

Urilyzer[®] 100 Pro



Release Notes SW version 2.1.2



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This release note combines the features which are implemented into the SW 1.1.2, SW 2.0.4 and SW 2.1.2 of the Urilyzer 100.

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A. Software version 1.1.2:332 release note

Urilyzer 100 Pro is a reflectance photometry-based benchtop urine analyzer designed for use with CombiScreen PLUS urine test strips. The new features in the latest version of the device software concern data output options, Quality Control solution management, power management, and Ethernet functionality.

Quality Control solution LOT expiry lockout option added

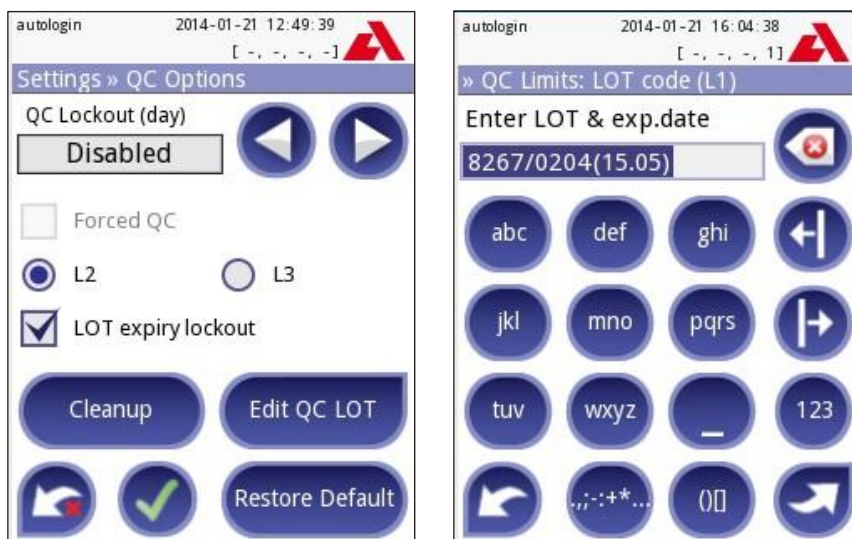


Figure 1: The QC Options screen, and an example of QC solution lot expiry date entry

If an operator selects the check box in the **Main»Options»Settings(1)»QC Options** screen, the expiry date is required for every lot of QC solution that the operator enters into the device database. The system will also keep track of the expiry date for each of the QC solution lots, and display an error message whenever an operator attempts to perform a QC measurement using a solution that is past its expiry date.

To enter an expiry date for a QC solution lot

1. Access the **Main»Options»Settings(1)»QC Options»Edit QC LOT** screen. Select the type of QC solution that you would like to add, and tap the **Next** button.
2. On the keyboard screen, enter the LOT number and the expiry date as a single string, without spaces. Put the expiry date inside parentheses to separate it from the LOT number. Use two digits for both the year and the month in the date. The system accepts both a MM/YY and a YY/MM date format. Use a

hyphen (-), a full stop (.), a slash (/), or an underscore (_) to separate the year and the month in the date. When you are done, tap the **Next** button.

➤ *Example LOT and expiry date entry: 8267/0204(15.05)*

➤ *If you enter an expiry date that refers to an earlier month than the current date and time stored in the system, the error message **E172: The entered time is expired** will be displayed.*

3. Refer to the relevant section of the Urilyzer 100 Operator's Manual, and adjust the QC parameter limits if necessary. To finish entering the QC solution lot, tap the **OK** button.

Health Level 7 (HL7) output standard implemented

HL7 data output is a selectable option on the **Main»Options»Settings(1)»Output** screen in the current version of the device software.

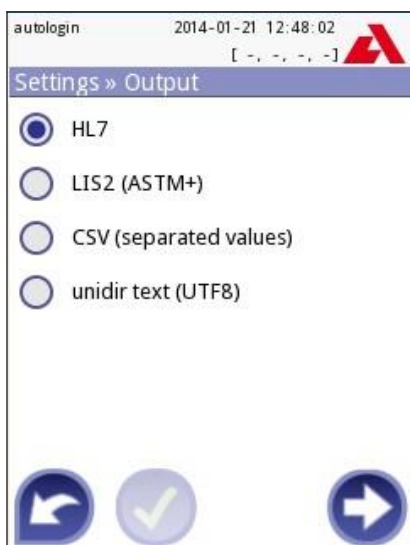



Figure 3: The Settings»Output screen with the new option selected

The option of automatically logging out the current operator after each measurement added

If the operator selects the **After measurement logout** check box on the **Main»Options»Settings(2)»Power Management** screen, the system requires a new login after each measurement that is performed on the device.

