Urisys 1100®

Operator's Manual

Roche

cobas®

Life needs answers

Symbols and Abbreviations

The packaging material, the identification plate on the instrument and the manual may contain the following symbols or abbreviations:

Please consult instructions for use

Caution (refer to accompanying documents). Please refer to safety-related notes in the manual accompanying this instrument.

Store at

Manufacturer

Date of manufacture

RoHS

Approvals
The Urisys 1100 analyzer (serial# 09652551 and higher) meets the requirements laid down in: Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

GTIN

Global trade item number

REF

Catalogue number

IVD

For in vitro diagnostic use

CE

This product fulfils the requirements of Directive 98/79/EC on in vitro diagnostic medical devices.

Table of Contents

1. Introduction

Revision History

Manual version	Software version	Revision date	Amendments
4.0	5.x	June 2008	Operator ID, limited lock-out function,Device ID, compatibility of barcode reader, ASTM protocol
5.0	5.x	2013-10	Cobas brand
6.0	5.x	2018-01	New material numbers Changed test strip handling Remove of the intended use of Combur[7]Test and Combur[5]Test on Urisys 1100.
7.0	>=5.7	2019-03	Combur[5] and Combur[7] removed from software flow chart.
8.0	>=5.7	2020-06	Quality control (QC) section added. Test strip tray lifetime added. Cleaning and maintenance section improved. Paragraph "Values obtained are implausible when compared with those from visual evaluation" revised in section "Error messages and troubleshooting". Paragraph „Control values fall outside the designated ranges" added in section "Error messages and troubleshooting".

The Urisys 1100 system is a reflectance photometer designed to read and evaluate the urine test strips Combur[10]Test® UX from Roche Diagnostics. It reads the strips under standardized conditions, saves the results to memory and outputs them via its own inbuilt printer and/or serial interface.

Combur[10]Test® UX test strips are marketed in Canada as Chemstrip 10 A test strips.

The Urisys 1100 system is designed for In Vitro Diagnostic (IVD) use by qualified physicians and laboratory staff.

BIOHAZARD: Treat all samples of human origin as being potentially infectious.
Always observe good laboratory practice.

Using the Urisys 1100 system eliminates factors known to affect visual evaluation of urine test strips, such as:
- Variable lighting conditions at the workplace
- People's individual skill at matching colors and their limits of concentration
- Different reaction times for the test strips
- Clerical errors
- Strong color of the urine sample

The following symbols are used throughout this document.

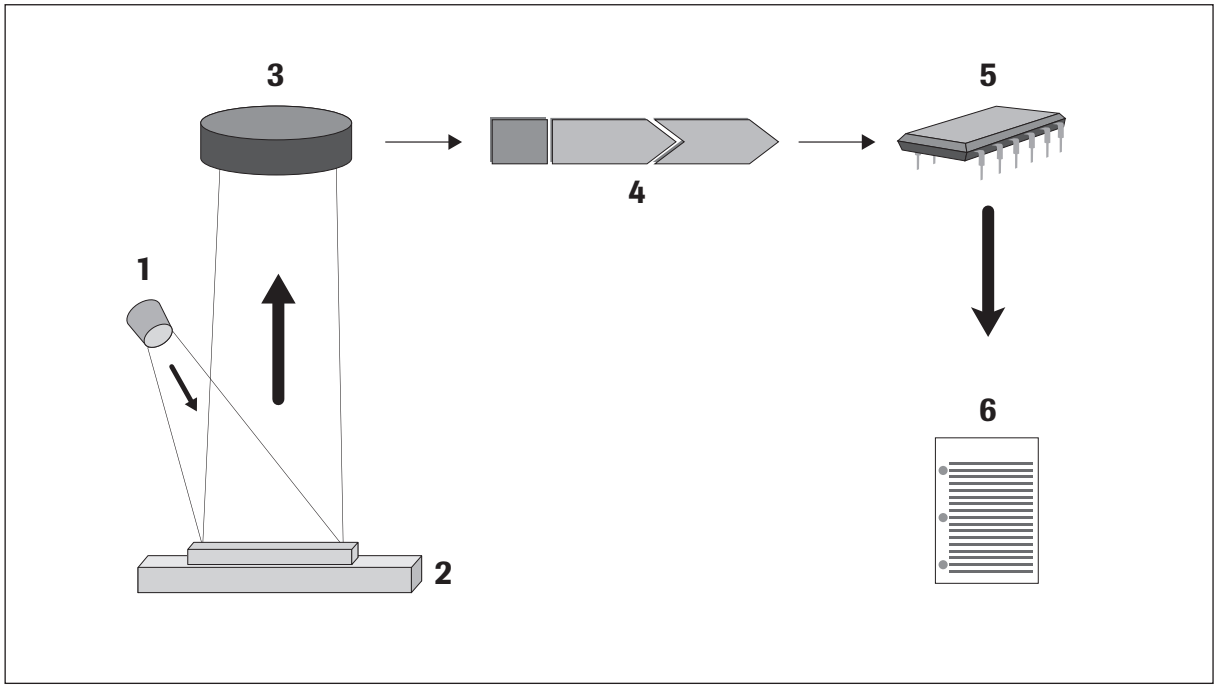
Symbols/Signs	Explanation
	**WARNING/CAUTION: Indicates a potentially hazardous situation that if not avoided could result in personal injury or damage to the instrument. This symbol is also used to highlight situations that can compromise results.**
	**BIOHAZARD: Indicates a potentially dangerous situation involving the presence of biohazardous material. All safety precautions must be taken to prevent personal injury or damage to the equipment.**
	**ATTENTION: Indicates special problems or important information. Read the accompanying text carefully.**

2. System Description

2.1 Measuring Principle

The test strip is placed on a sliding test strip tray, and a stepping motor moves it under the reading head, which remains stationary. The analyzer reads the reference pad, followed by each of the test pads on the strip.

The reading head contains LEDs that emit light at various wavelengths. Reading is done electro-optically, as follows:



The LED (1) emits light of a defined wavelength on to the surface of the test pad (2) at an optimum angle. The light hitting the test zone is reflected more or less intensely depending on the color produced on the test pad, and is picked up by the detector, a phototransistor (3) positioned directly above the test zone. The phototransistor sends an analogue electrical signal to an A/D converter (4), which changes it to digital form. The microprocessor (5) then converts this digital reading to a relative reflectance value by referring it to a calibration standard.

Finally, the system compares the reflectance value with the defined range limits (reflectance values that are programmed into the analyzer for each parameter) and outputs a semi-quantitative result (6).

Each test pad is read photometrically after a lead (incubation) time of about 55–65 seconds. In strongly alkaline urine samples, the Urisys 1100 system automatically corrects the result of the Specific Gravity test.

2.2 Components and Functions

Component	Function
1 Printer cover	Flips up for insertion of printer paper
2 Display/keypad	LCD display and three function keys for menu-driven operation and interfacing with the user
3 Test strip tray	Holds and anchors the strip
4 START button	▪ Starts the reading process ▪ Closes submenus and returns to the starting menu (Ready-to-Measure status)
5 On/Off switch	Powers the unit on and off
6 Serial interface	For connection to a personal or host computer
7 Power socket	Socket used to connect the analyzer to the mains adapter
8 5-pin DIN socket	For connecting a barcode reader or AT/PC keyboard

3. Software

3.1 Overview

The Urisys 1100 system's software provides a user interface that enables all laboratory-specific settings and recurrent functions to be selected via the liquid crystal display and function keys (see Sections 3.2 and 3.3).

The three function keys assume the particular function displayed on the second line of the liquid crystal display. The first line of the display is used for system status and user information.

