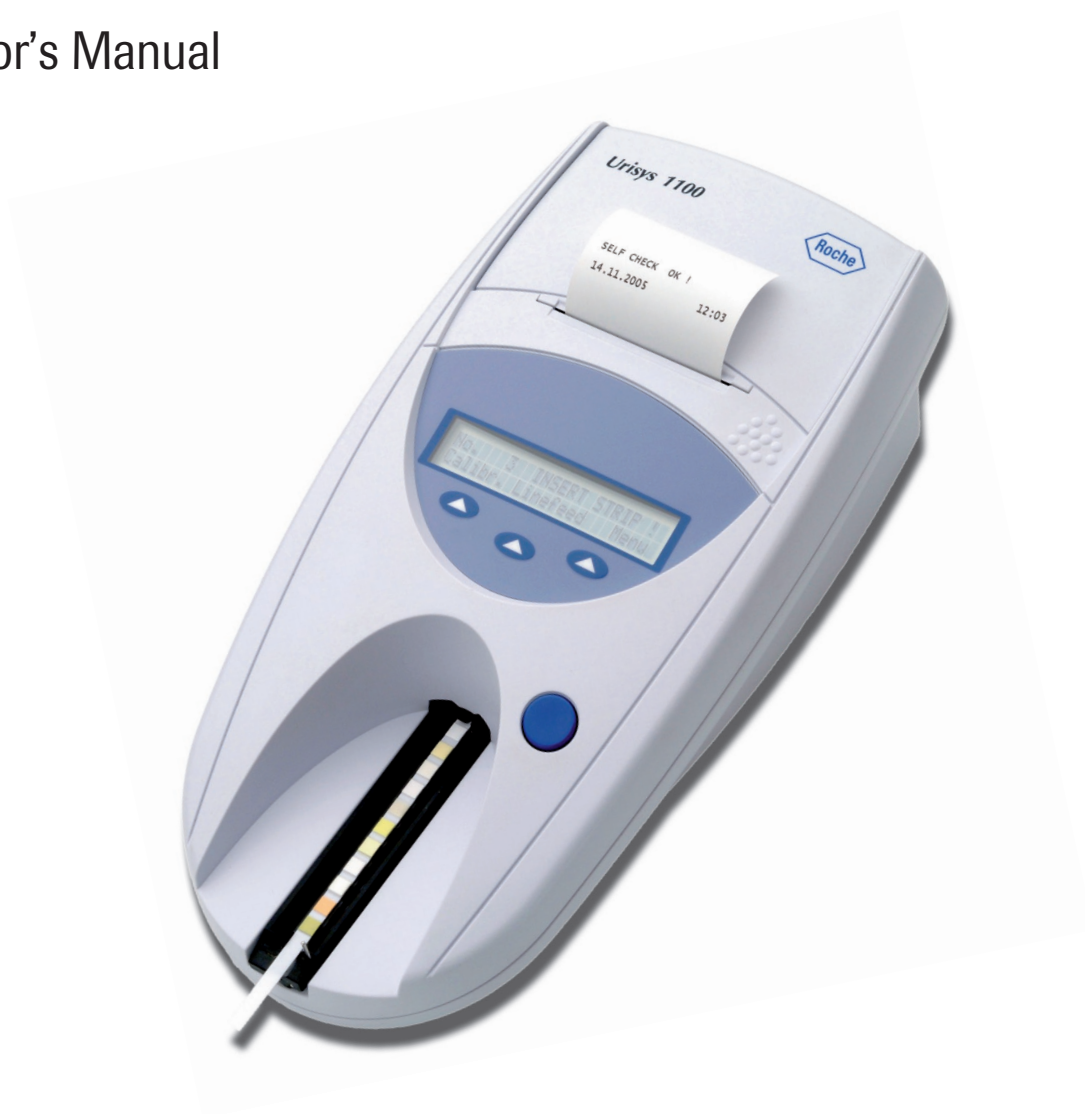# Urisys 1100®

cobas®

Operator's Manual

Roche

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

REF Catalogue number

IVD For in vitro diagnostic use

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

Last update:
2008-06

Table of Contents

1. Introduction

Manual version	Software version	Revision date	Amendments
03	6.x	June 2008	Operator ID, limited lock-out function, Device ID, compatibility of barcode reader, ASTM protocol

