LAURA

version 2



USER MANUAL

Last revised: 10-2018, UM/50/18/A

IVD CE



Contents

1. Introduction 3
   1.1 Intended use 3
   1.2 Measurement principle 3
   1.3 Buttons and interfaces 4
      1.3.1 Overview of the instrument 4
      1.3.2 Overview of connection of the instrument 4
   1.4 Icons and abbreviations 5
2. Installation 5
   2.1 Unpacking 5
   2.2 Set up the instrument 6
3. Routine operation overview 8
   3.1 User account, User Login 8
   3.2 Ready to measure status 10
   3.3 Measurement 11
   3.4 Patient identification 13
   3.5 Colour and clarity 15
   3.6 Comments 17
   3.7 Maintenance 18
4. Menu structure 20
   4.1 Menu overview 21
   4.2 Main menu 22
      4.2.1 Worklist 23
      4.2.2 Results 25
      4.2.3 Quality control 26
         4.2.3.1 Grey control strips 26
         4.2.3.2 Control urines Urinorm 28
         4.2.3.3 QC Timer 29
      4.2.4 Maintenance 30
      4.2.5 Set up of instrument 31
         4.2.5.1 Strip – parameter settings 32
            4.2.5.1.1 Printing order 32
            4.2.5.1.2 Unit settings 33
            4.2.5.1.3 Parameter table 34
            4.2.5.1.4 Sediment settings 35
            4.2.5.1.5 Sensitivity settings 35
         4.2.5.2 Printer 36
         4.2.5.3 Language Setting 36
         4.2.5.4 Date / Time setting 37
         4.2.5.5 LIS 38
         4.2.5.6 Customization 39
         4.2.5.7 Display/Sound 39
5. Service information 40
   5.1 Trouble-shooting 40
   5.2 Service information 41
   5.3 Safety information 42
   5.4 Producer 42
   5.5 Ordering information 42
   5.6 Warranty Conditions 42
6. Technical parameters 43
7. Serial interface protocol 44
8. Short Instructions 47
9. Index 49

1. Introduction

This manual contains operation and maintenance instructions for the LAURA photometer.

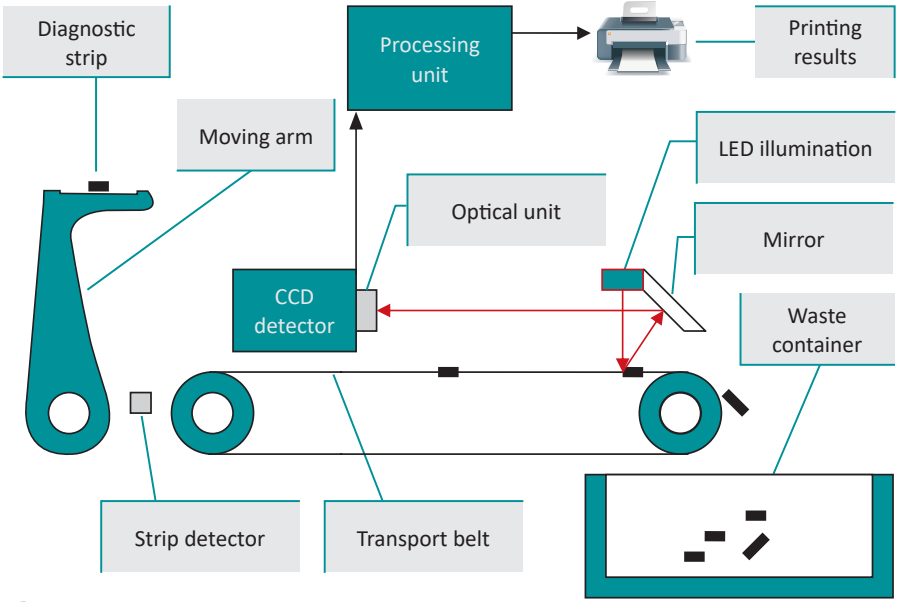
1.1 Intended use

The reader LAURA is a reflectance photometer for semi quantitative urine analysis for reading test strips PHAN® LAURA. The reader LAURA is designed for use in medical laboratories. The reader LAURA is a high throughput semi automatic instrument. The user dips the strip into the urine sample and places it into the reader slot, the rest of the measurement: timing, measurement and displacement of the strip is done by the reader.

The touchscreen displays instructions and prompts you through operations of the analyzer. In addition, you enter information through the touchscreen.

1.2 Measurement principle

The following drawing shows the theoretical working function of the reader LAURA. The strip is inserted onto the moving arm section. The built-in strip detector recognizes the inserted strip and starts to move it into the reader. The strip reaches the measuring position after approx. 55 sec. after placing on the moving arm.
The measurement area is illuminated by LEDs. The reflectance light goes directly into CCD unit with help of mirror and an optical unit. The CCD unit converts the reflectance light to the digital value and this value is transmitted to the microprocessor, which calculates the concentrating results and printed them by the built-in thermo printer.

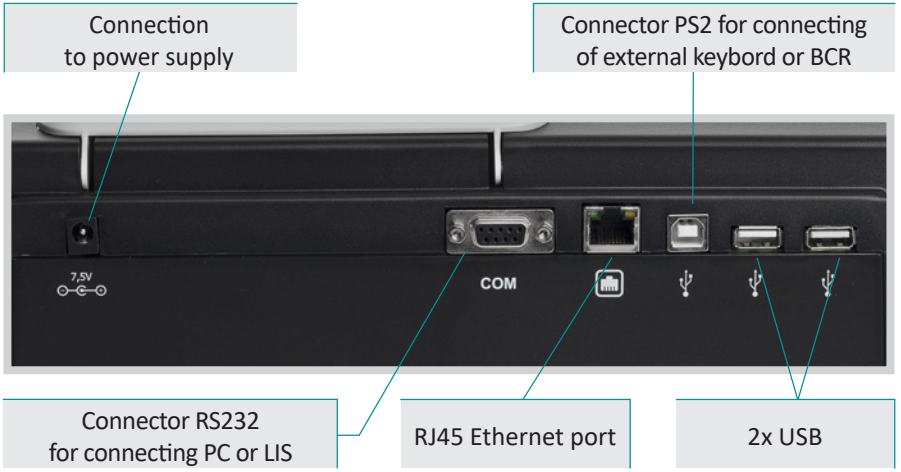


1.3 Buttons and interfaces

1.3.1 Overview of the instrument



1.3.2 Overview of connection of the instrument



1.4 Icons and abbreviations

ID	-	Patient identification code (a figure or a text, max. 15 characters)
Seq.No	-	Sequence number of the measurement
Sample	-	Urine specimen to be measured
REM	-	Remission value
BCR	-	Barcode reader
Host	-	Computer (Laboratory Information System)
BiLED	-	Bicolour (red/green) LED over the strip insert area

2. Installation

2.1 Unpacking

After unpacking the instrument, please check carefully that your package contains all the parts listed below, and check them for visible signs of damage.



Figure 1

- LAURA reader
- DC Adapter with 230 V (AC) cable
- Serial interface cable
- 1 moving arm
- 3 rolls of thermo printer paper
- Tube with control grey strips
- User manual

2.2 Set up the instrument

Follow the steps below:

- Select the working place.
- Choose a place for the reader which is flat and clean.

Do not place the device close to the window, centrifuge or heating surface. Protect it from the direct sun light, the intensive artificial light, vibrations and extreme temperature.

- Assemble the reader LAURA
- Placing the moving arm

Refer to Figure 2 and 3:



Figure 2



Figure 3

Pull the left plastic part towards the side and slide it out.

