



# accustrip® URS Reader

## User Manual



CAT. NO: UA850

The instrument is CLIA waived for Accustrip urine 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.gov/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.

# *User Manual*

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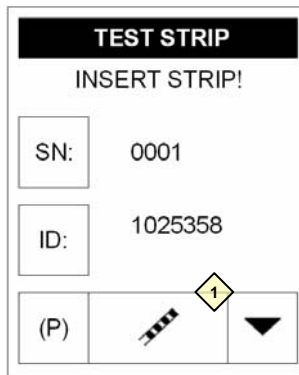
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### 1. Quickstart

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. 3.3-8). After the self test the start screen will appear on the display.



*Display 1 : Start menu*

- Dip a 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.

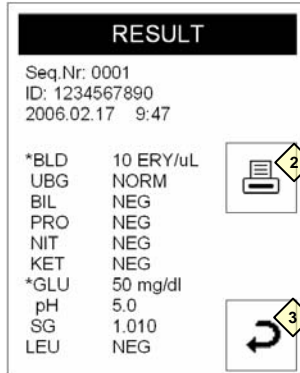
The instrument will automatically detect an applied strip. The measurement cycle will be started. A progress bar on the display shows the remaining measurement time.

Note: If "Autostart" (Chapter 10.5) is deactivated, the measurement must be started using the start control panel (Display 1-1).

**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 (Display 2-2) the result can be printed again. Choosing the return panel (Display 2-3) 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

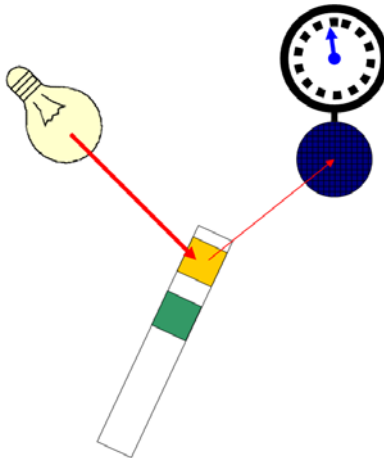
The instrument is a reflection photometer for the analysis of urine test strips. When measurements are performed under standardized conditions, measured values may be displayed, printed and transferred to a computer.

The instrument is designed for in-vitro diagnostic use (IVD) and should be used by healthcare professionals, only.

### 2.1 System Description

#### 2.1.1 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. 2.1: 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. Whenever samples are strongly alkaline, a density correction is automatically conducted.

### **2.1.2 Functional Principle**

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 (3.7 Use of the instrument).

### 3. Unpacking and Set Up

#### 3.1 List of delivered parts

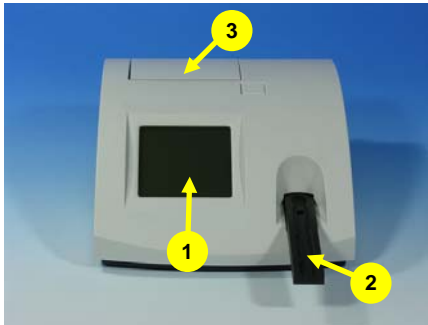
- instrument reflectometer
- Power pack 100 - 240 V, 47/63 Hz, 9V
- Printer paper
- User manual (this booklet)



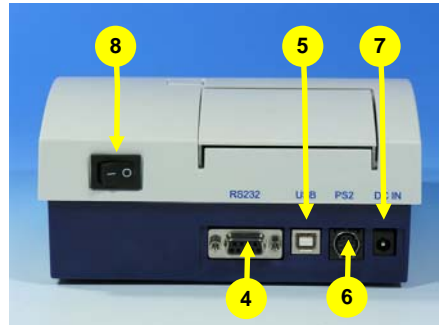
*Pic. 3.1 : Content*

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

## 3.2 Description of instrument parts



Pic. 3.2 : Front view



Pic. 3.3 : Backside view

Actuator	Function
1. Touch-Screen	Control of equipment functions
2. Test Strip Slide	Test strip retainer and automatic 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. PS/2 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

## 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)

### 3.4 How to plug the instrument in



*Pic. 3.4 : Power pack*



*Pic. 3.5 : DC in*

Three adapters are 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. 3.4). After plugging the power pack cable into the jack "DC in" (Pic. 3.3-7) and connecting the power pack to the power socket the instrument is ready for operation.

