**Software Version 5.x & 6.x** 

# **Urisys 1100**



# Technical Product Information & Serial Interface Description of Urisys 1100 Urine Analyzer

US SW Version 6.x & International SW Version 5.x



V.1.0

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## 1 General Notes

The data and information provided in this manual correspond to the state of knowledge existing at the time of introducing the Urisys 1100 on the market. Any important changes will be taken into account in the next edition of this Technical

Product Information for Urisys 1100 Instruments.

In any case, the respective packaging leaflet should be regarded as authoritative.

This Technical Product Information for Urisys 1100 was created for the telephone service and technical service staff.

## **Contacts:**

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## 2 Introduction

## 2.1 Urisys 1100 International

**Urisys 1100 international** is a reflectance photometer designed to read and evaluate urine test strips Combur<sup>10</sup>Test UX, Combur<sup>1</sup>Test and Combur<sup>5</sup>Test from Roche Diagnostics.

It reads the strips under standardized conditions, saves the results to memory and outputs them via its own built-in printer and/or serial interface.

Use of **Urisys 1100** eliminates factors known to affect visual evaluation of urine test strips, such as:

- Variable lighting conditions at the workplace
- People's individual skill at matching colors and their limits of concentration
- Different reaction times for the test strips
- Clerical errors
- Strong color of the urine sample

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

## 2.2 Urisys 1100 US version

**Urisys 1100 US version** a reflectance photometer designed to read and evaluate urine test strips Chemstrip 10 MD, Chemstrip 7 and Chemstrip 5 OB from Roche Diagnostics. It reads the strips under standardized conditions, saves the results to memory and outputs them via its own built-in printer and/or serial interface.

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

- Variable lighting conditions at the workplace
- People's individual skill at matching colors and their limits of concentration
- Different reaction times for the test strips
- Clerical errors
- Strong color of the urine sample

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

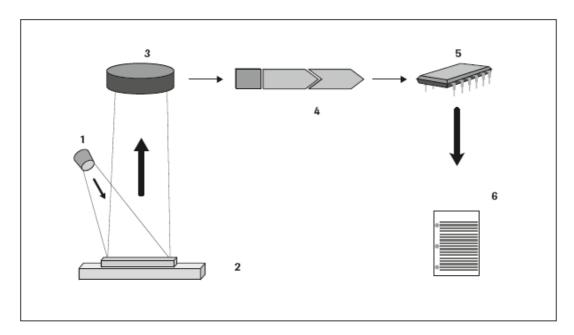
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## 3 System Description

## 3.1 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 first the reference pads, then each of the test pads on the strip.

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



The LED (1) emits light of a defined wavelength on to the surface of the test pad (2) at an optimum angle. The light hitting the test zone is reflected more or less intensely depending on the color produced on the test pad, and is picked up by the detector, a phototransistor (3), positioned directly above the test zone. The phototransistor sends an analogue electrical signal to a 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 evaluates the reflectance value according to the defined range limits (reflectance values that are programmed into the analyzer for each parameter) and outputs a semi-quantitative result (6). The test pads of the strip are read after a lead (incubation) time of about 55–65 seconds.

In strongly alkaline urine samples, Urisys 1100 automatically corrects the result of the Specific Gravity test.

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## **4 Components and Function**





2) Display / keypad

3) Test strip tray

4) START button

5) On/Off switch

6) Serial interface

7) Power socket

8) 5pin DIN socket



Flips up for insertion of printer paper

LCD display and three function keys for menudriven operation and interfacing with the user

Holds and anchors the strip

a) Starts the reading process

b) Closes submenus and returns to the starting

menu (Ready-to-Measure status)

Powers the unit on and off

For connection to a personal or host computer

Socket used to connect the analyzer to the

mains adapter

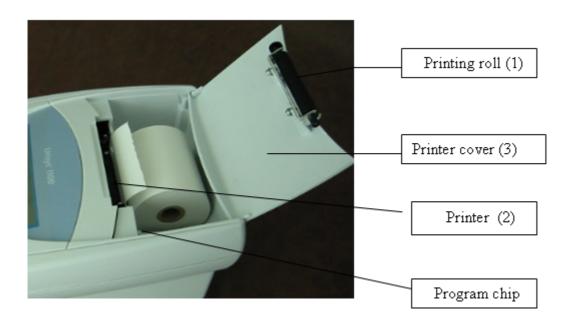
For connecting a barcode reader and/or AT/PC

keyboard

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## **5 Printer**

## 5.1 Printer description



## 5.2 Change of Printer

In case off mal function of Urisys 1100 printer (if printing is faulty) you need to replace printing unit (2).

You must to replace printing roll (1) on the printer cover (3) as well, since one does not work without the other.

#### Note:

The printing roll is <u>not</u> compatible with <u>other</u> printer units.

## 6 Software

## **6.1 Overview**

The Urisys 1100 Urine Analyzer software has a user interface that enables specific settings and recurrent functions to be selected via the liquid crystal display (LCD) and function keys (see Sections 6.2)

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The three functions keys correspond to the particular function displayed in 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.

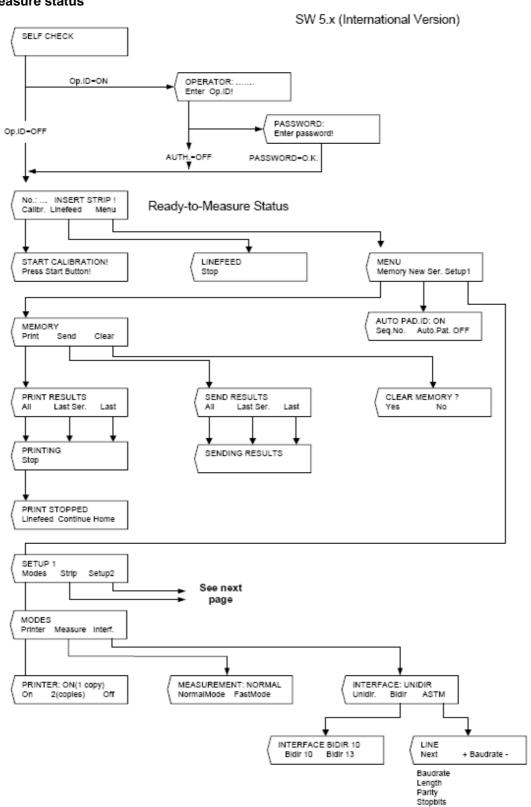
Pressing the START button within any submenu accepts selected instrument state or function, and returns the system to Ready-to-Measure status.

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.

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## 6.2 Menu Structure (Flowchart) international Version