Unpack the moving arm from the accessory box. A magnet is located at the bottom. Draw the arm with the magnet toward you, the hole can be seen from the other side. Slide the hole slightly onto the metal tab inside the instrument. There is no need to work with force, the magnet will set the moving arm to the correct place.

Check if the moving arm is in the correcct position.
Close the instrument by sliding the left part back to its position.

- Connect the power and interfaces
- Insert the serial cable and the keyboard or BCR to the reader (if used); use the PS2 input for the keyboard/BCR
- Insert the adapter output plug into reader.
- Insert the adapter main cable into the net

Inserting of the printer paper

- Open the printer cover by flipping out the upper part
- Place the paper roll to its holder and pull out approx. 10 cm of the paper to the front
- Close the cover while holding the paper tight with one hand. (Fig. 4)
- Push the cover in the middle or both sides until it clicks into its place

Never push the cover asymmetrically!



Figure 4

The reader LAURA is now ready to be turned on; switch on the master switch!

After power-on the display lights up and the reader carries out a self test. The optical head and built in calibration pad is checked during this test.

After having completed the test successful, the reader prints out the OK message and goes into the Login mode.

3. Routine operation overview

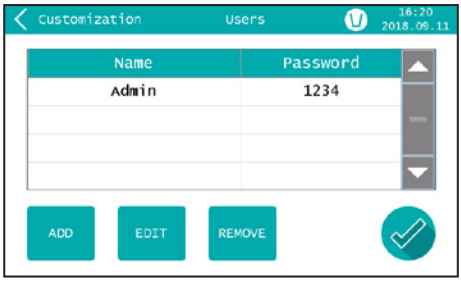
3.1 User account, User login

Based on the requirements of clinical laboratories, it is possible to clearly define the user who performed the urine sample evaluation. The LAURA urine reader offers a total of 10 possible user levels. 9 are optional, one is fixed (admin).

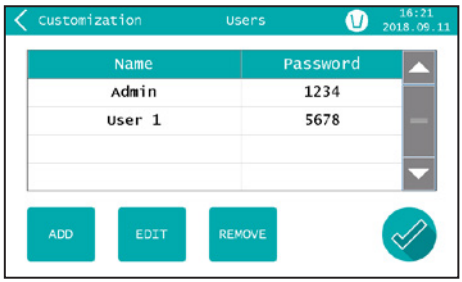
After turning on the LAURA urine reader and after the self-test is finished, the following screen is displayed:



The ADMIN account (login password 1234) has the ability to add / edit / delete user accounts in addition to features as a regular user. To manage your user accounts, press MENU - SETUP - CUSTOMIZATION - USERS. Select the option you want to continue.



Add a new account by pressing the ADD button. Enter the new user name and password and confirm with OK.



Or select a user account and press:

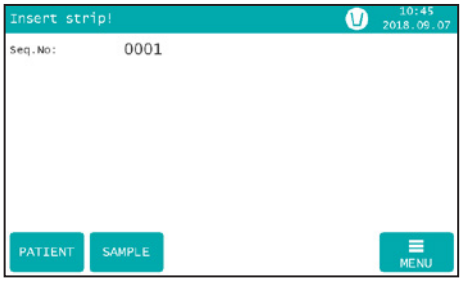
EDIT to edit the data of the current user.

REMOVE to delete the account.

User account names are an integral part of the measured results (urine samples and control measurements). Based on this information, it is always possible to identify the user who performed the measurements.

3.2 Ready to measure status

After switching on the instrument and user login LAURA is ready to measure.



In the Ready to Measure status the following possibilities are available for the user:

1) Start a new measurement process by placing a strip on the transport belts in the insert strip area.

2) Enter patient information:

- Enter patient information:

  o Seq.No
  o ID

- Enter sample information:

  o Select a sample colour from the predefined list
  o Select a sample clarity from the predefined list
  o Insert comment

3) Enter the menu by pressing the MENU icon.

3.3 Measurement

The instrument LAURA begins the measurement automatically when a strip is placed on the strip area on the moving arm.

To carry out a measurement do the following steps:

- Enter a new Seq.No. or ID if necessary.
- If you want to define appearance of the sample, select a colour or clarity from the offer - manually by buttons or by external BCR.
- Dip the reagent strip into the urine sample, wetting all pads.
- Drag the edge of the strip against the side of the sample tube while you remove it. Blot the excess urine from the strip by touching the edge of the strip on the paper towel (follow instruction for the strips PHAN® LAURA).
- Insert the strip into the insert strip area on the moving arm



Figure 5

LAURA has a build-in strip detector at the end of the insert area, under the moving arm. If the strip is placed correctly this detector will recognize it and the bicolour LED will flash green.

After a few seconds (2-7 seconds) the bicolour LED change the colour to the red and reader LAURA shift the strip into reader.

Do not touch the strip when the red LED is on!

The strip will reach the measurement position after 55 seconds. The reader measures the strip and prints the result.

Note: The reader LAURA increments the Seq.No. automatically and displays it. If the bicolour LED turns back green and the reader is ready to accept another strip.

The minimum time between placing two strips on the belt is 9 seconds.

- After the strip is measured, it falls into the waste container automatically.

Results with all information are stored in the memory.

When all placed strips have been measured, the instrument stops the transport belts and turns back into Standby mode. The LAURA reader automatically recognizes the type of inserted strip.

The device is compatible with the strips:
DEKAPHAN® LAURA
HEPTAPHAN® LAURA
PENTAPHAN® LAURA
TETRAPHAN® SG LAURA
DIAPHAN® LAURA
MICROALBUPHAN® LAURA

When the waste container is full, the icon of waste bin in the right upper corner of the screen starts blinking. In such a case the reader doesn't accept more strips. Don't touch the icon STOP.

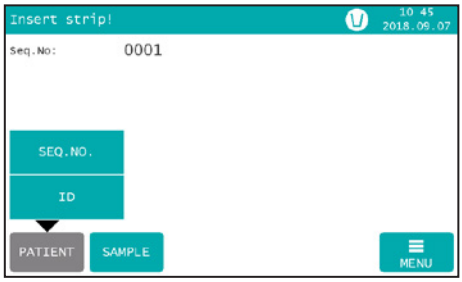
Wait until the already placed strips will be processed and the measurement stops automatically. Empty the waste container and continue with the next measurement.

3.4 Patient identification

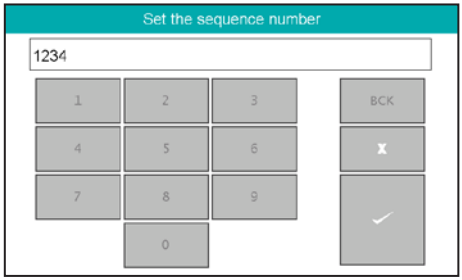
LAURA reader enabless 3 different sample (patient) identifications:

- Seq.No – working with Sequence Number
- Patient ID – working with Identification number
- Worklist – create the list of patients' ID before measurement

Sequence number



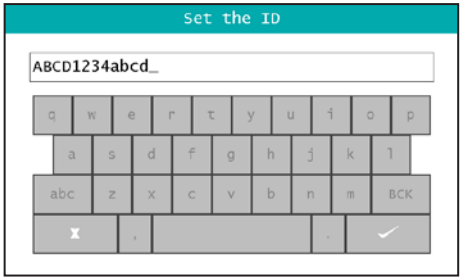
To change the sequence number, press the PACIENT button and select SEQ.NO.



When the numeric keypad is displayed, select the desired sequence number, which may range from 1-9999. Confirm with OK.

Identification number

If you want to enter ID, press PATIENT – ID, the letter pad will be displayed. Enter an ID with a maximum of 15 characters in a combination of letters and numbers. This ID could also be entered with an external keyboard or a barcode reader in the Ready to Measure status.



