Urisys 1100® Urine Analyzer

Operator's Manual

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General Information

Every effort has been made to ensure that the information contained in this manual is accurate at the time of printing. Not all functionality described in this manual may be available to all users. Roche Diagnostics reserves the right to make any further required changes to software without prior notice. Such changes may not immediately be reflected in this document.

Any screenshots in this publication have been added exclusively for the purpose of illustration. Configurable and variable data such as parameters, results, path names etc. visible therein must not be used for laboratory purposes.

This document is intended for the US market only. Caution: Federal law restricts this device to sale by or on the order of a physician.

This manual was created by the Roche Diagnostics Engineering Operations department. Direct questions or concerns regarding the contents of this document to:

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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.
	Manufacturer
	Date of manufacture
REF	Catalog number
IVD	For in vitro diagnostic use
Rx only	For prescription use only
GTIN	Global Trade Item Number
	Store at
c UL us LISTED	The system fulfills the Canadian and U.S. safety requirements (UL LISTED, in accordance with UL 61010A-1:02 and CAN/CSA-C22.2 No. 61010-1-04)

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1. Introduction

Manual version	Software version	Revision date	Amendments
04	6.x	December 2012	Minor revision of text. Operator ID, limited lock-out function, Device ID, compatibility of barcode reader, ASTM protocol
05	6.x	May 2016	Updated barcode scanner material number, website address and General Information section
06	6.x	September 2018	Remove references to Chemstrip® 7 and Chemstrip® 5 OB Test Strips, and test strip tray N; Removed reference to Model SA 125A-0735U-S (Sino-American Switching Adapter) power cable; Modified strip handling instructions.
07	> = 6.7	2019-03	Chemstrip® 5 and Chemstrip® 7 removed from software flow chart.
08	> = 6.7	2020-06	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® Urine Analyzer (Cat. No. 03617556001) is a reflectance photometer designed to automatically read and evaluate the results of Chemstrip® 10 MD* Test Strips from Roche Diagnostics. It reads the strips under standardized conditions, saves the results to memory, and outputs them via its internal printer and/or serial interface.

Using the Urisys 1100® Urine Analyzer eliminates factors known to affect visual evaluation of urine test strips, such as:

- Variable lighting conditions at the workplace
- Individual skill levels at matching test strip pad colors
- Different reaction times for the test strips
- Clerical errors
- Strong color of the urine sample

To perform a urinalysis test, simply dip the test strip in the urine sample, dab the long edge of the test strip lightly on absorbent paper to remove excess urine, and place it in the test strip tray with the pads facing upward. Then press the START button. Measurement is complete in 70 seconds, and results are automatically printed.

The following symbol is used throughout this document.

	**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.**

Roche Diagnostics provides technical support. If you have any questions or need assistance, please contact Roche Customer Support Center at 1-800-428-4674.

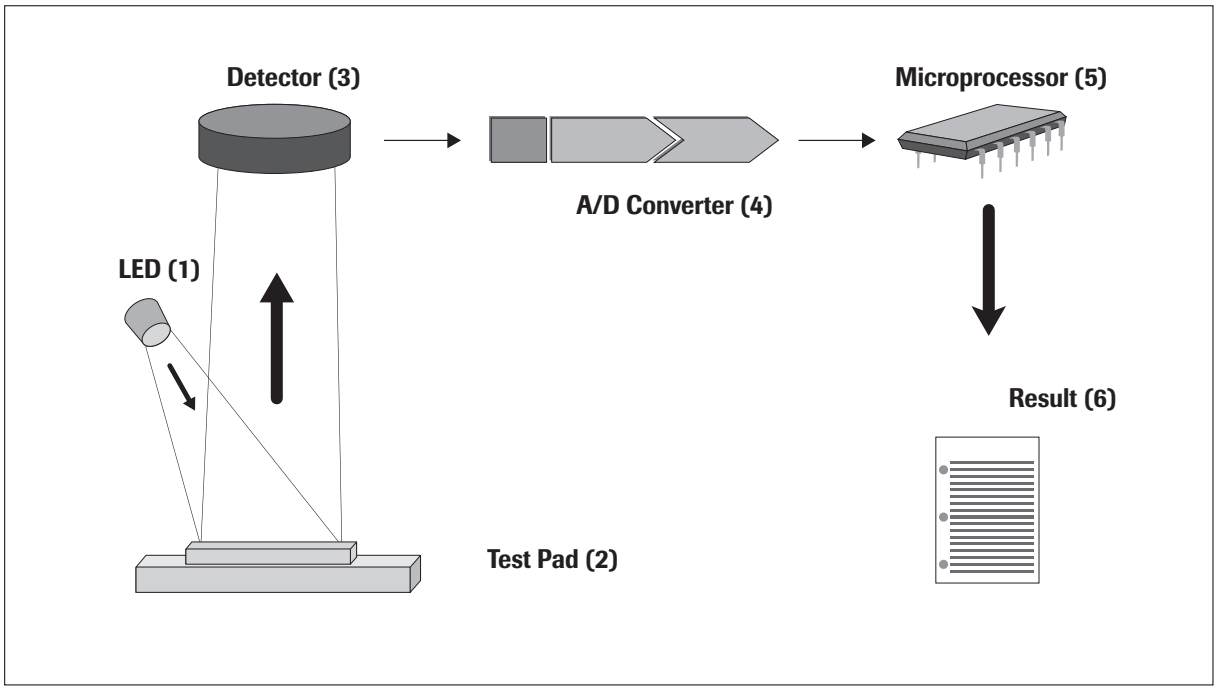
* Hospitals may use Chemstrip® 10 UA Urine Test Strips (Cat. No. 11895354160).