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

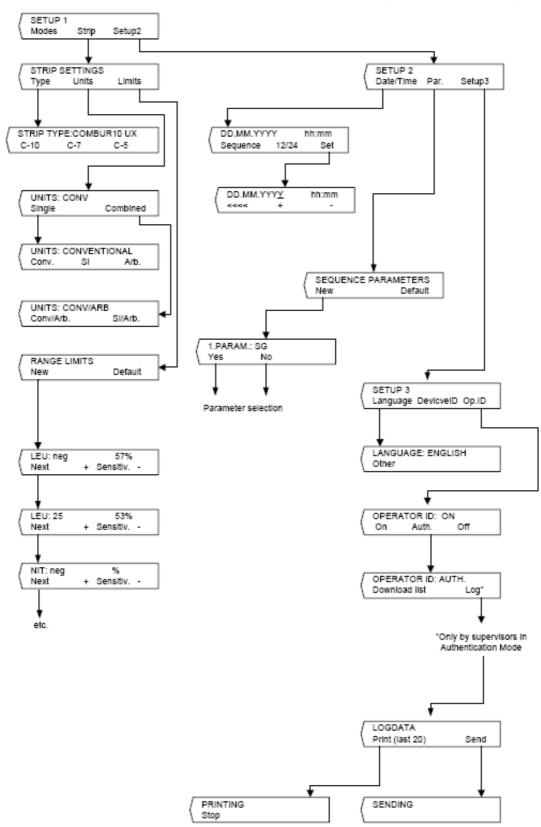


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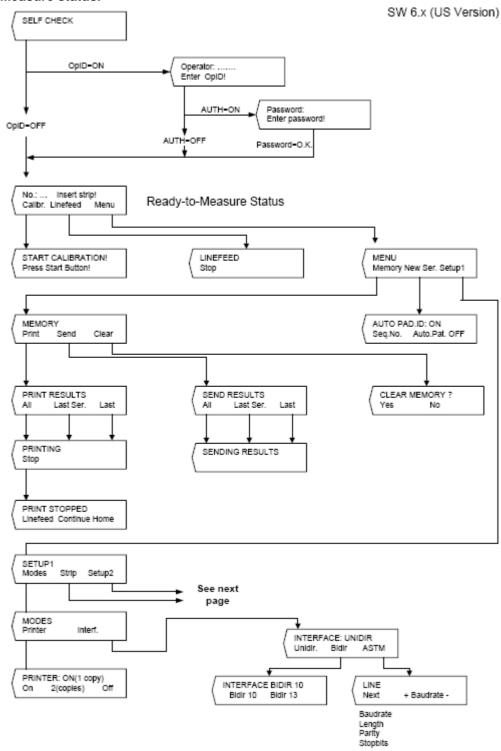
## SW 5.x (International Version)



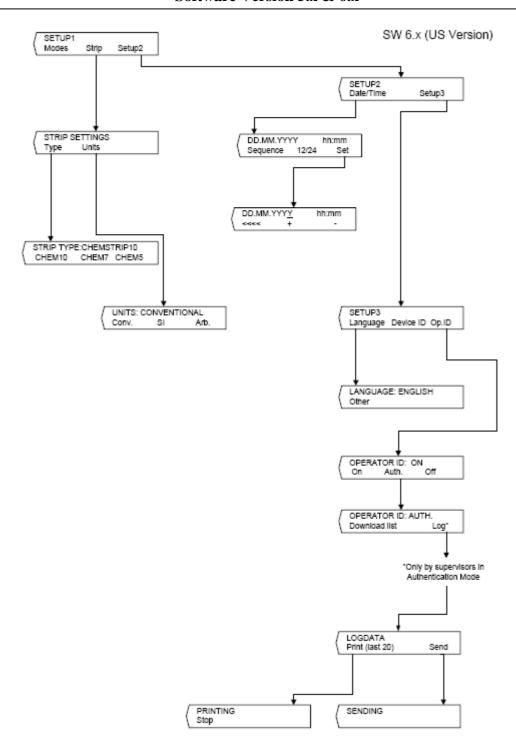
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## 6.3 Menu Structure (Flowchart) US Version

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



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## 7 Calibration

## 7.1 Urisys 1100 International

**Urisys 1100 International** is calibrated before leaving the factory. When installed, it must be recalibrated with Control-Test M calibration strips before the first samples are read, and thereafter every seven days. Control-Test M calibration strips consist of a grey plastic material, that is standardized to give constant, defined reflectance readings. The purpose of calibrating the analyzer is to compensate for ageing effects that influence the optical system and the grey reference pad in the strip tray. If the compensation needed is eccessive, 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.

When **Urisys 1100 International** is set to Combur<sup>10</sup>Test UX test strips, it automatically requests a new calibration every week. The "REPEAT CALIBRATION!" message is displayed following a successful self check and if one week passed after the last valid calibration.

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

#### 7.1.1 Procedure

- 1. Remove a calibration strip from the Control-Test M container. Be careful not to touch the pads and do not allow them to come into contact with urine.
- 2. Place the calibration strip, with the test pads facing upwards, on the tray so that it's leading edge is held by the clip at the front end of the insertion slot. The retaining bar must be open. 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.

- 3. Press the START button. An acknowledging beep sounds. The tray advances, the retaining bar closes, and the grey reference pad on the tray, then the calibration pads are read.
- 4. The tray is then transported back to the start position, and the retaining bar opens. Remove and throw away the used calibration strip. Use each calibration strip once only.
- 5. If the calibration is valid, the result is stored together with date and time, and printed (see below).

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

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

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

## 7.1.2 Calibration printout

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

#### 7.1.3 Calibration errors

If the results obtained for the reference pad or the calibration strips are out of programmed tolerances, one of the following messages appear: "REFERENCE PAD ERROR!", "CALIBRATION INVALID!" or "CALIBRATION ERROR!"

In the event of a calibration error or if the calibration was invalid, repeat the calibration procedure with a fresh Control-Test M calibration Strip.

Press the START button to return to the "START CALIBRATION" menu. Follow the same calibration procedure as above. When the message "CALIBRATION O.K." has been printed, proceed with the reading of test strips. If you continue to receive an error message, please call service.

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

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## 7.2 Urisys 1100 US version

**Urisys 1100 US version** 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 grey plastic material that is standardized to give constant, defined reflectance readings. Calibrating strips should remain in the vial until just prior to use and should only be used once.

The purpose of calibration of the analyzer is to compensate for ageing effects that influence the optical system and the grey 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.

When **Urisys 1100 US version** 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 the successful self check.

## 7.2.1 Procedure

- 1. Make sure that the test strip 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" massage 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 it's leading edge is held by the clip at the front end of the test strips tray. The retaining bar must be open. 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 grey reference pad on the tray and the calibration pads are read.
- 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 once only.

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## 7.2.2 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 are printed, for the orange LED (middle column) in the middle column and for the green LED (right column) in the right column.

#### 7.2.3 Calibration errors

If the results obtained for the reference pad or the calibration strips 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 "Calibration" menu. Follow the same calibration procedure as above. When the massage "CALIBRATION O.K." has been printed, proceed with the reading of test strips. If you continue to receive an error message (See chapter 9), call service

## 8 Cleaning and Maintenance

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

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

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

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

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## 8.1 Routine Cleaning

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

## 8.2 Daily Maintenance

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

- 1. Switch off the instrument.
- 2. Pull the tray out of the analyzer.
- 3. Rinse the contaminated parts of the tray under running water.
- 4. Clean with 70 % alcohol or another suitable disinfectant.
- 5. 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.
- 6. Dry the parts with a dry, lint-free cloth.

**CAUTION:** Take care not to damage the grey reference pad during cleaning, and ensure that it is completely clean and dry before proceeding to read.

**CAUTION:** Ensure that the positioning hole on the side of the tray is absolutely dry. This hole is used to ensure that the test strip tray is automatically positioned correctly in the instrument.

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

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## 9 Error Messages

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

E 1 REFERENCE PAD ERROR MIDDLE!	Cause: The middle portion of the reference pad on the tray is soiled or damaged.
	<b>Action:</b> Switch off the instrument. Carefully clean and dry the pad. Check if it is damaged (e.g. scratched, etc.). Insert the tray again, and then wait for the self check to finish. If the error message is repeated, replace the reference pad or use the spare tray. Recalibrate with Control-Test M (when using Combur <sup>10</sup> Test UX, US version Chemstrip Calibration Strip).
E 15 REFERENCE PAD ERROR BOTTOM!	Cause: The bottom portion of the reference pad on the tray is soiled or damaged.  Action: see E1
E 16 REFERENCE PAD ERROR TOP!	Cause: The top portion of the reference pad on the tray is soiled or damaged.  Action: see E1
E 2 WRONG STRIP!	Cause: The test strip used is different from the one for which the analyzer has been programmed (e.g. Combur <sup>10</sup> Test UX, US version Chemstrip 10 MD*). Press the START button. Repeat the measurement with the correct type of strip for which the analyzer has been programmed or change programmed type to the desired C5 or C7 strip.

