CLINITEK Status®+
Analyzer

Operator's Manual

SIEMENS

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CE

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Analyzer

Operator's Manual

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EC REP

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The information in this manual was correct at the time of printing. However, Siemens Healthcare Diagnostics continues to improve products and reserves the right to change specifications, equipment, and maintenance procedures at any time without notice.

If this instrument is used in a manner differently than specified in this manual, the protection provided by the equipment may be impaired.

Table of Contents

A Brief Description

NOTE: Feature availability may vary by geography due to regulatory registration.

NOTE: Due to software changes, some screens on the instrument may appear slightly different from those in this manual.

What does the analyzer do?

Your Clinitek Status®+ analyzer is a portable instrument for reading Siemens Healthcare Diagnostics urinalysis strips and Clinitest® immunoassay cassettes. No special training is needed to use this instrument. Several different Siemens urinalysis strips (e.g., Multistix® 10 SG) can be used with the analyzer as well as the Clinitest hCG Pregnancy Test.

The analyzer can be set up to be as simple or sophisticated as you prefer. You may simply insert a dipped urinalysis strip or a Clinitest cassette into the analyzer and the result will be reported (this is called a *Quick Test*).

Or, you have the option to enter an Operator Name, Patient Name and Patient ID. This added information will be reported along with the test results (this is called a *Full Test*).

The touch screen displays instructions and prompts you through operation of the analyzer. In addition, you enter information through the touch screen.

Do I have to calibrate?

You do not have to do anything to calibrate. The instrument performs a system test each time it is turned on. Then, each time a test is run, the instrument automatically calibrates. The white calibration bar (on the test table) provides NIST traceable calibration.

How does it work?

Testing starts (in the *Quick Test* mode) when either the ***Strip Test*** or ***Cassette Test*** is selected on the main menu screen.

Touching the ***Strip Test*** key prompts you to adjust the test table to accept a urinalysis strip. Then you touch the **START** key. You have 8 seconds to dip the test strip, blot the edge of the strip and place it on the test strip table. The table is partially pulled into the instrument for calibration and then pulled completely into the instrument to read the test strip.

Touching the ***Cassette Test*** key prompts you to adjust the test table to accept a cassette. Then you touch the **START** key. You have 8 seconds to draw the sample into a pipette and dispense it into the sample well of the cassette. The analyzer automatically calibrates and then pulls the table completely into the instrument where the cassette is read.

In the *Full Test* mode for either a ***Strip Test*** or ***Cassette Test***, you are prompted to enter an Operator Name, Patient Name and/or Patient ID prior to running a test.

A Brief Description

How do I get results?

Results will be displayed on the touch screen and printed (if desired). The results can also be transferred to a computer using a 9-pin null modem serial cable and the RS-232 serial port on the back of the instrument.

The analyzer stores results from 950 patient tests. You are able to recall past patient test results on the analyzer using the ***Recall Results*** function.

How is the analyzer powered?

The analyzer can be plugged into an electrical outlet for use on the bench top, or it can be powered by batteries and freely moved from one testing site to another. The batteries fit into an opening on the bottom of the instrument.

What about this Operator's Manual?

The Operator's Manual contains the directions you need to unpack the analyzer, use it for your daily Siemens urinalysis and Clinitest immunoassay testing and keep it in good working condition.

As you read through the Operator's Manual, you will find these symbols:

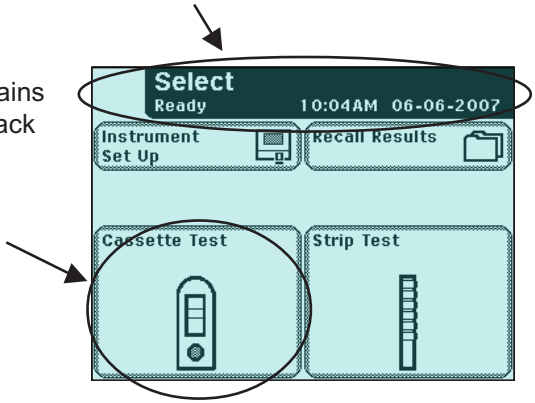
✎ NOTES: contain useful tips on using the analyzer. *Notes appear in italicized type.*

⚠CAUTION: should be followed carefully to ensure your analyzer operates correctly and is not damaged. **Cautions appear in bold type.**

In the Operator's Manual, you will notice some text is in ***bold/italic*** or **bold.**

Bold/italic text identifies screen names.

Bold text identifies a button (touch sensitive area) on the screen.



Understanding the Symbols and Display Icons

Instrument and Labeling Symbols

This section describes the symbols that appear on the exterior of the Clinitek Status+ analyzer, the power supply provided with the instrument, the carton in which the instrument was delivered and the supplies of reagent strips and cassettes which you will use with the instrument.

	Indicates that the input supply is direct current
	Identifies that the instrument is type B equipment, which provides a particular degree of protection against electric shock
Class 111	Identifies that the instrument is class 111 type equipment, which is equipment for connection to SELV (Separated Extra Low Voltage), i.e. a power supply
	Double insulated product or transformer may also identify class 2 equipment (power supply only)
	Identifies that the instrument is listed by Underwriters Laboratories as meeting U.S. and Canadian requirements for safety
	The CE mark identifies that the product complies with the applicable directives of the European Union
	Manufacturer
	European authorized representative
	Indicates a power on/off button
	Caution, consult accompanying documents
	*In vitro* diagnostic medical device
	Consult instructions for use

Understanding the Symbols and Display Icons

Indicates a serial port

This system contains certain toxic or hazardous substances or elements. The environmental protection use period for this system is 50 years. The system can be used safely during its environmental protection use period. The system should be recycled immediately after its environmental protection use period has expired.

Temperature limitation (18° 30° C)

Contents sufficient for (n) tests (100)

Use by YYYY MM

Catalog number

Serial number

Batch code

Biohazard

Indicates that this equipment is classified as Waste Electrical and Electronic Equipment under the European WEEE Directive. It must be recycled or disposed of in accordance with applicable local requirements.

Printed on recycled materials

Indicates compliance with RESY packaging standards

Understanding the Symbols and Display Icons

Keep this way up

Fragile, handle with care

Keep dry

Keep away from sunlight and heat

VDE Testing and Certification Institute Germany

Manufacturer's mark (FRIWO) and manufacturing location (Hong Kong)

Manufacturer's mark (FRIWO) and manufacturing location (Geratebau, Germany)

Encapsulated safety isolating transformer (short circuit proof)

Positive Temperature Coefficient (PTC) A thermistor device used to protect the transformer from short circuits or overload. This is an auto reset device.

Thermal cut out (TCO) This safety device disconnects the supply voltage to the transformer at a specific temperature. The operation temperature is stated below.

Ingress protection rating protected against the entry of solid objects >1 mm but no protection from liquids.

This symbol indicates a risk of electric shock.

Understanding the Symbols and Display Icons

Display Icons

There are seven icons which display in the top left of the display to show the mode of the instrument. They also appear on the selection area for each function. The icons are:

Instrument Set Up
This is displayed when the instrument is being set up to suit the users' requirements.

Strip Test (e.g., Multistix 10SG)
Shown when a test is being carried out using a reagent strip for urinalysis, and when results are displayed following a strip test.

Cassette Test (e.g., Clinitest hCG)
Displayed when a cassette test is being carried out and when results are shown after a cassette test.

Results recall
Used to show that results are being recalled from the instrument's memory.

Printer
This icon is displayed when results are being printed.

Data transfer to Personal Computer
Shows that data, including results, is being transferred to a PC.

Alert
Used when an error is being displayed.

There are two icons which may appear in the title bar.

Battery power
This has a maximum of four segments which show the level of battery power. It will be shown in the top right corner of the title bar when the instrument is battery powered.

Paper out
Appears in the top of the title bar when the printer paper/label roll needs replacing.

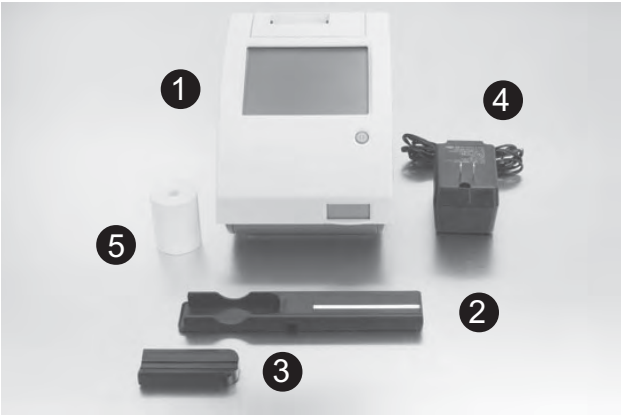
1 Unpacking & Set Up

Unpacking

Unpacking

1 Carefully remove the contents of the shipping carton. Check the carton and instrument for visible signs of damage; if seen, immediately contact the carrier.

2 Remove each of the wrappings and check for the following items:



1. Clinitek Status®+ analyzer
2. Test table

   ⚠ **Do not touch the white calibration bar.**
3. Test table insert

   If you are using a reagent strip that has 4 or fewer test pads, e.g., Uristix® 4, you must use a short test table insert. This has to be ordered separately (for a list of suppliers see Appendix A, Local Technical Support Providers and Distributors).
4. Power Supply

   If the power cord is not the style you need, contact your local representative (for a list of contacts see Appendix A, Local Technical Support Providers and Distributors).
5. Paper Roll

Depending on the model you have received, there may also be a Warranty Registration Card, Unpacking/Setup Guide, and/or Quick Reference Guide included.

Set Up

3 Analyzer Set Up

Place the instrument on a level work surface where the temperature and humidity are fairly constant.

⚠ The best temperature for using the instrument is between 22°C and 26°C (72°F and 79°F). Do not place the analyzer outside or near windows, ovens, hot plates, or radiators.

4 Plugging Analyzer In

Plug the appropriate end of the power cord into the power inlet socket located on the rear of the Clinitek Status+ analyzer. Plug the other end of the power cord into an AC electrical wall outlet.

⚠ Only use the power supply adapter included with the unit.