2. System Description

2.1 Measuring Principle

The test strip is placed on a sliding 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:

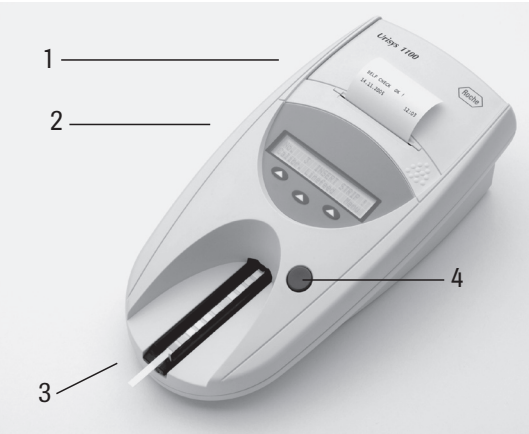


The LED (1) emits light of a defined wavelength on to the surface of the test pad (2) at an optimum angle. The light hitting the test zone is reflected proportional to the color produced on the test pad, and is picked up by the detector, a photo-transistor (3) positioned directly above the test zone. 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 about 55–65 seconds. In strongly alkaline urine samples, the Urisys 1100® Urine Analyzer 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
Program Chip (under printer cover)	Contains software needed to operate the analyzer and interpret results
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	a) Starts the reading process b) 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 AC adapter
8. 5-pin DIN socket	For connecting a barcode reader or AT/PC keyboard

3. Software

3.1 Overview

The Urisys 1100® Urine Analyzer software provides a user interface that enables specific settings and recurrent functions to be selected via the liquid crystal display (LCD) and function keys (see Sections 3.2 and 3.3).

The three function keys correspond to the particular function displayed on the second line of the LCD. The first line of the display is used for system status and user information.

The user interface is designed to be self-explanatory, therefore only details of the major functions are presented here.

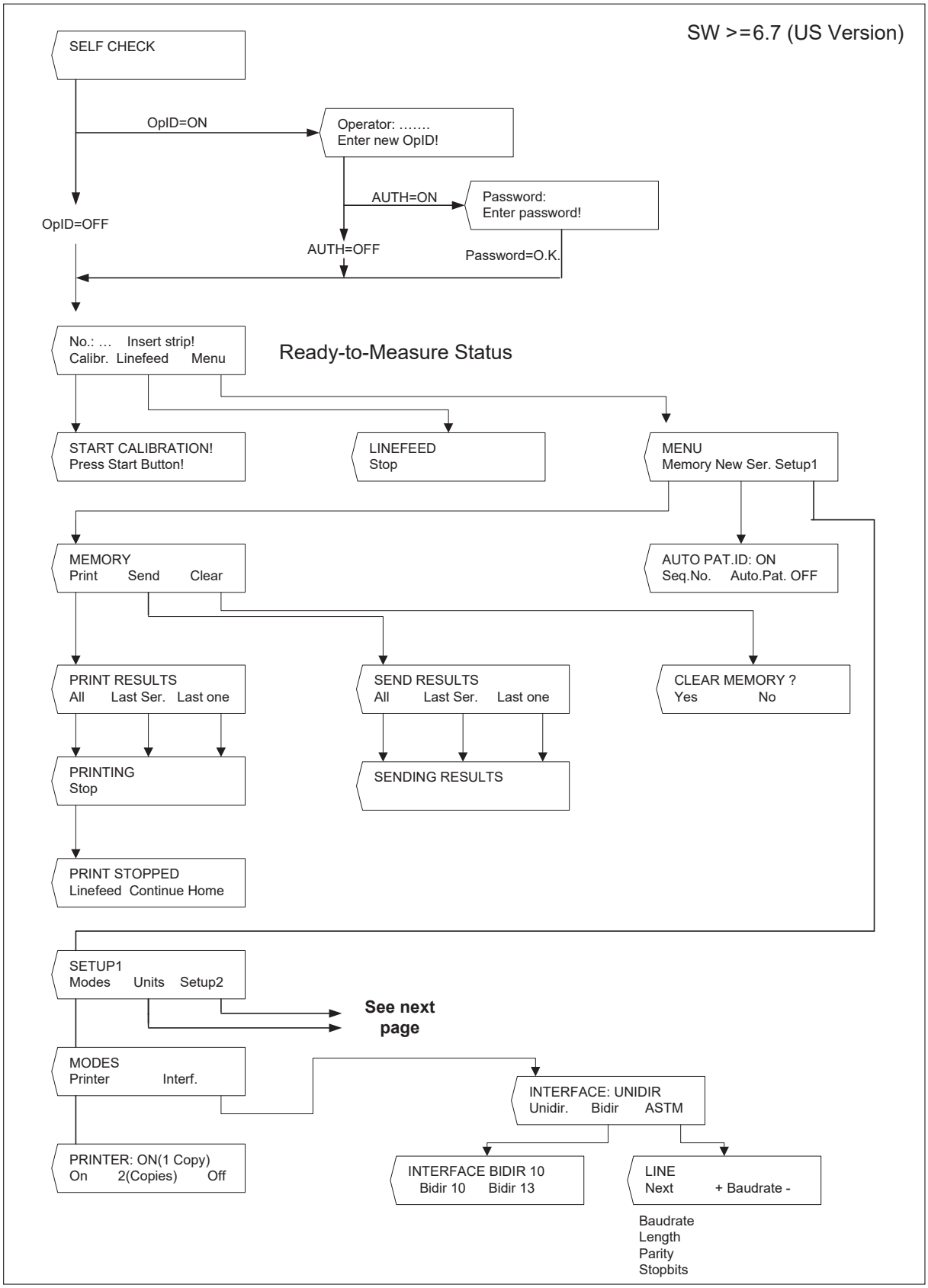
Pressing the START button within any submenu selects the designated instrument state or function, and returns the system to Ready-to-Measure status.

