# URYXXON<sup>®</sup> Relax

**Aedi-Tesi** vedr

# **User manual**







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#### 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. 4-(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.
- · Blot by touching the edge of the strip to a paper towel to remove excess urine.
- · Place the strip on the strip holder
- Slide or push the strip to the end of the channel. 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 measurement time.

Note: If "Autostart" (Chapter 9.5 "How to deactivate and activate the autostart") is deactivated, the measurement must be started using the start control panel

#### Notice:

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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 B the result can be printed again. Choosing the return panel  $\checkmark$  will lead back to the start screen.

Another analysis may be started by applying the next test strip.

Notice:

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.

#### 2. Introduction

The URYXXON<sup>®</sup> Relax is a reflection photometer for the analysis of urine test strips. The measurements are performed under standardised conditions, measured values may be displayed, printed and transfered to a computer. The URYXXON<sup>®</sup> Relax is designed for in-vitro diagnostic use (IVD) and should be used by healthcare professionals, only. Discuss each positive result with a doctor. In case of persisting symptoms repeat measurement.

#### 2.1. System description

#### 2.1.1. 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. 1: 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.

#### 2.1.2. Functional principle URYXXON<sup>®</sup> 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 *for 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 3.8 "Use of the instrument").

#### 3. Unpacking and set up

#### 3.1. List of delivered parts

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



Pic. 2: Content

Read the operating manual for URYXXON<sup>®</sup> Relax carefully before the first startup in order to ensure an error free operation.

#### 3.2. Advice on 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.

#### 3.3. 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)

#### 3.4. Description of instrument parts



Pic. 3: Front view



Pic. 4: Backside view

Actuator	Function
1. Touch-Screen	Control of equipment functions
2. Test Strip Sled	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 <sup>1</sup> max, 3 m)
5. USB-Interface	Connection of a computer (cable length <sup>1</sup> max. 3 m)
6. PS/2 Interface	Connection of a keyboard or a bar code scanner <sup>2</sup>
7. Mains Connection	Contact for the provided power pack
8. On/Off Switch (I/O)	Turning the equipment on and off

<sup>1</sup> We recommend to use shielded cables.

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<sup>2</sup> We recommend to make use of the hand scanner from MACHEREY-NAGEL.

3.5. How to plug the instrument in



Pic. 5: Power pack

Pic. 6: DC in

Four adapters are provided for adapting the power pack to the available mains connection. The adapter matching the mains connection is plugged on to the power pack (Pic. 5). After plugging the power pack cable into the jack "DC IN" (Pic. 4-⑦) and connecting the power pack to the power socket the URYXXON<sup>®</sup> Relax is ready for operation.

#### 3.6. How to load the printer paper



Pic. 7: Printer A

Pic. 8: Printer B

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Open the printer flap by pressing the rectangular key next to the printer flap (Pic. 7).



Pic. 9: Printer C

Pic. 10: 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. 9 + Pic. 10).

#### 3.7. How to install batteries (optional)

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



Pic. 11: Battery compartment

#### 3.8. Use of the instrument

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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.

#### 3.8.1. 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

Cancel action

display of equipment settings

#### 3.8.2. 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  $\checkmark$  select the highlighted line. You can leave the menu by pressing  $\checkmark$ .

#### 3.8.3. 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.

Today
ODate

Pressing the circle will activate a selection. Save your selection by pressing  $\checkmark$ . Pressing  $\checkmark$  will quit the menu without performing any changes.



#### 4. User menu

#### 4.1. Flow-chart of the menu structure



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#### 4.2. Description of the menu items

- SN: Chapter 5.5 "Changing the sequence number ("SN")"
- ID:

Chapter 5.4 "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 modify strip settings" Chapter 9.2 "How to protect settings from unauthorized access" Chapter 9.3 "How to turn the printer on and off" Chapter 9.4 "How to enable and disable acoustic signals" Chapter 9.5 "How to deactivate and activate the autostart" Chapter 9.6 "How to set energy saving options for the battery mode" Chapter 9.7 "How to change the language" Chapter 9.8 "How to set time and date" Chapter 9.9 "How to activate data transfer" Chapter 9.10 "How to change the text of the printout header" Chapter 9.11 "How to print the settings"

#### 5. Analysis of test strips

#### 5.1. How to perform a measurement

The URYXXON<sup>®</sup> 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 lintfree cloth.