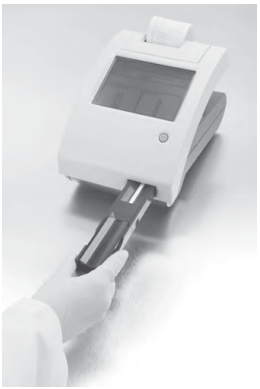
5 Installing Batteries
(Optional)

Place the analyzer on its side and remove the battery cover by pressing down on the tab and pulling out. Place the 6 new alkaline AA-size batteries into the analyzer. Replace the battery cover and turn the instrument back onto its base.

1 Unpacking & Set Up

Set Up

6 Inserting Test Strip Table



Insert the test strip table into the analyzer by holding it by the end opposite the white calibration bar and with the white bar facing up. Push the test table into the analyzer, pushing it in just over halfway.

> ⚠ **Do not push the test table fully into the analyzer as the test table may become jammed and prevent the use of the analyzer.**
>
> ⚠ **Do not touch the white calibration bar.**

7 Loading Test Table Insert

The test table insert adapts for use with a Siemens Healthcare Diagnostics urinalysis strip or Clinitest immunoassay cassette. One side is used for a strip test and the other side is used for a cassette test.

8 Interfacing to a Computer

The instrument can send results to a computer via the serial port located on the back of the analyzer. This requires a 9-pin null modem serial cable that can be purchased separately at an electronics store or from your Siemens Representative (for a list of suppliers see Appendix A, Local Technical Support Providers and Distributors).

9 Interfacing to the Clinitek Status Connector

The Clinitek Status connector allows for Ethernet or wireless network connectivity, Quality Control, increased security, bar code scanning, and additional features with the Clinitek Status+ analyzer.
This connector provides standard wired and wireless connectivity of the Clinitek Status+ system to your LAN, LIS, HIS, EMR, and allows for centralized control of all satellite Point of Care (POC) Clinitek Status+ analyzers.
Refer to the *Clinitek Status Connect System Operator's Guide*.

10 Analyzer Software Upgrades

From time to time Siemens will add new features and make improvements to the Clinitek Status+ instrument software.

These software updates will be available on an electronic memory card which is inserted into the software update socket. This socket is located under the printer cover and is on the left-hand side of the printer when you face the back of the instrument.

Updating the software is a simple procedure. Instructions for updating the software on your instrument will be supplied with the memory card.

11 Loading the Printer Paper or Label Roll

1. Open the printer cover by pulling up on the tab.

2. Open the paper roll compartment cover by pressing down on its tab and pulling out.

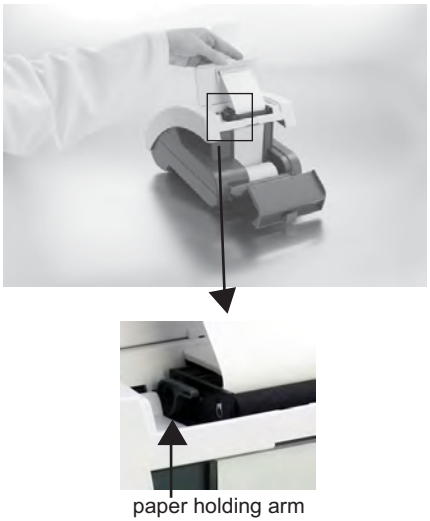
3. Lift the paper holding arm into the open, upright position.

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

5. Feed the paper up along wall and through the printer. Once you have approximately 4 inches (or 10 cm) of paper through the printer then feed the edge of the paper through the printer cover.

6. Push the paper holding arm down in to the closed position.

7. Close the printer and paper roll covers by clicking them into position.



The analyzer is set up to automatically print the results (to turn off the automatic print function see Section 5, Instrument Set Up).

The analyzer uses ordinary thermal paper as provided, or label stock (for ordering information see Appendix A, Local Technical Support Providers and Distributors).

12 Warranty Registration

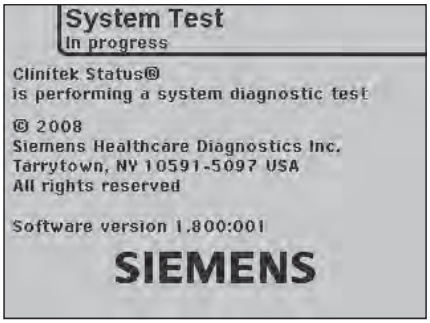
1. Lift the printer cover on the instrument and the serial plate with the instrument's serial number will be visible.

2. Write the serial number and installation date on the Warranty Registration Card. After the instrument has been successfully installed, complete the information on the Warranty Registration Card and return the card to your local Siemens office (for a contact list see Appendix A, Local Technical Support Providers and Distributors).

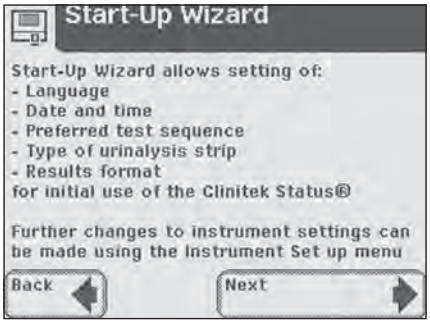
Powering Up

Press the on/off button ⏻ located on the front of the instrument.

This is the first screen displayed. The analyzer will run an automatic system diagnostic test each time it is turned on.



If this is the first time you have turned on the analyzer, you will be led through a Start-Up Wizard, a quick set-up procedure. If you require further instruction regarding the Start-Up Wizard see Section 3, page 3-1.



Powering Down

1. Before turning the analyzer off, always ensure that there is no strip or cassette on the test table and that the table and insert are clean.

2. Press the on/off button ⏻ for at least 2 seconds. The test table will retract into the analyzer. If there is no strip or cassette on the test table, the door will close and the analyzer will switch off.

If a strip or cassette is still on the test table, the test table will be pushed out and the analyzer will turn off. The test table will remain out. In order to retract the test table into the analyzer, turn the analyzer on, and then off (without a strip or cassette on the test table).

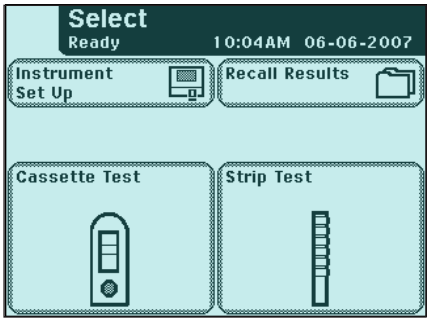
> ⚠ **Do not push the test table fully into the analyzer as the test table may become jammed and prevent the use of the analyzer.**

2 Interacting with the Touch Screen

Screens

Screens

The touch screen will guide you through the operation of the Clinitek Status®+ analyzer. The screen will display messages, instructions and options to which you respond by touching the appropriate area on the screen.



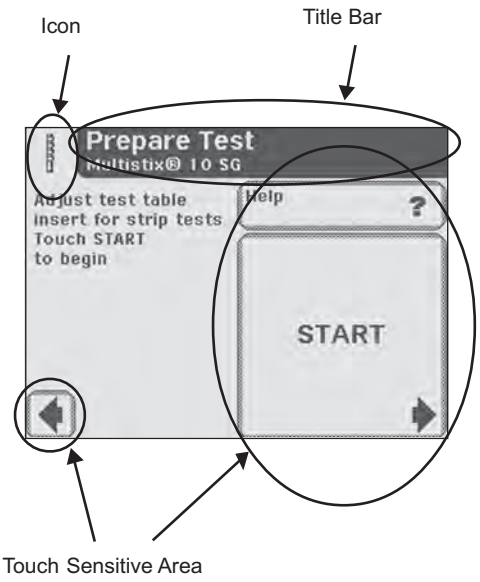
The first main screen you see is the ***Select*** screen. It displays the time and date, and indicates the 5 possible actions:

- Instrument Set Up
- Recall Results
- QC Test
- Cassette Test
- Strip Test

Each screen that follows the ***Select*** screen has an icon, title bar and touch-sensitive active areas.

In some cases, the screen will also display instructions, messages or error messages.

The icon indicates the main section in which you are working (1 of the 5 sections listed on the main ***Select*** screen).



2 Interacting with the Touch Screen

Screens

How to Touch the Screens

The screen needs to be touched lightly in the touch-sensitive area to activate a response.

If a touched area does not respond as expected, slide your finger across the appropriate selection area.

Where to Touch the Screens

There are three types of areas that respond to touching the screen.

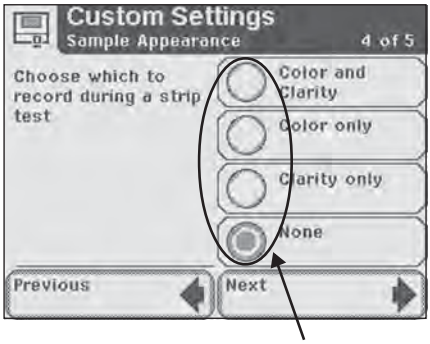
- Round Buttons
- Boxed Areas
- Scroll Arrows

⚠ Use of anything hard or pointed on the touch screen may cause damage.

Round Buttons

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

To change your selection, touch an unfilled circle. The newly selected circle (button) will now be highlighted. You then touch the **Next** button to move to the next screen.



Round Buttons

*In order to proceed, you will always touch the box with a right pointed arrow labeled **Next**.*

In order to go back, you will always touch the box with a left pointed arrow. These "back" option boxes vary in title.

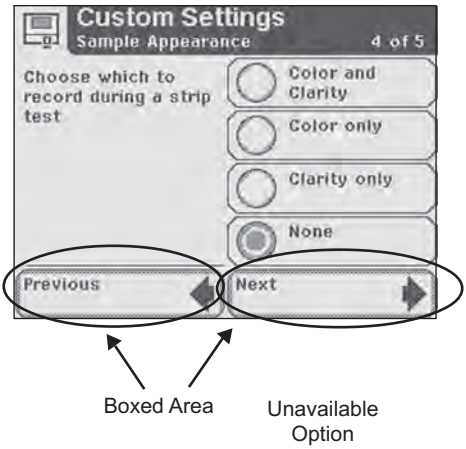
2 Interacting with the Touch Screen

Screens

Boxed Areas

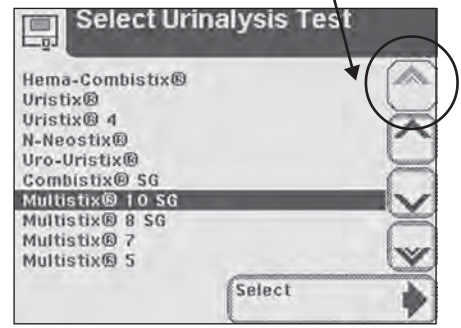
These are areas on the screen enclosed in boxes. Simply touch any area within the box to activate that function.

