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Number: 1151140703
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Mission®

U500 Urine Analyzer

Instruction Manual

ACON Laboratories, Inc.

IVD CE

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☐ US ■ OUS ☐ DOMESTIC ☐ OTHER

Description	Mission CE U500 manual (En) Lab-N		**Part Number**	1151140703	**Size** 142.5x210mm
Printing Contents			**L Number**		**Size**
Designer	rene	**Design Date/Version**	May 19, 2023 /A		
Artwork checked by		**Material**	封面：200g双铜+水性上光, 内页:80克双胶纸		**Checked by**
Approved by Customer		**Approved by Marketing/Sales**			
Approved by P.M.T.		**Approved by QA**			**Effective Date**

Table of Contents

Section 1 Introduction

The ***Mission***® U500 Urine Analyzer is a semi-automated reflectance photometer that analyzes the intensity and color of light reflected from the reagent areas of a urinalysis reagent strip. The analyzer throughput is 500 tests per hour and the measuring cycle is 7 seconds per test. The analyzer stores up to 2,000 patient records and prints the results in Conventional, SI, or Arbitrary units using an integrated internal or external printer.

The ***Mission***® U500 Urine Analyzer features automatic calibration, self-test capability and a color touch screen LCD for easy operation. A light emitting diode (LED) detects the presence of the strip, provides incubation timing, automatically transports the strip for analysis and deposits the strip into an internal waste tray. The combined strip platform and waste tray allows for one step easy cleaning. An optional barcode reader records patient identification (ID). Records can be transferred to a computer for further analysis using the RS232 serial port or the USB port located on the back of the analyzer. The simple user-friendly software is designed to minimize user training and maximize analyzer functionality.

Intended Use

The ***Mission***® U500 Urine Analyzer is intended for use in conjunction with the ***Mission***® Urinalysis Reagent Strips for the semi-quantitative detection of the following analytes in human urine: Glucose, Bilirubin, Ketone (Acetoacetic acid), Specific Gravity, Blood, pH, Protein, Urobilinogen, Leukocytes, Ascorbic Acid, Albumin, Creatinine, and Calcium, as well as the qualitative detection of Nitrite. The instrument is intended for professional, *in vitro* diagnostic use only.

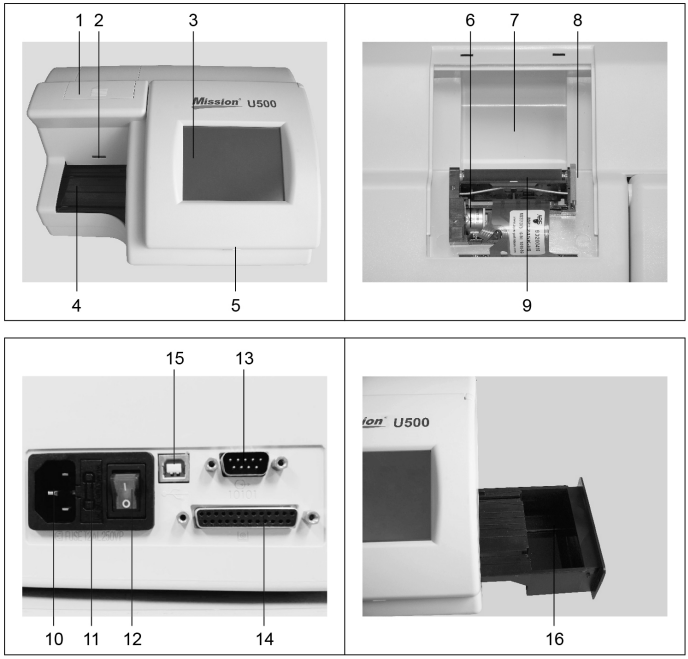
Note: **Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.**

Note: In this user guide, analyzer parts or components are referred to in **bold**, while display items on the screen are identified in ***bold italics***.

Section 2 Analyzer Components

2.1 Analyzer Components

1. Printer Cover
2. Strip Sensor Light Emitting Diode (LED)
3. Touch Screen Display (LCD)
4. Strip Loading Area
5. Display access slot
6. Thermal Printer
7. Printer Paper Roll Container
8. Printer release Lever
9. Printer Roller
10. Power Cord Connector
11. Fuse Holder / Spare Fuse
12. Power Switch
13. RS232C Connector
14. External Printer Connector
15. USB Port
16. Strip Platform and Waste Tray



2.2 Port Functions

10. Power Cord Connector	Power cord plug
13. RS232C Connector	Data transfer, barcode reader, software update
14. External Printer Connector	External printer
15. USB Port	Data transfer

Section 3 Initial Startup

Inspect the carton, analyzer and accessories for visible damage. Contact your local distributor if any visible damage exists. Remove the analyzer and other packaging contents from the carton. The analyzer kit includes:

No.	Components	Quantity
1	***Mission***® U500 Urine Analyzer	1
2	Strip Platform and Waste Tray	1
3	Printer Paper Rolls	2
4	Fuses (2.0 A)	2
5	Power Cord	1
6	Serial Splitter Cable (Optional)	1
7	Data Transfer Cable (RS 232C cable, Optional)	1
8	Barcode Reader (Optional)	1
9	Instruction Manual	1

Place the analyzer on a level surface. Allow 50 cm (20 inches) on all sides of the analyzer for access.

3.1 Load Printer Paper

Load **printer paper** following instructions in Section 8.

3.2 Install External Printer (Optional)

Plug the 25 pin printer cable from the compatible external printer into the **External Printer Connector** in the back of the analyzer.

3.3 Enable External Data Transmission (Optional)

Plug a compatible RS232C cable or USB cable from a computer to the **RS232C Connector or USB connector** in the back of the analyzer.

Data records are automatically sent to the computer at the same time as printing to the printer, where they can be received by suitable software installed on the computer. If the computer with software is not connected to the analyzer prior to performing a test, the operator can manually export each record one at a time, from a specific date, or all the data in the database.

3.4 Analyzer Software Updates

From time to time, ***ACON*** will add new features and make improvements to the U500 Urine Analyzer software.

These software updates will be available for download through the ***ACON*** Distributor Log In website. The updates will be downloaded on to the analyzer via the RS232C port located on the back of the instrument.

Updating the software is a simple procedure. When software updates occur, instructions will be provided to update the instrument.

3.5 Install Barcode Reader (Optional)

Plug the RS232C cable from the barcode reader into the **RS232C Connector** in the back of the analyzer using the cable supplied with the **Barcode reader**.

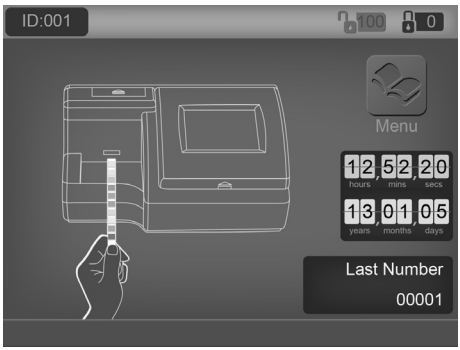
Refer to Appendix 5 Barcode Reader for specifications and compatibilities.

If both the optional **Barcode Reader** and external data transmission capability are used at the same time, use the serial splitter cable to connect both external computer and barcode reader to the analyzer **RS232C connector**.

3.6 Turn on Analyzer

Connect the power cord to the analyzer power connector, then into a suitable power outlet. Press the **Power Switch** located on the back panel to turn the analyzer on and initiate the Automatic Self-Test.

If the Automatic Self-Inspection passes, the Initial Screen below will be displayed indicating the analyzer is functioning properly.



Note: **If Strip Lockout is provided, the number in the screen upper right corner will display the number of strips remaining for use. If Strip Lockout is not provided, this number will not be displayed.**

The analyzer is now ready for operation with configuration defaults. Please refer to Section 4 for Analyzer Setup and Configuration, Section 5 for full analyzer operating details. If the Automatic Self-Inspection fails, a “Failed” Screen will be displayed indicating the source of the failure. Refer to Troubleshooting Table in Section 10 to correct the failure.

Note: **If “Waste tray full” is displayed when the waste tray is empty, please pull the waste tray out and reinsert it into the analyzer completely again when the analyzer shows “Initial screen”.**

Section 4 Analyzer Setup

4.1 Color Touch Screen LCD Navigation

All analyzer configuration is performed by using the color LCD touch screen. Selected icons shown below and text can be pressed with the finger to change settings or to enter or exit screens. If the analyzer does not respond, press the symbol or text for a slightly longer time or with slightly higher pressure to activate the touchscreen area. If the analyzer still does not respond, refer to **Section 10 Troubleshooting**.

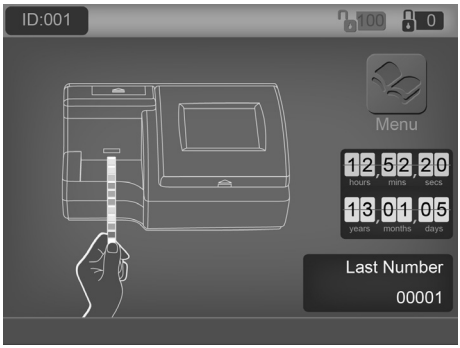
Caution: **Never use objects other than your finger to activate the touch screen. Hard or pointed objects may cause irreversible damage to the display.**

Symbol	Name	Description
	Main Menu	Navigates to the Main Menu from other screens
	Checkmark	Saves new selections and returns to the previous screen
	Cancel	Cancels any changes made and returns to the previous screen
	Clear	Clears incorrect numbers, cancels and returns to the previous screen on keypad screen
	Enter	Saves the new selection and returns to the previous screen on keypad screen
	Exit	Returns to the previous screen
	Exit	Returns to the previous screen
	Print	Prints displayed Test Results
	Export Database	Transfers records to an external computer
	Search	Searches and locates Test Results
	Previous Test Result	Displays the Previous Test Result in the Database
	Next Test Result	Displays the Next Test Result in the Database
	First Test Result	Displays the First Test Result in the Database
	Last Test Result	Displays the Last Test Result in the Database
	Previous 10th Test Result	Displays the Previous 10th Test Result in the Database

⏩	Next 10th Test Result	Displays the Next 10th Test Result in the Database
⊕	Plus	Calibrates the Touch Screen Liquid Crystal Display (LCD)
⋯	Manual barcode entry	Allows manual entry of a barcode.

4.2 Main Menu

After powering on the analyzer, the ***Initial Screen*** below is displayed, from which strip testing operations are normally performed.



A screensaver screen will show after 10 minutes of no activity to reduce the possibility of any permanent image on the screen.

Press the analyzer icon in the middle of the screen to show the barcode input screen for entering a new patient ID. Press the top left corner for User Login. Press the top right corner for entering a new canister code if the Strip Lockout function is enabled.

To display the Main Menu screen below, press . The Main Menu screen provides the analyzer setup options to customize the analyzer to operations at a particular testing site.

4.3 System Setup

Press ⚙ to display the system setup option screen used to configure the Printer Mode, Self Test Auto Print, Barcode Reader, Baud Rate, Print Copies, Screen Brightness, and, QC Test, and service modes.

If ***User Login*** is enabled and ***Operator ID*** is 11 through 20 the operator can only view the settings and run a QC test.

Once all selections are complete, press ☑ to save the selections and show the ***Main Menu*** screen.

Press ☒ to cancel all changes and show the ***Main Menu*** screen.

4.3.1 Printer Mode

Press ***Internal*** or ***External*** to select ***Printer Mode***. The text will turn blue to signify the setting chosen.

If ***Internal*** is selected, all test printouts will print on the Internal Printer.

If ***External*** is selected, all test printouts will print on the External Printer if connected. Refer to **Section 3.2 Install External Printer (Optional)** for more details.

4.3.2 Self-Test Auto Print

Press ***On*** or ***Off*** to select ***Self-Test Auto Print***. The text will be highlighted blue to signify the setting chosen.

If ***On*** is selected, after self-test, the analyzer will print the results.

If ***Off*** is selected, the analyzer will not print the results after the self-test.

4.3.3 Barcode Reader

Press ***Yes*** if the optional **Barcode Reader** is installed. Screens will be modified to accept barcoded sample IDs to be read with the optional **Barcode Reader**.

If the **Barcode Reader** is not installed, press ***No***.

4.3.4 Baud Rate

The ***Baud Rate*** is the communication speed for the **RS232C** port, used with the **Barcode Reader** or external computer. All devices connected to the **RS232C** port must be configured for the same baud rate, otherwise they will not work. The default baud rate for the **Barcode Reader** is 9600.

Press between the baud rate options. Select the desired baud rate.

4.3.5 Print copies

Print copies defines the number of result copies printed at one time. This can be set from 1 to 3.

4.3.6 Screen Brightness

Press ***Screen Brightness*** to change the light level of the analyzer screen. A lightness scale will appear. Select the darkest setting to lower the screen brightness or the lightest setting to raise it. Press ☑ to save the selection and return to the **System Setup** menu or press ☒ to return to the **System Setup** menu without making any changes.

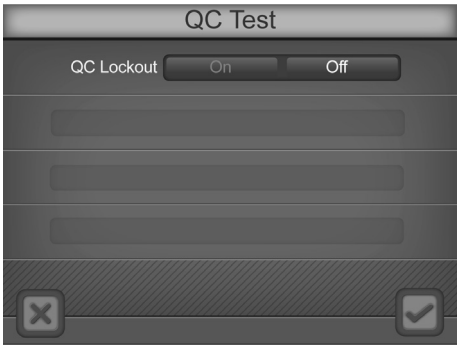
4.3.7 QC Test

Press ***QC Test*** to enter the ***QC Test*** screen to set, review and perform a QC test before the next scheduled test time.

QC Lockout

Select ***On*** or ***Off*** to turn the **QC Lockout** function ***On*** or ***Off***. The selection will be highlighted blue.

With QC Lockout ***Off***, the screen below will be shown:



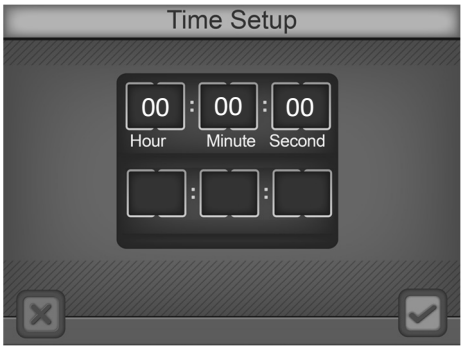
With QC Lockout ***On***, the screen below will be shown:

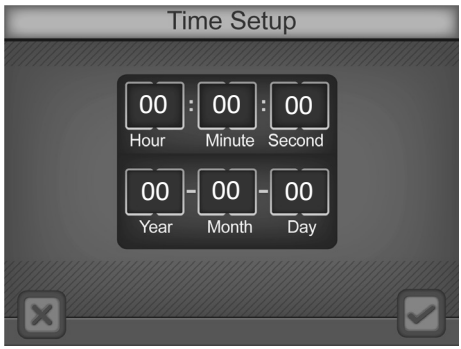
Time

Select ***Time*** to set the QC test time for ***Every 8 Hours, Daily, Weekly*** or ***Monthly***.

