Table of Contents

Section 1 Introduction

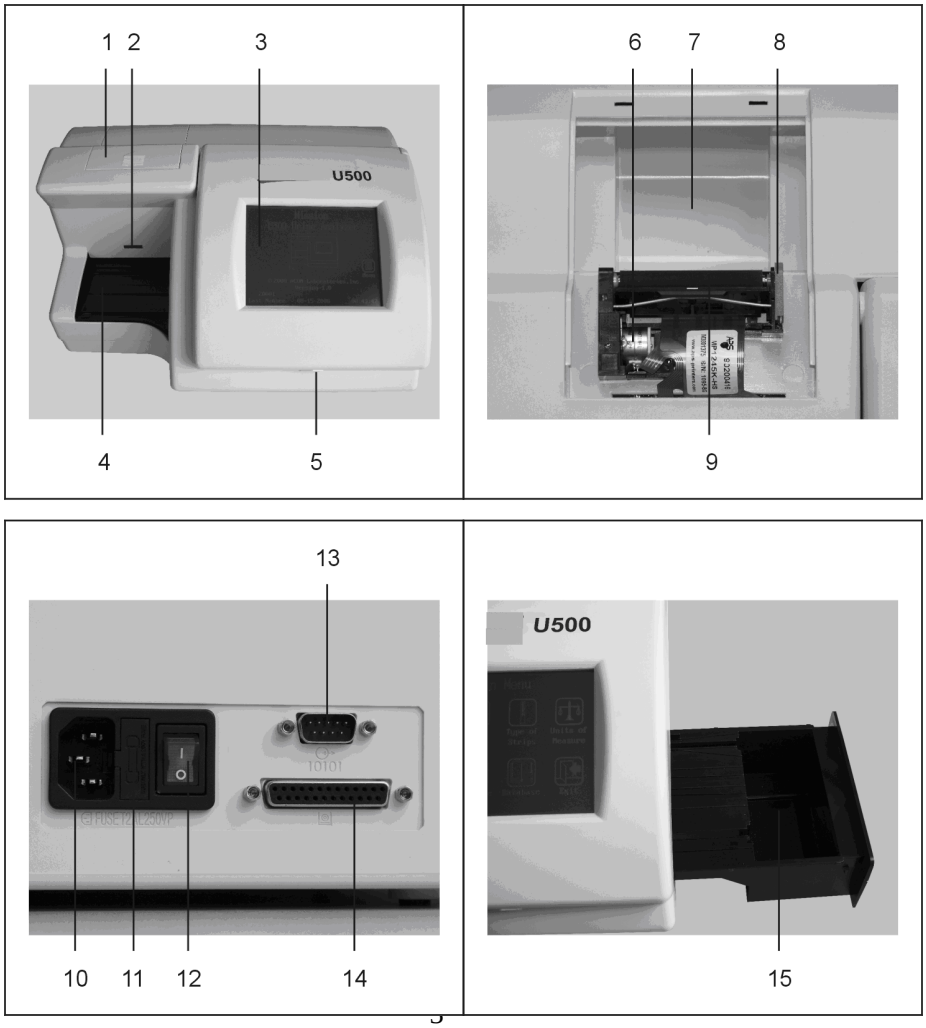
The *Intermedical*® U500 Urine Analyzer is a semi-automated reflectance photometer that analyzes the intensity and color of light reflected from the reagent areas of a urinalysis reagent strip. The analyzer throughput is 500 tests per hour and the measuring cycle is 7 seconds per test. The analyzer stores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

The *Intermedical*® U500 Urine Analyzer features automatic calibration, self-test capability and 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 allow for one step easy cleaning. An optional barcode reader records patient identification (ID). Records can be transferred to a computer for further analysis. The simple user-friendly software is designed to minimize user training and maximize analyzer functionality.

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

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. Strip Platform and Waste Tray



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 consists of the following components.

Component List

No.	Components	Quantity
1	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 80 x 50 cm on all sides of the analyzer for access.

Load Printer Paper

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

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.

Enable External Data TransIntermedical (Optional)

Plug a compatible RS232C cable from a computer to the **RS232C 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 must manually export each record one at a time.

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 3 Barcode Reader for specifications and compatibilities.

