Medi-Test

MACHEREY-NAGEL

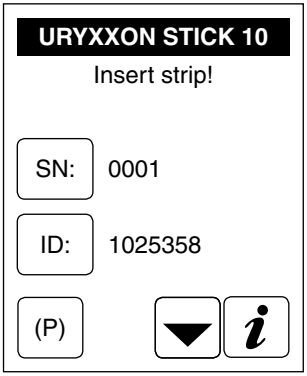
URYXXON® Relax

User manual

CE

1. Quickstart

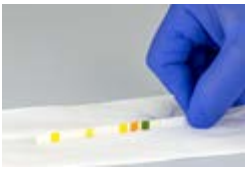
Unpack the instrument and place it on an even, hard surface. Connect the power supply and turn the equipment on with the On/Off-switch (Pic. 10-⑧). After the self test the start screen will appear on the display.



Display 1: Start menu

- Dip a test strip into the urine sample for approx. one second (Pic. 1).
- Blot by touching the edge of the strip to a paper towel to remove excess urine (Pic. 2).

Pic. 1: Dip test strip



Pic. 2: Remove excess urine

ATTENTION:
Please make sure to remove access of urine from the test strip to avoid a carryover into the instrument.

- Place the strip on the strip holder (Pic. 3)

Pic. 3: Correct

Pic. 4: Wrong

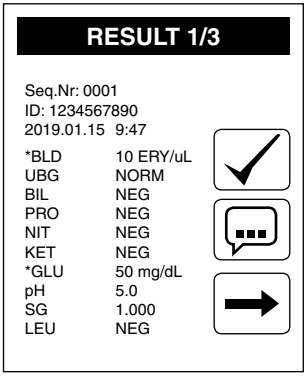
- Slide or push the strip to the end of the strip holder. Do not touch the reagent pads on the test strip.

The instrument will automatically detect an applied strip. The measurement cycle will be started. A progress bar on the display shows the remaining analysis time.

NOTE:
If "Autostart" (Chapter 9.21.3 "How to deactivate and activate the autostart") is deactivated, the measurement must be started using the start control panel  .

NOTE:
The strip will be drawn into the instrument after 30 sec.

At the end of the measurement the result will be displayed on the screen and transferred to the printer and interfaces.



Display 2: Result

By pressing the printer symbol [🖶] the result can be printed again. Choosing the return panel [↩] will lead back to the start screen.
Another analysis may be started by applying the next test strip.

NOTE:
To start a new measurement it is not necessary to go back to the start screen. A new strip is detected at any time and the measurement is then started automatically. When the comment function is activated the measurement result needs to be confirmed after entering the comment.

2. Introduction

This instruction for use is provided for the URYXXON® Relax model 930880 and 930880.XXXXXX.
The URYXXON® Relax is a portable and easy to use urine analyzer for professional use. It is designed to read test strips for urine analysis produced by MACHEREY-NAGEL only. The URYXXON® Relax provides semi-quantitative values, which may be displayed, printed and transferred. The connect options of the URYXXON® Relax are a software enhancement that can be activated via the settings of the instrument and allow for integration into laboratory information and management systems (LIMS). The tests performed with the URYXXON® Relax are intended for *in vitro* diagnostic use only.

2.1. Intended Use

The URYXXON® Relax is a portable reflectance photometer that instrumentally measures the reflectance of a reacted Medi-Test reagent strip for Urinalysis.
The URYXXON® Relax is intended to be used with compatible test strips from MACHEREY-NAGEL.

The URYXXON® Relax is intended for use as an *in vitro* diagnostic aid for screening in urine specimen for the detection of diabetes, metabolic abnormalities, liver diseases, biliary and hepatic obstructions, hemolytic diseases and diseases of kidney and urinary tract.

The URYXXON® Relax system allows for instrument integration into laboratory information and management systems (LIMS) and provides bidirectional data transfer (from/to the instrument). The URYXXON® Relax instrument is not intended to be used for near-patient testing.

2.2. Intended User

The URYXXON® Relax is intended for use by trained professionals with experience in human urine sampling.

2.3. Indications for use

For indication regarding the indications for use refer to the instructions for use of the used strips.

2.4. Testing population

For indication regarding the testing population refer to the instructions for use of the used strips.

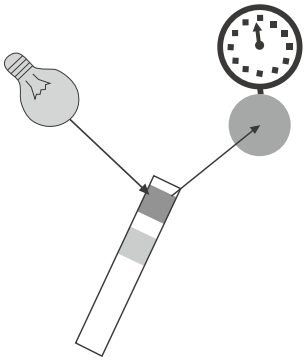
2.5. Sample material

For suitable sample material refer to the instructions for use of the corresponding test strips.

2.6. System description

2.6.1. Measuring principle

The test strip moves below a fixed measuring head on a sled with an embedded reference pad. The reflectometric analysis of the test strip and the reference field take place during withdrawal and release of the sled.



Pic. 5: Measuring Principle

The strip is illuminated with an LED and a detector registers the intensity of light reflected by the test strip at three different wavelengths. Using an internal calibration, the results are calculated from the reflection values. Whenever samples are strongly alkaline, a density correction is automatically conducted.

2.6.2. Functional principle URYXXON® Relax

A measurement is started by placing a strip on the holder. If the Autostart-feature is turned off, the measurement is started by pressing the start panel in the display. The result is shown on the display, printed out and released via the interfaces after the measurement has been completed. After three minutes the instrument will go to stand-by. Touching the screen will reactivate the instrument. All user inputs are performed via the touch-screen (Chapter 3.11 "Use of the instrument").

2.7. Safety warnings

The following safety warnings are used throughout the manual:
- DANGER: defines a danger which can result in serious injury or death.

- ATTENTION: defines a possible danger which can result in simple - mild injury. This symbol is also used to indicate user errors which can result in malfunction or damage to the device.
- NOTE: provides necessary additional information.

2.8. Labels on the device and the box

Pic. 6: Examplary carton label

Pic. 7: Exemplary type plate label

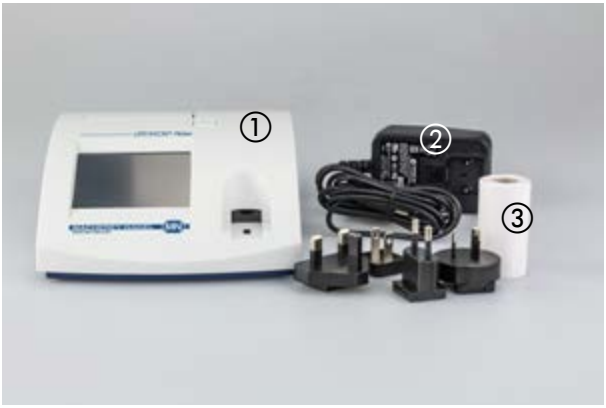
2.9. Symbols explanation

	Caution: Further information in user manual
	The medical device that has not been subjected to a sterilization process
	Keep away from sunlight
	Keep dry
	Temperature limits
	Should not be used if the package is damaged
	The medical device is intended for one use, or for use on a single patient during a single procedure
	Indicates the need for the user to consult the instructions for use
	Do not dispose of the device in common household waste
	Medical device manufacturer
REF	Manufacturer's catalogue number
LOT	Manufacturer's batch code
SN	Serial number of the device
	Date on which the medical device has been manufactured
	Date after which the medical device is not to be used
IVD	In vitro diagnostic device
CE	Indicates conformity with applicable harmonized standards.
9 V ⎓ / 1.5A	Power input specifications

3. Unpacking and set up

3.1. List of delivered parts

① URYXXON® Relax reflectometer
② Power pack 100 – 240 V, 47/63 Hz, 9 V, incl. adapter
③ Printer paper
+ User manual (this booklet)
+ Quick guide



Pic. 8: Content

Check all delivered parts for visible damages. In case a part is damaged, please contact your local distributor or MACHEREY-NAGEL.
Read the operating manual for URYXXON® Relax carefully before the first start-up in order to ensure an error free operation.

3.2. Consumables

- Printer paper, pack of five rolls, REF 93065
- Check solution for quality controls, Medi-Test Control, 1 test tube with 15 mL reagent solution Medi-Test Control N and 1 test tube with 15 mL reagent solution Medi-Test Control P, REF 93038
- 6 AA type batteries (optional)
- RS232 to LAN converter for connection to LIMS (Please contact MACHEREY-NAGEL for further information and instructions)

3.3. Note on ambient surrounding

If the device is exposed to higher temperature fluctuations (e.g. after transport or distribution), it must be switched on not before sufficient acclimatization is given. The device should not be used close to electrical fields (e.g. by microwaves, radio units et cetera). In worst case the measurement results can be affected.

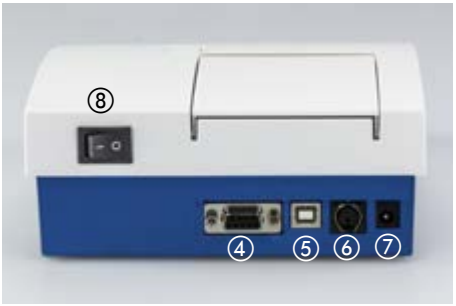
3.4. Setting up the instrument

Place the instrument on a hard, even surface where humidity and temperature are fairly constant. Make sure that the instrument is allowed to acclimate to room temperature prior to use.
Make sure that you

- Do not place the instrument near strong electromagnetic fields
- Do not place the instrument near heating plates, ovens or radiators
- Do not expose the instrument to strong light sources (i.e. direct sunlight)

3.5. Description of instrument parts

Pic. 9: Front view



Pic. 10: Backside view

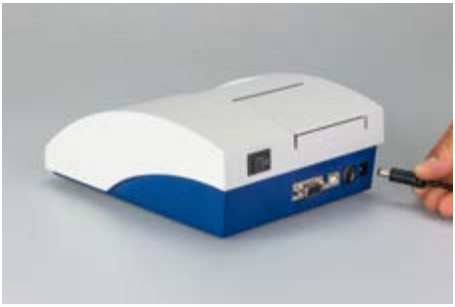
Actuator	Function
1. Touch-Screen	Control of equipment functions
2. Test Strip Slide	Test strip retainer and autonomous start of analysis
3. Printer Flap	Opening the printer flap for paper replacement
4. Serial Interface	Connection of a computer (cable length[1] max. 3 m)
5. USB - Interface	Connection of a computer (cable length[1] max. 3 m)
6. PS2 - Interface	Connection of a keyboard or a bar code scanner [2]
7. Mains Connection	Contact for the provided power pack
8. On/Off Switch (I/O)	Turning the equipment on and off

[1] We recommend to use shielded cables.
[2] We recommend to make use of the hand scanner from MACHEREY-NAGEL

ATTENTION:
Do only connect the intended devices to the corresponding interface. If you connect another device to the corresponding interface, the analyzer or the connected device may be damaged. Check all cables prior to use and verify the proper connection.

3.6. How to plug the instrument in

Pic. 11: Power pack



Pic. 12: DC in

Four adapters are provided for adapting the power pack to the available mains connection. The connector pins sealing is removed and the adapter matching the mains connection is plugged on to the power pack (Pic. 11). After plugging the power pack cable into the jack "DC IN" (Pic. 10-⑦)and connecting the power pack to the power socket the URYXXON® Relax is ready for operation.