The Urisys 1100® Urine Analyzer (Cat. No. 3617556) is a reflectance photometer designed to automatically read and evaluate the results of Chemstrip® 10 MD*, Chemstrip® 7 and Chemstrip® 5 OB 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, gently press the long edge of the test strip to a piece of absorbent paper for one second, 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 24-hour, 7-days-a-week, 365-days-per-year technical support. If you have any questions or need assistance, please contact Roche Technical Service at 1-800-428-4674.

* Hospitals may use Chemstrip 10 UA Urine Test Strips (Cat. No. 418003).

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:
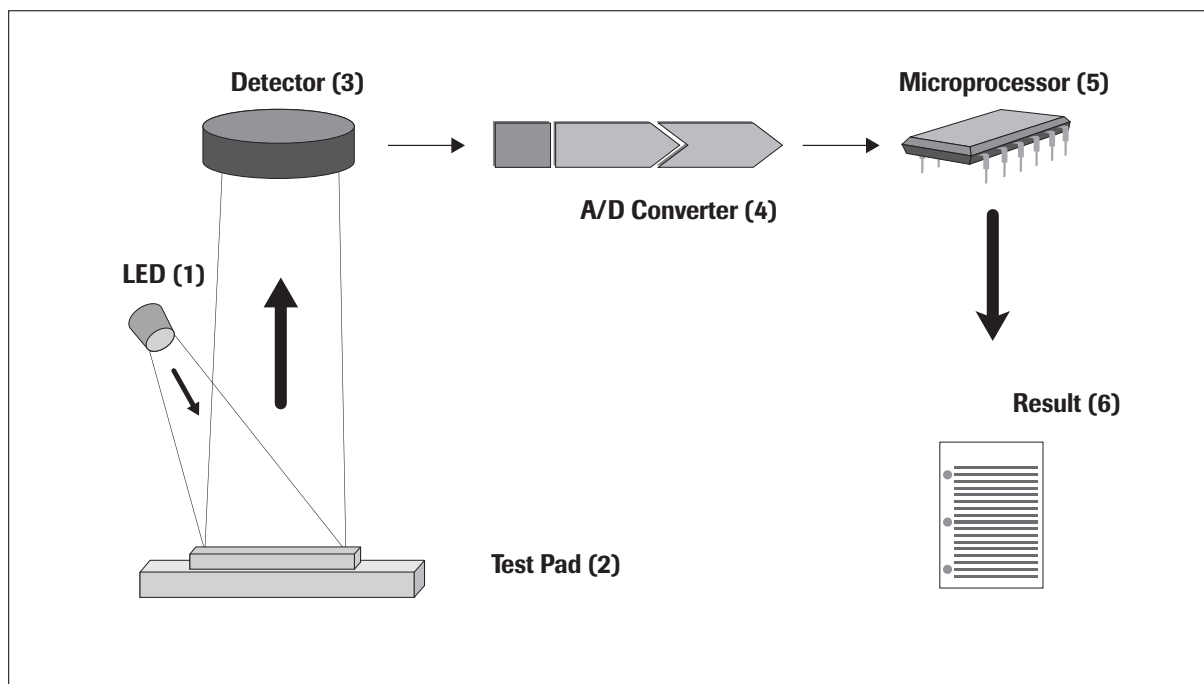
The LED (1) emits light of a defined wavelength on to the surface of the test pad (2) at an optimum angle. The light hitting the test zone is reflected proportional to the color produced on the test pad, and is picked up by the detector, a photo-transistor (3) positioned directly above the test zone. 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
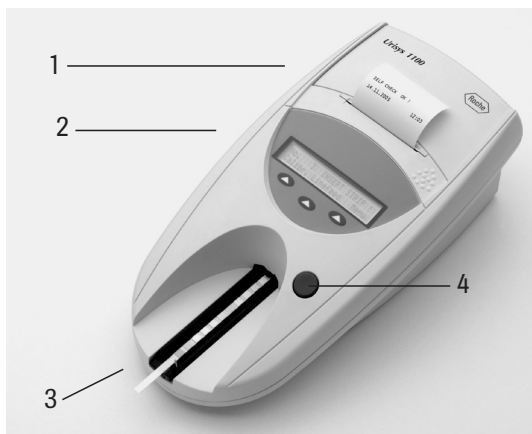
Component	Function
1. Printer cover	Flips up for insertion of printer paper
Program Chip (under printer cover)	Contains software needed to operate the analyzer and interpret results
2. Display/keypad	LCD display and three function keys for menu-driven operation and interfacing with the user
3. Test strip 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 adaptor
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.