#### Note:

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If auto mode (Chapter 9.5 "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 OF INFECTION:

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. Display of results

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



Display 4: Result

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. For the evaluation of the Microalbumin test strips, findings are displayed with an additional statement (Repeat with new sample, normal, abnormal, high abnormal). Additionally, it is possible to enable an acoustic signal for the findings "Repeat with new sample", "abnormal" and "high abnormal".



Display 5: Result Microalbumin

The printout is light-sensitive and may turn yellow when exposed to light during storage. For archiving purposes the printouts should be kept in a dark place (patient file) or as a photocopy.

The result displayed may be printed again by pressing  $\blacksquare$ . The return panel  $\checkmark$  will lead back to the start screen.



#### 5.3. Measurement errors

If the display shows "Measuring Error ..." 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.

#### 5.4. 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 D: in the start menu brings up an alphanumeric 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 6: Entering ID (numerics)

Display 7: 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.

#### Attention:

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

#### 5.5. 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 from this number on.



Display 8: Seq.-Input

#### 5.6. Transferring data to a PC

The results may be transferred to a PC via the USB- or RS232-interface.

A detailed description of the interface can be found in Chapter 13 "Interface description".



#### 6. Enter the main menu

Pressing  $\frown$  on the start screen will bring up the main menu.





Display 9: Start menu

Display 10: 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.

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#### 7. Recall results

The URYXXON<sup>®</sup> Relax has memory for 200 measurements. Every result is automatically saved after the analysis. After 200 measurements, new data will overwrite the eldest saved dataset.

Access the memory by pressing  $\boxed{\equiv}$  in the main menu  $\boxed{\checkmark}$ .



Display 11: Main menu

Display 12: Memory mode

#### 7.1. How to scroll through memory

Pressing 1 will bring up Display 13. Scrolling through the memory is possible by pressing the arrows on the right side. The next  $\longrightarrow$  or previous  $\longleftarrow$  result will be displayed.



Display 13: Memory contents

It is possible to print  $\square$  and send  $\square$  the dataset displayed. The memory menu will reappear upon pressing return  $\bigcirc$ .



#### 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 14).

SET FILTER PAR.		
Day Par		
X		

Display 14: Filtering

#### 7.2.1. Selecting the date

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By pressing Day you will reach the menu displayed below (Display 15).

DAY	
<ul> <li>Today</li> <li>All</li> <li>Date</li> </ul>	
X	

Display 15: 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  $\checkmark$ . After confirmation your selection will be displayed on the screen "SET FILTER PAR."

#### 7.2.2. Selecting search criteria

Pressing Par in Display 14 brings up Display 16.



Display 16: Select parameter

Use the arrow keys to select the desired criteria and confirm with  $\checkmark$ . The filter criteria will be displayed on the filter settings screen (Display 17).

#### 7.2.3. Display suitable matches

After setting "Day" and "Parameter" the search may be started by pressing  $\checkmark$  (Display 17).



Display 17: Filtering

When suitable matches are found, an option will appear, allowing to print the datasets  $\square$ , send them to a PC  $\square$  or display them on the screen  $\bigcirc$  (Display 18).



Display 18: Search result

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

#### 7.3. How to delete results from memory

Pressing  $\underline{\beta}_{\mu}$  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.

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#### 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.

Quality inspection tests are recommended:

- at the beginning of a day
- · when introducing a new test strip LOT
- · in case of doubtful test results
- · when a different person is operating the equipment

Upon pressing [1]? on the start menu the "Check mode" screen will appear (Display 19 + Display 20).





Display 19: Main menu

Display 20: 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 20) and may be printed for documentation purposes.

#### 8.2. How to perform a QC measurement

Prepare the check urines as described in the instruction leaflet and test them in test mode.