Worklist

This mode can be found in the MENU - Worklist.

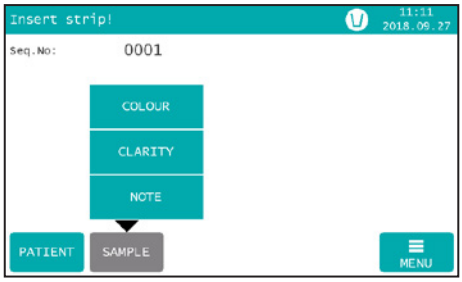
More sample IDs could be entered into the list before the measurement starts. The reader LAURA can accept up to 100 sample IDs and store them in memory. After all the IDs are entered and the worklist is confirmed, the reader displays the individual IDs gradually in selected order. Remove the strip from the tube and dip it in the appropriate sample. Then place the strip on the movable arm into the strip insertion area. Continue similarly with other samples.

Be careful to insert the strips in the same order as you put them in your list. Otherwise, the IDs and analyzed urine samples get mixed!

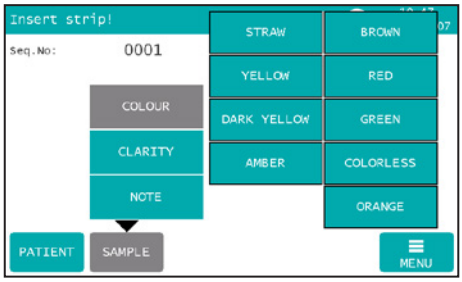
If the strip in the list could not be measured, press the SKIP button to skip it. The reader will display the following item in the list. For detailed description of this working mode please refer to: 4.2.1 Worklist.

3.5 Colour and clarity

User can set the colour and clarity information of the sample.



Colours and clarities are predefined and can be modified by the user in the Customisation menu (see 4.2.5.6). There are nine different colours and four different clarities available.



Enter information about colour and turbidity or other detailed sample information by touching the SAMPLE - COLOUR / CLARITY / NOTE field and selecting from the predefined options. The selected specification is displayed within the measured sample. If you want to change your selection, touch the SAMPLE - COLOUR / CLARITY / NOTE field again and select another option. If you want to delete your choice, touch the SAMPLE field again and then press the desired COLOUR / CLARITY/ NOTE button twice.

Description of colour and clarity can be performed directly or also by using of external bar code reader (BCR).

Special bar codes are used for prompt and comfortable entering of colour and clarity. If using BCR information is automatically entered into the line colour or clarity. For the routine usage of mentioned bar codes in the laboratory practice is recommended to make a copy and the lamination.

Bar codes – colour

COLOUR	BAR CODE
STRAW COLOURED	
YELLOW	
DARK YELLOW	
AMBER	
BROWN	
RED	
GREEN	
COLORLESS	
ORANGE	

CLARITY	BAR CODE
CLEAR	9 1 1 9
CLOUDY	9 1 2 9
TURBID	9 1 3 9
DARK	9 1 4 9

3.6 Notes

It is possible to add note (39 characters long) to the measurements at two different points:

- Before the measurement
- After the measurement - the result is selected from Results

To add a note before a measurement press SAMPLE – NOTE:

Figure shows the image how the display looks after entering all the available information.



Another option is to add a note after measurement. Select the respective result from memory and touch the fielt NOTE next to the result, see chapter 4.2.2.

Keep in mind that if you added a note before the measurement and you want to expand it for more information, you must rewrite the whole text in MENU-Results otherwise it would be overwritten with the new entry.

3.7 Maintenance

At the end of the working day the reader needs to be cleaned.

- Using the disposable waste lining for collecting of measured strips is recommended. Put the disposable waste lining to the waist container before measurement.

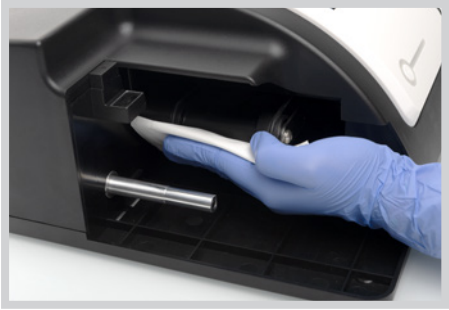
- Remove the waste container, located at the right side of the bottom part.



- Remove the disposable lining with strips and discard it. If you do not use a disposable lining, empty the container and carefully treat it with the usual disinfectant. Return the container to its place.

- Slide the left part of the instrument to the left and remove the moving arm. Rinse it under running water and clean with a disinfectant.

- Select the MENU - Maintenance function for cleaning the belts. The belts start to move.
- Clean the belts using a wet cloth moistened with a common disinfectant. See figure:



- While the cleaning is finished, press OK. Belts stop. Place the movable arm in the correct position, see chapter 2.2.

- Place the left part back to the instrument. For disinfection, use an alcohol disinfectant (max 85 %) such as ethanol, isopropanol, if necessary!



Do not use acetone, petrol or any agressive solvents for the cleaning!



All disinfected components has to be fully dry before placing back to the instrument!



Do not touch the mirror or the internal REF pad!

WASTE DISPOSAL:

Used strips should be treated as potentially infectious and should be disposed in accordance with local and national regulations relating to safe handling of such materials. Waste has to be recycled or put to municipal waste.

4. Menu structure

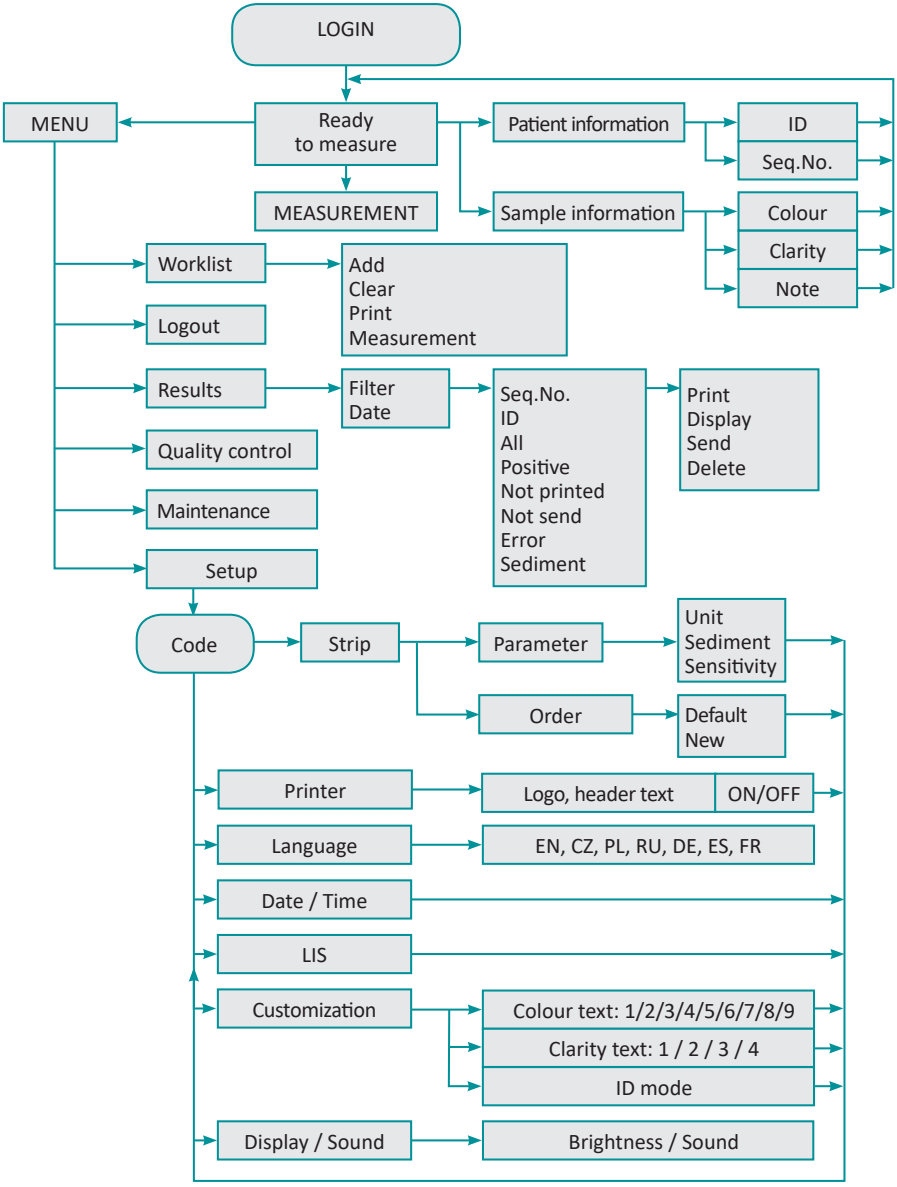
LAURA reader has a clear, well organized menu structure.