The boxed areas vary in size. The boxes located on the main ***Select*** screen are examples of larger areas. Smaller box selections include boxes such as the "Previous" and "Next" boxes found at the bottom of the screen.



Scroll Arrows

Press the up and down arrows on the right side of the screen to scroll through the list of information on the left side of the screen. Once the information on the left side of the screen is highlighted, touch the **Select** button to confirm your selection and move to the next screen.



If there are double arrows on the screen, these arrows (when touched) will take you to the top or bottom of the page.

When an option can be selected it will be shown with a thick black frame and will respond when touched. If an option is not available, it will be framed with a thin black line and not respond when touched.

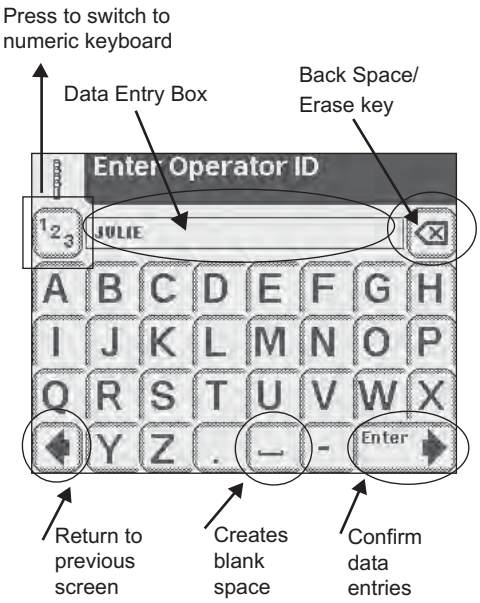
Keyboards

Using the Alpha-Numeric Keyboard

When the screen prompts you to enter information for Operator, Patient's Name and/or Patient Identification, a keyboard will appear on the screen.

Depending on how your analyzer is set up, either an alphabetic or numeric keyboard will be displayed first. The first keyboard displayed is referred to as "keyboard priority."

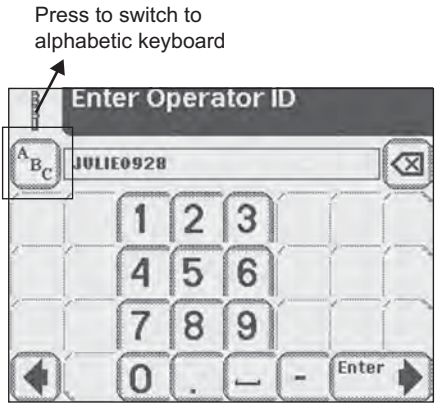
> *If you require further instruction regarding how to change keyboard priority see Section 5, Instrument Set Up.*



To switch between the keyboards, touch the **123** button to get to the numeric keyboard. Touch the **ABC** button to get to the alphabetic keyboard.

To type in a name, number, birth date, etc., touch the appropriate button. Your selections will appear in the data entry box.

If you switch between keyboards, all values will be retained in the data entry box on both keyboard screens.



The maximum number of characters allowed is 32. An audible tone will sound when you have exceeded the maximum number of characters.

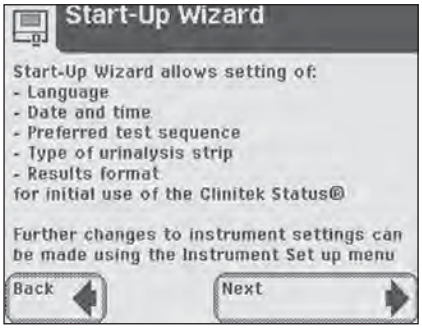
Once you have finished entering the information, touch **Enter** (from either keyboard screen).

3 Start-Up Wizard

The first time your Clinitek Status®+ analyzer is turned on (following an automatic system diagnostic test), it will take you through a quick set up procedure. This procedure will allow you to select the basic functions of the analyzer so you can use the analyzer with your choice of settings.

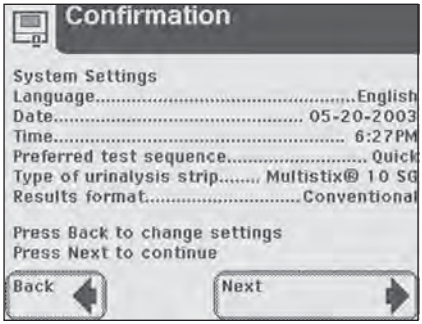
The ***Start-Up Wizard*** will allow you to select the following settings:

- Language
- Date and time
- Preferred test sequence (e.g., Quick Test or Full Test)
- Type of urinalysis strip
- Results format



If you require further instruction regarding how to change the settings see Section 5, Instrument Set Up.

Once you have selected your choices, the analyzer will display a ***Confirmation*** screen which allows you to check that your preferences are correct.



Quick Tests

Urinalysis Strip Test

BIOHAZARD Wear personal protective equipment. Use universal precautions. Refer to *Appendix H* for recommended precautions when working with biohazardous materials.

Testing is started from the main ***Select*** screen.

If you require more information regarding use and storage of test strips, please refer to the strip package insert.

Touch **Strip Test** to conduct a urinalysis strip test.

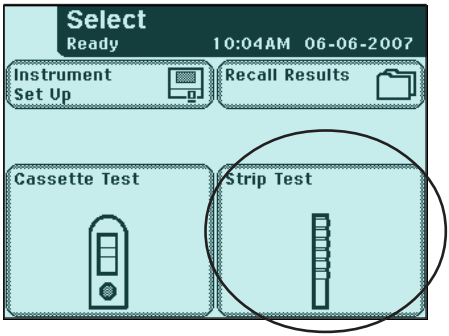
The next screen that appears is ***Prepare Test***.

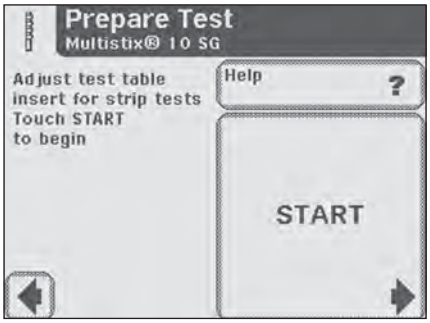
*If you would like the steps for urinalysis testing to be shown on the screen then touch **Help**.*

Make sure the test table insert has the reagent strip holder facing upward.

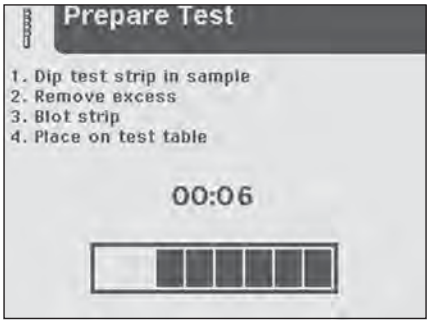
Also, have the test strip, urine sample and paper towel ready.

Touch the **START** button.





The next screen that appears is another ***Prepare Test***. This screen prompts you through the steps to prepare the test strip.



A timer displays how much time you have remaining to complete the steps.

You have 8 seconds to complete the following four steps:

1 Dip the reagent strip into the urine sample, wetting all pads. Immediately remove the strip from the urine.

NOTE: Do not dip the automatic identification band or color band in the urine sample.

2 Drag the edge of the strip against the side of the sample container as you remove it.

3 Blot by touching the edge of the strip to the paper towel to remove excess urine.

⚠ **Do not lay the pads on the paper towel or cover the pads by the paper towel.**

4 Place the reagent strip in the channel of the table with the test pads facing up. Slide strip to end of the channel.

At the end of the 8 second countdown, the test table and strip will automatically be pulled into the analyzer.

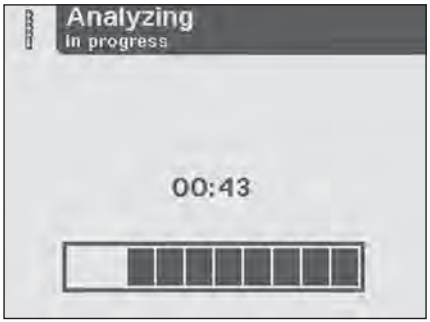
⚠ **Do not push or pull the test table.**

The Clinitek Status®+ analyzer will perform an automatic calibration each time a test is run.

⚠ **Be sure not to move or bump the table while the instrument is calibrating.**

NOTE: A warning message displays if you are not using a Siemens reagent strip. Press **OK** to continue. The Results may not display if you are using a non-Siemens reagent strip. Repeat the test using a Siemens reagent strip.

*The **Analyzing** screen will be displayed when the calibration has been completed and the analysis of the strip has begun.*



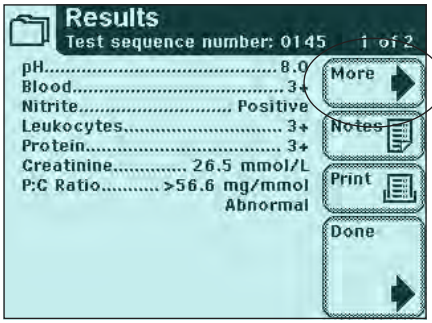
A timer will count down the time remaining in analyzing the strip results.

If the analyzer has been set up to automatically print the results, then the ***Printing*** screen will be displayed until the print out has been completed (otherwise the ***Results*** screen will appear).

The date, time and test sequence number will be printed along with the test results. “Not Entered” will be printed next to Color and Clarity.