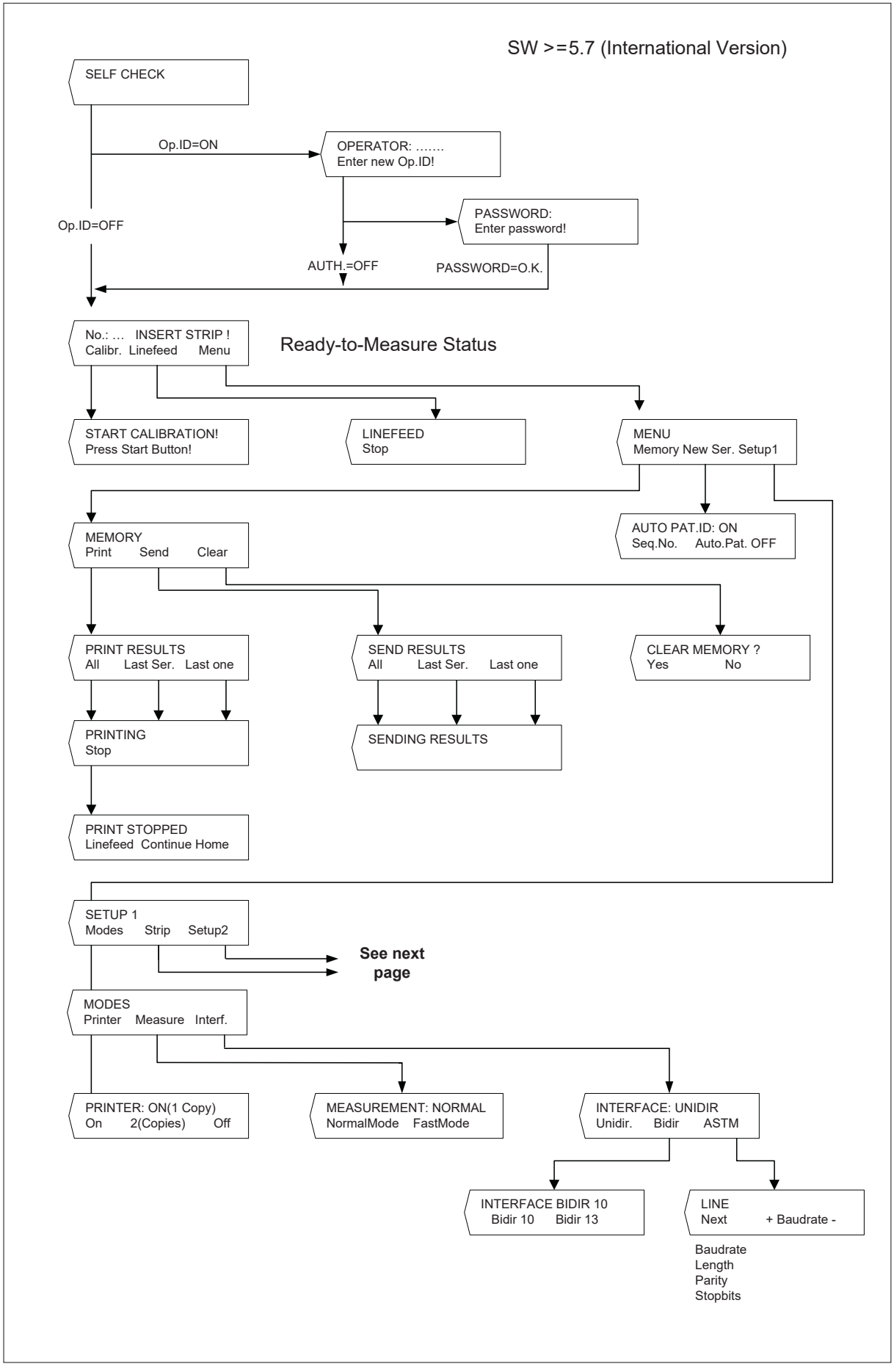
The user interface is self-explanatory, so that only details of the major functions are presented here.

Pressing the START button within any submenu accepts the chosen instrument state or function, and returns the system from menu display to Ready-to-Measure status.

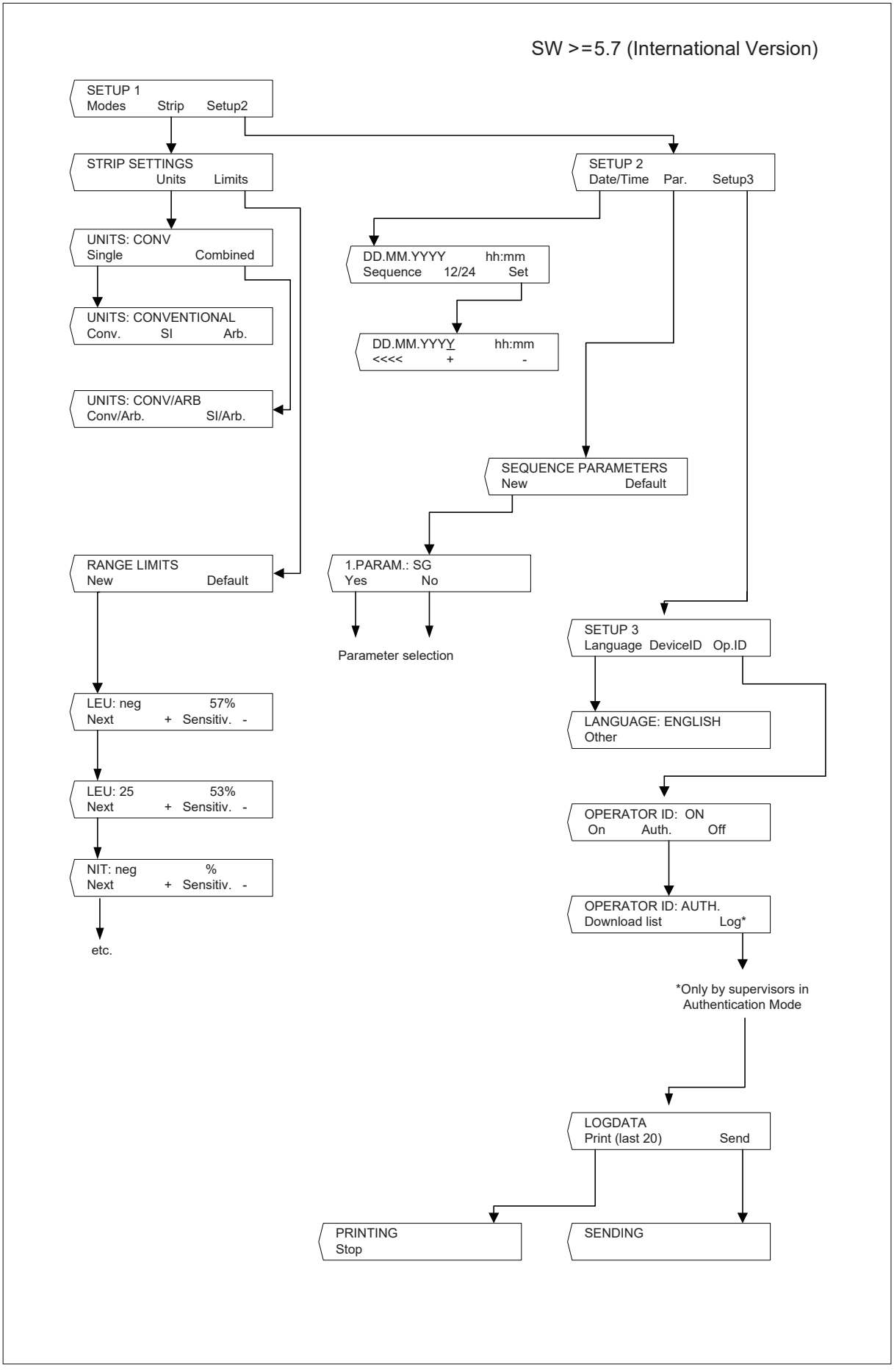
The instrument switches from the Ready-to-Measure status or the status displayed, respectively, to the Standby mode after 5 minutes of function key inactivity. During Standby, the date and time are displayed. Ready-to-Measure status can be resumed by pressing the START key, except when certain error messages are displayed (see Section 9).

3.2 Menu Structure (Flowchart)

Pressing the START button confirms the setting, closes the submenu, and resumes Ready-to-Measure status.



Pressing the START button confirms the setting, closes the submenu, and resumes Ready-to-Measure status.



3.3 Menu Functions

Self Check: During Self Check at power-on, the analyzer automatically checks that the program chip, the test strip tray transport mechanism, the printer connection and optical system are all OK. The test strip tray type is checked (see Section 4) to ensure that it correctly matches the strip type selected in the menu.

Calibration: For requesting calibration with Control-Test M (see Section 5).

Linefeed: Causes paper to advance. The linefeed is stopped by pressing the left function key ("Stop") (see Section 4).

New Series: For starting a new series of measurements at sequence number 1. It is also possible to have an Automatic Patient ID (see Section 7.1).

Memory: The analyzer can store up to 100 results together with date and time of measurement, sequence number and patient ID (if entered). Memory is automatically cleared every time the date changes.