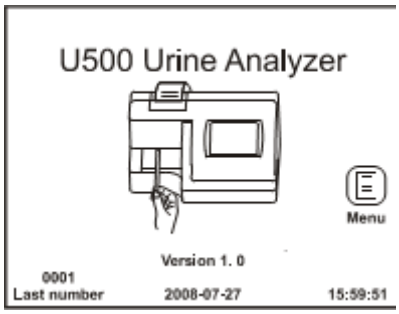
If both the optional **Barcode Reader** and external data transIntermedical capability are used at the same time, use the serial splitter cable to connect both external computer and barcode reader to the analyzer **RS232C connector**.

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.



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.

Section 4 Analyzer Setup

Touch Screen LCD Navigation

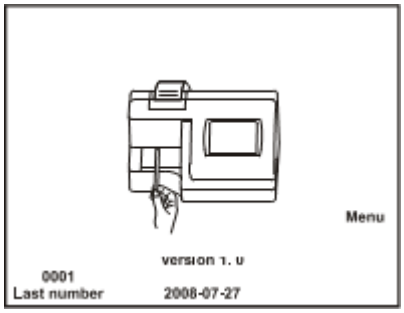
All analyzer configuration is performed by using the LCD touch screen. Selected icons shown below and text can be pressed with the finger to change settings or to enter or exit screens. If the analyzer does not respond, press the symbol or text for a slightly longer time or with slightly higher pressure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

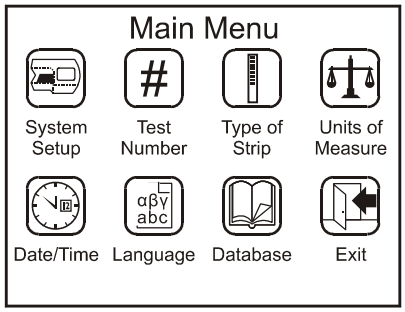
Symbol	Name	Description
	Main Menu	Navigates to the Main Menu from other screens
	Checkmark	Saves new selections and returns to the previous screen
	Cancel	Cancels any changes made and returns to the previous screen
	Clear	Clears incorrect numbers, cancels and returns to the previous screen on keypad screen
	Enter	Saves the new selection and returns to the previous screen on keypad screen
	Exit	Returns to the previous screen
	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)

Main Menu

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

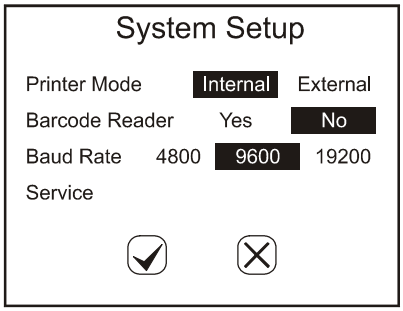


To display the Main Menu screen below, press the icon. The Main Menu screen provides the analyzer setup options to customize the analyzer to operations at a particular testing site.



System Setup

Press to display the system setup option screen used to configure the **Printer**, **Barcode Reader** and communication options.



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.

Printer Mode

Press ***Printer Mode*** to cycle the printer mode through the Internal and External settings. The selected mode will be highlighted.

Internal setting will print all test printouts to the Internal Printer.

External setting will print all test printouts to the External Printer if it is available.

Barcode Reader

Press ***Barcode Reader*** to highlight ***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 ***Barcode Reader*** to highlight ***No***.

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 ***Baud Rate*** to cycle the highlighted baud rate through the options. Select the desired baud rate and leave it highlighted.

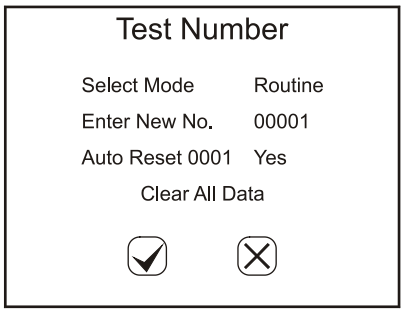
Service

Press ***Service*** to show the ***Password*** entry screen. Enter the 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. Contact your local distributor for the Service password if needed.

Test Number

Press under ⓝ to display the menu below for configuring 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.



Select Mode

Press ***Select Mode*** to cycle the selection 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***.