The user is guided trough the menu by the touch screen.

The menu functions are represented by buttons or list controls. Pressing the touch screen can activate the desired function. The pressed buttons are highlighted with grey colour.

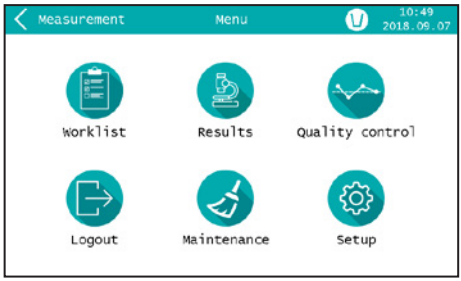
Pressing the arrow icon in the left upper corner of the bar on the screen the program jumps back to the previous menu level. The program jumps back to Standby if any button isn't pressed for 3 minutes.

4.1 Menu overview FLOWCHART



4.2 Main menu

After pressing the MENU in Ready to measure status the following main functions are available:



- WORKLIST
  More sample IDs could be entered before the measurement is started in this mode. The reader LAURA may accept up to 100 sample IDs and store them in memory. After all the IDs are entered the measurement may start. The reader displays the ID of sample which should be measured next.

- RESULTS
  LAURA reader has a capacity for the last 1 000 measurements. Stored measurement results contain all of their related information (date, time, note, colour…). Results may be selected from the memory, displayed, printed or sent to the computer anytime.

- QUALITY CONTROL
  The instrument measuring capability is checked using the grey control strips and control urines Urinorm. The instrument measures the grey control strips and compares the result to the predefined values. The test result is displayed and also printed for QC purposes. In the case of control urines Urinorm are results automatically compared with target values that are listed in pack insert of control urines Urinorm.

- MAINTENANCE
  This mode assists with cleaning the moving arm and transport belts. When this mode is activated the reader starts to run the transport belts while the measuring part remains off.

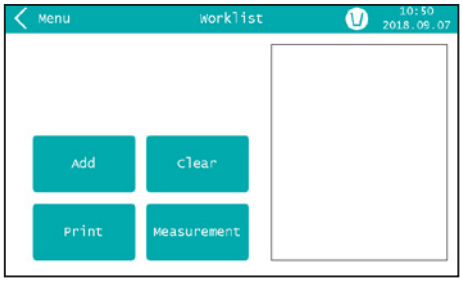
- SETUP
  In this menu point the working parameters of the reader may be set.

- LOG OUT
  Pressing the appropriate button will log out an existing user.

4.2.1 Worklist

This menu describes how to create a list of sample IDs and to start the measurement in Worklist mode.

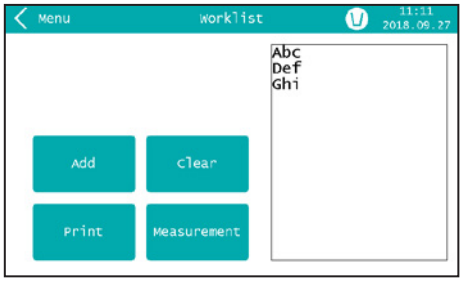
The following functions are available:



The individual menu functions could be activated by pressing the corresponding button.

The current worklist can be printed after pressing PRINT.

To enter new ID select button ADD:

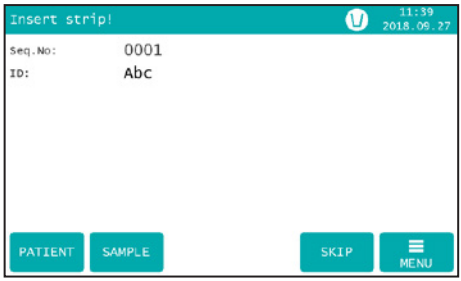


ID may be entered either by using the numeric or letter buttons or from an external keyboard or BCR. The amount of stored IDs is displayed. One list may contain up to 100 items. If the Worklist was not empty when entering the ADD mode the stored items figure displays the total number of stored IDs. The proces of entering ID is finished by pressing the EXIT button and the reader jumps back to the Worklist menu and is ready for measurement.

Select the CLEAR button to delete entire Worklist.

For measuring the samples from the Worklist press the button MEASUREMENT.

The display shows the following information:



The first sample of the list is automatically assigned with sequential number 1 and ID is displayed on the display. Dip the strip into the appropriate urine specimen and place it on the moving arm into the strip insertion area. The reader moves the strip in and asks for the next strip and displays the next saved ID. Dip another strip into the appropriate urine sample and place it on the moving arm. Repeat this procedure until you measure all the samples from the worklist. The ID saved in the instrument cannot be changed. If you are not able to measure any sample you can skip it by pressing SKIP button. The reader jumps to the next ID and the skipped ID remains in the list for further measurement.

Be careful to insert strips in the same order as you put it in your worklist. Otherwise, the IDs and analyzed urine samples get mixed!

4.2.2 Results

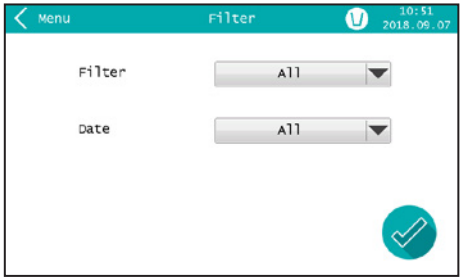
The reader has a non-volatile memory which automatically stores the last 1 000 measurements.
While the capacity of memory is full the oldest result will be overwritten by the new one without any warning.

When the current measurement is finished the reader stores the result along with the following parameters:

- Test result
- Type of the strip
- Seq.No
- ID
- Date and time
- Colour
- Clarity
- Note

The user may browse in the results selecting the MENU - Results.

User may use the FILTER and DATE criteria to find and sort results in Results:



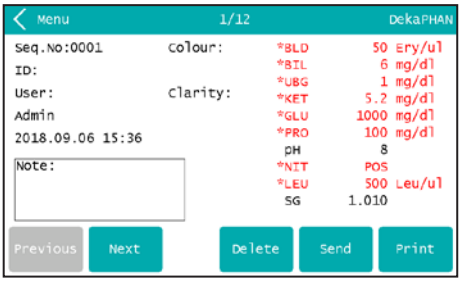
The results are searched according the entered parameters by pressing the confirmation button OK.