After memory has been erased, "NO RESULTS STORED" is displayed when "Memory" is pressed. Pressing the START button resumes Ready-to-Measure status. "MEMORY FULL" and the options "Print/Send/Clear" are displayed when the memory is full. Memory must be cleared before the analyzer can resume Ready-to-Measure status.

Print Results: For generating a printout of stored results. The options are as follows:
- **"All":** All results in memory
- **"Last Series":** The most recent series of readings
- **"Last One":** The most recent reading

Printing can be repeated as often as desired. Printing can be interrupted by pressing the left key ("Stop"), for example to allow a new roll of printer paper to be inserted ("Linefeed"), and subsequently resumed ("Continue"). The analyzer resumes Ready-to-Measure status when the "Home" key is pressed or when printing has finished.

Send Results: For sending stored results to the serial interface. Options are the same as for "Print Results". Results can be sent as often as required (see also Sections 7.7 and 10.1).

Clear Memory: Erases results from memory.

Mode: Choice of **Print**, **Measure** and **Interface** modes.

Printer: Printer options are:
- **"On":** The printer is switched on. Each result is printed once.
- **"2 Copies":** In Normal mode, each result is printed twice. Note: after serial readings (Fast mode) and when the printout is a repeat printout (activated by the "Print Results" function), each result is printed only once.
- **"Off":** For switching off the printer when the printout of results is only required at the end of a series of readings (activated by the "Print Results" function), or when results are to be sent via the interface to a personal computer or host only.

Measurement: Choice of measuring mode:
- **"NormalMode":** Read cycle 70 seconds, incubation within the analyzer (see Section 7.2)
- **"FastMode":** Read cycle 30 seconds, incubation outside the analyzer (see Section 7.4)

Interface: Choice of "unidirectional", "bidirectional" or "ASTM" data transfer. For further details, see Sections 7.7 and 10.

Logdata: Choice of sending the log files to the host PC or printing out the last 10 logged data. (Only by supervisors in Authentication mode)

Strip Settings: For selecting, units and range limit settings.

Units: Options are:
- **Conventional units** (mg/dL)
- **SI units** (mmol/L)
- **Arbitrary units** (1+, 2+, 3+, 4+)

Either single units or combined units (conventional/arbitrary or SI/arbitrary) can be selected.

The operator selects a unit in which the results are to be stored, printed and/or transferred to a computer. After a new unit has been selected, the repeat printout (activated by "Print Results") and all following printouts and/or data transfer (activated by "Send Results") will be in the newly chosen unit.

Range Limits: For changing the reflectance range limits. Changing the range limits for the result intervals alters evaluation sensitivity (see Sections 3.4 and 3.5).

Language: This enables the display language to be set. The "Other" option allows the operator to choose between English, German, Italian, Spanish and French.

Device ID: Displays the 5 digits device ID, which is part of the factory settings and cannot be changed.
The device ID will also be sent to the host.

Operator ID: Choice between **Normal** and **Authentication** modes for the operator identification. If activated the input of an operator ID will be required by the start of the instrument.

The Operator ID will appear in the result printout and will also be sent to the host PC. Authentication mode offers a lock-out function and requires the ASTM protocol. (Refer Section 4.2 and 7.6 for details.)

Parameter (Par.): For selecting the order and number of parameters in the patient report and for "unidirectional" data transfer.

To change the order or number of parameters in the patient report, press the function key on the left ("New") with the display showing "SEQUENCE PARAMETERS". This calls up the first item in the patient report ("1. PARAM.:") followed by the first parameter. Press "Yes" to confirm the parameter in the position shown. Pressing "No" causes the next test strip parameter to be offered for the first position (display = "1. PARAM.: PH"; etc.).

As soon as "Yes" has been pressed to confirm a parameter as the first item, the second item is shown with "2. PARAM.:" followed by the next, not yet confirmed, test strip parameter. Press "Yes" or "No" to select the parameter as the second item in the patient report, and so on.

If there are any test strip parameters that are to be suppressed in the patient report, terminate selection following the most recently confirmed parameter by pressing "START".

You can undo the selection by pressing the "Default" function key when the display shows "SEQUENCE PARAMETERS". The Urisys 1100 system always measures and memorizes all of the parameters on whichever test strip is used. If, after reading, you wish to reset the choice of parameters to the standard setting, you can reinstate the complete report through the "MEMORY/Print" or "MEMORY/Send" menu.

Date/time: For setting the date and time.

The factory default is the date in Day-Month-Year order and the time in hours (24-hour system) and minutes. If required, the time can be displayed in the "12-hour plus a.m./p.m." system. Pressing the "Sequence" key allows the date format to be changed to Month-Day-Year or Year-Month-Day. "Set" causes the date and time to be displayed and set. Pressing the left function key (<<<) moves the blinking cursor to the left. The time or date unit highlighted by the cursor can then be increased or decreased by pressing the keys (+ / -).

Pressing the START button confirms the setting, closes the submenu, and resumes Ready-to-Measure status.

3.4 Results Table

The Urisys 1100 system prints the results in the following gradation of concentration:

Parameter	Conventional Units (Conv.)	SI Units (SI)	Arbitrary Units (Arbitrary)
SG (Specific Gravity)	1.000 1.005 1.010 1.015 1.020 1.025 1.030	1.000 1.005 1.010 1.015 1.020 1.025 1.030	1.000 1.005 1.010 1.015 1.020 1.025 1.030
pH	5 6 6.5 7 8 9	5 6 6.5 7 8 9	5 6 6.5 7 8 9
LEU (Leukocytes)	neg 25 Leu/µL 100 Leu/µL 500 Leu/µL	neg 25 Leu/µL 100 Leu/µL 500 Leu/µL	neg 1+ 2+ 3+
NIT (Nitrite)	neg pos	neg pos	neg pos
PRO (Protein)	neg 25 mg/dL 75 mg/dL 150 mg/dL 500 mg/dL	neg 0.25 g/L 0.75 g/L 1.5 g/L 5.0 g/L	neg 1+ 2+ 3+ 4+
GLU (Glucose)	norm 50 mg/dL 100 mg/dL 300 mg/dL 1000 mg/dL	norm 3 mmol/L 6 mmol/L 17 mmol/L 56 mmol/L	neg 1+ 2+ 3+ 4+
KET (Ketone)	neg 5 mg/dL 15 mg/dL 50 mg/dL 150 mg/dL	neg 0.5 mmol/L 1.5 mmol/L 5 mmol/L 15 mmol/L	neg (+) 1+ 2+ 3+
UBG (Uribilinogen)	norm 1 mg/dL 4 mg/dL 8 mg/dL 12 mg/dL	norm 17 µmol/L 70 µmol/L 140 µmol/L 200 µmol/L	neg 1+ 2+ 3+ 4+
BIL (Bilirubin)	neg 1 mg/dL 3 mg/dL 6 mg/dL	neg 17 µmol/L 50 µmol/L 100 µmol/L	neg 1+ 2+ 3+
ERY (Erythrocytes)	neg 10 Ery/µL 25 Ery/µL 50 Ery/µL 250 Ery/µL	neg 10 Ery/µL 25 Ery/µL 50 Ery/µL 250 Ery/µL	neg 1+ 2+ 3+ 4+

3.5 Changing the Range Limits

The reflectance range limits for the lower concentration intervals can be altered to a limited extent for all test parameters except SG (specific gravity) and pH.

To change the range limits, choose “RANGE LIMITS” and press the left function key (“New”). The lowest interval for the first parameter is displayed next to the current range limit setting. Through the keys (+ / -), the reflectance value can be raised or lowered and evaluation sensitivity thus increased or decreased.

If the first positive concentration level is to be eliminated, the reflectance range limits of the negative/normal range can be lowered manually, and the reflectance range limit of the first positive concentration interval raised to this reflectance value.

Pressing “Next” stores that setting and moves to the next concentration interval or the next parameter.

The sequence can be terminated at any point by pressing the START button. The new range limits are printed out together with a date and timestamp and the analyzer resumes Ready-to-Measure status. All changes made to the limits are flagged with an asterisk on the printout after the concentration interval.

Pressing the “Default” key in the “RANGE LIMITS” display window reinstates the factory defaults and causes them to be printed together with a date and timestamp.

If range limits have been altered manually, all results are printed with an asterisk in the line below the Device ID.

Changed range limits apply only to the test strip type for which the changes are made.

CAUTION: The correctness of results obtained after the user has altered the ranges or reflectance values is not warranted by Roche Diagnostics. The user is responsible for validating the consistency of results after changes have been made.

