solo

User Manual

EUROLyser DIAGNOSTICA

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SYMBOLS AND ABBREVIATIONS

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

Symbol/Abbreviation	Explanation
CE	Conforms with the European directive 98/79/EC on in vitro diagnostic medical devices
IVD	In vitro diagnostic medical device
REF	Catalogue number / Order number
LOT	Lot number
SN	Serial number
	The contents are sufficient to perform <n> number of tests
	Best used by
	Temperature limitations
	Relative humidity limitations
	Manufacturer
	Date of production
STERILE	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	Hospital Information System
LCD	Liquid Crystal Display
AC	Alternating Current
DC	Direct Current
RFID	Radio Frequency Identification

Table 1

TABLE OF CONTENTS

INTRODUCTION

Intended use of the Eurolyser solo laboratory photometer

The Eurolyser solo laboratory photometer is for *in vitro* diagnostic (clinical chemistry) use only.

The solo laboratory photometer is very 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's manual

This user's manual will guide you through the installation, operation and maintenance of your Eurolyser solo laboratory photometer. The user's 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's manual the protection of the solo laboratory photometer may be influenced.

We recommend that you familiarize yourself with these instructions before operating the Eurolyser solo laboratory photometer.

Some of the information in this user's manual is marked with following symbols:

Operator's action

Warnings and precautions; see accompanying documents

Refer to the user's manual and follow the instructions

Inspecting the package contents

When unpacking the solo laboratory photometer, check the contents against the list below and examine the components for signs of shipping damage.

The solo package contains the:

- Eurolyser solo laboratory photometer
- Mains adapter
- Power cable
- User's manual

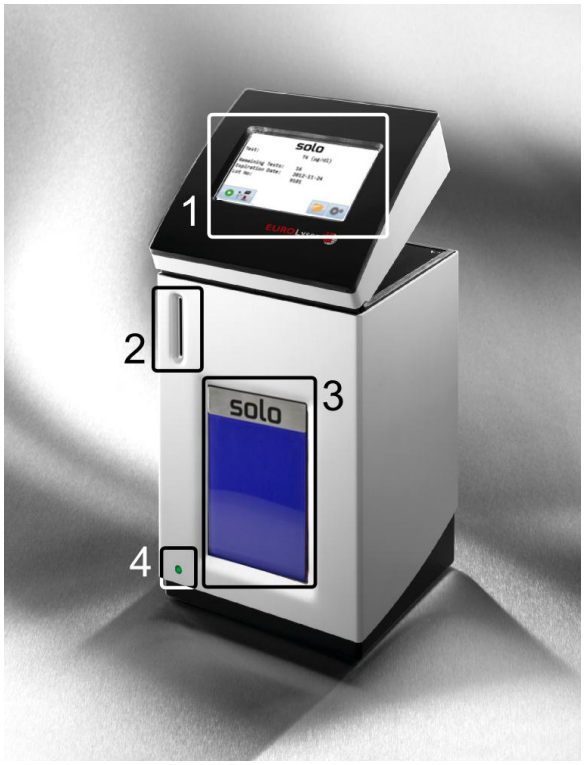
If any part of the package is missing or damaged, please report this to your supplier immediately.

We recommend that you keep the original packaging, in case the instrument ever needs to be transported.

SYSTEM DESCRIPTION

Description of the Eurolyser solo laboratory photometer

Figure 1 shows the main exterior parts of the solo laboratory photometer (front view).



1. Touch Display	The main user interface to operate the instrument and read the results
2. RFID Card Adapter	The RFID card is inserted here
3. Door	To insert and remove the tests
4. LED	The green light-emitting diode (LED) is illuminated when the instrument is connected to the power source

Figure 1

<u>Do not</u> open the door manually.

Figure 2 describes the main exterior parts of the solo laboratory photometer (rear view).

1 RS232 socket	Socket for an (optional) printer or / and barcode scanner
2 USB socket	PC connection
3 RS232 socket	PC connection
4 Power socket	Connects to the power supply

Figure 2

How to operate the **Eurolyser solo laboratory photometer**

The solo laboratory photometer is operated solely by means of the touch-screen. All the basic operating steps are displayed as symbols. An overview of these symbols can be found in Table 1 and Table 2. To activate a symbol, touch or tap it with a finger.

In order to perform a test, the RFID card enclosed in the test kit must first be inserted into the laboratory photometer. This card contains all the data needed to perform the routine tests. No analysis can be started without the RFID test card!

The door opens automatically once a test is initiated by pressing the button. The ERS cartridge is inserted into the slot in the front of the instrument. After entering all the requested data and activating the button on the touch screen, the door closes automatically and the testing procedure begins. After the analysis is completed, the door opens again automatically and the test cartridge can then be removed.

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

- **<u>Do not</u> open the door manually.**
- **Use only your fingers to touch the screen. Do not use pens or other hard or sharp objects.**

Figure 3

1. Commands / Information
2. Touch Buttons
3. RFID Card
4. Door (closed)

Screensaver

The screensaver activates after 10 minutes of idle time, dimming the touch screen. Touch the screen to re-activate it.

Indicator lights

The illuminated green diode (LED) shows that the instrument is connected to the power source. The instrument may be left plugged in indefinitely.

How the Eurolyser solo laboratory photometer works

The Eurolyser solo laboratory photometer is an open measuring system. That means it is able to use diverse reagents from multiple manufacturers. When tests are to be performed, the solo laboratory photometer is loaded with ERS cartridges, which are filled with reagents from the respective reagent manufacturers. The instrument can process end point tests as well as kinetic tests and – thanks to the latest LED technology – 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 mixed automatically within the instrument. The photometer unit performs the analysis with either one or two light diode(s). The absorption of light rays is measured during this process, and the measured value is then converted into the test result using mathematical methods. This result is then displayed on the touch screen. Optionally, the results can be exported to an external computer, an HIS, or they can be printed out using an external printer.

After the test process, the door opens automatically and the ERS cartridge can then be removed and discarded. After confirming the result, the instrument is ready to perform the next analysis.

Manufacturer’s calibration

The Eurolyser solo laboratory photometer 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 / TOUCH BUTTONS

The touch screen symbols and their functions

Tapping one of these symbols on the touch screen activates the described function. Every symbol that can appear while using the instrument is described here.

Symbol	Name	Function
	Start the testing entries	Opens the menu for additional testing entries
	Up	Selects one entry line or one value higher
	Down	Selects one entry line or one value lower
	Edit	Opens an entry or value so it can be edited
	Confirm	Confirms the input
	Cancel	Cancels the input
	Delete	Deletes the last character entered
	Option	Shows which element is selected
	Start the analysis	Starts the test analysis
	Printer	Starts printing
	Transmit	Starts data transmission
	Chart	Displays the photometer data of the last test
	Close door	Closes the door
	Results	Selects the results menu
	Forward	Go to the next page
	Backward	Go to the previous page
	Menu backward	Go to the previous menu
	Recycle bin	Go to the delete menu
	Settings	Go to the settings menu
	Sort up	Moves/sorts an entry one level up
	Sort down	Moves/sorts an entry one level down

Table 2

Additional symbols and special characters

Additional symbols or special characters that can appear on the touch screen during operation are described here. These symbols and special characters provide additional information only and cannot be activated by touching.

Symbol	Name	Function
	Insert cartridge	Command to insert the test cartridge
	Remove cartridge	Command to remove the test cartridge

Table 3

GETTING STARTED

The proper placement of the solo laboratory photometer

Place the instrument on a dry, clean, stable and level surface. Make sure that 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. Acclimate the instrument 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**

Connecting the power supply

- 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 (Figure 4).
- 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 37. The instrument is to be operated only using the power supply unit provided.

Figure 4

1 RS232 socket	Socket for an (optional) printer or / and barcode scanner
2 USB socket	PC connection
3 RS232 socket	PC connection
4 Power socket	Connects to the power supply

How to switch ON the Eurolyser solo laboratory photometer

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 15 minutes).

