accustrip® URS Reader

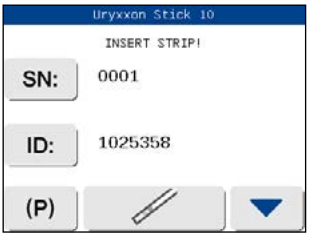
User Manual

CAT. NO: UA850

The Accustrip URS Reader is waived for Accustrip urinalysis reagent strips.
A certificate of CLIA waiver is required to perform the testing in a waived setting. If the laboratory does not have a Certificate of Waiver, the Application for Certification (Form CMS-116), can be obtained at http://www.cms.hhs.goc/clia/. The form should be mailed to the address of the local State Agency of the State in which the laboratory resides (http://www.cms.hhs.gov/clia/ssa-map.asp).
Laboratories with a certificate of waiver must follow the manufacturer's instructions for performing the test. If the laboratory modifies the instructions, the test no longer meets the requirements for waived categorization. A modified test is considered to be high complexity and subject to all CLIA requirements.

1. Quickstart

Unpack the instrument and place it on an even, hard surface. Connect the power supply and turn the equipment on with the On/Off-switch (Pic. 4-8). After the self test the start screen will appear on the display.



Display 1: Start menu

- Dip a test strip (Accustrip urine test strip) into the urine sample for approx. one second.
- Blot by touching the edge of the strip to a paper towel to remove excess urine.
- Place the strip on the strip holder.
- Slide or push the strip to the end of the channel. Do not touch the reagent pads on the test strip.

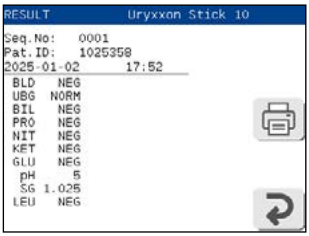
The instrument will automatically detect an applied strip. The measurement cycle will be started. A progress bar on the display shows the remaining measurement time.

Note: If "Autostart" is deactivated, the measurement must be started using the start control panel  *(see 10.5. How to deactivate and activate the autostart, page 32).*

NOTICE

The strip will be drawn into the instrument after 30 sec

After approximately 60 sec the result will be displayed on the screen (Display 2) and transferred to the printer and interfaces.



Display 2: Result

By pressing the printer symbol the result can be printed again. Choosing the return panel will lead back to the start screen.
Another analysis may be started by applying the next test strip.

NOTICE

To start a new measurement it is not necessary to go back to the start screen. A new strip is detected at any time and the measurement is then started automatically.

2. Introduction and intended use

The Accustrip URS Reader is a reflection photometer for the analysis of Accustrip urine test strips. The measurements are performed under standardized conditions, measured values may be displayed, printed and transferred to a computer.
The Accustrip URS Reader is designed for in-vitro diagnostic use (IVD) and should be used by healthcare professionals, only.

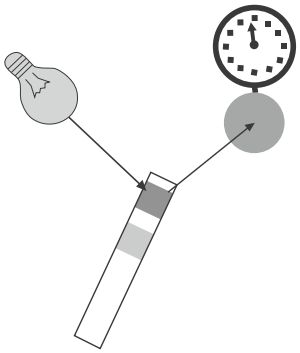
2.1. Intended Use and Indications for Use

The Accustrip URS Reader is intended for use as an in vitro diagnostic aid using urine specimens for screening for diabetis metabolic abnormalities, liver diseases, biliary and hepatic obstructions of the kidneys and urinary tract.
The test provided on Accustrip urine test strips for the determination of specific gravity, leucocytes, glucose, protein, blood, nitrite, pH, ketones, bilirubin and urobilinogen are considered routine urinalysis.

2.2. System description

2.2.1. Measuring Principle

The test strip moves below a fixed measuring head on a slide with an embedded reference pad. The reflectometric analysis of the test strip and the reference field take place during withdrawal and release of the slide.



Pic. 1: Measuring Principle

The strip is illuminated with an LED and a detector registers the intensity of light reflected by the test strip at three different wavelengths. Using an internal calibration, the results are calculated from the reflection values.

2.2.2. Functional Principle Accustrip URS Reader

A measurement is started by placing a strip on the holder. If the Autostart-feature is turned off, the measurement is started by pressing the start panel  in the display.
The result is shown on the display, printed out and released via the interfaces after the measurement has been completed. After three minutes the instrument will go to stand-by. Touching the screen will reactivate the instrument.
All user inputs are performed via the touch-screen *(see 3.8. Use of the instrument, page 14)*.

2.2.3. Safety warnings

The following safety warnings are used throughout the manual:

⚠ DANGER

Indicates an imminent or potentially hazardous situation which, if not avoided, will result in death or serious injury.

⚠ WARNING

Indicates an imminent or potentially hazardous situation which, if not avoided, could result in death or serious injury.

⚠ CAUTION

Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury.

NOTICE

Indicates a situation which, if not avoided, may result in malfunction or damage of the instrument. Information that clarifies facts in the text and that requires special attention.