4. Installation

WARNING: Read the Urisys 1100 Operator’s Manual carefully before installation, so as to ensure proper operation of the analyzer from the outset.

ATTENTION: If your analyzer has been exposed to marked changes in temperature and/or humidity, wait for it to acclimatize sufficiently before operating it.

ATTENTION: Upon receipt, check the contents of the box for completeness. If the contents have suffered any damage in transport, contact your local Roche representative.

Content:
- Urisys 1100 analyzer
- Adapter 100 V - 240 V, 50/60 Hz
- Power Cable
- Roll of printer paper
- 1 test strip tray, Type “C”, for reading Combur[10]Test® UX test strips
- Operator’s Manual

CAUTION: To ensure your readings are always accurate, do not set up the Urisys 1100 system in close proximity to devices that create high-frequency fields, as they may interfere and produce false results. Such devices include, for instance, walkie-talkies, mobile telephones, microwave ovens and diathermic equipment.

Instrument connection

Power-on

(1) Unpack the Urisys 1100 system and place it on a stable, level surface. Do not expose the analyzer to direct sunlight or other source of direct light (for example a spot lamp). For measurements of Combur[10]Test® UX test strips, the test strip tray with the type mark C on the reverse side is required.

(2) Connect the AC adapter to the power socket at the rear of the instrument and to a readily accessible AC wall socket.

Insertion of the test strip tray

(3) Pick up the test strip tray, Type "C", and with the retaining bar nearest to you pushed down (see Figure 1), slide it into the slot below the function keys, so that the near edge of the test strip tray is flush with the near edge of the analyzer (see Figure 2).

CAUTION: Be careful not to touch the grey reference pad (A). Contamination of the reference pad may impair the quality of the results obtained.

ATTENTION: The test strip tray must be replaced 18 months after first date of use or if the Urisys 1100 system cannot be calibrated despite several attempts (see Section 5, Calibration).

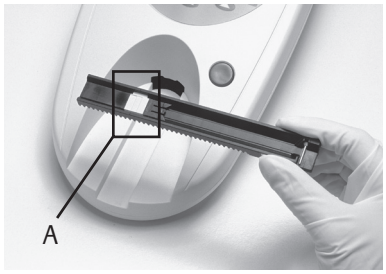


Figure 1


Figure 2

Paper Insertion

To release the printer paper cover, press the structured area immediately below the cover (see Figure 3). The cover can then be lifted back. Place the paper roll in the compartment and pull out the first few centimetres of paper to just beyond the edge of the compartment. The thermosensitive side of the paper (the outer surface of the paper roll) should be facing downwards (see Figure 4). Close the cover again by pressing until it locks audibly into position.

Figure 3

Figure 4

ATTENTION: To remove the printed test report, tear off the paper by pulling it in front across the edge.

(4) Switch on the Urisys 1100 system using the on/off switch at the rear of the instrument.

Self Check

(5) The analyzer automatically carries out a self check. The default language setting for the Urisys 1100 system is English. The instrument is factory set to read Combur[10]Test® UX test strips. It checks that the correct test strip tray has been inserted. On completion of the self check, the test strip tray is transported to the start position and the retaining bar opens (see Figure 5). "SELF CHECK OK" is printed together with a date and timestamp.

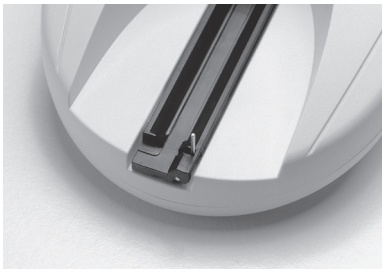


Figure 5

ATTENTION: If the message E9 Wrong Tray! is displayed after the Urisys 1100 system is switched on, press the START button. The selection menu STRIP TYPE is displayed. Select C-10 by pressing the left function key.

When the self test is finished a sound is heard from the printer. The display will show Insert Strip. If the paper has already been inserted, the printout "Self Check OK" is executed with date and time; this happens whenever the instrument is switched on. If an error occurs, consult the Operator's Manual or contact your local Roche Diagnostics service representative.

(6) Upon first use of the analyzer, the message "REPEAT CALIBRATION" appears after a successful self check. Press the "No" key to attain **Ready-to-Measure** status. **This also happens if the instrument is not used for more than seven days. To bring the instrument to Ready-to-Measure mode, insert the paper and execute the calibration.**

(7) To set the language of your choice, press the key sequence "Menu/Setup 1/Setup 2/Setup 3/Language/Other" (see Sections 3.2 and 3.3).

(8) The Urisys 1100 system leaves the factory with the default settings for Printer, Measure and Interface modes, Test Strip Type, Units, Language, Date/time format (see Section 3.2) and Operator ID. If your laboratory works differently, individual preferences can be entered via the menus.

(9) Calibrate the analyzer with Control-Test M (see Section 5).

Power-off

We recommend that the analyzer be switched off at the end of each working day and that the mains adapter be unplugged from the AC wall socket (see Section 8.1, Cleaning).

4.1 Operator ID

The Urisys 1100 software allows the activation/deactivation of the operator identification code, containing up to 12 alphanumeric characters. The Operator ID and Authentication mode can be activated in Setup 3.

! **ATTENTION: Please ensure that you have a barcode reader and/or an AT/PC keyboard prior to activation, as you will need one for this function.**

Normal

If activated, the operator ID is asked upon every restart of the system and coming out from sleep mode.
This operator ID can contain up to 12 alphanumeric characters and will be printed out together with the test results and will be sent to the host.

! **ATTENTION: If the maximum length of identification is exceeded the input cursor will skip to the first character and the identification will be overwritten.**

4.2 Authentication

It is possible to download up to 300 operator IDs with corresponding passwords (up to 12 alphanumeric characters) from the host PC via the ASTM protocol.

Device can be used only by an operator with ID and password in the downloaded list. Entry of incorrect operator ID and passwords causes a lock out. This prevents access of the instrument by unauthorised users.

Operators having supervisor rights (maximum 2) have access to all results, may send the instrument log file to the host or print the last 10 actions of the log file and may deactivate the authentication mode.

5. Calibration

The Urisys 1100 system is calibrated before leaving the factory. When installed, it must be recalibrated with Control-Test M calibration strips before the first samples are read, and thereafter every seven days. Control-Test M calibration strips consist of a grey plastic material that is standardized to give constant, defined reflectance readings. The purpose of calibrating the analyzer is to compensate for aging effects that influence the optical system and the grey reference pad in the test strip tray. If the compensation needed is excessive, for example because the reference pad is badly soiled, or an LED is defective and cannot emit the required amount of light, an error message is displayed (see below).

The Urisys 1100 system automatically requests a new calibration every week. This is why, when the instrument is installed, the "REPEAT CALIBRATION!" message is displayed following the successful self check and also one week after the latest valid calibration.

Press the left function key ("Yes") to read the "START CALIBRATION!" message.

Procedure

1. Remove a calibration strip from the Control-Test M container. Be careful not to touch the pads and do not allow them to come into contact with urine.

2. Place the calibration strip, with the test pads facing upwards, on the test strip tray so that its leading edge is held by the clip at the front end of the insertion slot. **The retaining bar must be open** (see Figures 6 and 7). Before calibrating, ensure that the test strip tray is clean and dry.

Figure 6

Figure 7

! **ATTENTION: It is very important that the calibration test strip locks into the instrument correctly in order to ensure the quality of the calibration.**

3. Press the START button. An acknowledging beep sounds. After warming up time, the test strip tray advances slightly, the retaining bar closes, and the grey reference pad on the test strip tray and the calibration pads are read.

4. The test strip tray is then transported back to the start position, and the retaining bar opens. Remove and dispose of the calibration strip. Use each calibration strip once only.

5. If the calibration is valid, the result is stored together with the date and time, and printed (see Figure 8). Remove the calibration strip and discard properly (follow test strip insert instructions).

Figure 8

CAUTION: Regular calibration is necessary to ensure the quality of the results obtained. Roche Diagnostics cannot warrant the correctness of results if the system is not calibrated regularly.

ATTENTION: You can recalibrate the system at any time, even if a week has not elapsed since the last calibration, for example if a Combur[10]Test® UX test strip has returned an implausible result. Start the calibration procedure by pressing the left function key ("Calibr.") with the analyzer in Ready-to-Measure mode. The message "START CALIBRATION !" appears. Follow the calibration procedure described above.