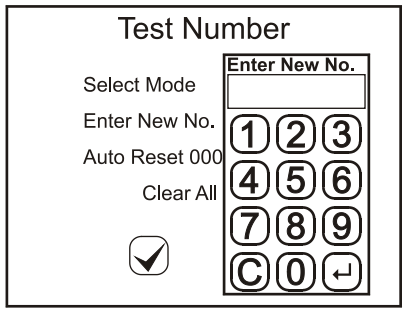
QC Test

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.

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.

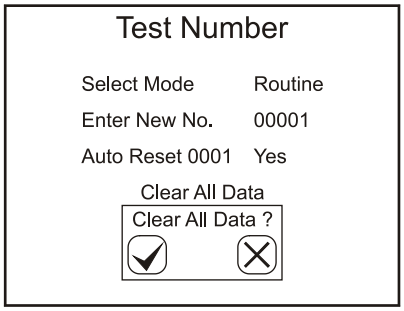
Warning: Maximum number of test results is 2000. After 2000 test results are stored in memory, new test results will begin overwriting (erasing) the oldest test results stored in memory.

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.

Clear All Data

Press ***Clear All Data*** to show a confirmation screen confirming you want to clear all patient and sample result data.



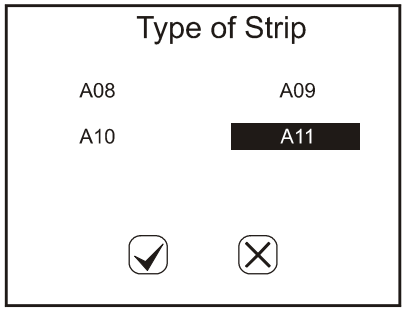
Press ☑ to continue to delete all data. After deleting data, the Test Number will reset to 00001, 10001 or 20001 depending on the Test Mode. Press ☒ to return to the ***Test Number*** screen without deleting data.

Type of Strip

From the ***Main Menu***, press i to change the strip type. The ***Type of Strip*** currently selected will be shown highlighted on the screen. Each strip type name defines the number of test parameters per strip, e.g. A08 is an 8 parameter strip.

Refer to Appendix 2 for a detailed list of parameters.

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.

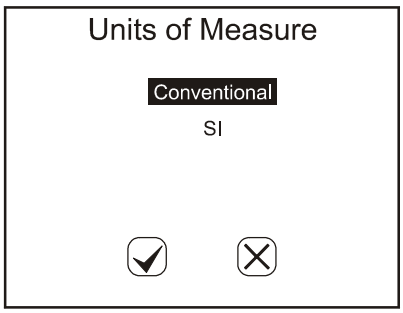


Press the type of stip you will be using for testing, highlighting the proper strip type. Once the proper strip type is selected, press ☑ to accept the change and return to the ***Main Menu*** screen. Press ☒ to return to the ***Main Menu*** screen without changing strip type.

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.

Note: Arbitrary results will be printed automatically regardless of the unit setting selected.



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

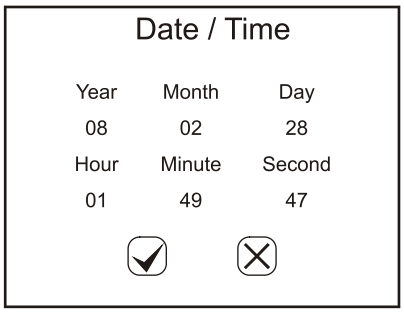
Date/Time

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

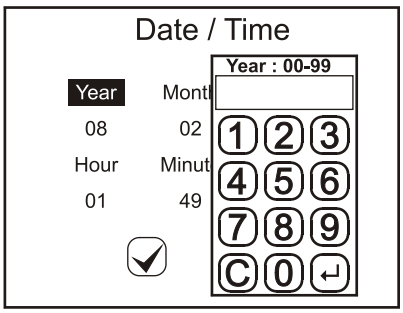
To change any of the Date or Time settings, press the appropriate display area, either the name or associated number. This will bring up the numeric keypad for entering the

proper Year, Month, etc. with the corresponding range of numeric input.

Note: If the number entered is out of its corresponding 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.

When all entries are complete, press ☑ to accept the changes and return to the ***Main Menu*** or press ☒ to return to the ***Main Menu*** without any changes.

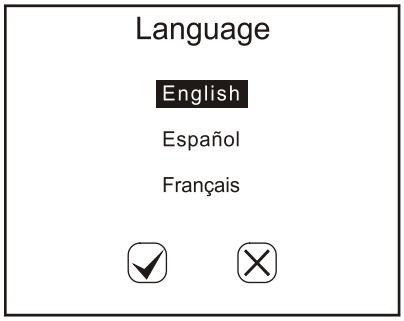
Language

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

Press the text areas to select the proper language.