-  This feature functions as stated only if the system does not detect any operator interaction after a measurement is performed. The system will NOT log off the current operator if he or she taps any buttons on the display. If the Auto print option is enabled (on the Options»User Options screen), the operator needs to tap the Measure button on the Result screen to confirm the automatic printing of the latest result. Because of this, the After measurement logout and the Auto print features cannot function at the same time.

Wi-Fi functionality added

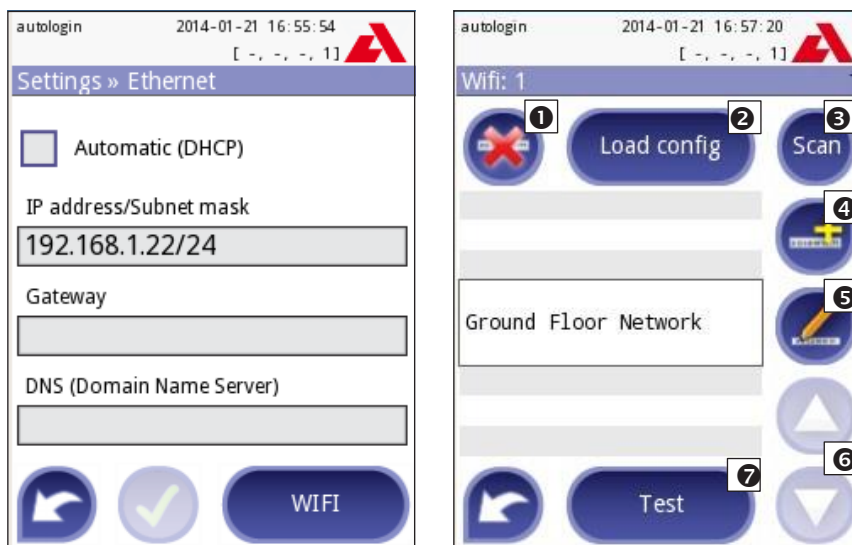


Figure 2: The Ethernet and the Wifi screens in the new version of the software.

To connect to an existing network

1. Insert a USB Wi-Fi adapter into one of the USB sockets at the back of the device. Access the **Main»Options»Settings(2)»Ethernet** interface screen. Tap the WIFI button.
2. Tap the Scan button. The system displays all the networks that are within range, listed by descending signal strength. Use the **Up** and **Down** arrow buttons (numbered 6 in Figure 2) to position the cursor over the network that you would like to connect to, and tap the **Add element** button (numbered 4 in Figure 2). On the keyboard screen that is displayed, enter the Password for the selected network, and tap **OK**.

3. Tap the **Scan** button once again to toggle it off. Use the **Up** and **Down** arrow buttons (numbered 6 in Figure 2) to position the cursor over the network that you are connecting to, and tap the **Test** button. A status text will be displayed below the name of the network. When the status text reads **COMPLETE**, the device is connected to the selected wireless network.

➤ *For functional bidirectional data transfer, you also need to have a receiving server set up.*

To add a new connection

1. Insert a USB Wi-Fi adapter into one of the USB sockets at the back of the device. Access the **Main»Options»Settings(2)»Ethernet interface** screen. Tap the **WIFI** button.
2. Tap the **Add element** button (numbered 4 in Figure 2). On the keyboard screen that is displayed, enter the ESSID (the name), and then the Password for the new wireless network.

➤ *A valid password is between 8 and 63 characters long.*

3. Use the **Up** and **Down** arrow buttons (numbered 6 in Figure 2) to position the cursor over the network that you are connecting to, and tap the **Test** button (numbered 7 in Figure 2). A status text will be displayed below the name of the network. When the status text reads **COMPLETE**, the device is connected to the selected wireless network.

To load pre-configured networks and advanced authentication protocols

The Urilyzer 100 system software includes a utility (the `wpa_supplicant` utility) that you can use to configure advanced wireless network options. To set up your preferred options, you need to supply the `wpa_supplicant` utility with the required configuration information in a text file.

1 Look up online the documentation on the proper format for `wpa_supplicant` configuration information. Create and bundle a '`wpa_supplicant.conf`' file, and, if necessary, a 'certificate' and a 'key' file in a zip file that you name **wpa_supplicant.conf.zip**. Include the string `/usr/local/WIFI/` in the pathname for the files. Do not put the files inside folders before you zip them.