SW 6.x (US Version)

SELF CHECK

OpID=ON → Operator: …….
Enter OpID!

AUTH=ON → Password:
Enter password!

OpID=OFF

AUTH=OFF

Password=O.K.

No.: …   Insert strip!
Calibr. Linefeed   Menu   Ready-to-Measure Status

START CALIBRATION!
Press Start Button!

LINEFEED
Stop

MENU
Memory New Ser. Setup1

MEMORY
Print   Send   Clear

AUTO PAD.ID: ON
Seq.No.   Auto.Pat. OFF

PRINT RESULTS
All   Last Ser.   Last

SEND RESULTS
All   Last Ser.   Last

CLEAR MEMORY ?
Yes   No

PRINTING
Stop

SENDING RESULTS

PRINT STOPPED
Linefeed Continue Home

SETUP1
Modes   Strip   Setup2

See next page

MODES
Printer   Interf.

INTERFACE: UNIDIR
Unidir.   Bidir   ASTM

PRINTER: ON(1 copy)
On   2(copies)   Off

INTERFACE BIDIR 10
Bidir 10   Bidir 13

LINE
Next   + Baudrate -

Baudrate
Length
Parity
Stopbits

Menu Structure (continued)

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

SW 6.x (US Version)

```
SETUP1
Modes     Strip     Setup2
```

```
SETUP2
Date/Time          Setup3
```

```
STRIP SETTINGS
Type     Units
```

```
DD.MM.YYYY          hh:mm
Sequence     12/24     Set
```

```
DD.MM.YYYY          hh:mm
<<<<          +          -
```

```
STRIP TYPE:CHEMSTRIP10
CHEM10     CHEM7   CHEM5
```

```
UNITS: CONVENTIONAL
Conv.          SI          Arb.
```

```
SETUP3
Language   Device ID  Op.ID
```

```
LANGUAGE: ENGLISH
Other
```

```
OPERATOR ID:  ON
On     Auth.        Off
```

```
OPERATOR ID: AUTH.
Download list          Log*
```