⚠ CAUTION

In case of a test strip sled blockage, switch off the device and turn it back on after 10 seconds. If the blockage persists, do not continue using the device and contact technical support.

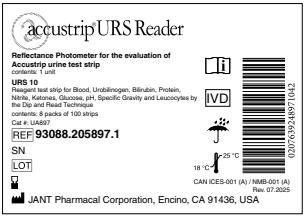
⚠ CAUTION

If liquids have entered the interior of the device, do not use it any further and contact technical support.

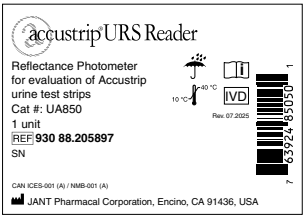
⚠ CAUTION

If there are any cracks or holes in the housing, stop using the device and contact technical support. If the software freezes, switch off the device and turn it back on after 10 seconds. If the software remains unresponsive, do not continue using the device and contact technical support.

2.2.4. Labels on the device and symbols



Shelf box label for product UA897



Shelf box label for product UA850

Type Plate Label

2.2.5. Symbols explanation

	Caution: Further information in user manual
	The medical device that has not been subjected to a sterilization process.
	Biological risc
	Keep away from sunlight.
	Keep dry.
	Temperature limits.
	Should not be used if the package is damaged.
	The medical device is intended for one use, or for use on a single patient during a single procedure.
	Indicates the need for the user to consult the instructions for use.
	Do not dispose of the device in common household waste.
	Medical device manufacturer.
REF	Manufacturer's catalogue number.
LOT	Manufacturer's batch code.
SN	Serial number of the device.
	Date on which the medical device has been manufactured.
	Date after which the medical device is not to be used.
IVD	In vitro diagnostic device.
CE	Indicates conformity with health, safety, and environmental protection standards for products sold within the European Economic Area
9 V ⎓ / 1.5A	Power input specifications.

3. Unpacking and Set Up

3.1. List of delivered parts

① Accustrip URS Reader
② Power pack 100 - 240 V, 47/63 Hz, 9V, incl. adapter
③ Printer paper
+ User manual (this booklet)

Pic. 2: Content

Read the operating manual for Accustrip URS Reader carefully before the first startup in order to ensure an error free operation.

3.2. Description of instrument parts

Pic. 3: Front view

Pic. 4: Backside view

Actuator	Function
1. Touch-Screen	Control of equipment functions
2. Test Strip Slide	Test strip retainer and autonomous start of analysis
3. Printer Flap	Opening the printer flap for paper replacement
4. Serial Interface	Connection of a computer
5. USB - Interface	Connection of a computer
6. USB - Interface	Connection of a keyboard or a bar code scanner
7. Mains Connection	Contact for the provided power pack
8. On/Off Switch (I/O)	Turning the equipment on and off
9. LAN-Interface	Connection to network (serial over LAN), not supported

3.3. Setting up the instrument

Place the instrument on a hard, even surface where humidity and temperature are fairly constant. Make sure that the instrument is allowed to acclimate to room temperature prior to use.
Make sure that you

- Do not place the instrument near strong electromagnetic fields.
- Do not place the instrument near heating plates, ovens or radiators.
- Do not expose the instrument to strong light sources (i.e. direct sunlight).
- Position the device with at least 5 cm of free space at the back to ensure safe access to the power switch.

3.4. Note on ambient surrounding

If the device is exposed to higher temperature fluctuations (e.g. after transport or distribution), it must be switched on not before sufficient acclimatization is given. The device should not be used close to electrical fields (e.g. by microwaves, radio units et cetera). In worst case the measurement results can be affected.

3.5. How to plug the instrument in

Pic. 5: Power pack

Pic. 6: DC in

An adapter is provided for adapting the power pack to the available mains connection. The adapter matching the mains connection is plugged on to the power pack (Pic. 5). After plugging the power pack cable into the jack "DC in" (Pic. 6) and connecting the power pack to the power socket the instrument is ready for operation.

3.6. How to load the printer paper

Pic. 7: Printer A

Pic. 8: Printer B

Open the printer flap by pressing the rectangular key next to the paper outlet (Pic. 7 and 8).

Pic. 9: Printer C

Pic. 10: Printer D

Unroll the paper roll by 5 cm and place the roll in the paper compartment with the end on the lower side. Fix the end of the paper to the housing with your fore-finger while closing the flap (Pic. 9 and 10).

3.7. How to install batteries (optional)

The instrument can be operated with 6 type AA batteries independent of the mains supply. The battery compartment is on the underside of the equipment. Notice the designated polarity (+/-) marked on the battery compartment while inserting the batteries.

Pic. 11: Battery compartment

3.7.1. Instrument self test

The instrument will perform an automatic self test each time it is turned on. If an error message appears, the instrument will not start measurements. In this case, please contact your local service provider.

3.7.2. Calibration

The instrument will perform an automatic calibration each time a test is run.

3.8. Use of the instrument

All user inputs are done via a touch-screen (touch-display). All functions are activated directly by slight pressure with the finger on explicit pictograms or text representing the menu items.