➤ *Examples of properly named certificate and key files:*

```
ca_cert="/usr/local/WIFI/ca.pem"  
client_cert="/usr/local/WIFI/user.pem"  
private_key="/usr/local/WIFI/user.prv"
```

2. Copy the zipped file to the root directory of a USB flash drive. Insert the USB flash drive into a USB socket at the back of the device.
3. Insert a working USB Wi-Fi adapter into a USB socket at the back of the device. Access the **Main»Options»Settings(2)»Ethernet interface** screen. Tap the **WIFI** button.
4. Tap the **Load config** button (numbered 2 in Figure 2) to load the zipped configuration files that you set up in step 1 above from the USB flash drive. The

system unzips and saves the files on the USB flash drive in the /usr/local/WIFI folder.

5. Exit and re-enter the **Wifi** screen to enable the modifications.

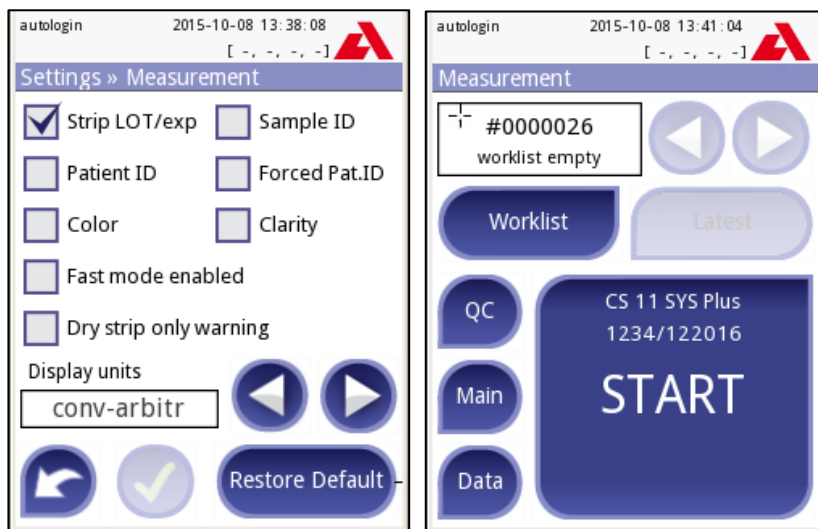
To edit or delete an existing wireless network

1. Insert a USB Wi-Fi adapter into one of the USB sockets at the back of the device. Access the **Main»Options»Settings(2)»Ethernet interface** screen. Tap the **WIFI** button.
2. Use the **Up** and **Down** arrow buttons (numbered 6 in Figure 2) to position the cursor over the network that you would like to modify or delete.
3. Tap the **Delete** or the **Edit** button (numbered 1 and 5, respectively, in Figure 2), as necessary. Follow the instructions and messages that are displayed.

B. Software version 2.0.4 release note

The new features in the latest version of the device software concern operator management, Strip LOT/Expiry management, QC input via barcode reader and settings management.

Strip LOT/Expiry management



The Settings-Measurement screen and the Measurement screen

Access the **Main»Options»Settings»Measurement** screen:

Strip LOT/exp:

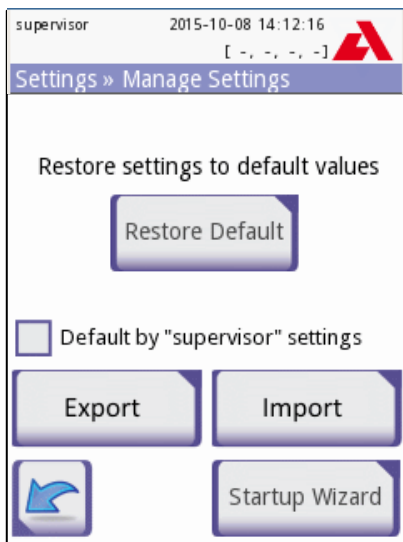
If you select this box, the system will prompt you to enter the strip LOT number you currently use with the expiry date at every single measurement. The system stores the information and at the next measurement it is enough to confirm the displayed data.

Forced Patient ID:

If you select this box, the system will require you to enter an ID for the patient whose urine sample you are analyzing. The measurement will not continue, if the Patient ID textbox is not filled in.

The Strip LOT/Exp information is placed on START button at measurement screen.

Settings management



Exporting and importing settings:

Supervisor level users can download settings to a flash drive and upload to one or multiple other analyzer/analyzers with this feature.

QC input via barcode reader

There are two ways to enter the QC ranges into the analyzer via a barcode:

1. Access **Measurement»QC**, dip the strip into the negative control solution, put the strip on the tray, press **"Start measure: Solution L1"** and scan the barcode "Level N".