Time Setup

Enter the ***Time Setup*** option by selecting ***Time Setup***.





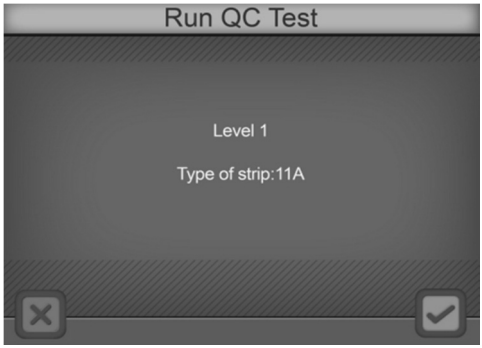
To change any of the ***Date*** or ***Time*** settings, press either the name or associated number in the display area. This will bring up the numeric keypad for entering the proper Year, Month, etc.

Notes:

- If the number entered is out of its range, the change will not be accepted.
- There is no ***Date Setup*** if QC tests are set for ***Every 8 Hours*** or ***Daily***.
- For the ***Monthly*** option, ***Date*** can be set from 01 to 28. 29, 30 and 31 are invalid.

Run QC Test

Press ***Run QC Test*** to perform a QC test before the next scheduled test time.

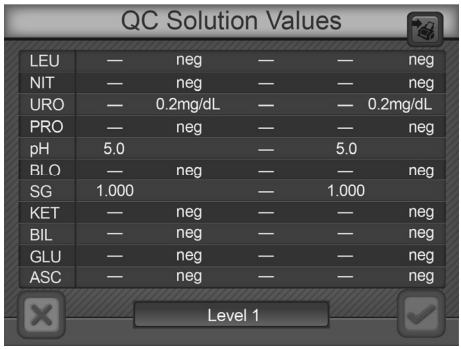


When a QC test is run for the first time, the analyzer will show the error screen below if QC values have not been set up. After 3 seconds, the screen will return to the QC Test screen.

Setting the Quality Control (QC) Values

On the **System Setup** menu, press ***Service*** to show the ***Password*** entry screen. Enter password to show the **QC Solution Values** setup screen.

Note: **The QC expected values are provided in the control solution packaging.**



Strips up to 11 parameters

- For strips up to 11 parameters, enter code **7532691** to set the QC solution values for the corresponding parameters.
- Press ***Level*** (bottom center of the screen) to cycle between level 1 and level 2 settings. Press each of the analyte QC Solution values to change the settings to the proper value. The left column is for setting the lower QC value. The right column is for setting the upper QC value.

Press  to print the current values. Press  to save the changes and exit the screen. Press  to cancel the changes and exit the screen.

Strips with more than 11 parameters

- For strips with more than 11 parameters, enter code **7532691** to set the QC solution values for the first 11 parameters on the screen.
- Press ***Level*** (bottom center of the screen) to cycle between level 1 and level 2 settings. Press each of the analyte QC Solution values to change the settings to the proper value. The left column is for setting the lower QC value. The right column is for setting the upper QC value.
- Exit the screen by pressing  to save the changes and return to the ***System Setup*** menu.
- On the ***System Setup*** menu, press ***Service*** to show the ***Password*** entry screen and then enter code **7532690** to set the QC solution values for the additional parameters.

Press  to print the current values. Press  to save the changes and exit the screen. Press  to cancel the changes and exit the screen.

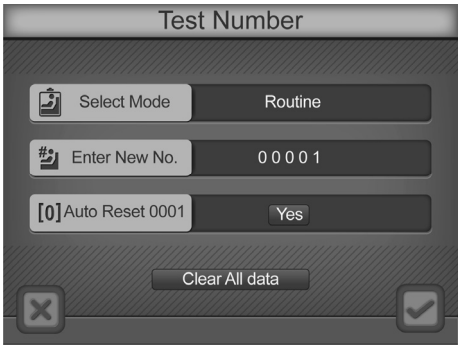
4.3.8 Service

From the ***System Setup*** menu, press ***Service*** to show the ***Password*** entry screen. Enter the required password to perform any service related operations. Press  to clear the last number entered. Press  to accept the number entered and enter the service screens.

Note: **Service mode is not normally accessible as part of analyzer operation. Servicing the analyzer should be performed by a professional engineer or technician only. For customer support, please contact your local technical support provider or distributor.**

4.4 Test Number

Press # for the menu to configure test numbers and operating mode. When configuration is complete, press ✓ to accept the change and return to the ***Main Menu*** screen. Press ✗ to return to the ***Main Menu*** screen without changing any parameters.



If ***User Login*** is enabled and ***Operator ID*** is 11 through 20 the operator can only view settings, change the testing mode and reset the testing number.

4.4.1 Select Mode

Press ***Select Mode*** to cycle through the three available modes.

Routine Test

Used for normal urine testing. The test number ranges from 00001 to 09999, always with a leading 0. It resets to 00001 every day automatically if ***Auto Reset 0001*** is ***Yes***.

Stat Test

Used for emergency urine testing. The test number ranges from 10001 to 19999, always with a leading 1. It resets to 10001 each day automatically if ***Auto Reset 0001*** is ***Yes***. If the QC test has failed the analyzer will automatically switch to ***STAT*** test and can not be changed.

QC Test

Used to test positive/negative controls. The test number ranges from 20001 to 29999 and resets to 20001 every day automatically if ***Auto Reset 0001*** is ***Yes***.

Note: **Ensure QC Test mode is used for testing positive and negative controls so test data can be easily searched for and identified.**

4.4.2 Enter New No.

The current ***Test Number*** will be displayed next to ***Enter New No***. Press ***Enter New No.*** to display the ***Numeric Keypad*** to change the Test Number to a new sequence.

Enter up to 4 digits by touching the ***Numeric Pads*** on the touchscreen. Press C to Clear the last number entered. Press ↵ to accept the number entered and return to the previous screen.

***Note*: The highest test number is X9999. After the test number reaches X9999 it will revert to X0001. X indicates the leading 0, 1 or 2 depending on test mode.**

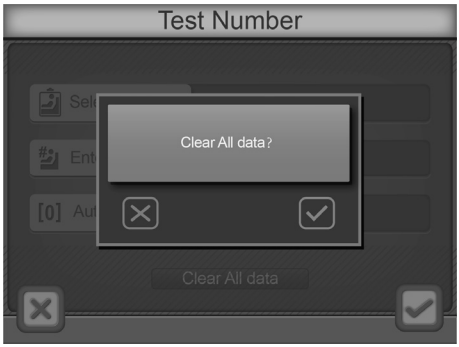
***Warning*: The maximum number of test results is 2,000. After 2,000 test results are stored in the memory, new test results will begin to replace the oldest test results stored in memory.**

4.4.3 Auto Reset 0001

Press ***Auto Reset 0001*** to cycle to ***Yes*** or ***No***. If ***Yes***, the test number will reset to 00001, 10001 or 20001 for Routine, Stat or QC modes when the power is switched off and then on again. If ***No*** the test number is unaffected by power cycling.

4.4.4 Clear All Data

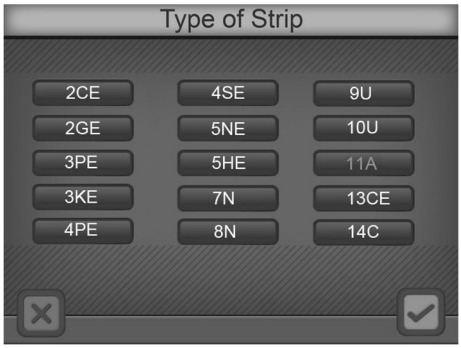
Press ***Clear All Data*** to show a confirmation screen.



Press ☑ to continue to delete all data. After deleting data, the Test Number will reset to 00001, 10001 or 20001 depending on the Test Mode. Press ☒ to return to the ***Test Number*** screen without deleting data.

4.5 Type of Strip

From the ***Main Menu***, press  to change the strip type. The ***Type of Strip*** currently selected will be highlighted. Each strip type name defines the number of test parameters per strip.



If ***User Login*** is enabled and ***Operator ID*** is 11 through 20 the operator can only view settings.

Note: **Ensure the type of strip selected corresponds with the strip to be used. If not, it will be detected and an error message will be displayed.**

Select the type of strip which will be used for testing. Press  to return to the ***Main Menu*** screen without changing strip type. Once the proper strip type is selected, press  to enter the ***Order of Strip*** screen.

The ***Order of Strip*** screen is used to select the order in which parameters are displayed on the results screen and on result print-outs. Next to each number, select the parameter desired. "--" means that there will be no parameter displayed for that number. For example, if LEU is selected for position 1, then LEU is the first parameter to appear on the results screen and on the print-out.

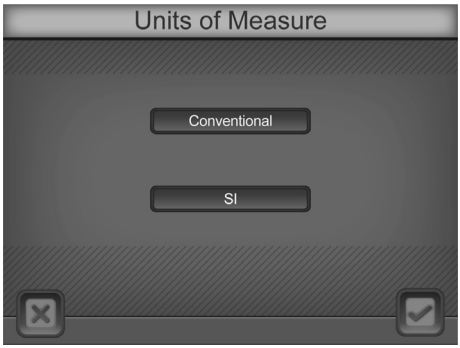
Once the proper order is selected, press ☑ to accept the change and return to the ***Main Menu*** screen. Press ☒ to return to the ***Main Menu*** screen without changing order of the parameters.

4.6 Units of Measure

From the ***Main Menu***, press ✎ to select ***Units of Measure*** using the screen below. Press either ***Conventional*** or ***SI*** to select either of these units on the touchscreen. The selection will be highlighted blue.

If ***User Login*** is enabled and ***Operator ID*** is 11 through 20 the operator can only view settings.

Note: **Arbitrary results will be printed automatically regardless of the units setting.**



Press ☑ to accept the changes and return to the ***Main Menu*** or press ☒ to return to the ***Main Menu*** without any changes.

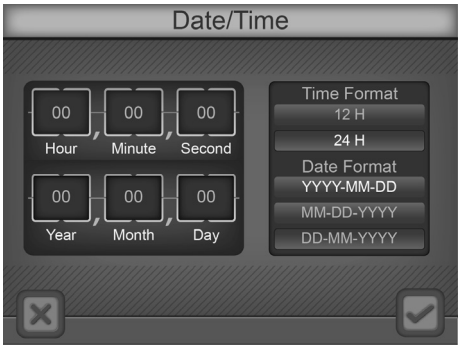
4.7 Date/Time

From the ***Main Menu***, press 🕒 to change Date or Time settings. The ***Date/Time*** screen will be shown.

To change any of the Date or Time settings, press the appropriate display area, either the name or associated number. This will bring up the numeric keypad for entering the proper Year, Month, etc. with the corresponding range of numeric input.

If ***User Login*** is enabled and ***Operator ID*** is 11 through 20 the operator can only view settings.

Note: **If the number entered is out of range, the change will not be accepted.**



As an example, the following screen is displayed when ***Year*** is pressed. The current year is visible as the new year is keyed into the keypad.

When the correct Year is entered, press ↵ to accept the number entered and return to the ***Date/Time*** screen. Press C to Clear the last number entered if an incorrect number is entered. Proceed to enter the correct numbers for all ***Date/Time*** entries.

The date format includes ***MM-DD-YYYY***, ***DD-MM-YYYY***, ***YYYY-MM-DD***, and the time format includes ***12H*** or ***24H***. Select the ***Date/Time*** formats and press ✔ to accept the changes and return to the ***Main Menu*** or press ✘ to return to the ***Main Menu*** without any changes.

4.8 Language

Press 💬 from the ***Main Menu*** to view the installed languages. The current setting will be highlighted blue.

Press the text areas to select the proper language.

If ***User Login*** is enabled and ***Operator ID*** is 11 through 20 the operator can

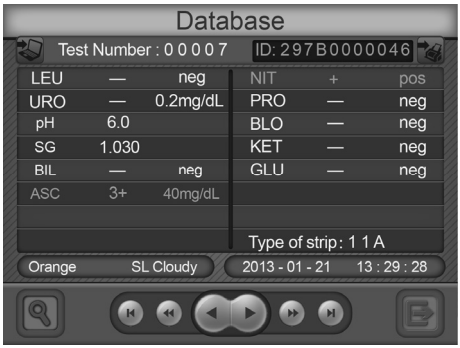
only view settings.

Note: **The analyzer software has all current languages installed. Select the correct language from the options shown on the screen.**

When the desired language is highlighted, press ☑ to accept the changes and return to the ***Main Menu*** or press ☒ to return to the ***Main Menu*** without any changes.

4.9 Database

To review data from processed strips, press ***Database*** under 🖹 from the ***Main menu*** to show the ***Database*** screen. The last saved record will be shown.



Press ◀ to view the previous record.
Press ◀◀ to view the previous 10th record.
Press ⏮ to view the first record.
Press ▶ to view the next record.
Press ▶▶ to view the next 10th record.
Press ⏭ to view the last record.

To search for and locate a specific test record, press [🔍] to show the data search screen. Records can be searched by the test number, patient ID, date, STAT results, QC results, and postivie results. Press [⎋] to exit the data search screen and return to the database screen.

4.9.1 Test Number

Press ***Test Number*** to show the numberic key pad on the touchscreen. Enter the test number needed. Press [↵] to accept the number entered. Press [C] to Clear the last number entered. The analyzer will pause briefly as it searches for the correct test record, displaying the record when it is found.

If the record is not found, a display screen will briefly be shown indicating ***Record Not Found***. This screen will disappear after a few seconds, or press the ***Record Not Found*** message screen area to remove it sooner.

Other adjacent test records can be found by pressing the appropriate arrow keys, moving forward or backward in the stored test data records.

If the test number entered has more than one record in the database, a message will be shown on the results screen with the first found record, with a note indicating ***Record X of Y***. ***X*** is the sequence number of the current record, and ***Y*** is the total number of records with the same test number in the database. By pressing ▶, ▶▶, ▶▌ the next, the next 10th and the last record can be found and displayed. By pressing ◀, ◀◀, ▌◀ the test records can be searched in the opposite direction. These keys will be limited to moving within the records with the same test number.

Example: If there are 100 records with a test number of 00001 in the database, enter 00001 with the search keypad to show the first found record, ***Record 1 of 100*** will be shown.

Press ◀ to view the second found record or ◀◀ for the eleventh found record. Press ▌◀ to locate the last found record (record 100). Press ◀, and the screen

below shows the second found record: ***Record 2 of 100***.

Press ⎋ to exit to the normal ***Database*** screen, where all records can be found in sequence by using the arrow keys.

Any displayed test record can be printed to the currently selected printer by pressing 🖶, or exported to a connected computer or LIS by pressing 🖳.

