CONSULT®

McKESSON

U120 TOUCH URINE ANALYZER
INSTRUCTION MANUAL

MFR #121-120TOUCH. For *in vitro* diagnostic use only.



General Questions? Call 1-800-777-4908
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Section 1 Introduction

The Consult® U120 Touch Urine Analyzer reads urine test strips. It stores results and prints reports without the need for special training.

The Consult U120 Touch Urine Analyzer runs a self-test each time the power switch is turned on. An optional barcode reader records the patient ID. The barcode reader verifies strip canister barcodes. Use only Consult Urine Reagent Strips with the canister barcode for correct results.

The Consult U120 Touch Urine Analyzer 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.

Intended Use
The Consult U120 Touch Urine Analyzer is intended for use in conjunction with the Consult Urine Reagent Strips (Microalbumin/Creatinine) for the semi-quantitative detection of Albumin and Creatinine. The instrument is intended for professional, in vitro diagnostic use only. The measurement are used to assist diagnosis of kidney functions. Positive results should be confirmed with quantitative method.

Consult Liquid Urine Controls and Consult Liquid Diptube Urine Controls are assayed urine controls intended for use in validating the precision of the analyzer's urine readings for Creatinine and Albumin.

Caution: Federal law restricts this device to sale by or on the order of a physician or other practitioner licensed by the law of the State in which he practices, to use or order the use of the device.

Note: Buttons on the Touchscreen are listed in **bold**. Display items on the screen are listed in ***bold italics*** in the manual.

The Consult U120 Touch Urine Analyzer is intended for indoor use.

Section 2 Analyzer Components

2.1 Analyzer Component Illustrations

1. Printer Cover
2. Liquid Crystal Display
3. Printer Roller
4. Printer Paper
5. Printer
6. Strip Holder Channel
7. Strip Holder
8. Strip Holder Stop
9. White Calibration Circle
10. Strip Holder Mount
11. Power Socket
12. Power Switch
13. USB Port
14. LAN Port
15. Standard RS232C Port



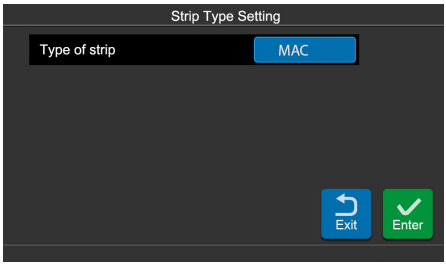
Section 3 Initial Startup

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

Plug the appropriate end of the power cord into the DC socket located on the back of the analyzer. Plug the other end of the power cord into an AC electrical wall outlet. Press the power switch (12) located on the back panel to turn the Consult U120 Touch Urine Analyzer on. The Consult U120 Touch Urine Analyzer will run a Self-Test. The analyzer will display the screen shown below.



Turn the Power Switch on. If the Self-Test passes, the **Strip Type Setting** screen will be shown.



If the type of strip is incorrect, touch the blue area next to ***Type of strip*** to cycle through the strip type options.
Select the ***Type of strip*** you need, and press **Enter** to access the **Main Menu** screen, shown below.
If the type of strip is correct press **Enter** to access the **Initial Screen.**



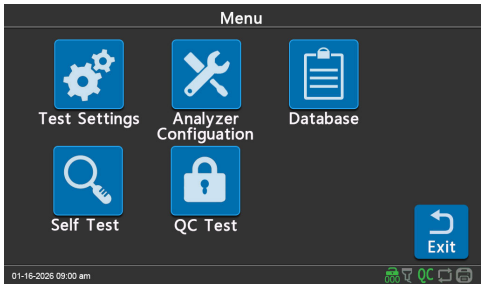
If the Self-Test fails, a ***Failed*** Screen will be displayed. The analyzer cannot be operated. Turn the power switch off, then on to re-test. Refer to **Section 10 Troubleshooting** to correct the failure.

Touch **MENU** to access the Test Settings, Analyzer Configuration, Database functions, Self-Test, QC Test and Help.

Touch **Test** to begin strip testing. Touch ***Operator*** for ***ID Admin*** (ID Administration – where IDs can be assigned to different operators).

Section 4 Analyzer Startup

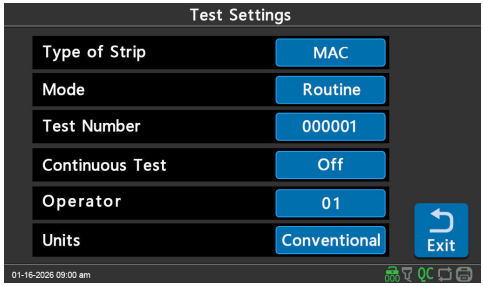
Touch **MENU** from the Initial screen to display the screen below.



Select from the options by touching the desired menu icon. Touch ***Exit*** to return to the Initial Screen.

4.1 Test Settings

Touch Test Settings to display the menu shown below.



Touch the blue area to cycle through the settings' options below. Touch **Exit** to return to the Main Menu.

Type of Strips includes MAC. Refer to Appendix 2 for details.

Type of Strip	MAC
Mode	Routine, QC
Test Number	User selected number
Continuous Test	On, Off (single test) (Function for moderate complexity labs only)
Operator	If User Login is off, Operator ID will be 01 through 10. If User login is on, Operator ID will be 11 through 20, and 100 is reserved for the Administrator (Function for moderate complexity labs only)
Units	Conventional Units

4.1.1 Type of Strip

Touch the blue area to cycle through the strip type options. The strip type defines the number of test parameters. Available strips are MAC (micro-albumin/creatinine). If ***User Login*** is enabled to control operator access, and Operator ID is 11 through 20, this setting cannot be changed. (User Login Function for moderate complexity labs only)
Refer to Appendix 2 for a detailed list of available parameters.

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

4.1.2 Mode

There are two test mode options. Touch the blue area to change the ***Mode.***

Routine Test

Use for normal urine testing. The default test number ranges from 1 to 99999. It resets to 1 every day automatically if ***Auto Number Reset*** is set to ***Yes.***

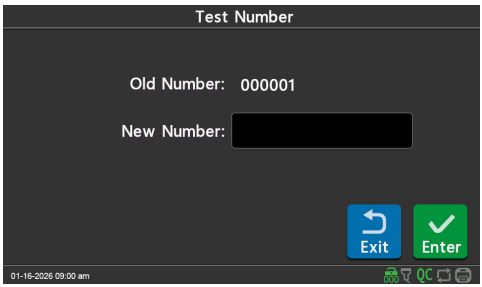
QC Test

Use to test positive/negative controls. If ***QC lockout*** is on, this test will be run automatically. The test number ranges from 200001 to 299999. It resets to 200001 every day automatically if ***Auto Number Reset*** is ***Yes.***

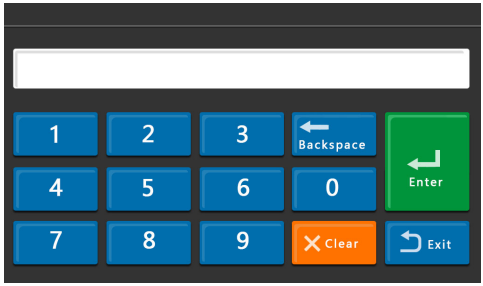
Note: Ensure QC Test mode is used for testing positive and negative controls. Use of any other mode will report the testing results as a regular specimen and will not display proper "Pass/Fail" QC test results.

4.1.3 Test Number

Touch the blue area next to **Test Number** to change the ***Test Number.***



Touch the area next to ***New Number*** to access the input screen below.



Touch **Enter** to save and exit. Touch **Exit** to delete any changes and keep the existing number.
The first digit in the number will depend on the ***Test Mode.*** The first digit will be ***0*** for ***Routine, 2*** for ***QC Test.*** This first digit is fixed and cannot be changed from this screen. Tests run after this number is changed and will be set sequentially from the new number.