ATTENTION: If you reply with "No" to the weekly "REPEAT CALIBRATION !" reminder, for example because you have used up your supply of Control-Test M calibration strips, the message "Repeat calibration" is printed together with each patient report from subsequent readings. Obtain a new pack of Control-Test M and recalibrate immediately.

Calibration printout
If the new calibration results are within the permitted range, the message "CALIBRATION O.K." is automatically printed with a date and timestamp and also a list of reflectance values for measuring positions 1–11 for the orange LED (middle column) and green LED (right column) (see Figure 9).

Figure 9

Calibration errors
If the results obtained for the reference pad or the calibration strip are outside the programmed tolerances, the following messages appear: "REFERENCE PAD ERROR !", "CALIBRATION INVALID !" or "CALIBRATION ERROR !".

In the event of a calibration error or if the calibration was invalid, repeat the calibration procedure with a fresh Control-Test M calibration strip. Press the START button to return to the "START CALIBRATION" menu. Follow the same calibration procedure as above. When the message "CALIBRATION O.K." has been printed, proceed with the reading of test strips. If you continue to receive an error message, see Section 9.

If the analyzer is switched off when one of the above-mentioned calibration status messages is displayed and then switched on again, it reverts to Ready-to-Measure status following a successful self check, provided that the most recent calibration was carried out not more than a week ago. Otherwise, the message "REPEAT CALIBRATION !" appears (see above).

6. Quality control (QC)

Quality control (QC) measurements ensure the proper functioning of the analyzer. A QC material for which the results are known is measured and the results are then compared against the defined ranges for these known results.

Use commercially available urine controls, or other suitable control material. Run a positive and negative control at least after the weekly calibration (see Section 5 Calibration) and when a new vial of test strips is opened.

Procedure

The test strip handling, measurement procedure, result reporting and data transmission in general are described in Section 7. For the QC measurements follow the instruction provided in Section 7.2 Normal mode (for Single Reading).

Values obtained for these controls should fall within the limits established by the laboratory or the manufacturer. If the measured results obtained are outside the established limits follow the troubleshooting actions provided in chapter 9 Error Messages and Troubleshooting: CONTROL VALUES FALL OUTSIDE THE DESIGNATED RANGES.

7. Reading Test Strips

7.1 Overview

The Urisys 1100 system is very easy to use. Simply insert the test strip when the sample number is displayed (refer to Section 7.2), then press the START button to commence reading. The analyzer can be operated in two different modes:

1. In **Normal Mode,** the Urisys 1100 system automatically waits for the strip to incubate for 55 seconds before it reads the first test pad. Seventy seconds after the START button is pressed, the measurement is completed and the test strip tray moves to the start position. Throughput in this mode is approximately 50 strips per hour.

2. In **Fast Mode,** which can be selected from the menu, the test strip is measured directly after START is pressed. In this case, it is up to the user to time the incubation period outside the analyzer (see Section 7.4). Using **Fast Mode** enables a 30-second cycle to be maintained.

Each time a strip is read, the grey reference pad in the test strip tray is evaluated to compensate for temperature and aging effects that may influence the optical system. If the compensation needed is excessive, for example because the reference pad is badly soiled or an LED is defective and cannot emit the required amount of light, an error message is displayed (see Sections 8.2 and 9).

The Urisys 1100 system assigns to each reading a consecutive sequence number (sample number) having a maximum of three digits. The sequence start number automatically reverts to 1 each time the date is incremented. You may, if you wish, reset the sequence number to 1 via the “New Series” function, for example when one series of measurements has been completed and another is due to begin.

In **Automatic Patient ID** mode the instrument will assign automatically unique serial numbers to the tests results which have no Patient IDs. These unique numbers are ascending serial numbers based on the total number of tests performed on the instrument and cannot be altered nor cleared.

Whenever there has been five minutes of inactivity, the analyzer automatically switches to **Standby** mode. The test strip tray advances slightly so as to close the retaining bar, and the display shows the date and time. The analyzer resumes Ready-to-Measure status when the START button is pressed.

7.2 Normal Mode (for Single Readings)

BIOHAZARD: Always wear protective gloves when handling and disposing of samples of human origin.

The Urisys 1100 system is ready to read when the display shows a sample number and “INSERT STRIP !”.

ATTENTION: To ensure that urinalysis is carried out correctly, read the package insert included with the test strips.

1. Dip the test strip briefly (1 sec) in the urine sample.

2. Draw the long edge of the strip along the rim of the specimen container to remove excess urine (see Figure 10).

Do not bend test strip

Figure 10

3. Place the test strip, with the test pads facing upward, on the test strip tray so that its leading edge is held by the clip at the insertion slot. **The retaining bar must be open** (see Figure 11). About 2 mm of strip must be held under the clip (see Figure 12).

Figure 11

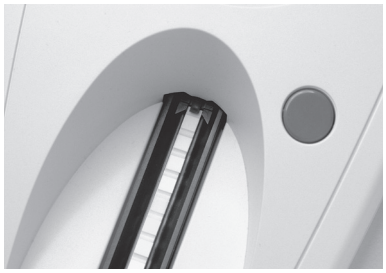


Figure 12

4. Press the START button (see Figure 13). An acknowledging beep sounds. After warming up time, the test strip tray advances slightly, the retaining bar closes, and the grey reference pad on the test strip tray is read (see Figure 14).

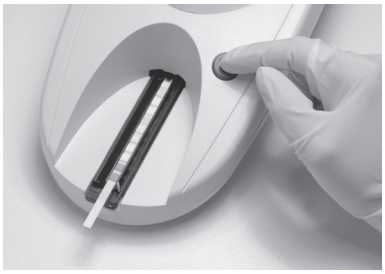


Figure 13

Figure 14

ATTENTION: Ensure that the retaining bar is locked into place and that the test strip is in the correct position. If the test strip is not correctly located in the middle of the test strip tray, move it gently to the side until it is properly aligned (see Figure 15). Be careful not to move the test strip tray.

Figure 15

5. Fifty-five seconds after the START button is pressed, the first test pad is measured, followed by the others. After that, the test strip tray returns to the start position and the retaining bar opens.

6. Remove and dispose of the test strip. Wipe any urine residues from the test strip tray with a lint-free cloth (see Figure 16).

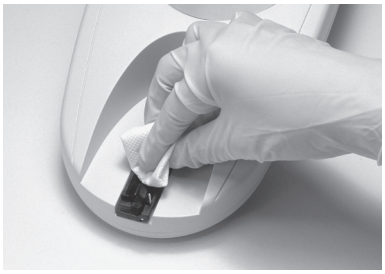


Figure 16

7. The result will be printed out and the next sample number will be displayed. The next test strip can be dipped, wiped off, placed in the test strip tray and read by pressing the START button. Refer to Section 7.6 for details of what must be observed when working with patient identification numbers.

7.3 Patient Report

The patient report is printed out together with the sequence number, device ID, operator ID, date and time. The patient's name will also appear on the print out if entered prior to measurement (see Section 7.6). Test results which diverge from negative or normal values are flagged with an asterisk before the parameter concerned. For selection of concentration units and the order of parameters in the patient report, see Section 3.3. An asterisk printed in the line below the heading but before the first parameter of the test results list indicates that the reading was taken with changed range limits (see Section 3.5)

Figure 17

Tear off the printout, if desired, by pulling it horizontally over the edge.

WARNING: Thermal printing paper is sensitive to light and liable to age on prolonged exposure to bright light. Patient reports are thus best kept in a place away from light and high temperature.

7.4 Fast Mode (for Serial Readings)

You can also perform serial readings provided that the strips are dipped and incubated for about 45 seconds outside the Urisys 1100 system. For this type of reading, "Fast Mode" should be selected from the menu. Place the test strips on the Urisys 1100 system test strip tray after allowing them to incubate for approximately 45 seconds, pressing START to begin each reading.

The reference pad is read immediately, followed by the test pads on the test strip. Reading is complete after 30 seconds and the next sample number appears in the display. When working in Fast Mode, ensure that you have a foolproof system for matching sequence numbers to samples.

Remarks:

1. Results obtained in Fast Mode are saved in memory immediately; however, printing is deferred. Printout of the whole series begins automatically following 60 seconds of inactivity. Check carefully whether all sequence numbers have been printed out. If any results are missing, press "Memory/Print" to printout stored results.

2. When Fast Mode is selected, the analyzer continues to operate in Fast Mode for the rest of the calendar day, even if the analyzer is switched off and then on again.