To connect with an external computer or LIS, please refer to the Data/Communication section.

Press ⎋ to exit the ***Database*** menu and return to the ***Main Menu***.

4.9.2 Patient ID

Press ***Patient ID*** to show the alphanumeric key pad to enter the patient ID. Press ↵ to accept the number entered. Press C to Clear the last number entered. The analyzer will pause briefly as it searches for the correct test record, displaying the record when it is found.

If the record is not found, a display screen will briefly be shown indicating ***Record Not Found***. This screen will disappear after a few seconds, or press the ***Record Not Found*** message screen area to remove it sooner.

Other adjacent test records can be found by pressing the appropriate arrow keys, moving forward or backward in the stored test data records.

If the patient ID number entered has more than one record in the database, a message will be shown on the results screen with the first found record, with a note indicating ***Record X of Y***. ***X*** is the sequence number of the current record, and ***Y*** is the total number of records with the same patient ID number in the database. By pressing ▶, ▶▶, ▶▌ the next, the next 10th and the last record can be found and displayed. By pressing ◀, ◀◀, ▐◀ the test records can be searched in the opposite direction. These keys will be limited to moving within the records with the same test number.

Press ⎋ to exit to the normal ***Database*** screen, where all records can be found in sequence by using the arrow keys.

Any displayed test record can be printed to the currently selected printer by pressing 🖶, or exported to a connected computer or LIS by pressing 🖳.

To connect with an external computer or LIS, please refer to the Data/Communication section.

Press ⎋ to exit the ***Database*** menu and return to the ***Main Menu***.

4.9.3 Date

Press ***Date*** to show the date format screen that was previously chosen (***MM-DD-YYYY***, ***DD-MM-YYYY***, ***YYYY-MM-DD)***. Press the appropriate display area, either the name or associated number. This will bring up the numeric keypad for entering the proper Year, Month, etc. with the corresponding range of numeric input. Press ↵ to accept the number entered. Press C to Clear the last number entered. When all three fields have been entered, press the ✓ to begin the search. The analyzer will pause briefly as it searches for the correct test record, displaying the record when it is found.

If the record is not found, a display screen will briefly be shown indicating ***Record Not Found***. This screen will disappear after a few seconds, or press the ***Record Not Found*** message screen area to remove it sooner.

Other adjacent test records can be found by pressing the appropriate arrow keys, moving forward or backward in the stored test data records.

If the date entered has more than one record in the database, a message will be shown on the results screen with the first found record, with a note indicating ***Record X of Y***. ***X*** is the sequence number of the current record, and ***Y*** is the total number of records with the same date in the database. By pressing ▶, ▶▶, ▶▌ the next, the next 10th and the last record can be found and displayed. By pressing ◀, ◀◀, ▌◀ the test records can be searched in the opposite direction. These keys will be limited to moving within the records with the same test number.

Press ⎋ to exit to the normal ***Database*** screen, where all records can be found in sequence by using the arrow keys.

Any displayed test record can be printed to the currently selected printer by pressing 🖶, or exported to a connected computer or LIS by pressing 🖳.

To connect with an external computer or LIS, please refer to the Data/Communication section.

Press ⎋ to exit the ***Database*** menu and return to the ***Main Menu***.

4.9.4 STAT Results

Press ***STAT Results*** to bring up the results screen with the first found record, with a note indicating ***Record X of Y***. ***X*** is the sequence number of the current record, and ***Y*** is the total number of records with the same date in the database. By pressing ▶, ▶▶, ▶▌ the next, the next 10th and the last record can be found and displayed. By pressing ◀, ◀◀, ▌◀ the test records can be searched in the opposite direction. These keys will be limited to moving within the records with

the same STAT result status.

If there are no STAT result records, a display screen will briefly be shown indicating ***Record Not Found***. This screen will disappear after a few seconds, or press the ***Record Not Found*** message screen area to remove it sooner.

Press  to exit to the normal ***Database*** screen, where all records can be found in sequence by using the arrow keys.

Any displayed test record can be printed to the currently selected printer by pressing  , or exported to a connected computer or LIS by pressing  .

To connect with an external computer or LIS, please refer to the Data/Communication section.

Press  to exit the ***Database*** menu and return to the ***Main Menu***.

4.9.5 QC Results

Press ***QC Results*** to bring up the results screen with the first found record, with a note indicating ***Record X of Y***. ***X*** is the sequence number of the current record, and ***Y*** is the total number of records with the same date in the database. By pressing ▶, ▶▶, ▶▌ the next, the next 10th and the last record can be found and displayed. By pressing ◀, ◀◀, ▐◀ the test records can be searched in the opposite direction. These keys will be limited to moving within the records with the same QC result status.

If there are no QC result records, a display screen will briefly be shown indicating ***Record Not Found***. This screen will disappear after a few seconds, or press the ***Record Not Found*** message screen area to remove it sooner.

Press  to exit to the normal ***Database*** screen, where all records can be found in sequence by using the arrow keys.

Any displayed test record can be printed to the currently selected printer by pressing  , or exported to a connected computer or LIS by pressing  .

To connect with an external computer or LIS, please refer to the Data/Communication section.

Press  to exit the ***Database*** menu and return to the ***Main Menu***.

4.9.6 Positive Results

Press ***Positive Results*** to bring up the results scree with the first found record, with a note indicating ***Record X of Y***. ***X*** is the sequence number of the current record, and ***Y*** is the total number of records with the same date in the database. By pressing ▶, ▶▶, ▶▌ the next, the next 10th and the last record can be found and displayed. By pressing ◀, ◀◀, ▐◀ the test records can be searched in the

opposite direction. These keys will be limited to moving within the records with the same Positive Results status.

If there are no positive result records, a display screen will briefly be shown indicating ***Record Not Found***. This screen will disappear after a few seconds, or press the ***Record Not Found*** message screen area to remove it sooner.

Press to exit to the normal ***Database*** screen, where all records can be found in sequence by using the arrow keys.

Any displayed test record can be printed to the currently selected printer by pressing , or exported to a connected computer or LIS by pressing .

To connect with an external computer or LIS, please refer to the Data/Communication section.

Press to exit the ***Database*** menu and return to the ***Main Menu***.

4.10 Memory

Up to 2,000 test records are automatically stored in memory. After 2,000 test records are stored in memory, the oldest test record will be erased (overwritten). For example, if 2,000 records are stored in the database, the next test record (2,001) will replace the first test record stored in memory.

To ensure the ability to identify and locate test records easily, it is recommended that overlapping test record numbers are kept to a minimum. In the event of a power failure, stored test records can be printed or downloaded when the power returns.

4.11 User Login

Press the top left corner of the Initial Screen to show the Administrator login screen. The Operator ID is preset to 100.

On entering this screen for the first time, leave the ***Passcode*** blank and press .

Press ☒ to return to the Initial Screen without enabling User Login.

4.11.1 ID Admin

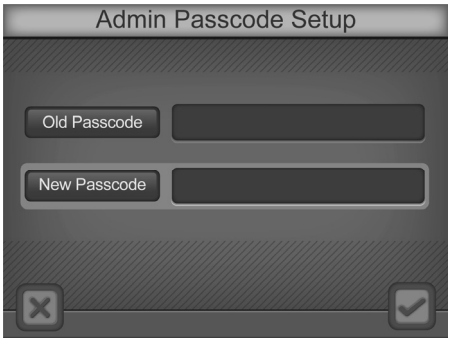
The Administrator screen is shown.

Press an option to make changes.

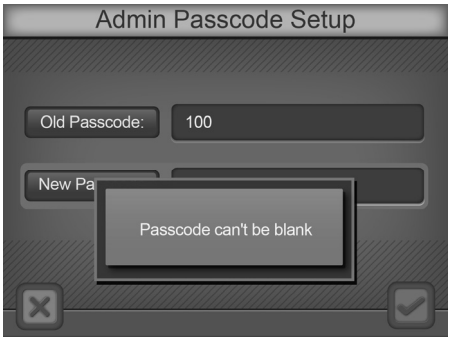
If Passcode is blank, user login is not yet enabled and only ***Admin Passcode Setup*** can be chosen. Press ☑ to save the changes and exit. Press ☒ to exit to the Initial Screen.

Admin Passcode Setup

To enable user lockout functions, select ***Admin Passcode Setup***.



A non-blank passcode must be entered into the ***New Passcode*** field to enable ***User Login***. If a blank is entered, a new screen will indicate the passcode is invalid. After 3 seconds, the screen will return to the login screen.



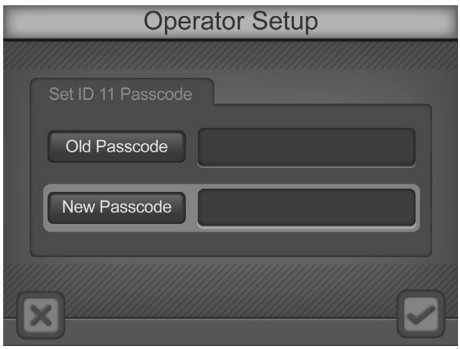
Press ☒ to keep the existing passcode and exit.

Scan or enter a valid ***Passcode*** and press ☑ to accept and exit. ***User Login*** will be enabled.

Operator Setup

After ***User Login*** is enabled, select ***Operator Setup***.

X indicates the ID is enabled. O indicates the ID is not enabled.
Press the desired ID to enter the the ***Passcode*** screen.



Scan or enter a new ***Passcode***. Press ☑ to save the settings and exit. Press ☒ to cancel the settings and exit. Enter a blank ***Passcode*** to disable the ID.

Logout

After the User Login is enabled, select Logout to log out from the screen above. The normal Login screen will be shown for a new operator login. See Section 5 for Login procedures.

Press ☑ to exit to the Initial Screen and press the top left corner of the screen to logout and display the Login Screen shown above.

Clear all IDs/Passcodes

To disable the User Lockout function, press ***Operator*** to enter the operator ID and type 100 in the User Login screen.

Press the top right corner and a new prompt, reading **Delete all Passcode/IDs**, will be displayed to disable this function. Press ☑ to delete this function and return to the User Login screen with the operator ID as 100. Press ☒ to return to the initial screen. The User Lockout function is now disabled.

Section 5 Analyzer Operation

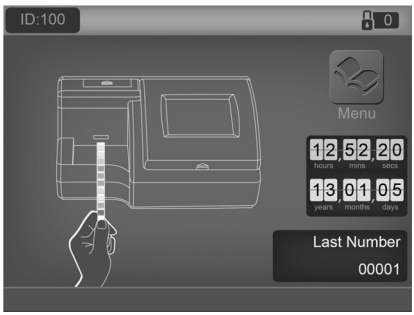
If ***User Login*** is not enabled, the Initial Screen will be shown after Self Test. Refer to **Section 3 Initial Startup**.

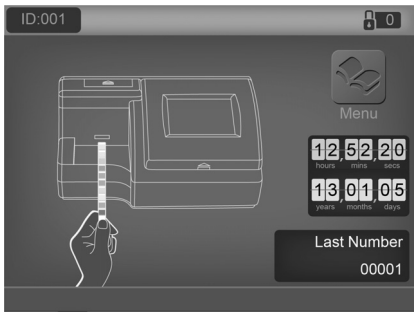
If User login is enabled, the analyzer will display a login screen after Self Test.

Press ***Operator*** to enter the Operator ID. Enter or scan the ***Passcode***. Press ☑ to run the analyzer. Press ☒ to return to the login screen.

If the ***Passcode*** is incorrect, the analyzer will indicate a passcode error. After 3 seconds, the screen will return to the login screen.

If the ***Passcode*** is correct, the analyzer will display the Initial Screen. The logged-in ID will be shown (11-20, or 100).





The user ID will be 11-20 for Operators. This provides access to operate the analyzer, change test mode and test number, and review settings. Press the top left corner of the Initial Screen to logout and display the Login Screen.

The user ID will be 100 for the Administrator. This provides full access to operate the analyzer and change settings. Press the top left corner of the Initial Screen to display the ID Admin Screen.

Check all settings and strip types before testing.

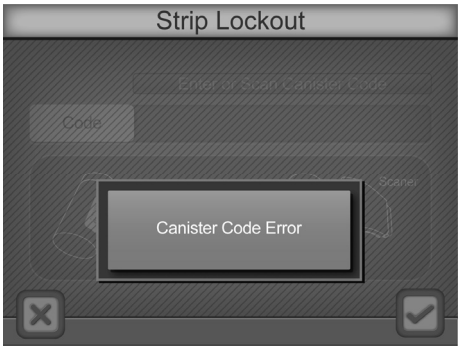
5.1 Entering the Canister Code

When a new canister of strips is required, the analyzer will request that a canister code is entered from the new canister. The code can be entered manually from the keypad, or scanned with the Barcode reader, if installed.

After self-testing, the screen below will be displayed.

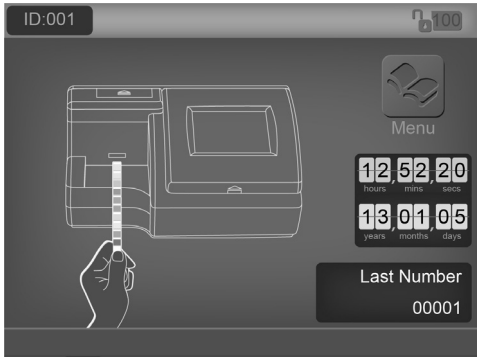
Scan or manually enter the canister code from the strip canister by pressing the data entry line. If the barcode reader is present, even if it is set to **NO**, it can be used to scan the canister code into the analzyer. Press the ***Code*** to display the ***Numeric Keypad*** to enter the new canister code manually. Press ☒ to cancel and exit the screen.

If the canister code is incorrect, the following screen will show.



Press ☒ to cancel and switch to the previous screen.

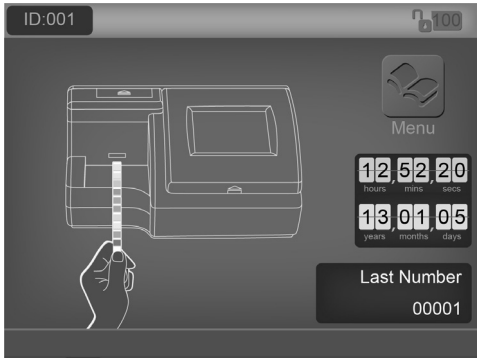
If the canister code is correct, the analyzer will proceed to the Initial Screen.



Note: **No more than 500 strips can be entered for one type of strip. If the number on the top right corner is less than 500, press it and enter a new canister code until the number is more than 500. If the number is more than 500, pressing this area will have no response.**

5.2 Operation without Barcode Reader

Ensure the analyzer is set up and operating as described in **Section 3 Initial Startup**, and analyzer parameters are configured properly as described in **Section 4 Analyzer Setup**. Turn the power switch located at the back panel of the analyzer on. The initial screen will be displayed indicating the analyzer is ready to begin testing strips, with an animated test strip icon indicating the analyzer is ready to accept strips for testing.