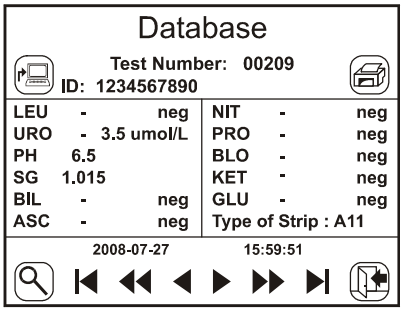
Note: Languages other than those shown here may be installed. Select the correct language from the options shown on the screen.

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.



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.

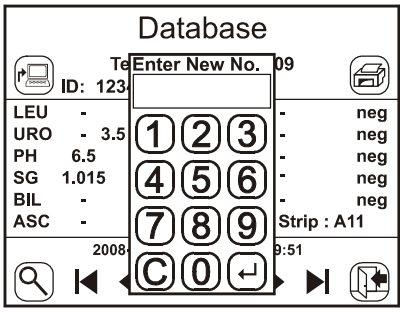
Press |◀ to view the first record.

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 numeric keypad.



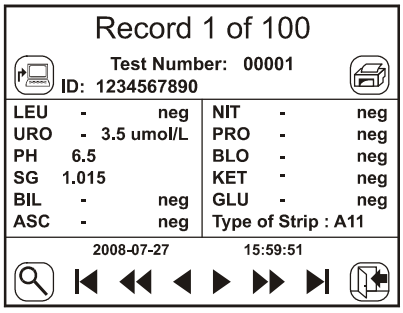
Enter the test ID by touching the ***Numeric Pads*** on the touchscreen. Press C to Clear the last number entered. Press ↵ to accept the number entered and return to the ***Database*** screen. The analyzer will pause briefly as it searches for the correct test record, displaying the record when it is 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.

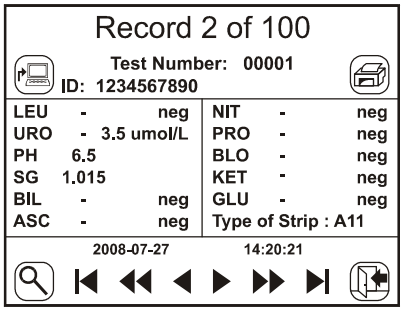
Other adjacent test records can be found by pressing the appropriate arrow keys, moving forward or backward in the stored test data records.

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.

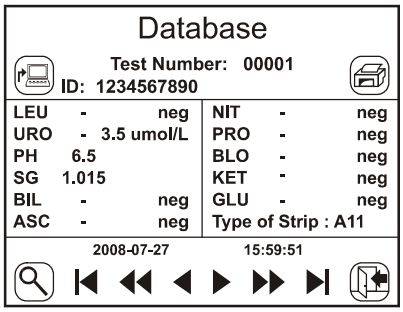
Example: If there are 100 records with a test number of 00001 in the database, enter 00001 with the search keypad to show the first found record, ***Record 1 of 100*** will be shown below.



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 below, 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***.

Memory

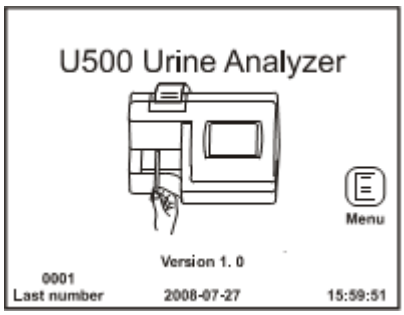
Up to 2000 test records are automatically stored in memory. After 2000 test records are stored in memory, the oldest test record will be erased (overwritten). For example, if 2000 records are stored in the database, the next test record (2001) will replace the first test record stored in memory.

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.

Section 5 Analyzer Operation

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.



Sample/Strip Preparation

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

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

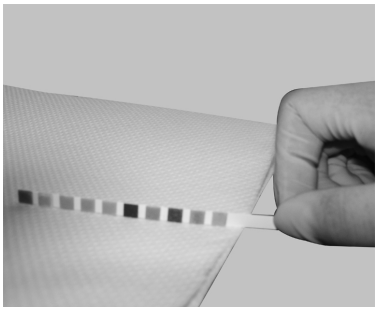
Remove the strips from the closed canister and use them as soon as possible. Close the canister tightly immediately after removing the strips.