3.7. How to load the printer paper

Pic. 13: Printer A

Pic. 14: Printer B

Open the printer flap by pressing the rectangular key next to the printer flap (Pic. 13).

Pic. 15: Printer C

Pic. 16: Printer D

Unroll the paper roll by 5 cm and place the roll in the paper compartment with the end on the lower side. Fix the end of the paper to the housing with your finger while closing the flap (Pic. 15 + Pic. 16).

3.8. How to install batteries (optional)

The URYXXON® Relax can be operated with 6 type AA batteries independent of the mains supply. The battery compartment is on the underside of the device. Notice the designated polarity (+/-) marked on the battery compartment while inserting the batteries.

Pic. 17: Battery compartment

3.9. Instrument self test

The instrument will perform an automatic self test each time it is turned on. If an error message appears, the instrument will not start measurements. In this case, please contact your local service provider.

3.10. Calibration

The instrument will perform an automatic calibration each time a test is performed.

3.11. Use of the instrument

All user inputs are done via a touch-screen (touch-display). All functions are activated directly by slight pressure with the finger on explicit pictograms or text representing the menu items.

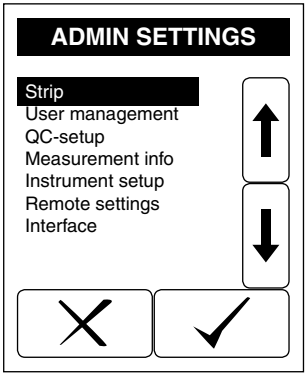
3.11.1. Buttons

Framed areas react to pressure and trigger the action linked to it. The caption of an area describes its function.
Examples:

✓	Confirm / perform action		Memory
✗	Cancel action		Emergency
	Enable/Disable		New user
	Equipment and user settings	PSW	Password
	QC-Evaluation		Enter main menu
?	Check mode		

3.11.2. Scroll Menu

Press the up-and-down arrows on the right side of the screen to scroll through a list of information on the left side of the screen. The desired information on the left side is highlighted.

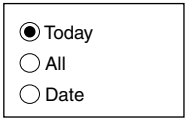


Display 3: Selective lists

Pressing ✓ will select the highlighted line. You can leave the menu by pressing ✗.

3.11.3. Round buttons

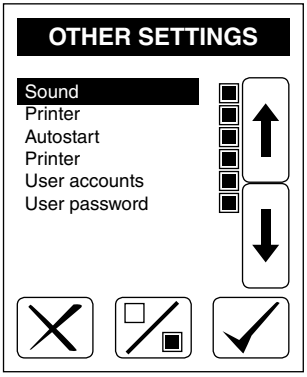
These buttons typically appear on screens that require a selection among serial items. The button with a filled circle is the current selection.



Pressing the circle will activate a selection. Save your selection by pressing [✓]. Pressing [✗] will quit the menu without performing any changes. Pressing the entry of the filled circle will deactivate the function in some menus (Chapter 9.22 "How to change the interface settings").

3.11.4. Check boxes

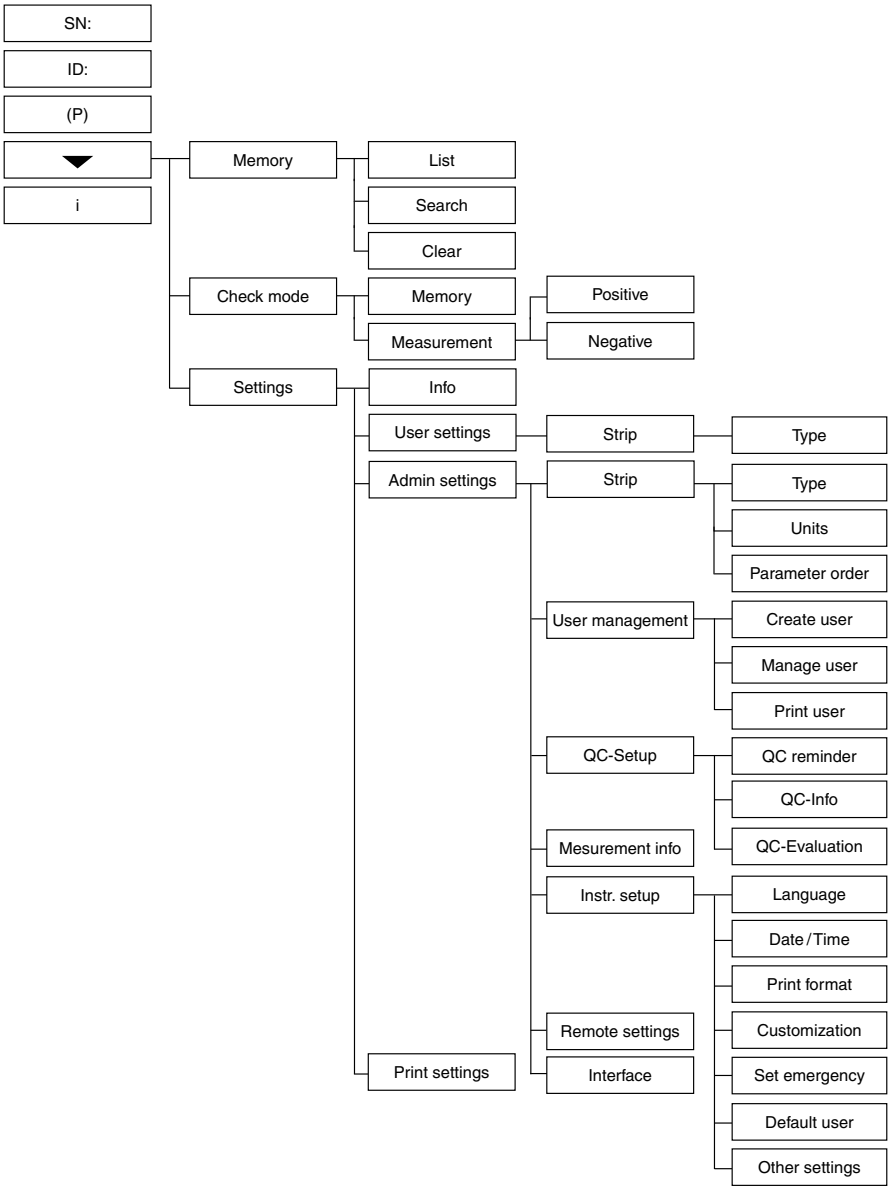
Check boxes typically appear on screens that require a multiple selection among a list of entries. The filled boxes represent a function being enabled, whereas an empty box means disabled. For switching from enabled to disabled press [☐/■]. Save your selection by pressing [✓]-Icon.



Pic. 18: Enable and disable check boxes

4. User menu

4.1. Flow-chart of the menu structure



4.2. Description of the menu items

- SN:
  Chapter 5.6 "Changing the sequence number ("SN")"
- ID:
  Chapter 5.2 "Entering the patient identification"
- (P):
  Standby
- ▼:
  Main menu
- Memory:
  Chapter 7 "Recall results"
- Check mode:
  Chapter 8 "Quality control testing"
- Settings:
  Chapter 9.1 "How to view system information"
  Chapter 9.2 "How to modify the strip type"
  Chapter 9.3 "Administrator settings"
  Chapter 9.4 "How to modify strip settings"
  Chapter 9.5 "User management"
  Chapter 9.6 "How to create a new user"
  Chapter 9.7 "How to edit a user"
  Chapter 9.8 "How to print a user list"
  Chapter 9.9 "QC-setup"
  Chapter 9.10 "How to set a QC reminder"
  Chapter 9.11 "How to change the QC measurement information"
  Chapter 9.12 "How to set the QC evaluation"
  Chapter 9.13 "How to change the measurement information"
  Chapter 9.14 "Instrument setup"
  Chapter 9.15 "How to change the language"
  Chapter 9.16 "How to set time and date"
  Chapter 9.17 "How to change the print format"
  Chapter 9.18 "How to change the text of the printout header"
  Chapter 9.19 "How to change the definitions for emergency measurements"
  Chapter 9.20 "How to change the default user"
  Chapter 9.21 "Other settings"
  Chapter 9.22 "How to change the interface settings"

5. Analysis of test strips

NOTE:
The equipment settings, their availability and functional behavior depend on the interface setting of the instrument. The equipment settings in this chapter describe the operation in unidirectional mode only. For switching into the bi-directional mode refer to chapter Chapter 9.22 "How to change the interface settings".
Changes applying to the settings in bidirectional interface
mode are described in “Chapter 10 "Device settings in bidirectional interface mode".

5.1. How to perform a measurement

The URYXXON® Relax is very easy to use. In order to start the measurement, the test strip is placed on the strip holder. The instrument automatically detects a new strip and starts the measurement. A progress bar appears, that indicates the remaining analysis time. After 30 seconds the test strip is drawn into the instrument.

NOTE:
Make sure to remove excess urine by blotting the test strip carefully on a lint-free cloth. For details on sample handling please refer to Chapter 1 "Quick-start".

NOTE:
If the autostart mode (Chapter 9.21.3 "How to deactivate and activate the autostart") is deactivated, the analysis needs to be started by pressing  on the touch-screen.

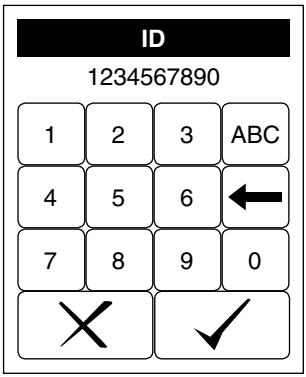
After the measurement, the instrument will release the analyzed test strip which can now be discarded. The result is displayed on the screen and is transferred via the interfaces and/or printed according to equipment settings.
For additional information on the test strip, please read the instruction leaflet that comes with the strips.

DANGER:
Urine and used test strips bare the danger of infection. Always use protective gloves during handling and disposal. The disposal of used test strips should be performed according to the regulations of the handling of potentially infectious material.

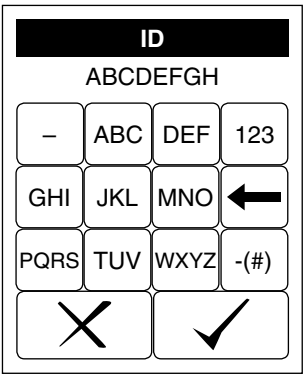
5.2. Entering the patient identification

The patient identification needs to be entered before starting the analysis. This can be done as follows:

- Directly on the equipment: Pressing [ID:] in the start menu brings up an alpha-numeric keypad. Enter the ID using the keys. To enter characters (i.e. "Miller") press [ABC] to change the character entry. Repeated pressing on the same field within 0.5 seconds switches through the characters displayed on the key. Wrong entries may be erased by pressing [←].