The instrument switches from the Ready-to-Measure status or displayed status, respectively, to the Standby mode after five minutes of function key inactivity. During Standby, the date and time are displayed. Ready-to-Measure status can be resumed by pressing the START button, except when certain error messages are displayed (see Section 8).

3.2 Menu Structure (Flowchart)

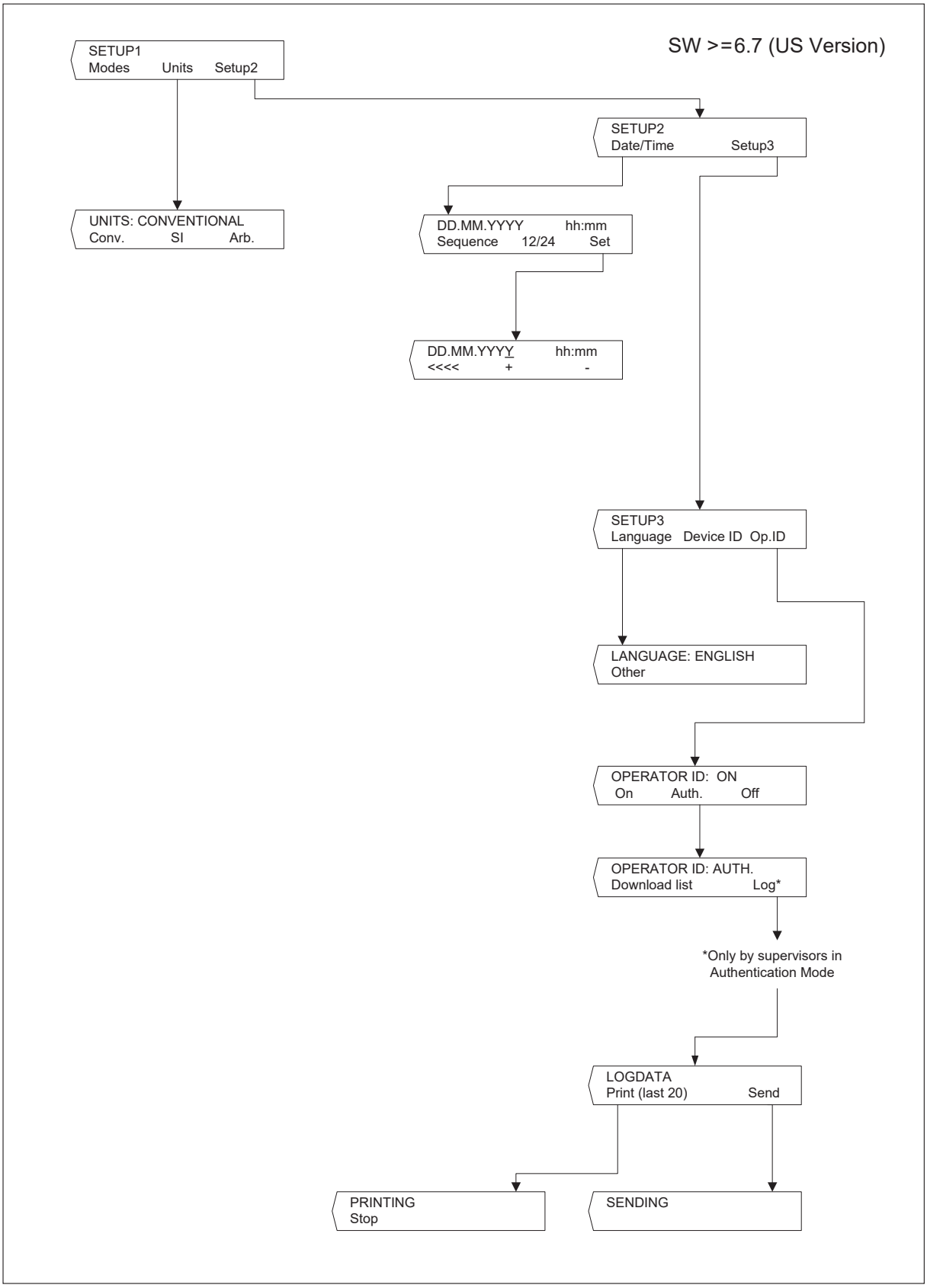
The flowchart below provides a visual display of the menu structure and how to access the various instrument settings and functions.

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



Menu Structure (continued)

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, tray transport mechanism, printer connection and optical system are all operating properly. The tray type is checked (see Sections 4 and 7.1) to ensure that it correctly matches the test strip type selected in the menu.

Calibration: For requesting calibration with Chemstrip Calibration Strip (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 6.1).

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 (i.e. for current date)
- **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 Sections 6.7 and 9.1).

Clear Memory: Erases results from memory.

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

Printer: Printer options are:
- **On:** The printer is switched on. Each result is printed once.
- **2 Copies:** Each result is printed twice. Note: 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 only to be sent via the interface to a personal or host computer.

Interface: Choice of **unidirectional**, **bidirectional** or **ASTM** data transfer. For further details, see Sections 6.7 and 9.

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)

* Hospitals may use Chemstrip® 10 UA Urine Test Strips (Cat. No. 11895354160).

Units Setting: For selecting units, options are:
- **Conventional units** (mg/dL)
- **SI units** (mmol/L)
- **Arbitrary units** (+, ++, +++, ++++)

The operator selects the units in which the results are to be stored, printed and/or transferred to a computer. After a new unit setting 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 units.

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 6.6 for details.)

DATE/TIME: For setting the date and time.