Handle the check solutions exactly as the patient samples. By pressing (Display 20) the sample selection will appear. You may select what type of control sample you want to analyze (Display 21).

CHECK MODE	
Negative     Positive     Control strip	
X	

Display 21: Check mode

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

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#### 8.3. Control strip

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 round button Control strip in the check mode measurement menu (Display 21). The instrument asks for insertion of the colored control strip (Display 22). 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. For additional information on the control strips or in case the values do not fit the should values in the control sheet, please consult the package insert, or contact MACHEREY-NAGEL directly.

Attention: Please do not touch the test fields of the control strip with your fingers.



Display 22: Insert control strip

### 9. Equipment Settings

Enter the main menu by pressing the menu key  $\frown$  to reach the "SETTINGS" display press  $\bigcirc$  (Display 23 + Display 24).



Display 23: Main menu

Display 24: Settings

#### 9.1. How to modify strip settings

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

#### 9.1.1. Type

The URYXXON<sup>®</sup> Relax is in principle able to analyze also non-medical strip types. When the equipment has data for various approved strip types, the strip type can be chosen in a selective list.

#### 9.1.2. 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

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

#### 9.1.3. 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  $\checkmark$ . After the last parameter the equipment will ask whether the setting is to

be saved. Save by pressing  $\checkmark$  or go back to the preprogrammed order by pressing  $\checkmark$ . A change of the parameter order for the strip parameter Microalbumin is not possible.

#### 9.1.4. Test Strip LOT

The LOT-administration of URYXXON<sup>®</sup> Relax is deactivated in the default setting. See Chapter 12.2 "How to control the LOT-control (LOT activate)".

#### 9.2. How to protect settings from unauthorized access

Select "Password" in the settings menu if you want to protect the instrument settings with a PIN. An option panel with the possibilities "ON" and "OFF" will be displayed. Selecting "ON" will enable the PIN-protection.

After enabling the PIN-protection a numerical pad will appear. Enter a 4-digit PIN and confirm by pressing  $\checkmark$ . The PIN will be asked for upon the next attempt to change the settings.

Attention:

A forgotten PIN can not be reconstructed. Only a complete reset of the instrument will delete the PIN-protection. This will result in loss of all results and settings!

#### 9.3. How to turn the printer on and off

Selecting "Printer" in the settings menu will bring up an option panel. Choose the desired option and confirm.

#### 9.4. How to enable and disable acoustic signals

Select "Sound" in the settings menu to enter the settings for acoustic signals.

#### 9.4.1. Acoustic confirmation of user inputs

In the preprogrammed settings all user inputs are confirmed with an acoustic signal. Disable or enable these signals by choosing "ON" or "OFF" in the box "Touch".

#### 9.4.2. Acoustic warning on positive results

In the preprogrammed settings an acoustic signal will be given on positive findings. Disable or enable this signal by choosing "ON" or "OFF" in the box "Positive".

#### 9.5. How to deactivate and activate the autostart

Select "Autostart" in the settings menu. In basic mode URYXXON® Relax auto-

matically detects an applied test strip and starts the measurement. This function may be deactivated via an option panel.

If Autostart is deactivated the analysis must be triggered by pressing a panel in the Start menu.

#### 9.6. How to set energy saving options for the battery mode

Select "Battery" in the settings menu. Settings in this menu 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 the option panels.

#### 9.7. How to change the language

Select "Language" in the settings menu. The language of the URYXXON<sup>®</sup> Relax menu can be switched to the following languages using the respective selective list:

English, Deutsch, Espanol, Francais, Italiano, Portugues, Polski, Türkce, Nederlands, Norsk, Svenska, Suomi, Dansk, Indonesia

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#### 9.8. 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  $\checkmark$ .

The date may be formatted in three ways. The active format is shown on a button  $\forall MD$  on the right hand side of the date (Display 25). Select a date format by pressing this button.

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

The time format may be changed to 12 or 24 hours with the button displayed next to the time 24.