<u>Do not</u> open the door manually.

Connecting optional equipment

The following optional devices – which are 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 an HIS or laboratory software

We recommend the DPU-414 from SEIKO as an optional printer, as described in the "Technical specifications" section on page **37**.

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 Datalogic Touch 65 barcode reader (Order number: SZ0400) please connect the RS232 cable to the outer RS232 socket at the analyzer (see illustration). Always connect the power supply to the barcode scanner correctly before using it.

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

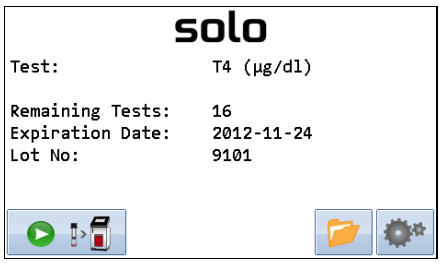
The barcode reader can handle barcodes up to 16 digits.

Figur 5

1 RS232 socket	Socket for an (optional) printer or / and barcode scanner
2 USB socket	PC connection
3 RS232 socket	PC connection
4 Power socket	Connects to the power supply

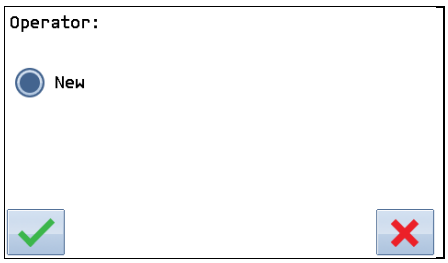
Using a barcode scanner

1. Start-up menu



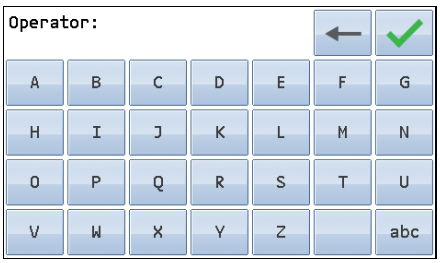
First start a test by touching  .

2. Operator menu*[1]



When you reached the operator menu you will be able to scan the operator with the barcode scanner. The operator will be created automatically.

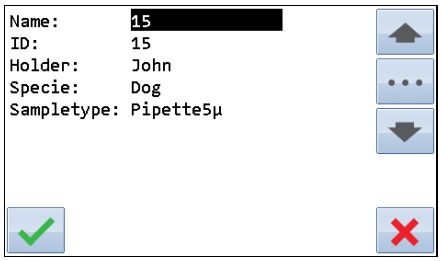
3. Operator insert menu*[1]



After you reached the operator insert menu you will also be able to scan the operator with the barcode scanner.

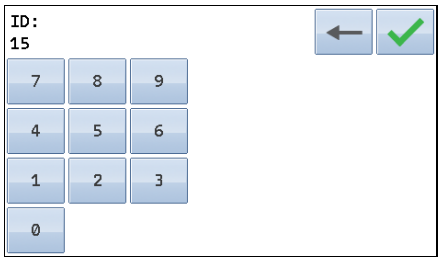
*[1] *Note: This menu only appears once the operator input is enabled (p. 21).*

4. Insert menu



When you reached the insert menu you will be able to scan the ID with the barcode scanner. Data will be put automatically into the ID field.

5. ID insert menu

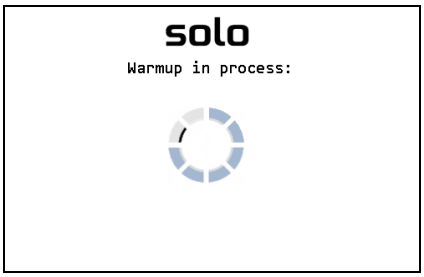


It is also possible to use the barcode scanner while being inside the ID insert menu.

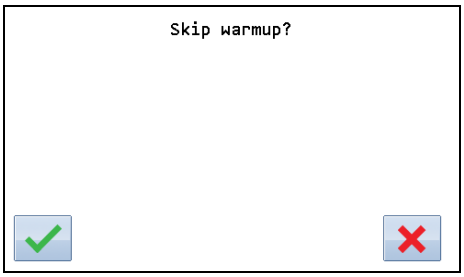
Note: One can either use the barcode scanner in the operator menu and insert menu or within the operator insert menu and ID insert menu.

The automatic start-up and warm-up processes

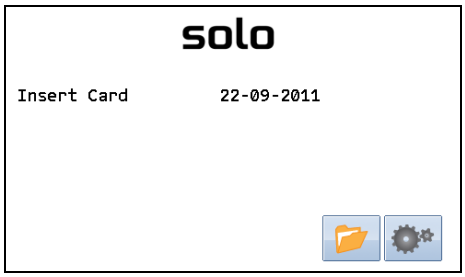
1. Warm-up menu



2. Interrupting the warm-up process (optional)



3. Start-up menu



The automatic start-up procedure starts as soon as the instrument is connected to the power supply. The instrument is warmed up to its proper working temperature in approx. 15 minutes.

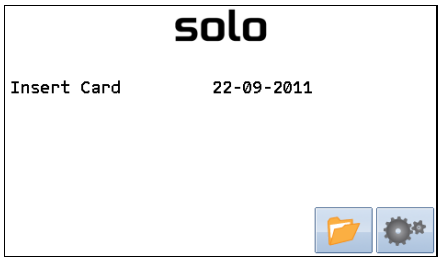
If you want to interrupt the warm-up process, just touch *Warmup in process*. A submenu appears; press ✓ to interrupt. However, if you don't want to interrupt the process, press ✗.

As soon as the entire progress indicator gets full and the initialization of the optical unit is completed (in a few more seconds), the start-up menu appears. The instrument is now operational.

Configure the Eurolyser solo photometer

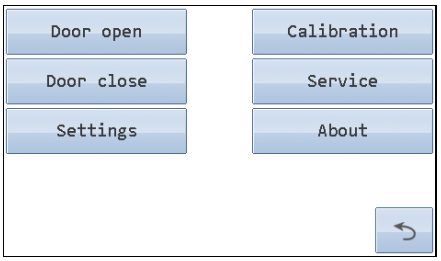
You can configure your Eurolyser solo laboratory photometer according to your needs before you begin using it. To go to the configuration menu, follow these steps:

1. Start-up menu



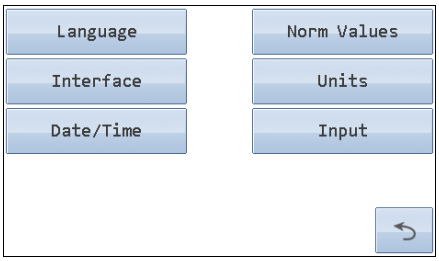
Touch  to go to the Settings menu.

2. Settings menu



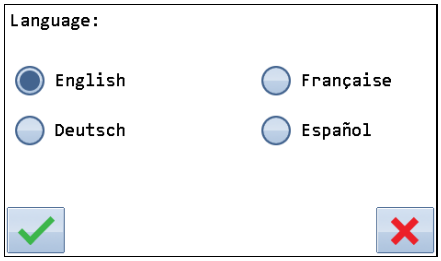
Touch *Settings*, to go to the Settings/Configuration menu.

3. Configuration menu



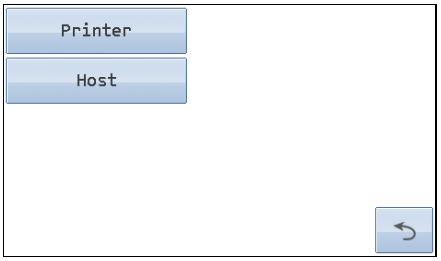
Touch the setting you want to configure.