5.2.1 Sample/Strip Preparation

Allow the strip, urine specimen, and/or controls to reach room temperature at 15-30 ºC (59-86 ºF) prior to testing.

Note**: Use strips of the same brand as the analyzer for proper function and accurate results.**

Remove the strips from the closed canister and use them as soon as possible.

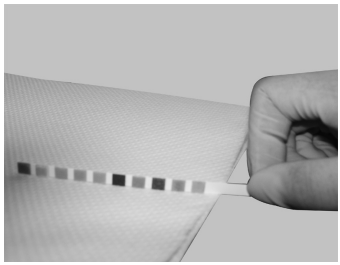
Close the canister tightly immediately after removing the strips.

5.2.2 Strip Processing and Test

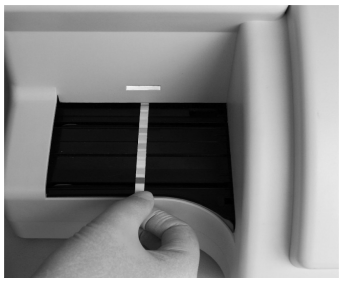
Using a new strip, completely immerse the reagent areas of the strip in fresh, well-mixed urine for about 2 seconds. Immediately remove the strip to avoid dissolving the reagents.

Note: **Immerse all strip pads completely into sample, or a *Strip* error may occur.**

While removing the strip from the urine, run the edge of the strip against the rim of the urine specimen container to remove excess urine. Hold the strip in a horizontal position and bring the edge of the strip into contact with an absorbent material (e.g. a paper towel) to avoid mixing chemicals from adjacent reagent areas and/or soiling hands with urine.



Place the strip with the reagent test pads facing up onto the **Strip Platform**, as shown below. A green **Strip Sensor LED** over the platform will illuminate to show a new strip is sensed, and will be transported and processed.



***Note*: Ensure the strip is placed properly onto the Strip Platform. Improper strip placement may cause the Strip Transport to malfunction, resulting in inaccurate readings. Incorrect strip placement may result in a blank test result, displaying only the date, time, and ID number.**

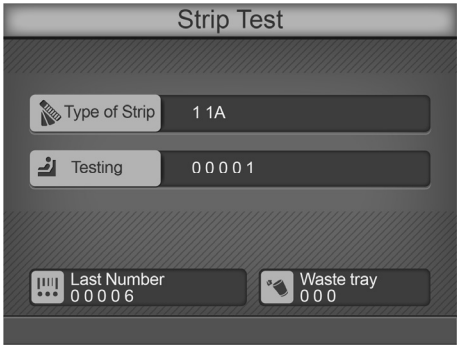
The strip will be processed sequentially through several internal incubation locations, taking 60 seconds total from accepting a strip at the loading area to displaying, storing and printing test results. Results will be automatically printed only if the **Internal Printer** is selected. Waste strips will be deposited into the **Waste Tray** automatically by the strip transport system.

The analyzer performs an automatic calibration each time a test is run. Results will be displayed on the screen and recorded in memory automatically. Any abnormal results will be highlighted on the screen and flagged on the print out.

***Warning*: Do not place foreign objects other than strips onto the Strip Platform.**

After the first strip is transported into the analyzer and the **Strip Sensor LED** turns off, repeat the above process to test additional urine specimens. A new specimen can be added approximately every 7 seconds.

Located in the lower left corner of the ***Strip Test*** screen, the last assigned test number is displayed.

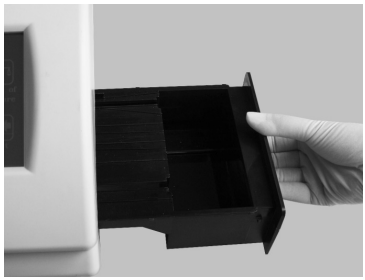


Remove used strips occasionally from the **Waste Tray** and discard the used strips according to local regulations. When the number of tested strips in the **Waste Tray** goes over 140, the analyzer will beep periodically and display a ***Waste Tray Full*** message over the results screen. To properly recognize when the waste tray is emptied, the analyzer must be powered on, with no strips being currently processed.

The analyzer will process the remaining strips on the **Strip Platform**, but will process no additional strips until the **Waste Tray** is emptied. Once the final strips are processed, a blinking ***Waste Tray Full*** message on the ***Initial Screen*** along with a large ***X*** over the ***Waste Tray*** area will be displayed.

Remove the **Strip Platform and Waste Tray** assembly and empty processed strips as necessary.

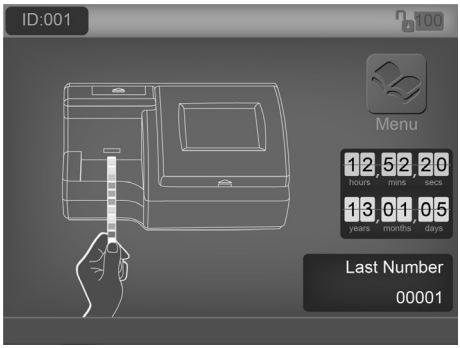
***Caution*: Do not remove the Waste Tray when the analyzer is processing strips. The strip transport mechanism could be damaged if it attempts to move strips with the Waste Tray partially removed.**



Perform daily cleaning when analysis is completed for the day. Refer to **Section 8 Maintenance**.

5.3 Operation with Barcode Reader

Ensure the analyzer is set up and operating as described in **Section 3 Initial Startup**, and analyzer parameters are configured properly as described in **Section 4 Analyzer Setup**, with ***Barcode Reader*** set to ***Yes***. Turn the power switch located at the back panel of the analyzer on. The initial screen will be displayed indicating the analyzer is ready to begin testing strips, with an animated test strip icon indicating the analyzer is ready to accept strips for testing.



5.3.1 Sample/Strip Preparation

Sample and strip preparation are identical to operation without Barcode Reader. Please refer to previous section for strip processing.

5.3.2 Scan or Manually Enter Barcode IDs

Holding the barcode reader over the barcode on the specimen container, press the Scan button on the Barcode Reader. A red illuminated line will appear over the barcode to be read. Move the barcode reader to align the red line over the barcode, and position it until the barcode reader beeps, indicating the barcode has been scanned. Once the code is scanned, a screen will appear with Patient ID, Mode, Test Number, Color, and Clarity information.

Patient ID

This field will show the patient ID and cannot be changed.

Mode

Press ***Mode*** to cycle through the desired testing mode, Routeine, STAT, or QC.

Test Number

The test number will be shown according to the set up in **Section 4 – Test Number**.

Color

To change the color of the urine specimen for testing, press ***Color*** to cycle through the 7 options: Other, Yellow, Orange, Red, Green, Blue, and Brown. Visually inspect the urine specimen and select the appropriate color.

Clarity

To change the clarity of the urine specimen for testing, press ***Clarity*** to cycle through the 5 options, Other, Clear, SL (slightly) Cloudy, Cloudy, and Turbid. Visually inspect the urine specimen and select the appropriate clarity.

After the correct information has been entered, press ☑ to continue to the barcode entry screen. This screen displays the scanned barcodes.

Barcodes can also be entered manually. Press ••• and the analyzer will display an entry box for the desired ***barcode***. Enter the barcode by selecting numbers on the ***Alphanumeric key*** on the touchscreen. Press Cancel to Clear the last number entered. Press OK to accept the number entered and return to the Barcode screen.

Up to 100 barcodes can be entered at the same time. Once entered, the samples must be run in sequence scanned.

Alternatively, each sample ID can be scanned one at a time. The analyzer will not process or accept a new strip unless it has a barcode for a strip placed on the **Strip Platform**.

***Note*: Do not change Barcode reader or Test number settings before all barcodes have been processed, otherwise remaining barcodes may be deleted.**

From the barcode entry screen, press ⎘ to continue to the initial screen for testing. Press ☒ to delete the last barcode entered.

5.4 Urine Controls QC Testing

Ensure the operating ***Mode*** is set to ***QC***. All test numbers in QC mode will begin with ***2***. This allows results to be searched for and found easily.

5.4.1 Strip Preparation

Allow the strip and urine controls to reach room temperature at 15-30ºC (59-86ºF) prior to testing.

***Note*: Use *Mission*® Urinalysis Reagent Strips for proper functioning and accurate results.**

Remove strips from the closed canister and use them as soon as possible. Close the canister tightly immediately after removing the strips.

5.4.2 Urine Control Test Procedures

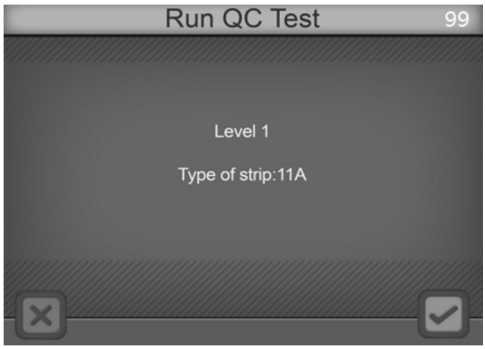
The urine control test procedures are the same as Normal Operation, no Barcode reader, or Normal Operation, Barcode reader installed. Refer to **Section 5 Analyzer Operation**.

The results obtained during the Quality Control test will be referenced by the analyzer with pre-programmed target values and report generated. If ***Printer*** is set to ***Internal***, the result will be printed.

If the QC test "Fails", please contact your local distributor for Technical Support.

5.5 QC Lockout

When ***QC lockout*** is turned **On**, the user will be notified when a QC test is required. The following screen will be displayed.



***Note*: Use *Mission*® Urinalysis Reagent Strips for proper functioning and accurate results.**

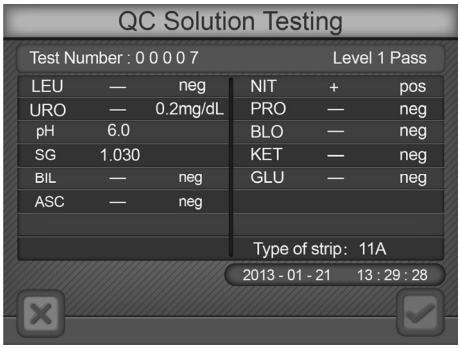
If it is the first time running a QC test, to set up the QC test values, refer to the section on Setting the QC Values in **Section 4 – Analyzer Setup**.

Press ☑ to Run QC tests. Press ☒ to return to the Initial screen. If canceled, the analyzer will change the test mode to ***STAT***. An "**E**" will be displayed after the test number on all printouts to show QC tests were out of date and pending.

The analyzer will run a Level 1 QC test first. Refer to the Strip Test section for

details on testing.

After testing, the analyzer will display the test results.



If any parameter is out of range, it will be highlighted and marked with a **"*"**.

If ***Printer*** is set to Internal, the result will be printed.

2021-03-22	09:31:48	
Level 1	Pass	
No.:	20001	(00000001)
LEU	-	neg
NIT	-	neg
URO	-	0.2 mg/dL
PRO	-	neg
pH	6.0	
BLO	-	neg
SG	1.020	
KET	-	neg
BIL	-	neg
GLU	-	neg
ASC	-	neg

2021-03-22	09:33:16	
Level 2	Pass	
No.:	20002	(00000002)
LEU	3+	500 Leu/μL
NIT	+	pos
URO	2+	4 mg/dL
PRO	3+	300 mg/dL
pH	8.0	
BLO	3+	200 Ery/μL
SG	1.020	
KET	2+	40 mg/dL
BIL	2+	2 mg/dL
GLU	1+	250 mg/dL
ASC	-	neg

Press ☑ to test control Level 2. The steps are the same as for Level 1.

When Both QC Tests pass, the "E" at the end of the test number will not be shown.

Section 6 Data/Communication

The analyzer is equipped with three connectors for external data transmission purposes. The largest connector is a 25 pin connector dedicated to an optional external printer. A standard **RS232C** connector is available for connecting to an external computer and to the optional **Barcode Reader**. A USB port is available for connecting to an external computer. If both **Barcode Reader** and external computer are used at the same time, the baud rates for the analyzer, **Barcode Reader** and external computer ports must be configured to the same baud rate to allow communication between all devices connected to the **RS232C** connector. A "Y" serial splitter cable, provided with the optional **Barcode Reader** must be used to connect both **Barcode Reader** and external computer to the **RS232C** connector at the same time.

For data transmission to an external computer, the analyzer requires an RS232C Cable or a USB Cable and appropriate (optional) communication software, such as Hyperterminal, to connect with a computer and export the database.

The communication protocol is shown below.

Data Format	
Baud Rate	4800, 9600, or 19200
Data Bit	8
Parity	0
Stop Bit	1
Flow Control	None

The analyzer can also connect to a Laboratory Information System (LIS) using data format parameters available in an additional Communication Insert.

The analyzer is able to transfer single results, results from a specific date, and all the results in the database.

For customer support, please contact your local technical support provider or distributor.

Section 7 Quality Control

Each lab should develop and use its own standards and procedures for performance. Test known positive and negative specimens/controls at the following events in accordance with local, state, and/or federal regulations or accreditation requirements.

- A new canister of strips is opened
- A new operator uses the analyzer
- Test results seem inaccurate
- After performing maintenance or service on the analyzer

If the QC tests do not provide expected results, perform the following checks:

- Ensure the strips used are not past their expiration date.
- Ensure strips are fresh from a new canister.
- Ensure the controls are not past their expiration date.
- Repeat the test to ensure no errors were made during the test.

For customer support, please contact your local technical support provider or distributor.

Section 8 Maintenance

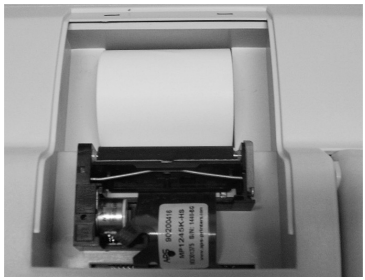
8.1 Loading Printer Paper

Pull up on the finger pull area marked to open the **Printer Cover**. Place the paper roll in the printer box and feed the paper under the printer feed roller until the paper sensor threads the paper through the printer. Pull the paper out, leaving 10 cm (4 inches) of extra paper above the **Printer Roller**. Thread the excess paper through the **Printer Paper Slot** in the **Printer Cover** and return the **Printer Cover** to its original closed position.

***Caution*:**

The printer will only print on the outside surface of the roll. If placed incorrectly, there will be no printout.

For easy printer paper loading, bend the leading edge of the printer paper upward toward the back of the analyzer. Push the leading edge of the printer paper through the feed and the printer paper will now easily feed through the Printer Roller.