3.8.1. Buttons

Framed areas react to pressure and trigger the action linked to it. The caption of an area describes its function.
Examples:

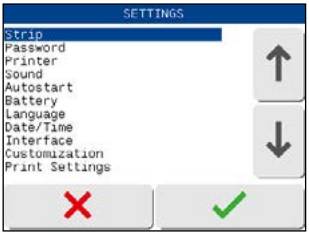
✓ Confirm / perform action

✗ Cancel action

Equipment settings

3.8.2. Scroll Arrows

Press the up-and-down arrows on the right side of the screen to scroll through a list of information on the left side of the screen. Once the desired information on the left side is highlighted, press ✓ to confirm your selection.



Display 3: Selective lists

Pressing ✓ will select the highlighted line.
You can leave the menu by pres-sing ✗.

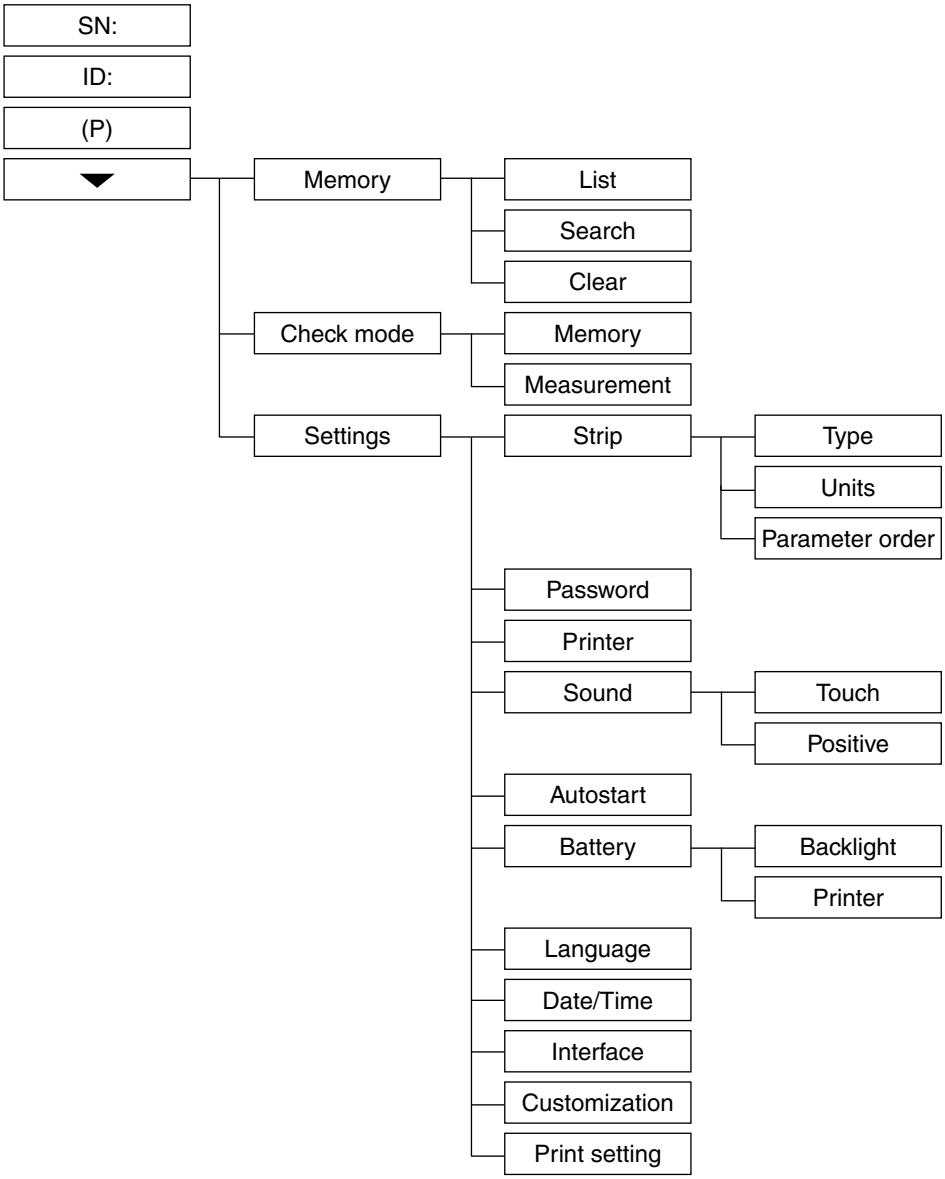
3.8.3. Round buttons

These buttons typically appear on screens that require a selection among serial items. The button with a filled circle is the current selection.

Pressing the circle will activate a selection. Save your selection by pressing [✓]. Pressing [✕] will quit the menu without performing any changes.