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E 3 STRIP MEASUREMENT ERROR!	Causes: 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 is pressed.
E 4 CALIBRATION ERROR!	<b>Cause:</b> Calibration values differ from those obtained in the last valid calibration, but they are within tolerance.
	<b>Action:</b> Press the START button. Repeat the calibration with a new calibration strip taken from the Control-Test M container. Ensure that the strip is properly positioned under the clip on the test strip tray
E 5	Cause: Calibration values are out of tolerance.
CALIBRATION INVALID!	Action: Check the reference pad for soiling or damage. Clean if necessary or use the spare tray. Repeat the calibration with a new Control-Test M Calibration Strip, US version Chemstrip Calibration Strip. If the error message appears again, the instrument is defective.
E 6 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.
	<b>Action:</b> Switch off Urisys <b>1100</b> . Insert the program chip and switch the instrument on again. If "CHIP ERROR" appears again, the instrument is defective.
E 8 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 fouled with urinary deposit and blocked.
	Action: Clean, blow through or dry the positioning hole (using a lint-free cloth) to ensure that it is

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	completely clean. Remove urinary deposits, if there are any, 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, use the spare tray.
E 9 WRONG TRAY!	Cause: The test strip tray used is not the one for the programmed test strip type, or the grey reference pad is missing from the tray, or there is an instrument error.
	<b>Action:</b> Press the START button. The strip type menu is displayed. The strip type must match the tray type. Use the correct tray, or order a new one. If the error message appears again, the instrument is defective.
E 10 LIGHT BARRIER ERROR!	<b>Cause:</b> The light barrier used to control the position of the test strip tray is defective or the tray transport is blocked.
	<b>Action:</b> Pull out the tray and return it to the start position. Press the START button. If the error message appears again, the instrument is defective.
E 12 OPTICS ERROR!	Cause: The reference pad is missing from the tray, or an LED or the phototransistor is defective.
	<b>Action:</b> Attach the reference pad or use the spare tray. Press the START button. If the error message appears again, the instrument is defective.
CLOSE PRINTER COVER	Cause: The printer cover is open. Action: Close printer cover.
E 14 INTERFACE ERROR!	Cause: Fault in data transfer to PC or host in bidirectional or ASTM mode.
	<b>Action:</b> 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.

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E18 INVALID OP.ID	Cause: The entered operator ID is not valid. Action: Enter a valid operator ID.
E19 LIST DOWNLOAD FAILED	Cause: The new operator ID list download failed. Action: No action. After 2 seconds next state starts with old list if there was
E20 NO VALID LIST	Cause: There is no valid list at all in the device.  Action: Try to download an operator ID list from the host or continue without authenticated operator
CHECK MEASUREMENT	Analyzer prints out software and chip version numbers and after a measurement, the result with 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	Causes: Test strip is incorrectly positioned; uncharacteristic test pad colors; proper incubation intervals not kept to during serial measurements; Wrong test strip, such as Combur 10 Test with US device, or US version Chemstrip 10 MD* strip with INT device, may have been used. Electromagnetic interference from other devices.  Action: Repeat the measurement with a new, instrument-compatible 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	Causes: "Printer: Off" has been selected, or the printer/software is defective.  Action: Insert paper if needed. Choose "Printer: On" in menu to re-activate the printer. Request a patient report via the "Print" function. If this fails, activate the "Linefeed" function. If there is still no response, the instrument is defective.

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THE ANALYZER WILL NOT READ EVEN THOUGH THE SEQUENCE NUMBER IS	Causes: Entering an ID from keyboard, it is not closed by Enter or cleared (e.g.: accidentally a button has been pressed).
DISPLAYED	<b>Action:</b> If an AT/PC keyboard is connected, press the Escape key, or switch Urisys 1100 off and back on again

## 10 Spare Parts

Part name	Material No
Printer, Thermo, with PCB	04340604001
Cover Printer	04340582001
Power Supply	04340647001
Cable USA Version	04340612001
Cable International Version	04340639001

## 11 Accessories

The following replacement parts are variable:

Part name	Material No
New Thermal paper (5 rolls, 50 mm diameter)	03666751001
Interface connection cable	11906186001
Reflotron keyboard engl.	11248723001
Program Chip Urisys 1100 International, Version 5.x	05345618001
Program Chip Urisys 1100 US Version, Version 6.x	05346380001
Spare reference pads (5 pieces)	11907131001

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## 12 Technical Information

**Dimensions:** Width: approx. 150 mm

Depth: approx. 290 mm Height: approx. 95 mm

Weight:  $\leq 0.8 \text{ kg}$ 

**Power supply:** External mains adapter, Model

SA 125A-0735U-S (Sino-American) Input: 100 – 240 V AC, 50/60 Hz, 800 mA

Output: 7.5 V DC, stab, 3000 mA Polarity: - — G — +

**Consumption:** Operating: max. 15 W

Standby: 1.3 W

**System description:** Type: reflectance photometer

Light source: 6 LED's (light emitting diodes)

Wavelengths: 555 nm (green) 3x

610 nm (orange) 3x

Reader head: 1 head with 6 LED's

Measuring cycle:

Normal Mode: approx. 70 sec Fast Mode: approx. 30 sec Max. throughput: approx. 50 strips/hour

Incubation time: 55-65 sec
Printer: thermal printer
Display: liquid crystal display,

2 lines of 24 characters

Memory: 100 samples
Date, time: integrated clock

Operating conditions:OperatingIn storageTemperature:+15 ° to + 32 °C-20 ° to + 70 °CRelative humidity:20 % to 80 %20 % to 85 %

Optimum operating conditions: Temperature: + 20 ° to + 26 °C

Relative humidity: 30 % to 60 %

Interfaces:

PC/HOST: serial, D-Sub socket, 9-pin, female, unidirectional,

bi-directional or ASTM protocol (selectable)

AT/PC keyboard: Barcode reader

5-pin DIN socket, female

Certification marks: UL, cUL

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## 13 Interface Description

## 13.1 Serial Connection

At the rear, **Urisys 1100** has a serial interface connector, through which it can be connected to a PC or central host computer.

On request, Roche Diagnostics can supply a suitable standard data cable (REF 11 906 186 001). The connected PC must satisfy the requirements with regard to electrical safety laid down in EN 60950.

The interface can be used for **uni-directional**, **bi-directional** or **ASTM** communication, selectable via the menu.

When the interface is set for unidirectional communication, the data are sent as an ASCII file and can be received via a terminal program. There is not any control of connection.

In bidirectional and ASTM mode, device waits for defined messages from host, checking connection.

In bidirectional mode there can be two Patient ID lengths. The entered Patient ID appears in the Urisys 1100 system display window and is also printed out and/or sent to the PC/Host along with the test results. 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 sensure that the correct data will be sent.

In ASTM mode, additional data can be send to or receive from host, and the line parameters can be modified.

**Line parameters:** 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.

C	onnection	is:
	ŀ	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
	2 —	2 — RxD 3 — TxD 4 — DTR 5 — GND 6 7

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

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## 13.2 Barcode Reader, AT/PC Keyboard port

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

Interface specification: 5-pin DIN socket, female

Pin out: 1 clock

2 data

3 n/c

4 GND

5 + 5 V

#### 13.3 Barcode Reader

Barcode Readers suitable for use with Urisys 1100 with SW Version 5.0 and above must meet the following specifications:

- Radio frequency interface class B according to EN 61326-1
- Electromagnetic interference immunity requirements for industrial locations according to EN 61326-1
- Part 15 of ECC rules for a class B computing device

The recommended barcode reader can read commonly used barcodes such as Coda bar, Code 39, Code 128 and Interleaved 2 of 5.

If both a barcode Reader and an external keyboard have to be connected, a data cable CAB 322 IBM AT/XT DIN is needed.

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## 14 Host Interface Description, Unidir and Bidir

### 14.1 Introduction

### 14.1.1 Document Purpose

This document provides the specifications for data transmission of results from a URISYS1100 Urine Analyzer to an external laboratory host computer via an asynchronous serial connection. This document defines the so called Unidir and Bidir type connections.

#### 14.1.2 Document Conventions

All example data streams will be represented as follows:

STX	•	Е	$\Diamond$	1234567001	ETX	99	CR
-----	---	---	------------	------------	-----	----	----

Space characters (ASCII 32) are represented by the  $\Diamond$  symbol. All ASCII values are represented in decimal base. STX, ETX, and CR are the only control characters used, and will be represented by standard acronyms, as shown above. Each field is contained within a box.

