
CLIAwaived™ Inc.

Automated Urinalysis Test System Quick Start Guide



Please refer to the User Manual for more detailed user information and protocols.

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**FDA 510(k) Cleared
CLIA Waived**

For *in-vitro* diagnostic use only

Quick Start Guide

Place the analyzer on a level surface. Allow 80 x 50 cm on all sides of the analyzer for access.

Plug the power cord into a power outlet, then press the power switch located on the back panel of the analyzer to turn the system on. The analyzer will run a self-test. With no strip holder installed, the self test will fail, indicating "Optical Sensor Failed." The Strip Holder Mount will be extended. Turn the analyzer power off.

Install Printer Paper

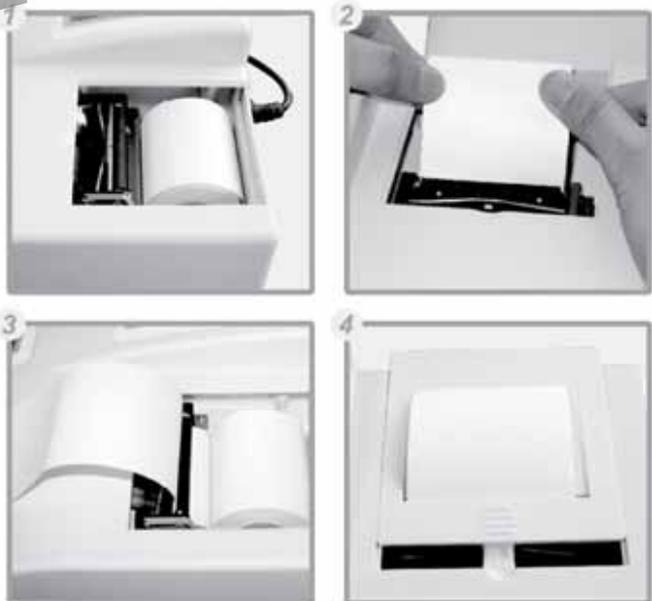
Pull up on the finger pull area marked  to open the **Printer Cover**. Place the paper roll in the printer box. The paper comes from the bottom of the roll up into the printer.

A green **Paper Release Lever** is located near the Printer Roller. Press the back end of the Paper Release Lever toward the front of the analyzer to release the pressure on the **Printer Roller**. Feed the paper under the Printer Roller until the end shows above the roller.

Pull the paper up. Leave 10 cm (4 inches) of extra paper above the Printer Roller.

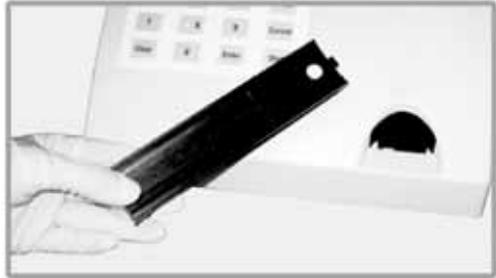
Press the front end of the green Paper Release Lever down to lock the Printer Roller. Thread the excess paper through the **Printer Paper Access Slot** in the Printer Cover.

Return the **Printer Cover** to its original closed position.



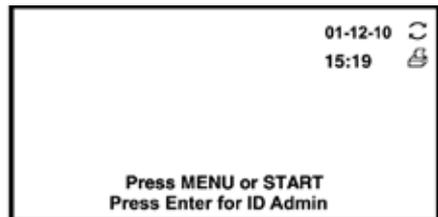
Install Strip Holder

Remove the plastic packaging from the provided Strip Holder. Place the Strip Holder on the Strip Holder Mount with the white calibration circle positioned toward the analyzer so that it slides loosely in the locating channel. Push the Strip Holder in toward the analyzer until it snaps into place and is held firmly on the Strip Holder Mount.