4. User Menu

4.1. Flow-chart of the Menu Structure



4.2. Description of the Menu Items

- SN:
  5.5. Changing the sequence number ("SN")
- ID:
  5.4. Entering the Patient Identification
- (P):
  Standby
- ▼:
  Main menu
- Memory:
  7. Recall results
- Check mode:
  9. Quality control testing
- Settings:
  10.1. How to modify strip settings
  10.2. How to protect settings from unauthorized access
  10.3. How to turn the printer on and off
  10.4. How to enable and disable acoustic signals
  10.5. How to deactivate and activate the autostart
  10.6. How to set energy saving options for the battery mode
  10.7. How to change the language
  10.8. How to set time and date
  10.9. How to activate data transfer
  10.11. How to print settings
  10.10. How to change the text of the printout header

5. Analysis of Test Strips

NOTICE

The instrument will perform an automatic calibration during each start.

5.1. How to perform a measurement

The instrument is very easy to use. In order to start the measurement, the test strip is placed on the strip holder. The instrument automatically detects a new strip and starts the measurement. A progress bar appears, that indicates the remaining analysis time. After 30 seconds the test strip is drawn into the instrument, after 60 seconds it is released.

NOTICE

Make sure to remove excess urine by blotting the test strip carefully on a lint-free cloth.

NOTICE

If "Autostart" is deactivated, the measurement must be started using the start control panel  *(see 10.5. How to deactivate and activate the autostart, page 32)*.

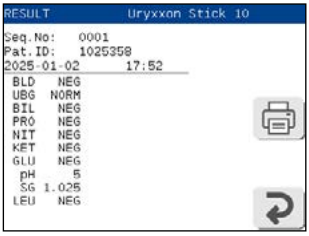
After the measurement, the instrument will release the analysed test strip which can now be discarded. The result is displayed on the screen and is transferred via the interfaces and / or printed according to equipment settings.
For additional information on the test strip, please read the package insert that comes with the strips.

⚠ DANGER

Urine and used test strips bare the danger of infection. Always use protective gloves during handling and disposal. The disposal of used test strips should be performed according to the regulations for the handling of potentially infectious material.

5.2. Display of Results

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



Display 4: Result

Positive findings are clearly marked by an asterisk (*) on the printout and on the display. Additionally, it is possible to enable an acoustic signal on positive findings.
The printout is light-sensitive and may turn yellow when exposed to light during storage. For archiving purposes the printouts should be kept in a dark place (patient file) or as a photocopy.
The result displayed may be printed again by pressing [🖶]. The return panel [↩] will lead back to the start screen.

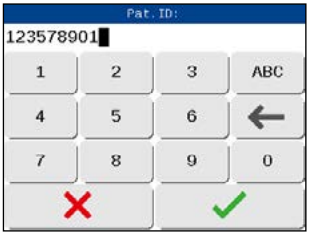
5.3. Measurement Errors

If the display shows "Measuring Error ..." instead of a result please read the instructions *(see 15. Error Messages and Fault Clearance, page 41).*
Repeat the measurement. In case of permanent errors please contact Customer Service *(see 17. Additional Information, page 44)*.

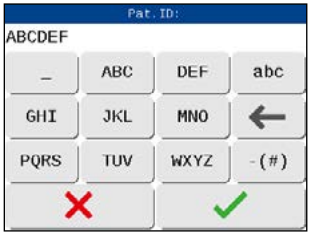
5.4. Entering the Patient Identification

The patient identification needs to be entered before starting the analysis. This can be done as follows:

a) Directly on the equipment: Pressing [ID:] in the start menu brings up an alphanumeric keypad. Enter the ID using the keys. To enter characters (i.e. "Miller") press [ABC] to change the character entry. Repeated pressing on the same field within 0.5 seconds switches through the characters displayed on the key. Wrong entries may be erased by pressing [←].



Display 5: Entering ID (numeric)



Display 6: Entering ID (letter)

b) Using a standard PC-keyboard: Connect the keyboard to the USB-jack Type A at the backside of the instrument (Pic. 4-⑥). User inputs on the keyboard will automatically be interpreted as patient identifications.
c) Using a bar code reader: Connect the barcode reader to the USB-jack Type A at the backside of the instrument (Pic. 4-⑥). Barcode readings will automatically be interpreted as Patient Identifications.

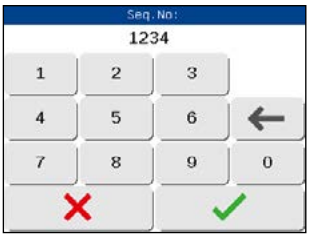
After entering the patient identification start the measurement. The Patient Identification is saved together with the diagnostic findings.

NOTICE

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

5.5. Changing the sequence number ("SN")

Pressing the field SN: in the start menu brings up a numerical pad. Enter a new sequence number using the keys on the pad. All following measurements will now be counted from this number on.



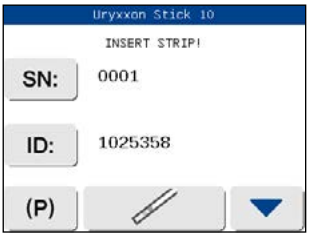
Display 7: Seq.-Input

5.6. Transferring data to a PC

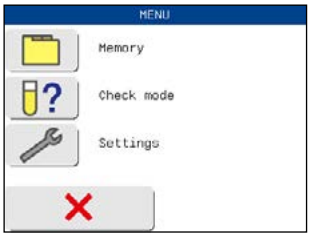
The results may be transferred to a PC via the USB-jack Type B or RS232-interface (Pic. 4).
A detailed description of the interface can be found in Chapter 14. Interface Description.