Display 4: Entering ID (numeric)



Display 5: Entering ID (letter)

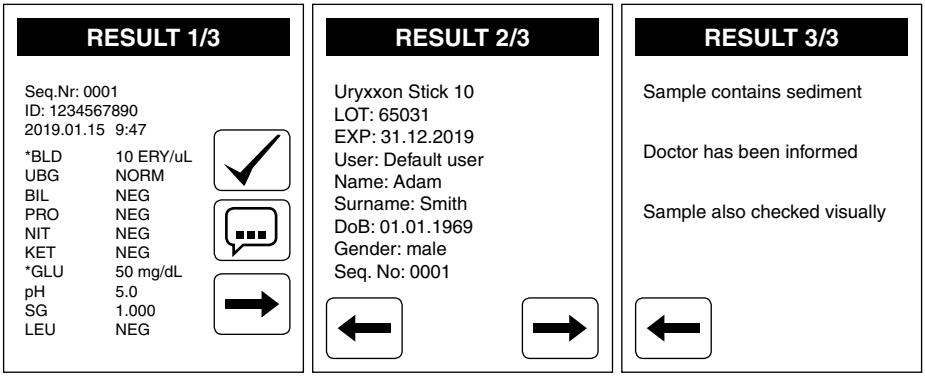
- Using a standard PC-keyboard: Connect the keyboard to the PS/2 jack in the backside of the instrument. User inputs on the keyboard will automatically be interpreted as patient identifications.
- Using a bar code reader: Connect the barcode reader to the PS/2 jack in the backside of the instrument. Barcode readings will automatically be interpreted as patient identifications.

After entering the patient identification start the measurement. The patient identification is saved together with the diagnostic findings.

NOTE:
A new ID cannot be entered before the present analysis has been completed.

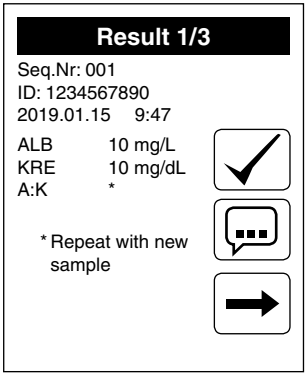
5.3. Display of results

The sequence number (Seq.No.) as well as the patient identification (ID) will be displayed with the results.



Display 6: Result screen 1–3

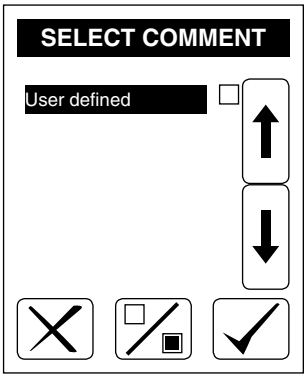
Positive findings are clearly marked by an asterisk (*) on the printout and on the display. Additionally, it is possible to enable an acoustic signal on positive findings. On the second page of the result view information on the used strip, the user, the patient ID and patient data are displayed. On the third page comments on the measurement will be displayed. This page is only visible when the comment function is enabled. Pages can be turned using the arrows → and ←.
For the evaluation of the Microalbumin test strips, findings are displayed with an additional statement (Repeat with new sample, normal, abnormal, high abnormal). If the acoustic warning for positive results is activated (Chapter 9.21.2 "Acoustic warning on positive results"), there will be sound for "Repeat with new sample", "abnormal" and "high abnormal" as well.



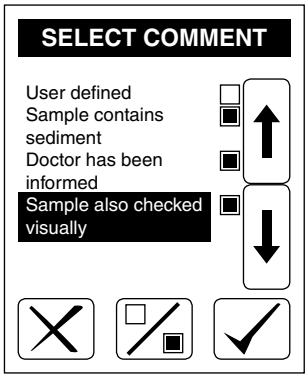
Display 7: Result Microalbumin

5.4. Enter a comment to a measurement

The URYXXON® Relax offers a comment function to add information to a normal measurement (patient test) or a QC measurement. When activated in the settings (see Chapter 9.13 "How to change the measurement information") a comment can or must be entered after a measurement. To enter a comment, press [...]. A menu to enter a comment will appear (Display 8 and Display 9).



Display 8: Enter comment (Unidir. mode)



Display 9: Enter comment
(with comments received from remote)

Setting the check box in the entry “User defined” by pressing [ ] will open a keypad to enter a comment. To enter the user defined comment use the alphanumerical pad on the display, an external keyboard or a barcode scanner. A user defined comment is limited to 30 characters. Confirming your entry will display the user specific comment in the list of comments. Confirming this view will store the comment together with the measurement result. The comment is added on result screen 3 (Display 6 Result screen 3), printed and sent together with the result.

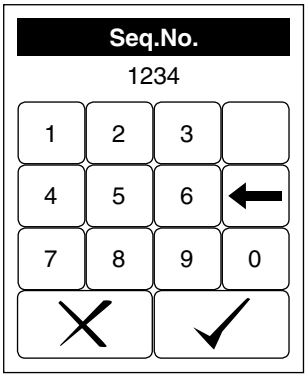
In bidirectional mode (see Chapter 9.22 "How to change the interface settings") the instrument supports the download of predefined comments from a remote system. These comments will be displayed underneath the user defined comment (Display 9). The user can select up to three different comments for a measurement.

5.5. Measurement errors

If the display shows a measurement error (e.g wrong strip) instead of a result please read the instructions in Chapter 14 "Error Messages and Fault Clearance".
Repeat the measurement. In case of permanent errors please contact MACHEREY-NAGEL service.
Measurement errors will be printed, send and stored according to the instrument settings.

5.6. Changing the sequence number ("SN")

Pressing SN: in the start menu brings up a numerical pad. Enter a new sequence number using the keys on the pad. All following measurements will now be counted starting from this number.



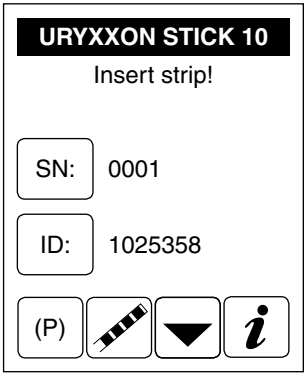
Display 10: Seq.-Input

5.7. Transferring data to a PC

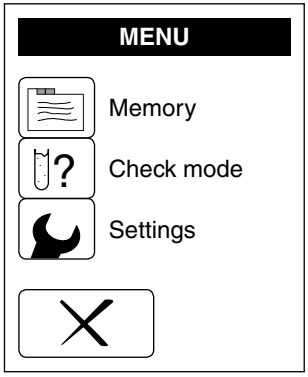
The results may be transferred to a PC via the USB- or RS232-interface.
A more detailed description of the interface can be found in Chapter 13 "Interface description".

6. Enter the main menu

Pressing [▼] on the start screen will bring up the main menu.



Display 11: Start menu

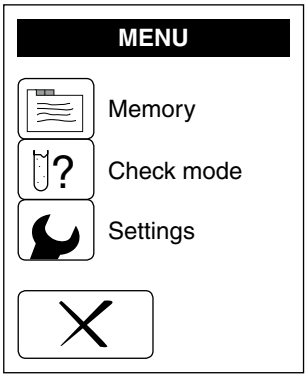


Display 12: Main menu

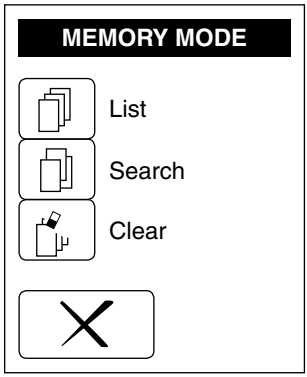
From here the other functions e.g. memory (Chapter 7 "Recall results"), the test mode (Chapter 8 "Quality control testing") as well as the settings (Chapter 9 "Equipment Settings") can be reached.

7. Recall results

The URYXXON® Relax has an internal memory for storage and recall of measurement results. Every result is automatically saved after the analysis. When the memory is full, new data will overwrite the eldest saved dataset.
Access the memory by pressing in the main menu .



Display 13: Main menu

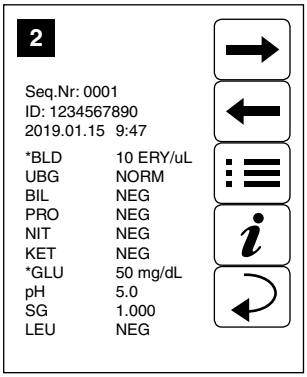


Display 14: Memory mode

In bidirectional mode (see Chapter 9.22 "How to change the interface settings") the instrument will show a warning message in case the memory is full and results have not been send to the remote system.

7.1. How to scroll through memory

Pressing will bring up Display 15. Scrolling through the memory is possible by pressing the arrows on the right side. The next or previous result will be displayed.

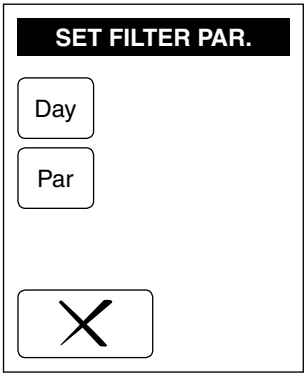


Display 15: Memory contents

Pressing [≡] opens a new dialog to print [🖶] and send [💻] the displayed dataset. The memory menu will reappear upon pressing return [↩]. By pressing the [*i*] further information about the sample can be obtained.

7.2. How to find specific results (filtering)

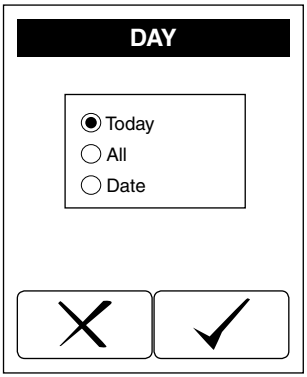
To find a result, you may select the date of the measurement and a specific parameter (Display 16).



Display 16: Filtering

7.2.1. Selecting the date

By pressing [Day] you will reach the menu displayed below (Display 17).

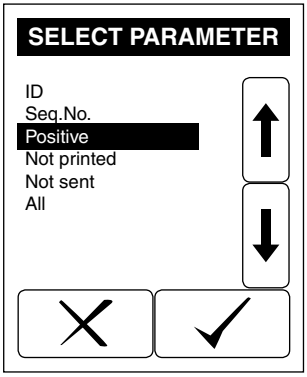


Display 17: Select day

Set the day with the buttons. Selecting "Date" will bring up a screen with the list of available dates (only days with measurements are shown on the screen). Select the desired date with the up-and-down arrows and confirm your selection by pressing [✓]. After confirmation your selection will be displayed on the screen "SET FILTER PAR."

7.2.2. Selecting search criteria

Pressing [Par] in Display 16 brings up Display 18.

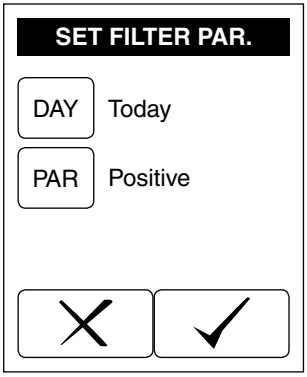


Display 18: Select parameter

Use the arrow keys to select the desired criteria and confirm with [✓]. The filter criteria will be displayed on the filter settings screen (Display 19).

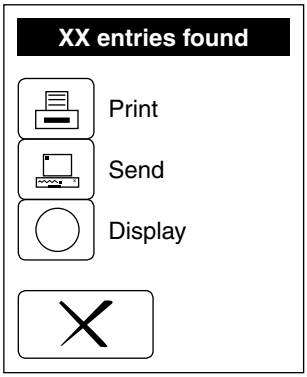
7.2.3. Display suitable matches

After setting "Day" and "Parameter" the search may be started by pressing [✓] (Display 19).



Display 19: Filtering

When suitable matches are found, an option will appear, allowing to print the datasets, send them to a PC or display them on the screen (Display 20).