### 3.5 How to load the printer paper



*Pic. 3.6 : Printer A*



*Pic. 3.7: Printer B*

Open the printer flap by pressing the rectangular key next to the paper outlet (Pic. 3.6).



*Pic. 3.8 : Printer C*



*Pic. 3.9 : 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 forefinger while closing the flap (Pic. 3.8).

### **3.6 How to install batteries (optional)**

The instrument can be operated with 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. 3.10 : battery compartment*

### **3.6.1 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.

### **3.6.2 Calibration**

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

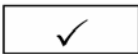
## **3.7 Use of the instrument**

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.

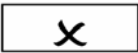
### **3.7.1 Buttons**

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

Examples:



Confirm / perform action



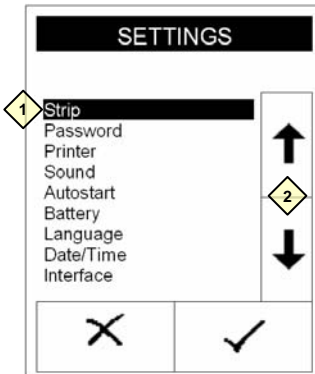
Cancel action



e.g. display of equipment settings

### 3.7.2 Scroll Arrows

Press the up-and-down arrows (Display 3-2) 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 (Display 3-1) 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 pressing  X.

### 3.7.3 Round buttons

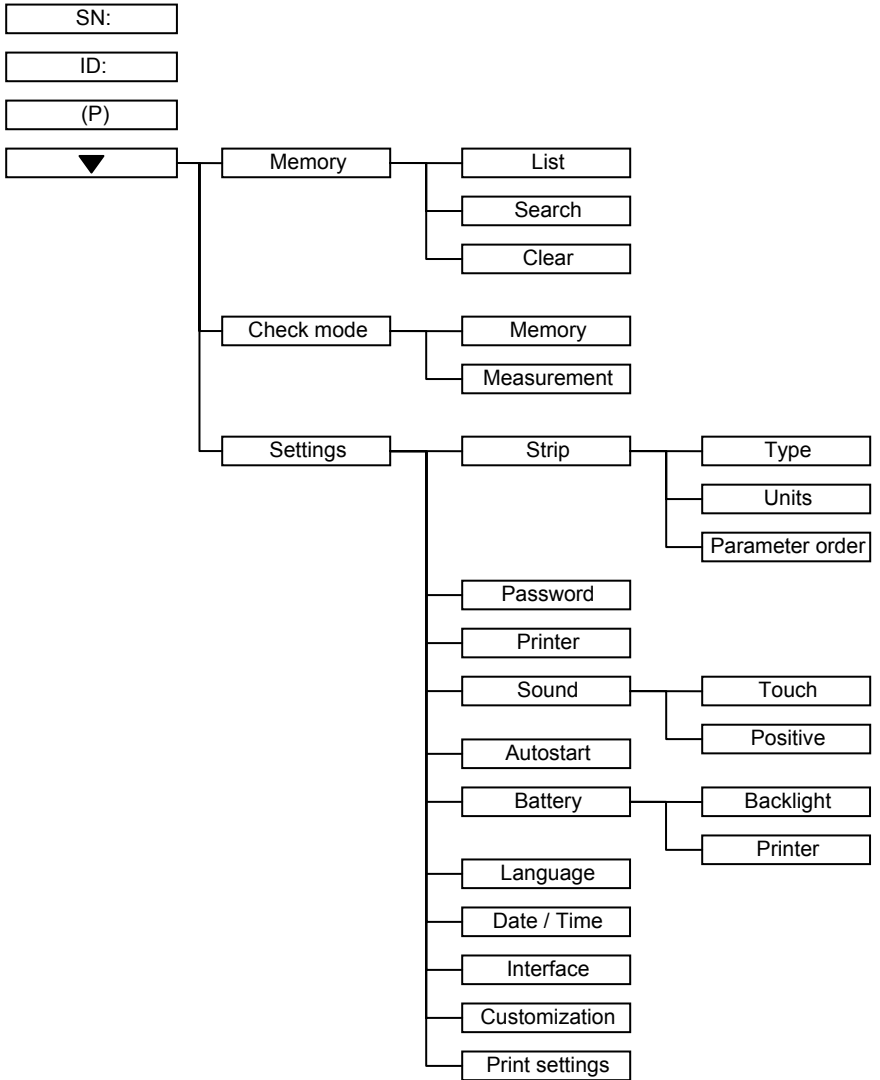
These buttons typically appear on screens that require a selection among serial items. The button with a filled circle is the current selection.