8.2 General Cleaning

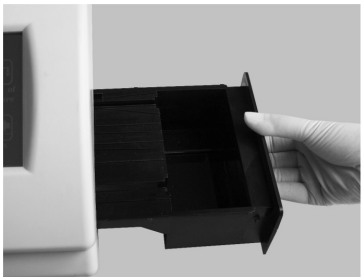
Keep the external of the instrument free of dust at all times. If needed, the external may be cleaned using a damp cloth. Do not use any type of solvent, oil, grease, silicone spray, or lubrication on any part of the instrument.

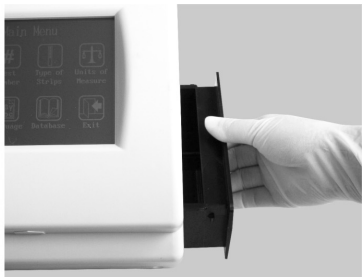
8.3 Waste Tray Removal and Cleaning

The **Strip Platform and Waste Tray** should be cleaned on a daily basis to remove sample deposits using the following procedure. On a monthly basis, depending on the number of strips processed, the **Strip Transport** mechanism should be inspected and sample deposits removed as necessary using the Strip Transport Cleaning procedure below.

8.4 Strip Platform and Waste Tray cleaning

Turn off the Power Switch and unplug the analyzer from primary power. Remove the **Strip Platform and Waste Tray** by pulling the **Waste Tray** out of the right side of the analyzer as shown below.





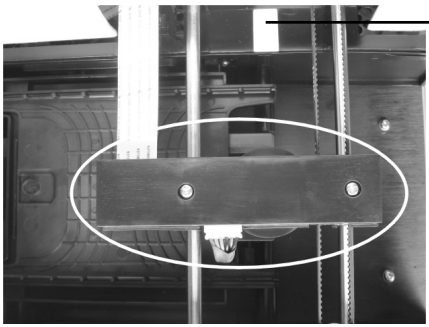
Clean the **Strip Platform and Waste Tray** using a cotton swab or cotton ball dampened with distilled water. Dry with a clean, dry cotton ball. With **Strip Platform and Waste Tray** removed, clean any remaining sample deposits from the strip loading area under the **Strip Platform** using a cotton swab or cotton ball dampened with distilled water. Take care to prevent any fluids from dripping into the transport mechanism. Dry with a clean, dry cotton ball.

8.5 White Calibration Pad Cleaning

Turn off the **Power Switch** and unplug the analyzer from primary power.

Remove the **Strip Platform and Waste Tray** by pulling the **Waste Tray** out of the right side of the analyzer as shown above.

Raise the hinged analyzer **Display Panel** by placing a finger under the **Display Access Slot** and pull up on the display. The display will rotate up, allowing access to the middle of the strip transport area and **Optical Assembly**, shown below.



Examine the **White Calibration Pad** to ensure there are no nicks or dirt present. Clean the **White Calibration Pad** as necessary using a cotton swab or cotton ball with distilled water. Dry with a clean, dry cotton ball.

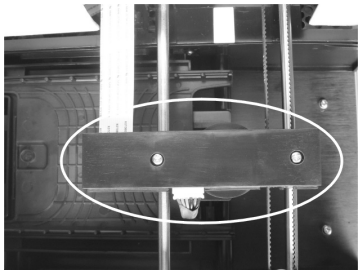
Place the **Strip Platform and Waste Tray** back into its slot in the analyzer, pushing it in until it is fully seated and flush with the outside of the analyzer.

8.6 Strip Transport Cleaning

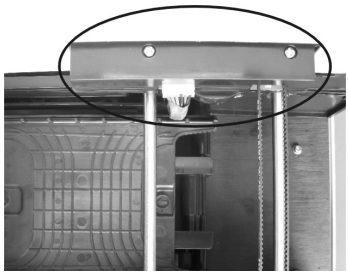
Turn off the **Power Switch** and unplug the analyzer from primary power.

Remove the **Strip Platform and Waste Tray** by pulling the **Waste Tray** out of the right side of the analyzer as shown above.

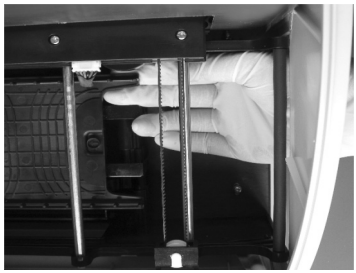
Raise the hinged analyzer **Display Panel** by placing a finger under the **Display Access Slot** and pull up on the display. The display will rotate up, allowing access to the middle of the strip transport area and **Optical Assembly,** shown below.

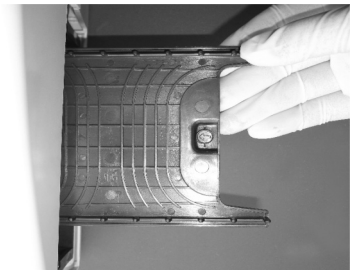


Push the **Optical Assembly** towards the back of the analyzer to allow enough space for removing the **Strip Transport**.



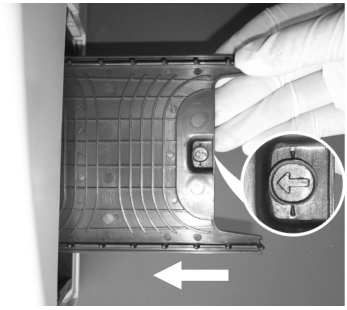
Remove the **Strip Transport** by lifting up on the corner and pulling the **Strip Transport** out of the right side of the analyzer as shown below.





Clean all visible sample deposits with a swab or cotton ball dampened with distilled water. Dry with a clean, dry cotton ball.

Place the **Strip Transport** back inside the analyzer, ensuring the arrows on the **Strip Transport** are pointed towards the inside of the analyzer.



***Warning*: Ensure the optical read-head is back to its center position before loading the Strip Platform and Waste Tray, otherwise permanent damage to the optical read-head assembly can occur.**

Lower the hinged **Display Panel** when cleaning is complete, snapping it closed.

***Caution*: Ensure the Display Panel is fully closed before resuming operation.**

Place the **Strip Platform and Waste Tray** back into its slot in the analyzer, pushing it in until it is fully seated and flush with the outside of the analyzer.

8.7 Cleaning Sample Deposits

Occasionally sample deposits may not be removed with the cleaning process above. To remove remaining deposits use the following procedure.

Turn off the Power Switch and unplug the analyzer from primary power.

Remove the **Strip Platform and Waste Tray** by pulling the **Waste Tray** out of the right side of the analyzer as shown above.

Clean the **Strip Platform and Waste Tray** and mechanical components using a cotton swab or cotton ball with 0.1 M Sodium Hydroxide (NaOH).

Clean the excess NaOH off the **Strip Platform and Waste Tray** and mechanical components using a cloth moistened with distilled water.

Dry the **Strip Platform and Waste Tray** and mechanical components with a clean, dry cotton ball.

Place the **Strip Platform and Waste Tray** back into its slot in the analyzer, pushing it in until it is fully seated and flush with the outside of the analyzer.

8.8 Sterilizing Process

Turn off the Power Switch and unplug the analyzer from primary power.

Remove the **Strip Platform and Waste Tray** by pulling the **Waste Tray** out of the right side of the analyzer as shown above.

Clean the **Strip Platform and Waste Tray** using a cotton swab or cotton ball with one of the following sterilizing solutions:

- 2% Glutaraldehyde (sufficient density): Refer to detailed instructions on the product label.
- 0.05% Sodium Hypochlorite Solution: Add 1 mL 5% Sodium Hypochlorite into 99 mL distilled water, or prepare a 1:100 dilution ratio with appropriate final volume.
- Isopropyl alcohol (70-80%).

Place the **Strip Platform and Waste Tray** back into its slot in the analyzer, pushing it in until it is fully seated and flush with the outside of the analyzer.

8.9 Fuse Replacement

Turn off the Power Switch and unplug the Power Cord from the Power Socket in the back of the analyzer.

Remove the Fuse Cover from the back of the analyzer.

Remove the Fuse and replace with a new Fuse.

Return the Fuse Cover to the original position, and then plug in the Power Cord into the Power Socket in the back of the analyzer.

8.10 Color Touch Screen LCD Calibration

Turn the analyzer Power Switch off, then on.

When the ***self-test*** being shown, press anywhere on **Color Touch Screen LCD**. The ***Color Touch Screen Calibration*** screen will be displayed, shown below.

Remove finger from the **Color Touch Screen LCD**, a **+** will be shown in the center of the screen.

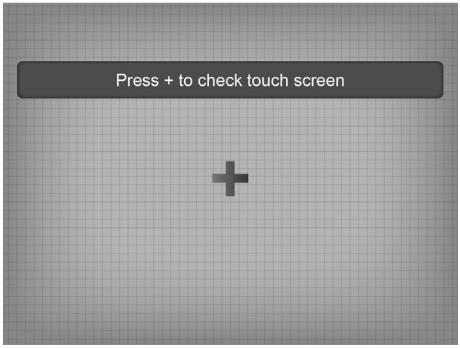
Press the **+** displayed on the center of the screen to begin calibration.

The **+** will move to the upper left area of the screen. Press the **+** displayed on the upper left of the screen.

The **+** will move to the upper right area of the screen. Again, press the **+** on the screen.

Repeat this process when the **+** is displayed in the lower right area of the screen. This process calibrates the touchscreen so the analyzer can interpret which areas are being touched during operation.

Note: **When touching the screen during the calibration process, ensure the finger is placed directly over the + sign. If you do not, the touch screen may be improperly calibrated and unable to respond properly to touch screen input.**



Section 9 Precautions

Observe the precautions listed below to ensure accurate results and proper operation of the analyzer.

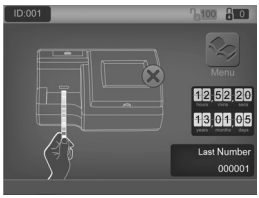
- The protection provided by the equipment may be impaired if used in a manner not defined in this user guide.
- Connect to a power connection which contains a working grounding plug.
- Wear gloves to avoid contact with potentially hazardous biological samples during processing strips, or analyzer components.
- The Analyzer is an electronic laboratory analyzer and must be handled properly for accurate and reliable results.
- Read and follow the Instruction Manual before operating the analyzer.
- Turn the Power Switch off and unplug the Power Cord before performing maintenance or service on the analyzer.
- Avoid storing or operating the analyzer in direct sunlight, excessive temperature or humidity. Refer to Appendix 1 Urine Analyzer Specifications for operating condition requirements.
- Never place anything on the Strip Platform to avoid collisions when the Strip Platform automatically advances the strip into the analyzer.
- Keep the analyzer clean and wipe it down frequently with a soft, clean, dry cloth.
- Do not remove the **Strip Platform and Waste Tray** when strips are being processed
- Do not clean the analyzer with substances such as gasoline, paint thinner, benzene compounds or other organic solvents to avoid any damage to the Strip Platform or other components.
- Do not wash the Touch Screen Liquid Crystal Display with water. To clean it, lightly wipe it with a clean, soft and dry rag or paper towel.
- Do not touch the Touch Screen Liquid Crystal Display with any hard objects. Use only your finger.
- The Strip Platform must be kept clean. Wipe down using fresh water daily. Refer to **Section 8 Maintenance**.
- Follow proper precautions and all local regulations when disposing of the analyzer and used accessories.
- Do not use the analyzer or strips outside of the operating temperature ranges listed below to ensure accuracy of test results:

  Analyzer: 0-40ºC (32-104ºF)

  Strips: 15-30ºC (59-86ºF)

Section 10 Troubleshooting

Problem	Solutions
Strip Error	• Ensure the type of strip used matches the type of strip setting. • Ensure the strip brand is compatible with the analyzer. • Ensure all of the test pads on the strip have been immersed in the specimen. • Ensure the test mode selected is QC Test if a calibration strip is to be used • Ensure that the Synchro-Strap is not damaged. Contact your local distributor for further instruction.
No Strip Error	• Insert Strip.
No display on screen	• Ensure power is connected to the analyzer. • Ensure Power Switch is turned on. • Examine the Fuse on the back of the analyzer to determine if it is damaged. Replace it if necessary. • Refer to Fuse Replacement in this section.
Fuse is damaged	• Turn off the Power Switch. • Disconnect the power cord. • Replace the damaged fuse with a new 2.0 A fuse. • Refer to Fuse Replacement in this section.
Internal Printer does not work	• Ensure Printer Paper Roll is installed properly. Refer to **Section 8 Maintenance**. • Ensure ***Printer Mode*** is set to ***Internal***. Refer to **Section 4 Analyzer Setup**.
Touch Screen LCD does not respond correctly	• Press the Symbol or Text for a slightly longer time or slide your finger across the screen. • Turn the Power Switch off and on to perform a Touch Screen Calibration. • Refer to Touch Screen LCD Calibration in this section.
Electronic System Test failed	• Turn the Power Switch off and on. • Examine the Fuse on the back of the analyzer to determine if it is damaged. Replace if necessary. Refer to Fuse Replacement in this section. • Ensure the Power Cable is plugged correctly and is not loose or damaged.
Mechanism System Test failed	• Remove any obstacles in the path of the Strip Platform • Do not touch the Strip Platform when it is moving • Turn the Power Switch off and on to perform Automatic Self-Inspection. Refer to **Section 5 Analyzer Operation**.

Printer Paper Empty Error 	• Ensure the Printer Paper Roll is installed correctly. • Refer to **Section 8 Maintenance**.
Strip Platform Removal Error 	• Install the **Strip Platform and Waste Tray** into the analyzer completely, flush with outside housing wall. • Refer to **Section 8 Maintenance**.
Waste Tray Full Error 	• Remove used strips from the **Waste Tray** when the analyzer is powered on. Discard used strips according to local regulations. Refer to **Section 8 Maintenance**.
Barcode Reader does not work	• Ensure the Barcode Reader is fully connected to the analyzer and connector screws are tightened. • Ensure ***Barcode Reader*** setting is ***Yes***. • Refer to **Section 4 Analyzer Setup**.
Barcode unreadable	• Ensure the barcode is compatible with the Barcode Reader.
Canister Code Error	• Ensure the canister code entered is correct • Ensure the type of strip used is the same as the analyzer setting.
QC Test Fail	• Ensure the control is correct. • Ensure the type of strip is correct. • Ensure the brand of strip is compatible with the analyzer. • Ensure all of the reagent pads of the strip have been immersed.
Optical Sensor Failed	• Ensure the White Calibration Pad is clean.
Excess Light Failed	• Ensure the waste tray is clean and has no other object on it.

For customer support, please contact your local technical support provider or distributor.