4. Language menu



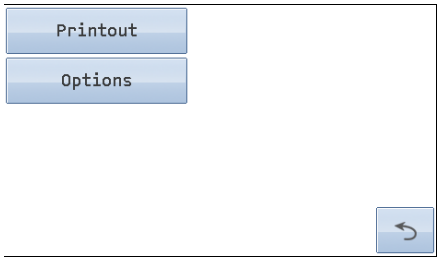
Touch the preferred language and confirm it with  .

5. Interface menu



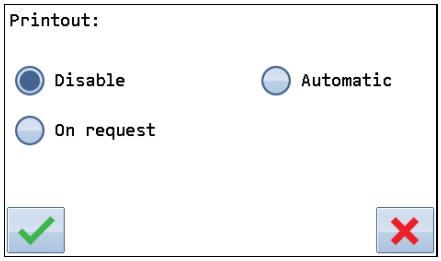
Select the interface you want to configure. Choose *Printer* to configure transmission to a connected printer. Choose *Host* to configure transmission to a host (e.g. a PC).

6. Interface printer menu



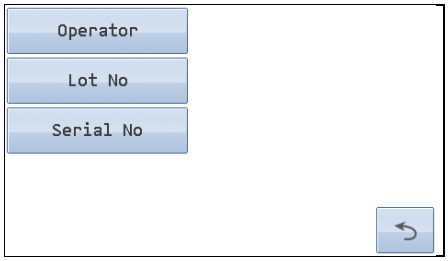
Select *Printout* for further configuration regarding printouts of test result(s). Select *Options* to configure whether *Operator*, *Lot No* or *Serial No* should be included in the printout or not.

7. Interface printout menu



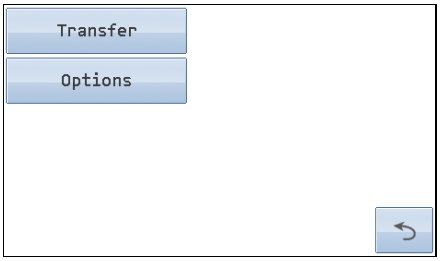
If a printer is connected:
Disable = printouts will never be provided.
Automatic = the results will be printed out after every measurement.
On request = printouts will only be provided on demand.

8. Interface printer option menu



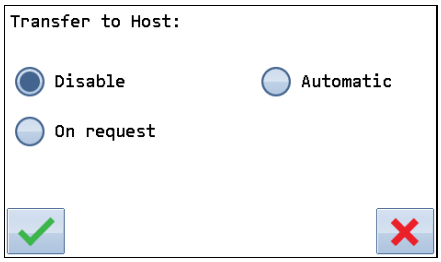
Select *Operator*, *Lot No* or *Serial No* to define if they should be included in the printout or not by choosing *Disable* or *Enable*.

9. Interface host menu



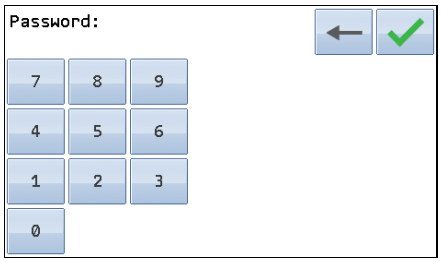
Select *Transfer* for further configuration regarding transfer of test result(s). Select *Option* to configure whether *Operator*, *Lot No* or *Serial No* should be included in the transfer and which baud rate is used when transferring to a host. The service password to change the settings is required.

10. Interface host transfer menu



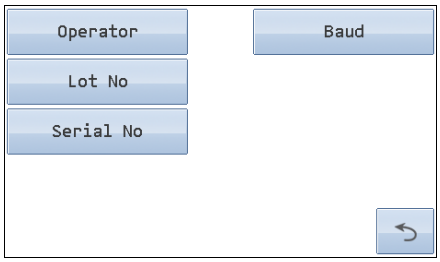
If a host (e.g. a PC) is connected:
Disable = data will never be transmitted.
Automatic = the results will be transmitted to the host after every measurement.
On request = data will only be transmitted upon request.

11. Password menu



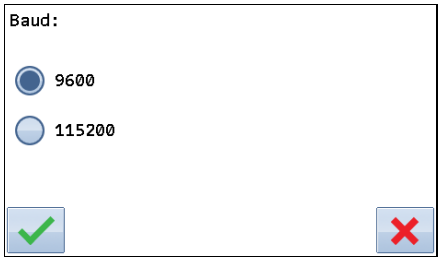
The service password is required to change interface host options.

12. Interface host option menu



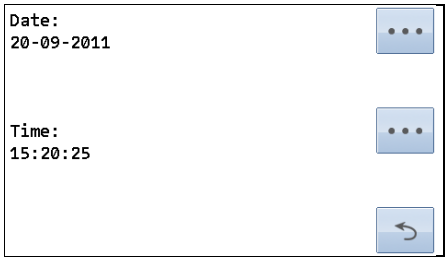
Select *Operator*, *Lot No* or *Serial No* to define if they should be included in the transfer to a host or not by choosing *Disable* or *Enable*. Select Baud to change the baud rate when transferring to a host.

13. Interface host baudrate menu



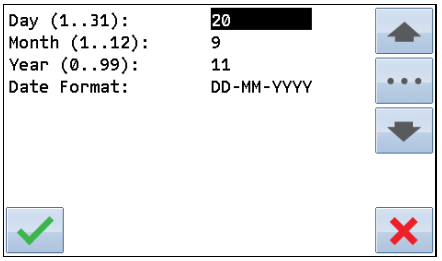
Select the desired baud rate for transferring to a host.

14. Date / time menu



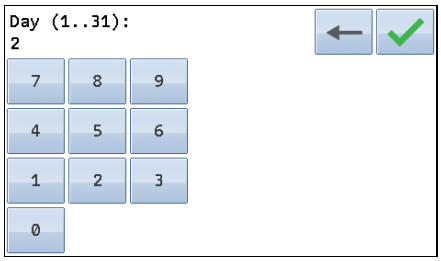
Touch ... to go to the Date detail and Time detail menus.

15. Date detail menu



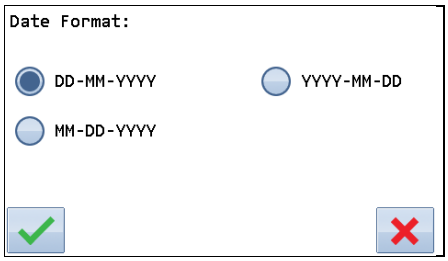
Touch ... to change the selected entry. Use ▼ or ▲ to navigate on the screen.

16. Day date menu



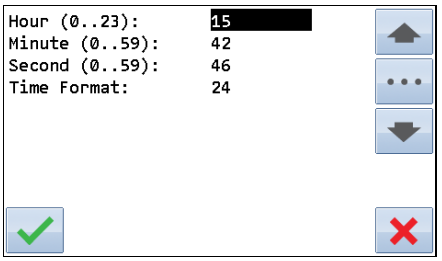
Touch the desired digits and confirm the selected date with ✓.

17. Date format menu



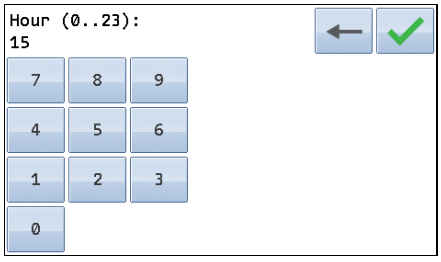
Select your preferred date format.
DD = Day
MM = Month
YYYY = Year

18. Time detail menu



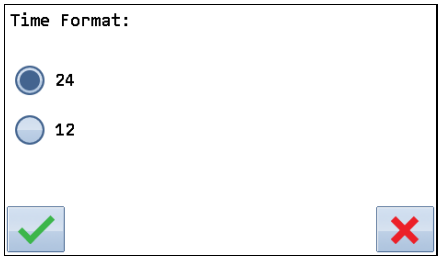
Touch ... to go to the Time input or Time format menus. To navigate within the screen, use ▼ and ▲.