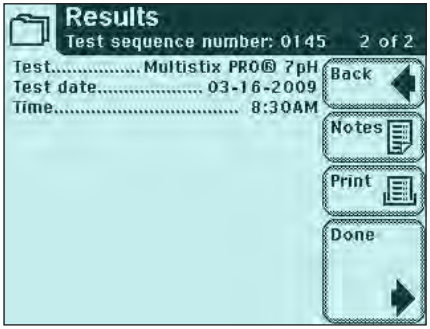
If the results are positive, an asterisk will appear next to the results (if “mark positive results” was selected in Instrument Set Up).*

The next screen displayed is the ***Results*** screen. The first page of the test results are displayed on the screen and the test table and strip are automatically pushed out of the analyzer.



To view the remaining test results, touch **More** on the screen.

If you are using reagent strips with a color strip or auto identification band, you can view Sample Interference notes about this test. From the **Results** screen, touch ***Notes***.



If Sample Interference notes are generated for this test, the Interference notes screen displays. Touch the up and down arrows to scroll through the notes. Touch ***Done*** to return to the main Results screen.

Up to 5 Sample Interference notes display on the screen. Use the up and down arrows to scroll through the notes. If enabled, the notes print with the test results.

If Sample Interference notes have been disabled in the setup, the NOTES button does not display.

NOTE: If you run a test with this feature disabled, no notes will be generated at the time of the actual test. If you enable the sample interface notes then recall the test results, the analyzer generates Sample Interference Notes for this patient test.

If the analyzer has not been set up to automatically print the test results, touch **Print** to have the results printed.

The results will automatically be sent to the connected PC if this option is set up in the analyzer.

> *If you require further instruction regarding how to set up the analyzer so the results are printed or sent to a computer automatically see Section 5, Instrument Set Up.*

From the test table, remove the used urinalysis strip and dispose of it according to your standard laboratory procedures. Wipe the table insert, if necessary.

Report the results to a laboratory supervisor or physician.

Touch **Done** to complete the test and return to main ***Select*** screen.

> *The results will be displayed on the screen for 2 minutes. After this time elapses, the display will return to main* ***Select*** *menu.*

Touch **Done** to return the Strip Test Prepare screen. You are ready to start the next test. If testing is complete, touch **Back** key to return to the ***Select*** menu.

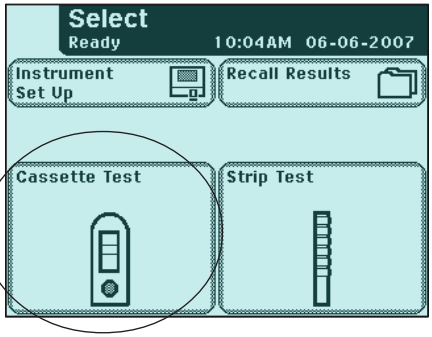
Cassette Test

BIOHAZARD Wear personal protective equipment. Use universal precautions. Refer to *Appendix H* for recommended precautions when working with biohazardous materials.

Testing is started from the main ***Select*** screen.

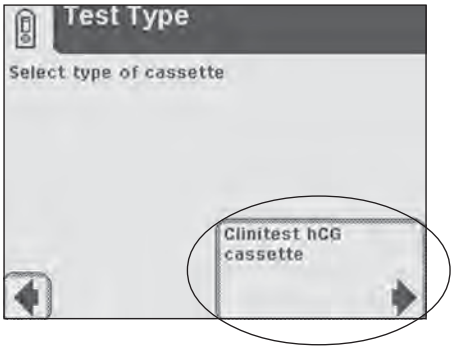
Please refer to the Clinitest® hCG cassette test package insert for more information regarding use and storage of test cassettes.

⚠ Bring the test cassette and patient sample to room temperature 20°C to 30°C (68°F to 86°F) prior to testing.



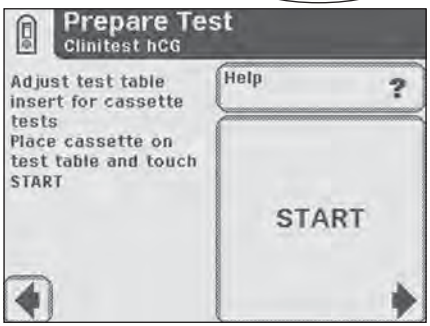
Touch **Cassette Test** to conduct the test.

The next screen that appears is ***Test Type***. Touch the **Clinitest hCG cassette** button.



The next screen that appears is ***Prepare Test*** screen.

*If you would like the steps for cassette testing to be shown on the screen then touch **Help**.*



Make sure the test table insert is in position for a cassette test.

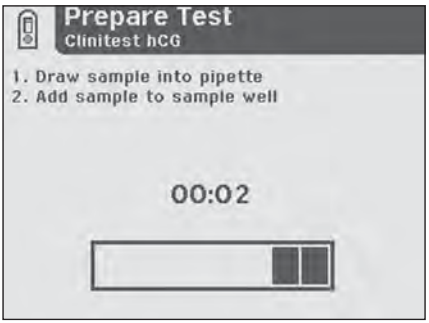
Remove the test cassette from the foil package and place the cassette on the test table.

> ⚠ **Once you touch the START button you have 8 seconds to draw the urine sample into the pipette and add the urine sample into the well on the cassette.**

Touch **START** button.

The next screen that appears is another ***Prepare Test***. This screen prompts you through the steps to prepare the cassette test.

A timer displays how much time you have remaining to complete the steps.



You have 8 seconds to complete the following two steps:

1 Draw the urine sample to the line marked on the pipette (approximately 0.2 mL).

2 Add entire contents of the pipette into the sample well of the test cassette.

At the end of the 8 second countdown, the test table and cassette will automatically be pulled into the instrument.

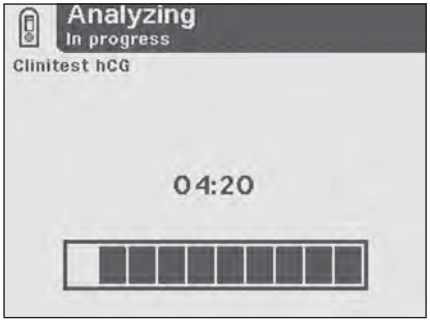
> ⚠ **Do not push or pull the test table**.

The Clinitek Status+ analyzer will perform an automatic calibration each time a test is run.

⚠ Be sure not to move or bump the table while the instrument is calibrating.

*The **Analyzing** screen will be displayed when the calibration has been completed and the analysis of the cassette has begun.*

A timer will count down the time remaining in analyzing the cassette results.



The Clinitest hCG test results are either negative, positive or borderline. The analyzer takes approximately 5 minutes to confirm a negative result. If the result is a clear positive, the analyzer will report it sooner. If the result is borderline, then you should retest, with a new sample, in 48 to 72 hours. Please refer to the Clinitest hCG cassette test package insert for complete instructions for use.

If the analyzer has been set up to automatically print the results, the ***Printing*** screen will be displayed until the print out has been completed (otherwise the ***Results*** screen will appear).

The date, time and test sequence number will be printed along with the test results.

The next screen displayed is the ***Results*** screen. The test results are displayed on the screen and the test table and cassette are pushed out of the analyzer.

The results will be printed automatically if this option is set up in the analyzer. If not, touch **Print** to print the results on the analyzer's printer.

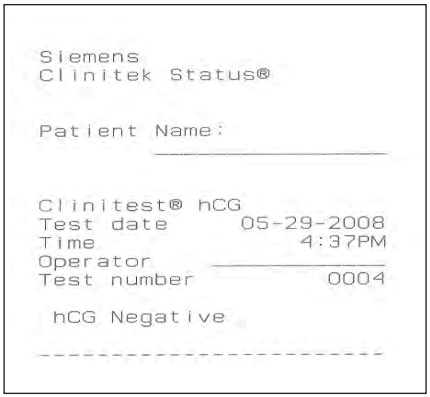
The results will automatically be sent to the connected PC if this option is set up in the analyzer.

If you require further instruction regarding how to set up the analyzer so results are automatically printed or sent to a computer see Section 5, Instrument Set Up.

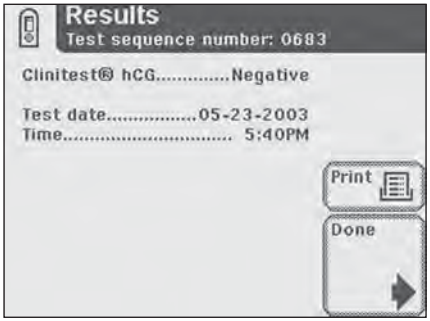
Remove the used cassette and dispose of it according to your standard laboratory procedures.

Report the results to a laboratory supervisor or physician.

Touch **Done** to complete the test and return to main ***Select*** screen.



If the result is positive, an asterisk will appear next to the result (if "mark positive results" was selected in Instrument Set Up).*



*The result will be displayed on the screen for 2 minutes. After this time elapses, the display will return to main **Select** menu.*

Full Tests

Urinalysis Strip Test

BIOHAZARD Wear personal protective equipment. Use universal precautions. Refer to *Appendix H* for recommended precautions when working with biohazardous materials.

A Full Strip Test allows you the option to enter an Operator Name, Patient Name and/or Patient ID prior to inserting a strip.

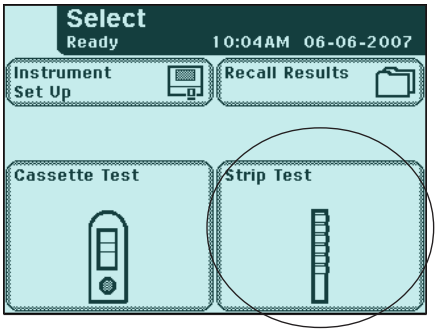
The procedures to enter the Operator and Patient data are presented in this section.

The strip testing process is identical to a Quick Strip Test.

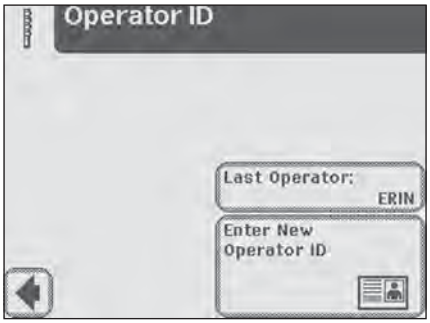
If you require further instruction regarding the procedures required for running a Siemens Healthcare Diagnostics urinalysis strip test see Section 4, Quick Tests.