Display 20: Search result

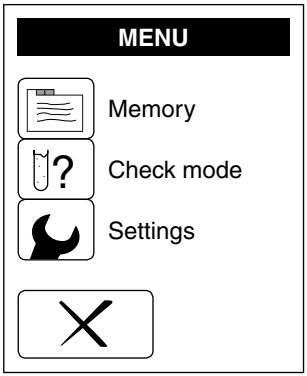
If no matching results are found, the equipment returns to the memory menu.

7.3. How to delete results from memory

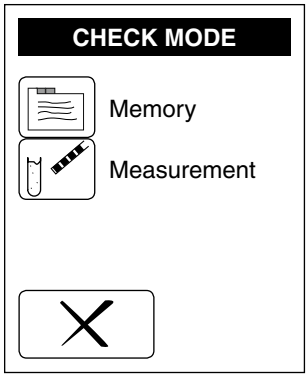
Pressing will delete all data in the memory. You need to confirm this again on a further screen. The quality control measurements are not affected by this action.

8. Quality control testing

Quality control measurements should be performed regularly with check solutions in order to ensure the correct functioning of the combination of equipment and test strips.
Every facility has to implement its own QC policy.
Upon pressing [?] on the start menu the "Check mode" screen will appear (Display 21 + Display 22).



Display 21: Main menu



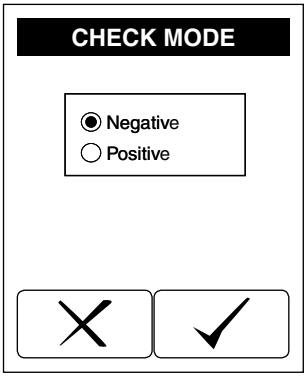
Display 22: Check mode

8.1. How to review old QC measurements

The equipment saves the results of the last 20 QC measurements in a separate memory. They may be displayed by pressing [ ] (Display 22) and may be printed for documentation purposes.

8.2. How to perform a QC measurement

Prepare the urine controls as described in the instruction leaflet and test them in test mode. Do not use water as negative control.
Handle the check solutions exactly as the patient samples. By pressing (Display 22) the sample selection will appear. You may select what type of control sample you want to analyze, either positive or negative (Display 23).



Display 23: Check mode

In case several results do not match the expected results (indications in the checking solutions' package inserts), please contact your local product representative or MACHEREY-NAGEL service.

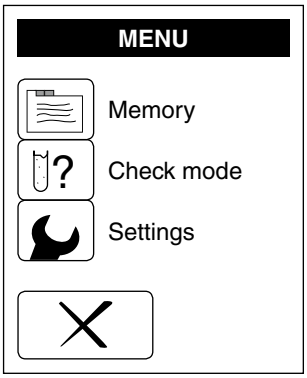
9. Equipment Settings

NOTE:
The equipment settings, their availability and functional behavior depend on the interface setting of the instrument. The equipment settings in this chapter describe the operation in unidirectional mode only. For switching into the bidirectional mode refer to chapter Chapter 9.22 "How to change the interface settings".
Changes applying to the settings in bidirectional interface
mode are described in “Chapter 10 "Device settings in bidirectional interface mode".

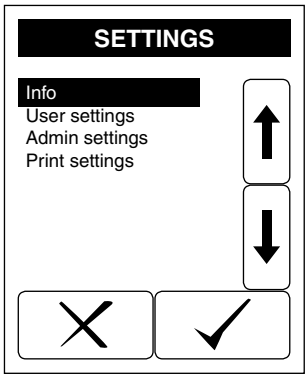
NOTE:
The following options are only available using the bidirectional interface setting, which are described in Chapter 10 "Device settings in bidirectional interface mode":

- Receive and display system messages
- Receive and display user messages
- Positive patient identification (PPID)
- User management with remote system
- Download of test strip data
- Download of control solution data
- Download of comments
- Block the instrument from remote
- Block users from remote
- Competence testing

Enter the main menu by pressing the menu key ▼ to reach the "SETTINGS" display press ✓ (Display 24 + Display 25).

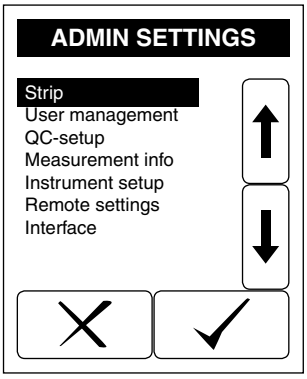


Display 24: User settings



Display 25: Settings

Within the “User settings” only the strip type can be changed. All other device settings will be handled within the entry “Admin settings” (Chapter 9.3 "Administrator settings").



Display 26: Admin settings

9.1. How to view system information

Choose the entry “Info” from the list of the settings and confirm the selection. The Info menu will display information about the device name, firmware version and the serial number of the device.

9.2. How to modify the strip type

The URYXXON® Relax has data for various approved test strip types. The test strip type can be chosen in a selective list.
In the "User settings" menu, the test strip type can be changed. Confirm the entry “Strip” in the user settings followed by confirming “Type” in the strip parameter settings. The required test strip can be chosen from the list. The chosen strip type will be the active strip in the measurement menu.

9.3. Administrator settings

The URYXXON® Relax allows a user management. Ex works the instrument is set to “Open mode", meaning no users are set and every user is allowed to do any changes. The instrument settings can be changed by choosing the list entry “Admin settings” in the settings menu (Display 26).

NOTE:
When the user mode is activated, only users with the role “Change settings” are allowed to enter the “Admin settings” (“Chapter 9.6 "How to create a new user"”).

9.4. How to modify strip settings

In the "Strip" menu, settings for result displaying and the different test strip types can be chosen.

9.4.1. Type

When the instrument has data for various approved test strip types, the strip type can be chosen from a selective list (Chapter 9.2 "How to modify the strip type").

9.4.2. Units

The URYXXON® Relax can report the results in different units:
- Conventional (e.g. 10 mg/dL)
- SI (e.g. 56 mmol/L)
- ARB, Plus-System (e.g. +++)
- Conventional + ARB
- SI + ARB

Choose the desired unit from the selective list. For the strip parameter Microalbumin the results can only be shown in conventional units.

NOTE:
In the interface modes “Unidir. V2” and “Bidirectional” the result will be send via the interface containing all available units (Conventional, SI and ARB).

9.4.3. Order of Parameters

The output order of the parameters may be customized via a selective list. The parameters need to be selected in the desired order and confirmed by pressing [✓]. After the last parameter the equipment will ask whether the setting is to be saved. Save by pressing [✓] or go back to the preprogrammed order by pressing [✗]. A change of the parameter order for the strip parameter Microalbumin is not possible.

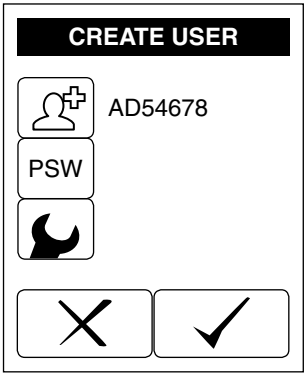
9.5. User management

The URYXXON® Relax allows for a user management of up to 50 users. Users can be created, managed and printed as a list.
Before creating a user, the setting for using the user management needs to be activated (Chapter 9.21.5 "How to activate the user accounts and user password").

9.6. How to create a new user

NOTE:
This option is not available in open mode. Please activate the user management first (Chapter 9.21.5 "How to activate the user accounts and user password").

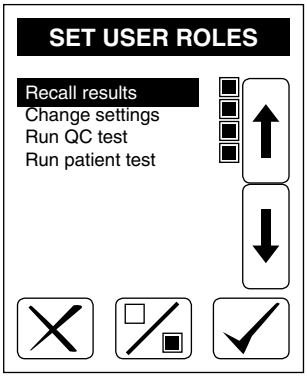
To create a new user, choose “Create user” from the list in the menu “User management”. To enter a new user press [👤+]. To enter a password for a new user press [PSW] (Chapter Display 27 "Create user"). To enter user name and password use the alphanumerical pad on the display, an external keyboard or a barcode scanner.



Display 27: Create user

To select the user roles, press . A check list of the four different user roles will open. Use the arrow key and to select and deselect the entries in the list. A user can be authorized for the following roles (Display 28):

- Recall results
- Change settings
- Run QC test
- Run patient test



Display 28: Set user roles

NOTE:
In default settings all roles are set enabled when creating a new user. This setting allows access to all levels and all actions. If the access for a new user should be limited, please change the user roles as described above.

9.7. How to edit a user

Users from the user list in the instrument can be deleted, enabled and disabled. To perform one of these actions, please choose the list entry “Manage users” in the menu “User management”. Press “USER” to enter the name of the user. Press “ACTION” to select the respective action. Confirming the action by pressing .

NOTE:
To change user name, password and roles of an existing user, please delete the current user and create a new user with the required data.

9.8. How to print a user list

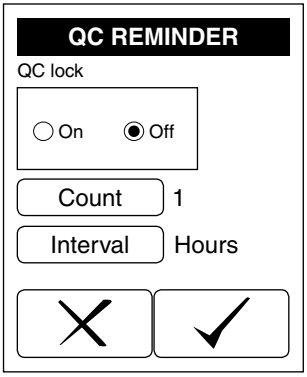
To print a user list select the list entry “Print users” in the menu “User management”. A list of all stored users with their respective roles and the user status (active or inactive) is printed. The order of the user list is based on the date when the user has been created.

9.9. QC-setup

The menu QC-setup allows to change the settings for QC measurements. Beside setting a QC reminder it is possible to activate an evaluation for the QC measurements. Furthermore a protocol for the required QC measurement information can be activated.

9.10. How to set a QC reminder

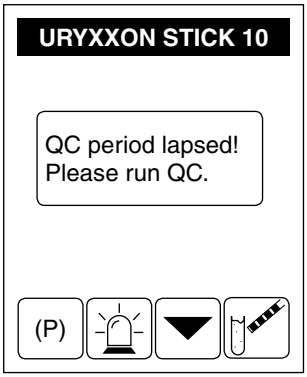
To activate a popup message as a reminder for quality control measurements, please choose the list entry “QC reminder” in the menu “QC setup”. To activate the QC reminder press the round button “On” (Display 29).



Display 29: Set QC reminder

The reminder is disabled by default. Press the Icons “Count” and “Interval” to choose the interval for the reminder. By combination of the two entries intervals starting from 1 hour to several years are possible. Pressing ✓ will store your entries.

When activated the device will display the advisory message “QC measurement required” each time the reminder is due (Display 30). The instrument will be locked for patient testing. Only emergency measurements are possible now, if this setting has been activated.



Display 30: QC lockout

To release the instrument for patient testing, please perform a positive and a negative QC measurement by pressing . Both measurements need to be evaluated as “Passed”.
Alternatively the QC lockout can be bypassed by pressing . The message “QC override” will be displayed shortly. The device allows to run a patient sample now, but the comment “QC override” will be added automatically to the measurement to assign that this measurement has been performed during QC lockout status.

NOTE:
To release the instrument for patient testing, please perform a positive and a negative QC measurement. Both measurements need to be evaluated as “Passed”.

9.11. How to change the QC measurement information

Besides the ID for negative and positive quality control measurement, the user can activate the option to obligatory assign the LOT number and expiration date of the used strips and control solution. To activate the respective information select the list entry “QC information” in the menu “QC setup” and use the arrow keys and to change the setting.
Activating the list entries “LOT” and/or “Control LOT” requires the input for the LOT and expiry information of the used strips and control solution prior to the QC measurement. The information can be entered via the alphanumerical pad on the display or an external keyboard.