Pressing the circle will activate a selection. Save your selection by pressing  ✓. Pressing  X 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:**
    - 10.2 Password
    - 10.1 Strip Parameters
    - 10.3 Printer
    - 10.4 Sound
    - 10.5 Autostart
    - 10.6 Battery
    - 10.7 Languages
    - 10.8 Date / Time
    - 10.9 Interface
    - 10.11 Print Settings
    - 10.10 Customization

### 5. Analysis of Test Strips

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


#### 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 which 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 auto mode (Chapter 10.5 Autostart) is deactivated, the analysis needs to be started by pressing  on the touch-screen.

After the measurement, the instrument will release the analyzed 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.

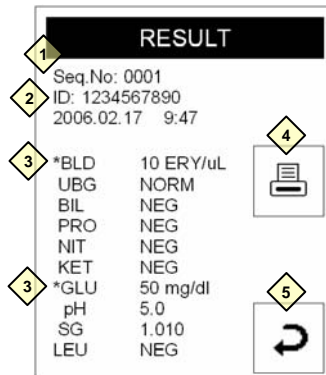
For additional information on the test strip, please read the package insert that comes with the strips.

**DANGER OF INFECTION:**

Urine and used test sticks bear 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 (Display 4-1) as well as the patient identification (Display 4-2) will be displayed with the results.



*Display 4 : Result*

Positive findings are clearly marked by an asterisk (\*) on the printout and on the display (Display 4-3). 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 (Display 4-4). The return panel (Display 4-5) will lead back to the start screen.

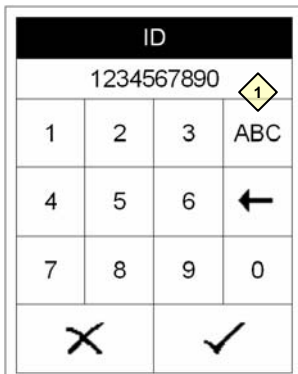
### 5.3 Measurement Errors

If the display shows "Measuring Error ..." instead of a result please read the instructions in Chapter 14. "Error Messages and Fault Clearance". Repeat the measurement. In case of permanent errors please contact Customer Service.

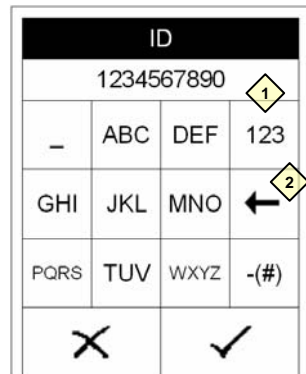
### 5.4 Entering the Patient Identification

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

- a) Directly on the equipment: Pressing  in the start menu brings up an alphanumeric keypad. Enter the ID using the keys. To enter characters (i.e. "Miller") press (Display 5-1) 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 6-2).



Display 5 : Entering ID (numerics)



Display 6 : Entering ID (letter)

- b) Using a standard PC-keyboard: Connect the keyboard to the PS/2 jack in the backside of the instrument. User inputs on the keyboard will automatically be interpreted as Patient Identifications.
- c) Using a bar code reader: Connect the barcode reader to the PS/2 jack in the backside of the instrument. 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.

**Attention:**

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

### 5.5 Changing the sequence number ("SN")

Pressing the field  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.


Seq.No.			
1234			
1	2	3	
4	5	6	←
7	8	9	0
✗		✓	

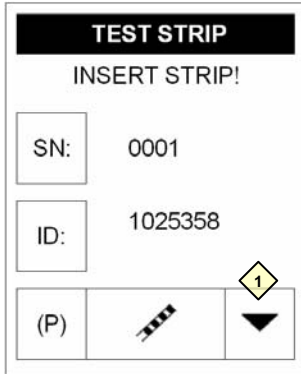
*Display 7 : Seq.-Input*

### 5.6 Transferring data to a PC

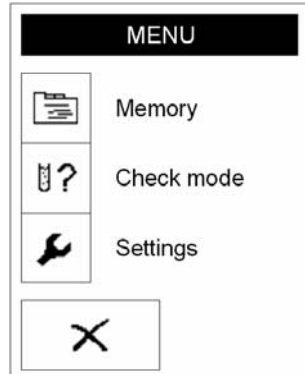
The results may be transferred to a PC via the USB- or RS232-interface. A detailed description of the interface can be found in Chapter 14 Interface Description.