Testing is started from the main ***Select*** screen.

Touch **Strip Test** to conduct a Siemens urinalysis strip test.



The next screen that appears is ***Operator Name***.



There are two options under Operator Name: **Last Operator** or **Enter New Operator Name.**

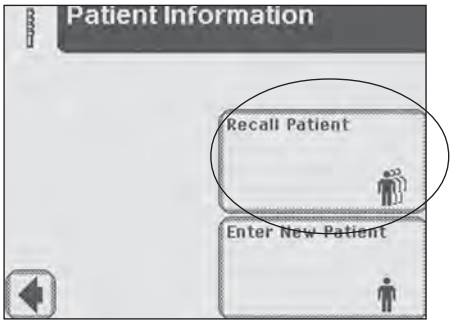
Option 1: Last Operator
If this option is enabled, the last operator that entered his/her Name will be displayed on the screen in the lower right side of the box. If you are this operator, then touch the **Last Operator** button to proceed.

Option 2: Enter New Operator Name
In order to enter the information for a new operator, touch **Enter New Operator Name** button. The next screen that is displayed is ***Enter Operator Name***.

Use the keyboards to enter Operator Name using a maximum of 13 characters. Touch **Enter** when you have finished entering the Name and to move to the next screen.

> *If you require further instruction regarding keyboard usage see Section 2, Interacting with the Touch Screen.*

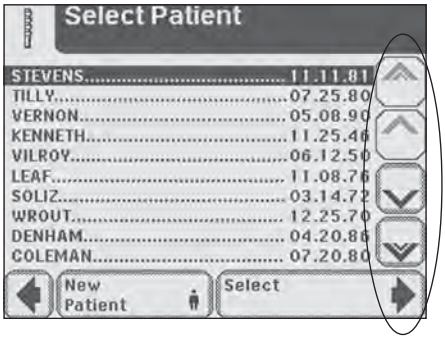
The next screen displayed is ***Patient Information.***



There are two options under Patient Information: **Recall Patient** or **Enter New Patient**.

Option 1: Recall Patient
In order to look up previous patients, touch **Recall Patient**.

If previous patient identification has been entered, a list of up to 950 patient results will appear on the screen. Use the up and down arrow buttons to scroll through the list of patients. The most recently performed test will be shown at the top. Once the patient is highlighted, touch **Select** button.



The next screen will be ***Prepare Test***.

A total of 950 patient tests can be stored in the analyzer. The tests are listed in chronological order. When the limit of 950 has been reached, the oldest test will be deleted from the analyzer. Deleted information cannot be retrieved from the analyzer.

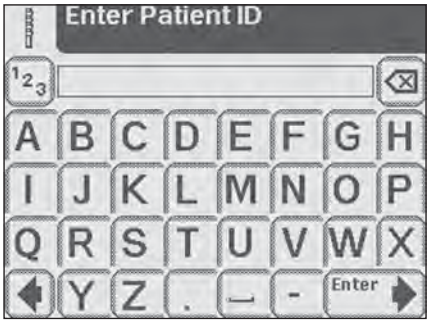
Option 2: Enter New Patient

In order to enter the information for a new patient, touch **Enter New Patient** button. The next screen displayed is ***Enter Patient Name***.

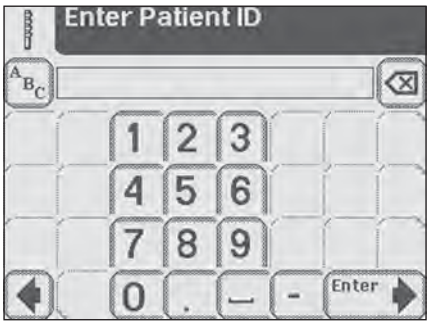
Use the keyboards to enter Patient Name using a maximum of 20 characters. Touch **Enter** when you have finished entering the patient's name and to proceed to the next screen.

If you require further instruction regarding keyboard usage see Section 2, Interacting with the Touch Screen.

The next screen displayed is ***Patient Identification***. Use the keyboards to enter Patient Identification using a maximum of 13 characters. Touch **Enter** when you have finished entering the patient's ID and to proceed to the next screen.



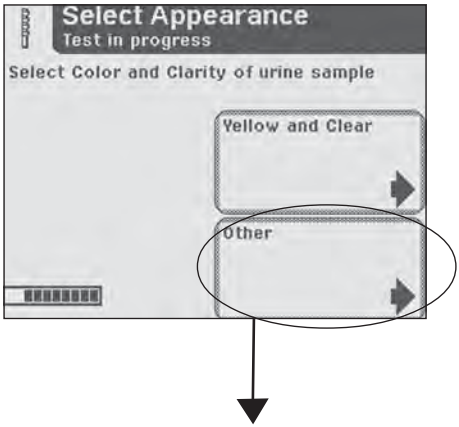
If you require further instruction regarding keyboard usage see Section 2, Interacting with the Touch Screen.



The next screen that appears is ***Prepare Test***.

> *If you require further instruction regarding the procedures for running a Siemens urinalysis strip test see Section 4, Quick Tests.*

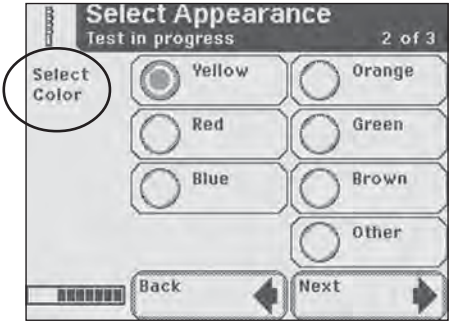
While the strip is being analyzed, a ***Select Appearance*** screen will be displayed. The urine sample must be visually observed and then the appropriate color and clarity must be selected.



If the urine sample is yellow and clear, touch the **Yellow and Clear** button.

If the urine sample is not yellow and clear, touch the **Other** button for more choices.

If you touched the **Other** button, select the appropriate color by touching the circle button that corresponds to the correct description.



NOTE: You can select only one color for a urine sample.

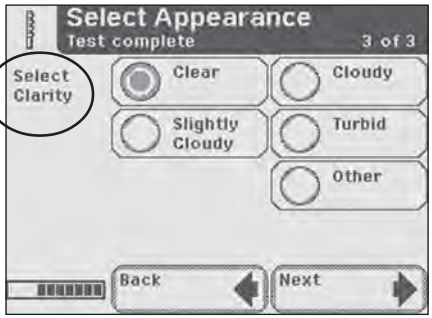
Select the clarity by touching the circle that corresponds to the correct description. Then touch **Next**.

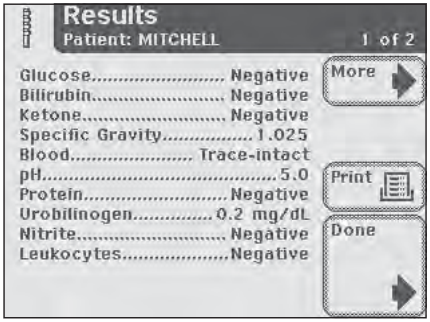
There is a time indicator on the ***Select Appearance*** screen that is counting down the time remaining in the analysis of the strip.

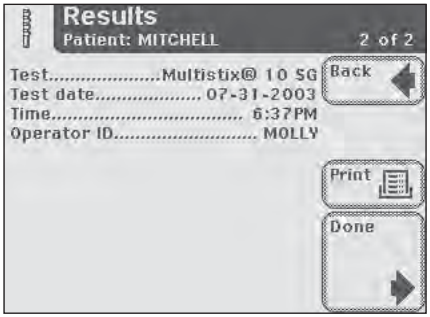
After color and clarity have been entered the next screen displayed will either be:

Analyzing – if the strip is still being analyzed

Results – if analyzing the strip has been completed







Entering the Strip Lot Number and Expiration Date

To enter strip lot information for a second strip test, perform the following steps:

1. At the *Select* screen, touch **Strip Test**.
   The *Strip* screen displays.
2. To use the last strip number and begin the test, touch **Use Last Lot**.
   To enter new strip data, touch **Enter new lot and expiration**.
   The *Strip Lot* screen displays.
3. Enter the strip lot number.
   Use the alpha keyboard to enter text.
   To enter numeric text, touch **123**.
4. Select **Enter**.
   The *Strip Expiration* screen displays.
5. Use the arrow keys to indicate the strip expiration date.
6. Touch **Enter**.
   The *Prepare Test* screen displays.
7. Touch **Start**.
   See above.

4 Testing

Full Tests

The test results displayed on the screen and the printout will include the following information:

- Patient Name, ID or both
- Type of strip used
- Test date
- Time
- Operator
- Test Number
- Color
- Clarity
- Results
- Sample Interference Notes

If the results are positive, an asterisk will appear next to the results (if "mark positive results" was selected in Instrument Set Up).*

Cassette Test

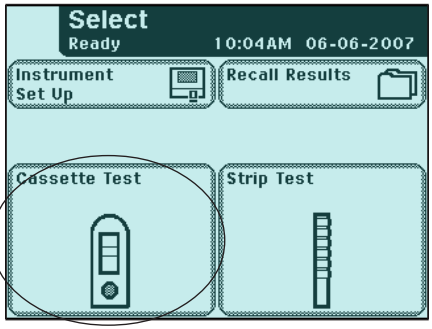
BIOHAZARD Wear personal protective equipment. Use universal precautions. Refer to *Appendix H* for recommended precautions when working with biohazardous materials.

A Full Cassette Test allows you the option to enter an Operator, Patient Name and/or Patient ID prior to inserting a cassette.

The procedures to enter the Operator and Patient data are presented in this section.

The cassette testing process is identical to a Quick Cassette Test.

> *If you require further instruction regarding the procedures for running a Siemens Clinitest immunoassay test see Section 4, Quick Tests.*

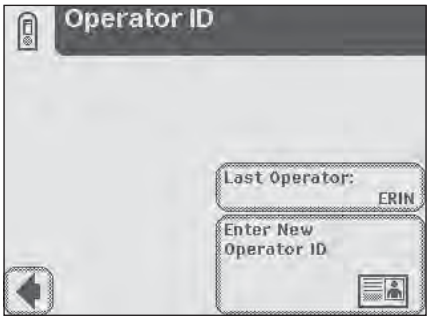


Testing is started from the main ***Select*** screen.