19. Time input menu



Touch the digits to enter the time and confirm your selection with ✓.

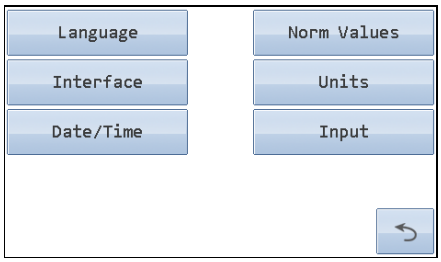
20. Time format menu



Select either the 12-hour time format (1 – 12 AM/PM) or the 24-hour time format (0 – 23).

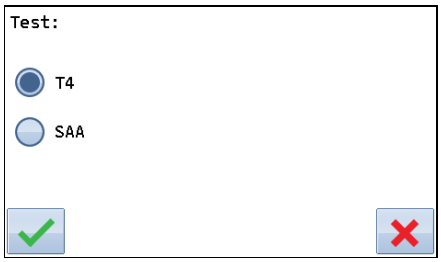
Setting the normal values and the units, using a T4 test as demonstration

1. Configuration menu



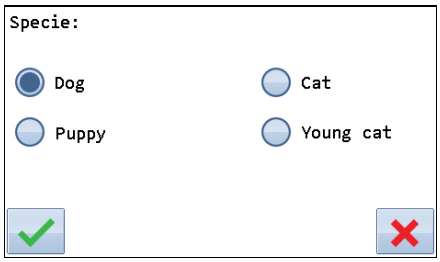
Touch *Norm Values* to change the norm values.

2. Test selection menu*[1]



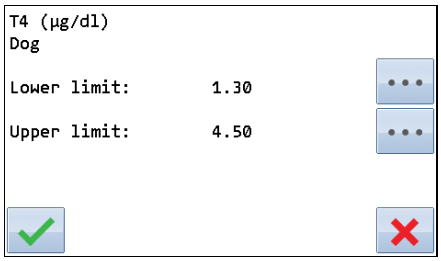
Confirm the selection of T4 with ✓.

3. Limits menu



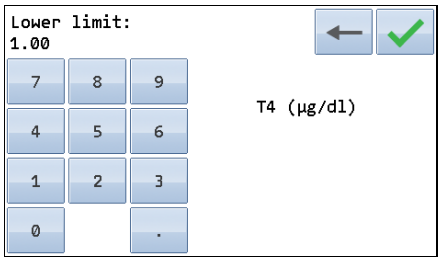
Select the specie you want to edit with ✓.

4. Limits detail menu



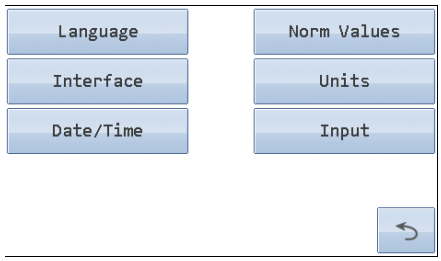
Edit the according limits by pressing the • • • Button.

5. Limits change menu



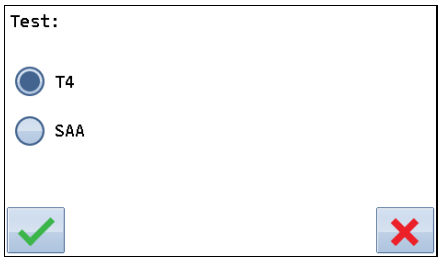
Enter the desired value by pressing the number buttons.

6. Configuration menu



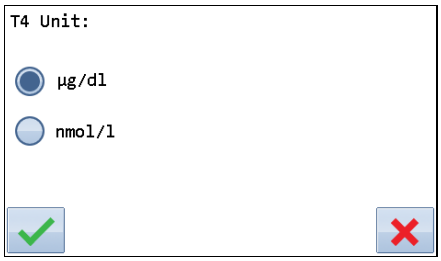
Touch *Units* to change the units.

7. Test selection menu*[1]



Confirm the selection T4 with ✓.

8. Units selection menu

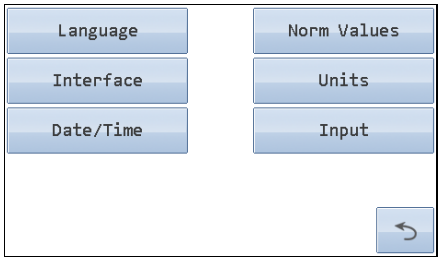


Touch the selected unit and confirm it with ✓.

This description is only an example, as the configuration of the Eurolyser laboratory photometer models varies, depending on the tests used.

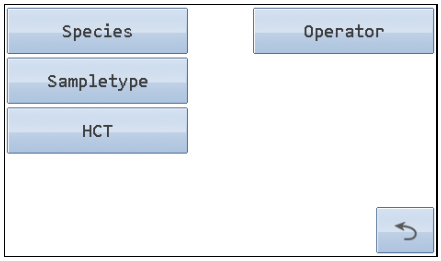
*[1] *Note*: If only one test is used on the solo, the test selection menu will be skipped.

9. Configuration menu



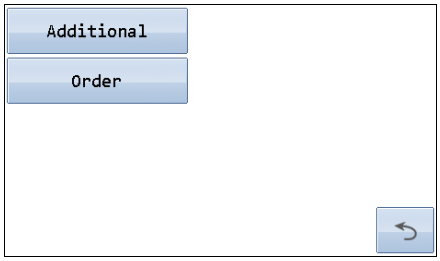
Touch *Input* to reach the input menu.

10. Input menu



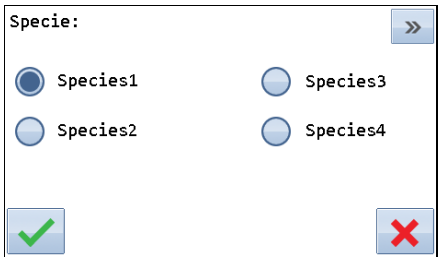
Select which values to change from the Input menu.

11. Default specie menu



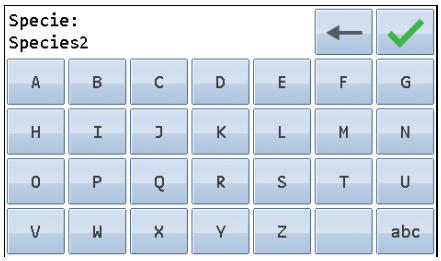
Select which additional specie is to be added with *Additional*. Choose *Order* to change the order of the specie.

12. Additional specie menu*[2]



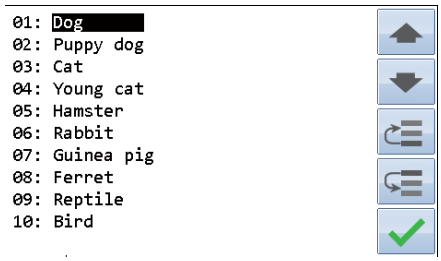
Select which specie entry should be edited and confirm with ✓.

13. Specie entry menu



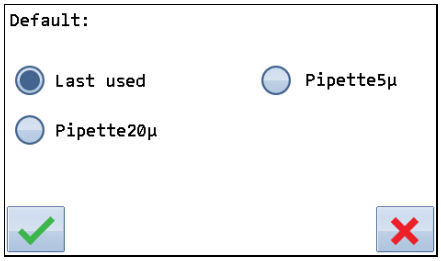
Enter the species' name and confirm the entry with ✓. To delete an incorrect entry, use ←.

14. Specie order menu



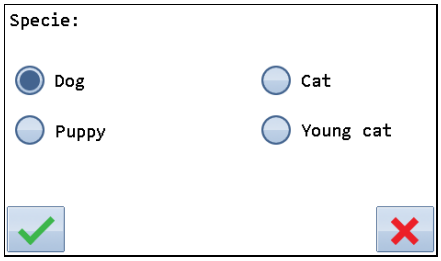
Select which entry should be edited by browsing with the cursor buttons. Change the order up or down with the and buttons.