9.12. How to set the QC evaluation

The URYXXON® Relax allows for the evaluation of quality control measurements as “Passed” and “Failed”. Select the list entry “QC evaluation” in the menu “QC setup” and press the round button “QC user” to activate the QC evaluation. The default setting is “Off”.

NOTE:
The QC evaluation option will be automatically set to “QC user” when the QC reminder option is enabled.

9.13. How to change the measurement information

For the measurement of patient samples different information can be entered. The default setting of the instrument is, that no sample information are required. By changing the measurement info settings, different sample information can be made obligatory. To activate the respective information select the list entry “Measurement information” in the menu “Admin settings” and use the arrow keys and  to change the setting.

Activating the entry “Emergency measurement” allows the user to run an emergency measurement using the icon  . An emergency measurement can be necessary when the user login fails, the user does not own an account or the QC reminder is active.

Activating the list entry “Patient ID” requires the input of a patient ID. If deactivated, the entry of a patient ID is optional.

Activating the list entry “Comment” requires the input of a user comment after the measurement. If deactivated, the input of a comment is not possible. Activating the list entries “Comm. QC fail” and “Comment path” requires the input of a comment in case of a failed QC and a pathologic patient sample. If deactivated, the input of a comment for both cases is not required.

Activating the list entry “LOT” requires the input of the used test strip LOT. The instrument will automatically ask for the LOT and expiry information of the used test strips prior to the measurement of a patient sample. The information can be entered via the alphanumerical pad on the display or an external keyboard. If deactivated, the entry of a strip LOT is not possible.

9.14. Instrument setup

Within this menu entry the setup for the instrument can be changed.

9.15. How to change the language

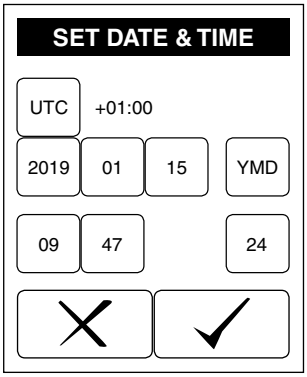
Select "Language" in the instrument setup menu. The language of the URYXXON® Relax menu can be switched to the following languages using the respective selective list:
English, Deutsch, Espanol, Francais, Italiano, Portugues, Polski, Türkce, Nederlands, Magyar, Norsk, Svenska, Suomi, Dansk, Indonesia

9.16. How to set time and date

Select "Date/Time" in the setting menu. To change, press on the respective number. A numerical pad appears. Enter the correct number and confirm by pressing [✓].
The date may be formatted in three ways. The active format is shown on a button [YMD] on the right hand side of the date (Display 31). Select a date format by pressing this button.

Displayed Format Abbreviation	Meaning	Example
YMD	Year - Month - Day	2007-12-17
DMY	Day . Month . Year	17.12.2007
MDY	Month / Day / Year	12/17/2007

Changing the displayed format will influence the time format during the use of the instrument and the printout, but will not affect the format of the data send via the interfaces.
The time format may be changed to 12 or 24 hours with the button displayed next to the time [24].



Display 31: Date / time

To account for the time zone, please change the numbers for hour and minutes by pressing [UTC].

NOTE:
The UTC time setting is only important when using the interface mode “Bidirectional and Unidir. V2”. The UTC will be sent together with the result.

9.17. How to change the print format

The information on the printout can be customized. By default the sequence number, patient ID, operator ID, strip LOT, control LOT and empty fields will be printed. To activate or deactivate the respective information on the printout select the entry “Print format” in the menu “Instrument setup” and use the arrow keys and  to change the setting.
Activating the option “Print empty” will always print the chosen fields, even if they are empty.

9.18. How to change the text of the printout header

Select "Customization" in the settings menu. The first two lines of the printout may be filled with a user-specific identifier. Each line contains 23 characters.
To enter the text an external keyboard or the alphanumerical pad on the display can be used. The keys on the touch-screen are linked to several letters. Repeated pressing within half a second switches through the letters displayed on the key.

9.19. How to change the definitions for emergency measurements

The URYXXON® Relax allows performing an emergency measurement to bypass different scenarios during instrument operation (e.g. patient ID unknown). In case an emergency icon has been pressed to bypass a missing information, the required field (e.g. patient ID) will be automatically filled with the text entered in the menu “Emergency def.”. To change the default settings select the entry “Emergency def.” in the menu “Instrument setup” and use the arrow keys to choose the respective entry. To enter the new definition use the alphanumerical pad on the display, an external keyboard or a barcode scanner. An overview about the entered information can be obtained by printing the instrument settings (Chapter 9.23 "How to print the settings").

9.20. How to change the default user

The URYXXON® Relax starts with deactivated user mode by default. The default user on the printouts is announced as “Default user”. The name of the default user, which will be stored, printed and send can be changed selecting the entry “Default user” in the menu “Instrument setup”. To enter the new definition use

the alphanumerical pad on the display, an external keyboard or a barcode scanner. An overview about the entered information can be obtained by printing the instrument settings (Chapter 9.3 "Administrator settings").

9.21. Other settings

9.21.1. Acoustic confirmation of user inputs

Press  behind the entry "Sound" to enable or disable acoustic signals.

9.21.2. Acoustic warning on positive results

In the preprogrammed settings, an acoustic signal will be given on positive findings. Press  behind the entry "Sound Pos." to enable or disable acoustic signals for positve findings.

9.21.3. How to deactivate and activate the autostart

In basic mode, URYXXON® Relax automatically detects an applied test strip and starts the measurement. This function may be deactivated by pressing  behind the entry "Autostart".
If autostart is deactivated, the analysis must be triggered by pressing a panel in the Start menu.

9.21.4. How to turn the printer on and off

Press  behind the entry "Printer" to enable or disable the printer.

9.21.5. How to activate the user accounts and user password

Selecting “User accounts” in the menu “Other settings” will activate the user mode of the device. After instrument start, a user login is required. If the entry “User password” has been activated additionally, there will also be a password required for the user login at instrument start.

NOTE:
After activation of the user accounts in the menu “Other settings” there will be automatically created a user with administrator rights (all roles active). The default settings of this user are:
User name: Admin
Password: 1111
Please make sure to delete this user after creation of a new user with administrator rights to avoid unauthorized access by third parties.

9.21.6. How to set energy saving options for the battery mode

Press  behind the entry "Printer Batt." to enable or disable the printer.

Press  behind the entry "Backlight" to enable or disable the backlight of the display.
Both settings will only apply when the instrument is operated with batteries.
To increase the lifetime of the batteries, the LCD backlight and the printer can be turned off using these options.

9.22. How to change the interface settings

Select "Interface" in the settings menu. The data transfer via the interfaces can be activated or deactivated via an option panel. By default the interface is switched on and set to “Unidir. V1” interface mode. To switch off the data transfer, please press the currently filled entry. The different interface modes offer the following options:

- Unidir. V1: Unidirectional ASCII protocol to report patient results
- Unidir. V2: Advanced ASCII protocol to report patient results and quality control results with comprehensive information on user, device serial number,…
- Bidirectional: Interface mode for bidirectional communication with remote software tools (e.g. connection to POCcelerator™ from SIEMENS)

ATTENTION:
Setting the instrument to bidirectional interface mode without connection to a remote system will reduce the functionality to a limited number of options and will only allow for a limited number of emergency measurements.

NOTE:
A comprehensive description of the interface data protocols can be obtained from your local product representative or MACHEREY-NAGEL directly.

9.23. How to print the settings

Select "Print Settings" in the settings menu to print the equipment settings for documentation purposes. Information with an asterisk mark activated functions. Thermal printings fade with time. Therefore, please store it in a dark place or copy the printout.

10. Device settings in bidirectional interface mode

NOTE:
The URYXXON® Relax is configured to operate in unidirectional interface mode ex works. To operate the instrument in bidirectional interface mode, please refer to chapter “Chapter 9.22 "How to change the interface settings"”.

When set to bidirectional interface mode, changes to the device settings will apply. In following these changes and additional settings are described in detail.

ATTENTION:
When activating the bidirectional interface mode in the interface settings, make sure that the device is connected to a remote system, which is programmed to communicate with the instrument. Otherwise, the instrument will only offer the possibility of emergency measurements!

Switching on the instrument will start the automatic self-test followed by a status request of the instrument to the remote system. The instrument is able to receive a list of LOT-numbers, comments and messages from the remote system. Furthermore, an exchange of information on patient data and the QC-status takes place during use of the instrument. A popup message indicates an ongoing information exchange.

NOTE:
In case the connection to the remote systems fails, a communication error will be displayed accompanied by a warning sound. In this case only emergency measurements of patient tests are possible. These results are stored on the instrument and send to the remote system automatically after establishing the next successful connection.

NOTE:
Changing the instrument from bidirectional to unidirectional mode is only possible, if the instrument is connected to a remote system. Otherwise a system reset is required (Chapter 12.1 "How to reset the system (Load Default)").

10.1. Administrator settings

10.2. User management

In bidirectional mode, the URYXXON® Relax allows for an access control with different users. When access control is activated (see Chapter 9.21.5 "How to activate the user accounts and user password"), a user login is required at each instrument start and each time the instrument is reactivated from standby. The

entered user name and password are validated against a user list on the remote system. After successful validation, the user can operate the instrument according to the activated user roles.

NOTE:
In bidirectional mode the user management is only possible, when a user list is active on the remote system.

10.3. How to print a user list

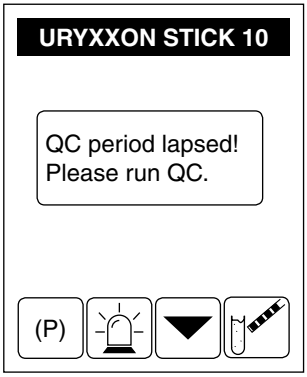
To print a list of users select the list entry “Print users” in the menu “User management”. The instruments prints a list of the first 100 users stored on the remote system with their respective roles and the user status (Active or Inactive). The order of the user list is based on the order in the remote system.

10.4. QC-setup

For general information on the QC-setup please refer to Chapter 9.9 "QC-setup".

10.5. How to set a QC reminder

When activated the device will display the advisory message “QC measurement required” each time the reminder is due (Display 32). The instrument will be locked for patient testing. An emergency measurement is still possible, if this setting is activated.



Display 32: QC lockout

To release the instrument for patient testing, please perform a positive and a negative QC measurement by pressing .
When QC-evaluation is set to “QC user” (see Chapter 9.12 "How to set the QC evaluation"), the results need to be evaluated by the user as being passed or failed. Both measurements need to be evaluated as “Passed” to unlock the

instrument again.The device will be automatically unlocked after performing a positive and a negative control measurement (see Chapter 8.2 "How to perform a QC measurement").
When QC-evaluation is set to “Off” (see Chapter 9.12 "How to set the QC evaluation"), there is no need to evaluate the QC measurement.

10.6. How to change the QC measurement information

In bidirectional mode the entered information for the LOT number and expiration date of control solution and test strips are checked against the remote system, in case this option is set in the remote system settings (see Chapter 10.11 "How to change the remote settings"). When validation of the LOT number or expiration date fails, using this LOT is not allowed. The user needs to use a valid LOT number or use the emergency command to bypass the LOT and expiry check. In case the LOT check is not supported by the remote system the LOT entry will fail and the user needs to use the emergency command or deactivate this setting.