Touch **Cassette Test** to conduct an hCG pregnancy test.

The next screen that appears is ***Operator Name***.

There are two options under Operator Name: **Last Operator** or **Enter New Operator Name.**



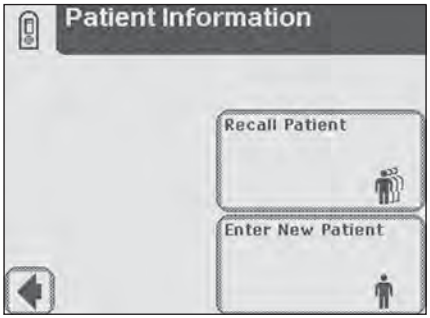
Option 1: Last Operator
If this option is enabled, the last operator that entered his/her Name will be displayed on the screen in the lower right side of the box. If you are this operator, then touch the **Last Operator** button to proceed.

Option 2: Enter New Operator Name
In order to enter the information for a new operator, touch **Enter New Operator Name** button. The next screen that is displayed is ***Enter Operator Name***.

Use the keyboards to enter Operator Name using a maximum of 13 characters. Touch **Enter** when you have finished entering the name and to move to the next screen.

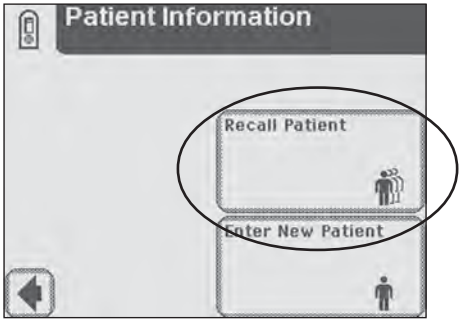
> *If you require further instruction regarding keyboard usage see Section 2, Interacting with the Touch Screen.*

The next screen displayed is ***Patient Information.***

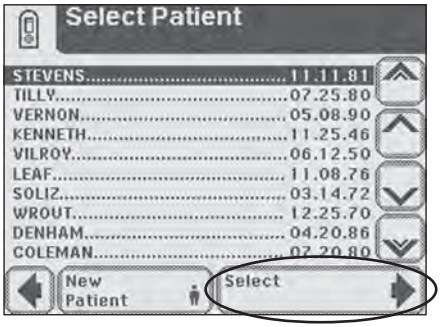


There are two options under Patient Information: **Recall Patient** or **Enter New Patient**.

Option 1: Recall Patient
In order to look up previous patients, touch **Recall Patient**.



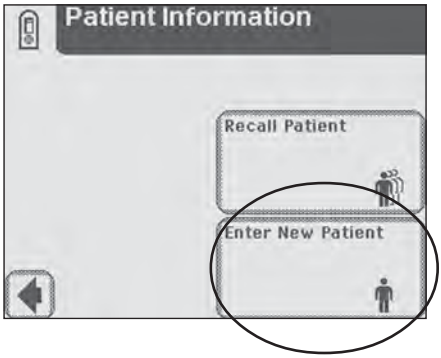
If the previous patient identification has been entered, a list of up to 950 patients will appear on the screen. Use the up and down arrow buttons to scroll through the list of patients. The most recently performed test will be shown at the top. Once the patient is highlighted, touch the **Select** button. The next screen will be ***Test Type***.



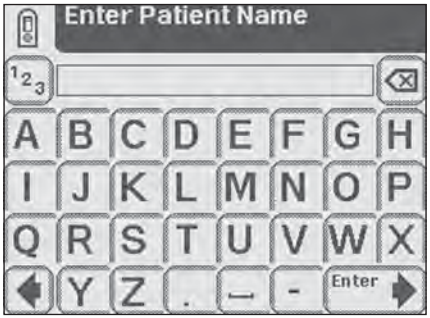
A total of 950 patient tests can be stored in the analyzer. The tests are listed in chronological order. When the limit of 950 has been reached, the oldest test will be deleted from the analyzer. Deleted information cannot be retrieved from the analyzer.

Option 2: Enter New Patient

In order to enter the information for a new patient, touch the **Enter New Patient** button. The next screen displayed is ***Enter Patient Name***.

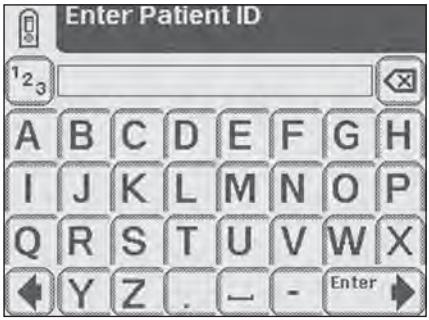


Use the keyboards to enter Patient Name using a maximum of 20 characters. Touch **Enter** when you have finished entering the patient's name and to move to the next screen.

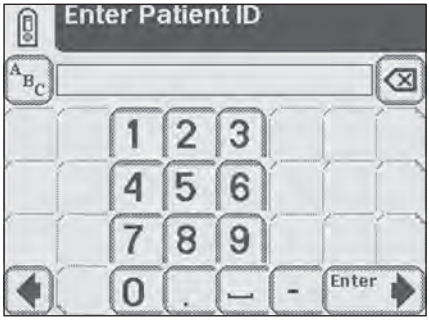


If you require further instruction regarding keyboard usage see Section 2, Interacting with the Touch Screen.

The next screen displayed is ***Enter Patient ID***. Use the keyboards to enter Patient Identification using a maximum of 13 characters. Touch **Enter** when you have finished entering the patient's ID and are ready to proceed to the next screen.

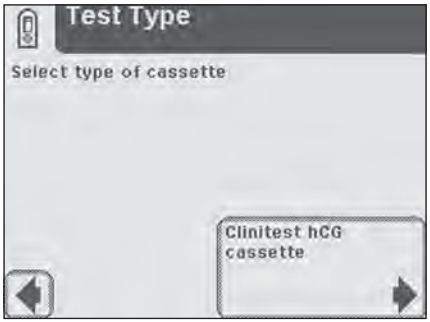


If you require further instruction regarding keyboard usage see Section 2, Interacting with the Touch Screen.



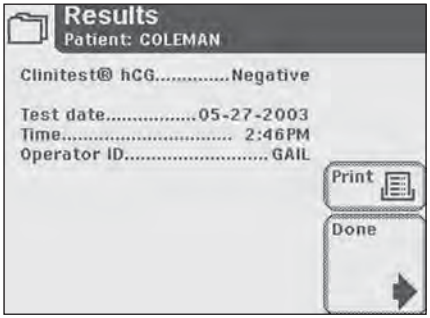
The next screen that appears is ***Test Type***.

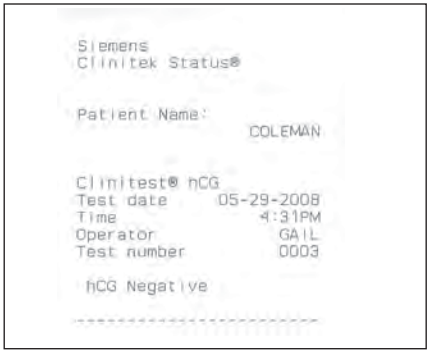
If you require further instruction regarding the procedures for running a Clinitest hCG cassette test see Section 4, Quick Tests.



The test results displayed on the screen and the printout will include the following information:

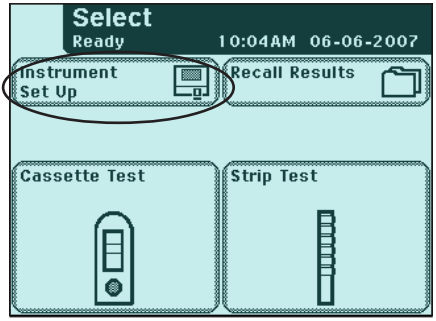
- Patient Name, ID or both
- Type of Clinitest cassette test Test date
- Time
- Operator
- Test Number
- Result





If the result is positive, an asterisk will appear next to the result (if "mark positive results" was selected in Instrument Set Up).*

Instrument Set Up



Your Clinitek Status®+ analyzer allows you to change settings to suit your workplace requirements.

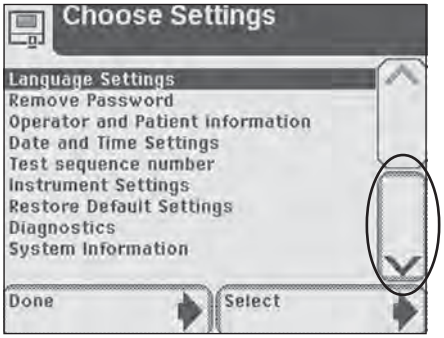
> *If no customizing is desired, the analyzer will automatically be programmed with default settings (to view default settings please see Appendix D: Instrument Default Settings).*

Touch **Instrument Set Up** in order to initiate changing the settings.

If a password has been set, the ***Enter Password*** screen will be displayed. Enter the password into the data entry box. The characters you enter will be displayed as asterisks.

Touch **Enter** to proceed to a list of settings.

Settings
Use the up and down arrows to scroll through the ***Choose Settings*** screen.

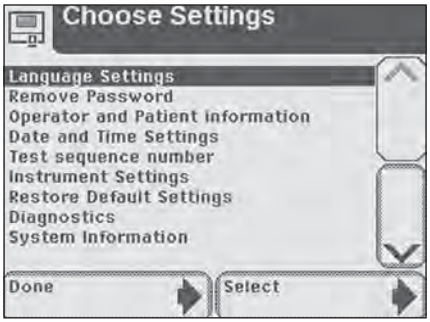


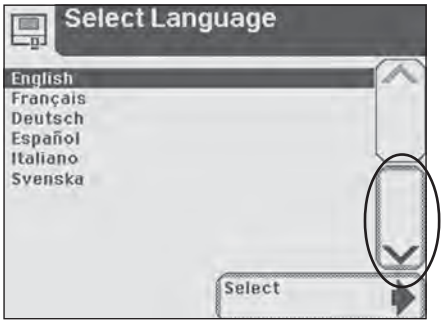
Touch **Select** when you have highlighted the setting you want to change.