15. Default sample type menu*[3]



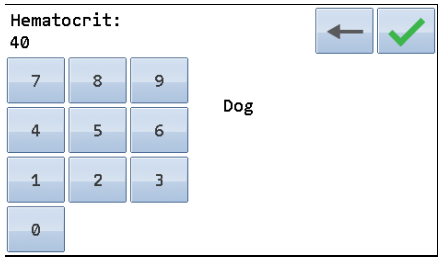
Select which type of sample should be marked by default. *Last used* means the sample type last used will be selected.

16. Specie menu



Select which specie's HCT should be changed ✓.

17. HCT default input menu

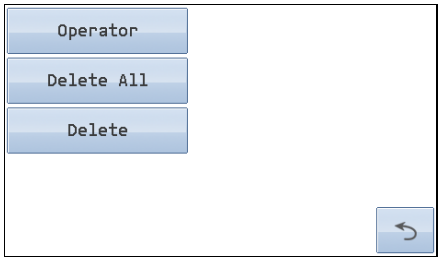


Enter the hematocrit value and confirm it by pressing ✓.

*[2] *Note*: Additionally to the pre-defined species one can add up to 10 more free-defined species.

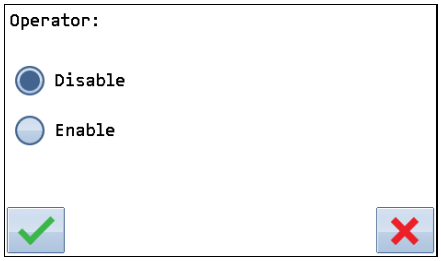
*[3] *Note:* If more than one test is used on the solo you will have to select the test you want to edit the default settings.

18. Operator menu



Select *Operator* to change the default settings for operator input (see 14). Touch *Delete All* to delete all currently saved operators. Touch *Delete* to delete a single operator.

19. Default operator menu



Select *Disable* if you want to disable selecting an operator when performing a test. Select *Enable* to use operators when performing a test. Accept new settings with ✓.

How to switch OFF the analyzer

Completely turning off the instrument can only be accomplished by disconnecting it from the power supply. It is not necessary to switch the instrument off every day. When the instrument is in start screen mode, the “power safe” function dims the screen after it has been idle for 10 minutes. Touching the screen will re-illuminate it to its customary level of brightness.

TESTING PROCEDURES

Overview of the testing and measuring procedures

Allow the ERS test cartridge to reach room temperature before use. If the solo laboratory photometer 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.

How to run a control test, if necessary:

- Insert the RFID card from the test kit into the slot on the front of 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.
- 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.
- Export the result to an (optional) external computer, or print the result with an (optional) external printer.
- Verify that the result lies within the mandatory limits for the control material (according to the control material's package insert).

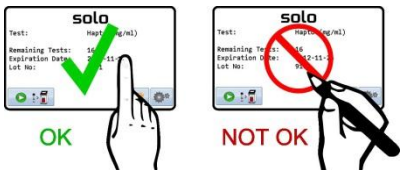
To analyze a patient sample:

- Insert the RFID card from the test kit into 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 analyzer and start the analysis.
- The result will be displayed.
- The result will be saved in the instrument's memory.
- Export the result to an (optional) external computer, or print the result with an (optional) external printer.

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 test kit.

Operating safety precautions

When operating the laboratory photometer:



- **Use only your fingertip to operate the touch screen. Do not use pens or any other objects that may scratch or damage the screen.**
- **If an error message appears on the screen during an analysis, please consult the "Troubleshooting" section on page 35.**

- **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 and closes automatically. Do <u>not</u> try to open or close the door manually.**

When handling a test cartridge:

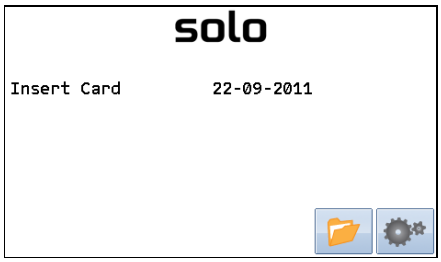
- **Do not use test cartridges after their expiration date, or when the test cartridges have not been stored in accordance with the regulations.**
- **Do not use the test cartridge if the packaging is damaged or if fluids have leaked.**
- **The test cartridge must reach room temperature (18-28°C; 64,4- 82.4 °F) before use.**
- **Use gloves when handling and disposing of the test cartridges, patient samples and sample collection equipment, because they pose a potential biohazard.**
- **Use the test cartridge only once.**
- **Only use the test cartridges that are specified and approved by the manufacturer.**

See the package insert that comes with all test cartridges suitable for use with the Eurolyser solo laboratory photometer 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.

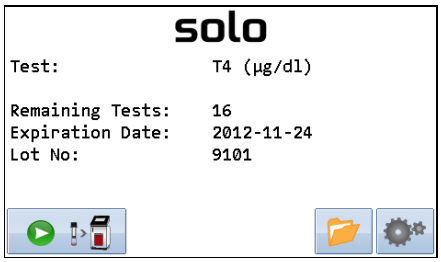
Analyzing a patient's sample

1. Startup menu



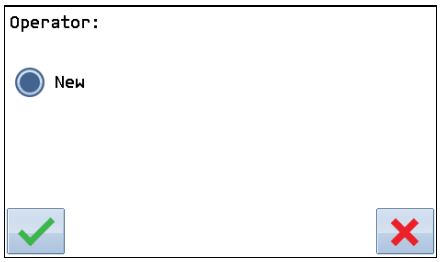
Take the provided RFID card out of the test package and insert it into the instrument.

2. Main menu



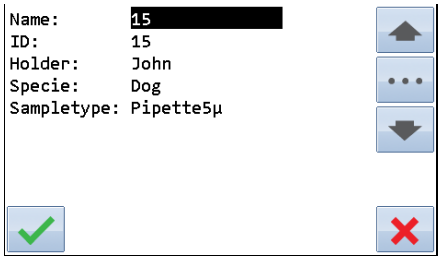
The instrument automatically reads the card, displays the type of test, number of tests, the expiry date and lot number. Touch , the door opens automatically.

3.Operator input menu*[1]



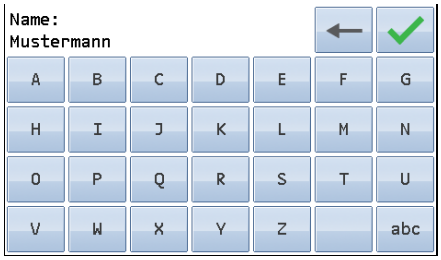
The first time when performing a test you will be prompted to input an operator. Choose *New* to define an operator. All saved operators will be shown in this menu whenever you perform another test.

4. Input menu



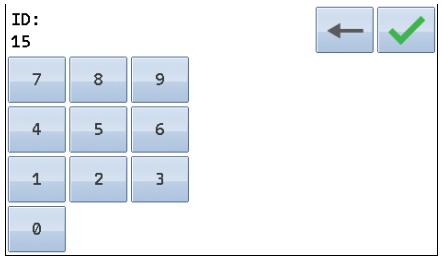
Touch ••• The ABC menu appears. To navigate within the input menu, use and .

5. ABC menu



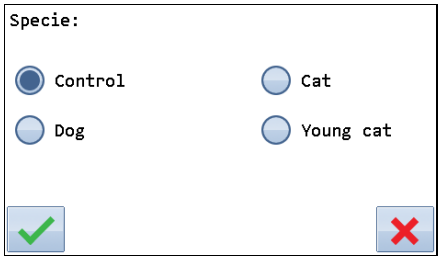
Enter the name and confirm the entry with . To delete an incorrect entry, use ←.