Display 25: Date / time

#### 9.9. How to activate data transfer

Select "Interface" on the settings menu. The data transfer via the interfaces can be activated or deactivated via an option panel.

#### 9.10. 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.

#### 9.11. How to print the settings

Select "Print Settings" in the settings menu to print the equipment settings for documentation purposes. Thermo printings fade with time. Therefore, please store it in a dark place or copy the printout.

#### 10. Cleaning and maintenance

#### DANGER OF INFECTION:

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.

#### 10.1. How to clean the housing

The instrument housing may be wiped with a cloth. Mild cleaning agents or disinfectants may be used. Ensure that no moisture permeates the equipment.

#### 10.2. How to clean 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.

The strip holder can be removed from its transport mechanism and should be cleaned with water and - when necessary - with cleaning agent or disinfectant (Pic. 12). Make sure that the instrument is turned off before removing the test sled.

After cleaning, push the transport mechanism all the way into the instrument (Pic.13). The strip holder should be put back on the transport mechanism carefully. Turn the instrument on to review the correct positioning of the strip holder. The rectangular notches of the transport mechanism and the strip holder must be placed on top of each other (Pic. 14).



Pic. 12: Test sled (bottom view)



Pic. 13: Notch A



Pic. 14: Notch B

#### 11. Table of results

Param.	CONV	SI	ARB
	NEG	NEG	NEG
BLD	10 Ery/μL	10 Ery/μL	+
	50 Ery/μL	50 Ery/μL	++
	250 Ery/µL	250 Ery/µL	+++
	NORM	NORM	NORM
	2 mg/dL	35 µmol/L	+
UBG	4 mg/dL	70 μmol/L	++
	8 mg/dL	140 µmol/L	+++
	<u>12 mg/dL</u>	<u>200 µmol/L</u>	++++
	NEG	NEG	NEG
BII	1 mg/dL	17 µmol/L	+
512	2 mg/dL	35 µmol/L	++
	4 mg/dL	<u>70 µmol/L</u>	+++
	NEG	NEG "	NEG
PRO	30 mg/dL	0.3 g/L	+
	100 mg/dL	1 g/L	++
	500 mg/aL	<u>5 g/L</u>	+++
NIT	NEG	NEG	NEG
	PUS	PUS	+
	NEG 05. mag/dl	NEG 0.5 mm al/l	NEG
KET	25 mg/dL	2.5 mmol/L	+
	100 mg/aL	10 mmol/L	++
GLU	NURIVI 50 ma/dl		
GLU	150 mg/dL	2.0 mmol/L	+
	> 500  mg/dL	> 27.8  mmol/l	++
	<u>≥ 500 mg/u∟</u> 5	5	5
	6	6	5
	65	65	65
pH	7	7	7
	8	8	8
	9	9	9
	1.000	1.000	1.000
	1.005	1.005	1.005
	1.010	1.010	1.010
SG	1.015	1.015	1.015
	1.020	1.020	1.020
	1.025	1.025	1.025
	1.030	1.030	1.030
	NEG	NEG	NEG
	25 Leu/µL	25 Leu/µL	+
	75 Leu/µL	75 Leu/µL	++
	500 Leu/µL	500 Leu/µL	+++

## Manual URYXXON<sup>®</sup> Relax

Param.	CONV	SI	ARB
	10 mg/L	—	-
	30 mg/L	_	_
ALD	80 mg/L	_	_
	150 mg/L	_	_
	10 mg/dL	-	_
	50 mg/dL	_	_
KRE	100 mg/dL	_	_
	200 mg/dL	_	_
	300 mg/dL	-	—

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, ALB - Albumin, KRE - Creatinine





\* Repeat with new sample

#### 12. Service menu

The URYXXON<sup>®</sup> 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 26). Upon request input the PIN "1234". A selective list with different menu items appears.



Display 26: Service menu

#### 12.1. How to reset the system (Load Default)

Select "Load default" from the service menu. The instrument will be reset to delivery status. All settings modified by the user will be cleared!