3. Fast Mode is cancelled as soon as the date is automatically incremented.

WARNING: When performing serial measurements in Fast Mode, allow the strips to react for approximately 45 seconds before inserting them in the Urisys 1100 system and pressing START. False-low or false-negative results may be obtained for some parameters if the reaction time is too short. Likewise, false-high results may be obtained for some parameters if the incubation time outside the Urisys 1100 system is too long.

7.5 Strip Measurement Error

If "STRIP MEASUREMENT ERROR !" appears, the test strip and/or analyzer have probably been incorrectly used. Refer to Section 9 for details.

7.6 Entering Patient ID, Operator ID and Authentication Password

Patient ID
When the analyzer is ready to measure ("INSERT STRIP !" displayed), you may enter a Patient ID not exceeding 13 characters in length against the currently shown sequence number by means of a barcode reader or AT/PC keyboard (see Section 10.2). The Patient ID can be verified in the display window and entered again if necessary. The last Patient ID entered is stored when the START button is pressed, i.e. when reading commences, and is printed out and/or sent to the serial interface together with the test result.

Operator ID
If the operator ID is activated, the instrument request the input of the operator ID immediately after the self check is performed when the instrument is turned on, or when it leaves the stand-by mode. You may enter an operator ID up to 12 alphanumeric characters by means of a barcode reader or an AT/PC keyboard.

Authentication
In the authentication mode the user will be required to input his/her apart from the operator ID list, also the corresponding password in order to have access to the instrument and the test results he/she had performed.
Operators with supervisor rights have access to all results, may send the instrument log file to the host or print the last 10 actions of the log file and may deactivate the authentication mode.
The list of operator IDs with corresponding passwords may be updated from the host PC using the "Download List" function key.

ATTENTION: A new Patient ID should only be entered from the keyboard after the preceding measurement has been completed and results printed out (Normal Mode). This allows the operator to check correct entry directly in the display.

ATTENTION: If a Patient ID is entered via the barcode reader while a test strip is being read, the Urisys 1100 system assigns that ID to the next sample number in the sequence. The Patient ID can only be erased by switching the Urisys 1100 system off and then on again before starting the next reading.

ATTENTION: If an identification will be entered and does exceed the maximum lengths of 13 characters for the patient Id or the 12 characters for the operator ID the cursor will move to the beginning (left side) of the display and delete the previously written characters.

When data are entered from the keyboard, each character appears immediately in the display. It can be erased by backspacing, and corrected as necessary. **Press the keyboard ENTER key to terminate input,** otherwise the Urisys 1100 system cannot start reading. Press the keyboard Escape key to delete the entire entry or turn the Urisys 1100 system off and then on again.

7.7 Data Transmission to a PC or Host Computer

In **unidirectional** mode, the results are transmitted immediately together with the sequence number, Patient ID (if entered), date and time.
In **bidirectional** mode, transmission can only be accomplished by using the “Send” function when “MEMORY” is displayed. If a bidirectional PC/host communication link cannot be established, the Urisys 1100 system aborts transmission after several attempts and reports an “INTERFACE ERROR !” (see Section 9).
In **ASTM** mode the results, sequence number, Operator ID, Device ID, Patient ID (if entered), date and time of the measurement, and of the last calibration will be sent to the host.

For further information on the serial interface, refer to Section 10.1.

! **ATTENTION: Ensure that all required data is backed up on a regular basis.**

8. Cleaning and Maintenance

The Urisys 1100 system is designed for maintenance-free operation. Protect the instrument from extremes of temperature and high atmospheric humidity (see Section 11), and keep it out of bright light (direct sunlight, spot lamps, etc.).

Maintain hygiene by keeping the exterior parts and surfaces of the instrument clean. For cleaning we recommend applying a commercial cleaning agent or disinfectant (preferably 70 % alcohol) with a moist cloth. Take care that no liquid enters the instrument.

8.1 Cleaning the instrument

1. Switch off the instrument
2. Pull the test strip tray out of the instrument
3. Moisten a cloth with water or a neutral detergent, wring it out (the cloth must be damp not soaked) and clean the exterior parts and surfaces of the instrument.
4. Afterwards moisten a cloth with disinfectant (preferably 70% alcohol), wring it out (the cloth must be damp not soaked) and wipe the exterior parts and surfaces of the instrument.

CAUTION: Ensure that no liquid enters the instrument, wipe the housing, and never spray it!
Let the housing dry before proceeding to read.

8.2 Cleaning the Test Strip Tray

BIOHAZARD: Liquid waste and strip waste are potentially biologically hazardous. Always wear gloves if handling those materials. Dispose of the used test strips according to the regulations for handling potentially infectious material.

When inserting and removing test strips, take care that no urine residues come into contact with the retaining bar mechanism.

After each reading

To prevent carry-over and an accumulation of urinary deposit, wipe off residues for urine from the test strip tray with a dry, lint-free cloth after each reading (see Figure 18).

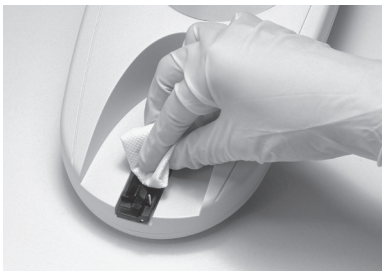


Figure 18

At the end of each working day, clean the test strip tray with water and, if necessary, with a commercial cleaning agent and disinfectant.

At the end of each working day

1. Switch off the instrument.
2. Pull the test strip tray out of the instrument.

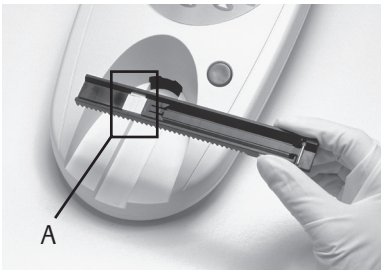


Figure 19

CAUTION: Be careful not to touch the grey reference pad (A). Contamination of the reference pad may impair the quality of the results obtained.

ATTENTION: To avoid contamination of the grey reference pad (A), you can remove it before cleaning (see Figure 21).

3. Rinse the strip tray under running water. Slight crystalline deposits, especially those contaminating the retaining bar mechanism or the cogs on the underside of the test strip tray and the positioning hole, may be removed with a soft brush.
4. Disinfect the test strip tray using 70% alcohol or another suitable disinfectant.
5. Dry the parts with a dry, lint-free cloth
6. Insert the reference pad if taken out before cleaning.

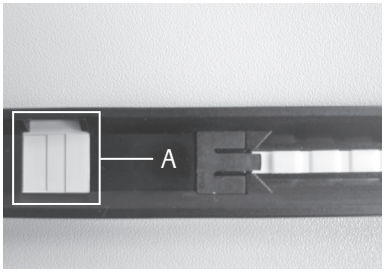


Figure 20

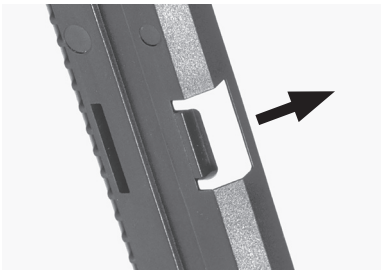


Figure 21

CAUTION: Ensure that the positioning hole (B) on the side of the test strip tray is absolutely dry (see Figure 22). This hole is used to ensure that the test strip tray is automatically positioned correctly in the instrument.

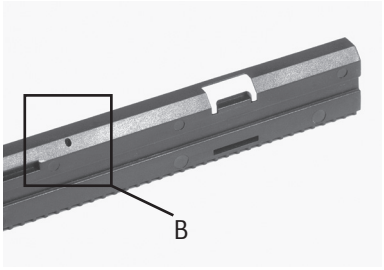


Figure 22

CAUTION: Take care not to damage the grey reference pad during cleaning. Ensure that there are no scratches on the surface and it is completely clean and dry before proceeding to read. If needed, replace it by a spare reference pad.
After replacing the grey reference pad, the instrument has to be calibrated. The instrument will not request the calibration automatically if the replacement happens within the weekly calibration period.

7. Pick up the cleaned test strip tray and, with the retaining bar nearest to you and closed (down), slide it into the slot below the function keys, so that the near edge of the test strip tray is flush with the near edge of the instrument.
8. If you wish to proceed with the next readings directly after cleaning the test strip tray, switch the Urisys 1100 system on again. During the self check the system will verify that the reference pad is in good condition for reading and that the positioning hole in the test strip tray (see Figure 22) is free. If not, an error message will be displayed (see Section 9).