The factory default is the date in Month-Day-Year order and the time in hours (12-hour clock) and minutes. If required, the time can be displayed in the "24-hour clock" mode. Pressing the "Sequence" key allows the date format to be changed to Day-Month-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 Default Settings

The Urisys 1100® Urine Analyzer comes equipped with the following default settings. These can be changed using the function keys to page through the menus and the START button to activate the new settings selection. (See Sections 3.2 and 3.3.)

Parameter	Default Setting	Optional Setting
Print results	Printer On, (one copy)	Printer On (two copies) Printer Off
Interface mode	Uni-directional	Bi-directional
Operator ID	Off	On / Authentication Mode (ASTM)
Language	English	German, Italian, Spanish, French
Date/time format	Date: Month-Day-Year Time: 12-hour clock	Date: Day-Month-Year / Year-Month-Day Time: 24-hour clock
Reporting Unit	Conventional units	SI units or Arbitrary Units
Test Strip Type	Chemstrip® 10	n/a

Follow the flowchart in section 3.2 to determine the menu pathway to a particular setting. Use the function keys and the START button to access and change the setting.

Please contact Roche Customer Support Center at 1-800-428-4674 if you need assistance.

3.5 Results Table

Urine test strip measurement values can be reported in either conventional units, SI units, or arbitrary units. The following table lists the levels of concentration that are reported for each format.

Parameter	Conv.	SI	Arbitrary
Specific Gravity (SG)	1.000	1.000	1.000
	1.005	1.005	1.005
	1.010	1.010	1.010
	1.015	1.015	1.015
	1.020	1.020	1.020
	1.025	1.025	1.025
	1.030	1.030	1.030
pH	5	5	5
	6	6	6
	6.5	6.5	6.5
	7	7	7
	8	8	8
	9	9	9
LEU (Leukocytes)	neg	neg	neg
	25 Leu/µL	25 Leu/µL	TR
	75 Leu/µL	75 Leu/µL	+
	500 Leu/µL	500 Leu/µL	++
NIT (Nitrite)	neg	neg	neg
	pos	pos	+ (pos)
PRO (Protein)	neg	neg	neg
	TR	TR	TR
	30 mg/dL	0.30 g/L	+
	100 mg/dL	1.00 g/L	++
	500 mg/dL	5.00 g/L	+++
GLU (Glucose)	norm	norm	norm
	50 mg/dL	3 mmol/L	TR
	100 mg/dL	6 mmol/L	+
	250 mg/dL	14 mmol/L	++
	> 1000 mg/dL	> 56 mmol/L	+++
KET (Ketone)	neg	neg	neg
	15 mg/dL	1.5 mmol/L	+
	50 mg/dL	5 mmol/L	++
	150 mg/dL	15 mmol/L	+++
UBG (Urobilinogen)	norm	norm	norm
	1 mg/dL	17 µmol/L	+
	4 mg/dL	68 µmol/L	++
	8 mg/dL	135 µmol/L	+++
	$\geq$ 12 mg/dL	$\geq$ 203 µmol/L	++++
BIL (Bilirubin)	neg	neg	neg
	1 mg/dL	17 µmol/L	+
	3 mg/dL	50 µmol/L	++
	6 mg/dL	100 µmol/L	+++
BLD (Erythrocytes)	neg	neg	neg
	TR	TR	TR
	50 Ery/µL	50 Ery/µL	+
	250 Ery/µL	250 Ery/µL	++

4. Installation

Please read the Urisys 1100® Urine Analyzer Operator's Manual carefully before installation, to ensure proper operation of the analyzer.

4.1 Unpacking

Carefully remove the contents of the Urisys 1100® Urine Analyzer box and check for the following items:

Contents:
1. Urisys 1100® Urine Analyzer
2. AC adapter (100 V - 240 V, 50/60 Hz)
3. Power cord
4. Roll of printer paper
5. Test strip tray, Type C, for reading Chemstrip® 10 MD Test Strips

Items included, but not pictured:
- Operator's Manual including Policies and Procedures CD
- User Training CD
- Quick Reference Guide
- Warranty Card

4.2 Installation and Power-on Procedure

Set-Up

(1) Place the Urisys 1100® Urine Analyzer on a stable, level surface. To ensure accurate readings, please take the following environmental precautions:

- Do not set the analyzer in close proximity to devices that create high-frequency fields, as they may interfere and produce false results. Such devices include; walkie-talkies, mobile telephones, microwave ovens and diathermic equipment.
- Do not expose the analyzer to direct sunlight or strong artificial light.
- If the analyzer has been exposed to significant changes in temperature and/or humidity, allow it to sit at room temperature for at least four hours before operating.

(2) Connect the Power cord and AC adapter. Then connect the AC adapter to the power socket at the rear of the instrument. Plug the power cord into a readily accessible AC power outlet.

Insertion of Test Strip Tray

(3) Select the appropriate test strip tray. Use Type C to read Chemstrip® 10 MD Urine Test Strips. The type of tray is indicated on the underside of the tray.

(4) Hold the test strip tray with the gray reference pad facing up and towards the analyzer (see Figure 1).

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

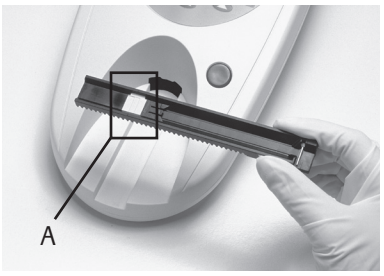


Figure 1

(5) Slide the test strip tray into the slot below the function keys until the retaining bar closes (see Figure 2).

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

Figure 2

Paper Installation

(4) Release the printer paper cover by pressing the area immediately below and to the right of the printer paper slot (see Figure 3). The cover can then be lifted back. Place the paper roll in the compartment and pull out the first few inches 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.