6. Numeral menu



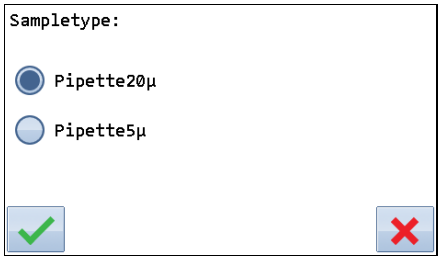
Enter the patient ID and confirm it with . To delete an incorrect entry, use ←.

7. Input menu – Specie / Control



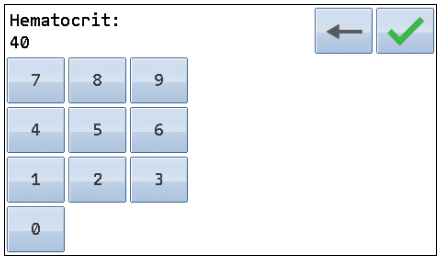
Touch *Control or the desired specie* and confirm the selection with .

8. Sample type menu
(not for all tests)



Touch *Pipette20µ* **or** *Pipette5µ* and confirm the selection with .

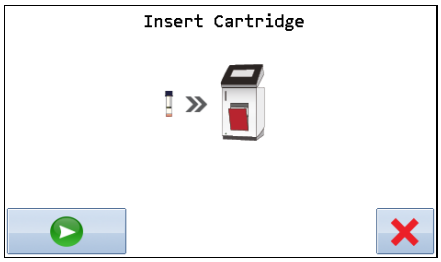
9. Hematocrit menu
(not for all tests/sampletypes)



Enter the hematocrit value and confirm it with .

*[1] *Note: This menu only appears once the operator input is enabled (p. 21).*

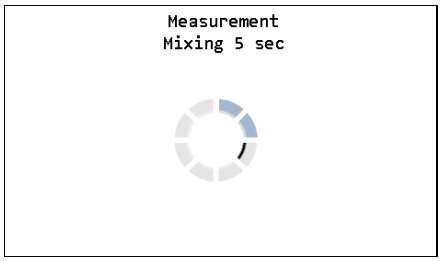
10. Start analysis menu



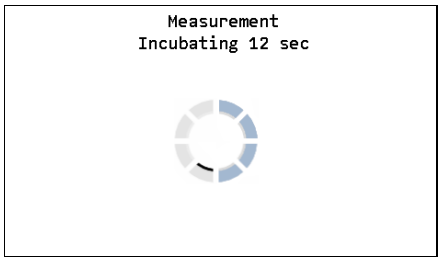
Fully insert the test cartridge into the analyzer. Touch the door closes and the test is performed automatically.

The instrument displays the following information during the automatic testing process:
(Varies by test type)

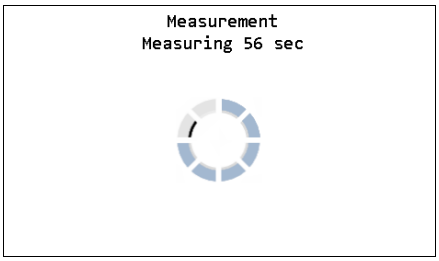
11. Mixing



12. Incubating



13. Measuring

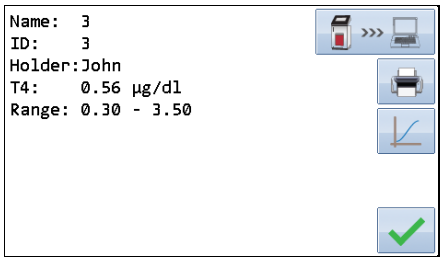


- **Be sure to handle the test cartridge according the instructions on the package insert.**
- **Be sure the test cartridge is properly sealed before you insert it into the analyzer.**
- **Be sure the test cartridge is fully inserted into the proper opening in the analyzer.**
- **Use ONLY manufacturer-approved test cartridges, otherwise serious damage to the solo photometer or inaccurate test results may occur.**
- **Do not attempt to open or close the door manually.**

Viewing and processing the test results

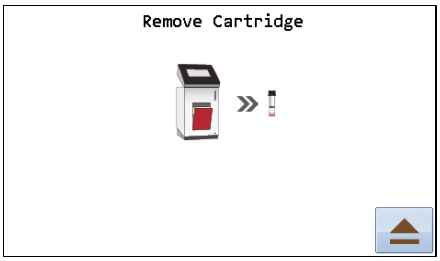
The solo laboratory photometer can store up to 250 patient and control results in its memory. When this capacity is exceeded, the oldest results are overwritten in chronological order.

1. Single result menu



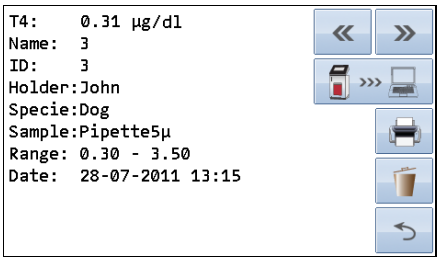
The result is shown. Touch to print it. Touch ››› to export it to an HIS or PC, or touch to display the photometric data. Remove the cartridge and touch to close the menu and end the test. If you do not remove the cartridge before accepting the result the Remove cartridge menu will appear.

2. Remove cartridge menu



The instrument automatically opens the door. Remove the test cartridge and discard it. Touch to close the door. The main menu appears.

3. Overall result menu



To scroll through the results, touch or Touch to print the result(s); touch ››› to send the result(s) electronically. Touch to delete the result(s). Touch to return to the main menu.

- **Whenever the transmission of the operator id, lot number and serial number is activated in the appropriate settings menu (pp. 16 – 17) they will be transfered to the printer or a host system automatically and can be viewed on printouts or the computer / host system.**

QUALITY CONTROL

A quality control program should be performed on a regular basis to verify the Eurolyser solo laboratory photometer 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 solo 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 solo laboratory photometer before using QC kits from other suppliers.

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

Handling the QC control materials

Consult the package insert that comes with each control kit for detailed instructions on the storage and handling of the control materials.

Follow the instructions in the "Analyzing a patient's sample" sections (pp. 24-25) 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 the above instructions have been followed, but the control results are still not within the permitted range, contact your local Eurolyser solo laboratory photometer supplier for assistance before proceeding with tests on 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.

CALIBRATION

All test kits that are made for the Eurolyser solo photometer are calibrated by the manufacturer during production. A calibration of the photometer therefore is not necessary.

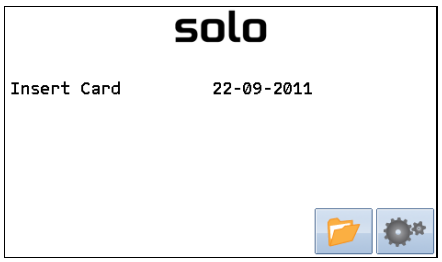
Nevertheless the instrument offers the opportunity to do a specific calibration if the operator wishes to.

The instrument is set to perform either an automatic calibration using a calibration kit or a manual calibration by entering a factor.

You'll need the proper calibration kit to perform an automatic calibration. The kits differ depending on the type of test being performed. Please follow the instructions in the calibration kit's package insert.

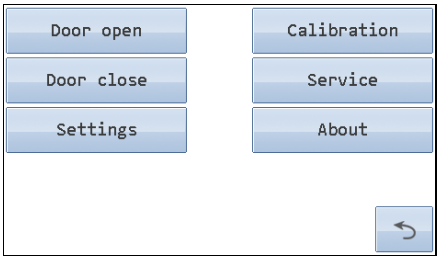
Performing an automatic calibration

1. Start-up menu



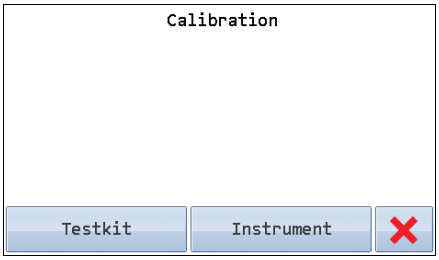
Touch  to go to the Settings menu.