## 6. Enter the Main Menu

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



*Display 8 : Start menu*




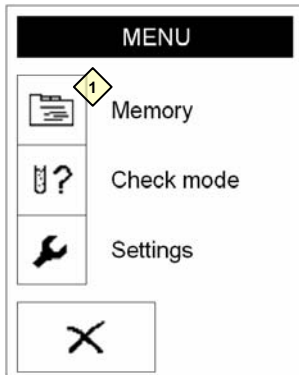
*Display 9 : Main menu*

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.

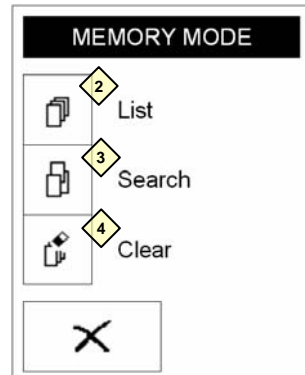
## 7. Recall results

The instrument has memory for 200 measurements. Every result is automatically saved after the analysis. After 200 measurements, new data will overwrite the oldest saved dataset.

Access the memory by pressing (Display 10-1) in the Main menu .



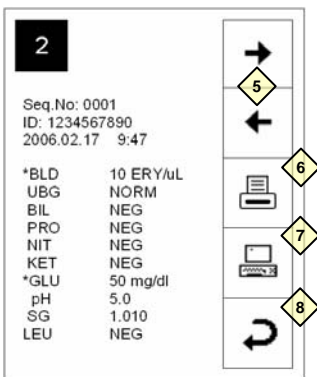
*Display 10 : Main menu*



*Display 11 : Memory mode*

### 7.1 How to scroll through memory

Pressing (Display 11-2) will bring up (Display 12). Scrolling through the memory is possible by pressing the arrows (Display 12-5) on the right side. The next [→] or previous [←] result will be displayed.



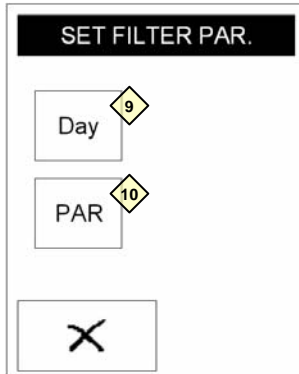
*Display 12 : Memory contents*

It is possible to print (Display 12-6) and send (Display 12-7) the dataset displayed. The memory menu will reappear upon pressing Return (Display 12-8).



### 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” (Display 13-9) you will reach the menu displayed below.

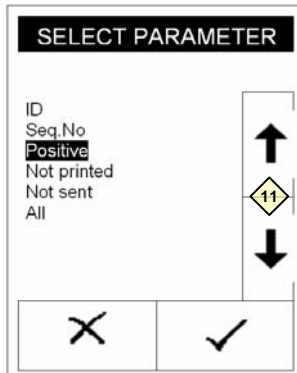


*Display 14 : Select day*

Set the day with the buttons (Display 14). 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 (Display 13-10, "SET FILTER PAR.") brings up display (Display 15).



*Display 15 : Select parameter*

Use the arrow keys (Display 15-11) to select the desired criteria and confirm with  ✓. The filter criteria will be displayed on filter settings screen (Display 16).

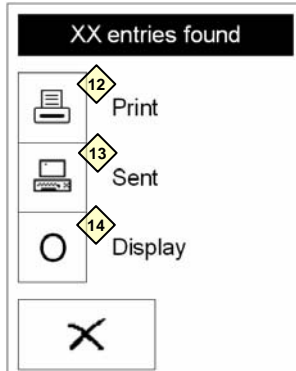
## 7.2.3 Display suitable matches

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 (Display 17-12), send them to a PC (Display 17-13) or display them on the screen (Display 17-14).



*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  (Display 11-4) will delete all data in the memory. You will need to confirm this again on another 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 strip with the instrument in the hands of the Lay-users, met the primary performance criteria that 90% of the results should be within  $\pm$  one level of the expected results.