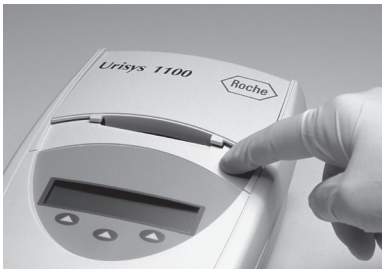


Figure 3

Figure 4

Self Check

(5) Switch on the Urisys 1100® Urine Analyzer using the on/off switch at the rear of the instrument. The analyzer will then automatically perform a self check. The analyzer is factory set to read Chemstrip® 10 MD test strips. It checks that the correct tray has been inserted. On completion of the self check, the tray returns to the start position and the retaining bar opens (see Figure 5). If the self check is completed sucessfully, the message "Self Check OK" will print along with the time and date.

Figure 5

ATTENTION: If the message E9 Wrong Tray! is displayed after the Urisys 1100® Urine Analyzer is switched on, press the START button. Then selection menu STRIP TYPE is displayed, select CHEM 10 by pressing the function key.

Calibration

(6) Upon first use of the analyzer, the message "REPEAT CALIBRATION" appears after a successful self check. This also happens if the analyzer is not used for more than seven days. Calibration must be performed using a Chemstrip Calibration Strip prior to reading patient samples when using the Chemstrip® 10 MD Test Strip. See Section 5 for details on this calibration procedure.

Modifying Settings

(7) The Urisys 1100® Urine Analyzer leaves the factory with default settings for Printer Results, Interface Mode, Test Strip Type, Reporting Units, Language, Date/time format (see Section 3.4) and Operator ID. Individual facility preferences can be entered via the menus. See Section 3 for details on modifying instrument settings through the software menus.

4.3 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.

NOTE: 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.

4.4 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 unauthorized 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 following section applies when the Urisys 1100® Urine Analyzer is used with Chemstrip® 10 MD Test Strips.

Overview

The Urisys 1100® Urine Analyzer is calibrated before leaving the factory. When installed, it must be recalibrated with a Chemstrip Calibration Strip before the first samples are read, and thereafter every seven days. Chemstrip Calibration Strips consist of a gray plastic material that is standardized to give constant, defined reflectance readings. Calibration strips should remain in the vial until just prior to use and should only be used once.

The purpose of calibrating the analyzer is to compensate for aging effects that influence the optical system and the gray reference pad in the 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 section below on calibration errors).

The Urisys 1100® automatically requests a new calibration every week. In addition, when the instrument is installed, the "REPEAT CALIBRATION!" message is displayed following a successful self check.

Procedure

1. Make sure that the test strip tray is clean and dry.

2. If the message, "REPEAT CALIBRATION" is on the display, press the START button. If the analyzer is in the Ready-to-Measure mode, use the left function key to select "Calibr.". Next, the "START CALIBRATION" message is displayed.

3. Remove a calibration strip from the Chemstrip Calibration Strip container. Be careful not to touch the pads and do not allow them to come into contact with urine.

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

5. Press the START button. The display will then read, "Heat up! Please wait, xx sec left." Once the countdown is finished, the measurement begins. If calibration results are acceptable, the message "CALIBRATION O.K." is displayed and results are printed.

6. The tray then returns to the start position, and the retaining bar opens. Remove and dispose of the calibration strip. Use each calibration strip only once.

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

Calibration printout
If the new calibration results are within the acceptable range, the message "CALIBRATION O.K." is displayed. Results are stored in memory and automatically printed along with time and date. A list of reflectance values for measuring positions 1–11 for the orange LED are printed in the middle column and for the green LED in the right column. (See Figure 8).

Figure 8

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

In the event of a calibration error, repeat the calibration procedure with a fresh Chemstrip 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 8.

6. Reading Test Strips

6.1 Instrument Overview

The Urisys 1100® Urine Analyzer is very easy to use. Simply insert the test strip when the display reads "Insert Strip", then press the START button. The analyzer automatically waits for the strip to incubate before it reads the first test pad. Seventy seconds after the START button is pressed, the measurement is completed and the test strip tray returns to the start position. Throughput is approximately 50 test strips per hour.

Each time a test strip is read, the gray reference pad in the 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 7.1 and 8).

The Urisys 1100® Urine Analyzer assigns 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 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.

After five minutes of inactivity, the analyzer automatically switches to **Standby** mode. The 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.

6.2 Quality Control Recommendations

Commercial control material may be used for quality control. Please contact Roche Customer Support Center at 1-800-428-4674 for a list of available control solutions. Positive and negative controls must be tested daily, or when a new vial of strips is opened (including every lot change), or whenever calibration is performed. Values obtained for these controls should fall within the limits established by the laboratory or the control manufacturer. If control values fall outside the designated ranges follow the instructions provided in paragraph Control values fall outside the designated ranges (see section 8 Error Messages and Troubleshooting).

6.3 Routine Urine Testing

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

The Urisys 1100® Urine Analyzer is ready to read when the display shows a sample number and "INSERT STRIP !".

Procedure

1. Dip the test strip briefly (one second) in the urine sample. Draw the long edge of the strip along the rim of the specimen container to remove excess urine. Dab the long edge of the strip lightly on absorbant paper to remove excess urine. Make sure that each pad is blotted. Always wear protective gloves when handling and disposing of samples of human origin (see Figure 9).

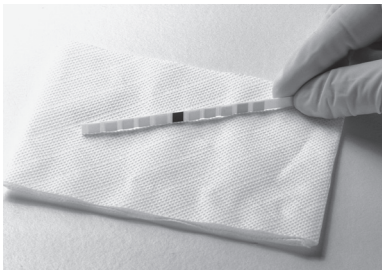


Figure 9

2. Place the test strip, with the test pads facing upward, on the tray so that its leading edge is held by the clip at the end of the test strip tray. **The retaining bar must be open** (see Figure 10). About 2 mm of strip must be held under the clip (see Figure 11).