10.7. How to set the QC evaluation

The URYXXON® Relax allows for the evaluation of quality control measurements as “Passed” and “Failed”. Select the list entry “QC-Evaluation” in the menu “QC setup” and press the round button “QC user” to activate the QC evaluation. The default setting is “Off”.

ATTENTION:
In bidirectional mode the POC coordinator should evaluate, which measures for QC evaluation need to be taken. A QC evaluation can happen by the QC-user or also via the remote system.

10.8. How to change the measurement information

For general information on the measurement information settings please refer to Chapter 9.13 "How to change the measurement information".
In bidirectional mode the entered information for the LOT number and expiration date of control solution and test strips are checked against the remote system, in case this option is set in the remote system settings (see Chapter 10.11 "How to change the remote settings"). When validation of the LOT number or expiration date fails, using this LOT is not allowed. User needs to use a valid LOT number or use the emergency command to bypass the LOT and expiry check.

10.9. Instrument setup

Within this menu entry the setup for the instrument can be changed.
For general information on the instrument setup please refer to Chapter 9.14 "Instrument setup".

10.10. Other settings

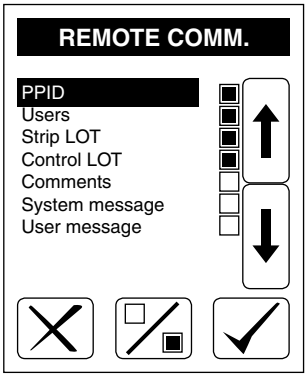
10.10.1. How to activate the user accounts and user password

Selecting “User accounts” in the menu “Other settings” will activate the user mode of the instrument. After the instrument start, a user login is required. If the entry “User password” has been activated additionally, there will also be a password required for the user login at instrument start.

ATTENTION:
When activating the “User accounts” make sure that the device is connected to a remote system, which is prepared to run the user authentication process with the URYXXON® Relax. Otherwise, the device cannot be accessed by a user and only offers the possibility of emergency measurements!

10.11. How to change the remote settings

The menu “Remote setting” is only available in bidirectional interface mode (see Chapter 9.22 "How to change the interface settings"). Selecting the menu opens a selection list to set the different remote settings with a check box (Display 33).



Display 33: Set remote comm.

Activating the entry “PPID” allows the request of patient information from the remote system. After entering the patient ID and confirmation, the instruments displays the patient information name, surname, date of birth (DoB) and gender. By confirming the information, the user positively identifies that the ID matches the patient.

Activating the entry “User” allows for a user validation against the remote system (see Chapter 9.5 "User management").

Activating the entry “Strip LOT” enables the download of strip LOT data at each start of the instrument. The strip LOT data entered before the measurement are checked against these downloaded data (Chapter 10.6 "How to change the QC measurement information").

Activating the entry “Control LOT” enables the download of control LOT data at each start of the instrument. The strip LOT data entered before the measurement are checked against these downloaded data (Chapter 10.6 "How to change the QC measurement information").

Activating the entry “Comments” enables the download of a list of predefined comments from the remote system. These comments will be displayed in a list when entering a comment after the measurement when choosing the comment option (see Chapter 5.4 "Enter a comment to a measurement"). The instrument can download up to seven predefined comments with a length of up to 30 characters.

Activating the entry “System message” enables the download of a system message from the remote system. This message will be displayed after the self-test during instrument start. The user needs to confirm this message. The message is limited to 100 characters.

Activating the entry “User message” enables the download of a user specific message from the remote system. This message will be displayed for the specific user after login with the respective user name. The user needs to confirm this message. The message is limited to 100 characters.

10.12. QC lockout

In bidirectional mode, the instrument can be locked from remote. In this case the instrument displays the message “locked from remote” after the instrument start. In this status, it is still possible to perform an emergency measurement and a QC measurement depending on the user roles. When performing an emergency measurement, the comment “QC override” is automatically attached to the measurement result.

NOTE:
The instrument can only be unlocked via the remote system again.

11. Disinfection

DANGER:
Urine and used test strips bare the danger of infection. Always use protective gloves during handling and disposal. The disposal of used test strips should be performed according to the regulations for the handling of potentially infectious material.

11.1. How to clean and disinfect the housing

Use commercially available disinfection wipes to clean and disinfect the instrument from the outside.

ATTENTION:
Do not use liquids that can enter the instrument as these may cause permanent damage of the instrument.

Clean the surface of the instrument with a disinfection wipe.

11.2. How to clean and disinfect the strip holder

Wipe off urine residues from the strip holder with a lint-free cloth after each measurement. This prevents carry-over and drying of urine residues.
To remove the strip holder for more comprehensive cleaning, make sure to turn the instrument off. Pull the strip holder from the metal sled below (Pic. 19). Wipe down the strip holder with disinfection wipes. When removed from the instrument, you may also use water with a soft brush and/or liquid disinfectants.
After cleaning, insert the holder on the metal sled (Pic. 20). The rectangular notches of the transport mechanism and the strip holder must be placed on top of each other (Pic. 21). Use reasonable force to push the strip holder completely onto the metal sled. Doing so the metal sled and the strip holder will be pushed back completely into the housing. If you get an error message after turning the instrument on: Turn the instrument off and push the strip holder again on the metal sled with more force.

Pic. 19: test sled (bottom view)

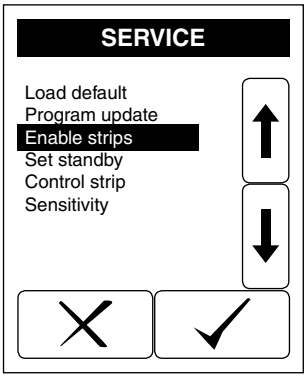
Pic. 20: Reinsertion of the test strip holder

Pic. 21: Check alignment of notches

ATTENTION:
Ensure that the strip holder is completely clean and dry before inserting.

12. Service menu

The URYXXON® Relax has a password protected service menu. To enter the service menu press the touch-screen three times during the self test after turning the equipment on (Display 34). Upon request input the PIN "1234".
A selective list with different menu items appears.



Display 34: Service menu

12.1. How to reset the system (Load Default)

Select "Load default" from the service menu. Confirming this entry will call up a safety question. Pressing ✓ will reset the delivery status.

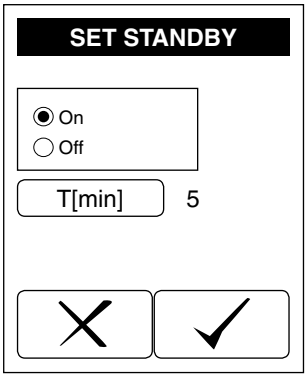
NOTE:
All settings modified by the user will be cleared!

12.2. How to update the instrument (Program update)

Select "Program update" from the service menu. The instrument now expects the upload of a new firmware. Follow the instructions that come with the update-file to finalize the update process.

12.3. How to set the standby (Set standby)

Ex-works the standby mode of the instrument is enabled and set to three minutes. To change the standby time or to switch off the standby select the entry “Set standby” from the service menu. Select the round button “Off” to disable the standby. Press the T[min]-Icon to enter the time after which the device will go to standby (Display 35).



Display 35: Set standby

12.4. How to run a control strip measurement

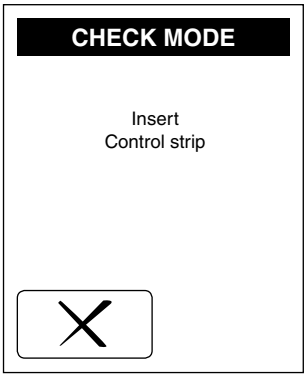
The check mode for control strips allows you to check the correct functioning of the instrument using special color control strips. You can order these control strips from MACHEREY-NAGEL.

Choose the entry Control strip in the service menu. The instrument asks for insertion of the colored control strip (Display 36). The measurement of the control strip starts automatically as soon as the strip is placed on the sled, if the autostart is activated. Once the measurement has been completed, the measured values are immediately displayed and / or printed. The result of the measurement is not stored. The values are so called remission values for the pre-colored test pads on the control strip. These values have to be compared to a set of standard values from the control strip package instructions.

The result of the control strip measurement must be evaluated by pressing and choosing the entry "Passed" or "Failed".

For additional information on the control strips or in case the values do not fit the expected value ranges in the control sheet, please consult the package insert, or contact MACHEREY-NAGEL directly.

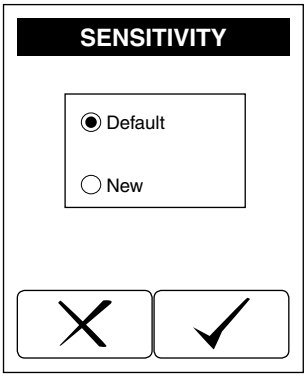
ATTENTION: Do not touch the test fields of the control strip with your fingers.



Display 36: Insert control strip

12.5. How to change the sensitivity

Select "Sensitivity" to adjust the sensitivity settings. The sensitivity of the URYXXON® Relax may be adjusted within specified borders for all parameters except the pH value (Display 37).



Display 37: Sensitivity A

NOTE:
Faulty measurement results due to manipulated sensitivity are sole responsibility of the operator of the equipment.

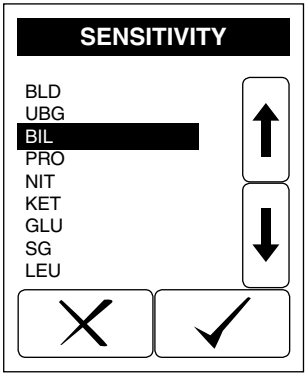
12.5.1. Settings Reset

By selecting the option panel "Default" and confirming with ✓ all sensitivity values are reset to delivery status of the URYXXON® Relax.

12.5.2. Appointing new Sensitivity Settings

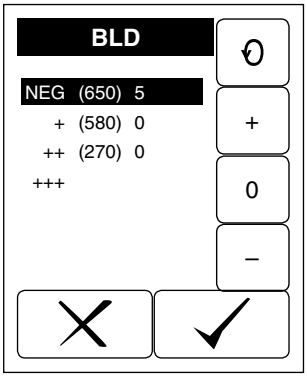
NOTE:
Technical and medical knowledge is required to appoint new sensitivity settings. If you do not feel confident, leave this menu without changes.

By selecting the option panel "New" and confirming with ✓ the parameter selection will appear (Display 38).



Display 38: Sensitivity B

Use the arrows to select the parameter that should be modified. Confirm your choice by pressing ✓. Display 39 will appear.



Display 39: Sensitivity C

The settings apply to the currently set test strip.

12.5.3. Reported value – (original threshold) – modification

Press [0] to select the value that you would like to modify. Three informations are in each line:
The information is always defined "X(Y)Z", e.g. "NEG (650) 0"

- X: Measurement value "NEG"
- Y: Specific border "650"
- Z: Change "0"

Press the buttons [+] and [–] to increase or decrease the threshold value. Press [0] to return to the original threshold value.
Confirm your modifications by pressing [✓]. For the parameter Microalbumin the reported values for Kreatinin and Albumin have to be changed separately.

13. Interface description

The URYXXON® Relax may be connected to a computer via the RS232- or the USB-interface (work station or laboratory information system).