Note: Specimens may be assigned the same test number. They will be distinguished by test date and time in the Database.

4.1.4 Continuous Test

(Function for moderate complexity labs only)

Touch the blue area next to ***Continuous Test*** to cycle between **Off** or **On**. When the selection is correct, Touch ***Exit*** to return to the Main Menu.

Continuous Test – Off (Single Test Mode)

Test one strip at a time. Single Test Mode performs 60 tests per hour.

Continuous Test - On (Function for moderate complexity labs only)

Test strips one after another. ***Continuous Test*** Mode performs up to 120 tests per hour. When ***Continuous Test*** is on, the color of symbol will be green.

4.1.5 Operator ID

(Function for moderate complexity labs only)

Touch the blue area next to control operator access, and press **ENTER** to increase the number by one. After ***10,*** it reverts to ***01***. If ***User Login*** is enabled and ***Operator ID*** is 11 through 20, this setting cannot be changed. Select ***EXIT*** and press ***ENTER*** to return to the Main Menu.

4.1.6 Units

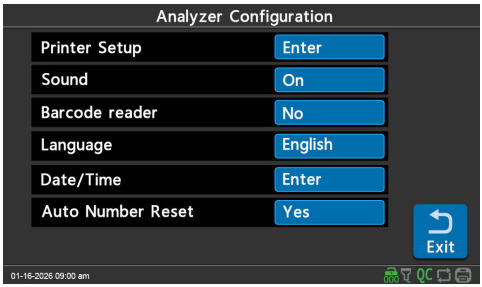
(Function for moderate complexity labs only)

Touch the blue area next to ***Units*** to cycle the units between ***Conventional*** or ***SI*** units. If ***User Login*** is enabled to control operator access, and ***Operator ID***

is 11 through 20, this setting cannot be changed**.** Touch ***Exit*** to return to the ***Main Menu.***
Note: For the US the factory default values are set to Conventional.

4.2 Analyzer Configuration

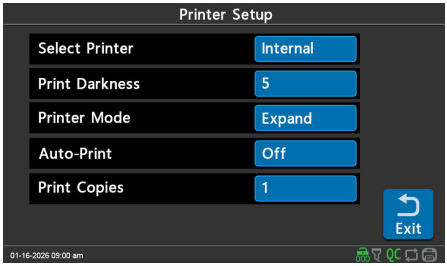
Touch ***Analyzer Configuration*** from the ***Main Menu*** to display the screen below.



Touch the blue area next to the Options to make changes. After all changes are made, Touch ***Exit*** to save changes and return to the ***Main Menu***. If ***User Login*** is enabled and Operator ID is 11 through 20, this Menu cannot be changed.

4.2.1 Printer Setup

Touch the blue area next to ***Printer Setup*** to display the screen below.



Touch the blue area next to the options listed below to cycle through the selection choices.

Select Printer	Internal or External
Print Darkness	1 to 9
Printer Mode	Normal or Expand fonts
Auto-print	On or Off
Print Copies	1 to 3

After all changes are made, touch ***Exit*** to save changes and return to the previous ***Menu.***

Select Printer

Internal prints the results on the internal printer. The  icon will display on the screens.

External prints the results on an external printer. The  icon will display on the screens. Contact your local distributor for a list of printers and printer cables that can be used.

Print Darkness

Print darkness ranges from 1 to 9. The darkest is 9. After 9 it reverts to 1. The default is 5.

Printer Mode

Normal prints the standard font size and saves paper. ***Expand*** prints a larger font size and uses more paper.

Auto-print

Auto-print On prints the results after each test. The print symbol color is **green**. ***Auto-print Off*** requires touching the **Print** button to print the results. The print symbol color is **gray.**

Print Copies

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

4.2.2 Sound

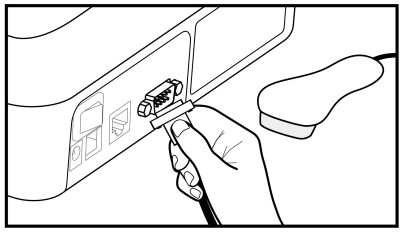
Touch the blue area next to ***Sound*** to cycle the options to ***Off, On*** and ***Prompts.*** These options function as listed below.

Off – internal speaker is ***Off*** in all cases.
On – Internal speaker is ***On*** in all cases (Buttons and prompts).
Prompts – Internal speaker is ***On*** only for prompts to the operator.

Touch **Exit** to save changes. The screen will return to the **Main Menu.**

4.2.3 Barcode reader

Touch the blue area next to ***Barcode reader*** to cycle between ***Yes*** or ***No.*** Yes displays prompt for full usage of the Barcode reader. The color of Barcode reader icon  is green. If ***Yes*** is selected, plug in the barcode reader (as illustrated in the picture below) and the unit is ready for the operator to begin scanning barcodes.



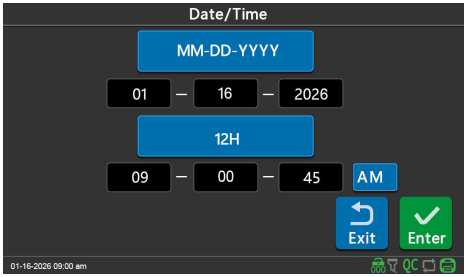
If the optional Barcode reader is not present the color of Barcode reader icon is gray, this setting should be set to ***No.***
Touch **Exit** to save changes. The screen will return to the ***Main Menu.***

4.2.4 Language

(Default language is set to English)
Select ***Language*** *(This function is for moderate complexity CLIA designation labs only)*
Touch the blue area next to ***Language*** to cycle through the language options. Each time the blue area is touched the language changes.
Touch Exit to save changes. The screen will return to the ***Main Menu.***

4.2.5 Date/Time

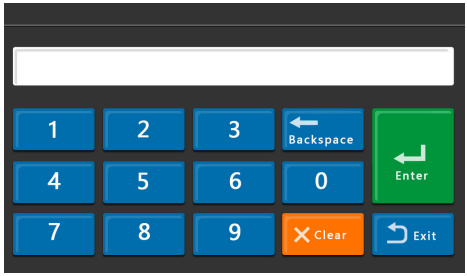
Touch the blue area next to ***Date/Time*** to display the screen to change the date/time as shown below.



Touch date format in the blue area to cycle date format to ***MM-DD-YYYY, YYYY-MM-DD*** or ***DD-MM-YYYY.***

Touch time format in the blue area to cycle between ***24H*** or ***12H. 12H*** displays the time with ***AM/PM*** symbols.

Touch ***the area with the numbers*** to enter the input screen below.



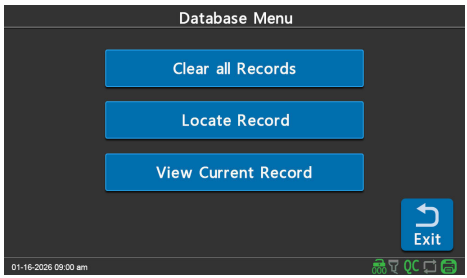
Touch **Enter** to save and Exit, Touch **Exit** to Exit to previous screen without change.
Touch **AM** or **PM** in the blue area to circle between **AM** or **PM**.
Touch Enter to save the changes and **Exit** the screen. Touch **Exit** to not accept any changes and exit the screen.

4.2.6 Auto Number Reset

Touch the blue area next to ***Auto Number Reset*** to cycle between ***Yes*** or ***No.*** If Yes, the test number will reset to 000001 or 200001 for Routine or QC modes each day. If ***No***, the test number is unaffected by date.