*Only by supervisors in
Authentication Mode

```
LOGDATA
Print (last 20)          Send
```

```
PRINTING
Stop
```

```
SENDING
```
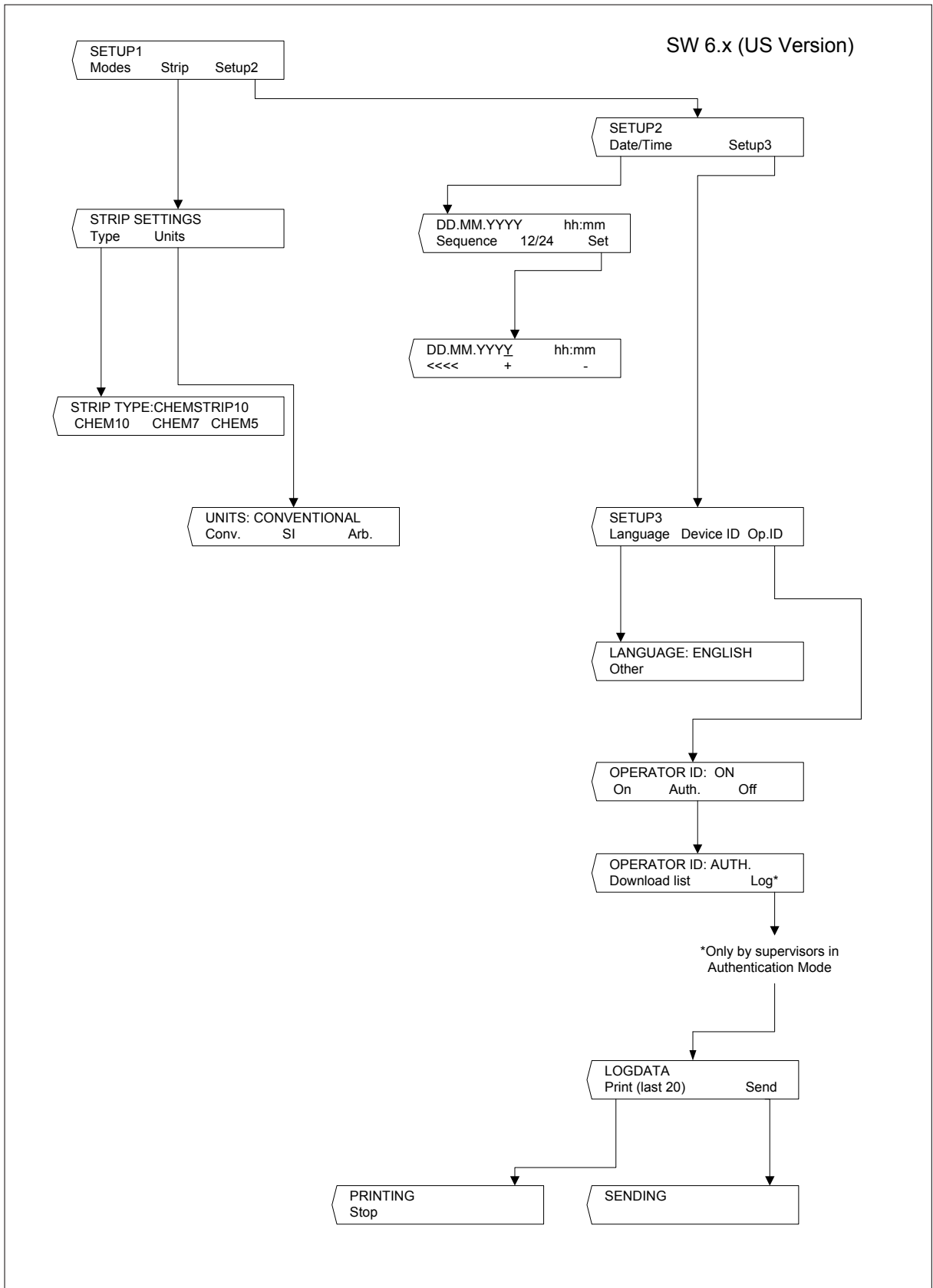
3.3   Menu Functions

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)

Strip Settings: For selecting test strip type and units.

Strip Type: Choice of test strip type:
- **Chemstrip 10 MD* Test Strip (CHEM 10)**
- **Chemstrip 5 OB Test Strip (CHEM 5)**
- **Chemstrip 7 Test Strip (CHEM 7)**

The Urisys 1100® Urine Analyzer leaves the factory configured for Chemstrip 10 MD Test Strips. If you intend to use Chemstrip 5 OB or Chemstrip 7 Test Strips, you will need to use the appropriate test strip tray (see Sections 4.3 and 11).