## 14.2 Analyzer overview

## 14.2.1 Analyzer Description

The URISYS1100 Urine Analyzer is a semi-automated reflectance photometer intended for in-vitro semi-quantitative reading of urine test strips. The urine test strips are multiparameter strips used for the determination of specific gravity, pH, leukocytes, nitrite, glucose, ketone, urobilinogen, bilirubin and blood in urine. The analyzer can store results for up to 100 strips in memory

#### 14.2.2 Operation Modes

- Several different modes of operation are available,
  - using Patient Identifier (Pat.ID) as sample identifier or not,
  - using Operator identifier (Op.ID) or not.
  - using Authenticated mode (Op.ID with password) or not.
- Operation using uni-directional, bi-directional or "ASTM" protocol in serial data connection
- Operating with real time printing or reprint/resend data from memory

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#### 14.3 Protocols Bidir and Unidir

#### Overview

According to setting, the interface is a simple uni- or bi-directional serial interface. All communications originate at the analyzer.

In case of bi-directional communication the host needs only to:

- Send a packet (MOR) to tell the analyzer whether it is ready to receive when analyzer requests attention.
- Send a packet (MOR) to tell the analyzer that the last result packet was good, and please send another.
- Send a packet (REP) to tell the analyzer that the last received packet had an error, so please send it again.
- Handle two possible message lengths only Pat.ID can be 10 or 13 characters long.

#### 14.3.1 Bi-directional case:

## **Packet Types**

The URISYS 1100 Urine Analyzer uses different packets to determine the operation of the host interface and to transfer results.

The types of packets are:

Packet	Sender	Description	Frame ID	Example
REP	Host	Repeat Request	? (63 <sub>10</sub> )	STX?ETX3>CR
SPM	Analyzer	Start	< (60 <sub>10</sub> )	STX <etx3=cr< td=""></etx3=cr<>
		Communication		
MOR	Host	Send next	> (62 <sub>10</sub> )	STX>ETX3?R
		packet		
SPE	Analyzer	Results Packet	; (59 <sub>10</sub> )	STX;EDataETXxx <sup>1</sup> CR
END	Analyzer	End	: (58 <sub>10</sub> )	STX:ETX3;CR
		Communication		

All of the packets have a fixed format and content.

The checksums (after ETX in samples) can be calculated using two different algorithms, "a" and "b".

The checksums will always be the same (within the used Algorithm, as "a" in this example) with the exception of the SPE, which will vary since SPEs contain different results.

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<sup>&</sup>lt;sup>1</sup> xx represents the checksum, which will vary depending on the Results Packet content. For more information, see the chapter 14.8

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## 14.3.2 Timing and Handshaking

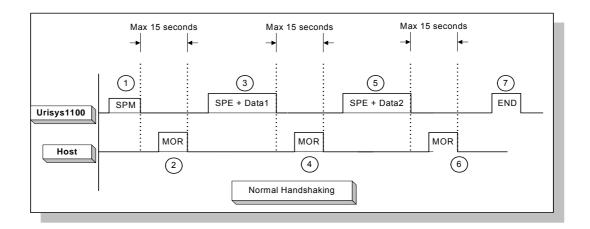
## **Description**

The *URISYS1100* will always act as the 'master' in communicating with the host. As the master, the URISYS1100 always initiates conversations.

The following diagrams and tables describe normal and abnormal communication exchanges.

## **Normal Operation**

After a series of strips have been processed, the operator can send results to the host. The following diagram and table shows the sequence of events

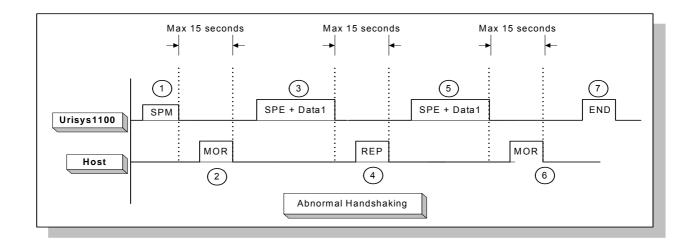


Event	Description
1	The URISYS1100 sends the SPM message to the host,
	requesting permission to send results.
2	The host responds with the MOR message, giving the URISYS1100 permission to send a result.
3	The URISYS1100 sends the SPE message, which contains
	results for the first sample.
4	The host responds with the MOR message, giving the
	URISYS1100 permission to send the next result.
(5)	The URISYS1100 sends the SPE message, which contains
	results for the second sample.
6	The host responds with the MOR message, giving the
	URISYS1100 permission to send the next result.
7	The URISYS1100 sends the END message, telling the host it is
	finished sending results. The host does not reply to this message.

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## **Abnormal Operation**

After a series of strips have been processed, the operator can send them to the host. The following diagram and table shows the sequence of events when trouble occurs, and only one sample is being sent.



Event	Description
1	The URISYS1100 sends the SPM message to the host, requesting permission
	to send results.
2	The host responds with the MOR message, giving the URISYS1100 permission
	to send a result. The host must respond within 15 seconds.
3	The URISYS1100 sends the SPE message, which contains results for the first
	sample.
4	The host responds with the REP message, giving the URISYS1100 permission
	to send the first sample again.
(5)	The URISYS1100 sends the SPE message, which again contains results for the
	first sample.
6	The host responds with the MOR message, giving the URISYS1100 permission
	to send the next result.
7	The URISYS1100 sends the END message, telling the host it is finished
	sending results. The host does not reply to this message.

### **Special Notes**

- 1. The host should only send the MOR or REP messages, and in response to only the REP, SPE, or SPM packets from the analyzer.
- 2. The analyzer will attempt to send it's packets (SPM or SPE+DATA) for a total of four times, terminate the communication cycle and post the 'No host connect.' message to the LCD.
- 3. Upon receipt of four consecutive REP packets from the host, the analyzer will send the END packet, terminate the communication cycle and post the 'No host connect.' message to the LCD.
- 4. Each result which is already sent stays available in memory to be sent more times.
- 5. In case the Host answered with REP after SPM, SPM will be repeated.

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## 14.4 Results Report Structure

The results packet has a structure as shown below:

					Units Settings		
					Conven-	SI	Arbitrary
					tional +	+ Arbitrary	
04 4	0.1	1.			Arbitrary		
	Stop		Content	Comment	Example 1	Example 2	Example 3
1	1	1	STX	Start of Text (ASCII 02)	STX	STX	STX
2		1	;  -	Frame ID (ASCII 59)	, 	;  -	, 
3	3	1	E	Function Code (ASCII 69)	E	E	E
4	4	1	Space	0	\$ F4004.45000	\$ FACOA 450000	\$ 5.400.4.4E00.00.4
5	17	13	Chars	Sample ID	012	54621456980 12	546214569801 2
18	18	1	Space		$\Diamond$	<b>♦</b>	$\Diamond$
19	23	5	nnnnn	Sequence Number	◊◊◊◊1	<b>◊◊◊◊1</b>	<b>◊◊◊◊1</b>
24	24	1	Space		$\Diamond$	<b>♦</b>	$\Diamond$
25	26	2	nn	Measurement Day of Month	12	12	12
27	27	1	Separator	. (ASCII 46)			
28	29	2	nn	Measurement Month	01	01	01
30	30	1	Separator	. (ASCII 46)	-		
31	32	2	nn	Year	98	98	98
33	33	1	Space		<b>◊</b>	♦	♦
34	35	2	nn	Measurement Hour	11	11	11
36	36	1	Separator	: (ASCII 58)	:	:	:
37	38	2	nn	Measurement Minute	58	58	58
39	39	1	Space		$\Diamond$	<b>♦</b>	$\Diamond$
40	41	2	SG	Specific Gravity Test Name	SG	SG	SG
42	46	5	nnnnn	Specific Gravity Result	1.020	1.020	$\Diamond\Diamond\Diamond\Diamond\Diamond$
47	51	5	Chars	Specific Gravity Arbitrary	$\Diamond\Diamond\Diamond\Diamond\Diamond$	$\Diamond\Diamond\Diamond\Diamond\Diamond$	$\Diamond\Diamond\Diamond\Diamond\Diamond$
52	52	1	Space		<b>◊</b>	<b>◊</b>	$\Diamond$
53	54	2	PH	pH Test Name	PH	PH	PH
55	57	3	nnn	pH Results	<b>◊◊6</b>	<b>◊◊6</b>	$\Diamond\Diamond\Diamond$
58	62	5	Chars	pH Arbitrary	00000	◊◊◊◊◊	$\Diamond\Diamond\Diamond\Diamond\Diamond$
63	63	1	Space	,	<b>\( \)</b>	◊	◊
64	66	3	LEU	Leukocyte Test Name	LEU	LEU	LEU
67	77	11	Chars	Leukocyte Result		♦neg♦♦♦♦♦♦♦	♦♦neg♦♦♦♦♦♦
78	82	5	Chars	Leukocyte Arbitrary	⊹oneg	≎≎neg	≎≎neg
83	83	1	Space		♦ O	♦ ♦	♦ O
84	86	3	NIT	Nitrite Test Name	NIT	NIT	NIT
87	89	3	Chars	Nitrite Result	pos	Pos	◊◊◊◊+
90	94	5	Chars	Nitrite Arbitrary	◊◊◊◊+	◊◊◊◊+	◊◊◊◊+
95	95	1	Space	That is a state of y	◊	◊	◊
96	98	3	PRO	Protein Test Name	PRO	PRO	PRO
99	109	11	Chars	Protein Result	015000mg/dl		◊◊+++◊◊◊◊◊◊
110	114	5	Chars	Protein Arbitrary	♦ 130 √ √ 111g/ui	0000000000000000000000000000000000000	◊◊+++
115	115	1	1 _	1 Totali 7 ii bili di y	◊	\(\frac{\partial}{\partial}\)	◊
116	118	3	Space GLU	Clucase Test Nama	GLU	∨ GLU	∨ GLU
119	129	11	Chars	Glucose Test Name Glucose Result			\$\\ \\$\\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \
130	134		ł	Glucose Result Glucose Arbitrary		◊◊◊6◊mmol/l	
135	135	5	Chars	Ciucose Aibilialy	◊◊◊++	♦ ♦ •	◊◊◊++
		1	Space	Katana Taat Nama	♦ VET	♦ VET	♦ VET
136	138	3	KET	Ketone Test Name	KET	KET	KET
139	149	11	Chars	Ketone Results		oneg◊◊◊◊◊◊◊	♦♦neg♦♦♦♦♦♦
150	154	5	Chars	Ketone Arbitrary	♦♦neg	◊◊neg	⇔neg
155	155	1	Space		♦	<b>◊</b>	♦
156	168	3	UBG	Urobilinogen Test Name	UBG	UBG	UBG
159	169	11	Chars	Urobilinogen Results	norm\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	norm◊◊◊◊◊◊◊	◊◊neg◊◊◊◊◊◊
170	174	5	Chars	Urobilinogen Arbitrary	≎≎neg	♦♦neg	≎≎neg

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175	175	1	Space		♦	♦	<b>◊</b>
176	178	3	BIL	Bilirubin Test Name	BIL	BIL	BIL
179	189	11	Chars	Bilirubin Results	♦neg♦♦♦♦♦		
190	194	5	Chars	Bilirubin Arbitrary	≎≎neg	≎≎neg	◊◊neg
195	195	1	Space		♦	♦	<b>◊</b>
196	198	3	BLD	Blood Test Name	ERY	ERY	ERY
199	209	11	Chars	Blood Results	◊◊50◊Ery/ul	◊◊50◊Ery/ul	◊◊+++◊◊◊◊◊◊
210	214	5	Chars	Blood Arbitrary	◊◊+++	◊◊+++	◊◊+++
215	215	1	Space		<b>◊</b>	♦	<b>◊</b>
216	220	5	Chars	Instrument identifier	82441	82441	82441
221	221	1	Space		♦	♦	<b>◊</b>
222	233	12	Chars	Operator identifier	Davidoff◊◊◊	Davidoff◊◊◊◊	Davidoff◊◊◊◊
					<b>◊</b>		
234	234	1	Space		<b>♦</b>	<b>♦</b>	$\Diamond$
235	235	1	Not Used	Not Used	$\Diamond$	$\Diamond$	$\Diamond$
236	236	1	ETX	End of Text ETX	ETX	ETX	ETX
237	238	2	Chars	Checksum	Nn	Nn	nn
239	239	1	CR	Carriage Return (213)	CR	CR	CR

#### Remark:

All result-packet-structures are as follows: first 4 digits: numbers, 5th digit: space, last 6 digits: Units (right hand orientated).

Checksum in this example are not calculated (nn)!

## **Units Settings**

The URISYS1100 system has flexible unit's settings that include the following: (all examples are taken from the Result Packet Structure table on the previous pages, using the Protein test)

Setting	Result Example	Arbitrary Example
Conventional	♦150♦♦mg/dl	◊◊+++
SI	1.50◊◊◊◊g/l	◊◊+++
Arbitrary	$\Diamond \Diamond + + + \Diamond \Diamond \Diamond \Diamond \Diamond \Diamond \Diamond$	◊◊+++

### **Important Notes**

- 1. The above example is demonstrating the maximum protocol length in case of 13 Pat. ID. Characters.
- 2. If Pat. ID. is selected for 10 characters; the length of the protocol will be shortened by these 3 characters.
- 3. If the setting is for Arbitrary only, then information of results arbitrary too.
- 4. The operator ID max 12 character long
- 5. If operator ID is not used, ID shows "OFF" text

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## **14.5 Interface Parameter**

## **Cable Connections**

The table below summarizes the connections needed for host communication.

URISY	S1100			Host	
DTE Signal	9 Pin Female	Signal Direction	9 Pin Male	25 Pin Male	DCE Signal
RxD	2	4	2	3	TxD
TxD	3	$\Rightarrow$	3	2	RxD
GND	5	<b>\$</b>	5	7	GND
DTR	4	4	4	20	DTR

## **Communication Parameters**

The required serial interface parameters are listed in the table below.

<b>Parameter</b>	Value
Baud Rate	9600
Word Length	8 bits
Parity	None
Stop Bits	1

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#### 14.6 Checksum Calculation

#### Overview

All of the messages require dynamic verification of checksums utilizing two different possibilities of calculations (Algorithm "a" and Algorithm "b").

The analyzer will analyze received checksum, and it will compare it all the time with "Algorithm a" or with "Algorithm b". Thus Algorithm with positive check result remains as active calculation Algorithm (see Auto adaptation).

The host needs only send the required packets along with the known checksums. The host can also check the REP, SPM, and END messages against stored messages to ensure integrity.

For the results packets (SPE) however, Roche highly recommends that the host interface program uses the checksum to ensure data integrity of the result packets. This section describes how the checksum works.

## **Autoadaption**

URISYS1100 is in a position to adapt itself automatically to the procedure used by the host (checksum a or b). If an error is discovered when checking the test bytes of the used protocol, the check will be continued using the algorithm of the alternative procedure. If, using the alternative test procedure, the test bytes are recognized as correct, this procedure will be used for all protocols in future. This new setting is retained even after the power has been switched off. If the alternative procedure does not recognize any correct test bytes either, an REP protocol is transmitted and there is no change of test procedure.

#### Algorithm a

This check sum is a kind of longitudinal parity test (Longitudinal Redundancy Check, LRC) of the bits contained in the data protocol. The protocol is linked bit by bit to XOR. The resulting byte is then split into two bytes (to avoid the occurrence of control characters) and attached to the protocol.

All bytes beginning with STX (inclusive) up to ETX (inclusive) are taken into account in the formation of the LRC. Some laboratory computers have a manufacturer-specific transmit/receive driver implemented which cuts off the STX in protocols and does not allow it to get into the user software. In this case, the user must first switch off block testing in the host.