2. Settings menu



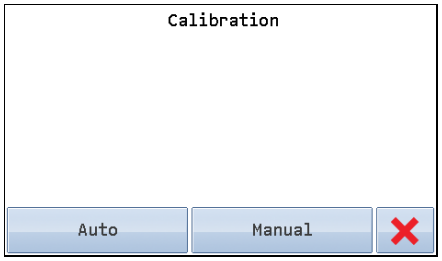
Touch *Calibration* to go to the Calibration options menu.

3. Calibration options menu



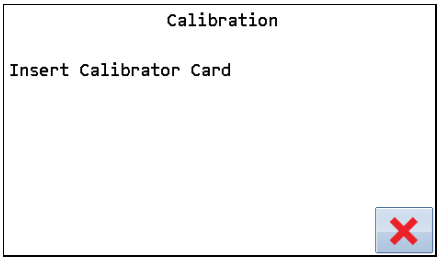
Select *Test kit* to go to the Calibration options menu.

4. Calibration options menu



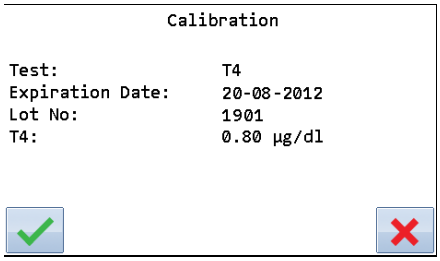
To perform an automatic calibration, touch *Auto***.**

5. Calibration card menu



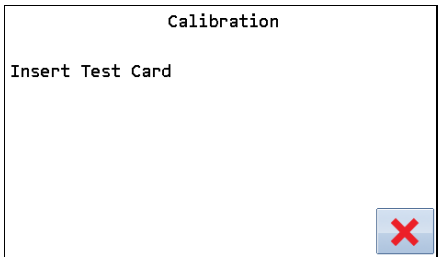
The instrument asks you to insert the **calibration** RFID card supplied with the calibration kit.

6. Calibration data menu



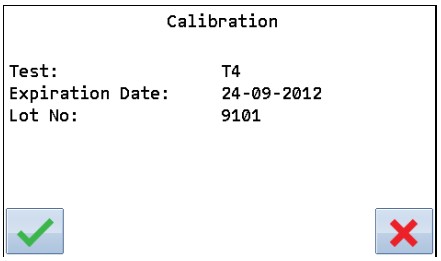
The instrument reads the calibration data from the card. Confirm it with ✓.

7. Insert test card menu



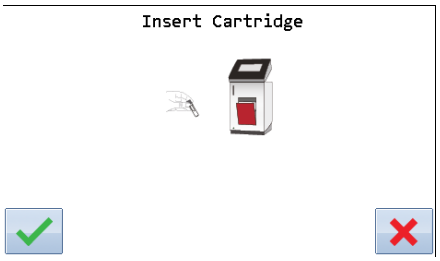
Insert the **test** RFID card supplied with the test kit. The confirmation menu appears.

8. Confirmation menu



Confirm the data of the test to be calibrated with ✓.

9. Start analysis menu

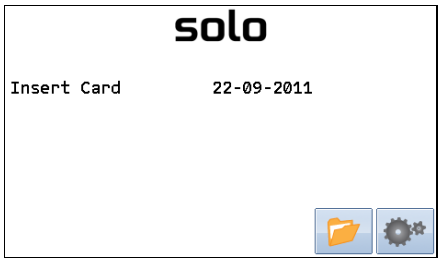


Fill the test cartridge with the calibration material according to the instructions on the calibration kit's package insert. Insert the cartridge and touch ▶.
The calibration will be performed automatically.

⚠ **Note: the calibration applies only to the respective test kit being used!**
If the above instructions have been followed, but the control results are still not within the permitted range, contact your local Eurolyser solo laboratory photometer supplier for assistance before performing the next test on a patient's sample.

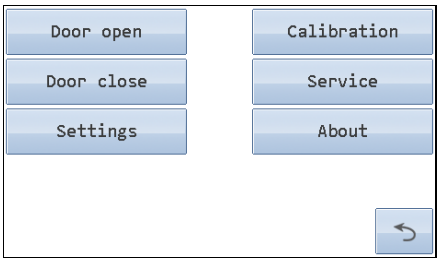
Performing a manual calibration

1. Start-up menu



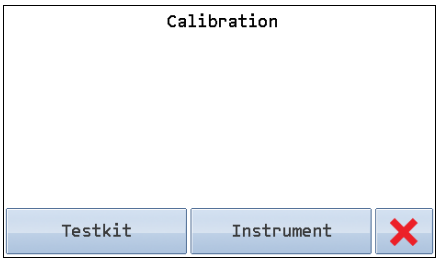
Touch ⚙ to go to the Settings menu.

2. Settings menu



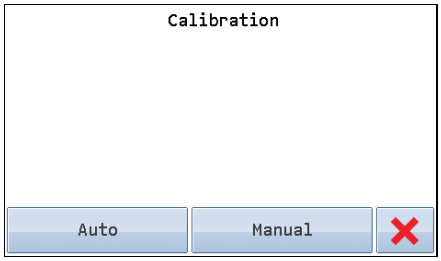
Touch *Calibration* to go to the Calibration options menu.

3. Calibration options menu



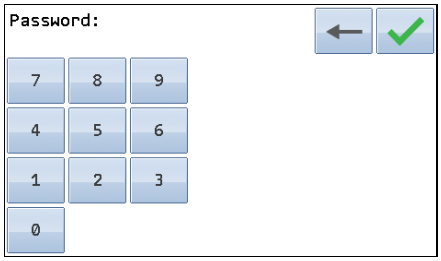
Select *Test kit* to go to the Calibration options menu.

4. Calibration options menu



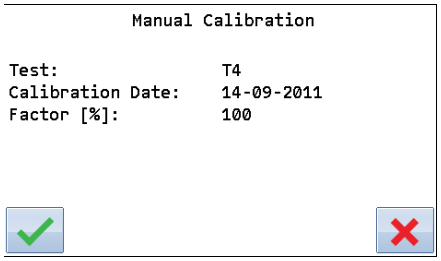
To perform a manual calibration, touch *Manual***.**

5. Password menu



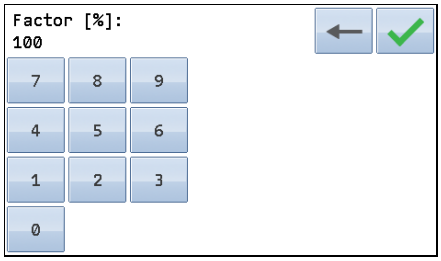
Enter the password. The default setting is 3010. Confirm it with ✓.

6. Manual calibration menu



The data of the test kit to be calibrated is displayed. Confirm it with ✓.

7. Detail entry menu



Change the factor according to the difference from the target value of a control serum. Confirm it with ✓. To delete an incorrect entry, use ←.

Example of how to determine the manual calibration factor

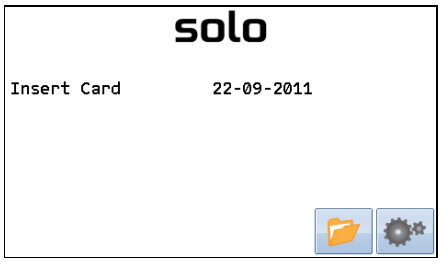
The calibration factor can be determined empirically by analysing a control serum:
The target value of the control serum is e.g.: 3.6mg/l – 6.4mg/l
The measured value of the control serum is e.g.: 8.00 mg/l

⚠ In this case, the value is too high, the calibration factor must be decreased (the default value is 100). Decrease the calibration factor by 5 units.
The default value is 100, set the new factor at 95 and repeat the measurement of the control serum.

If the result is still outside the control serum's specified range decrease the factor by another 5 units and repeat the procedure.