9. Error Messages and Troubleshooting

Error messages are shown in the display but are not printed out. Following 5 minutes of inactivity, the analyzer switches to Standby mode. The error message is displayed again when the START button is pressed. In the event that the instrument is defective, contact your local Roche Diagnostics representative.

E1 REFERENCE PAD ERROR MIDDLE!

Cause: The middle portion of the reference pad on the test strip tray is soiled or damaged.
Action: Switch off the instrument. Carefully clean and dry the pad. Check if it is damaged (e.g. scratched, etc.). Insert the test strip tray again, then wait for the self check to finish. If the error message is repeated, replace the reference pad or use the spare test strip tray. Recalibrate with Control-Test M.

E15 REFERENCE PAD ERROR BOTTOM!

Cause: The bottom portion of the reference pad on the test strip tray is soiled or damaged.
Action: see E1

E16 REFERENCE PAD ERROR TOP!

Cause: The top portion of the reference pad on the test strip tray is soiled or damaged.
Action: see E1

E2 WRONG STRIP !

Cause: The test strip used is different from the one for which the analyzer has been programmed (Combur[10]Test® UX test strips).
Action: Press the START button. Repeat the measurement with Combur[10]Test® UX.

E3 STRIP MEASUREMENT ERROR !

Causes: No test strip is present on the test strip tray, or the strip is incorrectly positioned on the test strip tray, the urine on the test strip has dried, the test strip has not been dipped in urine.
Action: Press the START button. Repeat the measurement with a new test strip. Ensure that all test pads are dipped in the urine sample. Insert the strip correctly and ensure that the retaining bar is closed properly after START is pressed.

E4 CALIBRATION ERROR !

Cause: Calibration values differ from those obtained in the last valid calibration.
Action: Press the START button. Repeat the calibration with a new calibration strip taken from the Control-Test M container. Ensure that the strip is properly positioned under the clip on the test strip tray (see Section 5).

E5 CALIBRATION INVALID !

Cause: Calibration values are out of tolerance.
Action: Check the reference pad for soiling or damage. Clean if necessary (see Section 8.2) or use the spare test strip tray. Repeat the calibration with a new Control-Test M calibration strip (see Section 5). If the error message appears again, the instrument is defective.

E6 CHIP ERROR !

Cause: The program chip on the right of the analyzer underneath the printer cover (see Figure 23) is missing, is not making contact, is defective or contains an old software version.
Action: Switch off the Urisys 1100 system. Insert the program chip and switch the instrument on again. If "CHIP ERROR" appears again, the instrument is defective.

Figure 23

E7 MISSING TRAY !

Cause: No test strip tray inserted or test strip tray not inserted far enough to be engaged by the motor.
Action: Insert the test strip tray correctly (see Section 4). Press the START button.

E8 TRAY POSITION ERROR !

Cause: The positioning hole in the test strip tray (see Figure 24) is soiled or still wet after cleaning; the retaining bar is open while the test strip tray is advancing or the retaining bar mechanism is fouled with urinary deposit and blocked. (See Section 8.2)
Action: Clean, blow through or dry the positioning hole (using a lint-free cloth) to ensure that it is completely patent. Remove urinary deposits, if there are any, including those on the underside of the test strip tray. Insert the test strip tray again and press the START button. Ensure that the retaining bar is down and locked into place while the reading is taking place. If the error message appears again, use the spare test strip tray.

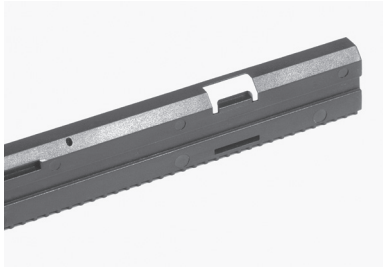


Figure 24

E9 WRONG TRAY !

Cause: The test strip tray used is not the one for the programmed test strip type, or the grey reference pad is missing from the test strip tray, or there is an instrument error.
Action: Press the START button. The strip type menu is displayed. The strip type must match the test strip tray type. Use the correct test strip tray, or order a new one (see Section 13). If the error message appears again, the instrument is defective.

E10 LIGHT BARRIER ERROR !

Cause: The light barrier used to control the position of the test strip tray is defective or the test strip tray transport is blocked.
Action: Pull out the test strip tray and return it to the start position. Press the START button. If the error message appears again, the instrument is defective.

E11 MOTOR STEP ERROR !

Cause: The stepping of the motor is out of tolerance or the advance of the test strip tray is blocked. This may be due to
- soiling on or between the cogs
- worn or broken cogs
- defective motor.

Action: Carefully clean the test strip tray. Remove any urinary deposits, including those on the underside of the test strip tray and the cogs. If the test strip tray is damaged insert the spare test strip tray. Press the START button. If the error message appears again, the instrument is defective.

E12 OPTICS ERROR !

Cause: The reference pad is missing from the test strip tray, or an LED or the phototransistor is defective.
Action: Attach the reference pad or use the spare test strip tray. Press the START button. If the error message appears again, the instrument is defective.

CLOSE PRINTER COVER

Cause: The printer cover is open.
Action: Close printer cover.

NO PAPER IN PRINTER

Cause: No paper has been inserted or roll is finished.
Action: Insert new roll of paper and close printer cover. After elimination of printer errors the results can be printed from the instrument‘s memory using the “Print” function.

E14 INTERFACE ERROR !

Cause: Fault in data transfer to PC or host in **bidirectional** or **ASTM** mode.
Action: Check the data cable. Verify that the PC or host is ready to receive data. Use the “Send” function to transfer data or press “Home” to resume Ready-to-Measure status.

E17 INVALID PASSWORD!	**Cause:** The entered password doesn't match. **Action:** Enter a correct password.
E18 INVALID OP.ID!	**Cause:** The entered operator ID is not valid. **Action:** Enter a valid operator ID.
E19 LIST DOWNLOAD FAILED	**Cause:** The new operator ID list download failed. **Action:** No action. After 2 seconds next state starts with old list if there was.
E20 NO VALID LIST!	**Cause:** There is no valid list at all in the device. **Action:** Try to download an operator ID list from the host or continue without authenticated operator.
CHECK MEASUREMENT	Analyzer prints out software and chip version number and 3-digit numbers without naming the parameters. **Cause:** Service function is activated. **Action:** Press the "Back" function key to return to the main menu.
VALUES OBTAINED ARE IMPLAUSIBLE WHEN COMPARED WITH THOSE FROM VISUAL EVALUATION	**Cause:** Test strip incorrectly positioned, uncharacteristic test pad colors, proper incubation intervals not kept to during serial measurements. The wrong test strip, such as Combur[10]Test® test strips, may have been used. **Action:** Repeat the measurement with a new instrument-compatible test strip. Follow the directions carefully and ensure the test strip is correctly inserted (see Section 7.2). Repeat calibration if necessary. Repeat the measurement. If the problem persists, perform a quality control (see Section 6). **Cause:** Electromagnetic interference from other devices (see Section 4). **Action:** Remove external sources of interference, if there are any.
CONTROL VALUES FALL OUTSIDE THE DESIGNATED RANGES	**Cause:** Test strip incorrectly positioned. The wrong test strip, such as Combur[10]Test® test strips, may have been used. **Action:** Repeat calibration if necessary. Repeat the measurement with a new instrument-compatible test strip. Follow the directions carefully and ensure the test strip is correctly inserted (see Section 7.2). **Cause:** The test strip tray is older than 18 months and the above described troubleshooting steps failed. **Action:** Replace the test strip tray by a spare tray. Calibrate the analyzer using a new calibration strip. Repeat the measurement with a new instrument-compatible test strip. Follow the directions carefully and ensure the test strip is correctly inserted (see Section 7.2). **Cause:** Electromagnetic interference from other devices (see Section 4). **Action:** Remove external sources of interference, if there are any. **Cause:** The analyzer is older than 5 years and all troubleshooting steps failed. **Action:** Replace the instrument. **Cause:** The analyzer is less than 5 years old and all troubleshooting steps failed. **Action:** Contact your local Roche Diagnostics representative for support.
NO PRINTOUT	**Causes:** "Printer: Off" has been selected, or the analyzer is operating in "Fast Mode" (see Section 7.4), or the printer/software is defective, or the printer is out of paper. **Action:** Insert paper if needed. Choose "Printer: On" to re-activate the printer. Request a patient report via the "Print" function. If this fails, activate the "Linefeed" function. If there is still no response, the instrument is defective.
THE ANALYZER WILL NOT READ EVEN THOUGH THE SEQUENCE NUMBER IS DISPLAYED	**Action:** If an AT/PC keyboard is connected, press the Escape key, or switch the Urisys 1100 system off and back on again.