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	Chemstrip 5 OB Chemstrip 7

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 Technical Service at 1-800-428-4674 if you need assistance.

* Hospitals may use Chemstrip 10 UA Urine Test Strips (Cat. No. 418003).

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 adaptor (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
6. Test strip tray, Type N, for reading Chemstrip® 5 OB and Chemstrip® 7 Test Strips

Items included, but not pictured:
• Operator's Manual incl. Policies and Procedures CD
• Program Chip
• User Training CD
• Quick Reference Guide
• Warranty Card

* Hospitals may use Chemstrip 10 UA Urine Test Strips (Cat. No. 418003).

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 adaptor. Then connect the AC adaptor 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. Use Type N to read either Chemstrip 5 OB or Chemstrip 7 Urine Test Strips. The type of tray is indicated on the underside of the tray. See Section 4.3 for details on using the Urisys 1100® Urine Analyzer with Chemstrip 5 OB or Chemstrip 7 Urine Test Strips.

Hold the test strip tray with the gray reference pad facing up and towards the analyzer (see Figure 1). Slide the test strip tray into the slot below the function keys until the retaining bar closes (see Figure 2).

Figure 1

Figure 2

Be careful not to touch the gray reference pad. Contamination of the reference pad may impair the quality of the results obtained.

* Hospitals may use Chemstrip 10 UA Urine Test Strips (Cat. No. 418003).

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. The selection menu STRIP TYPE is displayed. If you use the Chemstrip 10 MD Test Strips, select CHEM 10 by pressing the left function key. If you use Chemstrip 5 OB or Chemstrip 7 Test Strips, select CHEM 5 or CHEM 7 respectively, by pressing the corresponding function keys.

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.

ATTENTION: If Chemstrip 5 OB or Chemstrip 7 Test Strips are used, calibration is not necessary with the Chemstrip Calibration Strips. The instrument calibration is performed automatically via the gray reference field on the test strip tray.

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.

* Hospitals may use Chemstrip 10 UA Urine Test Strips (Cat. No. 418003).

4.3   Modification for Chemstrip 5 OB and Chemstrip 7 Urine Test Strips

For readings with Chemstrip 5 OB or Chemstrip 7 Test Strips, the Type N test strip tray is required to accomodate the shorter test strips. It is necessary to modify the "strip type" setting on the analyzer to either "Chem 7" or "Chem 5" as appropriate. To do this, press START and use the function keys to select "Menu", followed by "Setup 1", "Strip", and then "Type". Select the appropriate strip type from the menu. Press START to confirm and then insert the Type N test strip tray into the reader. The Urisys 1100® Urine Analyzer is now ready.

For Chemstrip 5 OB and Chemstrip 7 Urine Test Strips, calibration with the Chemstrip Calibration Strip is not necessary. The instrument calibration is performed via the gray reference pad on the test strip tray.

Please note that the Chemstrip 5 OB and Chemstrip 7 Urine Test Strips do not have a compensation pad. Consequently, when used with either of these strips, the Urisys 1100® Urine Analyzer does not compensate for strong intrinsic urine coloration and occasional false-positive readings may occur.

4.4 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.

4.5 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.

---

* Hospitals may use Chemstrip 10 UA Urine Test Strips (Cat. No. 418003).

5.   Calibration

The following section only applies when the Urisys 1100® Urine Analyzer is used with Chemstrip 10 MD* Test Strips. When using Chemstrip 5 OB or Chemstrip 7 Test Strips, the calibration procedure described below is not necessary (see Section 4.3).

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).

When the Urisys 1100® Urine Analyzer is set to read Chemstrip 10 MD* Test Strips, it 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.

Figure 6

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.

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. An acknowledging beep sounds. The tray advances slightly, the retaining bar closes, and the gray reference pad on the tray and the calibration pads are read.