It is important that the strip is correctly positioned and ready to be read within 5-10 seconds of dipping strip.

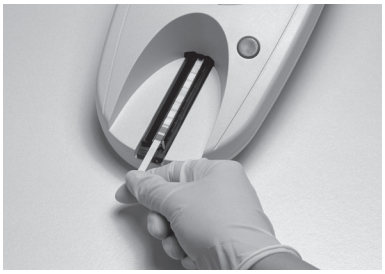


Figure 10

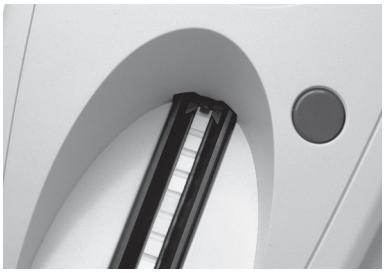


Figure 11

ATTENTION: To avoid incorrect readings due to a discoloration of the test strip pads, the strip vial must be closed immediately after removal of a test strip, using the original desiccant-filled stopper.

3. Press the START button (see Figure 12). The display will read “Measurement starts in xx sec.” The display counts down until start. During this time, the strip incubates and the retaining bar remains open.

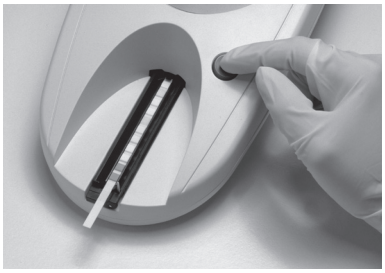


Figure 12

Figure 13

4. If the test strip is not correctly located in the middle of the tray, move it gently to the side until it is properly aligned (see Figure 14). Be careful not to move the tray.

Figure 14

5. After the strip incubates, the measurement begins with the Reference pad and then all test strip pads are read. The tray returns to the Start position and the retaining bar opens.

6. The results are printed and the next sample number appears on the display.

7. Remove and dispose of the test strip. Wipe any urine residue from the tray with a lint-free cloth (see Figure 15).

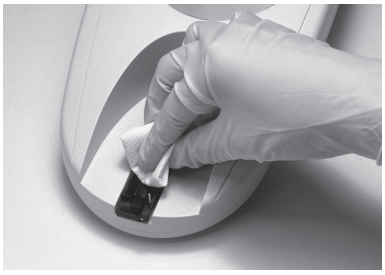


Figure 15

6.4 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 6.6). Test results which diverge from negative, normal, or trace values are flagged with an asterisk before the parameter concerned. For details regarding various print settings and how to modify them, see Section 3.3.

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

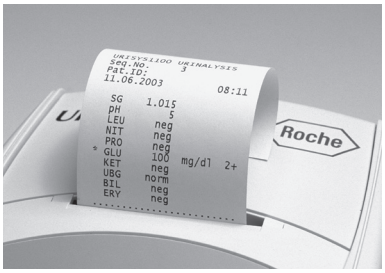


Figure 16

Thermal printing paper is sensitive to light and subject to fade with prolonged exposure to bright light. Patient reports should be kept in a place away from direct light. For anticipated storage beyond 5 years it is recommended that reports are photocopied for storage.

6.5 Strip Measurement Error

If "STRIP MEASUREMENT ERROR !" appears, the test strip and/or analyzer have probably been incorrectly used. Refer to Section 8 for details.

6.6 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 (up to 13 characters in length) against the currently shown sequence number by means of a barcode reader or AT/PC keyboard (see Section 9.2). 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 begins) and is printed and/or sent to the serial interface together with the test result.

A new Patient ID should only be entered from the keyboard after the preceding measurement has been completed and results printed out. This allows the operator to check correct entry directly on the display.

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

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.

When data is 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® Analyzer cannot start reading. Press the keyboard Escape key to delete the entire entry or turn the analyzer off and then on again.

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

6.7 Data Transmission to a PC or Host Computer

In **unidirectional** mode, the results are transmitted immediately 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® Urine Analyzer aborts transmission after several attempts and reports an "INTERFACE ERROR !" (see Section 8).

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 connecting to a serial interface, refer to Section 9.1.

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

7. Cleaning and Maintenance

The Urisys 1100® Urine Analyzer is designed for nearly maintenance-free operation. Protect the instrument from extremes of temperature and high atmospheric humidity (see Section 10), 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 solution of either 70% alcohol or 10% bleach with a moist cloth. It is important that no liquid enters the instrument.

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

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

7.1 Routine Cleaning

Wipe the test strip tray with a dry and soft lint-free cloth as needed (see Figure 17). This is important to prevent carry-over of urine between patients and accumulation of urine residues that might hamper smooth operation of the instrument. When wiping, be careful not to move the tray and that the retaining bar remains open.

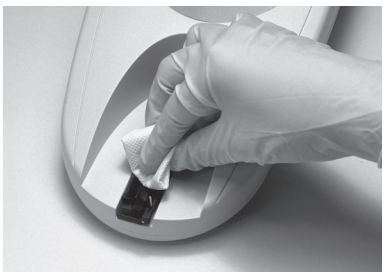


Figure 17

7.2 Daily Maintenance

Cleaning the instrument

1. Switch off the instrument
2. Pull the test strip tray out of the instrument
3. Moisten a cloth with water, 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 or 10% bleach), 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.