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LRC-Byte =	LRC1-Byte =	Byte1 XOR Byte2 XOR Byte3 XOR Byte last LRC1-Byte = high-Nibble (shifted by 4 bits) of the LRC-Byte OR 30 <sub>16</sub> LRC2-Byte = low-Nibble of the LRC-Byte OR 30 <sub>16</sub> Example:				
	,	Bit-No.				
		8 7 6 5 4 3 2 1 0 1 1 0 0 0 1 0 0 0 0 0 0 0 1 1 0 0 1 1 0 1 1 0 0 0 1 1 1 1				
	LRC-Byte	0 1 0 1 0 0 1 1				
	high-Nibble low-Nibble	0 1 0 1 0 0 1 1				
		0 0 1 1 0 0 0 0 /* 30 <sub>16</sub> */ 0 0 0 0 1 0 1 /* high-Nibble */				
	==:	0 0 1 1 0 1 0 1 				
		0 0 1 1 0 0 0 0 /* 30 <sub>16</sub> */				
	OF	0 0 0 0 0 1 1 /* low-Nibble */				
		0 0 1 1 0 0 1 1				
	==: Further ex	=====================================				

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END-Protocol: ©: ♥3;

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## Algorithm b

This check sum is calculated by adding together the bytes to be transferred, the individual bytes being interpreted as positive, whole numbers. STX, the check sum, ETX and CR are not included in the addition. The result of the addition is taken as modulo 256. The resulting number can be represented by a single byte. The two half-bytes of this number are represented as hexadecimal figures ("0".."9", "A".."F"). Leading zeros are included.

If your software does not have a decimal-hexadecimal routine or function that can return a leading zero, the below algorithms may be helpful.

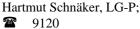
CS1-Byte = INT ((CS / 16)) + 48 for INT ((CS / 16)) 
$$\leq$$
 9 = INT ((CS / 16)) + 55 for INT ((CS / 16))  $\geq$  10

CS2-Byte = (CS modulo 16) + 48 for (CS modulo 16) 
$$\leq$$
 9 = (CS modulo 16) + 55 for (CS modulo 16)  $\geq$  10

Further examples: MOR-Protocol:©>♥3E

REP-Protocol: ©?♥3F SPM-Protocol: ©<♥3C END-Protocol: ©:♥3A

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## 14.7 Unidir sample outputs byte-to-byte

### Unidirectional Data description of Urisys1100 Interface Single Unit results

Bits	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	
line																									
1	U	R	I	L	U	Х	-	S		U	R	I	N	Α	N	Α	L	Υ	S	E					
2	S	е	q		N	r					X	X	X												
3	Р	а	t		ı	D	:					X	X	X	X	X	X	X	X	X	X	X	X	X	
4	X	X	X	X	X	X	X	X	X	X					X	X	X	X	X	X	X	X	X	X	(15-24:Date/Time)
5	0	р			ı	D	:						X	X	X	X	X	X	X	X	X	X	X	X	(9-24 operator identifier)
6	D	е	V	i	С	е		ı	D	:			X	X	X	X	X								(13-17 Device identifier)
7	X																								(1 Changed limit flag)
8	X		S	G					X	X	X	X	X						X	X	X	X	X	X	(19-24: Unit)
9	X		р	Н					X	X	X	X	X						X	X	X	X	X	X	(19-24: Unit)
10	X		L	Е	U				X	X	X	X	X						X	X	X	X	X	X	(19-24: Unit)
11	X		N	I	Т				X	X	X	X	X						X	X	X	X	X	X	(19-24: Unit)
12	X		Р	R	0				X	X	X	X	X						X	X	X	X	X	X	(19-24: Unit)
13	X		G	L	U				X	X	X	X	X						X	X	X	X	X	X	(19-24: Unit)
14	X		K	Е	Т				X	X	X	X	X						X	X	X	X	X	X	(19-24: Unit)
15	X		U	В	G				X	X	X	Х	X						X	X	Х	X	Х	X	(19-24: Unit)
16	X		В	I	L				X	X	X	X	X						X	X	X	X	X	X	(20-24: Unit)
17	X		Ε	R	Υ				X	X	X	X	X						X	X	X	X	X	X	(19-24: Unit)
18	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X					(1-20 calibration warning)

Interface Setting: 9600 Baud, 8 Bit, 1 Stop Bit, NO Parity

Explanation: x = variable Output (could be space in some cases)

Remark: all Data transmitted in ASCII, if application running with windows, data has to be transformed in ANSI.

## Unidirectional Data description of Urisys1100 Interface Combined Unit results

Bits	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
line																								
1	U	R	I	L	U	Х	-	S		U	R	I	N	Α	N	Α	L	Υ	S	Е				
2	S	е	q		N	r					Х	Х	Х											
3	Р	а	t			D	••					X	X	X	X	X	X	X	X	Х	X	X	X	X
4	X	X	X	X	X	X	X	X	X	X					X	X	X	X	X	Х	X	X	X	X
5	0	р			I	D	••						X	X	X	X	X	X	X	X	X	X	X	X
6	D	е	V	i	С	е		ı	D	:			X	X	X	X	X							
7	X																							
8	Х		S	G					X	X	X	X	X		Х	X	X	Х	X	Х			X	X
9	X		р	Η					X	X	X	X	X		X	X	X	X	X	Х			X	X
10	X		L	Е	U				X	X	X	X	X		X	X	X	X	X	X			X	X
11	X		N	ı	Т				X	X	X	X	X		X	X	X	X	X	X			X	X
12	X		Р	R	0				X	X	X	X	X		X	X	X	X	X	Х			X	X
13	X		G	L	U				X	X	X	X	X		X	X	X	X	X	X			X	X
14	X		K	Ε	Т				X	X	X	X	X		X	X	X	X	X	X			X	X
15	X		U	В	G				X	Х	X	X	X		X	X	X	Х	Х	Х			X	X
16	X		В	I	L				X	X	X	X	X		X	X	X	X	X	Х			X	X
17	X		Е	R	Υ				X	X	X	X	X		X	X	X	X	X	Х			X	X
18	Х	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X				

(9-24 operator identifier) (13-17 Device identifier) (1 Changed limit flag) (15-20 unit1, 23-24 unit2) (15-20 unit1, 23-24 unit2)

(15-20 unit1, 23-24 unit2) (15-20 unit1, 23-24 unit2) (1-20 calibration warning)

(15-24:Date/Time)

Interface Setting: 9600 Baud, 8 Bit, 1 Stop Bit, NO Parity

Explanation: x = variable Output (could be space in some cases)

Remark: all Data transmitted in ASCII, if application running with windows, data has to be transformed in ANSI.

## **Unidirectional Log data output of Urisys1100**

Bits	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	1
line																									
1	U	R	I	L	U	Х	-	S		U	R	ı	N	Α	N	Α	L	Υ	S	Е					
2	D	е	٧	i	С	е		I	D	:			Х	Х	X	X	X								(13-17 Device identifier)
3																									
4	X	X	X	X	X	X	X	X	X	X	X	X								X	X	X	X	X	(1-12:Date/Time, 20-24 action: On, Off or Login)
5	0	р			ı	D	:						X	X	X	X	X	X	X	X	X	X	X	X	(13-24 operator identifier)
6	Р	а	S	S	W	0	r	d	:				X	X	X	X	X	X	X	X	X	X	X	X	(13-24 password)
7																									
8	X	X	X	X	X	X	X	X	X	X	X	X								X	X	X	X	X	(1-12:Date/Time, 20-24 action: On, Off or Login)
9	0	р			ı	D	:						X	X	X	X	X	X	X	X	X	X	X	X	(13-24 operator identifier)
10	Р	а	S	s	W	0	r	d	:				X	X	X	X	X	X	X	X	X	X	X	X	(13-24 password)
11																									
12	X	X	X	X	X	X	X	X	X	X	X	X								X	X	X	X	X	(1-12:Date/Time, 20-24 action: On, Off or Login)
13	0	р			1	D	:						х	х	х	х	х	х	х	х	х	х	х	х	(13-24 operator identifier)
14	P	a	s	s	w	0	r	d	:				X	X	X	X	X	X	X	X	X	X	X	X	(13-24 password)
15	_						-																		
16	X	X	X	х	х	X	X	х	х	х	х	х								х	X	X	х	х	(1-12:Date/Time, 20-24 action: On, Off or Login)
17	0	р			ı	D	:						Х	Х	Х	Х	Х	X	Х	Х	X	Х	Х	Х	(13-24 operator identifier)
18	Р	а	S	S	w	0	r	d	:				Х	Х	X	Х	Х	Х	Х	Х	Х	Х	Х	Х	(13-24 password)

<sup>\*</sup>The last 20 Log event printed and sent out in Unidir.