- Select the FILTER criterion:
  - o All - all stored result
  - o ID - enter the respective ID
  - o Seq.No - enter the respective Seq.No.
  - o Not printed - results that have not yet been printed
  - o Not sent - results that have not yet been sent
  - o Positive – results that at least 1 parameter is positive
  - o Sediment – results that at least 1 values is higher then the sediment limit of respective parameter; these limits may be defined in Parameter settings
  - o Error - results that have failed

- Select the DAY of the measurement:

  o All - regardless of the measurement date
  o Today - search only among results measured today
  o Specific date – search only the desired date (The program offers only those dates where the results are available)

Once the selected criteria have been entered the results are shown on the display and other options are available:



  o Print – selected results will be printed
  o Send - selected results will be sent to HOST, RS232
  o Delete - selected results will be deleted

Use button Previous/Next to scroll through the list of selected results.

The currently displayed result could be updated with a note. Positive parameters are marked with* and are highlighted in red colour.

4.2.3 Quality control

Quality control mode provides the check of optical parts of the instruments and also checks the whole system test strip - instrument LAURA using control urines Urinorm.

4.2.3.1 Grey control strips

The purpose of this test is to verify that the optical measuring part of the instrument works properly. Perform this test once a week or if you receive suspicious result in normal use. For testing the instrument the grey control strips are provided in the LAURA reader package.

Perform this test best before starting routine measurement.

To perform this test follow instructions below:

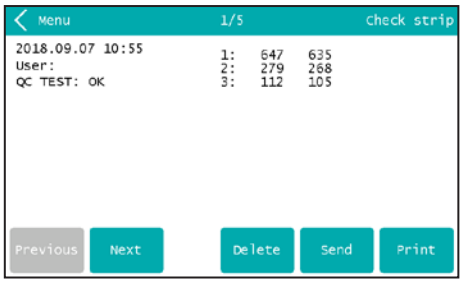
- Empty the waste container and clean it carefully!

Control strip falls into the waste container after measurement. Proper cleaning of the waste container prevents contamination and thus the degradation of the control strip!

- Press the MENU – Quality control
- Press the 14-digit number button and enter the calibration code for the batch of the control strips. Copy the code from the tube with control strips or use the BCR. Confirm with OK
- Press Check strip
- Take out one grey strip from the tube
- Place the grey strip onto the moving arm
- The reader starts the measurement
- Wait for the measurement is completed

After measurement the reader compares the obtained remission values to the predefined ranges stored in the instrument. After that it displays and prints out the result. When the measured values are in compliance with the predefined values the result is QC Test: OK.

Example of display after measurement in Quality Control mode:



Keep the print out for QC reference. If the test fails QC Test Error will be reported and the wrong result displayed in red. In this case repeat the test with another check strip. If it reports an error again call the service.

Keep the grey strips always in the tube, do not touch the surfaces by hand, and handle them with care. The strips are reusable. All important information is on the label of the grey strips!

4.2.3.2 Control urines Urinorm

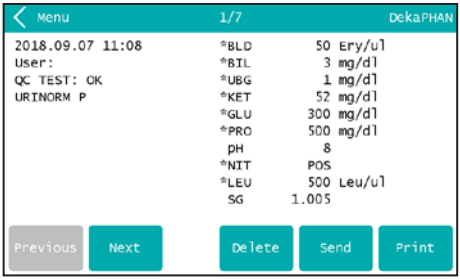
Urinorm control urines are designed for verification and confirmation of precision and accuracy of PHAN® LAURA diagnostic strips as well as LAURA urine analyser (for the visual and objective evaluation). Measured values are automatically compared with target values.

Test performance:

- Press the button MENU - Quality control - Urinorm (N, P)
- Remove 2 test strips from the tube
- After pressing the button Urinorm N the display shows a flag to insert the test strip dipped into Urinorm N
- Dip the first strip into the tube of Urinorm N, remove excess amount of control urine and place the strip on the moving arm
- Wait for the measurement
- Press the button Urinorm P
- Dip the second strip into the tube of Urinorm P, remove excess amount of control urine and place the strip on the moving arm
- Wait for evaluation

After the evaluation is finished the results are automatically compared with target values that are stored in the instrument and is completely identical with the target values in the pack insert of control urines Urinorm.

Example of the display after the measurement of control urines Urinorm:



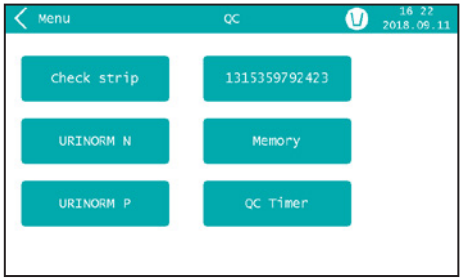
Save the results in printed form as proof of the measurements for inspection.

Unsatisfactory result (not corresponding to predefined values) is highlighted in red and printout contains two exclamation marks. In this case repeat the test with another pair of test strips/new bottle of control urine Urinorm N/P. If the error message appears again please contact the service.

4.2.3.3 QC Timer

After logging in as an admin set the QC timer and QC lock function – choose how often run quality control with control urines and control strips. If the device does not pass the check it gets locked for further measurement of patient urine. The user is forced to repeat the control measurement until it has a satisfactory result. Then the device is unlocked.

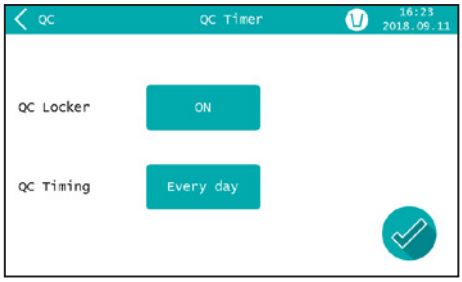
This mechanism eliminates the occurrence of any incorrect results issued due to malfunction of the device / diagnostic strips.



QC locker - if the device does not pass through the control measurement it gets locked for patient measurements samples.

QC interval - choose how often the control measurements should be performed. They are 4 options: every 8 hours, every day, every week, every month.

These functions could be activated independently of each other.



4.2.4 Maintenance

This mode allows user to clean the transport belts. While this function is activated the reader runs on the transport belts without starting a measurement. The reader LAURA can be opened and the belts could be accessed and wiped off easily (Fig. 5). To quit this mode press the OK button.

Do not touch the mirror or the internal REF pad!

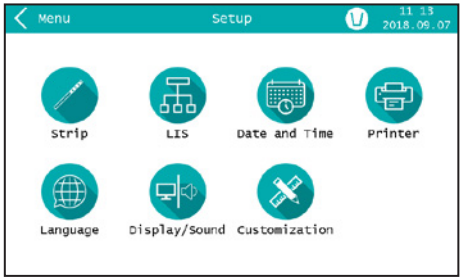
For more information please refer to section 3.6.



4.2.5 Set up of instrument

This menu point of the instrument is used for setting of working parameters. The settings are protected by the access password 2134.

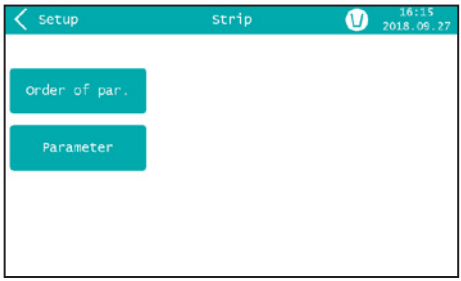
The working parameters are organized as follows:



- Parameter – strip and measurement related parameters:
  ORDER of parameter at printing
  UNIT of parameters
- Printer - enable the printer, printing the logo, device name, headers, and greeting line
- Display/Sound
- Language –7 predefined options
- Date / Time – set the date and time and the date format
- LIS – serial communication parameter settings
- Customization –defining colour and clarity texts, ID mode

4.2.5.1 Strip - parameter settings

This menu point is divided into two submenus:



- Printing order
- Unit settings

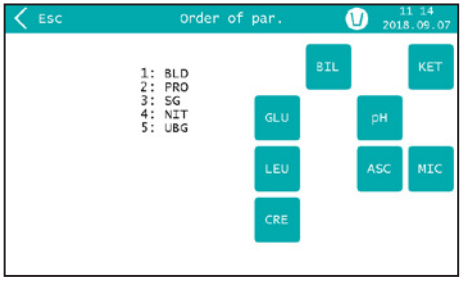
4.2.5.1.1 Printing order

For setting the parameter printing order press MENU – Setup – Strip – Order of parameters.