6. Enter the Main Menu

Pressing ▼ on the start screen will bring up the main menu.



Display 8: Start menu

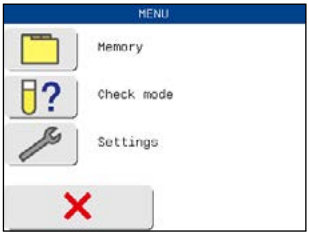


Display 9: Main menu

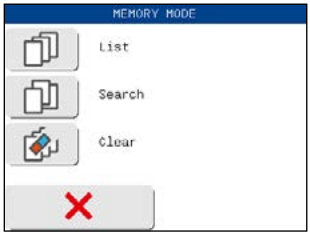
From here the other functions e.g. memory (7. Recall results), the test mode (9. Quality control testing) as well as the settings (10. Equipment Settings) can be reached.

7. Recall results

The instrument has an internal memory for storage and recall of measurement results. Every result is automatically saved after the analysis. When the memory is full, new data will overwrite the eldest saved dataset.
Access the memory by pressing in the Main menu .



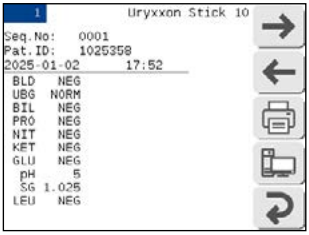
Display 10: Main menu



Display 11: Memory mode

7.1. How to scroll through memory

Pressing will bring up Display 12. Scrolling through the memory is possible by pressing the arrows on the right side. The next or previous result will be displayed.

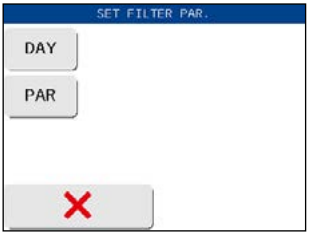


Display 12: Memory contents

It is possible to print and send the dataset displayed. The memory menu will reappear upon pressing Return .

7.2. How to find specific results (filtering)

To find the result you may select the date of the measurement and a specific parameter.



Display 13: Filtering

7.2.1. Selecting the Day

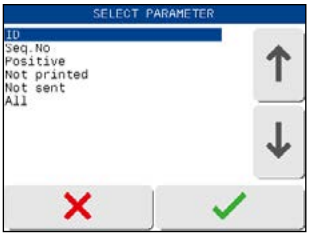
By pressing the panel Day you will reach the menu displayed below.

Display 14: Select day

Set the day with the buttons. Selecting "Date" will bring up a screen with the list of available dates (only days with measurements are shown on the screen). Select the desired date with the up-and-down arrows and confirm your selection by pressing ✓. After confirmation your selection will be displayed on the screen 'SET FILTER PAR.'

7.2.2. Selecting Search Criteria

Pressing PAR brings up Display 15.



Display 15: Select parameter

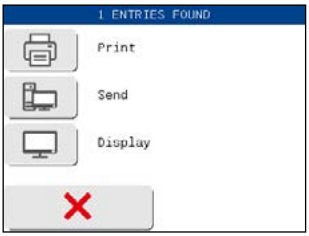
Use the arrow keys to select the desired criteria and confirm with ✓. The filter criteria will be displayed on filter settings screen (Display 16).

7.2.3. Display suitable matches

After setting "Day" and "Parameter" the search may be started by pressing ✓.

Display 16: Filtering

When suitable matches are found, an option will appear, allowing to print the datasets, send them to a PC or display them on the screen.



Display 17: Search result

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

7.3. How to delete results from memory

Pressing will delete all data in the memory. You need to confirm this again on a further screen.

8. Expected waiver performance

At 3 sites, 66 untrained users with no laboratory experience tested randomized samples using the Accustrip urine reagent strips and the Accustrip URS Reader. The CLIA waiver study demonstrated that the performance of the Accustrip URS Reader is acceptable in the hands of non-technical users when only the Quick Reference Guide is used to learn and perform tests. The performance of the Accustrip urine reagent strips with the Accustrip URS Reader, in the hands of the Lay-users, met the primary performance criteria that 90% of the results should be within ± one level of the expected results.