## 15 ASTM protocol

#### 15.1 General

The ASTM protocol of "Urisys1100 cobas" device

The Urisys1100 device can output data in four ways:

printing data on built-in printer as 24 ASCII character long messages sending data in Unidir mode to host, format is the same as in printing sending data in Bidir mode to host sending data to host in "cobas" mode, using the so called ASTM protocol.

Device implements the Profile 1 of EN ISO 18812:2003 to send results to host PC (so this protocol fulfils the ASTM E1394-91 standard requirements). The only used message type is the M1.

In this type of data transmission always the Urisys 1100 device is the master. In this protocol the result message must contain the following records

Η	1x		Header of the message
Ρ	1x		(Patient data, not used; empty record.)
Ο	1x		Order - definition of the test and the sample
R	n x	n>=1	Result numerical data and units one record – one parameter
С	m x	0<=m<=n	The flag of the previous result as comment, if there is a flag
L	1x		Message terminator

One message can contain one test result. One test result is: all the data, concerning for one sample measurement.

#### Additionally device can ask and receive operator name list from host

Asking:	
ASKIIIQ.	

Answer:

Н	1x		Header of the message
M	1x		Request for operator identifiers and their passwords lists
L	1x		Message terminator
Н	1x		Header of the message
M	n x	n>=1	Names and passwords of n (max 300) operators
L	1x		Message terminator

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#### Data flow in the different cases

Normal re	tluze	send

Device	
sends	Host sends
(ENQ)	
	(ACK)
"H" record	
	(ACK)
"P" record	
	(ACK)
"O" record	
	(ACK)
"R" record	
	(ACK)
"C" record	, ,
	(ACK)
(more "R"-s a	nd "R + C"-s)
	(ACK)
"L" record	• ,
	(ACK)
(EOT)	

### **OpID** list request

Device sends	Host sends
301103	i iosi serius
(ENQ)	
	(ACK)
"H" record	
	(ACK)
"M" record R0	QO
	(ACK)
"L" record	
	(ACK)
(EOT)	

### OpID list download

Device

DEVICE	
sends	Host sends
(ENQ)	
,	(ACK)
"H" record	(
	(ACK)
"M" record OL	• •
W TOOGTO OL	(ACK)
"M" record OL	` '
W TECOTO OL	
	(ACK)
(more "M" reco	ords)
	(ACK)
"L" record	
	(ACK)
(EOT)	
(-0.)	

#### Log data send

Device	
sends	Host sends
(ENQ)	
,	(ACK)
"H" record	
	(ACK)
"M" record LC	)G
	(ACK)
"L" record	
	(ACK)
(EOT)	

## 15.2 Sending normal measurement data

		0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16				
Start	ENQ																					
	(ACK)																					
H record	STX	1	Н	V^&			"SEN"							Р		"DTS"		CR	ETX	"CHS"	CR	LF
	(ACK)																					
P record	STX	2	Р	1														CR	ETX	"CHS"	CR	LF
	(ACK)																					
O record		3	0	1	"S_ID"	"S_NO"	"SID"	R						Х			"DTM"	CR	ETX	"CHS"	CR	LF
	(ACK)																					
R record	STX	4	R	"RN"	"RNN"	"RES"	"UNI"					"DTC"	"OpID"					CR	ETX	"CHS"	CR	LF
	(ACK)																					
C record	STX	5	С	"RN"	- 1	"FL"	- 1											CR	ETX	"CHS"	CR	LF
	(ACK)																					
R record																						
	(ACK)																					
			Ш																			
	(ACK)																					
R record																						
	(ACK)																					
C record																						
	(ACK)	L																				
Lrecord	STX	2	L	1	N													CR	ETX	"CHS"	CR	LF
<u></u>	(ACK)																					-
End	EOT																					

Mandat	ory chai	racters			Unic	mess	age dat	а			
Unic te	st data				Emp	ty field	S				
Not use	ed fields	3		Fron	n 2	15 all ι	used fie	lds star	t with	vertical	line
				char	acter	(ASCII	124), as	s field s	epara	itor.	

# 15.3 Requesting operator ID list download

		0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16				
Start	ENQ																					
	(ACK)																					
H record	STX	1	I	۱۸&			"SEN"							Р		"DTS"		CR	ETX	"CHS"	CR	LF
	(ACK)																					
M record	STX	2	М	1	RQO													CR	ETX	"CHS"	CR	LF
	(ACK)																					
Lirecord	STX	3	L	1	N													CR	ETX	"CHS"	CR	LF
·	(ACK)																					
End	EOT																					

Mandat	tory chai	racters			Unic n	nessag	ge data				
Unic te	Unic test data				Empty	fields					
Not us	Not used fields			From	215	all use	d fields	start wi	th verti	cal line	
				chara	cter (AS	3CII124	l), as fie	eld sepa	rator.		

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# 15.4 Operator identifier list download

		0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16				
Start	ENQ																					
	(ACK)																					
H record	STX	1	Ι	lν8			"SEN"							Р		"DTS"		CR	ETX	"CHS"	CR	LF
	(ACK)																					
M record	STX	2	М	"OI_N"	OL	"OpID"	"PW"	"SV"	NOL									CR	ETX	"CHS"	CR	LF
	(ACK)																					
M record	STX	3	М	"OI_N"	ΟL	"OpID"	"PW"	"SV"	NOL									CR	ETX	"CHS"	CR	LF
	(ACK)																					
M record	STX	4	M	"OI_N"	OL	"OpID"	"PW"	"User"	NOL									CR	ETX	"CHS"	CR	LF
	(ACK)																					
	(ACK)																					
Lirecord	STX	2	L	1	N													CR	ETX	"CHS"	CR	LF
	(ACK)																					
End	EOT			_																		

Mandat	tory chai	racters			Unic	mes	sage	data			
Unic te	st data				Emp	ty fie	lds				
Not use	ed fields	3		From	12'	15 all	used	fields s	tart wit	h vertica	Il line
				chara	acter	(ASC	11124)	, as field	dsepa	rator.	

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# 15.5 Sending LOG data

		0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16				
Start	ENQ																					П
	(ACK)																					
H record	STX	1	Η	۱ <u>۸</u> &			"SEN"							Р		"DTS"		CR	ETX	"CHS"	CR	LF
	(ACK)																					
M record	STX	2	M	"RN"	LOG	LGDat												CR	ETX	"CHS"	CR	LF
	(ACK)																					
Lirecord	STX	3	L	1	N													CR	ETX	"CHS"	CR	LF
	(ACK)																					
End	EOT																					

Mandat	tory chai	racters			Unic	mess	age d	lata			
Unic te	st data				Empt	y field	is				
Not use	Not used fields			From	215	5 all u	ised fi	elds sta	rt with	vertical	line
				chara	icter (/	ASCII	124), a	as field	separ	ator.	