Strip Processing and Test

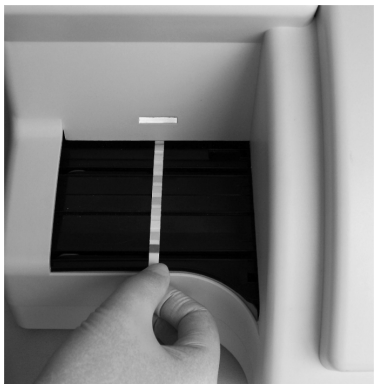
Using a new strip, completely immerse the reagent areas of the strip in fresh, well-mixed urine for about 2 seconds. Immediately remove the strip to avoid dissolving the reagents.

Note: Immerse all strip pads completely into sample, or a ***Dry 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.

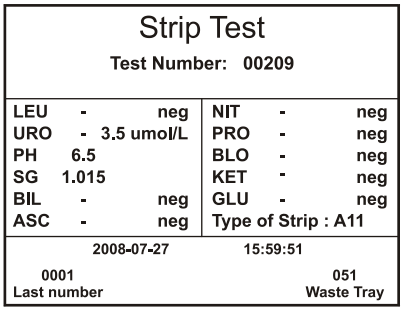
The analyzer performs an automatic calibration each time a test is run. Results will be displayed on the screen and recorded in memory automatically. Any abnormal results will be highlighted on the screen and flagged on the print out.

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

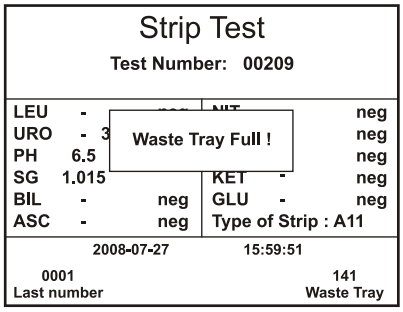
Platform.

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.

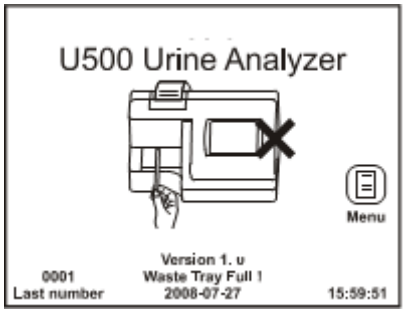
Located in the lower left corner of the ***Strip Test*** screen, the last assigned test number is displayed.



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.

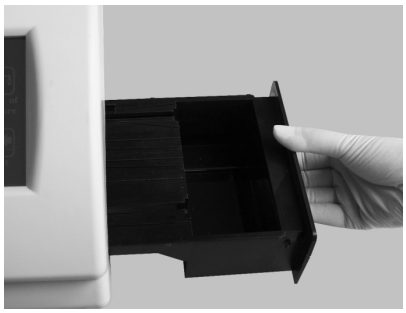


The analyzer will process the remaining strips on the **Strip Platform**, but will process no additional strips until the **Waste Tray** is emptied. Once the final strips are processed, a blinking ***Waste Tray Full*** message on the ***Initial Screen*** along with a large ***X*** over the ***Waste Tray***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



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

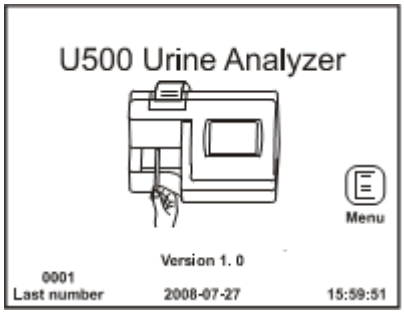
Caution: Do not remove the **Waste Tray** when the analyzer is processing strips. The strip transport mechanism could be damaged if it attempts to move strips with the **Waste Tray** partially removed.



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

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.