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

Analyte	Concentrations tested	Exact Agreement (%) Lay-user	Concentration	Exact and + One (1) color block Level (%) Lay-user
Ascorbic Acid	0, 10, 20	98.5, 92.4, 100%	10	96.9
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

## 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.

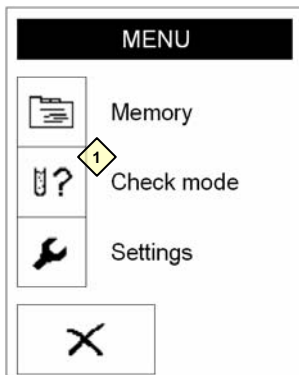
If proper results are not obtained, consult your local product representative or contact Customer Service by calling the number given at the end of this manual for advise on testing techniques and results.

### 9.1 How to run a quality control test

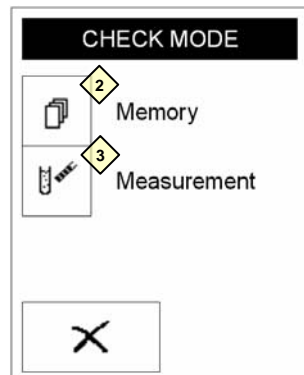
Prepare the urine controls as described in the package insert and test them in test mode.

Handle the urine control solutions exactly as patient samples.

Upon pressing  (Display 18-1) on the start menu  the "CHECK MODE" screen will appear.

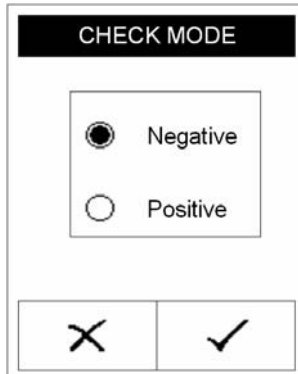


Display 18 : Main menu



Display 19 : Check mode

By pressing the panel (Disp. 19-3) 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.

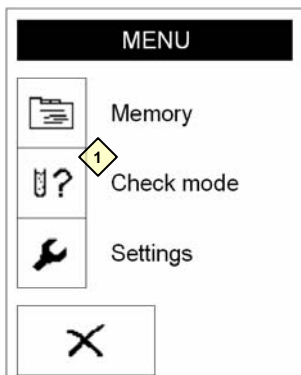
### 9.2 How to review old QC measurements

The equipment saves the results of the last 20 QC measurements in separate memory. They may be displayed by selecting memory (Display 19-2) and may be printed for documentation purposes.

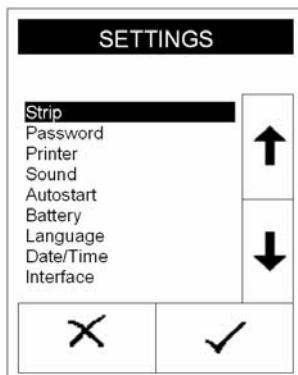


## 10. Equipment Settings

Enter the main menu by pressing the menu key  to reach the "SETTINGS" display press  (Display 21-1).



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 menu.

### **10.1.2 Order of Parameters**

The output order of the parameters may be customized 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 Stick LOT**

The LOT-administration of the instrument is deactivated in the default setting. See Chapter 13.2 "LOT activate".

### 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 choices “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 for upon the next attempt to change the settings.

**Attention:**

A forgotten PIN can not 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 'Touch'.

### **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 and Hungarian.

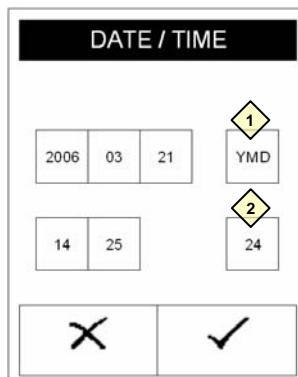
## 10.8 How to set time and date

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 (Display 23-1) 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 (Display 23-2).



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 OF INFECTION:**

Urine and used test sticks bear the danger of infection. Always use protective gloves during handling and disposal. The disposal of used test sticks 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 stick retainer must be placed on top of each other (Pic. Notch B).