4.3 Database

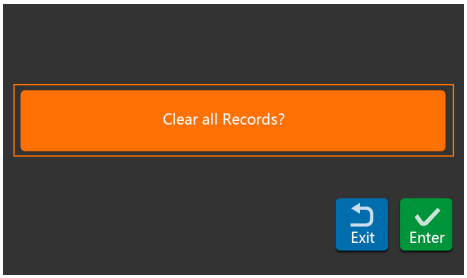
Touch ***Database*** to display the screen below.



Select by touching the blue areas to enter each screen and locate a record.
Up to 2000 records can be stored in memory. If **User Login** is enabled and ***Operator ID*** is 11 through 20, the operator can only review data stored in the analyzer. (The User Login function is for moderate complexity CLIA labs only.)
Caution: Use a number higher than the previous test number.
If there are 2000 records stored in memory, the next test result will erase and replace the oldest record.
Records may have the same number but different dates and times.

4.3.1 Clear All Records

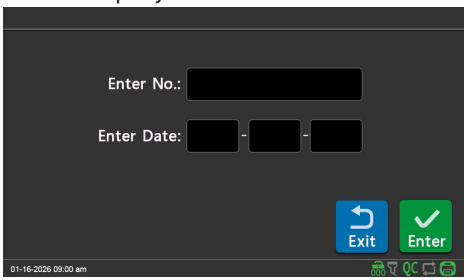
(The User Login function is for moderate complexity CLIA labs only.) Touch ***Clear all Records*** to display the screen below. If User Login is enabled and ***Operator ID*** is 11 through 20, the analyzer will not respond.



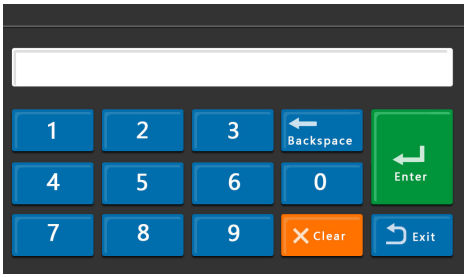
Touch **Enter** to delete all records. A prompt will appear. **Once records are deleted, they cannot be recovered**. The **Test Number** will reset to 000001 or 200001 depending on the Test Mode. Touch **Exit** to return to the previous screen.

4.3.2 Locate Record

Touch ***Locate Record*** to display the screen below.



Touch the ***text box areas*** to enter the input screen below.



Enter the ***Test Number*** and/or ***Date***. Touch **Enter** to view the results.

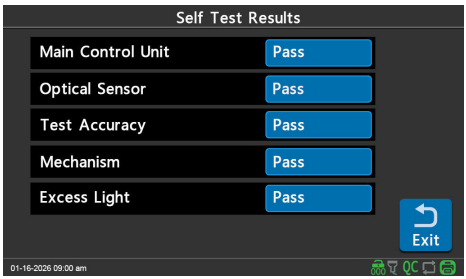
If only the ***Test Number*** is entered records with the current ***Date*** will be searched.
If there is no ***Test Number*** with the current ***Date***, the latest previous Date will be searched. For example, assume the current date is 2026-04-11. There are two records with the same Test Number but dates of 2026-04-10 and 2026-04-04. The test from 2026-04-10 will be displayed.
If there is no record found ***Record not found*** will be displayed. Touch Exit on the screen to return to the ***Database Menu.***
Touch **Print** to print a record.
Touch ↑ to view the previous record. Touch ↓ to view the next record.
Touch **Exit** to return to the previous screen. Additional records can be located, reviewed, or printed.

4.3.3 View Current Record

Touch ***View Current Record*** to show the data from the current or last record.
Touch ***Print*** to print a record once it is displayed.
Touch ↑ to view the previous record. Touch ↓ to view the next record.
Touch ***Exit*** to return to the previous screen.

4.4 Self-Test

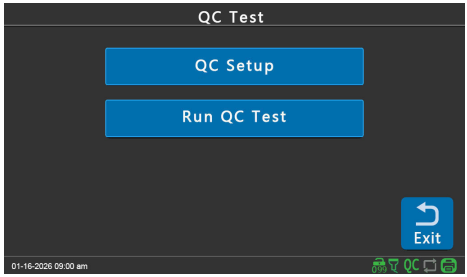
Touch ***Self-Test*** to perform self-tests. A results screen will display the results of each test.



After each test, a ***pass*** or ***fail*** will be displayed on the screen. If any results fail, the unit will not operate. Refer to **Section 10 Troubleshooting.**
Touch **Exit** to return to the ***Main Menu.***

4.5 QC Test

Touch ***QC Test*** to display the screen below. If **User Login** is enabled and ***Operator ID*** is 11 through 20 the operator can only view settings and run a QC test. (The User Login function is for moderate complexity CLIA labs only.)



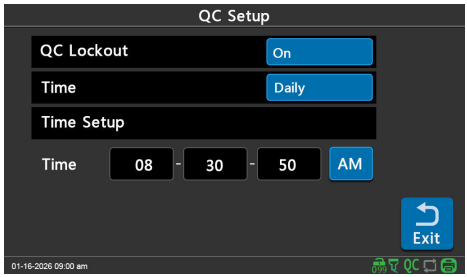
Touch ***QC Setup*** to Setup QC setting.
Touch ***Run QC Test*** to Enter QC Test mode
Touch ***Exit*** to return to the previous ***Menu.***

4.5.1 QC Setup

Each lab should set its own standards and procedures for performance. Test known controls (i.e., Consult Liquid Urine Controls) in case of any of the following events, following local, state, and/or federal requirements:

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

The QC test frequency is set to Daily by default.
Touch ***QC Setup*** to access the screen below.



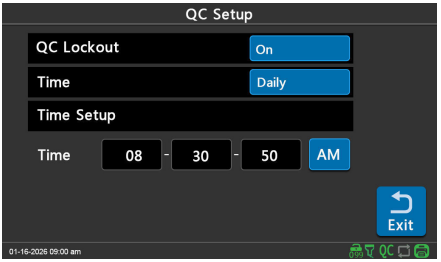
The **QC** symbol is displayed. QC Lockout timing can be set for ***Every 8 Hours, Daily, Weekly*** or ***Monthly.***

Time

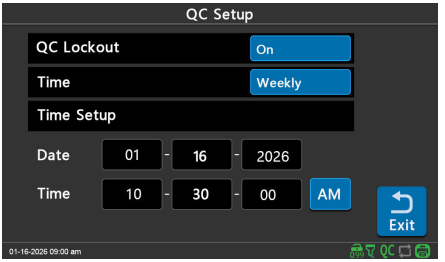
Touch the blue area next to **Time** to set the QC test for ***Every 8 Hours, Daily, Weekly*** or ***Monthly.***

Time Setup

Touch the number areas of the ***Date*** and ***Time*** to enter the text input screen, change each of the time and date digits until the desired date and time is shown. Touch **Exit** to save and exit to the previous screen.



Every 8 Hours/Daily



Weekly/Monthly

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.

4.5.2 Run QC Test

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

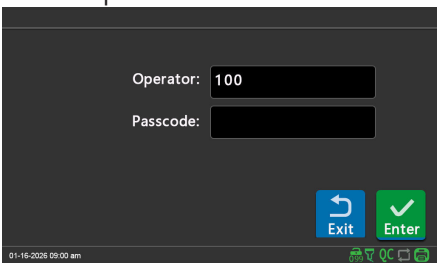
4.5.3 Setting the QC Values

QC values for Consult Liquid Urine Controls (microalbumin and creatinine) are preset by the manufacturer at the factory.

4.6 User Login

(This function is for moderate complexity CLIA labs only)

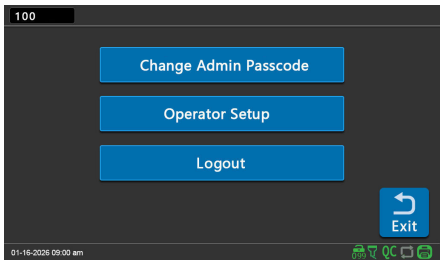
Press **Operator** from the Initial Screen to show the Administrator login screen. The Operator ID is preset to 100.