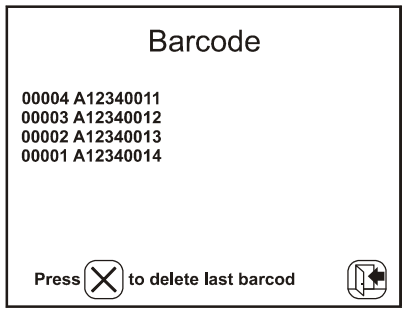


Sample/Strip Preparation

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

Scan 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. The barcode entry screen will be shown, displaying the scanned barcodes.



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 at the same time as sample processing, 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**.

New samples can be scanned and processed at any time prior to completion of strips currently being processed.

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

Section 6 Data/Communication

The analyzer is equipped with two connectors for external data tranIntermedical 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**. 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 transIntermedical to an external computer, the analyzer requires an RS232C 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. Contact your local distributor for details.

Section 7 Quality Control

Each lab should develop and use its own standards and procedures for performance. Test known positive and negative specimen controls at each of the following events:

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

- Each new day of testing
- A new canister of strips is opened
- A new operator uses the analyzer
- Test results seem inaccurate

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

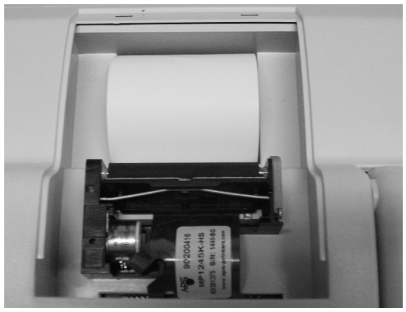
- Ensure the strips used are not past their expiration date.
- Ensure strips are fresh from a new canister.
- Ensure the controls are not past their expiration date.
- Repeat the test to ensure no errors were made during the test.
- If QC testing still does not provide expected results, contact your local distributor.

Section 8 Maintenance

Loading Printer Paper

Pull up on the finger pull area marked **OPEN** 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.

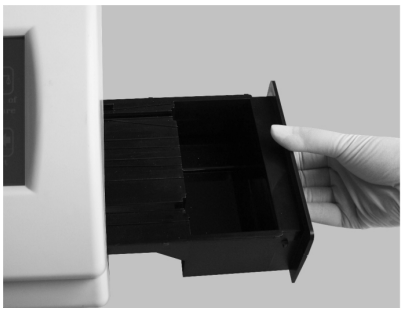


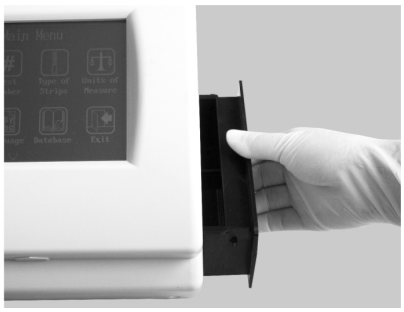
Waste Tray Removal and Cleaning

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.

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.





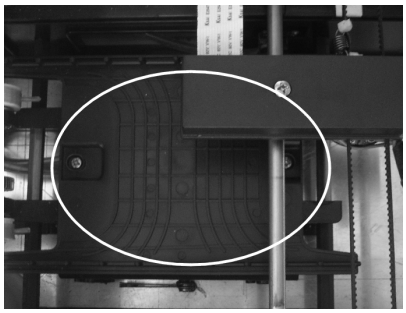
Clean the **Strip Platform and Waste Tray** using a cotton swab or cotton ball dampened with distilled water. Dry with a clean, dry cotton ball. With **Strip Platform and Waste Tray** removed, clean any remaining sample deposits from the strip loading area under the **Strip Platform** using a cotton 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.

Strip Transport Cleaning

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

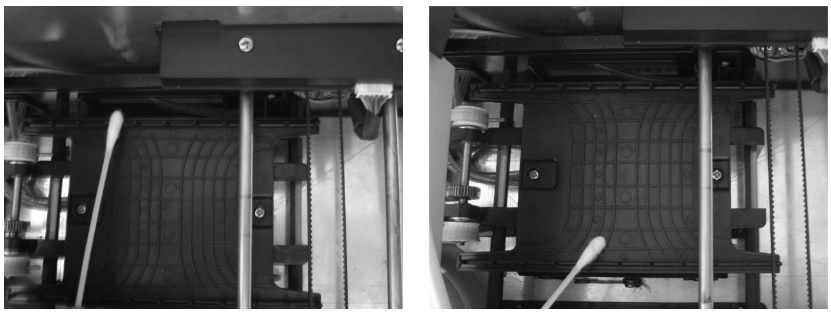
Remove the **Strip Platform and Waste Tray** by pulling the **Waste Tray** out of the right side of the analyzer as shown above.