Cleaning the Test Strip Tray

1. Switch off the instrument.

2 Pull the test strip tray out of the instrument.

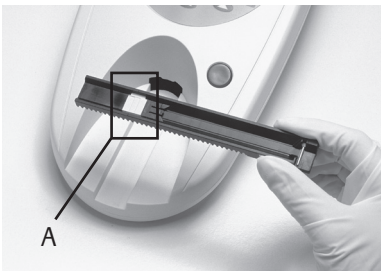


Figure 18

CAUTION: Be careful not to touch the gray reference pad (A) (see Figure 18 and Figure 19). Contamination of the reference pad may impair the quality of the results obtained.

ATTENTION: To avoid contamination of the gray reference pad (A), you can remove it before cleaning (see Figure 20).

3. Rinse the test strip tray under running water.

4. Remove any crystalline deposits, especially those contaminating the retaining bar mechanism or the cogs on the underside of the test strip tray with a soft brush.

5. Wipe down the test strip tray with either 70% alcohol or 10% bleach. Dry with a soft lint-free cloth. To avoid corrosion, do not leave the test strip tray to soak in bleach, alcohol, or other solutions.

6. Insert the reference pad if taken out before cleaning.

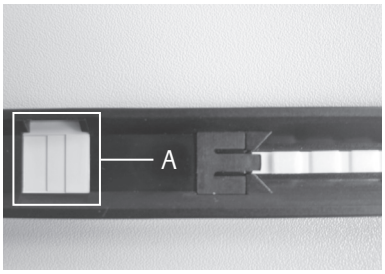


Figure 19

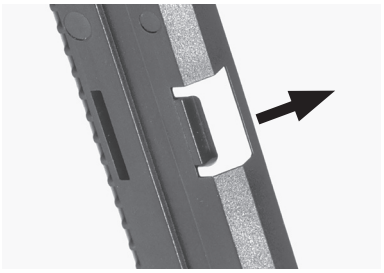


Figure 20

CAUTION: Ensure that the positioning hole (B) on the side of the test strip tray is absolutely dry (see Figure 21). This hole is used to ensure that the test strip tray is automatically positioned correctly in the instrument.

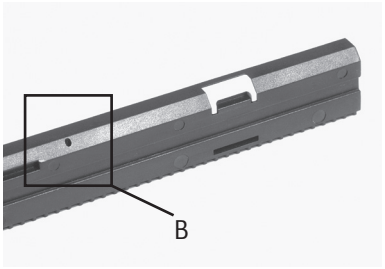


Figure 21

CAUTION: Take care not to damage the gray 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 gray 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. Install the test strip tray by holding the tray opposite the end with the gray reference pad and inserting the test strip tray into the slot below the function keys.

8. If you wish to proceed with the next readings directly after cleaning the test strip tray, switch the instrument 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 21) is free. If not, an error message will be displayed (see Section 8).

8. Error Messages and Troubleshooting

Error messages are shown in the display but are not printed out. Following five 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 not operating properly, contact Roche Customer Support Center at 1-800-428-4674.

E1 REFERENCE PAD ERROR MIDDLE!	**Cause:** The middle portion of the reference pad on the 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 tray again, then wait for the self check to finish. If the error message appears again, contact Roche Customer Support Center at 1-800-428-4674. Recalibrate with Chemstrip Calibration Strip.
E15 REFERENCE PAD ERROR BOTTOM!	**Cause:** The bottom portion of the reference pad on the tray is soiled or damaged. **Action:** see E1
E16 REFERENCE PAD ERROR TOP!	**Cause:** The top portion of the reference pad on the 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 ("Chem 10" test strip). **Action:** Press the START button. Repeat the measurement with the type of strip for which the analyzer has been programmed.
E3 STRIP MEASUREMENT ERROR !	**Cause:** No test strip is present on the tray, or the strip is incorrectly positioned on the 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 button 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 Chemstrip Calibration Strip container. Ensure that the strip is properly positioned under the clip at the end of 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 7.1). Repeat the calibration with a new Chemstrip Calibration Strip (see Section 5). If the error message appears again, contact Roche Customer Support Center at 1-800-428-4674.
E6 CHIP ERROR !	**Cause:** The program chip on the right of the analyzer underneath the printer cover is missing, is not making contact, is defective or contains an old software version. **Action:** Switch off the Urisys 1100® Urine Analyzer. Insert the program chip and switch the instrument on again. If "CHIP ERROR" appears again, contact Roche Customer Support Center at 1-800-428-4674.
E7 MISSING TRAY !	**Cause:** No tray inserted or tray not inserted far enough to be engaged by the motor. **Action:** Insert the tray correctly (see Section 4). Press the START button.

E8 TRAY POSITION ERROR !

Cause: The positioning hole in the tray is soiled or still wet after cleaning; the retaining bar is open while the tray is advancing; or the retaining bar mechanism is blocked by urinary deposit (See Section 7.1).
Action: Clean, blow through or dry the positioning hole (using a lint-free cloth) to ensure that it is completely clear. Remove urinary deposits, including those on the underside of the tray. Insert the 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, contact Roche Customer Support Center at 1-800-428-4674.

E9 WRONG TRAY !

Cause: The test strip tray used is not the correct one for the programmed test strip type, or the gray reference pad is missing from the tray.
Action: Press the START button. The strip type menu is displayed. The strip type must match the tray type (see Section 4.2). Use the correct tray. If the error message appears again, contact Roche Customer Support Center at 1-800-428-4674.

E10 LIGHT BARRIER ERROR !

Cause: The light barrier used to control the position of the test strip tray is defective or the tray transport is blocked.
Action: Pull out the tray and return it to the start position. Press the START button. If the error message appears again, contact Roche Customer Support Center at 1-800-428-4674.

E11 TRAY STEP ERROR !

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

Action: Carefully clean the tray. Remove any urinary deposits, including those on the underside of the tray and the cogs. Press the START button. If the error message appears again, contact Roche Customer Support Center at 1-800-428-4674.

E12 OPTICS ERROR !