NOTE:
A comprehensive description of the interface data protocols can be obtained from your local product representative or MACHEREY-NAGEL directly.

13.1. Serial interface

Protocol RS232, 19200 Baud, 8 bit, no parity (Pic. 10-④)
Connection plug arrangement:

PIN	Signal	Description	Direction
1	Nc	Not wired	
2	RxD	Data reception	Input
3	TxD	Send	Output
4	Nc	Not wired	
5	GND	Signal ground	--
6	Nc	Not wired	
7	Nc	Not wired	
8	Nc	Not wired	
9	Nc	Not wired	

13.2. USB 1.1-interface

USB-jack Type B (Pic. 10-⑤). The instrument will be identified as a serial interface. The driver for the interface module may be downloaded from the MACHEREY-NAGEL homepage (***www.mn-net.com***).

13.3. Transmission protocol

The data is released via the interfaces as plain text. The received dataset corresponds to the format of the printout.

13.4. Barcode scanner, PC-keyboard

A USB-jack Type A (Pic. 10-⑥) is provided for connection of a keyboard or barcode scanner.

NOTE:
Make sure that the barcode scanner is set to the same language as the device to avoid character misinterpretation.

14. Error Messages and Fault Clearance

The instrument differentiates between different types of error messages. Advisory error messages are of less importance and are displayed on the screen during handling the instrument (e.g. Please remove strip). When the corrective action has been performed, the analyzer removes the message from the screen. If an error message occurs during testing it will be displayed on the screen or in the result view instead of the result. Messages are displayed in plaintext and are self-explanatory.

Error Message / Error	Cause	Solution
"Dry Strip"	The test strip wasn't dipped completely	Repeat measurement with a new strip
"Wrong Strip"	A wrong test strip has been detected (wrong type) or the strip is completely dry	Use correct test strips
"Wrong Position"	The strip hasn't been pushed into the strip retainer far enough	New measurement, place strip in right position
"Printer out of paper"	Paper roll empty or printer flap open	Replace paper and close printer flap
"Battery Low"	Batteries are low	Exchange batteries or use power pack
Instrument doesn't start	Power supply not installed or defect	Check whether all connections are plugged in and whether the power socket is functioning
"N/A in open mode"	User management has not be activated, yet.	Check, if the list entry for "User accounts" is set in the menu "Other settings" (Chapter 9.21.5 "How to activate the user accounts and user password").

Error Message / Error	Cause	Solution
“QC measurement required”	The QC reminder function is activated. The QC measurement is due and the device is blocked for running patient samples.	Run a positive and a negative control, which must both be evaluated as “Passed”. Afterwards the device will be unlocked again. Alternatively an emergency measurement can be performed, when the emergency measurement option is enabled. Otherwise contact your POC coordinator.
“Login failed”	User information are not entered correctly. User does not exist. User is blocked by the system.	Check the entry of the user name and retry the entry. Check, if user really exists. Check correctness of password. Check, if user is active or blocked. Contact your POC coordinator for further information. Use the emergency icon  to run an emergency measurement.
"Mech. error"	Hardware error	Please check the correct positioning of the strip holder. Please contact your local distributor of MACHEREY-NAGEL directly.

Error Message / Error	Cause	Solution
"LOT not found"	Entered LOT number is not known in remote system.	Check the entry and retry input. Please enter a valid LOT number. Use the emergency icon to run an emergency measurement. Please contact your POC coordinator.
"Patient not found"	Patient ID is not known to the remote system.	Check the entry and retry input. Please enter a valid LOT number. Use the emergency icon to run an emergency measurement. Please contact your POC coordinator.
"Communication error"	Connection to the remote system failed. Remote system is currently not available. Wrong connection settings.	Please check the connection cables. Please contact POC coordinator. If connection to a remote system is not wanted, a system reset needs to be performed to change the settings again (Chapter 12.1 "How to reset the system (Load Default)")
"Measurement error"	An error during the measurement occured.	Please repeat the measurement.

In case an error cannot be solved by the aid of the instructions above, please contact your local distributor or the MACHEREY-NAGEL Service.

15. Warranty

The warranty for this equipment has a duration of 24 months from the date of purchase. The original copy of the bill serves as a certificate and must be submitted in case of assertion of a warranty claim. The warranty expires in case of improper handling and/or maintenance of the equipment; it does not comprise defects due to the external power supply.
The warranty is limited to the repair of faulty parts or – at our sole discretion – to the delivery of a faultless substitute. The warranty period of 24 months is not affected by claiming on the warranty during this period. There is no right of withdrawal.
Further claims are excluded. Hereunto we count in particular all claims for damages evolving from consequential damages or indirect damages.
Additionally the relevant version of our general sales terms and delivery conditions apply as printed on all price lists.

16. Technical information

16.1. Technical data

Required electric supply:
Mains transformer:
Input 100~240 V
Output 9 V⎓1.5 A
Alternative: battery operation with 6 mignon batteries 1.5 V (AA).
Dimensions:
Height: 7.5 cm
Width: 16 cm
Depth: 20 cm
Weight:
710 g (without batteries and power pack)
Range of ambient air temperature:
10 °C–40 °C
Humidity:
20 %–80 % (non-condensing)
The following test-strips from MACHEREY-NAGEL are programmed for evaluation:
Medi-Test URYXXON® Stick 10 REF 93068
Medi-Test Microalbumin REF 930874

16.2. Security standards

The URYXXON® Relax is a medical device and is in compliance with the IVD directive 98/79/EC as device itself as well as in combination with the designated test strips. The URYXXON® Relax is ROHS-conform and complies with directive 2011/65/EU.

16.3. Analytical and Clinical Performance Characteristics

16.3.1. Table of results

Param.	Conventional	International	ARB
BLD	NEG	NEG	NEG
	10 Ery/µL	10 Ery/µL	+
	50 Ery/µL	50 Ery/µL	++
	250 Ery/µL	250 Ery/µL	+++
UBG	NORM	NORM	NORM
	2 mg/dL	35 µmol/L	+
	4 mg/dL	70 µmol/L	++
	8 mg/dL	140 µmol/L	+++
	12 mg/dL	200 µmol/L	++++
BIL	NEG	NEG	NEG
	1 mg/dL	17 µmol/L	+
	2 mg/dL	35 µmol/L	++
	4 mg/dL	70 µmol/L	+++
PRO	NEG	NEG	NEG
	30 mg/dL	0.3 g/L	+
	100 mg/dL	1 g/L	++
	500 mg/dL	5 g/L	+++
NIT	NEG	NEG	NEG
	POS	POS	+
KET	NEG	NEG	NEG
	25 mg/dL	2.5 mmol/L	+
	100 mg/dL	10 mmol/L	++
	300 mg/dL	30 mmol/L	+++
GLU	NEG	NEG	NEG
	NORM	NORM	NORM
	50 mg/dL	2.8 mmol/L	+
	150 mg/dL	8.3 mmol/L	++
	≥ 500 mg/dL	≥ 27.8 mmol/L	+++
pH	5	5	5
	6	6	6
	6.5	6.5	6.5
	7	7	7
	8	8	8
	9	9	9
SG	1.000	1.000	1.000
	1.005	1.005	1.005
	1.010	1.010	1.010
	1.015	1.015	1.015
	1.020	1.020	1.020
	1.025	1.025	1.025
	1.030	1.030	1.030
LEU	NEG	NEG	NEG
	25 Leu/µL	25 Leu/µL	+
	75 Leu/µL	75 Leu/µL	++
	500 Leu/µL	500 Leu/µL	+++
ASC	NEG	NEG	NEG
	10 mg/dL	0.6 mmol/L	+
	20 mg/dL	1.1 mmol/L	++

Param.	Conventional	International	ARB
ALB	10 mg/L	–	–
	30 mg/L	–	–
	80 mg/L	–	–
	150 mg/L	–	–
KRE	10 mg/dL	–	–
	50 mg/dL	–	–
	100 mg/dL	–	–
	200 mg/dL	–	–
	300 mg/dL	–	–
A:C	< 30 mg/g	–	–
	30–299 mg/g	–	–
	≥ 300 mg/g	–	–

Table 1: Results for Medi-Test parameters

Meaning of the used abbreviations:
BLD - Blood, UBG - Urobilinogen, BIL - Bilirubin, PRO - Protein, NIT - Nitrite, KET - Ketone, GLU - Glucose, SG - specific gravity of the urine (density), LEU - Leukocytes, ASC - Ascorbic acid, ALB - Albumin, KRE - Creatinine, A:C - Albumin:Creatinine ratio.

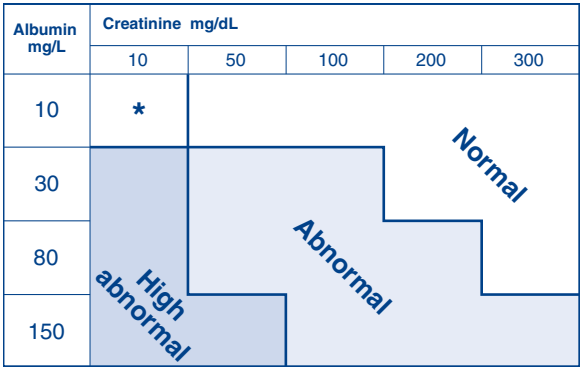


Table 2: Evaluation for Microalbumin

* Repeat with new sample

16.3.2. Precision

The precision was evaluated by using the commercially available control solution Medi-Test Control, manufactured by MACHEREY-NAGEL, Düren, Germany. This Control is used for daily routine system check of the URYXXON® urinalysis system. It is available as a 2 level set (Medi-Test Control N = level 1 (N): negative-normal, Medi-Test Control P = level 2 (P): positive values). The analytical performance was evaluated by calculating specificity, sensitivity, positive predictive value (PPV) and negative predictive value (NPV).

Precision within series

	BIL	BLD	GLU	KET	LEU	NIT	PRO	UBG
Total measurements	40	40	40	40	40	40	40	40
True positive	20	20	20	20	20	20	20	20
False positive	0	0	0	0	0	0	0	0
False negative	0	0	0	0	0	0	0	0
True negative	20	20	20	20	20	20	20	20
Specificity, %	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
Sensitivity, %	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
PPV %	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
NPV %	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

Precision LOT-to-LOT

	BIL	BLD	GLU	KET	LEU	NIT	PRO	UBG
Total measurements	60	60	60	60	60	60	60	60
True positive	30	30	30	30	30	30	30	30
False positive	0	0	0	0	0	0	0	0
False negative	0	0	0	0	0	0	0	0
True negative	30	30	30	30	30	30	30	30
Specificity, %	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
Sensitivity, %	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
PPV %	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
NPV %	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

Precision day-to-day

	BIL	BLD	GLU	KET	LEU	NIT	PRO	UBG
Total measurements	100	100	100	100	100	100	100	100
True positive	50	50	50	50	50	50	50	50
False positive	0	0	0	0	0	0	0	0
False negative	0	0	0	0	0	0	0	0
True negative	50	50	50	50	50	50	50	50
Specificity, %	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
Sensitivity, %	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
PPV %	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
NPV %	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

16.3.3. Microalbumin

For determination of the performance data of Medi-Test Microalbumin, urine samples from urological practice were used which had been obtained as part of daily routine urine control. The measured albumin and creatinine values were compared with the results of the respective reference method (immunoturbidimetric assay for albumin and colorimetric Jaffé method for creatinine).