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 cleaning.

Clean all visible sample deposits with a swab or cotton ball dampened with distilled water. Take care to prevent any fluids from dripping into the analyzer mechanism. Dry with a clean, dry cotton ball.



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.

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.

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:

1. 2% Glutaraldehyde (sufficient density): Refer to detailed instructions on the product label.
2. 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.
3. Isopropyl alcohol (70-80%).

Pour the sterilizing solution into a narrow vessel 10 cm (4 inches) high.

Soak the **Strip Platform and Waste Tray** in the sterilizing solution for 10 minutes.

Take the **Strip Platform and Waste Tray** out, clean and dry it.

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.

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.

Touch Screen LCD Calibration

Turn the analyzer Power Switch off, then on.

Prior to the ***Initial Screen*** being shown, press anywhere on **Touch Screen LCD**. The ***Touch Screen Calibration*** screen will be displayed, shown below.

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

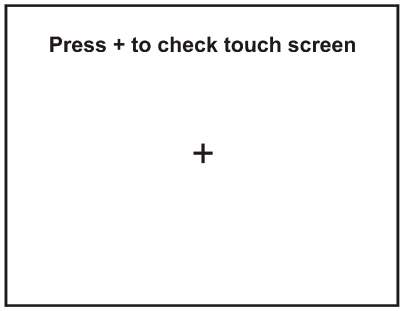
Press the **+** displayed on the center of the screen to begin calibration.

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

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

Repeat this process when the **+** is displayed in the lower left and upper left 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 touchscreen may be improperly calibrated and unable to respond properly to touchscreen 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, corrosive gas, strong electromagnetic interference or vibration. Refer to Urine Analyzer Specifications in Appendix 1 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
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 6, Load Printer Paper. 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 Operating Instructions in Section 5.
Printer Paper Empty Error	Ensure the Printer Paper Roll is installed correctly. Refer to Section 6 Load Printer Paper.
Strip Platform Removal Error	Install the ***Strip Platform and Waste Tray*** into the analyzer completely, flush with outside housing wall. Refer to Waste Tray Removal, Cleaning and Emptying in Section 8.

Waste Tray Full Error	Remove used strips from the ***Waste Tray***. Discard used strips according to local regulations. Refer to Section 8.Waste Tray Removal, Cleaning and Emptying.
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.

Contact your local distributor to receive additional technical support if you are unable to resolve the problems.

Appendix 1 Urine Analyzer Specifications

Feature	Specifications
Methodology	Reflectance Photometer
Detection	Photosensitive Diode
Throughput	500 tests/hour
Measuring Cycle	7 seconds/test
Memory	3,000 Results
Strip Incubation Time	1 minute
Wavelength	525 nm and 635 nm
Waste Disposal Capacity	Up to 150 Strips
Data Transfer	Standard RS232C connector (cable optional)
Capabilities	Internal thermal Printer (included) 25 Pin External Printer Connector (included) External Printer (optional) Barcode Reader (optional)
Calibration	Automatic
Available Languages on Screen	English, Spanish, French(others as installed)
Meter Operating Conditions	0-40ºC (32-104ºF); ≤85% Relative Humidity (non-condensing)
Strip Operating Conditions	15-30ºC (59-86ºF); ≤75% Relative Humidity (non-condensing)
Power Source	100-240 V AC, 50-60 Hz
Dimensions (L x W x H)	35.5 cm × 27.4 cm × 19.5 cm (14.4” x 10.8” x 7.7”)
Display Dimensions (L x W)	11.5 cm × 9.0 cm (4.5” x 3.5”)
Weight	4.0 kg (8.82 lbs)

This product complies with EN 61326.

Appendix 2 Compatible Urinalysis Reagent Strips

No. of Parameters	Strip Code on Analyzer	Analytes
8	A08	Leukocytes, Nitrite, Protein, pH, Blood, Specific Gravity, Ketone and Glucose
9	A09	Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin and Glucose
10	A10	Leukocytes, Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin and Glucose
11	A11	Leukocytes, Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose and Ascorbic Acid

Note:

- Ensure that the type of strip selected corresponds with the strip to be used. If not, it will be detected and display an error.
- Only use strips of the same brand as the analyzer for proper function and accurate results.
- **Above configurations shown for 8 through 11 parameters as available options. Other compatible strip configurations are available with between 1 and 11 parameters from the table below, as defined in the analyzer selectable strip configuration settings.**

Performance Characteristics of Urinalysis Reagent Strips

The performance characteristics of the *Intermedical*® 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 – 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).
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); cumene hydroperoxide; 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).
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).
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).