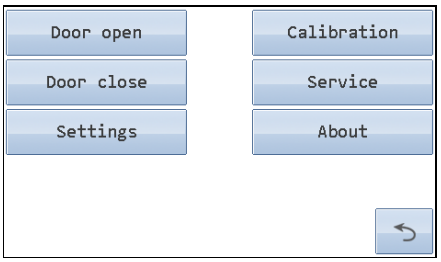
Performing an instrument calibration

1. Start-up menu



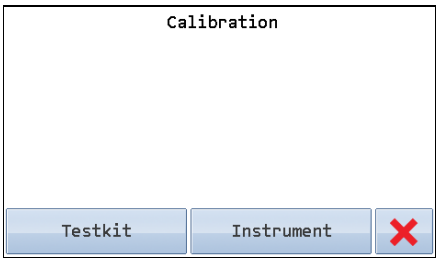
Touch  to go to the Settings menu.

2. Settings menu



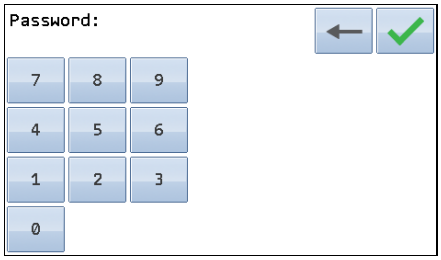
Touch *Calibration* to go to the Calibration options menu.

3. Calibration options menu



Select *Instrument* to perform an instrument calibration.

4. Password menu

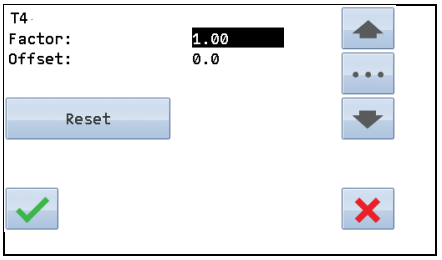


Enter the password. The default setting is 3010. Confirm it with ✓.

5. Test selection menu*[1]

Confirm the selection T4 with ✓.

6. Factor and Offset input menu



Enter the factor and the offset accordingly. Confirm them with ✓.

*[1] *Note*: If only one test is used on the solo, the test selection menu will be skipped.

CLEANING INSTRUCTIONS

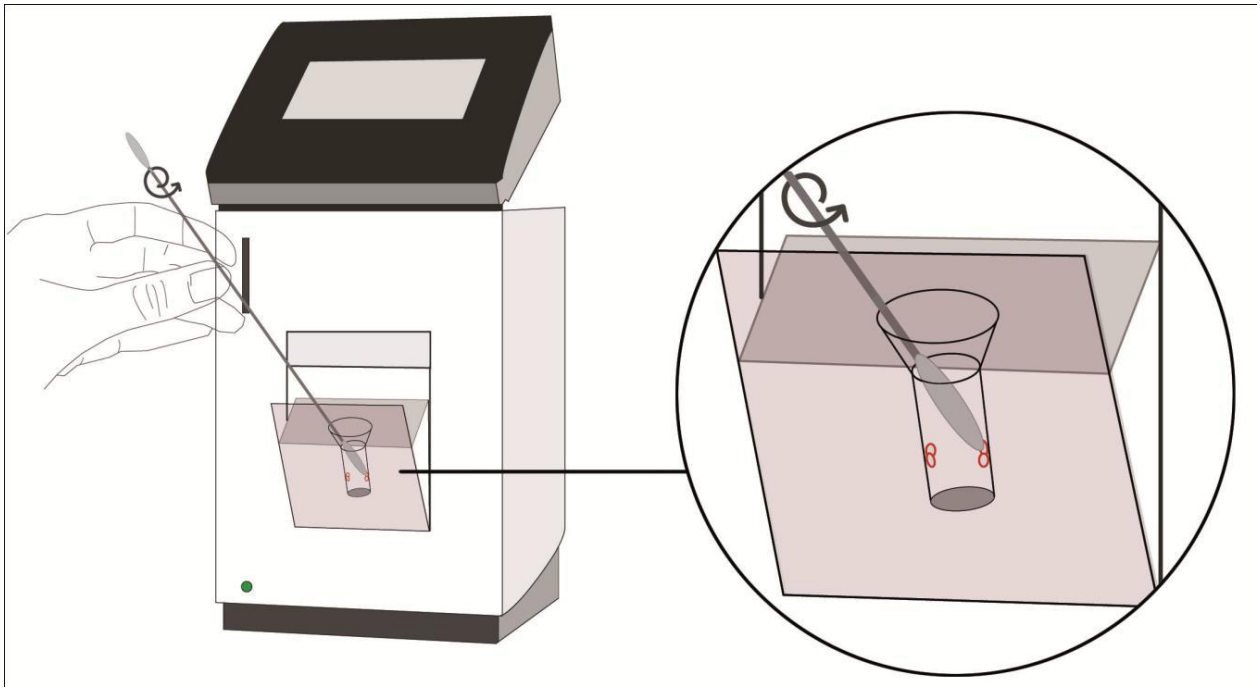
Cleaning the Touch Display

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

Do not use any liquid except of water when cleaning the touch display!
To avoid damage do not spill liquid onto the display!

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 touch panel with isopropyl alcohol!
Refer to “Cleaning the Touch Display” on how to clean the touch panel.

The exterior may be cleaned with a clean, lint-free cloth moistened with isopropyl alcohol. Wipe down the exposed surfaces.

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 Default 115200
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: Snoopy	
ID:	Text	ID: 1234	
Holder:	Text	Holder:John Doe	
Specie:	Text	Specie:Dog	
Sample:	Text	Sample:Blood	Optional
HCT:	Value	HCT: 40	Optional
Testname:	Value and unit	T4: 2.48 µg/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
No results	No test results are stored	Perform the test
Calibration failed	The calibration values are outside the prescribed range. An error occurred during calibration.	Repeat the calibration with a new test kit or a new calibrator. If the problem reocurrs, 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.
Calibration required	The calibration interval has been exceeded	Perform a new calibration
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 is outside the measuring range (e.g. if 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 sample type?	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 sampletype 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 contact your local dealer	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 solo laboratory photometer dealer for technical assistance.

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

- the serial number of your solo laboratory photometer
- 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 solo’s error messages

TECHNICAL SPECIFICATIONS

Eurolyser solo laboratory photometer

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
Display	Standard color LCD display with back light and integrated touch panel
Buffer battery	BR2032
Fuse	2.5 amperes, self-healing
Dimensions	260 x 145 x 140 cm (H x B x T)
Weight	3.5 kg (unpackaged)
Communications interface	RS232, USB
Tolerance conditions:	Work space: 18 - 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

Options

Thermo printer	Seiko DPU-414
Interface	Serial
Mains adapter	100-240 VAC
Barcode reader (scanner)	Datalogic Touch65
Reading area	63mm
Max. resolution	0.10mm (4mils)
Mains adapter	100-240 VAC

DECLARATION OF CONFORMITY

Declaration of conformity with IVD directives

The Eurolyser solo laboratory photometer is in compliance with all provisions in the directive 98/79/EC on In Vitro Diagnostic medical technology products and is CE-marked as conforming to standards.

Safety standards

The Eurolyser solo laboratory photometer has been tested and conforms to the safety standards IEC/EN 61010-1, IEC/EN 61010-2-081 and IEC/EN 61010-2-101, as well as to the EMC standard IEC/EN 61326.

SHUT DOWN AND WASTE MANAGEMENT

For proper waste management according to the directive 2002/96/EG please contact your local dealer. Used cartridges need to be disposed with the laboratory waste and according to its' correct regulations. Before shutting down the solo laboratory photometer for the purpose of a repair or dispense it is needed to make sure there is no cartridge left within the solo laboratory photometer. For the purpose of delivering the solo laboratory photometer it is also required to protect the photometer with its' original delivered packaging and packaging inserts.

MANUFACTURER DATA

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