When viewing this screen for the first time, leave the **Passcode** blank and press **Enter** to enter the Administrator screen. Press **Exit** to return to the Initial Screen without enabling User Login.

4.6.1 ID Admin

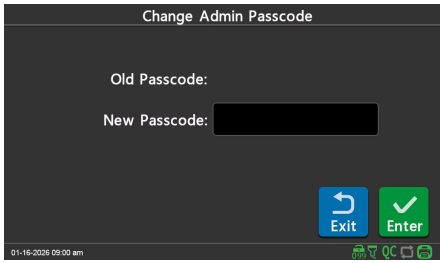
The Administrator screen is shown.



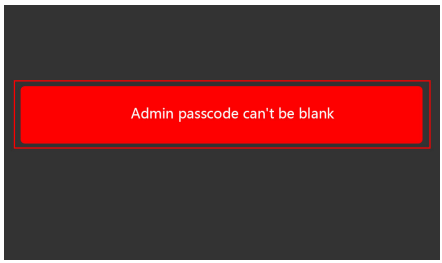
Touch the blue areas to select a menu option. If **Passcode** is blank, user login is not yet enabled and only ***Change Admin Passcode*** can be chosen. Press **Exit** to return to the Initial Screen.

<u>Change Admin Passcode</u>

Change the passcode from blank to a valid passcode, select ***Change Admin Passcode.***



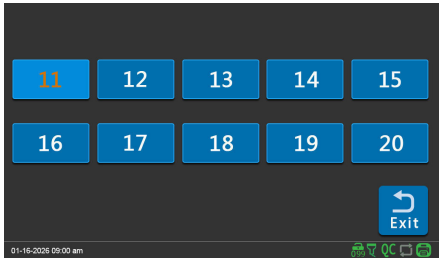
A passcode must be entered to enable ***User Login.*** If the passcode is left blank, a new screen will indicate the passcode is invalid.



After 3 seconds, the screen will return to the login screen. Press **Exit** to keep the existing passcode and exit. Scan or enter a valid Passcode and press **ENTER** to accept and exit. ***User Login*** will be enabled

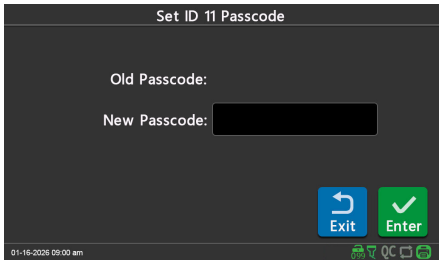
Operator Setup

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



Light blue with red numbers means the ID is enabled. Dark blue with white numbers means the ID is not enabled

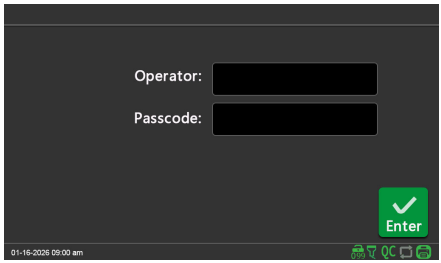
Touch the corresponding ID to enter the ***Passcode*** screen.



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

Logout

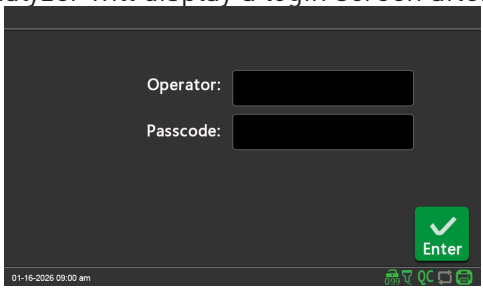
After the User Login is enabled, select ***Logout*** to log out. The normal Login screen will be shown for a new operator login. See Section 5 for Login procedures.



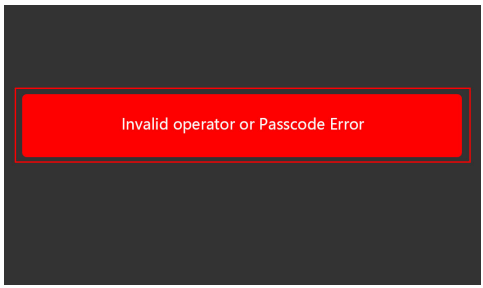
If you forgot the passcode, please call 1-800-838-9502 for technical assistance.

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 *(This function is for moderate complexity CLIA labs only)*, the analyzer will display a login screen after **Self-Test.**



Enter the ***Operator*** ID and enter or scan the ***Passcode***. Touch ***Enter*** to run the analyzer.
If the ***Operator*** or ***Passcode*** is incorrect, the analyzer will indicate an operator or a passcode error.



After 3 seconds, the screen will return to the login screen.
If the ***Operator*** and ***Passcode*** entries are correct, the analyzer will display the **Initial Screen**. The logged-in Operator will be shown.





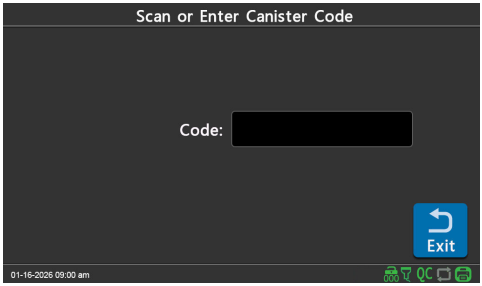
The user ID will be 11-20 for Operators. This provides access to operate the analyzer, change test modes, and test number, and review settings. Touch ***Operator*** from the Initial Screen to logout and display the Login Screen.
The user ID will be 100 for the Administrator. This provides full access to operate the analyzer and change settings. Touch ***Operator*** from the Initial Screen to logout and display the Login Screen. Touch the **Test** icon on the Initial Screen to test strips. Check all settings and strip types before testing.
During testing, the screens will display icons showing the status, options available and prompts for testing:

No. 000001	The sequential test number assigned to the next test to be run. In ***Routine*** Mode, the first digit will be ***0***. In ***QC*** Mode, the first digit will be ***2***.
MAC	Indicates the proper strip to be tested. Select the strip configuration using the **MENU** function from the Initial Screen. The strip type must match the strip being used or result will not be displayed.
Mode	Indicates the current mode setting. Available modes are ***Routine*** and ***QC.*** Touch the blue area next to **Mode** from the ***Test Settings*** screen to change the mode. Continue to Touch the blue area next to **Mode** to cycle through each mode.
	When visible, the analyzer is set to **Continuous Test**. When the icon is green, Continuous Test is set to test up to 120 tests per hour. When the icon is gray, Single Test is set to test one strip at a time up to 60 tests per hour.
	When visible, the printer is set to the ***Internal Printer.*** When the icon is green, ***Auto-Print*** is ***On***. Test data is automatically sent to the internal printer and data ports after each test. When the icon is gray, ***Auto-Print*** is ***Off.*** Press **Print** to send results to the printer and data port. Red × indicates out-off-paper.
	When visible, the printer is set to ***External Printer.*** When the icon is green, ***Auto-Print*** is ***On***. Test data is automatically sent to the external printer and data ports after each test. When the icon is gray, ***Auto-Print*** is ***Off***. Press **Print** to send results to the external printer and data port.
	When visible, indicates the Barcode reader is enabled. When the color is green, indicates the Barcode reader is enabled. If this is icon gray, it indicates the Barcode reader is disabled.
	Strip Lockout is available. The analyzer will only test strips with correct barcodes.
QC	When the scheduled test time arrives, a beep will be heard to inform the user that a QC test is required before performing additional tests.