Figure 7

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.**

* Hospitals may use Chemstrip 10 UA Urine Test Strips (Cat. No. 418003).

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 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 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 Diagnostics Technical Service at 1-800-428-4674 for recommended 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, and repetition of the assay excludes errors in technique, contact Roche Technical Service at 1-800-428-4674.

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. Touch the long edge of the strip to absorbant paper for one second making sure that each pad is blotted. Always wear protective gloves when handling and disposing of samples of human origin (see Figure 9).
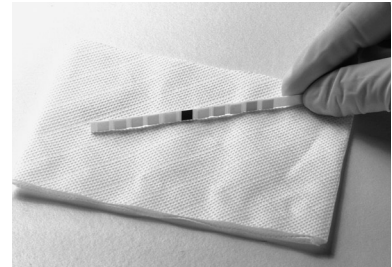

Figure 9

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). An acknowledging beep sounds. The tray advances slightly, the retaining bar closes, and the gray reference pad on the tray is read (see Figure 13).
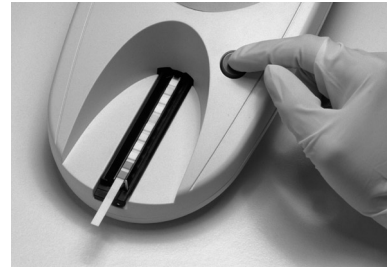

Figure 12

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. Seventy seconds after the START button is pressed, all test strip pads are read. The results are printed and the next sample number appears on the display.

6. The test strip tray returns to the starting position and the retaining bar opens. Remove and dispose of the test strip. Wipe any urine residue from the tray with a lint-free cloth (see Figure 15).
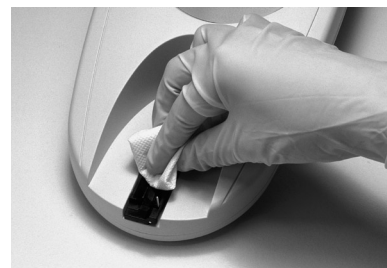

Figure 15

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.

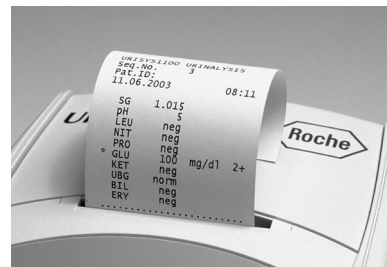Tear off the printout, by pulling it horizontally over the edge.

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 soft, lint-free cloth as needed (see Figure 15). This is important to prevent carry-over of urine between patients and accumulation of urine residues that might hamper smooth operation of the analyzer. When wiping, be careful not to move the tray and that the retaining bar remains open.
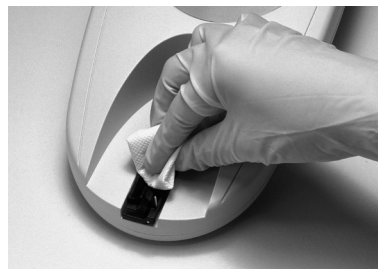

Figure 15

7.2 Daily Maintenance

Clean the test strip tray with water and disinfect with 70% alcohol or 10% bleach daily.

1. Switch off the analyzer.

2. Pull the test strip tray out of the analyzer.

3. Rinse 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.

⚠ **Be careful not to damage the gray reference pad during the cleaning process. Make sure the reference pad is completely clean and dry before proceeding to read test strips.**

⚠ **Be sure the positioning hole on the side of the tray is absolutely dry (see Figure 17). This hole is used to ensure that the test strip tray is automatically positioned correctly in the instrument.**

Figure 17

* Hospitals may use Chemstrip 10 UA Urine Test Strips (Cat. No. 418003).

6. Install the test strip tray by holding the tray opposite the end with the gray reference pad and inserting the tray into the slot below the function keys.