Appendix 1 Urine Analyzer Specifications

Feature	Specifications
Methodology	Reflectance Photometer
Detection	Photosensitive Diode
Throughput	500 tests/hour
Measuring Cycle	7 seconds/test
Memory	2,000 Results
Strip Incubation Time	1 minute
Wavelength	525 nm and 635 nm
Waste Disposal Capacity	Up to 150 Strips
Analyzer Ports	Standard RS232C Port for Barcode Reader or Data Transfer, 25 Pin Parallel Port for External Printer USB Port for Data Transfer
Capabilities	Internal Thermal Printer (included), Optional External Printer (not included), RS232C Barcode Reader (optional), RS232C Data Transfer Cable (optional) USB Data Transfer Cable (optional)
Calibration	Automatic
Available Languages on Screen	English (default in US and select countries) and all available languages
Analyzer Operating Conditions	0-40 ºC (32-104 ºF); ≤85% Relative Humidity (non-condensing)
Strip Operating Conditions	15-30 °C (59-86 ºF); ≤85% Relative Humidity (non-condensing)
Power Source	100-240 V AC, 50-60 Hz
Dimensions (L x W x H)	36.6 cm × 28.3 cm × 19.5 cm (14.4” x 11.1” x 7.7”)
Display Dimensions (L x W)	11.5 cm × 9.0 cm (4.5” x 3.5”)
Weight	5.10 kg (11.24 lbs)

This product complies with EN 61326.

Appendix 2 Performance Characteristics of Urinalysis Reagent Strips

The performance characteristics of the ***Mission***® Urinalysis Reagent Strips (Urine) have been determined in both laboratory and clinical tests. The following table indicates performance characteristics for each parameter.

Reagent	Composition	Sensitivity-Visual Reading	Sensitivity – *Mission*® U500 Urine Analyzer Reading
Leukocytes (LEU)	derivatized pyrrole amino acid ester; diazonium salt; buffer; non-reactive ingredients	Detects leukocytes as low as 9-15 white blood cells (Leu/μL) in clinical urine.	Detects leukocytes as low as 12-15 white blood cells (Leu/μL) in clinical urine.
Nitrite (NIT)	p-arsanilic acid; N-(1-naphtyl) ethylenediamine; non-reactive ingredients	Detects sodium nitrite as low as 0.05-0.1 mg/dL in urine with a low specific gravity and less than 30 mg/dL ascorbic acid.	Detects sodium nitrite as low as 0.05 mg/dL in urine with a low specific gravity and less than 30 mg/dL ascorbic acid.
Urobilinogen (URO)	p-diethylaminobenzaldehyde; buffer and non-reactive ingredients	Detects urobilinogen as low as 0.2-1.0 mg/dL (3.5-17 μmol/L).	Detects urobilinogen as low as 0.8-1.0 mg/dL (13.6-17 μmol/L).
Urobilinogen (URO) - 14C/13 CE	4-methoxybenzene diazonium tetrafluoroborate; buffer and non-reactive ingredients	Detects urobilinogen as low as 0.8-1.0 mg/dL (13.6-17 μmol/L).	Detects urobilinogen as low as 0.8-1.0 mg/dL (13.6-17 μmol/L).
Protein (PRO)	tetrabromophenol blue; buffer and non-reactive ingredients	Detects albumin as low as 7.5-15 mg/dL (0.075-0.15 g/L).	Detects albumin as low as 12-15 mg/dL (0.12-0.15 g/L).
pH	methyl red sodium salt; bromthymol blue; non-reactive ingredients	Permits the quantitative differentiation of pH values within the range of 5-9.	Permits the quantitative differentiation of pH values within the range of 5-9.

Blood (BLO)	3,3',5,5'-tetramethylbenzidine (TMB); diisopropylbenzene dihydroperoxide; buffer and non-reactive ingredients	Detects free hemoglobin as low as 0.018-0.060 mg/dL or 5-10 Ery/µL in urine specimens with ascorbic acid content of <50 mg/dL.	Detects free hemoglobin as low as 0.018-0.060 mg/dL or 5-10 Ery/µL in urine specimens with ascorbic acid content of <50 mg/dL.
Specific Gravity (SG)	bromthymol blue indicator; buffer and non-reactive ingredients; poly (methyl vinyl ether/maleic anhydride); sodium hydroxide	Determines urine specific gravity between 1.000 and 1.030. Results correlate with values obtained by refractive index method within ±0.005.	Determines urine specific gravity between 1.000 and 1.030. Results correlate with values obtained by refractive index method within ±0.005.
Ketone (KET)	sodium nitroprusside; buffer	Detects acetoacetic acid as low as 2.5-5 mg/dL (0.25-0.5 mmol/L).	Detects acetoacetic acid as low as 4-5 mg/dL (0.4-0.5 mmol/L).
Bilirubin (BIL)	2, 4-dichloroaniline diazonium salt; buffer and non-reactive ingredients	Detects bilirubin as low as 0.4-1.0 mg/dL (6.8-17 µmol/L).	Detects bilirubin as low as 0.8-1.0 mg/dL (13.6-17 µmol/L).
Bilirubin (BIL) - 14C/13 CE	2, 6-dichloroaniline; buffer and non-reactive ingredients	Detects bilirubin as low as 0.4-1.0 mg/dL (6.8-17 µmol/L).	Detects bilirubin as low as 0.8-1.0 mg/dL (13.6-17 µmol/L).
Glucose (GLU)	glucose oxidase; peroxidase; potassium iodide; buffer; non-reactive ingredients	Detects glucose as low as 50-100 mg/dL (2.5-5 mmol/L).	Detects glucose as low as 80-100 mg/dL (4-5 mmol/L).
Glucose (GLU)-14C/13 CE	glucose oxidase; peroxidase; 3,3',5,5'-tetramethylbenzidine (TMB); buffer; non-reactive ingredients	Detects glucose as low as 25-40 mg/dL (1.25-2 mmol/L).	Detects glucose as low as 25-50 mg/dL (1.25-2.5 mmol/L).
Ascorbic Acid (ASC)	2,6-dichlorophenolindophenol; buffer and non-reactive ingredients	Detects ascorbic acid as low as 5-10 mg/dL (0.28-0.56 mmol/L).	Detects ascorbic acid as low as 8-10 mg/dL (0.45-0.56 mmol/L).

Albumin (ALB)	bis(3',3"-diiodo-4',4"-dihydroxy-5',5"-dinitrophenyl)-3,4,5,6-tetrabromosulfonephthalein; buffer; non-reactive ingredients	Detects albumin between 10-150 mg/L.	Detects albumin between 10-150 mg/L.
Creatinine (CRE)	copper acetate; diisopropylbenzene dihydroperoxide; 3,3',5,5'-tetramethylbenzidine; buffer; non-reactive ingredients	Detects urine creatinine between 10 - 300 mg/dL	Detects urine creatinine between 10 - 300mg/dL
Calcium (CA)	o-Cresolphthalein Complexon; buffer and non-reactive ingredients	Detects urine calcium between 4mg/dL (1.0 mmol/L) and 40mg/dL (10 mmol/L)	Detects urine calcium between 4mg/dL (1.0 mmol/L) and 40mg/dL (10 mmol/L)

***Notes*:**

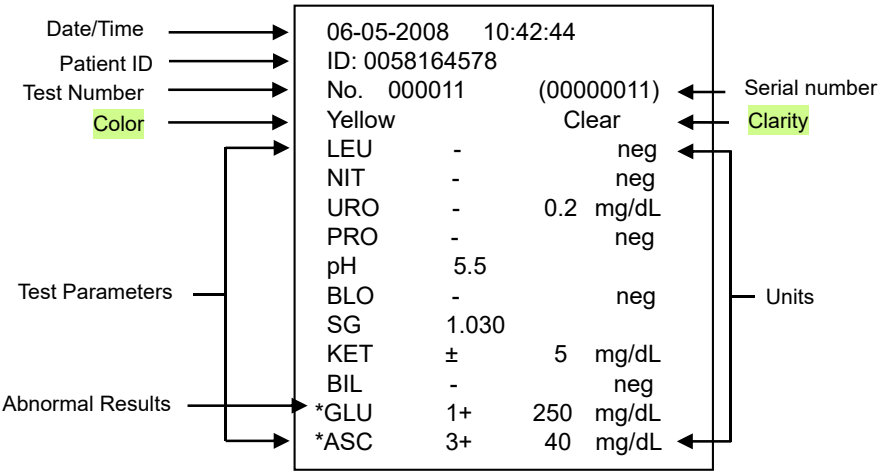
- For the parameter arrangement and combination of different Urine Reagent Strips, please refer to the product information on the ***Mission***® Urinalysis Reagent Strips kit box or canister label.
- Ensure that the type of strip selected corresponds with the strip being used. If not, it will be detected and display that there is an error.
- Only use ***Mission***® Urinalysis Reagent Strips with this analyzer for accurate results.

Appendix 3 Urinalysis Strip Parameter Table

Parameter Name (Abbreviation on Display)	Arbitrary	Conventional	SI
Leukocytes (LEU)	- ± 1+ 2+ 3+	Neg 15 Leu/μL 70 Leu/μL 125 Leu/μL 500 Leu/μL	Neg 15 Leu/μL 70 Leu/μL 125 Leu/μL 500 Leu/μL
Nitrite (NIT)	- +	Neg Pos	Neg Pos
Urobilinogen (URO)	- ± 1+ 2+ 3+	0.2 mg/dL 1 mg/dL 2 mg/dL 4 mg/dL 8 mg/dL	3.5 μmol/L 17 μmol/L 35 μmol/L 70 μmol/L 140 μmol/L
Protein (PRO)	- ± 1+ 2+ 3+	Neg 15 mg/dL 30 mg/dL 100 mg/dL 300 mg/dL	Neg 0.15 g/L 0.3 g/L 1.0 g/L 3.0 g/L
pH	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0
Blood (BLO)	- ± 1+ 2+ 3+	Neg 10 Ery/μL 25 Ery/μL 80 Ery/μL 200 Ery/μL	Neg 10 Ery/μL 25 Ery/μL 80 Ery/μL 200 Ery/μL
Specific Gravity (SG)	1.000 1.005 1.010 1.015 1.020 1.025 1.030	1.000 1.005 1.010 1.015 1.020 1.025 1.030	1.000 1.005 1.010 1.015 1.020 1.025 1.030
Ketone (KET)	- ± 1+ 2+ 3+	Neg 5 mg/dL 15 mg/dL 40 mg/dL 80 mg/dL	Neg 0.5 mmol/L 1.5 mmol/L 4.0 mmol/L 8.0 mmol/L

Bilirubin (BIL)	- 1+ 2+ 3+	Neg 1 mg/dL 2 mg/dL 4 mg/dL	Neg 17 µmol/L 35 µmol/L 70 µmol/L	
Bilirubin (BIL) ---13CE/14C	- 1+ 2+ 3+	Neg 1 mg/dL 3 mg/dL 6 mg/dL	Neg 17 µmol/L 50 µmol/L 100 µmol/L	
Glucose (GLU)	- ± 1+ 2+ 3+	Neg 100 mg/dL 250 mg/dL 500 mg/dL 1000 mg/dL	Neg 5 mmol/L 15 mmol/L 30 mmol/L 60 mmol/L	
Glucose (GLU) ---13CE/14C	- ± 1+ 2+ 3+ 4+	Neg 50 mg/dL 100 mg/dL 250 mg/dL 500 mg/dL 1000 mg/dL	Neg 2.8 mmol/L 5.6 mmol/L 14 mmol/L 28 mmol/L 56 mmol/L	
Ascorbic Acid (ASC)	- 1+ 2+ 3+	Neg 10 mg/dL 20 mg/dL 40 mg/dL	Neg 0.56 mmol/L 1.14 mmol/L 2.28 mmol/L	
Albumin (ALB)	10 mg/L 30 mg/L 80 mg/L 150 mg/L	10 mg/L 30 mg/L 80 mg/L 150 mg/L	10 mg/L 30 mg/L 80 mg/L 150 mg/L	
Creatinine (CRE)	10 mg/dL 50 mg/dL 100 mg/dL 200 mg/dL 300 mg/dL	10 mg/dL 50 mg/dL 100 mg/dL 200 mg/dL 300 mg/dL	0.9 mmol/L 4.4 mmol/L 8.8 mmol/L 17.7 mmol/L 26.5 mmol/L	
Calcium (CA)	4 mg/dL 10 mg/dL 20 mg/dL 30 mg/dL 40 mg/dL	4 mg/dL 10 mg/dL 20 mg/dL 30 mg/dL 40 mg/dL	1.0 mmol/L 2.5 mmol/L 5.0 mmol/L 7.5 mmol/L 10 mmol/L	
A:C	<30 mg/g <30 mg/g 30-300 mg/g >300 mg/g	Normal Dilute Normal Abnormal High Abnormal	<3.4 mg/mmol <3.4 mg/mmol 3.4-33.9 mg/mmol >33.9 mg/mmol	Normal Dilute Normal Abnormal High Abnormal
P:C	<30 mg/g <30 mg/g 30-150 mg/g 150-300 mg/g 300-500 mg/g >500 mg/g	Normal Dilute Normal Abnormal Abnormal Abnormal Abnormal	<3.4 mg/mmol <3.4 mg/mmol 3.4-17.0 mg/mmol 17.0-33.9 mg/mmol 33.9-56.6 mg/mmol >56.6 mg/mmol	Normal Dilute Normal Abnormal Abnormal Abnormal Abnormal

Appendix 4 Result Print-Out



Arbitrary results will always be printed automatically. Conventional or SI results will be printed based on the units selected.

Arbitrary Results:

- All positive results except pH, Specific Gravity (SG), Albumin (ALB), Creatinine (CRE) and Calcium(CA) will be reported as 1+, 2+, or 3+.
- Positive results for pH, Specific Gravity (SG), Albumin (ALB), Creatinine (CRE) and Calcium(CA) will be reported with the respective data.
- Negative results for Leukocyte, Nitrite, Urobilinogen, Protein, Blood, Ketone, Bilirubin, Glucose and Ascorbic Acid will be reported as "-".

Conventional or SI:

- All positive results except Nitrite (NIT) will be reported with the respective data in front of the units. Nitrite positive results will be reported as "pos".
- All negative results except Urobilinogen (URO), Albumin (ALB), Creatinine (CRE) and Calcium (CA) will be reported as "neg." The negative results of Urobilinogen (URO), Albumin (ALB), Creatinine (CRE) and Calcium (CA) will be reported with the respective data in front of the units.

Appendix 5 Barcode Reader

The ***Mission***® Barcode Reader is an optional laser barcode scanner. The Barcode Reader connects to the analyzer to scan the patient (ID) barcode numbers on the specimen containers. The Barcode reader can scan the following:

• Code 39 (Standard/ Full ASCII)	• Codabar (NW-7)	• Code 128
• Italy Pharmacode	• UPCA	• EAN 128
• French Pharmacode	• UPCE	• MSI
• Industrial 25	• EAN8	• Plessey
• Interleave 25	• EAN13	• Telepen
• Matrix 25	• Code 93	• RSS

***Note*: A maximum of 25 characters can be read by the barcode reader, displayed, stored, and transmitted by the analyzer.**

***Warning*: The Barcode reader is a Class 2 Laser Product.**

DO NOT stare into the laser beam.