	Negative percent agreement	Positive percent agreement	Overall percent agreement
URYXXON® Relax (N=612)			
Albumin [1)]	83.6 %	85.0 %	84.2 %
Albumin/creatinine ratio [2)]	84.8 %	89.5 %	86.4 %

[1)] Here a negative assessment corresponds to the result 10 mg/L albumin, a positive assessment to the result 30, 80 or 150 mg/L albumin.

[2)] Here a negative assessment corresponds to the result “Normal”, a positive assessment to the result “Abnormal” or “High Abnormal”.

16.3.4. Linearity

Assay reportable range:
Bilirubin: neg. – 1 – 2 – 4 mg/dL
Blood: neg. – 10 – 50 - 250 erythrocytes/µL
Glucose: neg. - norm. – 50 – 100 – 150 – 500 – ≥1000 mg/dL
Ketones: neg. – 25 – 100 – 300 mg/dL
Leucocytes: neg. – 25 – 75 – 500 leucocytes/µL
Nitrite: neg. – pos.
pH: 5 – 6 – 7 – 8 – 9
Protein: neg. – 30 – 100 – 500 mg/dL
Ascorbic acid: neg - 10 - 20 mg/dL
Albumin: 10 - 30 - 80 -150 mg/L
Creatinin: 10 - 50 - 100 - 200 - 300 mg/dL
specific gravity: 1.000 – 1.005 – 1.010 – 1.015 – 1.020 – 1.025 – 1.030
Urobilinogen: norm. – 2 – 4 – 8 – 12 mg/dL

16.3.5. Cut-off concentration

The Cut-Off-Concentration (Medical decision point) has been defined as the concentration, where minimum 50% of the results are positive.

Parameter	Detection limit URYXXON® Relax
Ascorbic acid	approx. 5 mg/dL
Albumin[3)]	not applicable
Bilirubin	approx. 0.8 mg/dL
Blood	approx. 4 Ery/µL
Creatinin[3)]	not applicable
Glucose	approx. 35 mg/dL
Ketones	approx. 10 mg/dL
Leucocytes	approx. 15 Leu/µL
Nitrite	approx. 0.05 mg/dL
Protein	approx. 15 mg/dL
Urobilinogen	approx. 0.5 mg/dL

[3)] For Performance data on these parameters, please refer to Chapter 16.3.3 "Microalbumin")

16.4. Electromagnetic Compatibility

The URYXXON® Relax as a medical device is subject to particular precautions with regard to electromagnetic compatibility (EMC) and has to be installed and put into operation as described in Chapter 3 "Unpacking and set up". High frequency communication equipment (mobile phones, etc.) can influence the functionality of the URYXXON® Relax. By using other cables or equipment than mentioned in Chapter 3.5 "Description of instrument parts", there is a consisting danger of other influences on URYXXON® Relax. Furthermore, by using other equipment the effective radiant power could increase or the interference resistance could decrease. Please do not arrange the URYXXON® Relax in a pile when using it. If there is an urgent need to pile the URYXXON® Relax, an extra observation of instrument is necessary which controls and ensures the conventional use of instrument.

Essential performance features:
The URYXXON® Relax do not display wrong negative measuring results in tested conditions from EMC-test.

Electromagnetic transient emissions

The URYXXON® Relax is destined for an electromagnetic environment as described below. The user of URYXXON® Relax should ensure that instrument is used in such environment.

Transient emissons measurement	**Accordance**	**Electromagnetic environment - guideline**
RF-Emissions according with CISPR 11	Group 1	The [URYXXON® Relax] needs RF-energy only for its inner functions. Therefore the amount of RF-Emission is very low and it is improbably that instruments in closer surrounding get disturbed.
RF-Emissions according with CISPR 11	Class B	The [URYXXON® Relax] can be used in all institutions including residential area and areas which are directly connected to the public power supply, no matter if public power supply supplies buildings for residential purpose.
Emissons of harmonic components according with IEC 61000-3-2	Class A	
Emissions of voltage fluctuation / flicker according with IEC 61000-3-3	in accordance	

Electromagnetic interference resistance

The URYXXON® Relax is destined for an electromagnetic environment as described below. The user of URYXXON® Relax should ensure that instrument is used in such environment.

Interference resistance-test	IEC 60601-Immunity test level	Compliance-level	Electromagnetic environment – guideline
Electrostatic discharge according with IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	The floor covering should be made of wood, cement or ceramic tile. If floor covering is made of synthetic materials, air humidity must be 30 % at least.
Electrical fast transients / bursts according to IEC 61000-4-4	± 2 kV for power line ± 1 kV for input- and output power	± 2 kV for power line ± 1 kV for input- and output power	The quality of supply voltage should be like the typical voltage for business or hospital environment.
Surges Line-to-line according with IEC 61000-4-5	± 1 kV voltage outer conductor-outer conductor ± 2 kV voltage outer conductor-ground	± 1 kV voltage outer conductor-outer conductor ± 2 kV voltage outer conductor-ground	The quality of supply voltage should be like the typical voltage for business or hospital environment.
Voltage dips, short interruptions and variation of supply voltage according with IEC 61000-4-11	< 5 % UT (> 95 % break in of UT) for 1/2 period 40 % UT (60 % break in of UT) for 5 periods 70% UT (30 % break in of UT) for 25 periods < 5 % UT (> 95 % break in of UT) for 5 s	< 5 % UT (> 95 % break in of UT) for 0,5 period 40 % UT (60 % break in of UT) for 5 periods 70 % UT (30 % break in of UT) for 25 periods < 5 % UT (> 95 % break in of UT) for 5 s	The quality of supply voltage should be like the typical voltage for business or hospital environment. If the user of [URYXXON® Relax] requires continued function in case that energy supply is interrupted, we recommend to supply [URYXXON® Relax] with power from an uninterruptible power supply or a battery.
RATED power frequency magnetic field (50/60 Hz) according with IEC 61000-4-8	3 A/m	3 A/m	The magnetic fields should have the typical values like for business or hospital environment.

ANNOTATION UT is the alternating current voltage of net before the use of the immunity test level.

Electromagnetic interference resistance

The URYXXON® Relax is destined for an electromagnetic environment as described below. The user of URYXXON® Relax should ensure that instrument is used in such environment.

Interference resistance-test	IEC 60601-Immunity test level	Compliance-level	Electromagnetic environment – guideline
			Portable and mobile radio equipments should not be closer to URYXXON® Relax than the recommended protection ratio which can be calculated with the equation that is applicable to the transmitter frequency. **Recommended protection ratio:**
Conducted disturbances induced by RF fields according with IEC 61000-4-6	3 V rms-value 150 kHz to 80 MHz	3 V	$d = 1{,}2\ \sqrt{P}$

[a] The field intensity of stationary transmitter, e.g. base stations for cordless telephones and mobile radio equipment, amateur radio stations, AM and FM radio and television station, can not be predestinated precisely. For the identification of the electromagnetic environment regarding the stationary transmitter, a survey about the electromagnetic phenomena of area should be made. If the measured field intensity at the place where URYXXON® Relax is used is higher than the compliance level mentioned in the list above, an extra observation of instrument is necessary as an evidence for the conventional functionality. In the case that unusual performance features occur, additional actions like changing the direction of instrument or moving the URYXXON® Relax to another place is necessary.

[b] Across the frequency range from 150 kHz to 80 MHz the field intensity should be lesser than 3 V/m.

Blazed disturbances induced by RF fields according to IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1{,}2\ \sqrt{P}$ for 80 MHz to 800 MHz $d = 2{,}3\ \sqrt{P}$ for 800 MHz to 2,5 GHz with *P* as rated power of transmitter in watt (W) according to description of transmitters manufacturer and d as recommended protection ratio in meters (m). The field intensity of stationary radio transmitter should be lower than the level of compliance[b] in all frequencies according to an analysis on site[a]. In the vicinity of instruments which have following symbol disturbances are possible.

ANNOTATION 1 In case of 80 MHz or 800 MHz the higher frequency rang is valid.

ANNOTATION 2 These guidelines are not applicable for all cases. The propagation of electromagnetic volumes is influenced by the absorbtion and reflection of buildings, items and humans.

[a] The field intensity of stationary transmitter, e.g. base stations for cordless telephones and mobile radio equipment, amateur radio stations, AM and FM radio and television station, can not be predestinated precisely. For the identification of the electromagnetic environment regarding the stationary transmitter, a survey about the electromagnetic phenomena of area should be made. If the measured field intensity at the place where URYXXON® Relax is used is higher than the compliance level mentioned in the list above, an extra observation of instrument is necessary as an evidence for the conventional functionality. In the case that unusual performance features occur, additional actions like changing the direction of instrument or moving the URYXXON® Relax to another place is necessary.

[b] Across the frequency range from 150 kHz to 80 MHz the field intensity should be lesser than 3 V/m.

Recommended protection ratio between portable and mobile RF-telecommunication device and the URYXXON® Relax

The URYXXON® Relax is destined for the use in electromagnetic environments where RF-disturbances are controlled. The user of URYXXON® Relax can avoid electromagnetic disturbances by observing the minimum distance – dependent on the output power of telecommunication device, see list below - between portable and mobile RF-telecommunication devices (transmitter) and the URYXXON® Relax.

Rated power of transmitter W	**Protection ratio, dependent on transmitter frequency** m		
	150 kHz to 80 MHz $d = 1.2\ \sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\ \sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2.3\ \sqrt{P}$

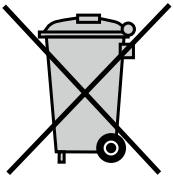
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters whose maximum rated power is not listed above, the recommended protection ratio d in meter (m) can be calculated by using the equation from the particular column, where as *P* is the maximum rated power of transmitter in watt (w) according to description of manufacturer.

ANNOTATION 1 In case of 80 MHz or 800 MHz the higher frequency rang is valid.

ANNOTATION 2 These guidelines are not applicable for all cases. The propagation of electromagnetic volumes is influenced by the absorbtion and reflection of buildings, items and humans.

16.5. Waste disposal



Waste disposal according to EU Directive 2012/19/EU. In compliance with national legal regulations (EU Directive 2012/19/EU), MACHEREY-NAGEL disposes old instruments free of charge.

NOTE:
Disposal using public waste disposal facilities is not permitted. In case of disposal, please contact your MACHEREY-NAGEL representative.

17. Additional Information

17.1. Manufacturer Information

MACHEREY-NAGEL GmbH & Co. KG
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Fax: +49 2421 969-199
E-mail: info@mn-net.com
Internet: *www.mn-net.com*

NOTE:
Please note that any serious incident that has occured in relation to the product shall be reported immediately to the manufacturer and the competent authority of the member state in which the incident occured. European vigilance contact points:
http://ec.europa.eu/growth/sectors/medical-devices/contact_de

17.2. Version history

Manual URYXXON® Relax EN, V 1.00 / 04.06, April 2006
Manual URYXXON® Relax EN, V 2.00 / 03.08, March 2008
Manual URYXXON® Relax EN, V 2.02 / 10.10, October 2010
Manual URYXXON® Relax EN, V 2.10 / 02.14, February 2014
Manual URYXXON® Relax EN, V 3.00 / 03.15, March 2015
Manual URYXXON® Relax EN, V 5.00 / 04.19, April 2019
Manual URYXXON® Relax EN, V 5.00C / 06.19, June 2019