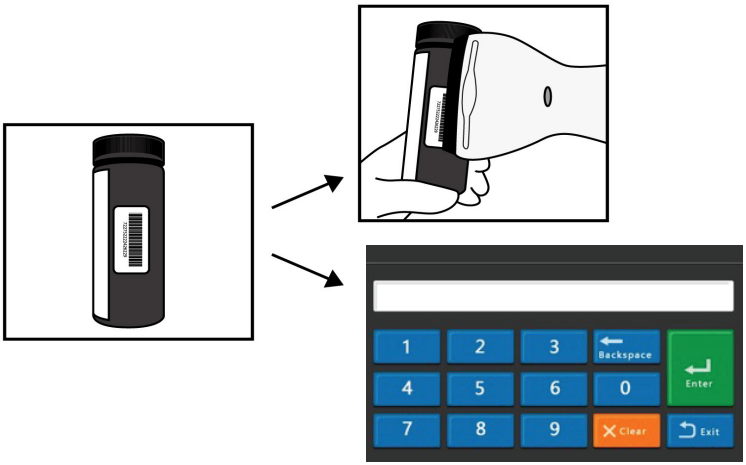
5.1. Entering Canister Code

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 via the **keyboard**, or scanned with the Barcode reader, if installed.

At first startup, the Strip Holder will fully extend. The screen below will be displayed.

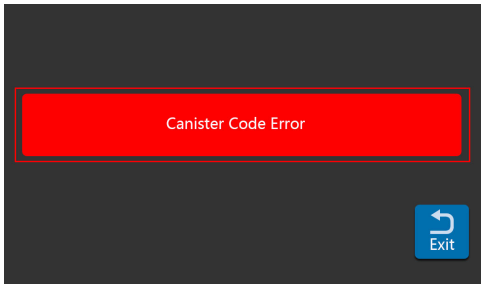


Scan or manually enter the canister code from the strip canister. To manually enter the canister code, touch the blank area after **Code** to access the keyboard below.



Touch **Enter** to save and return to the previous screen. Touch **Exit** to cancel the changes and exit the screen.

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



Touch **Exit** to return to the previous screen.
If the canister code is correct, the analyzer will proceed to the test Screen.



When there are only 5 strips remaining, the number of strips under the icon will flash to notify the user that a new canister of strips is required.
When the current run is completed, enter the new canister code. The number under the icon will be increased accordingly.

Note: Refer to the following for more information on the Strip Lockout function. Once a canister code is accepted, the analyzer will automatically recognize the Type of Strip and the number of strips per canister. The analyzer will keep track of the number of strips remaining in the canister and available for testing, under the lock icon. **Continue testing as usual until the analyzer prompts you that a new canister code is required. When the analyzer prompts that a new canister code is required, scan or manually enter a canister code from a new canister to be used.** The analyzer will not accept canister codes that have already been entered and will lockout the user until a new canister code is entered.

5.2 Normal Operation, No Barcode Reader

5.2.1 Sample/Strip Preparation

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

Note: Only Consult Urine Reagent Strips work with the Consult U120 Touch Urine Analyzer. Use of any other strips will result in "Strip Error" Message.

Remove the strips from the closed canister. Use them as soon as possible. Tightly close the canister after removing the strips.

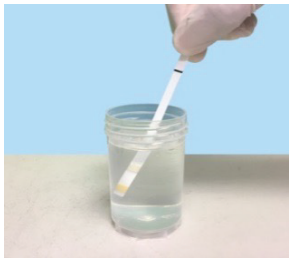
5.2.2 Strip Test – Single Test Mode

(This function is for CLIA-Waived settings)

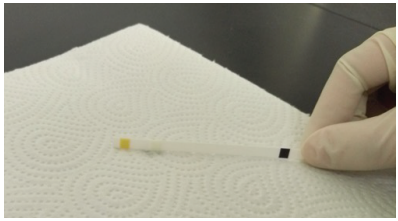
Once **Test** is touched, the screen below will show.



Dip the reagent strip into the fresh, well-mixed urine specimen, wetting all the pads. Immediately remove the strip from the urine to avoid dissolving the reagents. Run the edge of the strip against the side of the specimen container.



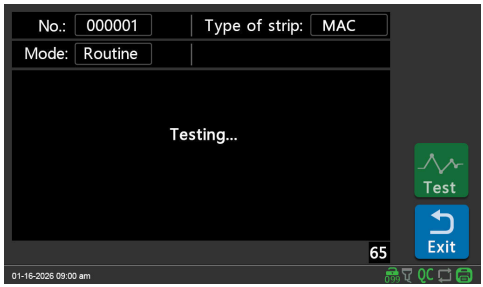
Blot by pressing the edge of the strip to an absorbent material (e.g. a paper towel) to remove the excess urine. This prevents mixing chemicals from adjacent reagent areas.



Place the strip on the strip holder with the reagent area facing up. Make sure the strip end touches the Strip Holder Backstop as shown below.



Touch **Test** again.



The countdown clock is displayed on the bottom right. The clock will start to countdown from ***65.***

Note:

- In order to avoid contamination of the strip holder and/or the optical sensor, make sure that the strip holder is fully extended and at a standstill before placing or removing a urine strip from the strip holder.
- When the countdown clock on the display reaches 1, the Strip Holder will carry the strip inside and begin testing.

- An automatic calibration is done before each test.
- The results will be displayed on the screen and stored in memory after each test. Any abnormal results will be highlighted on the screen and flagged on the printout.
- If **Auto-print** is set to **On** the results will be printed. If **Auto-print** is set to **Off,** Touch **Print** to print the results.

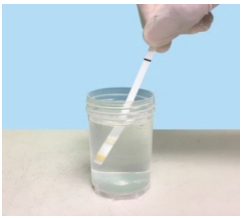
Remove the used strip from the Strip Holder when the strip carrier moves out. Discard the used strip according to local regulations.
Repeat the previous steps to test more urine.

5.2.3 Strip Test – Continuous Test Mode

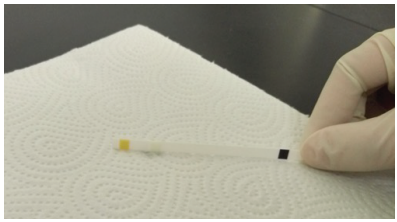
(This function is for moderate complexity CLIA designation labs only)
Touch **Test** to show the testing screen. Once **Test** is pressed, the screen below will be shown.



Dip the reagent strip into the fresh, well-mixed urine specimen, wetting all the pads. Immediately remove the strip from the urine to avoid dissolving the reagents. Run the edge of the strip against the side of the specimen container.



Blot by pressing the edge of the strip to an absorbent material (e.g. a paper towel) to remove the excess urine. This prevents mixing chemicals from adjacent reagent areas.



Place the strip on the strip holder with the reagent area facing up. Make sure the strip end touches the Strip Holder Backstop as shown below.



Touch **Test** again.
The countdown clock is displayed on the bottom right. The clock will start to countdown from ***65.***



Place the first strip onto the Strip Holder Channel. Ensure the reagent pads face up.
Make sure the end of the strip touches the Strip Holder Backstop.
Listen for the next triple beep and/or see the countdown clock reach ***32.***
Immerse a second strip in fresh, well-mixed urine. Repeat the strip testing steps above. Lay the second urine-exposed strip on a paper towel, with reagent pads up. Wait for the first strip to complete testing and the Strip Holder to move out.

Listen for the next triple beep and/or see the countdown clock reach ***2.*** Immerse the third strip in fresh, well-mixed urine. Repeat the strip testing steps above. Lay the third strip on a paper towel with reagent pads up. Wait for the Strip Holder to move out.

> **Note:** When the countdown clock reaches 1, the Strip Holder will carry the first strip inside. The countdown clock also returns to ***30***. The results will be displayed on the screen for several seconds and stored in memory. If ***Auto-print*** is ***on***, the results will be printed.