10. Connecting to Other Devices

10.1 Serial Interface

At the rear, the Urisys 1100 system has a serial interface through which it can be connected to a PC or central host computer. This is not an RS 232 type interface.

On request, Roche Diagnostics can supply a suitable standard data cable (see also Section 13). The connected PC must satisfy the requirements with regard to electrical safety laid down in EN 60950.

The interface can be used for **unidirectional**, **bidirectional** or **ASTM** communication, selectable via the menu.

When the interface is set for unidirectional communication, the data are sent as an ASCII file and can be received via a terminal program.

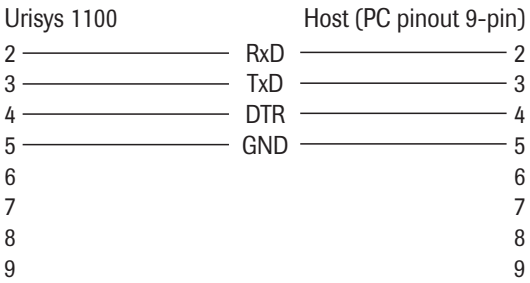
The entered Patient ID appears in the Urisys 1100 system display window and is also printed out and/or sent to the PC/ host along with the test results (see Section 7.6). If bidirectional communication with a PC or host computer has been selected, the maximum length of the Patient ID used (either 10 or 13 characters) must be preprogrammed via the display message "INTERFACE: BIDIR." and the function "10/13" to ensure that the correct data is sent.

For further information and specifications for operation in **bidirectional** or **ASTM** mode, e.g. for connection to a host computer, contact Roche Diagnostics.

Interface specification: 9600 baud, 8 bits, 1 stop bit, no parity (for unidirectional and bidirectional modes).
Selectable baud rates in ASTM mode: 1200, 2400, 4800, 9600, 19200 and 38400.

Data cable: D-sub, 9–pin, male on instrument side, female on PC side.

Connections:



CAUTION: The use of a data cable not meeting the Roche Diagnostics specification can cause data to be lost or corrupted.

10.2 Barcode Reader, AT/PC Keyboard

Sample or Patient IDs, Operator IDs and corresponding passwords can be entered against each sample sequence number displayed on the LCD, either via a barcode reader (see recommended reader) or via an AT/PC keyboard, e.g. the Reflotron keyboard from Roche Diagnostics (see ordering Information chapter 11). Power is supplied by the barcode reader interface.

Interface specification: 5-pin DIN socket, female

Pinouts:

1	clock
2	data
3	n/c
4	GND
5	+ 5 V

Barcode Reader
Barcode readers suitable for use with Urisys 1100 with SW Version 5.0 and above must meet the following specifications:
- Radio frequency interference class B according to EN 61326-1
- Electromagnetic interference immunity requirements for industrial locations according to EN 61326-1

There is a recommended barcode reader to read commonly used barcodes such as Codabar, Code 39, Code 128 and Interleaved 2 of 5.
If a barcode reader and an external keyboard have to be connected a data cable CAB 322 IBM AT/XT DIN is needed.

For questions regarding the operation of the Urisys 1100 system with barcode readers, please contact your local Roche Diagnostics representative.

11. Technical Information and Notices

11.1 Technical Data

Dimensions:	Width:	approx. 150 mm
	Depth:	approx. 290 mm
	Height:	approx. 95 mm
Weight:	≤ 0,8 kg	
Power supply:	External mains adapter Input: 100 - 240 V AC, 50/60 Hz, 800 mA Output: 7.5 V DC, 3000 mA Polarity: – ⟵◦⟵ +	
Consumption:	Operating:	max. 15 W
	Standby:	1.3 W
Noise level:	50 dB	
System description:	Type:	reflectance photometer
	Light source:	6 LEDs (light emitting diodes)
	Wavelengths:	565 nm (green) 3x 610 nm (orange) 3x
	Reader head:	1 head with 6 LEDs
	Measuring cycle:	Normal Mode: approx. 70 sec Fast Mode: approx. 30 sec
	Incubation time:	55-65 sec
	Printer:	thermal printer
	Display:	liquid crystal display, 2 lines of 24 characters
	Memory:	100 samples
	Date, time:	integrated clock

Operating conditions:	Operating	In storage
Temperature:	+15 ° to + 32 °C	– 20 ° to + 70 °C
Relative humidity:	20 % to 80 %	20 % to 85 %
Optimum operating conditions: Temperature:	+ 20 ° to + 26 °C	
Relative humidity:	30 % to 60 %	

Lifetime:
Test strip tray: 18 months after first date of use

Interfaces:
PC/HOST: serial, D-Sub socket, 9-pin, female, **unidirectional**, **bidirectional** or **ASTM** protocol (selectable)
AT/PC keyboard: Barcode reader
5-pin DIN socket, female
Certification marks: UL, cUL

11.2 Safety Notices

This analyzer was designed and manufactured to comply with the following international regulations “Safety requirements for electrical equipment for measurement, control and laboratory use” and left the factory in a safe condition. In order to keep the instrument in a perfect and safe condition, it is up to the user to observe all instructions and warnings included in this manual.

CE This product fulfils the requirements of Directive 98/79/EC on in vitro diagnostic medical devices.

c UL us Issued by Underwriters Laboratories Inc. (UL) for the USA and Canada.

The instrument must only be operated with the prescribed power supply unit (Class II protection).

The instrument is classified as Category II for overvoltage and Degree 2 for pollution according to IEC 664.

Opening covers or removing parts of the instrument, except where this can be achieved manually without the use of any tools, may expose voltage-carrying components. Connectors can be live, too. Never try to maintain or repair an open instrument which is carrying voltage.

If you suspect that the instrument can no longer be operated safely, turn it off and take steps to ensure that no one will subsequently attempt to use it. Make sure that only trained members of staff operate the Urisys 1100 analyzer.

Any personal computer to which the analyzer is connected must meet the EN 60950, UL 60950/CSA C22.2 No. 60950 requirements for data processing equipment.

If the instrument is to be taken out of operation entirely and disposed of, it must be disposed of in conformity with the relevant legal regulations and in co-ordination with your local authority, if appropriate.
Please note that the instrument may potentially be infectious. It should therefore be decontaminated before disposal, e.g. by cleaning the housing and the test strip tray with 70 % alcohol.

! **ATTENTION: The data and information contained in this manual are accurate at the time of going to press. Any substantial changes will be incorporated in the next edition. In case of conflict between this manual and information given in package inserts, the package inserts shall take precedence.**

11.3 Guarantee

The statutory guarantee provisions on rights in consumer goods sales in the country of purchase shall apply.

12. Contact Information

For all questions about the Urisys 1100 analyzer that are not answered in this operator's manual, contact your Roche representative.

To find your Roche contact details
1. Visit our website at www.roche.com.
2. Choose Roche Worldwide at the top of the page.
3. Choose your country to find the appropriate local office contact information.

13. Ordering Information

The analyzer, consumables and accessories are:

Catalogue No. (REF)	
03617548001	Content: Urisys 1100 analyzer, External mains adapter, Program Chip, Test Strip Tray C, Printer Paper, Operator's Manual, Quick Reference Guide, power cable.
03666735001	Test strip tray Type C for Combur[10]Test® UX test strips
11544373xxx	Combur[10]Test® UX (100 test strips)
11379208119	Chemstrip 10 A
11379194263	Control-Test M (50 calibration strips)
06431321001	Thermal paper (20 rolls)
11906186001	Interface connection cable
11248685001	Reflotron keyboard for patient ID entry (German)
11248723001	Reflotron keyboard for patient ID entry (English)
11248707001	Reflotron keyboard for patient ID entry (French)
11248715001	Reflotron keyboard for patient ID entry (Italian)
11248995001	Reflotron keyboard for patient ID entry (Spanish)
11428667001	Reflotron keyboard for patient ID entry (Schwedish)
11428675001	Reflotron keyboard for patient ID entry (Norwegian)

The following replacement parts are available:

11907131001	Spare reference pads (5 pieces) Program Chip

14. Alphabetical Index

CE

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03617572018 (03) 2020-06 EN