Analyte	Concentrations tested	Exact Agreement (%) Lay-user	Concentration	Exact and ± One (1) color block Level (%) Lay-user
Bilirubin	0, 1, 4	100, 92.4, 100	1	95.5
Blood	0, 10, 250	100, 96.9, 71.2	10	96.9
Glucose	0, 50, 500	98.5, 83.3, 100	50	100
Ketone	0, 25, 300	96.9, 100, 98.5	25	100
Leukocyte	0, 25, 500	98.5, 62.1, 100	25	96.9
Nitrite	Neg, pos	98.5, 100		100
pH	5, 6, 8	98.5, 93.9, 100	6	93.9
Protein	0, 30, 500	100, 98.5, 100	30	98.5
Specific Gravity	1.005, 1.010, 1.015, 1.025	95.5, 81.8, 46.9, 100	1.005, 1.010, 1.015, 1.025	95.5, 100, 98.5, 100
Urobilinogen	0.2, 2, 5	100, 95.5, 98.5	2	100

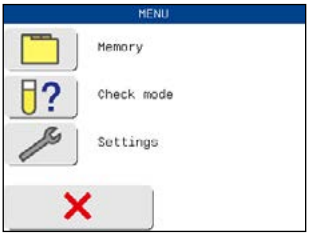
Table 1: Percent Agreement of the instrument results to Target Levels for Lay-users

9. Quality control testing

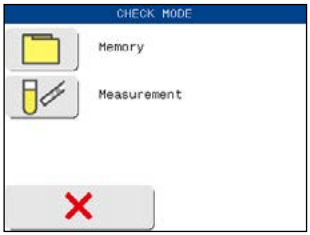
Test at least one known negative and one known positive specimen or control, whenever a new bottle of strips is first opened, for each new shipment, for each new LOT or at least monthly. Quality control samples should be run like a patient sample. Do not use water as negative control. Positive and negative control solutions provide a convenient basis for a quality control program. Contact the service number for ordering information.
If proper results are not obtained, consult your local product representative or contact Customer Service by calling the number given at the end of this manual for advise on testing techniques and results.

9.1. How to run a quality control test

Prepare the urine controls as described in the package insert and test them in test mode.
Handle the urine control solutions exactly as patient samples.
Upon pressing [?] on the start menu the "CHECK MODE" screen will appear.

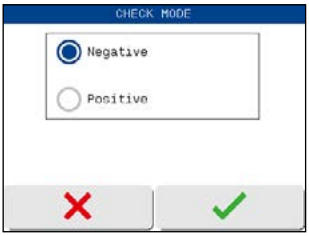


Display 18: Main menu



Display 19: Check mode

By pressing the panel [ ] the sample selection will appear. Select the type of control sample you want to analyze.



Display 20: Control sample

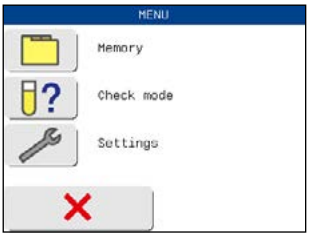
After pressing [✓] the instrument expects the test strip.

9.2. How to review old QC measurements

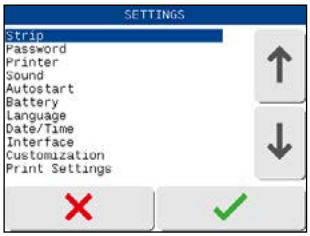
The equipment saves the result of the QC measurements in a separate memory. They may be displayed by selecting memory  and may be printed for documentation purposes.

10. Equipment Settings

Enter the main menu by pressing the menu key ▼ to reach the "SETTINGS" display press ↺.



Display 21: Main menu



Display 22: Settings

10.1. How to modify strip settings

10.1.1. Units

The instrument can report the results in different units:

- Conventional (e.g. 10 mg/dL)
- SI (e.g. 56 mmol/L)
- ARB, Plus-System (e.g. +++)
- Conventional + ARB
- SI + ARB

Choose the desired unit from the selective list.

10.1.2. Order of Parameters

The output order of the parameters may be customised via a list of selections. The parameters need to be selected in the desired order and confirmed by pressing ✓. After the last parameter, the equipment will ask whether the setting is to be saved. Save by pressing ✓ or go back to the preprogrammed order by pressing ✗.

10.1.3. Test strip LOT

The LOT-administration of the instrument is deactivated in the default setting *(see 13.2. How to control the LOT-control (LOT activate), page 37)*.

10.2. How to protect settings from unauthorized access

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

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

NOTICE

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

10.3. How to turn the printer on and off

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

10.4. How to enable and disable acoustic signals

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

10.4.1. Acoustic confirmation of user inputs

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

10.4.2. Acoustic warning on positive results

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

10.5. How to deactivate and activate the autostart

Select "Autostart" in the settings menu. In basic mode the instrument automatically detects an applied test strip and starts the measurement. This function may be deactivated via an option panel.
If "Autostart" is deactivated the analysis must be triggered by pressing a panel in the Start menu.

10.6. How to set energy saving options for the battery mode

Select "Battery" in the settings menu. Settings in this menu will only apply when the instrument is operated with batteries.
To increase the lifetime of the batteries, the LCD backlight and the printer can be turned off using the option panels.

10.7. How to change the language

Select "Language" in the settings menu. The language of the instrument menu can be switched to the following languages using the respective selective list:
English, German, Spanish, French, Italian, Portuguese, Polish, Turkish, Dutch, Hungarian, Norwegian, Swedish, Finnish, Danish, Indonesian

10.8. How to set time and date

Select "Date/Time" in the setting menu. To change, press on the respective number. A numerical pad appears. Enter the correct number and confirm by pressing [✓].
The date may be formatted in three ways. The active format is shown on a button [YMD] on the right hand side of the date. Select a date format by pressing this button.