Touch **Done** to return to the main ***Select*** screen.

Language Settings

Use the up and down arrows to scroll through the list of languages. Touch **Select** when you have highlighted the desired language.





Before changing the language an alert screen will be displayed requesting you to confirm your decision.

Touch **No** to continue with same language and retain current settings. The display will return to ***Choose Settings***.

Touch **Yes** to change the language.

⚠ **Changing the language will…**

- **delete all results from the memory.**
- **change the instrument settings to the defaults for the new language (default settings are listed in Appendix D: Instrument Default Settings).**

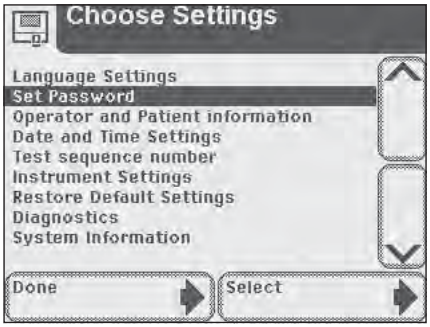
Password

> *When a password has been set, no changes can be made to the **Instrument Set Up** until the password has been entered.*

Set Password

Enter a password into the data entry box using the alphabetic and/ or numeric keyboards (maximum 12 characters).

> *Keep a record of the password to be sure to have access to **Instrument Set Up** when required.*



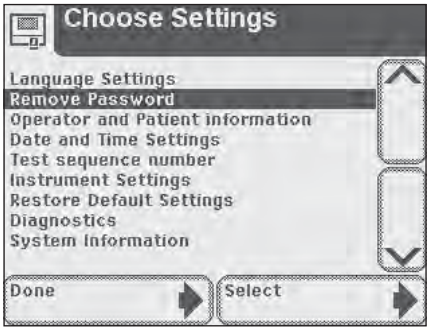
Touch **Enter** to confirm the password and return to ***Choose Settings***.

Touch **Done** to return to main ***Select*** screen.

Remove Password

Once a password has been entered the option will change from **Set Password** to **Remove Password**.

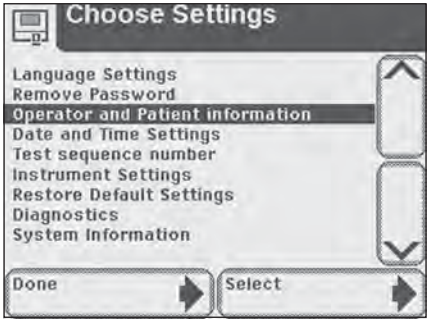
Highlight the **Remove Password** option and touch **Select**. The option displayed will change to **Set Password** and a password will no longer be needed to access **Instrument Set Up.**



Touch **Done** to return to the ***Select*** Menu.

Operator and Patient Information

Selecting this option will allow you to choose display options for data entry.

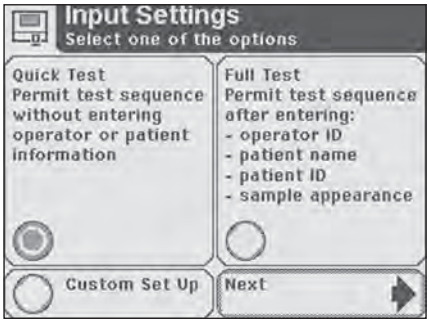


The ***Input Settings*** screen allows you to select 1 of 3 test sequences.

Quick Test
A test without any operator or patient information required. The test will be identified by a sequential test number when the results are displayed or printed.

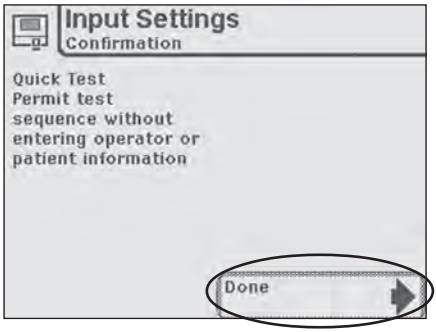
Full Test
The operator will be prompted to enter the following data during testing:

- Operator Name
- Patient's Name
- Patient Identification
- Sample Appearance (Color and Clarity) of urine sample, when testing with a urinalysis strip.



Custom Set Up
This allows you to customize the data to be entered when conducting a test.

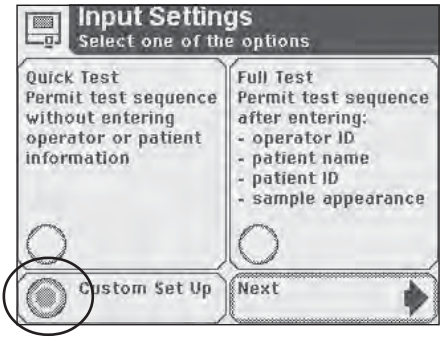
On the ***Input Settings*** screen, touch a round button in the box of the preferred test sequence. Then touch **Next** for test sequence confirmation.



Touch **Done** on the ***Input Settings*** screen to return to the ***Choose Settings*** screen.

Custom Settings

Touch the round button in the **Custom Set Up** box to customize selections for data entry. Touch **Next**.



The next 5 screens present choices for customizing your testing.

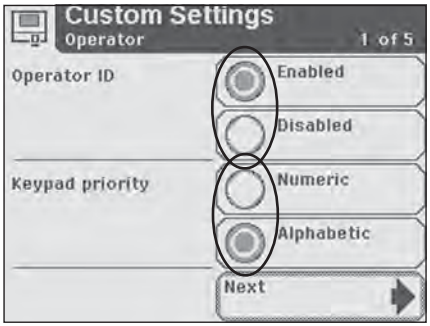
Choose settings by touching and highlighting a round button for each category.

Proceed through all 5 screens by touching **Next** at the bottom of each screen.

<u>Screen 1 of 5</u>

Operator Name – allows you to choose whether Operator Name will be required for running a test – **Enabled** (on) or **Disabled** (off).

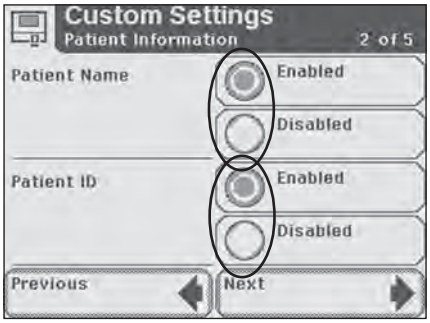
Keypad priority – allows you to select either the **Numeric** or **Alphabetic** keyboard to be presented as the first keyboard during data entry.



Screen 2 of 5

Patient Name – allows you to choose whether patient name will be required for running a test – **Enabled** (on) or **Disabled** (off).

Patient ID – allows you to choose whether Patient ID will be required for running a test – **Enabled** (on) or **Disabled** (off).

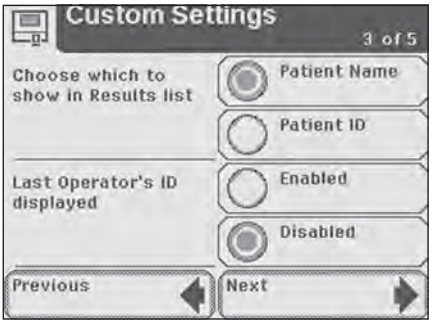


A total of 950 patient records can be stored in the analyzer. When the limit of 950 has been reached, the oldest test will be deleted from the analyzer. Deleted information cannot be retrieved from the analyzer. If Patient's Name and Patient ID are both disabled, a sequential test number will be shown with the test results.

Screen 3 of 5

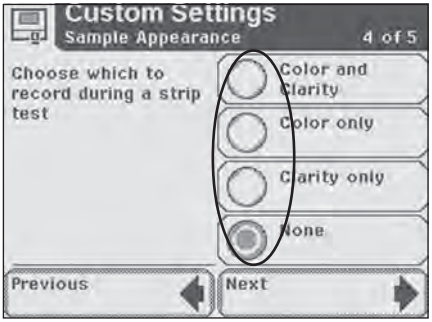
Choose which to show in Results list – allows you to choose whether **Patient Name** or **Patient ID** will be included in the list of results.

Last Operator's Name displayed – allows you to choose whether a "Select Last Operator" option is available to the user when you are prompted to enter an Operator Name during Strip or Cassette Testing – **Enabled** (on) or **Disabled** (off).



Screen 4 of 5

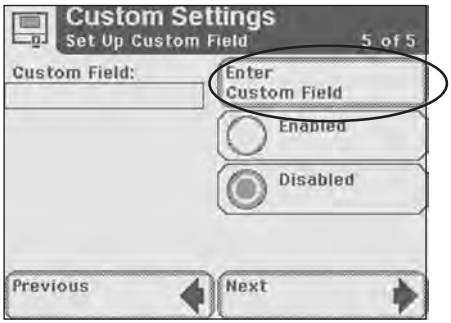
Choose which to record during a strip test – allows you to select which sample details you would like to be recorded during a strip test – **Color and Clarity, Color only, Clarity only** or **None** (no sample information).



Screen 5 of 5

Custom Field – allows you to name the custom field in order to customize data entry.

To name the custom field, touch the **Enter Custom Field** box.



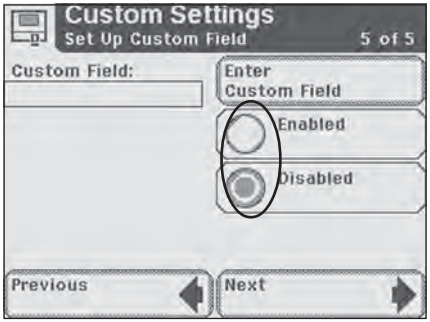
The next screen displayed is ***Enter Custom Field***. Use the keyboards to enter a custom field (e.g., Physician Name). Touch **Enter** to return to the ***Custom Settings*** screen.

If you require further instruction regarding keyboard usage see Section 2, Interacting with the Touch Screen.

Touch the round button next to **Enabled** (on) to highlight and activate this custom setting.