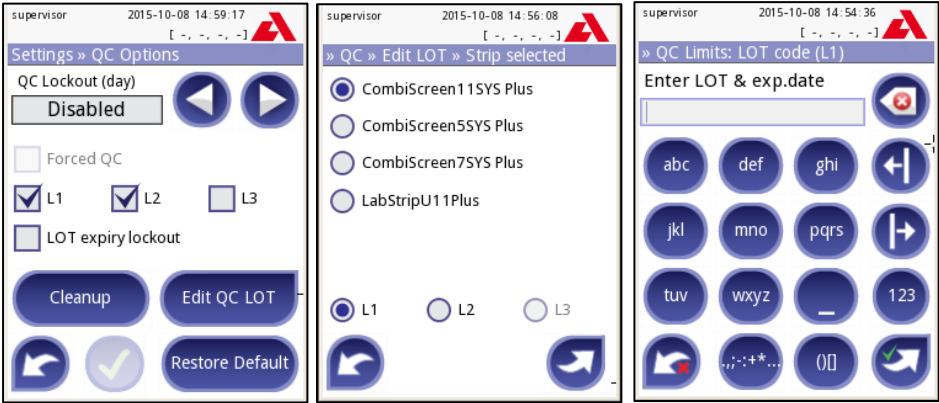
Repeat the step after the measurement with solution L2 and the barcode "Level P".

For another measurement with the same LOT you just need to confirm the LOT number.

2. Access **Main»Options»Settings»QC Options**, mark L1 and L2, press **"Edit QC LOT"**, select "L1", press "next" and scan the barcode "Level N", check and confirm with the green tick, press **"Edit QC LOT"**, select "L2", press "next" and scan the barcode "Level P".

The barcodes for both ways are located at the end of the package insert of the Control PN control solution.

Urilyzer 100 Pro



The barcodes for both ways is located at the end of the package insert of the Control PN control solution:

	Level N	Level P
Urilyzer 100		

Operator management

In **Options»Settings (2)»Operators** you will find 2 new buttons:

A: Data Exchange: You can: Clear, Import and Export Operators Lists here (available only to Supervisor and Service level operators)

B: Operators list can be filtered here



Additional Maintenance (E90 handling)

Warning:

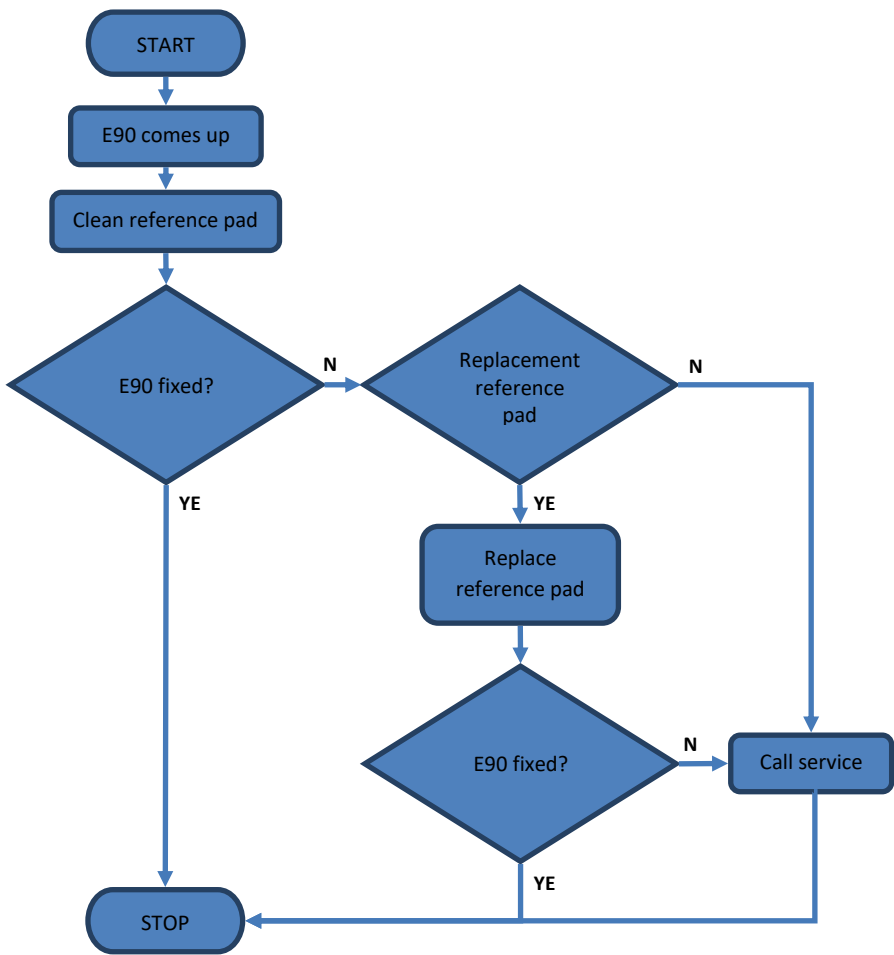
Don't use any sprayer/atomizer for cleaning the device! Use only wet towel dipped in a mild detergent!