Remove the completed first strip after the Strip Holder moves out. Immediately place the second strip on the Strip Holder before the countdown clock reaches ***1***. The Strip Holder will carry the new strip inside for analysis.

> **Note:** The operator has about 8 seconds to discard the used strip and place the next strip on the Strip Holder.

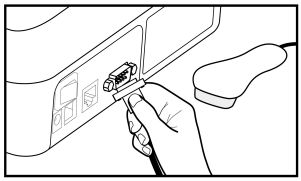
After the first time the countdown clock reaches ***1***, it will return to ***30*** instead of ***65***. A triple beep occurs every 30 seconds. This prompts the operator to immerse a new strip.

Discard the used strip according to local regulations.
Repeat the above process for additional urine specimens.
Press **Cancel** to stop testing when all tests are done.

5.3 Normal Operation, Barcode Reader Installed

In the Barcode setup screen, if **Yes** is selected, plug in the barcode reader, as described below, and the unit is ready for the operator to begin scanning barcodes.

Turn off the analyzer and plug the **RS232C cable** from the **Barcode reader** into the **Standard RS232C Port** in the back of the analyzer. Use the cable supplied with the Barcode reader. Refer to **Appendix 4 Barcode reader** for specifications and compatibilities.



If both the **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 **Standard RS232C** port.

Turn the power switch located at the back panel of the analyzer on. Ensure the analyzer parameters are configured properly as described in **Section 4 Analyzer Setup**, with ***Barcode Reader*** set to ***Yes.***

5.3.1 Strip Test – Single Test Mode with Barcode Reader

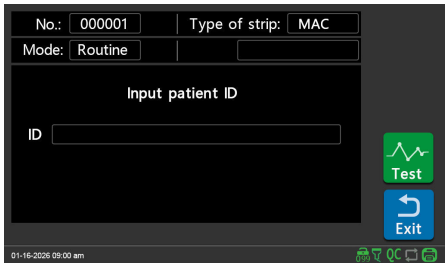
Touch **Test** from the Initial Screen.

The analyzer will prompt the user to scan the Barcode ID with the Barcode reader. If a Barcode reader is installed, holding the Barcode reader over the barcode on the specimen container.

Touch 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. Position it until the Barcode reader beeps, indicating the barcode has been scanned. When the reading has been completed, it will appear next to ID. ID will reflect the last barcode read by the reader. It will change every time a new barcode is read until **Test** is touched to begin the test.

If a **Barcode reader** is not installed, enter the ***ID*** manually using the numerical keyboard. Touch **Test** to begin the test.

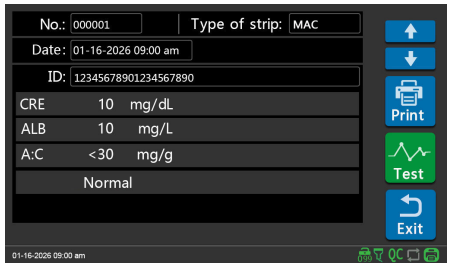
After the ***ID*** is entered, the patient ***ID*** will display. Review the patient ID before testing the strip.



Touch **Test** after the patient ***ID*** has been entered to display the next screen.



Touch **Test** again to begin strip testing. The strip is tested the same as other single test modes. The results screen will show the sample ID in the ***ID*** field.



If ***Auto-print*** is ***Off***, Touch **PRINT** from the results screen to print results. Touch **Exit** to return to the previous barcode entry screen.

5.3.2 Strip Test – Continuous Test Mode with Barcode Reader

(This function is for moderate complexity CLIA labs only)

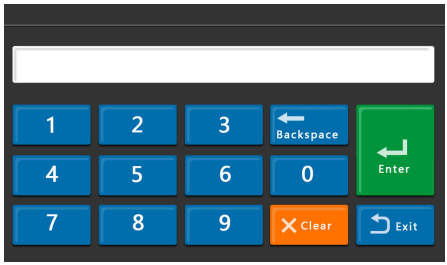
If ***Barcode reader*** is ***On*** and is Green, samples are tested in batch mode. Holding the Barcode reader over the barcode on the specimen container, Touch the Scan button on the Barcode reader. A red illuminated line will appear over the barcode to be read. Move the Barcode reader to align the red line over the barcode.

When the Barcode reader beeps the barcode has been scanned. All sample barcode IDs in a batch are read and stored in memory in sequence. Samples must be run in the same sequence as scanned. This ensures IDs and samples correspond. Prompts are displayed to show the next sample to be tested.
Touch **Test** to begin the batch mode.

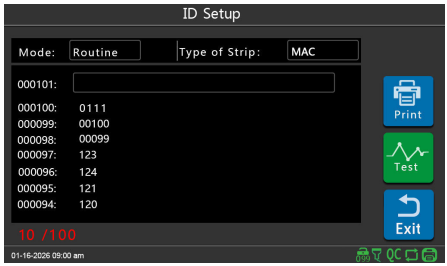


Touch **Exit** to return to the ***Initial screen.***
Touch the area next to the test number to access the numerical keyboard and edit the Barcode ID.





Using the keyboard or barcode reader to enter the Barcode ID, press **ENTER** to confirm the ID entered and enter the next number.
Press **CLEAR** to clear the entered ID. Touch **PRINT** to print the list of IDs. Touch **Exit** to cancel the changes and Exit the screen.



Touch **Test** to save the changes and Exit the screen.

Up to 100 barcodes can be read. The screen will indicate how many barcodes have been read.

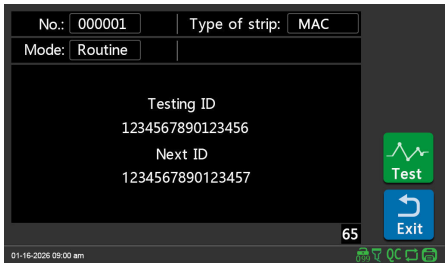
Note: Do not change ***Barcode reader*** or ***Test number settings*** before all barcodes have been processed. Otherwise, remaining barcodes may be deleted.

Touch **Test** to begin strip testing. The testing screen will be displayed as shown below. This screen example shows a total of 10 strips to be run. It asks for the first strip to be placed on the Strip Holder.

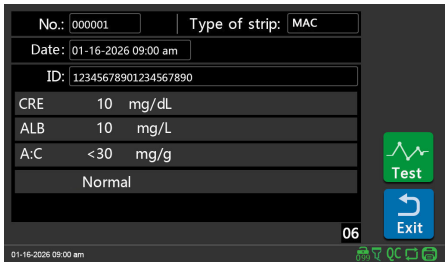
Note: In order to avoid contamination of the strip holder and/or the optical sensor, make sure that the strip holder is fully extended and at a standstill before placing or removing a urine strip from the strip holder.



The next screen shows the barcode of the sample to be run and the next sample ID to be run. This reduces the possibility of error and mismatch between the barcode and the sample to be run.



When the test is complete, the **Results Screen** will show briefly. The next strip can be placed on the Strip Holder.



Stop testing by Touching ***Exit*** when the button is lit. All other testing procedures are the same as testing with no barcode.

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 59-86ºF (15-30ºC) prior to testing.

Note: Use Consult Urine Reagent Strips (Microalbumin/Creatinine) 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.

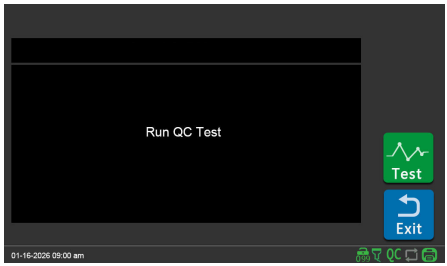
5.4.2 Urine Control Test Procedures

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 ***Auto-print*** is set to ***On***, the result will be printed.
If the QC test "Fails", please contact technical support at 1-800-838-9502.