Cause: The reference pad is missing from the tray, or an LED or the phototransistor is defective.
Action: Attach the reference pad. Press the START button.
If the error message appears again, contact Roche Customer Support Center at 1-800-428-4674.

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 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 not a valid list at all in 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 or uncharacteristic test pad colors. The wrong test strip, may have been used. **Action:** Repeat the measurement with a new test strip. Follow the directions carefully and ensure the test strip is correctly inserted (see Section 6.3). Repeat calibration if necessary. Repeat the measurement. If the problem persists, perform a quality control (see Section 6.2). **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 Chemstrip® 10 with SG 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 6.3). **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 6.3). **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 Roche Customer Support Center at 1-800-428-4674.
NO PRINTOUT	**Cause:** "Printer: Off" has been selected, 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, contact Roche Customer Support Center at 1-800-428-4674.
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® Urine Analyzer off and back on again.

9. Connecting to Other Devices

9.1 Serial Interface

At the rear, the Urisys 1100® Urine Analyzer 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.

Roche Diagnostics has a suitable standard data cable available for sale (see Section 11).

The interface can be used for **unidirectional, bidirectional** or **ASTM** communication, selected via the menu.
When the interface is set for unidirectional communication, the data is sent as an ASCII file and can be received via a terminal program.

The entered Patient ID appears in the Urisys 1100® Urine Analyzer display window and is also printed and/or sent to the PC/host along with the test results (see Section 6.6). 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 Customer Support Center at 1-800-428-4674.

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:

Urisys 1100® Urine Analyzer		Host (PC pinout 9-pin)
2	RxD	2
3	TxD	3
4	DTR	4
5	GND	5
6		6
7		7
8		8
9		9

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

9.2 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. A suitable keyboard is available from Roche Diagnostics (see Section 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® Urine Analyzer with SW version 6.0 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
- Part 15 of FCC rules for a class B computing device.

Roche recommends the QuickScan™ QD2131 linear imager 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® Urine Analyzer with barcode readers, please contact your local Roche Diagnostics representative.

10. Technical Information and Notices

10.1 Instrument Specifications

Dimensions:	Width:	approx. 150 mm
	Depth:	approx. 290 mm
	Height:	approx. 95 mm
Weight:		≤ 0.8 kg
Power supply:	External mains adapter, power cable	
	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
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:	approx. 70 sec
	Max. throughput:	approx. 50 strips/hour
	Incubation time:	55-65 seconds
	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
	59 to 90 °F	-4 to 158 °F
Relative humidity:	20% to 80%	20% to 85%

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

Interfaces:

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

Certification marks: UL, cUL

10.2 Safety Notices

This analyzer was designed and manufactured to comply with 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.

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. 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® Urine Analyzer.

Any personal computer to which the analyzer is connected must meet the EN 60950, UL 60950 and 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 printing.
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.

10.3 Warranty

Roche Diagnostics warrants the Urisys 1100® Urine Analyzer against defects in material and workmanship (except for consumable items) for a period of one year from date of purchase. Roche Diagnostics **will replace the instrument** and all parts which prove to be defective and are subject to such warranty.

This warranty does not apply to an instrument not used according to instructions or damaged by accident, alteration, misuse, tampering, and/or abuse.

THE FOREGOING WARRANTY SHALL BE IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESSED, IMPLIED OR STATUTORY, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

ROCHE DIAGNOSTICS SHALL HAVE NO FURTHER OBLIGATION OR LIABILITY WITH RESPECT TO THE INSTRUMENT OR PARTS THEREOF OR ITS SALE, OPERATION, OR USE, AND ROCHE DIAGNOSTICS NEITHER ASSUMES NOR AUTHORIZES THE ASSUMPTION OF ANY OBLIGATION OR LIABILITY IN CONNECTION WITH SAID INSTRUMENTS OR PARTS THEREOF.

CUSTOMERS’ SOLE AND EXCLUSIVE REMEDY IN CONTRACT, TORT, OR UNDER ANY OTHER THEORY AGAINST ROCHE DIAGNOSTICS, RESPECTING THE INSTRUMENT, PARTS THEREOF AND THE USE OF SAME SHALL BE THE REPLACEMENT OF THE INSTRUMENT AND ITS PARTS AS DESCRIBED ABOVE. IN NO CASE SHALL ROCHE DIAGNOSTICS BE LIABLE FOR SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES.

11. Ordering Information and Replacement Parts

The analyzer, consumables, replacement parts and accessories are:

Catalog No.

03617556001	Urisys 1100® Urine Analyzer Contents: Power Supply with AC Adapter and US Power Cord, Program Chip, Test Strip Trays (Type C), Printer Paper, Operator's Manual with Policies and Procedures CD, Quick Reference Guide, and User Training CD.
03260763160	Chemstrip® 10 MD Urine Test Strips (100 test strips)
11379194160	Chemstrip Calibration Strip (50 calibration strips)

Replacement Parts:

04340612001	Power Cord (US)
08747385001	AC Adapter
03666735001	Test strip tray Type C for Chemstrip® 10 MD
06431321001	Thermal paper (20 rolls)
11907131001	Spare reference pads (5 pieces)

Optional accessory items:

11248693001	Keyboard for patient ID entry (English)
11906186001	Interface Cable
07945809001	QuickScan™ QD2131 linear imager

Please contact Roche Customer Support Center at 1-800-428-4674 for questions regarding these items. To order, please contact your local distributor or call Roche Diagnostics Customer Service at 1-800-428-5076 to locate a distributor near you.

12. Contact Information

Address

Roche Diagnostics Corporation
9115 Hague Road
Indianapolis, IN 46256
USA

Phone Numbers

Main switchboard: 317-521-2000
Customer Service: 800-428-5076
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