Yearly maintenance:

If the device is routinely operated at or close to peak throughput, the reference pad may need more frequent replacement.

Check whether the test strip tray is in good working condition: the central test strip channel should be even and smooth and the serrated edge on the bottom should be intact. Replace the test strip tray if necessary. If you did not change it with the test strip tray, replace the reference pad on the test strip tray.

Flowchart E90:



C. Software version 2.1.2.364 release note

The new features in the latest version of the device software concern data output options, strip type management and the availability of a Chinese printout.

POCT1-A2 protocol implemented

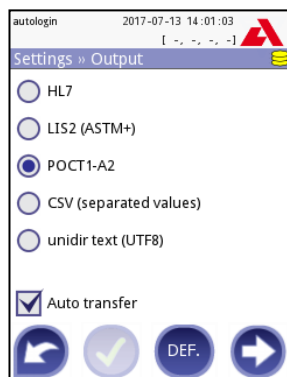
The POCT1-A2 standard protocol allows bidirectional communication in Point-of-Care environments with near-patient testing and is intended to be applied between the Urilyzer® 100 Pro and data managers (middleware). POCT features provided by the instrument are described in detail in the next sections. The POCT1-A2 protocol is specified in detail in the Interface description, which is available upon request and provides information to middleware developers or data manager developers to facilitate the attachment of Urilyzer® 100 Pro to a local laboratory information system (LIS).

Urilyzer® 100 Pro supports POCT1-A2 communication protocol through TCP/IP network connection. Before activating POCT1-A2, it needs to be clarified and set from the ethernet menu if automatic (DHCP) or static IP address is used.

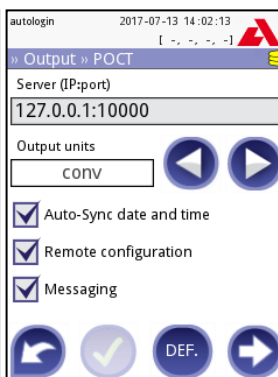
Selecting POCT1-A2 protocol

POCT1-A1 can be selected from the **Main»Options»Settings(1)»Output** menu (refer to picture 1) and related settings are available as shown in picture 2 and 3. An overview of POCT settings is given in table 1.

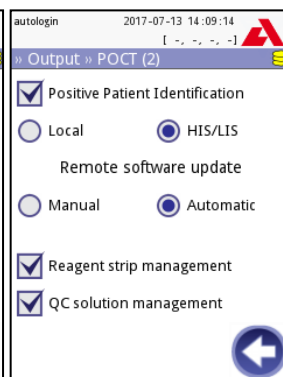
Type the server and port number in the Server (IP:port) field. Please separate the server IP and the port number with a “:”, as shown in picture 2.



Picture 1



Picture 2



Picture 3

Parameter	Type of setting	
Server (IP:port)	Editable field	
Output units	SI; arbitr; conv (default)	
Auto-sync date and time	Enabled; disabled (default)	
Remote configuration	Enabled (default); disabled	
Messaging	Enabled; disabled (default)	
Positive Patient Identification (PPID)	Disabled (default); Enabled then select	
	Local	HIS/LIS
Remote software update	Manual (default); automatic	
Reagent strip management	Enabled; disabled (default)	
QC solution management	Enabled; disabled (default)	

Table 1: Urilyzer® 100 Pro POCT1-A2 settings

Auto-sync date and time

The data manager has the possibility to synchronize all devices, which are connected to the middleware, with the same date and time.

Remote configuration

Device settings can be set remotely by data manager through remote configuration directive. Device configuration is executed upon first start-up and/or during booting of the instrument. The possible configurations are shown in the table below. For details please refer to the interface description.