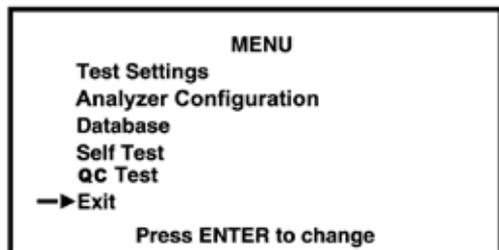
Power Up Analyzer

Turn the Power Switch on. The Self-Test will be run again with the Strip Holder Mount retracted. The Initial Screen will be displayed. Press **MENU** to show the Menu screen to configure the analyzer.



Configure Analyzer

Select options by pressing ▲ or ▼ until the Selection Arrow (→) is next to the option. Press **ENTER** to show the options in a new screen or cycle through the settings as listed below. Select **Exit** and press **ENTER** to return to the Initial Screen.



Select Type of Strip

Select **Type of Strip** and press **ENTER** to change the strip type. Each strip type defines the number of test parameters per strip, in this case 10 parameters. Each press of the **ENTER** key cycles through all options. Press **ENTER** until **Type of Strip** matches the strips to be used.

Test Settings		↻
Type of Strip	10 SG	🖨️
Mode	STAT	
Test Number	100001	
Continuous Test	On	
Operator	01	
Units	SI	
→ Exit Press ENTER to change		

Select Mode

Select **Mode** and press **ENTER** to change the mode to **Normal**.

Select Continuous Test Mode

Select **Continuous Test** and press **ENTER** until **Off** is displayed for **Single Test**.

Select Units

Select **Units** and press **ENTER** to select either **Conventional** or **SI** units. Select **Exit** and press **ENTER**. Select **Analyzer Configuration** and press **ENTER**.

Analyzer Configuration		↻
Printer Setup		🖨️
Sound :	On	
Barcode reader :	No	
Language :	English	
Date/Time		
Auto Number Reset	Yes	
→ Exit Press ENTER to change		

Select Date/Time

Select **Date/Time** to show the Date/Time menu. Selecting **Date Format** and **Time Format**, then pressing **ENTER** will cycle these selections through the available options. Select the proper format.

Date/Time	07-15-08 11:04 am
Date Format:	MM - DD -YY
Time Format:	12 Hour
Set Date and Time	
→ Exit	
Press ENTER to change	

Select **Set Date/Time** and press **ENTER**. Follow on-screen directions to set the current date and time. Press **ENTER** to accept the changes and exit the screen. Press **ENTER** again to exit the Date/Time menu.

Date/Time	07-15-08 11:04 am
▲ ▼ to change	◀ ▶ to move
Press ENTER to accept CANCEL to exit	

Set Language

Select Language and press Enter to cycle through the available display languages, leaving the selection on the chosen language.

Analyzer Configuration		⌂
Printer Setup		⌂
Sound :	On	
Barcode reader :	No	
Language :	English	
Date/Time		
Auto Number Reset	Yes	
→ Exit	Press ENTER to change	

Barcode Reader (Optional)

If no Barcode Reader is present, leave this selection at No. If Barcode Reader is present, set this setting to Yes. Refer to the detailed instructions for installing and configuring this option in the User Manual.

Sound

Select **Sound** and press **ENTER** to cycle through the audio options. Leave this setting at **On** for all audio prompts and indications.

Printer Setup

Select **Printer Setup** and press **ENTER** to show the Printer Setup screen. Select the **Printer Select** and press **ENTER** to cycle through **Internal** or **External** options. Leave at **Internal** to use the internal printer.

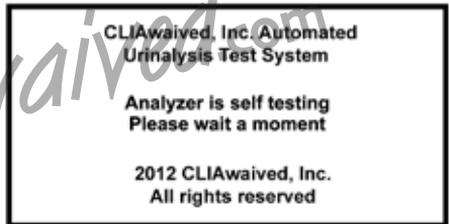
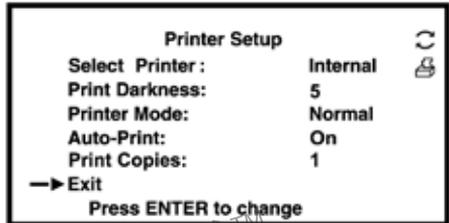
Select **Auto-Print** and press **ENTER** to cycle through Auto-Print **Off** or **On**. Leave at **On** to automatically print all results.