Appendix 6 Catalog

Product Name	Catalog Number	Components	Quantity
Mission® U500 Urine Analyzer	U211-101-101	***Mission***® U500 Urine Analyzer	1
		Strip Platform/Waste Tray	1
		Printer Paper Rolls	2
		Fuses (2.0 A)	2
		Power Cord	1
		Instruction Manual	1
Mission® U500 Urine Analyzer with Barcode Reader	U211-111-101	***Mission***® U500 Urine Analyzer	1
		Strip Platform/Waste Tray	1
		Printer Paper Rolls	2
		Barcode Reader (RS232C)	1
		Serial Splitter Cable (RS232C)	1
		Fuses (2.0 A)	2
		Power Cord	1
		Instruction Manual	1
Mission® Barcode Reader	U221-111-101	Barcode Reader (RS232C)	1
		Serial Splitter Cable (RS232C)	1
Mission® Printer Paper Rolls	U121-101-101	Thermal Paper (0.06m x 20m): 200 results/roll	4
	U121-101-102	Sticker Paper (0.06 m x 9 m): 100 results/roll; Optional	4
Mission® Data Transfer Kit	U127-131-101	Data Transfer Cable (RS232C)	1
		Package Insert	1
	U127-131-102	Data Transfer Cable (USB)	1
		Package Insert	1

Appendix 7 Index of Symbols

	Consult instructions for use		Manufacturer
	Date of Manufacturer		Catalogue number
	*In vitro* diagnostic medical device		Batch code
	Serial number		Grounding
	Do not dispose along with household waste		Contains sufficient for <*n*> tests
	Keep away from sunlight		Use-by date
	This Side Up		Power Socket
	Keep Dry		Fragile, handle with care
FUSE T2AL250VP	Fuse type		25 Pin Parallel External Printer Port
	Serial Port		Importer
	Distributor	EC REP	Authorized representative in the European Community

Appendix 8 Warranty

Please complete the warranty card included in the packaging. Mail it to your local distributor to register your purchase.

For your records, write the purchase date of your starter kit here.

***Note*: This warranty applies only to the analyzer in the original purchase, and does not apply to the other materials included with the analyzer.**

ACON warrants to the original purchaser that this analyzer will be free from defects in materials and workmanship for a period of one year (12 months). The one year starts from the later of the date of original purchase or installation (except as noted below). During the stated one year period, ***ACON*** shall replace the unit under warranty with a reconditioned unit or, at its option, repair at no charge a unit that is found to be defective. ***ACON*** shall not be responsible for shipping charges incurred in the repair of such an analyzer.

This warranty is subject to the following exceptions and limitations:

This warranty is limited to repair or replacement due to defects in parts or workmanship. Parts required which were not defective shall be replaced at additional cost, and ***ACON*** shall not be required to make any repairs or replace any parts that are necessitated by abuse, accidents, alteration, misuse, neglect, failure to operate the analyzer in accordance with the operations manual, or maintenance by anyone other than ***ACON***. Furthermore, ***ACON*** assumes no liability from malfunction or damage to analyzers caused by the use of strips other than strips manufactured by ***ACON***. ***ACON*** reserves the right to make changes in the design of this analyzer without obligation to incorporate such changes into previously manufactured analyzers.

Disclaimer of Warranties

This warranty is expressly made in lieu of any and all other warranties express or implied (either in fact or by operation of law) including the warranties of merchantability and fitness for use, which are expressly excluded, and is the only warranty given by ***ACON***.

Limitations of Liability

In no event shall ***ACON*** be liable for indirect, special or consequential damages, even if ***ACON*** has been advised of the possibility of such damages.

For warranty service, please contact your local distributor.

Mission® U500 Urine Analyzer Warranty Card

Please complete this warranty card and mail it to your local distributor to register your purchase within 30 days of purchase. Refer to **Appendix 8 Warranty** in the Instruction Manual for details and terms of the product warranty.

Date of Purchase	Purchaser	Analyzer Serial Number (e.g. SN 0000000. See label on back of analyzer)
Organization Name		Address
Telephone Number		Email Address

Mission® U500 Urine Analyzer

Clinical Accuracy | 15 Strip Combinations | 8 Software Languages | Urine Clarity & Color for POCT

High Accuracy and Reliability

- Up to 500 tests/hour for medium volume labs or small hospitals
- Large color touchscreen display offers intuitive menu navigation
- Ability to input urine color and clarity for better reference
- Flags abnormal results automatically
- 15 combinations of strips available, including Microalbumin, Creatinine, Ascorbic Acid and Calcium
- Strip Lockout prevents using strips of another brand with a customized canister code
- Order of parameters can be selected for display and printout
- Urine clarity and color can be captured
- Automatic strip detection and alignment
- Reads strips with up to 14 parameters, including Microalbumin, Creatinine and Calcium
- 8 languages preloaded into the software
- Automatic calibration
- USB Port and RS232C Port for data transfer to a computer and LIS

Large Color Touchscreen | **Automatic Strip Detection** | **Easy Access to Strip Carrier**

Strip Combinations for U500 Urine Analyzer

Catalog Number	Numbers of Parameters	Type of Strip U500 Analyzer	Parameter Order (First parameter is closest to strip handle)	Parameter													
				ASC	GLU	BIL	KET	SG	BLO	PH	PRO	URO	NIT	LEU	ALB	CRE	Ca
U031-141	14	14C	Ca/Blo/pH/Cre/Nit/Ket/SG/Asc/Glu/Bil/Pro/Alb/Uro/Leu	*	*	*	*	*	*	*	*	*	*	*	*	*	*
U031-131	13	13CE	Blo/pH/Cre/Nit/Ket/SG/Asc/Glu/Bil/Pro/Alb/Uro/Leu	*	*	*	*	*	*	*	*	*	*	*	*	*	
U031-111	11	11A	Asc/Glu/Bil/Ket/SG/Blo/pH/Pro/Uro/Nit/Leu	*	*	*	*	*	*	*	*	*	*	*			
U031-101	10	10U	Glu/Bil/Ket/SG/Blo/pH/Pro/Uro/Nit/Leu		*	*	*	*	*	*	*	*	*	*			
U031-091	9	9U	Glu/Bil/Ket/SG/Blo/pH/Pro/Uro/Nit		*	*	*	*	*	*	*	*	*	*			
U031-081	8	8N	Glu/Ket/SG/Blo/pH/Pro/Nit/Leu[1]		*		*	*	*	*	*		*	*			
U031-071	7	7N	Glu/Ket/Pro/pH/Blo/Nit/Leu		*		*		*	*	*						
U031-051	5	5NE	Blo/pH/Pro/Ket/Glu		*				*		*		*	*			
		5NE	Glu/Pro/Nit/Blo/Leu		*				*		*		*	*			
U031-041	4	4PE	Glu/Pro/Nit/Leu		*						*		*	*			
		4SE	Glu/SG/pH/Pro		*			*		*	*						
U031-031	3	3PE	Glu/pH/Pro		*					*	*						
		3KE	Glu/Ket/Pro		*		*				*						
U031-021	2	2GE	Glu/Pro		*						*						
		2CE	ALB/CRE												*	*	

Specifications

Feature	Specifications
Analyzer Type	Semi- Automatic
Methodology	Reflectance Photometry
Detection	Photosensitive Diode
Throughput	500 tests/ hour / (Measuring cycle: 7 seconds/ test)
Lockout Functions	Strip Lockout: Available Upon Request; User/QC Lockout: Included with option to turn ON/OFF
Memory	Last 2,000 results
Strip Incubation Time	1 Minute
Wavelength	525 and 635 nm
Default Strips*	2, 3, 4, 5, 7, 8, 9, 10, 11, 13, and 14 Parameters (108 mm x 5 mm)
Strips Available*	1- 14 Parameters (108 mm x 5 mm); see URS Parameters
Parameter Order	Can select the order of parameters for display and print out
Total Combinations per Analyzer*	15 combinations available currently; capacity for unlimited
Software Languages*	8 languages
Analyzer Ports*	RS232C Port for Barcode Reader, Data Transfer, and Software Update USB Port for Data Transfer, 25 Pin Parallel Port for External Printer
Data Entry Capabilities*	Urine Color and Clarity - Manual Entry / Operator ID/Patient ID - Manual Entry and Barcode Reader (Up to 25 characters)
Data Transfer Options*	Data for single entry, all the data in database, data from specific date
Data Search Options*	Test number, positive results, patient ID, date, STAT results, QC results
Software Updates*	Download software from ACON website and update analyzer via RS232C Cable
Connection Capabilities*	RS232C port for Software Update (included) / RS232C Barcode Reader (optional) / USB or RS232C Data Transfer Cable (optional)
Screen Type*	LCD color touchscreen
LIS Interface*	HL-7 compliant
Calibration	Automatic
Operating Conditions	0 – 40 °C (32 – 104 °F); ≤ 85% RH
Storage Conditions	- 5 – 50 °C (23 – 122 °F); ≤ 90% RH
Power Source	100 - 240 Volts AC, 50- 60 Hz
Dimensions (L x W x H)	36.6 cm x 28.3 cm x 19.5 cm (14.4” x 11.1” x 7.7”)
Display Dimensions (L x W)	11.5 cm x 9 cm (4.5” x 3.5”)
Weight	4.0 kg (8.8 lbs.) without batteries or power supply

*Enhanced Feature

Ordering Information

Product Name	Catalog Number	Components		Kit Box Dimensions (L x W x H) & Weight Carton Dimensions (L x W x H) & Weight			Number of Kits/ Carton
U500 Urine Analyzer	U211-101	1 Urine Analyzer 1 Strip Platform/ Waste Tray 2 Printer Paper Rolls	2 Fuses (2.0A) 1 Power Cord 1 Instruction Manual	51.0 cm x 42.0 cm x 38.5 cm; 7 kg			1
				20.1” X 16.5” x 15.2”; 246.9 oz			
Printer Paper Rolls	U121-101	4 Printer Paper Rolls		**Thermal Paper** (0.06 m x 20 m): 200 results/roll	12.0 cm x 12.0 cm x 6.5 cm; 0.360 kg	63.0 cm x 37.0 cm x 30.0 cm; 19.4 kg	50
					4.7” x 4.7” x 2.6”; 12.7oz	24.8” x 14.6” x 11.8”; 42.8 lbs	
				Sticker Paper (0.06 m x 9 m): 100 results/roll	12.0 cm x 12.0 cm x 6.5 cm; 0.40 kg	63.0 cm x 37.0 cm x 30.0 cm; 21.4 kg	
					4.7” x 4.7” x 2.6”; 14.1oz	24.8” x 14.6” x 11.8”; 47.2 lbs	

CE Marked for sale in the European Community and 510(k) Cleared

aconlabs.com

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10125 Mesa Rim Road, San Diego, CA 92121, U.S.A.
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Email: info@aconlabs.com

PN 2170004201 • Date 7/17

Mission® Urinalysis Strips and Controls

Mission® Urinalysis Reagent Strips

Simple to use

- Analytical sensitivity comparable to market leaders
- High quality color chart ensures accurate visual reading
- Compatible for visual and analyzer reading
- Over 35 different combinations available

Multiple Packaging Options

Canister Packaging

- Available in 25, 50, and 100 strips per canister
- Available in 150 strips per canister without MA/CRE Combo

Pouch Packaging

- Individually packaged strips available in kits of 3 or 6 strips for visual reading only (includes 1 color chart)
- Unique packaging maintains 2 year shelf life for all strips in the kit

Shelf Life

- 2 year shelf life for unopened canisters offers cost savings
- 3 month shelf life for strips in opened canisters

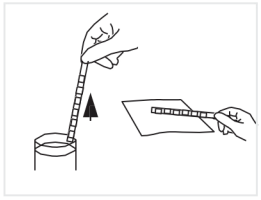
High Quality Color Chart

Large Choice of Parameter Combinations

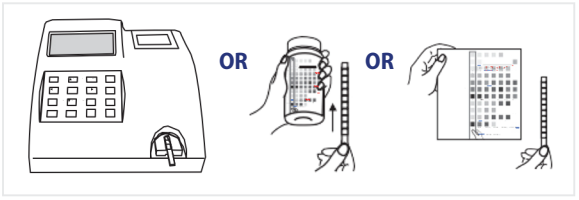
Individually Pouched Strips

Reagent Strips 3 Easy Steps

STEP 1
Immerse strip into urine



STEP 2
Remove excess urine



STEP 2
Obtain results by analyzer or visual reading

Urinalysis Reagent Strip – Combinations for Visual Reading

Catalog Number	Number of Parameters	Type of Strip	Parameter Order (First parameter is closest to strip handle)	ASC	GLU	BIL	KET	SG	BLO	PH	PRO	URO	NIT	LEU	ALB	CRE	CA
U031-141	14	14C	Ca/Blo/pH/Cre/Nit/Ket/SG/Asc/Glu/Bil/Pro/Alb/Uro/Leu	*	*	*	*	*	*	*	*	*	*	*	*	*	*
U031-131	13	13CE	Blo/pH/Cre/Nit/Ket/SG/Asc/Glu/Bil/Pro/Alb/Uro/Leu	*	*	*	*	*	*	*	*	*	*	*	*	*	
U031-111	11	11A	Asc/Glu/Bil/Ket/SG/Blo/pH/Pro/Uro/Nit/Leu	*	*	*	*	*	*	*	*	*	*	*			
U031-101	10	10U	Glu/Bil/Ket/SG/Blo/pH/Pro/Uro/Nit/Leu		*	*	*	*	*	*	*	*	*	*			
U031-091	9	9U	Glu/Bil/Ket/SG/Blo/pH/Pro/Uro/Nit		*	*	*	*	*	*	*	*	*				
U031-081	8	8U	Glu/Bil/Ket/Blo/pH/Pro/Uro/Nit		*	*	*		*	*	*	*	*				
		8N	Glu/Ket/SG/Blo/pH/Pro/Nit/Leu1		*		*	*	*	*	*		*	*			
		8S	Glu/SG/Blo/pH/Pro/Uro/Nit/Leu		*			*	*	*	*	*	*	*			
		8K	pH/Glu/Bil/Pro/Uro/Nit/Leu/Ket		*	*	*			*	*	*	*	*			
U031-071	7	7N	Glu/Ket/Pro/pH/Blo/Nit/Leu		*		*		*	*	*		*	*			
U031-061	6	6N	Glu/Pro/pH/Blo/Nit/Leu		*				*	*	*		*	*			
		6U	Bil/SG/Blo/Uro/Pro/Nit			*		*	*		*	*	*				
U031-051	5	5B	Glu/Ket/Pro/pH/Blo		*		*		*	*	*						
		5N	Glu/Pro/Nit/Blo/Leu		*				*		*		*	*			
		5S	Glu/SG/Pro/pH/Blo		*			*	*	*	*						
		5U	Bil/Uro/Leu/Nit/Blo			*			*			*	*	*			
U031-041	4	4P	Glu/Pro/Nit/Leu		*						*		*	*			
		4S	Glu/SG/pH/Pro		*			*		*	*						
		4B	Glu/Pro/pH/Blo		*				*	*	*						
		4K	Glu/Ket/Pro/pH		*		*			*	*						
		4G	Pro/Glu/Leu/Blo		*				*		*			*			
		4N	Pro/Nit/Blo/Leu						*		*		*	*			
U031-031	3	3P	Glu/pH/Pro		*					*	*						
		3K	Glu/Ket/Pro		*		*				*						
		3G	Glu/Ket/pH		*		*			*							
		3N	Blo/Nit/Leu						*				*	*			
U031-021	2	2G	Glu/Pro		*						*						
		2K	Glu/Ket		*		*										
		2N	Nit/Leu										*	*			
		2B	Blo/Leu						*					*			
		2U	Bil/Uro			*						*					
		2S	SG/pH					*		*							
		2C	Alb/Cre												*	*	
U031-011	1	1B	Blo						*								
		1P	pH							*							
		1G	Glu		*												
		1K	Ket				*										
		1R	Pro								*						