Setting	Remotely configurable parameters
Default	
Date & Time	Definition of date and time format as well as delimiter
Measurement	Strip LOT/exp.; Set Sample ID; Set Patient ID; Forced Patient ID; Color; Clarity; Dry Strip only warning; Fast mode; Display units; Patient ID length
Print	Operator ID; Patient ID; Device S/N; Sediment recommendation; Strip LOT; Print blank; Units;
POCT1-A2	Server; Output unit; Automatic Sync. of Date and Time; Remote configuration; Messaging; Positive Patient Identification; Remote SW update; Strip reagent management; QC solution management
Output	Module (= protocol, e.g. HL7, POCT1-A2); Auto transfer of results
QC	Lockout period (days); Forced QC; Level of urine control solution (Mode L1, Mode L2, Mode L3); LOT expiry lockout
Power	LCD off time, Logout time; Power off time; After measurement logout
Database	Circular memory; Warning at circular memory limit; Prewarning

Setting	Remotely configurable parameters
Ethernet	Automatic (DHCP); IP mask; IP gateway; IP DNS
Color	Definition of different color options
Clarity	Definition of different clarity options
AuthGen (Security level)	Auto login; Self add operators; Password not required; Operators on login screen; LIS operator list check; LIS operator list only; security setting mode (Open system, Anonymous usage, Self-add, Self-add with password, Secure, Custom)
CS5SYS Plus	(Settings referred to CS 5 SYS PLUS): Sensitivity of test pads; Displayed pad order; Sediment recommendation
CS7SYS Plus	(Settings referred to CS 7 SYS PLUS): Sensitivity of test pads; Displayed pad order; Sediment recommendation
CS11SYS Plus	(Settings referred to CS 11 SYS PLUS): Sensitivity of test pads; Displayed pad order; Sediment recommendation
CS11SYS	(Settings referred to CS 11 SYS): Sensitivity of test pads; Displayed pad order; Sediment recommendation
Strip	Strip type selection

Table 2: Summary of remotely configurable settings

Messaging

The data manager can send free text messages only to logged in operators. To confirm or to exit the message, the operator has to type on the Urilyzer® 100 Pro screen. Remote messages can be addressed to the operator or the instrument.

Positive Patient Identification (PPID)

The device can receive information about the patient, including the patient ID, name, birthdate and gender. PPID function helps to avoid patient mismatch in the hospital environment since operators need to assure that the results are linked to the corresponding patient.

Two different PPID workflows are supported by the Urilyzer® 100 Pro:

1. HIS/LIS PPID

start measurement >> ... >> enter patient ID >> PPID query to Data Manager
>> PPID information or error message shows up >> message confirmed >> continue measurement

This workflow requires constant HIS/LIS connection since patient information is queried during the measurement from HIS/LIS. During the measurement, the patient ID is entered (picture 4) and the device receives the corresponding patient information from the HIS/LIS system (picture 5) that needs to be confirmed by entry of the patient birthdate (year) as shown in picture 6.

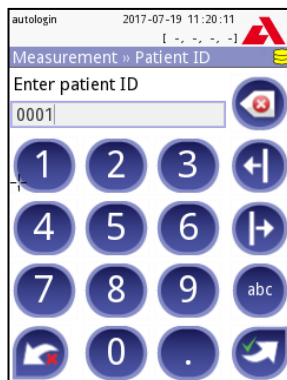
2. Local PPID

start measurement >> ... >> enter patient ID >> PPID query to local patient database >> PPID information or error message shows up >> message

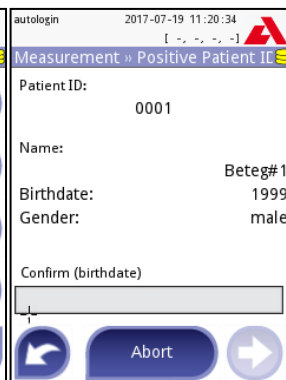
confirmed >> continue measurement

Local PPID does not require a stable connection since the patient list is transferred to the instrument and the patient identification is performed on the instrument. The workflow itself is the same as described for HIS/LIS PPID but the PPID is sent to local database instead of the data manager.

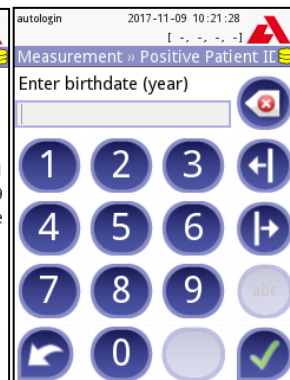
In general, PPID function does not work on worklist testing.



Picture 4



Picture 5



Picture 6

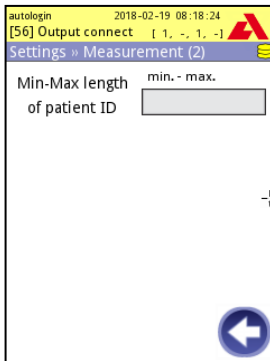
By asking to confirm the patient ID with the birthyear, please type in the following format: yyyy
For example: 2001

Configurable length of patient ID string

The minimum and the maximum characters of the patient ID string can be set from the Settings > Measurement (page 2) menu (refer to picture 7 and 8). The maximum patient ID string length is 31 characters.



