CUBE Instrument it is also required to protect the photometer with its original delivered packaging and packaging inserts.

For proper waste management according to the directive 2002/96/EG please contact your local dealer. Used cartridges need to be disposed with laboratory waste and according to the corresponding regulations.

MANUFACTURER INFORMATION



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