Press the DEFAULT button and the printing order will correspond to the Parameter order of the strip DEKAPHAN® LAURA.

The instrument enables to change this order according to the users needs. In this case press the NEW button.

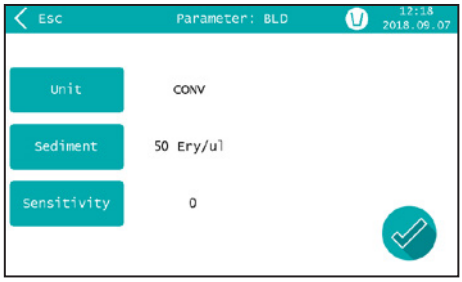
The display shows all the parameters and the desired printing order is selected by touching the respective parameter one by one.



4.2.5.1.2 Unit settings

Reader LAURA allows the user to set the units individually for each parameter. Press MENU – Setup – Strip – Parameter – select parameter you would like to edit. Units can be selected according to the following menu on the display:

Possibilities for settings of units are CONV, SI and ARB or their combination.



- Automatic SG recount

Urine specimens having a pH of 7 or higher shifts measured results for a specific density (SG) to lower values. For urine with a pH of 7 or higher it should always be added 0.005 to SG result value so that the results would be more comparable to the higher reference method such as a urometer or a refractometer. LAURA reader includes a feature which ensures the automatic conversion of the SG result into pH.

In the case of SG recount activation always if the pH is 7 or higher a value 0.005 is automatically added to the SG result. If the SG recount is deactivated the result for SG is not converted according to pH result.

In Quality control mode the SG recalculation is deactivated even if it is turned on.

4.2.5.1.3 Parameter table

The following table summarizes the possible reported values.

Parameter	CONV		SI		ARB
	value	unit	value	unit	value
BLD	NEG	Ery/µl	NEG	Ery/µl	NEG
	10		10		1+
	50		50		2+
	250		250		3+
LEU	NEG	Leu/µl	NEG	Leu/µl	NEG
	25		25		1+
	75		75		2+
	500		500		3+
BIL	NEG	mg/dl	NEG	µmol/l	NEG
	1		17		1+
	3		51		2+
	6		103		3+
UBG	NORM	mg/dl	NORM	µmol/l	NORM
	1		17		1+
	3		51		2+
	6		102		3+
	12		203		4+
KET	NEG	mg/dl	NEG	mmol/l	NEG
	5.2		0.5		±
	16		1.5		1+
	52		5		2+
	156		15		3+
GLU	NORM	mg/dl	NORM	mmol/l	NORM
	50		2.8		1+
	100		5.5		2+
	300		17		3+
	1000		55		4+
PRO	NEG	mg/dl	NEG	g/l	NEG
	30		0.3		1+
	100		1		2+
	500		5		3+
pH	5				
	6				
	6.5				
	7				
	8				
	9				
NIT	NEG				
	POS				
SG	1.000				
	1.005				
	1.010				
	1.015				
	1.020				
	1.025				
	1.030				

4.2.5.1.4 Sediment settings

The reader LAURA can filter the results in order to find out which samples should be investigated for sediment analysis. The limit value for sediment may be set for all pamateres: MENU – Setup – Strip – Parameter – select parameter – Sediment. If the obtained result is higher than chosen limit the measurement is marked for further analysis of sediment. After all the measurements are finished the instrument may print a list with the Seq.No and ID of those samples where at least one parameter was higher then the defined sediment limit.

Follow the instructions below:

- Select MENU
- Select Results
- Set Date: Today
- Set Filter: Sediment
- Confirm OK

The reader LAURA will print a list of samples that should be sent to urine sediment analysis.

4.2.5.1.5 Sensitivity settings

The reader LAURA allows the user to slightly change the instrument sensitivity for each parameter individually.

For the change of sensitivity press MENU – Setup – Strip – Parameter – select parameter – Sensitivity

The sensitivity can be set in ± 5 level where:
0 is no change,
-1 to -5 is less sensitive
+1 to +5 is more sensitive

The sensitivity value changes the measured remission value before it is compared to the predefined remission borders. The change is valid proportionally for the whole measuring range from NEG to the highest POS value.

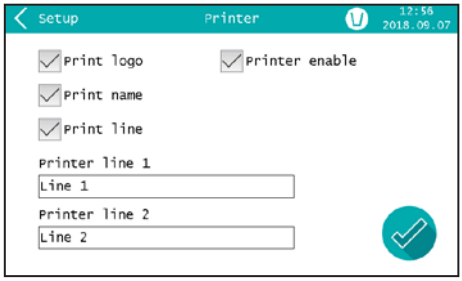


Notice that the sensitivity has an influence on the instrument performance!

4.2.5.2 Printer

In this menu point user may switch ON/OFF following options:

- Printer
- Printing of logo
- Printing of instrument name
- Printing of greeting lines (2. lines)

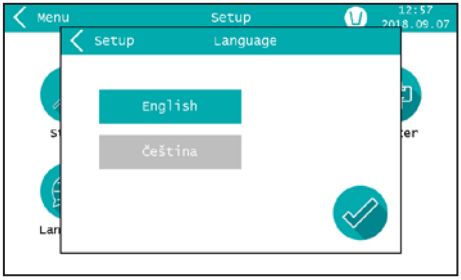


Printer ON /OFF indicates whether the results will be printed automatically after measurement or not.
It is possible to switch off this feature; in this case the instrument will measure the strip and store the result in memory but it wouldn't be printed.
The result can be printed anytime after the printer is turned on. Turn on the printer, select the results in Results and choose PRINT.
Printing a greeting line allows user to print his own text. This text is printed every time the device is turned on.

4.2.5.3 Language Setting

The user can set the communication language of the device here.

Press MENU – Setup – Language and select the language you wish to communicate with by touching the appropriate button. Press OK to confirm.

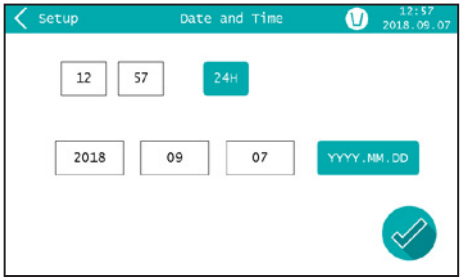


The following languages are available:
English
German
French
Czech
Polish
Spanish
Russian

4.2.5.4 Date / Time setting

The Time and the Date format may be set in this menu point.

Select the MENU – Setup - Date / Time and the following screen will appear:



Change of the date or time is done by touching the respective button.

The numeric keypad is displayed. Enter the desired values and confirm with OK. Once the time and date are correct adjust the date format by touching the blue buttons.

Pressing the button repeatedly switches between all available options.The following formats could be used:

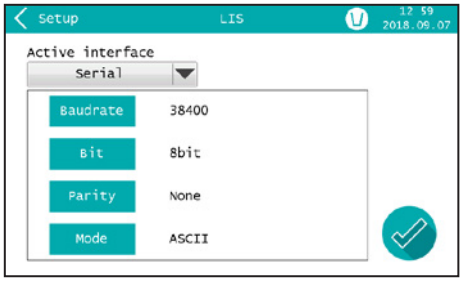
Year – Month – Day (YYYY-MM-DD)
Day – Month – Year (DD-MM-YYYY)
Month – Day – Year (MM-DD-YYYY)

Time can be set to 12 hours or 24 hours format.