Picture 7



Picture 8

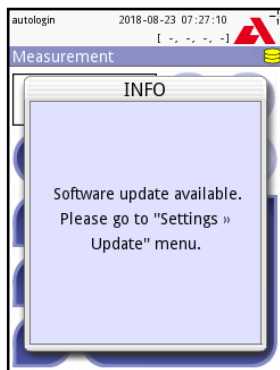
Remote software update

At institutions with multiple Urilyzer® 100 Pro devices, software updates may be processed remotely as they can be supervised by the data manager.

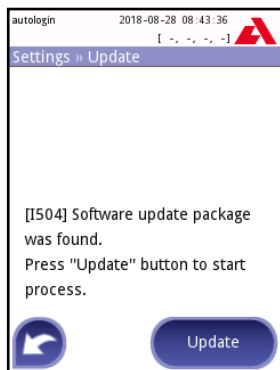
Download and installation of a software update are separated processes. If remote software update is enabled package is downloaded automatically. The update is split from the Data Manager and transferred in packages to the Urilyzer® 100 Pro. Once all packages have been transferred successfully, the device assembles the whole package and the software update is installed according to settings (manually or automatically).

Installation of the remotely deployed software update can be executed according to the following setting:

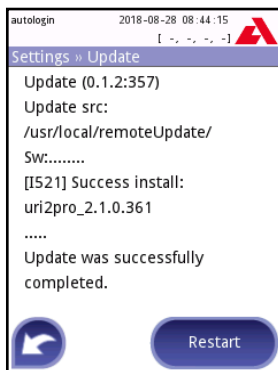
1. **Automatic**
Software update is executed automatically during next boot-up of the instrument.
2. **Manual (Default)**
Operator needs to start and confirm the installation of the software update manually.
 - 1) The Middleware will send the Update to the Urilyzer® 100 Pro.
 - 2) A new window will appear on the device and ask the operator to manage to the „Settings >> Update“ menu. Please confirm the window, by tapping on the window. (Picture 9)
 - 3) After that, the device will ask the operator to tap on the update button (Picture 10).
 - 4) When the update installation is over, the device asks the operator to restart the device (Picture 11).



Picture 9



Picture 10



Picture 11

WARNING: Remote software update is recommended to be used in case a stable network connection is available. When an update package is ready to be remotely deployed in an institution testing is recommended on a single dedicated instrument.

Reagent strip Management / QC solution Management

The device receives a list of permitted test strips / QC solution LOTs and expiry dates. A test strip / QC solution can only be used if it is accepted based on the list. Once the device receives a new list, it will overwrite the previous list. If the operator tries to use a LOT from the old list, which is unsupported by the new list, the operator receives a message to use another supported LOT (picture 12).

The correct format of the test strip and QC solution LOT (picture 13 and 14) contains the LOT number, followed by the expiry date in round brackets. Please scan the LOT barcode or type in according to the following format:
xxxx/xxxx(yyyy-mm)

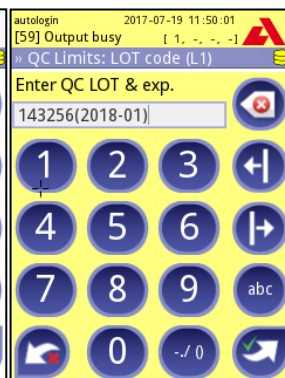
For example:

Strip LOT: 8672/4578(2019-04)

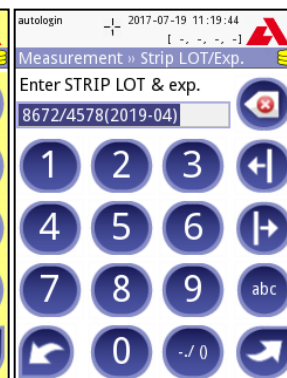
QC LOT: 143256(2018-01)