#### 12.2. How to control the LOT-control (LOT activate)

Select "LOT activate" from the service menu to activate the LOT-control. This will minimize the risk of using expired test strips. You will be asked for the LOT of strips currently used. The system will give a warning when the test strips are expired. After 100 measurements the system will ask for the LOT-number of the next tube.

#### 12.2.1. Entry of test strips' LOT

If LOT-control is activated, the actual LOT-number of the test strips can be entered using "Strip" in the menu "Settings" (Display 27).

When selecting "LOT number" a numerical pad will appear, which can be used for entering the LOT printed on the strip packaging. If the entry does not have the format expected for a LOT number, an error message will appear.

After entering the LOT, information on the number of strips from that LOT is requested. For example, if three boxes of the same LOT are present, please enter "300" for the number of strips (Display 28).



Display 27: LOT code



Display 28: LOT size

#### NOTE:

The instrument counts the number of strips. If the number of measurements reaches the previously entered number of strips of that LOT the instrument requests to enter a new LOT number. Then, please enter the LOT number of the strips you want to use.

#### 12.2.2. Warning on expired test strips

The date of expiry of the test strips is calculated from the LOT-number. If the expiry date has passed, a warning will appear (Display 29). If you choose to continue without entering a new LOT, Display 30 appears. Please choose the number of measurements you would like to perform without additional warnings.



Display 29: Expire date A

Display 30: Expire date B

#### NOTE:

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MACHEREY-NAGEL is not responsible for wrong measurement results due to expired test strips.

#### 12.3. How to change the sensitivity

Select "Sensitivity" to adjust the sensitivity settings. The sensitivity of the URYXXON<sup>®</sup> Relax may be adjusted within specified borders for all parameters except the pH value (Display 31).

SENSITIVITY				
	Default			
	◯ New			
	XX			

Display 31: Sensitivity A

#### NOTE:

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

#### 12.3.1. Settings Reset

By selecting the option panel "Default" and confirming with  $\checkmark$  all sensitivity values are reset to delivery status of the URYXXON<sup>®</sup> Relax.

#### 12.3.2. Appointing new Sensitivity Settings

Please note that technical and medical knowledge is required. If you do not feel confident, leave this menu without changes.

By selecting the option panel "New" and confirming with  $\checkmark$  the parameter selection will appear (Display 32).



Display 32: Sensitivity B

Use the arrows to select the parameter that should be modified. Confirm your choice by pressing  $\checkmark$ . Display 33 will appear.



Display 33: Sensitivity C

#### 12.4. Reported value - (original threshold) - modification

Press  $\bigodot$  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"

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Press the buttons (+) and (-) to increase or decrease the threshold value. Press  $(\circ)$  to return to the original threshold value.

Confirm your modifications by pressing  $\checkmark$ . For the parameter Microalbumin the reported values for Kreatinin and Albumin have to be changed separately.

#### 12.5. How to update the instrument

Select "Program update" from the service menu. The URYXXON<sup>®</sup> Relax now expects the upload of a new firmware. Follow the instructions that come with the update-file to finalize the update process.

#### 13. Interface description

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

#### 13.1. Serial interface

Protocol RS232, 19200 Baud, 8 bit, no parity (Pic. 4-④) 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

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USB-jack Type B (Pic. 4-(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 PS/2 jack (Pic. 4-6)) is provided for connection of a keyboard or barcode scanner.

#### 14. Error Messages and Fault Clearance

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)	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
"No 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 connec- tions are plugged in and whether the power socket is functioning

In case a fault cannot be cleared 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.

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E-mail: info@mn-net.com Internet: *www.mn-net.com* 

#### 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) Test strips programmed for evaluation: Medi-Test UBYXXON® Stick 10

Medi-Test Microalbumin

#### 16.2. Security standards

The URYXXON<sup>®</sup> 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<sup>®</sup> Relax is ROHS-conform and complies with directive 2011/65/EU.