Clinical Comparison Study

The performance of the *Intermedical*® U500 Urine Analyzer in combination with the use of *Intermedical*® Urinalysis Reagent Strips was compared to a predicate, commercially marketed urine analyzer in a clinical study. Results are presented in the table below:

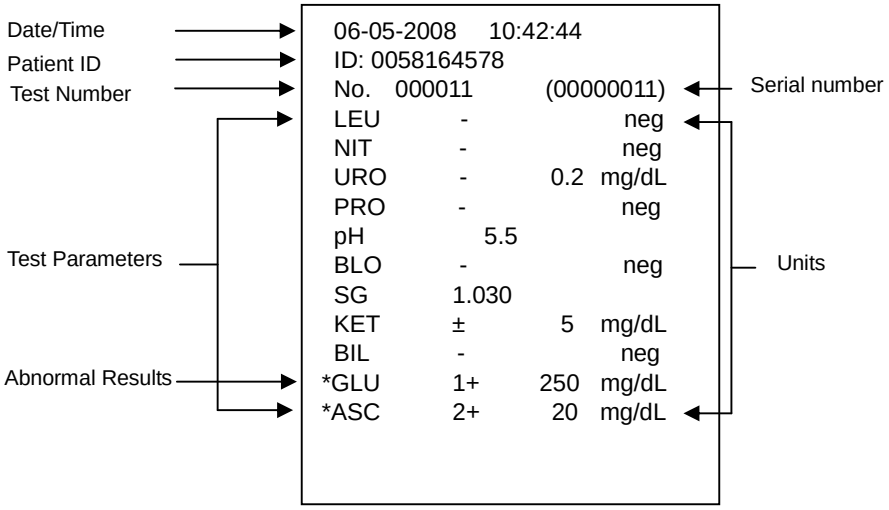
Analyte	**% Agreement within ± 1 Color Block (95% C.I.*)**
Leukocytes	98.4% (95% - 99%)
Nitrite	>99% (97% - 100%)
Urobilinogen	>99% (97% - 100%)
Protein	93.8% (88% - 97%)
pH	84.5% (77% - 90%)
Blood	96.9% (92% - 99%)
Specific Gravity	86.8% (80% - 92%)
Ketone	>99% (97% -100%)
Bilirubin	93.8% (88% - 97%)
Glucose	99.2% (96% - 99%)

* C.I.: Confidence Interval

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)	- +	N/A	N/A
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
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
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

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 and Specific Gravity (SG) will be reported as 1+, 2+, or 3+.
- Positive results for pH and Specific Gravity (SG) 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) will be reported as "neg." Negative results of Urobilinogen (URO) will be reported with the respective data in front of the units.

Appendix 5 Barcode Reader

The *Intermedical*® U500 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: Up to 25 digits can be read for each barcode.

Appendix 6 Catalog

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

Appendix 7 Index of Symbols

	Attention, see instructions for use		Manufacturer		Authorized Representative
	For In vitro diagnostic use only		Lot Number	REF	Catalog #
	Store between 0-40°C		Tests per kit	SN	Serial number
	Keep away from sunlight and heat		Use by		Serial port
	Keep dry		Fragile, handle with care		This side up
FUSE T2AL250VP	Fuse type		25 Pin Parallel External Printer Port		Power Socket
	Grounding		Biohazard		

Appendix 8 Warranty

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

INTERMEDICAL Laboratories, Inc. 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, *INTERMEDICAL* 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. *INTERMEDICAL* 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 *INTERMEDICAL* 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 *INTERMEDICAL*. Furthermore, *INTERMEDICAL* assumes no liability from malfunction or damage to analyzers caused by the use of strips other than strips manufactured by *INTERMEDICAL*. *INTERMEDICAL* 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 *INTERMEDICAL*.

Limitations of Liability

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

For warranty service, please contact your local distributor.

***Intermedical*® 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