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

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

Display 23: Date / time

10.9. How to activate data transfer

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

10.10. How to change the text of the printout header

Select "Customization" in the settings menu. The first two lines of the printout may be filled with a user-specific identifier. Each line contains 23 characters.

To enter the text an external keyboard or the alphanumerical pad on the display can be used. The keys on the touch-screen are linked to several letters. Repeated pressing within half a second switches through the letters displayed on the key.

10.11. How to print settings

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

11. Cleaning and Maintenance

DANGER

Urine and used test strips bare the danger of infection. Always use protective gloves during handling and disposal. The disposal of used test strips should be performed according to the regulations for the handling of potentially infectious material

11.1. How to clean the housing

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

11.2. How to clean the strip holder

Wipe off urine residues from the strip holder with a lint-free cloth after each measurement. This prevents crustification and drying of urine residues.
The strip holder can be removed from its transport mechanism and should be cleaned with water and - when necessary - with cleaning agent or disinfectant. Make sure that the instrument is turned off before removing the test slide.
After cleaning, the strip holder should be put back onto its transport mechanism carefully. The rectangular notches of transport mechanism and strip retainer must be placed on top of each other (Pic. 14).

Pic. 12: Test slide (bottom view)

Pic. 13: Notch A

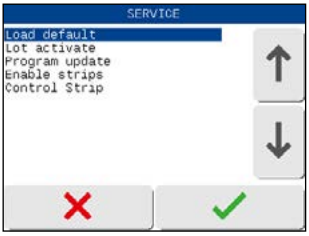
Pic. 14: Notch B

12. Table of Results

Param.	CONV	SI	ARB
BLD	NEG	NEG	NEG
	10 Ery/µL	10 Ery/µL	+
	50 Ery/µL	50 Ery/µL	++
	250 Ery/µL	250 Ery/µL	+++
UBG	NORM	NORM	NORM
	2 mg/dL	35 µmol/L	+
	4 mg/dL	70 µmol/L	++
	8 mg/dL	140 µmol/L	+++
	12 mg/dL	200 µmol/L	++++
BIL	NEG	NEG	NEG
	1 mg/dL	17 µmol/L	+
	2 mg/dL	35 µmol/L	++
	4 mg/dL	70 µmol/L	+++
PRO	NEG	NEG	NEG
	30 mg/dL	0.3 g/L	+
	100 mg/dL	1 g/L	++
	500 mg/dL	5 g/L	+++
NIT	NEG	NEG	NEG
	POS	POS	+
KET	NEG	NEG	NEG
	25 mg/dL	2.5 mmol/L	+
	100 mg/dL	10 mmol/L	++
	300 mg/dL	30 mmol/L	+++
GLU	NEG	NEG	NEG
	NORM	NORM	NORM
	50 mg/dL	2.8 mmol/L	+
	150 mg/dL	8.3 mmol/L	++
	≥ 500 mg/dL	≥ 27.8 mmol/L	+++
pH	5	5	5
	6	6	6
	6.5	6.5	6.5
	7	7	7
	8	8	8
	9	9	9
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
LEU	NEG	NEG	NEG
	25 Leu/µL	25 Leu/µL	+
	75 Leu/µL	75 Leu/µL	++
	500 Leu/µL	500 Leu/µL	+++

13. Service Menu

The instrument has a password protected service menu. To enter the service menu press the touch-screen three times during the self test after turning the equipment on. Upon request input the PIN "1111".
A menu with different options appears.



Display 24: Service menu

13.1. How to reset the system (Load Default)

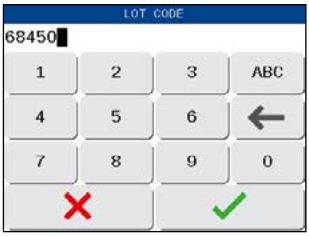
Select "Load default" from the service menu. The instrument will be reset to delivery status. All settings modified by the user as well as the memory will be cleared!

13.2. How to control the LOT-control (LOT activate)

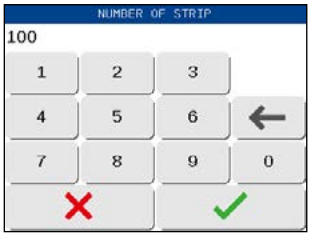
Select 'LOT activate' from the service menu to activate the LOT-control. This will minimize the risk of using expired test strips. You will be asked for the LOT of strips currently used. The system will give a warning when the test strips are expired. After 100 measurements the system will ask for the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

13.2.1. Entry of test strips LOT

If LOT-control is activated, the actual LOT-number of the test strips can be entered using 'Strip' in the menu 'Settings'.
When selecting “LOT number“ a numerical pad will appear, which can be used for entering the LOT printed on the stick packaging. If the entry does not have the format expected for a LOT number, an error message will appear.
After entering the LOT, information on the number of strips from that LOT is requested. If three boxes of the same LOT are present, please enter '300' for the number of strips.