TYPE OF STRIP: 1-10 Parameters – 510(k) Cleared, CLIA Waived and CE Marked for sale in the European Community; 11-13 and 14 Parameters only CE Marked for sale in the European Community

Mission® Urinalysis Strips and Controls

Mission® **Urine Controls**

Accurate

- Use with Mission® and Mission® Expert Urinalysis Reagent Strips and Urine Analyzers for optimum quality control
- Validate urinalysis results and prevent procedure errors

Quick Testing

- Ensures accurate results for all parameters
- Obtain quick results in any setting
- Competitively priced

Two Types of Urine Controls available

- Ready to use without dissolving in distilled water
- 24 months shelf life for unopened controls at 2 - 8 ºC
- Two Packaging Options

Dropper Tip Bottles

– Dropper tip bottles provide efficient use of the control solution
– Easily drop the control solution onto each reagent pad using the dropper tip bottle
– Controls can be used up to 30 days at room temperature
– Controls can be used until the expiration date if kept refrigerated

Diptubes

– Diptube packaging allows for QC testing in a way similar to using a urine specimen
– Simply dip the strip into the control solution and read results, or place on strip tray for analyzer reading
– Controls can be used 30 days at room temperature
– Do not dip more than 20 strips into the tube to avoid inaccurate results
– Controls can be used until the expiration date if kept refrigerated

High Quality Color Chart

Large Choice of Parameter Combinations

Dropper bottles or Dip Tubes

Mission® Urinalysis Strips and Controls

Urine Control Specifications

Features	Specifications	
Product Name	Liquid Urine Control	Liquid Diptube Urine Control
Test Parameters	LEU, NIT, URO, PRO, pH, BLO, SG, KET, BIL, GLU, ASC, ALB, CRE, CA (13)	
Solution Detection Levels	**Level 1**	**Negative:** LEU, NIT, URO, PRO, pH, BLO, SG, KET, BIL, GLU, ASC, ALB, CRE, CA
	Level 2	**Positive:** LEU, NIT, URO, PRO, pH, BLO, SG, KET, BIL, GLU, ALB CRE, CA and Negative ASC
Compatible Urine Strips	Mission® Urinalysis Reagent Strips and Mission® Expert Urinalysis Reagent Strips	
Reading Time/Stability	Refer to insert	Refer to insert
Storage Temperature	2 - 8 ˚C	2 - 8 ˚C
Unopened Control Shelf Life	24 months	24 months
Opened Control Stability	30 days at 15 - 30 °C or until the expiration date at 2 - 8 °C	30 days at 15 - 30 °C or until the expiration date at 2 - 8 °C
Maximum Tests per Unit	20 to 40 tests/bottle	20 tests/diptube

Ordering Information

Product Name	Product Number	Components	Kit Box Dimensions (LxWxH) & Weight	Carton Dimensions (LxWxH) & Weight	# Kits /Carton
Liquid Urine Control	**U021-011**	**Level 1:** 3 x 10 mL /bottle; Level 2: 3 x 10 mL/bottle	85 mm x 55 mm x 60 mm; 107 g	400 mm x 270 mm x 345 mm; 5.2 kg	198
		Level 1: 3 x 5 mL/bottle; Level 2: 3 x 5 mL/bottle	85 mm x 55 mm x 60 mm; 75 g	400 mm x 270 mm x 345 mm; 4.2 kg	198
		Level 1: 1 x 10 mL/bottle; Level 2: 1 x 10 mL/bottle	55 mm x 28 mm x 60 mm; 41 g	400 mm x 270 mm x 345 mm; 6.6 kg	228
		Level 1: 1 x 5 mL/bottle; Level 2: 1 x 5 mL/bottle	55 mm x 28 mm x 60 mm; 31 g	400 mm x 270 mm x 345 mm; 5.5 kg	228
Liquid Diptube Urine Control	**U021-071**	**Level 1:** 2 x 12 mL/diptube; Level 2: 2 x 12 mL/diptube	130 mm x 55 mm x 55 mm; 101 g	385 mm x 255 mm x 320 mm; 4.7 kg	30
		Level 1: 1 x 12 mL/diptube; Level 2: 1 x 12 mL/diptube	130 mm x 55 mm x 55 mm; 62 g	385 mm x 255 mm x 320 mm; 3.5 kg	30

All Urine Controls are 510(k) Cleared, CLIA Waived and CE Marked for sale in the European Community

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Email: info@aconlabs.com

PN 2170004302 • Date 12/17

Liquid Urine Control

Package Insert

REF U021-011	**English**
REF U021-021	
REF U021-031	

For validating visual and analyzer reading of urinalysis.
For in vitro diagnostic use only.

INTENDED USE

The Liquid Urine Control is intended for use in validating the visual and analyzer reading of urinalysis. The results should be compared to the expected results listed below to ensure the consistent performance of *Mission*® and *Mission*® *Expert* Urinalysis Reagent Strips and Urine Analyzers. The Liquid Urine Control is available in two levels and is ready to use for monitoring routine urinalysis.

PRECAUTIONS

- For *in vitro* diagnostic use only. Do not use after the expiration date.
- All materials should be considered potentially hazardous and handled in the same manner as an infectious agent.
- Discard if there is excessive turbidity or evidence of microbial contamination.
- The used materials should be discarded according to local regulations after testing.
- This product is not intended for use as a standard.
- The use of quality control materials is an important part of good laboratory practices. Quality control materials are an objective method of assessing techniques or practices in use.

REAGENTS

The product is a liquid stable control prepared from simulated human urine with added chemicals, constituents of animal origin, preservatives and stabilizers. The control does not include human resource materials. Various pure chemicals are used to adjust each analyte level.

STORAGE AND STABILITY

- Store and ship at 2-8℃ (35-46℉). Do not freeze.
- Controls are stable until the expiration date printed on the bottle label when stored at 2-8℃ (35-46℉).
- All analytes are stable for 20 days at 2-30℃ (35-86℉) once opened and stored with the cap on tightly.

MATERIALS

Materials Provided

- Liquid Urine Control Level 1 and/or Level 2
- Package Insert

Materials Required But Not Provided

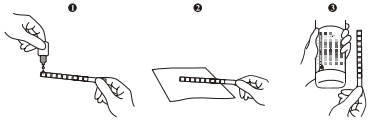
- Strips
- Timer

DIRECTIONS FOR USE

Allow all test materials to reach room temperature (15-30°C) prior to testing.

1. Invert the urine control bottle 3 times to ensure reproducible results, then remove the cap. While holding the urinalysis reagent strip, invert the urine control bottle and gently squeeze the urine control bottle to dispense the urine control. Ensure each reagent area on urinalysis reagent strip is completely saturated with urine control. See illustration 1 below.
   Note:
   - Do not touch the tip of the urine control bottle to the reagent areas on the urinalysis reagent strip to avoid contamination.
   - Dispense the remaining hanging drop of urine control before turning the urine control bottle upright.

   Dispose of the hanging drop of urine control to avoid contaminating the unused control with reagents from the urinalysis reagent strip.
2. Hold the strip in a horizontal position and bring the edge of the strip into contact with an absorbent material (e.g. a paper towel) to avoid mixing chemicals from adjacent reagent areas and/or soiling hands with the urine control. See illustration 2 below.
3. Compare the reagent areas to the corresponding color blocks on the canister label at the specified times. Hold the strip close to the color blocks and match carefully. See illustration 3 below.
   Note:
   - Results may be read up to 2 minutes after the specified times.
   - Results may also be read using the *Mission*® and *Mission*® *Expert* Urine Analyzers. Refer to the Instruction Manual for details.
4. Clean the dropper tip, and immediately replace the cap tightly.



EXPECTED VALUES

The expected values listed on the following page should only be used for the specific lots printed. Expected values were obtained from replicate analysis. The urine control and urinalysis reagent strip lots can create slight differences in expected results. Different laboratory methods, instruments and reagents can create variations between laboratories and variations over time. Use the results provided as reference only. It is recommended that each laboratory establish its own parameters of precision.
Note: The color reactions of Urobilinogen and Bilirubin reagent areas on the urinalysis reagent strips may produce colors that are atypical when visually compared to the color blocks on the color chart.

LIMITATIONS

The *Mission*® Liquid Urine Control can only be used with *Mission*® and *Mission*® *Expert* Urinalysis Reagent Strips and Urine Analyzers. Ensure reproducible results by inverting the urine control bottle 3 times before each use. Interpretation of visual results depends on several factors: the variability of color perception, the presence or absence of inhibitory factors, and the lighting conditions when the strip is read. Each color block on the color chart does not correspond to a specific concentration, but it does correspond to a range of analyte concentrations.

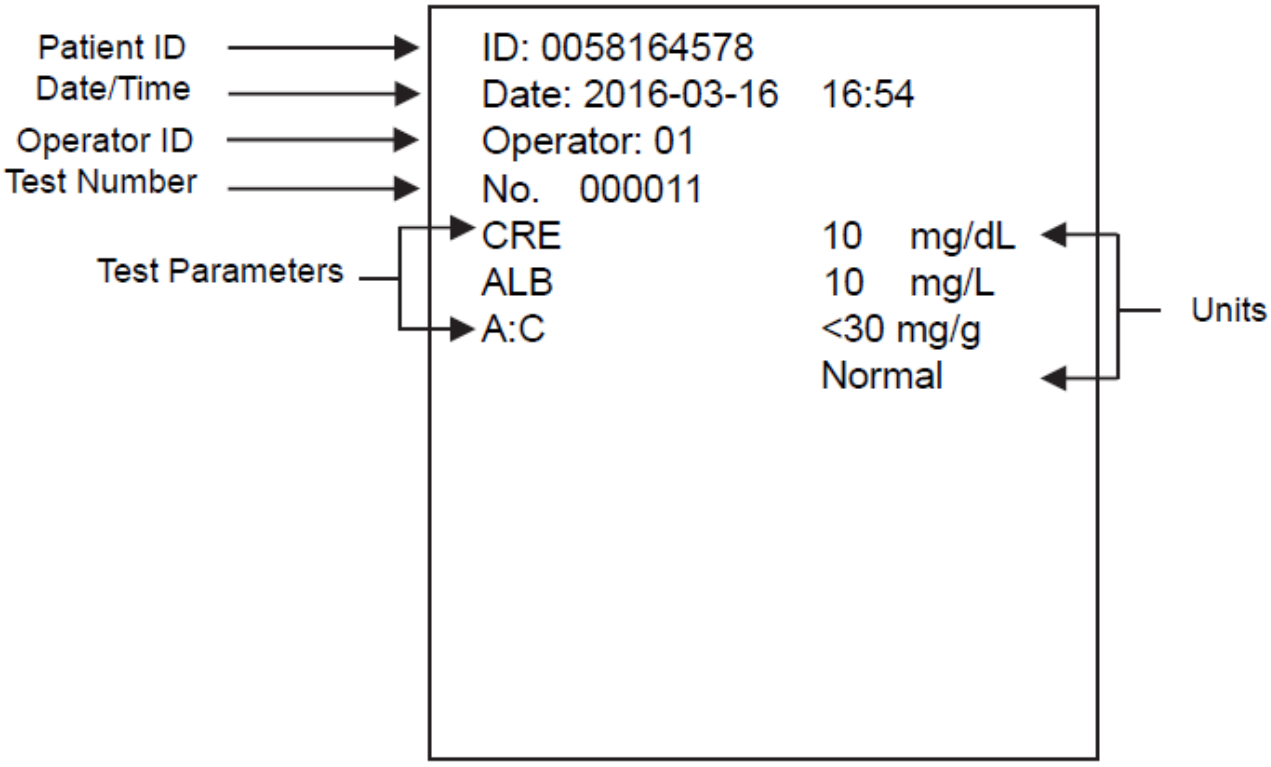
Index of Symbols

	Attention, see instructions for use	Σ	Tests per kit		Manufacturer
IVD	For *in vitro* diagnostic use only		Use by	EC REP	Authorized Representative
8°C / 2°C	Store between 2-8°C	LOT	Lot Number	REF	Catalog #

***ACON* Laboratories, Inc.**
10125 Mesa Rim Road,
San Diego, CA 92121, USA

EC REP
MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

Number: 1150529002
Effective date: 2010-xx-xx


Patient ID
Date/Time
Operator ID
Test Number
Test Parameters
ID: 0058164578
Date: 2016-03-16 16:54
Operator: 01
No. 000011
CRE 10 mg/dL
ALB 10 mg/L
A:C <30 mg/g
Normal
Units

ACON Laboratories, Inc.
10125 Mesa Rim Road. · San Diego, CA 92121 · USA
Tel: (858) 875-8000 · Fax: (858) 875-8099 · E-mail: info@aconlabs.com

November 11th 2016

CERTIFICATION LETTER

This letter is to certify that, Vitalie Goreacii, employed by Sanmedico SRL located at: Republic of Moldova, city Chisinau, str. Petricani 88/1 of. 10, MD-2059, have received all required training and is enabled and authorized to provide services with installation, commissioning, and maintenance to the products listed below:

Mission® U120 Urine Analyzer
Mission® U120 Ultra Urine Analyzer
Mission® U500 Urine Analyzer
Mission® PT/INR Coagulation Monitoring System
Mission® Cholesterol Monitoring System
Mission® Ultra Cholesterol Monitoring System
Mission® HB Hemoglobin Testing System
Mission® Plus HB Hemoglobin Testing System
OnCall® Glucose Meter

For further questions or inquiries regarding this matter, please refer to the contact information below.

Sincerely

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Certificate of Completion

Presented to

Ms. POHILCO Irina

for successfully completing the training course on operating and setting up the Mission U500 and Mission U500 Expert Urine Analyzers

Certified Trainer: Catherine Lemercier Catherine Lemercier

Dated: March 14, 2024 03/14/2024

aconlabs.com

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