#### 16.2.1. Technical documentation

The URYXXON<sup>®</sup> 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<sup>®</sup> Relax. By using other cables or equipment than mentioned in Chapter 3.4 "Description of instrument parts", there is a consisting danger of other influences on URYXXON<sup>®</sup> Relax. Furthermore, by using other equipment the effective radiant power could increase or the interference resistance could decrease. Please do not arrange the URYXXON<sup>®</sup> Relax in a pile when using it. If there is an urgent need to pile the URYXXON<sup>®</sup> Relax, an extra

observation of instrument is necessary which controls and ensures the conventional use of instrument.

Essential performance features:

The URYXXON<sup>®</sup> Relax do not display wrong negative measuring results in tested conditions from EMC-test.

#### **Electromagnetic transient emissions**

The URYXXON<sup>®</sup> Relax is destined for an electromagnetic environment as described below. The user of URYXXON<sup>®</sup> 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 <sup>®</sup> 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 <sup>®</sup> Relax] can be used in all institutions including residential area and areas which are directly con- nected 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 / flick- er according with IEC 61000-3-3	in accordance		

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#### 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 dis- charge according with IEC 61000-4-2	± 6 kV contact dis- charge	± 6 kV contact dis- charge	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.	
	± 8 kV air discharge	± 8 kV air discharge		
Electrical fast tran- sients/bursts accord-	$\pm 2 \text{ kV}$ for power line	$\pm 2$ kV for power line	The quality of supply voltage should be like the typical voltage for business or hospital environment.	
ing to IEC 61000-4-4	± 1 kV for input- and output power	± 1 kV for input- and output power		
Surges Line-to-line according with IEC 61000-4-5	± 1 kV voltage outer conductor-outer con- ductor	± 1 kV voltage outer conductor-outer con- ductor	The quality of supply voltage should be like the typical voltage for business or hospital	
	± 2 kV voltage outer conductor-ground	± 2 kV voltage outer conductor-ground	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	< 5 % UT (> 95 % break in of UT) for 0,5 period	The quality of supply voltage should be like the typical voltage for business or hospital environment. If the user of [URYXX- ON <sup>®</sup> Relax] requires continued function in case that energy sup- ply is interrupted, we recommend to supply	
	40 % UT (60 % break in of UT)	40 % UT (60 % break in of UT)		
	for 5 periods	for 5 periods		
	70% UT (30 % break in of UT) for 25 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 5 s	[URYXXON <sup>®</sup> Relax] with power from an uninterruptible power supply or a battery.	
RATED power fre- quency 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-Immu- nity test level	Compliance- level	Electromagnetic environment – guideline
			Portable and mobile radio equip- ments should not be closer to URYXXON <sup>®</sup> Relax than the recommended protection ratio which can be calculated with the equation that is applicable to the transmitter frequency.
			Recommended protection ratio:
Conducted distur- bances induced by RF fields according with IEC 61000-4-6	3 V rms-value 150 kHz to 80 MHz	3 V	<i>d</i> = 1,2 √P
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
			<i>d</i> = 2,3 √P for 800 MHz to 2,5 GHz
			with <i>P</i> as rated power of trans- mitter in watt (W) according to description of transmitters manu- facturer and d as recommended protection ratio in meters (m).
			The field intensity of stationary radio transmitter should be lower than the level of compliance <sup>b</sup> in all frequencies according to an analysis on site <sup>a</sup> .
			In the vicinity of instruments which have following symbol disturbances are possible.
			((t <sub>2</sub> ,))

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.

<sup>a</sup> 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<sup>®</sup> 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<sup>®</sup> Relax to another place is necessary.

 $^{\scriptscriptstyle b}$  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 $^{\!\otimes}$ Relax

The URYXXON<sup>®</sup> Relax is destined for the use in electromagnetic environments where RF-disturbances are controlled. The user of URYXXON<sup>®</sup> 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<sup>®</sup> Relax.

Rated power of transmitter W	Protection ratio, dependent on transmitter frequency m			
	<b>150 kHz to 80 MHz</b> $d = 1.2 \sqrt{P}$	<b>80 MHz to 800 MHz</b> $d = 1.2 \sqrt{P}$	<b>800 MHz to 2,5 GHz</b> <i>d</i> = 2.3 √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.

#### 16.3. 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.