ATTENTION: Be careful not to touch the gray reference pad. Contamination of the reference pad may impair the quality of the results obtained.

7. If you wish to proceed with the next readings directly after cleaning the test strip tray, switch the analyzer 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 17) 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 Diagnostics Technical Service 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 Diagnostics Technical Service at 1-800-428-4674. Recalibrate with Chemstrip Calibration Strip (when using Chemstrip 10 MD*).

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 (e.g. "Chem 10" test strip, "Chem 5" test strip, "Chem 7" 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 Diagnostics Technical Service 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 Diagnostics Technical Service 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 Diagnostics Technical Service 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 setting, 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 Diagnostics Technical Service 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 Diagnostics Technical Service 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 Diagnostics Technical Service 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 Diagnostics Technical Service 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 an 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. Electromagnetic interference from other devices (see Section 4). **Action:** Repeat the measurement with a new test strip. Follow the directions carefully and ensure the test strip is correctly inserted. Repeat calibration if necessary. Remove external sources of interference, if there are any.
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 Diagnostics Technical Service 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 Diagnostics Technical Service 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.

<div align="center">

Connections:

</div>

Urisys 1100® Urine Analyzer   Host (PC pinout 9-pin)

Urisys 1100®			Host
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.

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® 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:** | $\leq$ | 0.8 kg |

Power supply: External mains adapter, Model SA 125A-0735U-S (Sino-American Switching 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 |

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%

Interfaces:
PC/HOST: (selectable) serial, D-Sub socket, 9-pin, female, **unidirectional, bidirectional** or **ASTM** protocol

AT/PC keyboard: 5-pin DIN socket, female
Barcode reader

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.

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. 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. Roche Diagnostics **will replace the instrument** provided written notice of defect within 30 days of occurence, all parts which prove to be defective and 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 OR REPAIR OF THE INSTRUMENT AND ITS PARTS AS DESCRIBED ABOVE. IN NO CASE SHALL ROCHE DIAGNOSTICS BE LIABLE FOR INCIDENTAL OR CONSEQUENTIAL DAMAGES.

11. Ordering Information and Replacement Parts

The analyzer, consumables, replacement parts and accessories are:

Catalogue No.

3617556	Urisys 1100® Urine Analyzer
	Contents: Power Supply with AC Adaptor and US Power Cord, Program Chip, Test Strip Trays (Type C and N), Printer Paper, Operator's Manual with Policies and Procedures CD, Quick Reference Guide, and User Training CD.
3260763	Chemstrip® 10 MD Urine Test Strips (100 test strips)
1008552	Chemstrip® 7 Urine Test Strips (100 test strips)
1893467	Chemstrip® 5 OB Urine Test Strips (100 test strips)
418007	Chemstrip Calibration Strip (50 calibration strips)

Replacement Parts:

4340612	Power Cord (US)
4340647	AC Adaptor (Model SA125-0735U, 100 V - 240 V, 50-60 Hz)
3666735	Test strip tray Type C for Chemstrip® 10 MD
3666913	Test strip tray Type N for Chemstrip® 5 OB/Chemstrip® 7
3617599	Urisys 1100® Urine Analyzer Operator's Manual including Policies and Procedures CD
3755533	Urisys 1100® Urine Analyzer User Training CD
3617564	Quick Reference Guide
3666778	Warranty Card
3666751	Thermal paper (5 rolls)
1907131	Spare reference pads (5 pieces)
05346380 001	Program chip Urisys 1100® Urine Analyzer USA

Optional accessory items:

1248693	Keyboard for patient ID entry (English)
1906186	Interface Cable
05382262 001	Barcode Reader

Please contact Roche Diagnostics Technical Service 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
PO Box 50457
Indianapolis, IN 46250-0457
USA

Phone Numbers

Main switchboard: 317-521-2000
Customer Service: 800-428-5076
Technical Service: 800-428-4674

Websites

www.poc.roche.com
www.diavant.com

CE

Roche