4.2.5.5 LIS

This menu is used for setting the connection between the reader LAURA and laboratory information system (LIS) or directly with PC. The reader LAURA has an RS 232 serial interface to HW connection. This interface can be configured according to the HW computer. The format of the data sent through the serial line is described bellow.

In this menu point the parameters of the RS 232 interface could be adjusted as follows:



Baudrate: Baud rate could be selected in the range 2 400 – 38 400 Bd

Bit: bit length of 8 or 9 bits

Parity: parity none, even or odd

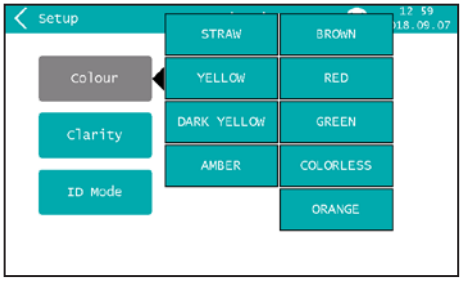
Press OK to make the selection valid

To return to the main MENU without any changes touch the arrow in the left upper corner. Details for connection are written in serial interface protocol – please refer to chapter 7.

4.2.5.6 Customization menu

In the Customization submenu user may define urine colour and urine specifications or de/activate ID mode. Text can be entered via the alphanumeric keypad of the device or via an external keyboard.

- COLOUR - After pressing the button 9 predefined urine colours will appear. Touch the options to change the names. Text can contain up to 10 characters. Confirm with OK.
- CLARITY - After pressing the button 4 predefined urine clarity will appear. Touch the options to change the names. Text can contain up to 10 characters. Confirm with OK.
- ID mode - When enabled samples can be measured after entering the patient ID only.

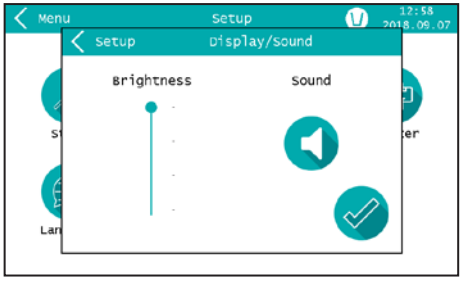


4.2.5.7 Display / Sound

Pressing the Display / Sound button allows user to adjust the sound and brightness of the screen.

Sound - Touch the button repeatedly to turn on / off the sound

Brightness - Shift the button to select the brightness of the display



5. Service information

Reader LAURA is a highly sensitive and accurate optical measuring device. All optical parts such as a mirror, lens, reference strip, etc., are set up using special tools in production. Do not move the instrument cover and never touch the mirror and the REF box when the machine is open for cleaning.

5.1 Trouble-shooting

In case of any error please refer to the following table. It helps to identify the possible cause of the error and gives the instruction how to solve it.

ERROR DESCRIPTION	POSSIBLE CAUSES	CORRECTIVE ACTION
Reader cannot be switched on. LCD remains dark.	Power supply is not connected, or wrong type.	Check the power supply and the connections.
Selftest failed.	The instrument os not closed.	Close all the movable parts tightly to the instrument. Insert the waste container.
Strip is not detected. BiLED is not functional.	Strip is placed extremely to the side. Strips detector is dirty or damaged. Reader is in ID mode and ID was not entered.	Move the strip into the centre of the area for inserting strip. Check the detector and clean it. Enter the ID.
Reader recognizes the inserted strip, BiLED flashes green but the strips in not transported into the device.	Reader doesn't print or the printout isn't visible. Printer cover is not closed. Paper is placed with wrong side up. Wrong type of paper is used.	Check the printer for damage. Close the printer cover. Make sure you use the correct type of paper and the rol lis placed in correct position
Reader rozpozná vložený proužek. Dioda svítí zeleně, avšak proužek není transportován dovnitř přístroje k vyhodnocení.	Transport mechanism is damaged.	Make sure that the moving arm and transport belts are in a correct position.
Host communication failed.	Serial cable is not connected or connected incorrectly. Interface mode is turned OFF or entered parametres are not in corcondance with the HOST settings.	Make sure that the serial cable is correctly connected. Make sure that the Interface mode is turned ON and all the parametres are correctly entered.
Reader shows: Measurement error.	Wrong type of strip was inserted. Strip was inserted incorrectly. Dry or not fully wet stripp was inserted.	Repeat the measurement. Make sure that you are using correct type of strips. Ensure all the diagnostic zones on strip are soaked with the urine sample.

NUMBER OF ERROR CODES	CODE	DESCRIPTION
1	ERR EE	EEprom fails HW error
2	ERR RTC	RTC ack fails HW error
3	ERR COMM	communication error
4	ERR EXTLIGHT	external light too high
5	ERR WRONGSTRIP	wrong strip
6	ERR STRIPWIDTH	strip is too wide
7	ERR SRSTRIP	strp angle too high
8	ERRDRYSTRIP	strip is not fully wet
9	ERR PAPER	printer is out of paper
10	ERR LOGIN	Login failed
11	ERR OPEN	upper part open
12	POP EMPTY	Empty memory
13	POP EMPTYWL	Worklist empty
14	POP NEWVAL	Setting stored

5.2 Service information

In case of an error try to solve it according to the above troubleshoot guide first. If the failure remains, please contact your distributor for service.

DO not open the reader's case!

5.3 Safety information

The reader LAURA complies with the EMC directive 2014/30/EU and low voltage directive 2014/35/EU.

LAURA instrument in combination with PHAN® LAURA test strips complies with the requirements of IVD directive 98/79/EC.

5.4 Producer

Producer of the system LAURA and diagnostic strips PHAN® LAURA:

Erba Lachema s.r.o.
Karásek 2219/1d, 621 00 Brno
Czech Republic

5.5 Ordering information

Product	**Cataloque number**
LAURA *version 2*	INS00063
DEKAPHAN LAURA	URPH0028
HEPTAPHAN LAURA	URPH0027
PENTAPHAN LAURA	URPH0026
TETRAPHAN SG LAURA	URPH0025
DIAPHAN LAURA	URPH0024
MICROALBUPHAN LAURA	URPH0029
Control strips for LAURA *version 2*	URPH1002

Spare parts	**Cataloque number**
moving arm	50005207
transport belts	50005208
adapter for LAURA *version 2*	50005209
serial cable for LAURA *version 2*	50003512
Waste container LAURA *version 2*	50005210
thermopaper roll 57/50/12	51000230

5.6 Warranty Conditions

The warranty conditions are specified in each purchase contract. In Appendix to the purchase contract are also specified consumable parts or equipment that are not covered by the warranty servise.

6. Technical parameters

General	Dimension	300 x 287x 148 mm
	Weight	3,2 kg
	Power source	External adapter 100-240V/ 50-60Hz 7,5V 5.34A
	Power consumption max / standby	35W / 1W

Measurement	Methode	Reflection photometry
	Throughput	min. 400 Strip/hour
	Optic viewing area	100 mm
	Pixel resolution	640 pixel/ 100 mm
	AD resolution	12 bit

User Interface	Printer	58mm graphical thermal printer, 24char/line
	LCD	800x480 pixel

Memory	Capacity	1000 measurement results with date, ID, and comments
	RTC	Lithium battery kept real time clock

Interfaces	Host interface	RS232 Serial interface, 2400-19200Bd
	BCR/keyboard	PS2 standard interface

Recommended operating environment	Temperature	15–35 °C Optimal range 20-25 ºC
	Humidity	20–80 %
	Place	Horizontal surface No shock or vibration

Storing / transport	Temperature	-20–60 °C
	Humidity	20–90 %

7. Communication protocol

LIS Setup

Warning: Some of the texts in Section 12 (LIS Setup) are presented in the English language. The communication protocol is based on the international standards; therefore, some parts of this Section have not been translated!