Select **Print Copies** and press **ENTER** to select the number of copies to print, from 1 to 3.

Select **Exit** and press **ENTER** to exit this screen.

Select **Exit** and press **ENTER** to return to the Menu screen.

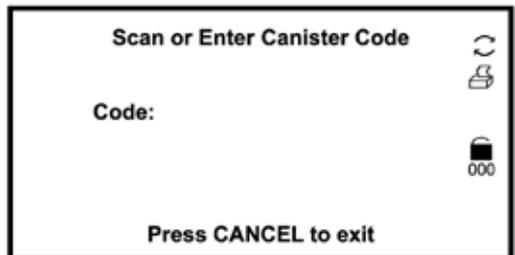
This completes the analyzer setup functions. Select **Exit** and press **ENTER** to return to the Initial Screen.



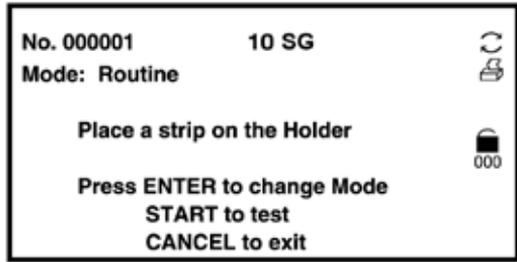
Begin Testing

Press the **START** key to extend the Strip Holder and show the testing menu screen. Scan using a barcode reader or manually enter the canister code from the canister. If the canister code is correct, the analyzer will display the initial screen.

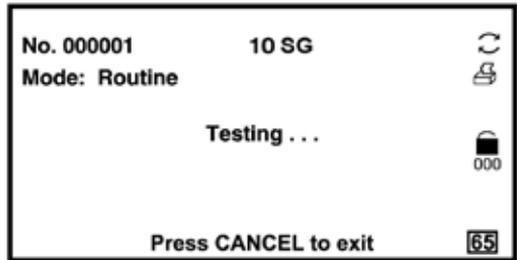
Note: QC and User Lockout functions are available. Refer to the User Manual for details.



Press **START** again to show the testing screen. A timer will show in the lower right of the screen, beginning at **65** seconds. Dip a new strip into the urine sample to be tested. Drain excess sample from the strip and place it on the Strip Holder when the timer reaches **62**.



A triple beep will be heard. The test strip will remain on the strip carrier until it is moved onto the analyzer. The strip pads are read and the results displayed. The Strip Holder returns the strip to the extended position. The strip can then be removed and a new sample analyzed.



Refer to the User Manual for more advanced processing and settings.

Printed Results

Arbitrary units will always be printed. Either Conventional or SI unit results will also be printed, depending on the units setting.

Patient ID	_____	ID: 0058164578	
Date/Time	_____	Date: 2008-07-15 16:54	
Operator ID	_____	Operator: 01	
Test Number	_____	No. 000011	
		LEU - neg	
		NIT - neg	
		URO - 0.2 mg/dL	
		PRO - neg	
		pH 5.5	
Test Parameters		BLO - neg	Units
		SG 1.030	
		KET ± 5 mg/dL	
		BIL - neg	
Abnormal Results		*GLU 1+ 250 mg/dL	

CLIA-waived Information

The CLIAwaived, Inc.™ Automated Urinalysis Test System is CLIA-waived when used with strips of the same brand as the analyzer. Only laboratories with a Certificate of CLIA Waiver may use this analyzer in a waived setting. Users should read this complete test procedure before performing a test using this analyzer. Failure to adhere to these instructions for use and for performing QC testing is considered off-label use. Off-label use is categorized as high complexity and subject to all CLIA regulations.

Service and Support

For technical support or other customer services, please call 1-888-882-7739.

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