Picture 12



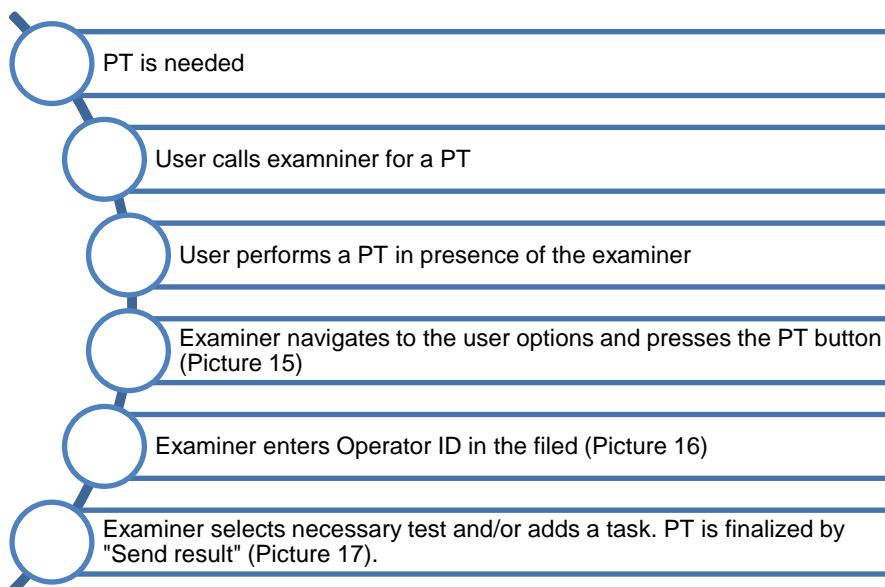
Picture 13



Picture 14

Proficiency test feature

Proficiency testing (PT) is used to qualify expired operators for the use of the Urilyzer® 100 Pro according to a defined schedule of the institution. The proficiency test itself is not supported by the instrument, but the Urilyzer® 100 Pro is able to send a **"Proficiency Test Result"** message to the data manager after an approved proficiency test. This function helps higher level operators (administrator or above) in the examination process of the proficiency test. The flowchart below shows the workflow of a proficiency test.



The proficiency test is executed by the operator in the presence of the examiner (administrator or higher level). To send the proficiency test result, the operator who has executed the proficiency test needs to enter the Options > User Options menu (see picture 15).

The examiner has to press the Proficiency button and type or scan in his/her operator ID and password if required (picture 16). The examiner is responsible to approve that the test has been successfully executed by the operator. The following types of proficiency test are available for selection (picture 17):

- successful patient test
- successful QC Test
- successful optional task, which can be described in the editable field below (picture 17)
-

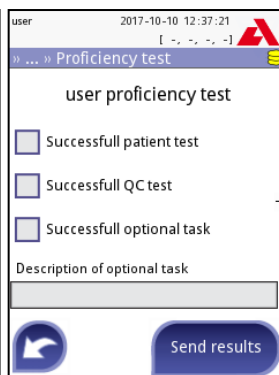
Finally, the examiner can send the results to the data manger by pressing the 'Send results' button.



Picture 15



Picture 16



Picture 17

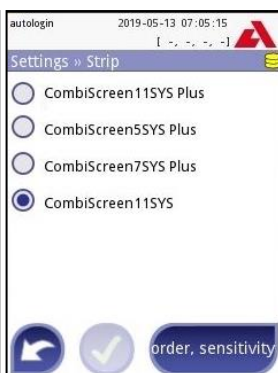
Strip type management

According to the intended use, the CombiScreen 11SYS urine test strip is now selectable from the following menus:

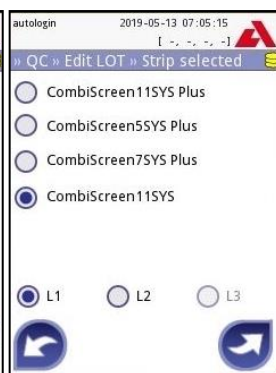
- Main > Options > Strip lot (Picture 18)
- Main > Options > Settings > Strip options (Picture 19)
- Main > Options > Settings > QC Options > Edit QC LOT > Strip selected (Picture 20)



Picture 18



Picture 19



Picture 20

Chinese (simplified) printout

A simplified Chinese printout can be set from the menu Main > Options > Settings > Language. The following information can be shown on the printout (depending on settings):

English	Chinese
Bilirubin BIL	胆红素
Urobilinogen UBG	尿胆原
Ketones KET	酮体
Ascorbic acid ASC	维生素 C
Glucose GLU	尿糖
Protein PRO	尿蛋白
Blood BLD	尿隐血
pH	酸碱度
Nitrite NIT	亚硝酸盐
Leucocytes LEU	白细胞
Specific gravity SG	尿比重
Date	日期
Sample ID	样品编号
Patient ID	患者编号
Device S/N	设备序列号
Operator ID	操作员编号
Strip LOT	试纸批次
Color	颜色
Clarity	清晰度
Comment	注释
Expiry	有效期
Strip Expiry	试纸有效期
Sediment recommendation	沉降建议