5.5 QC Lockout

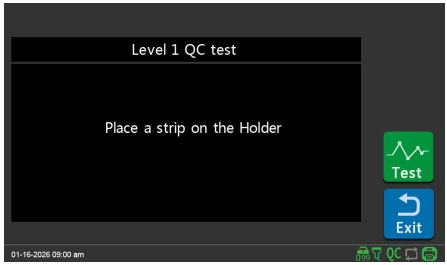
The user will be notified when a QC test is required. The following screen will be displayed. The QC symbol color is green.



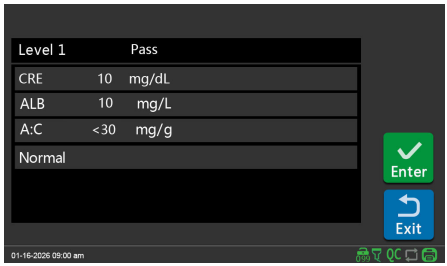
Note:

- Use Consult Urine Reagent Strips and urine controls for proper functioning and accurate results.
- QC values for Consult Liquid Urine Controls (microalbumin and creatinine) are preset by the manufacturer at the factory.

Touch **Exit** to return to the Initial Screen.
Touch **Enter** to run QC tests.



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 testing results.



If any parameter is out of range, it will be highlighted.
If ***Auto-print*** is set to ***On***, the result will be printed.
Touch **Enter** to test control Level 2. The steps are the same as for Level 1.

Date: 2026-01-16		16:54
Operator: 11		
Level 1	Pass	
No. 200021		
CRE	10	mg/dL
ALB	10	mg/dL
A:C	<30	mg/g
Normal		

Date: 2026-01-16		16:56
Operator: 11		
Level 2	Pass	
No. 200022		
CRE	300	mg/dL
ALB	150	mg/dL
A:C	30-300	mg/g
Abnormal		

If the QC test fails, the analyzer will be back to QC lockout screen:



Section 6 Data/Communication

The RS232, USB, and LAN ports can communicate with an external (optional) PC.

If **Auto-print** is **On**, the printed data on the internal printer is also sent to the RS232, USB, and LAN port. Connect either a RS232, USB, or LAN cable to the back of the analyzer to a PC with suitable software.

6.1 External Printer

The RS232 port can connect to an optional external printer for printing data.

6.2 Barcode Reader

The RS232 port can also connect to an optional Barcode reader. It can read and enter barcoded sample ID information.

6.3 Service and Support

For US customers, call 1-800-838-9502 for technical assistance regarding details on data transfer, printing data, and/or barcode reader.

Section 7 Quality Control

Quality control test is used to validate the tests strip performance and urine analyzer operation. Errors resulting from user operation can also be detected in Quality Control test. Each lab should use its own standard and procedures for performance. Test known positive and negative specimens/controls in case of 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
- Whenever test results are in doubt

If the QC tests do not provide expected results following errors may have occurred and perform recommended checks:

- Deterioration of the reagent strip areas due to exposure to light, ambient moisture, or heat. Ensure strips are fresh from a new canister stored as per the instructions provided and repeat QC procedure.
- Ensure that the strips used are not past their expiration date.
- Deterioration of the control solution. Ensure the controls are not past their expiration date.
- Repeat the test to ensure no errors were made during the test.

To run a quality control test:

- Wet each pad of a new urine strip with the controls.
- Blot off excess liquid. Place the strip on the strip holder.
- Press “Test”.
- Compare QC results with the expected values. If the QC results do not match, do not test any patient samples until the problem is fixed. Repeat until the results are correct. See User Manual.

For US customers, call technical support toll free at 1-(800)-838-9502 for additional information.

Section 8 Maintenance

8.1 Loading Printer Paper

Open the printer cover by pulling up on the tab.

Place the new paper roll into the printer paper compartment with the paper unrolling from underneath and towards the compartment wall.

Pull about 4 inches or 10 centimeters of paper past the top edge of the paper compartment

Note: Do not feed paper underneath the paper roller.

Close the printer paper compartment by clicking the cover back into its original position. Press the printer cover after you close the cover to ensure that it is closed properly.



1



2



3



4

8.2 General Cleaning

Keep the surface of the instrument free of dust at all times. If needed, the external surfaces 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 Daily Cleaning

8.3.1 Remove the Strip Holder

Touch **Test** to fully extend the Strip Holder/Mount.
Turn off the Power Switch after the Strip Holder/Mount is fully extended. Hold the Strip Holder Mount and put the thumb against the holder to remove the Strip Holder from its mount as shown below.

8.3.2 Clean the Strip Holder

Clean the Strip Holder using a lint free/non-absorbent cotton swab/ball with distilled water if sediment is seen. Dry with a clean, dry cotton ball. Examine the White Calibration Circle to ensure there are no nicks or dirt present. Clean the White Calibration Circle as necessary using a cotton swab or cotton ball with distilled water. Dry with a clean, dry cotton ball.

> **Note:** The White Calibration Circle should be replaced if any nicks or non-removable dirt are found. For US customers, call technical support toll free at 1-(800)-838-9502 for details.

8.3.3 Load the Strip Holder

Grasp the Strip Holder by its sides as shown below. Place the Strip Holder on the Strip Holder Mount with the white Calibration Circle facing up and positioned towards the analyzer. It will slide loosely in the locating channel. Push the Strip Holder in towards the analyzer until it snaps into place. It will be held firmly on the Strip Holder Mount. Ensure the Strip Holder is installed properly. If not properly installed onto the Strip Holder Mount, the Calibration Circle will not be in the correct position. The analyzer will display "Optical Sensor Failed."

> **Note:** When correctly positioned, the Strip Holder will snap into place, with the White Calibration Circle not visible. See illustration below.



8.3.4 Return the Strip Holder/Mount to Its Internal Position

Turn the Power Switch on and wait for the Strip Holder/Mount to move inside the analyzer and stop. Turn the Power Switch off or begin testing strips.
Please refer to **Section 5 Analyzer Operation.**

8.4 Sample Holder Cleaning

Remove the Strip Holder and repeat Daily Cleaning above.
Clean the Strip Holder using a lint free non-absorbent cotton swab or ball with one of the following cleaning 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 cleaning solution into a narrow vessel 4 inches (10 centimeters) high.
Dip the Strip Holder into the cleaning solution

Caution: Ensure the White Calibration Circle does not touch the solution.

Soak the Strip Holder in the cleaning solution for 10 minutes.
Remove the Strip Holder, clean and dry it.
Load the Strip Holder and return the Strip Holder/Mount to its original position.

Section 9 Precautions

For accurate results, follow the precautions below when operating 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.

• Avoid storing or operating the analyzer in direct sunlight, excessive temperature, or humidity. Refer to **Appendix 1 Urine Analyzer Specifications** for operating condition requirements.

• Do not use the analyzer near a strong radiation source; otherwise it may interfere with the ability of the analyzer to function normally.

• **Never place anything within 2.5 inches of the front of the unit. This will avoid interference with the Strip Holder.**

• Keep the unit clean. Wipe it frequently with a soft, clean and dry cloth. Use fresh water when needed.

• Do not clean the unit with substances such as gasoline, paint thinner, benzene compounds or other organic solvents. This will avoid any damage to the Strip Holder, White Calibration Circle, or other components.

• Do not wash the LCD with water. Lightly wipe the LCD with a clean, soft, and dry rag.

• The Strip Holder must be kept clean. Wipe the Strip Holder using fresh water daily. Refer to **Daily Cleaning** in **Section 8.**

• Follow all local regulations when discarding the unit or its accessories.

• Do not use the unit or the strips outside of the operating temperature ranges below.