## 15.6 Abbreviations in result tables

Abbrev.	Content (sample)	Meaning	Place
CHS	(CheckSum)	Checksum of the record**	x18
DTC	20070321	Date of last menu calibration	R10
DTM	20070322154726	Date/Time of the test	O15
DTS	20070322154726	Date/time of the message	H14
FL	*^M	* (the flag of not-normal range, if result is not neg/norm) and M (limit modification mark, if one or more limits for this parameter are modified - limit table is INTUSER.)	C4
LOG	LOG	See SM	M3
LGDat	20070322154726^ON^L .Normann^Heureka	Date/time of log event, the event (On, Off, Login), the used OpID, the used password	(LOG)M4
NOL	11	Number of OpIDs in the valid authentication list (min 1, max 300)	(OL)M7
OI_N	1	Place number in OpID authentication list (1NOL)	(OL)M2
OL	OL	See SM	M3
OpID	L. Norman^A	Name or code of the operator (max 12 chars), code of authentication (A,N)***	R11, (OL)M4
PW	Petike	Password to the operator name or code before (12 chars)	(OL)M5
RES	25^1+	Result in setted system (SI or CONV or ARB) + result in ARB system *	R4
RESC	375^315	Compensated and raw results in (R%) x10	(SM)M5
RESR	587	Reference pad raw results in (R%) x10	(SM)M6
RN	3	Record serial number, generaly the same as parameter ser.no. in cases of normal or CheckMode results, and 099 in case of LOG data.	R2, C2, (SM)M2, (LOG)M2
RNN	3^LEU	Parameter serial number, see parameter code list	R3, (SM)M4
RQO	RQO	See SM	M3
S_ID	Kovacs Janos	Patient identifier (max 13 characters)	O3
SM(R)	SM	Record sub_ID: Service Mode (CheckMode) Reference result (SMR), or measuring pad result(SM), or request for OpID list (RQO), or OpID List (OL), or Log data (LOG);	M3
S_NO	187^008^C10	MeasNo (165535); SerNo (1100), within the given series; strip type setting (C5, C7, C10); MeasNo is an independent serial no of the test, automatically restarts, can not be set or clear.	O4
SEN	URISYS1100^75943^S	Device type, device ID, sw version, limit table type (INT/USA/INTUSER)	H5

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	W1.2^USA		
SID	Urinalysis^Incubated	Type of measurement; fixed text: Urinalysis^Incubated, or Urinalysis^Fast, or CheckMode Meas^Incubated, or CheckMode Meas^Fast	O5
SV	User	code of rights (SV=supervisor, User=not supervisor)	(OL)M6
SZIN	Orange	Color of test, in CheckMode (Orange, Green) for each parameter	(SM)M6
UNI	Leu/ul	The setted result unit (ARB has no unit)	R5

*Param names.	result values	and units corres	pond to valid limit table	(INT or USA)

\*\*Calculation of checksum:

This check sum is calculated by adding together the bytes to be transferred, the individual bytes being interpreted as positive, whole numbers. CR and ETX are included in the addition, STX Not. The result of the addition is taken as modulo 256. The resulting number can be represented by a single byte. The two half-bytes of this number are represented as hexadecimal figures ("0".."9", "A".."F"). Leading zeros are included.

Byte0=(STX)

CHS = (Byte1 + Byte2 + ... + ByteLength-1) modulo 256

\*\*\*Authentication code A=authentic OpID; N=not authentic ID or not ID used

# 15.7 Parameter names and codes (RNN)

Test code	Test number				
SG	1				
рН	3				
LEU					
NIT	4				
PRO	5				
GLU	6				
KET	7				
UBG	8				
BIL	9				
ERY	10				
COMP	11				
RefLo	12				
RefMid	13				
RefHi	14				

## 15.8 ASTM Communication samples of Urisys 1100

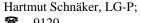
#### Normal measurement result send

17:50:24,405 Urisvs 1100 - ASTM Host Simulator [V 6.8d]

```
U1100 17:56:22,233 [ENQ]
HOST 17:56:22,233 [ACK]
U1100 17:56:22,280 [STX]1H|\^&|||URISYS1100^99305^SW5.31^INT|||||||P||20090116184200[CR][ETX]F8[CR][LF]
HOST 17:56:22,280 [ACK]
U1100 17:56:22,296 [STX]2P|1[CR][ETX]3F[CR][LF]
HOST 17:56:22,311 [ACK]
U1100 17:56:22,358 [STX]3O|1||001^00036^C10|Urinalysis^Incubated|R|||||X|||20090116184100[CR][ETX]00[CR][LF]
HOST 17:56:22,358 [ACK]
U1100 17:56:22,389 [STX]4R|01|01^-SG|1.020|g/cm3|||||20090116|LNorman^A[CR][ETX]BB[CR][LF]
HOST 17:56:22,405 [ACK]
U1100 17:56:22,436 [STX]5R|02|02^·pH|····7||||||20090116|LNorman^A[CR][ETX]09[CR][LF]
HOST 17:56:22,436 [ACK]
U1100 17:56:22,483 [STX]6R|03|03^LEU|··neg^··neg|·Leu/ul|||||20090116|LNorman^A[CR][ETX]0B[CR][LF]
HOST 17:56:22,483 [ACK]
U1100 17:56:22,530 [STX]7R|04|04^NIT|..neq^..neq|||||20090116|LNorman^A[CR][ETX]BD[CR][LF]
HOST 17:56:22,530 [ACK]
U1100 17:56:22,577 [STX]0R|05|05^PRO|--neg|-mg/dl-||||20090116|LNorman^A[CR][ETX]D1[CR][LF]
HOST 17:56:22,577 [ACK]
U1100 17:56:22,624 [STX]1R|06|06^GLU|·norm^··neg|·mg/dl·||||20090116|LNorman^A[CR][ETX]2D[CR][LF]
HOST 17:56:22,624 [ACK]
U1100 17:56:22,671 [STX]2R|07|07^KET|··neg^··neg|·mg/dl·||||20090116|LNorman^A[CR][ETX]CA[CR][LF]
HOST 17:56:22,671 [ACK]
U1100 17:56:22,717 [STX]3R|08|08^UBG|·norm^··neg|·mg/dl·||||20090116|LNorman^A[CR][ETX]29[CR][LF]
HOST 17:56:22,717 [ACK]
U1100 17:56:22,764 [STX]4R|09|09^BIL|··neg^··neg|·mg/dl·||||20090116|LNorman^A[CR][ETX]C3[CR][LF]
HOST 17:56:22,764 [ACK]
U1100 17:56:22,811 [STX]5R|10|10^ERY|...50^...3+|.Ery/ul|||||20090116|LNorman^A[CR][ETX]A9[CR][LF]
HOST 17:56:22,811 [ACK]
```

#### Software Version 5.x & 6.x

```
U1100 17:56:22,827 [STX]6C|10|||*||[CR][ETX]96[CR][LF]
HOST 17:56:22,827 [ACK]
U1100 17:56:22,842 [STX]7L|1|N[CR][ETX]0A[CR][LF]
HOST 17:56:22,858 [ACK]
U1100 17:56:22,858 [EOT]
OpID list request and download
   17:49:36,889 Urisys 1100 - ASTM Host Simulator [V 6.8d]
Request
U1100 17:49:45,561 [ENQ]
HOST 17:49:45,561 [ACK]
HOST 17:49:45,624 [ACK]
U1100 17:49:45,639 [STX]2M|1|RQO[CR][ETX]AA[CR][LF]
HOST 17:49:45,639 [ACK]
U1100 17:49:45,655 [STX]3L|1|N[CR][ETX]06[CR][LF]
HOST 17:49:45,655 [ACK]
U1100 17:49:45,671 [EOT]
Download
HOST 17:49:47,686 [ENQ]
U1100 17:49:47,686 [ACK]
HOST 17:49:47,733 [STX]1H|\^&|||Host||||||P||20081208174945[CR][ETX]76[CR][LF]
U1100 17:49:47,733 [ACK]
HOST 17:49:47,764 [STX]2M|1|OL|LNorman|Pass|SV|3[CR][ETX]6D[CR][LF]
U1100 17:49:47,780 [ACK]
HOST 17:49:47,811 [STX]3M|2|OL|123456789012|Password9012|SV|3|CR]|ETX]B0|CR]|LF]
U1100 17:49:47,811 [ACK]
HOST 17:49:47,842 [STX]4M|3|OL|UserName|UserPW|User|3[CR][ETX]7F[CR][LF]
U1100 17:49:47,858 [ACK]
HOST 17:49:47,889 [STX]5L|1[CR][ETX]3E[CR][LF]
U1100 17:49:50,374 [ACK]
HOST 17:49:50,389 [EOT]
```



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#### Log data send

\* 17:48:52,217 Urisys 1100 - ASTM Host Simulator [V 6.8d]