Display 25: LOT code



Display 26: LOT size

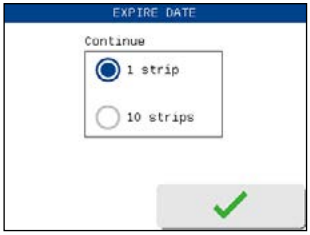
NOTICE

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

13.2.2. Warning on expired test strips

The date of expiry of the test strips is calculated from the LOT-number. If the expiry date has passed, a warning will appear (Display 27). If you choose to continue without entering a new LOT, Display 28 appears. Please choose the number of measurements you would like to perform without additional warnings.

Display 27: Expire date A



Display 28: Expire date B

13.3. How to update the instrument

Select "Program update" from the service menu. The instrument now expects the upload of a new firmware. Follow the instructions that come with the update-file to finalize the update process.

14. Interface Description

The instrument may be connected to a computer via the RS232 or the USB-jack Type B interface (Pic. 4) (work station or laboratory information system).

14.1. Serial Interface

Protocol RS232, 19200 Baud, 8 bit, no parity
Connection plug arrangement:

PIN	Signal	Description	Direction
1	Nc	Not wired	
2	RxD	Data reception	Input
3	TxD	Send	Output
4	Nc	Not wired	
5	GND	Signal ground	--
6	Nc	Not wired	
7	Nc	Not wired	
8	Nc	Not wired	
9	Nc	Not wired	

14.2. USB 1.1-Interface

USB-jack Type B (Pic. 4-⑤). The instrument will be identified as a serial interface.
Please contact your local service provider regarding the necessary driver for your PC.

14.3. Transmission Protocol

The data is released via the interfaces as plain text. The received dataset corresponds to the format of the printout.

14.4. Barcode Scanner, PC-Keyboard

A USB-jack Type A (Pic. 4-⑥) is provided for connection of a keyboard or bar code scanner.

14.5. Ethernet-Interface

The RJ45 jack (Pic. 4-⑨) is not supported.

15. Error Messages and Fault Clearance

Messages are displayed in plaintext and are self-explanatory.

Error Message / Error	Cause	Solution
"Dry Strip"	The test strip wasn't dipped completely	Repeat measurement with a new strip
"Wrong Strip"	A wrong test strip has been detected (wrong type)	Use correct test strips
"Wrong Position"	The strip hasn't been pushed into the strip retainer far enough	New measurement, place strip in right position
"No Paper"	Paper roll empty or printer flap open	Replace paper and close printer flap
"Battery Low"	Batteries are low	Exchange batteries or use power pack
Instrument doesn't start	Power supply not installed or defect	Check whether all connections are plugged in and whether the power socket is functioning

In case an error cannot be cleared following the instructions above, please contact your local distributor or Customer Service *(see 17. Additional Information, page 44).*

16. Technical Information

16.1. Technical Data

Required electric supply

Mains transformer:
Input 100–240 V
Output 9 V = 1.5 A
Alternative: battery operation with 6 mignon batteries 1.5 V (AA).

Dimensions

Height: 7.5 cm (3.0 inches)
Width: 16 cm (6.3 inches)
Depth: 20 cm (7.9 inches)

Weight

720 g (without batteries and power pack)

Memory:

200 results and 20 QC samples (for SN: URXXXX and UR2XXXX)
1000 results and 100 QC samples (for SN: UR3XXXX)

Range of Ambient Air Temperature

10–40 °C (50–104 °F)

Humidity

20–80 %
Protection class
Type 1 (UL 50E) / IP00

Application area

Commercial indoor laboratory

16.2. Security standards

This equipment and the designated test strips are in compliance with IVD directive 98/79/EC. It is ROHS-conform and complies with directive 2011/65/EU.
EMC class B according CISPR 11:
The instrument can be used in all institutions including residential area and areas which are directly connected to the public power supply, no matter if public power supply supplies buildings for residential purpose.
The maximum sound level and maximum sound pressure are subject to the limits specified in ISO 3746 or ISO 9614-1.

16.3. Waste Disposal

Dispose hazardous, infectious or biologically contaminated materials in a safe and acceptable
manner and in accordance with all local and regulatory requirements.

16.4. CAN ICES

This equipment is classified as industrial, scientific, and medical (ISM) equipment and complies with the requirements of the Canadian Interference-Causing Equipment Standard ICES-001, issue 5, Class A.

17. Additional Information

17.1. Customer Service

If you have any questions after reading the manual or if you need further technical assistance, please contact Customer Service:

17.2. Manufacturer Information

Jant Pharmacal Corporation, 16255 Ventura Blvd., Suite 505, Encino, California
91436 USA
Telephone: (800) 676-5565
E-Mail: info@accutest.net

17.3. Version history

Manual V1.01 USA / 01-2009, January 2009
Manual V1.01 USA / 07-2018, July 2018
Manual V2.00 USA / 02-2020, February 2020
Manual V3.01 USA / 02-2025, February 2025
Manual V3.02 USA / 09-2025, September 2025