Strips: 59-86ºF (15-30ºC)

Section 10 Troubleshooting

Problem	Solutions
Improper Strip Position	• Adjust the strip so the strip end touches the Strip Holder Backstop and is centered in the Strip Holder Channel
Strip Missing	• Insert strip
Strip Error	• Make sure strip matches analyzer setting (see **Type of Strip** in **Section 4)** • Make sure the brand of strip is compatible with the analyzer (i.e., Consult Urine Reagent Strip for microalbumin/creatinine). • Make sure all the test pads on the strip have been immersed in the specimen • Ensure the test strip is not tilted or upside down
No display on screen	• Turn the Power Switch on • Make sure power is applied to the Analyzer
Printer does not work	• Make sure Auto-Print is set to On. Refer to **Printer Setup** instructions • Load paper if necessary. • Ensure Printer Setup is set for Internal if an external printer is not connected • Ensure paper roll is placed correctly. If incorrect, there will be no printout • Clean printer roller with ethanol • See that the proper side of the thermal paper is inserted in the printer
Main Control Unit Failed	• Turn the Power Switch off, then on. Perform a Self-Test. Refer to Manual **Self-Test** section
Optical Sensor Failed	• Ensure the Strip Holder is locked onto the Strip Holder Mount correctly. The Strip Holder should snap into place and locked onto the Strip Holder Mount. • Ensure the white Calibration Circle is clean • Clean the Strip Holder and refer to Daily Cleaning section • Turn the Power Switch off, then on. Perform a Self-Test. Refer to Manual **Self-Test** section
Test Accuracy Failed	• Turn the Power Switch off, then on. Perform a Self-Test. Refer to Manual **Self-Test** section

Mechanism Failed	• Remove any obstacles in the path of the Strip Holder • Do not touch the Strip Holder when it is moving • Turn the Power Switch off, then on. Perform a Self-Test. Refer to Manual **Self-Test** section
Excess Light Failed	• Ensure the analyzer is kept away from direct light • Ensure the white calibration circle is clean • Ensure the Strip Holder is positioned correctly on the Strip Holder Mount. Refer to Daily Cleaning section • Turn the Power Switch off, then on. Perform a Self-Test. Refer to Manual **Self-Test** section
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 the reagent pads of the strip have been immersed
Internal Battery Failed	• Stop testing and contact technical support at 1-(800)-838-9502

For US customers, call technical support toll free at 1-(800)-838-9502 for details.
Hours of operations are: 8 am to 8 pm Eastern Standard Time (EST)

Appendix 1 Urine Analyzer Specifications

Feature	Specifications
Methodology	Reflectance Photometer
Detection	Photosensitive diode
Throughput	Single Test Mode: 60 tests/hour Continuous Test Mode: 120 tests/hour
Memory	Last 2000 results
Strip Incubation Time	1 minute
Detection Wavelengths	525 nm and 635 nm
Analyzer Ports	Standard RS232C Port for Barcode Reader or External Printer or Data Transfer USB and LAN ports for Data Transfer
Capabilities	Internal Thermal Printer (included), Optional External Printer (not included), RS232C Barcode Reader (optional), USB or RS232C Data Transfer Cable (optional)
Major Readable Barcodes	See Appendix 4
Available Languages on Screen	English (default in US and select countries) and all available languages
Analyzer Operating Conditions	32-104 ºF (0-40 ºC); ≤85% Relative Humidity (non-condensing)
Strip Operating Conditions	59-86 ºF (15-30 ºC); ≤85% Relative Humidity (non-condensing)
Power Source	12V DC 5A adapter (Input：100-240V AC, 50/60Hz, 1.4-0.7A)
Dimensions (L X W X H)	9.8 in x 8.2 in x 3.9 in (25.4 cm x 21.5 cm x 10.4 cm)
Display Dimensions (L X W)	5.9 in x 3.1 in (15.4 cm x 8.6 cm)

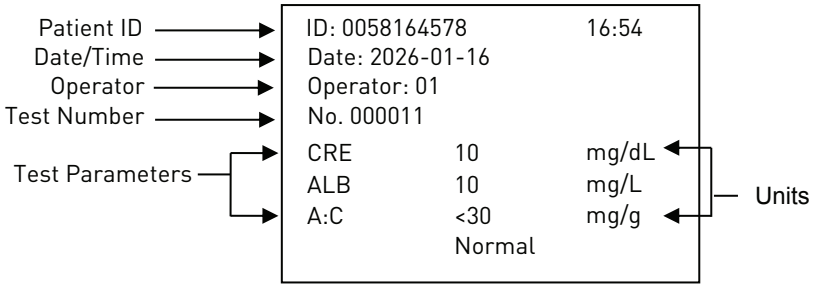
This product complies with EN 61326.

Appendix 2 URS Parameter Table

Parameter Name (Abbreviation on Display)	Arbitrary / Conventional	SI
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
Creatinine (CRE)	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
A:C	<30 mg/g Normal 30-300 mg/g Abnormal >300 mg/g High Abnormal	<3.4 mg/mmol Normal 3.4-33.9 mg/mmol Abnormal >33.9 mg/mmol High Abnormal

Appendix 3 Result Print-Out

The printed results are shown below.



Depending on the type of strip selected, the analyzer recognizes the parameter order and automatically ranks the display and printing sequence of each parameter. Conventional results will always be printed automatically. Abnormal results, or results of pathological significance will be marked with an *.
All results will be reported with the respective data in front of the units.

Appendix 4 Barcode Reader

The Consult Barcode reader is a 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
• Code 93	• EAN8	•Plessey
• Interleave 25	• EAN13	•Telepen
• RSS		

Note: A maximum of 20 characters can be read by the barcode reader, and displayed, stored, and transmitted by the analyzer.

Appendix 5 Catalog

Product Description	MFR#	Components	Quantity
Consult U120 Touch Urine Analyzer	121-120TOUCH	Urine Analyzer	1
		Printer Paper Rolls	2
		Power Supply	1
		Quick Start Guide	2
		Instruction Manual	2
Consult U120 Touch Urinalysis Kit	121-10SGTOUCHPROMO5	Urine Analyzer	1
		Consult 10SG Urine Reagent Strips	4
		Consult Urine Reagent Strips (Microalbumin/Creatinine)	1
		Printer Paper Rolls	2
		Power Supply	1
		Quick Start Guide	2
		Instruction Manual	2
		Barcode Reader	1
		Serial Splitter Cable (RS232C)	1
Consult Barcode reader	121-BR	Barcode Reader	1
		Serial Splitter Cable (RS232C)	1
Consult Printer Paper Rolls	121-PP	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
Consult Data Transfer Cable	121-DTC	Data Transfer Cable (RS232C or USB)	1
		Package Insert	1

Appendix 6 Index of Symbols

SN	Serial number	MFR #	Manufacturer #		Caution
	DC Power		USB port		LAN port
	Serial port		Direct current		Keep away from sunlight and heat
	Keep dry		Fragile, handle with care		This Side Up
	Temperature limit		Humidity limitation		Stacking limit by number
	Continuous test		Barcode reader	QC	QC Lockout
	Strip lockout		Internal printer		External printer
	Don't disassemble		Indoor use only		Do not open risk of electric shock
	10 years of environment protection use period		Energy consumption	R_x ONLY	CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician
IVD	*In vitro* diagnostic medical device		Do not dispose along with household waste		

Appendix 7 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. It does not apply to the other materials included with the analyzer.

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

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

For warranty service, please call 1-800-838-9502.

Consult U120 Touch Urine Analyzer Warranty Card

Please complete this warranty card and mail it to McKesson Medical-Surgical Inc., McKesson Brand Marketing, 9954 Mayland Drive, Richmond, VA 23233. You must register your purchase within one year of purchase. Refer to **Appendix 7 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**