*Pic. 8.1 : test slide  
(bottom view)*



*Pic. 8.2 : Notch A*



*Pic. 8.3: Notch B*

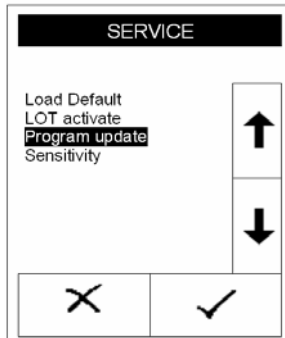


## 12. Table of Results

Param.	CONV	SI	ARB	Param.	CONV	SI	ARB
BLD	NEG	NEG	NEG	GLU	NEG	NEG	NEG
	10 Ery/ $\mu$ l	10 Ery/ $\mu$ l	+		NORM	NORM	NORM
	50 Ery/ $\mu$ l	50 Ery/ $\mu$ l	++		50 mg/dl	2,8 mmol/l	+
	250 Ery/ $\mu$ l	250 Ery/ $\mu$ l	+++		150 mg/dl	8,3 mmol/l	++
UBG	NORM	NORM	NORM		> 500 mg/dl	> 27,8 mmol/l	+++
	2 mg/dl	35 $\mu$ mol/l	+	pH	5	5	5
	4 mg/dl	70 $\mu$ mol/l	++		6	6	6
	8 mg/dl	140 $\mu$ mol/l	+++		6,5	6,5	6,5
	12 mg/dl	200 $\mu$ mol/l	++++		7	7	7
BIL	NEG	NEG	NEG		8	8	8
	1 mg/dl	17 $\mu$ mol/l	+		9	9	9
	2 mg/dl	35 $\mu$ mol/l	++	SG	1,000	1,000	1,000
	4 mg/dl	70 $\mu$ mol/l	+++		1,005	1,005	1,005
PRO	NEG	NEG	NEG		1,010	1,010	1,010
	30 mg/dl	0,3 g/l	+		1,015	1,015	1,015
	100 mg/dl	1 g/l	++		1,020	1,020	1,020
	500 mg/dl	5 g/l	+++		1,025	1,025	1,025
NIT	NEG	NEG	NEG		1,030	1,030	1,030
	POS	POS	+	LEU	NEG	NEG	NEG
KET	NEG	NEG	NEG		25 Leu/ $\mu$ l	25 Leu/ $\mu$ l	+
	25 mg/dl	2,5 mmol/l	+		75 Leu/ $\mu$ l	75 Leu/ $\mu$ l	++
	100 mg/dl	10 mmol/l	++		500 Leu/ $\mu$ l	500 Leu/ $\mu$ l	+++
	300 mg/dl	30 mmol/l	+++				

### 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 sticks' 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.

LOT CODE			
68450			
1	2	3	
4	5	6	←
7	8	9	0
✗		✓	

Display 25 : LOT code

NUMBER OF STRIP			
100			
1	2	3	
4	5	6	←
7	8	9	0
✗		✓	

Display 26 : LOT size

**NOTICE:**

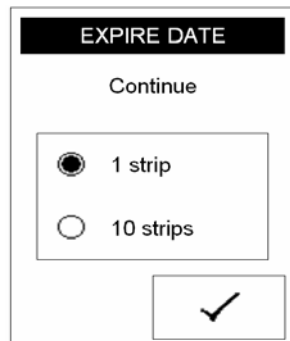
The instrument counts the number of strips. If the number of measurements reaches the previously entered number of strips for that LOT, the instrument will request the entry of a new LOT-number. Then, please enter the LOT number of the strips you want to use.

### 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-interface (work station or laboratory information system).

#### 14.1 Serial Interface

Protocol RS232, 19200 Baud, 8 bit, no parity (Picture 3.3-4)  
Connection plug arrangement:

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

#### 14.2 USB 1.1-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 PS/2 jack (Pic. 3.3-6) is provided for connection of a keyboard or bar code scanner.

## **15. Error Messages und Fault Clearance**

Messages are displayed in plain text and are self-explanatory.

<b>Error Message / Error</b>	<b>Cause</b>	<b>Solution</b>
“Dry Stick“	The test strip wasn't dipped completely	Repeat measurement with a new strip
“Wrong Stick“	A wrong test strip has been detected (wrong type)	Use correct test strips
“Wrong Stick 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 message cannot be cleared by following the above instructions, please contact your local distributor or Customer Service.

## 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:*

710 g (without batteries and power pack)

*Range of Ambient Air Temperature:*

5 - 40 °C (41 - 104 °F)

*Humidity:*

20-80%

### 16.2 Security standards

The instrument is in compliance with directive 89/336/EEC and conforms to the German EMV - Law. Furthermore it complies with directive 73/23/EEC.

This equipment and the designated test strips are in compliance with IVD directive 98/79/EC.

### 17. Customer Service

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

Telephone: (800) 676-5565

E-mail: [info@accutest.net](mailto:info@accutest.net)

Jant Pharmacal Corporation, 16255 Ventura Blvd., Suite 505, Encino, California 91436 USA