General

LAURA analyser may be connected to a laboratory information system (LIS). Such an interconnection is anticipated in case of most of the installations – it comprises identification of samples on the basis of barcodes which are generated at the time of acceptance of each respective sample (they contain information regarding analyses required for each respective sample). The Section covering the setup provides any and all required information for successful interconnection.

Items required for communication with LIS:

- Connection between LAURA analyser and LIS;
- Configuration of LAURA analyser.

Connection between LAURA analyser and LIS may be achieved via:

- RS232 port;
- Ethernet connection.

Communication via Serial Port

- Connection between LAURA analyser and LIS via the serial port exploits RS232 serial interface featuring DB-9 connector. Only the Pin2 (RD) and Pin3 (TD) used in communication.

Communication via ethernet

- The network connection between LAURA analyser and LIS is achieved through a serial cable connected to RJ45 (Category 5) connector located on the rear side of LAURA analyser.

Modes of Operation

DOWNLOAD Mode

In this mode of operation LIS send a worklist to LAURA analyser.

- H line (header)
- O line – one or more (order)
- L line (end of message)

Example:

```
H|\^&||| P|1|00010032||| |||
O|1|00010032|| ||||||||||
L|1
```

	Field#	Detail	Value or remarks
H Line			
	Field n°1:	Header ID	H
	2	Field delimiter	generally: |
		Repetition delimiter	generally: \
		Component delimiter	generally: ^
		Escape character	generally: & but unused
	3	Unused Field	
	4	Unused Field	
	5	Automate ID	LAURA
	6 => 11	Unused Field	
	12	Processing ID	P (Patient)
	13	Version N°	E 1394-97
	14	Date & time of message	YYYYMMDDHHMMSS
O line			
	1	O	
	2	Sequence number	
	3	Sample ID	
	4 =>11	Unused Field	
	12	Code action	C to cancel a test
	13 =>16	Unused Field	
L Line			
	1	L	
	2	Sequence number	

RESULT mode
As soon as an analysis is performed completely, LAURA analyser may send its results to LIS.

The message containing results of an analysis contains the following items:
- H line (header)
- P line (patient)
- O line – one or more (order)
- For each line or one more R lines (result)
- L line (end of message)

Example:
H|\^&||| LAURA |||||||P|E 1394-97|20150106142536
P|1|00010032|||CLAUDE^DOMINIQUE|||
O|1|00010032||^^^CHEMESTRY|R||||Regular Primary||||||
R|1|^^^SG|1.020||||N|F||||20150106112502||
R|2|^^^LEU|Neg.|Leu/µL|||N|F||||20150106112933||
…
L|1

Chemical part:
SG, LEU, NIT, PH, ASC, PRO, GLU, KET, UBG, BIL, BLD
Field no. 13 contains information about the date and time of measurement (as recorded following completion of analysis of a sample using LAURA analyser). The format of date and time is as follows:
YYYYMMDDHHMMSS

	Field#	Detail	Value or remarks
H Line			
	Field n°1:	Header ID	H
	2	Field delimiter	generally: |
		Repetition delimiter	generally: \
		Component delimiter	generally: ^
		Escape character	generally: & but unused
	3	Unused Field	
	4	Unused Field	
	5	Automate ID	LAURA
	6 => 11	Unused Field	
	12	Processing ID	P (Patient) or Q(CQ)
	13	Version N°	E 1394-97
	14	Date & time of message	YYYYMMDDHHMMSS
P line			
	1	P	
	2	Sequence number	
	3	Sample ID or Seq. No.	If has sample ID then use ID otherwise Sequence number
	4	Unused Field	
	5	Unused Field	
	6	Unused Field	
	7	Unused Field	
	8	Unused Field	
	9	Unused Field	
O line			
	1	O	
	2	Sequence number	
	3	Sample ID or Seq. No.	If has sample ID then use ID otherwise Sequence number
	4 =>16	Unused Field	
R line			
	1	R	
	2	Sequence number	
	3	Analysis parameters:	
		component # 1,2,3: unused	
		component # 4: Analysis parameters	See list of results
	4	result	
	5	unit	
	6	Unused Field	
	7	Error codes	
	8	Nature of abnormality	Generally: N
	9	Result status	Generally: F (Final)
	10 => 12	Unused Field	
	13	Date/time completion	YYYYMMDDHHMMSS
L Line			
	1	L	
	2	Sequence number	

8. Short Instructions

1. Check carefully if the instrument is complete and all parts are placed in correctly (waste container, transport belts etc.).

2. Connect the instrument to the plug with the relevant cable, check if there is a connection between the instrument and external plug.

3. Switch on the instrument with the main switch.

4. Wait till the instrument performs the self-test.

5. Set the mode of the results (direct printing after analysis, printing after measurement of all samples, sending to the external net etc.).

6. Now you can start with measurement in the mode SeqNo or you can start with creating of the Worklist in MENU/Worklist.

7. Complete the measurements of urine samples; follow all recommendations during the operation, which are included in the instruction of the diagnostic strips.

8. Perform the everyday cleaning after having finished your daily measurements.

9. Now you can leave the instrument switched on in Standby mode or you can switch it off using the main switch.

9. Index

Adapter 4, 5, 7, 42, 43
Quality control 21, 26, 27, 28, 29
Clarity 10, 11, 15, 16, 17, 21, 25, 31, 39
Colour 15, 16, 21, 22, 25, 38, 39
Comments 13, 14, 33
Customization 15, 29
Date 15, 16, 18, 19, 23, 28, 33, 34
ID 5, 8, 9, 10, 11, 15, 16, 17, 18, 19, 23, 26, 27, 30, 33, 34
Installation 5, 14
Interface 4, 5, 6, 15, 23, 27, 28, 30, 33, 34
Language 15, 23, 27
Logo 15, 23, 29
Measurement 3, 5, 7, 8, 9, 10, 11, 13, 14, 15, 16, 18, 19, 20, 21, 26, 27, 28, 30, 33, 34, 35
Memory 9, 11, 13, 15, 16, 18, 19, 26, 27, 28, 30, 33
Menu 8, 11, 12, 13, 14, 15, 16, 17, 18, 20, 23, 24, 26, 27, 28, 29, 34, 35
Parameter 13, 19, 23, 24, 25, 26, 30, 34
Printer 3, 4, 5, 7, 15, 23, 27, 29, 30, 33
Sample 3, 5, 8, 9, 10, 11, 12, 14, 15, 16, 17, 18, 21, 26, 27, 30, 35
Sediment 15, 19, 26
Sensitivity 15, 26
Seq.No 5, 8, 9, 10, 15, 18, 19, 26, 34
Set up 6, 16, 23
Sound 15, 23, 27
Strip 3, 4, 5, 8, 9, 10, 11, 14, 15, 16, 18, 20, 21, 22, 23, 24, 27, 30, 34
Time 9, 15, 16, 18, 19, 23, 27, 28, 33, 34
Units 24
Worklist 10, 11, 15, 17, 18, 35

Erba Lachema s.r.o.

Karásek 2219/1d, 621 00 Brno, Czech Republic
Tel.: +420 517 077 111
E-mail: diagnostics@erbamannheim.com
www.erbalachema.com

IVD CE