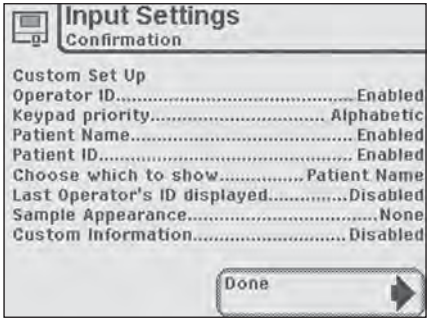
Touch the round button next to **Disabled** (off) to deactivate the custom setting.

Touch **Previous** to scroll back through custom setting screens to review.



Touch **Next** to proceed to the ***Input Settings*** screen which will provide a list of the selections made in **Custom Set Up**.

Touch **Done** to confirm and return to the ***Choose Settings*** screen.



Managing Urine Colors

The following sections describe how to customize and set urine color choices and urine clarity for Siemens strip tests. When you print patient test results, you can include urine color, clarity, or color and clarity in the printout. Urine color and clarity are optional; you can choose not to print these parameters. Urine color and clarity are available only in Full Test or Custom mode.

Setting and Customizing Urine Colors

You can choose from one of 10 instrument-provided colors and add up to 4 customized colors to patient test results.
To include instrument-provided colors, perform the following steps:

1. At the *Select* screen, touch **Instrument Set Up**.
   The *Choose Settings* screen displays.
2. Use the arrow keys to select **Operator and Patient information**.
3. Touch **Select**.
   The *Input Settings* screen displays.
4. Touch **Custom Set Up**.
5. Touch **Next**.
   The *Custom Settings-Operator* screen 1 of 5 displays.
6. Touch **Next** 3 times.
   The *Custom Settings-Sample Appearance* screen 4 of 5 displays.

7. Touch **Edit colors**.
   The *Sample Appearance-Select colors* screen 1 of 3 displays.
8. To choose colors, touch the button for the color you want.
   To remove a selected color, touch that color button again.
9. Touch **Next**.
   The *Sample Appearance-Select colors* screen 2 of 3 displays.
10. To choose colors, touch the button for the color you want.
11. Touch **Next**.
    The *Sample Appearance-Select colors* screen 3 of 3 displays.
12. Touch **Next** 3 times.
    The *Input Settings-Confirmation* screen displays.
13. Touch **Done** twice to return to the *Select* screen.

Adding Customized Colors

To enter up to 4 custom colors, perform the following steps:

1. At the *Sample Appearance-Select colors* screen 3 of 3, touch **Enter custom color 1** (**2**, **3**, or **4**) corresponding to each custom color.
2. Enter the custom color.
   Use the alpha keyboard to enter text.
   To enter numeric text, touch **123**.

NOTE: The maximum number of characters for each color is 10.

3. Touch **Enter**.
   The *Sample Appearance-Select colors* screen 3 of 3 displays.

⚠ CAUTION
Do not edit a custom color that already exists because doing so deletes all patient records stored on the system.

   If a custom color exists, the *Sample Appearance* screen displays.
   Touch **Yes**, to edit that custom color and delete all records.
   Touch **No**, to return to the *Sample Appearance Select Colors* screen 3 of 3.
4. Touch **Next** 3 times.
   The *Input Settings-Confirmation* screen displays.
5. Touch **Done** twice to return to the *Select* screen.

Managing Strip Lot Number and Expiration Date

You can enter the strip lot number and expiration date and associate this information with each patient record. Once entered, the information is retained for the next test, or you can enter a new lot number and expiration date.
You can set the instrument to prompt for new strip information or use the information from the last strip before each patient test.

Setting Strip Information Prompt

To set the prompt for strip information, perform the following steps:

1. At the *Select* screen, touch **Instrument Set Up**.
   The *Choose Settings* screen displays.
2. Use the arrow keys to select **Instrument Settings**.
3. Touch **Enter**.
   The *Instrument Settings* screen displays.
4. Use the arrow keys to select **Urinalysis Test Settings**.
5. Touch **Select**.
   The *Urinalysis Test Settings* screen displays.
6. Touch **Next**.
   The *Urinalysis Test* screen displays.
7. To prompt for strip information before each test, touch **Enabled**.
   To bypass a prompt to enter strip information before each test, touch **Disabled**.
8. Touch **Done** 3 times to return to the Select screen.

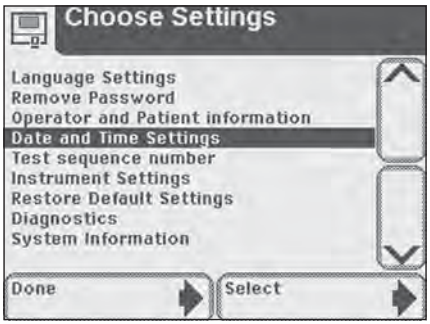
Date and Time Settings

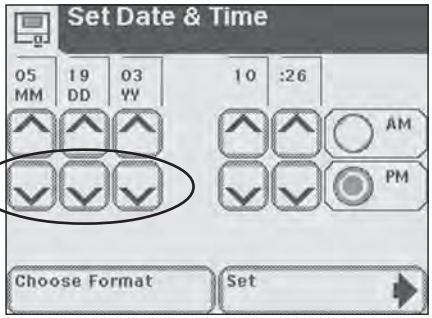
The date and time are displayed on the ***Select*** screen and are recorded with test results.

The format of the date and time are displayed along with specific date and time values.

If the date and time values are incorrect, use the up and down arrow buttons to adjust the date and time to the correct values. Touch **AM** or **PM** if you are in the 12-hour time format. Touch **Set** to confirm your choices and move to the next screen.

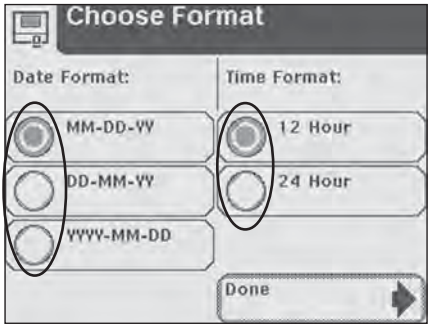
If the format is not correct for your workplace, for example, you prefer DD-MM-YY to MM-DD-YY or 24-hour clock to 12-hour clock, touch **Choose Format.**





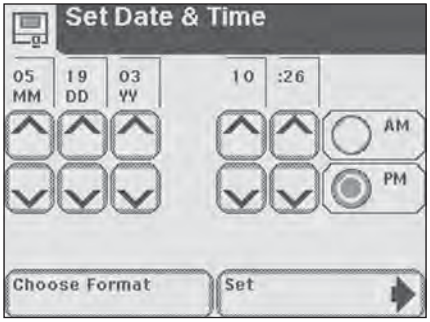
The next screen displayed is ***Choose Format***. Touch the round button that corresponds to your choice of a date format and a time format. Touch **Done** to return to ***Set Date & Time.***

If the date and time are in the format which you need, select **Done**.



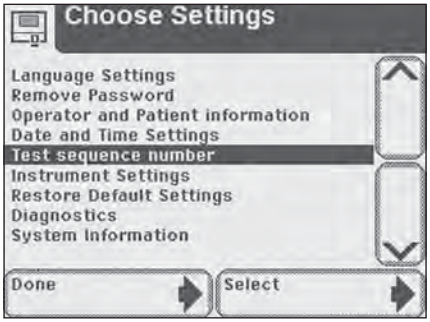
*The **AM** and **PM** selections will not be available if the time is in the 24 hour format.*

The ***Set Date & Time*** display will show the date and time in the formats selected. Select **Set** to confirm your choices and return to the ***Choose Settings*** screen.



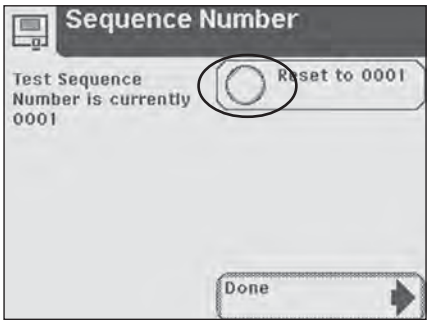
Test Sequence Number

The test sequence numbers run from 0001 to 9999 and can be reset. The screen shows the next test number.



Touch the **Reset to 0001** round button if you would like to reset the numbers to start at 0001 for the next test.

Touch **Done** to confirm the reset or to leave the screen if you have not selected the option to reset the number. You will return to the ***Choose Settings*** screen.



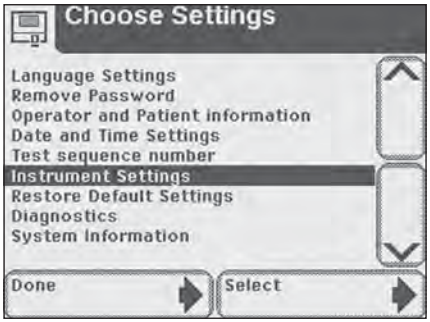
Instrument Settings

This section has a series of screens which control the way in which the Clinitek Status+ analyzer displays information and operates.

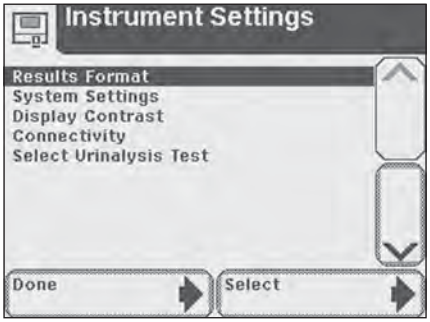
There are 8 Instrument Setting items.

- Results Format
- System Settings
- Display Contrast
- Connectivity
- Select Urinalysis Test
- Authorized Operator
- Printer Settings
- QC Settings

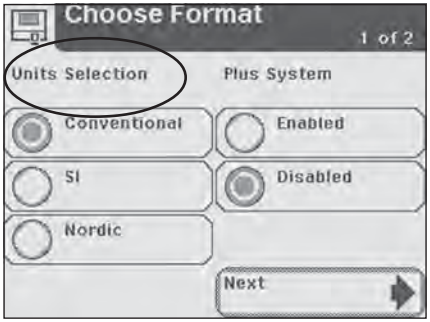
Use the up and down arrows to highlight a setting item and touch **Select.**



Results Format
This allows you to select the format in which you would like the results to be displayed and printed.

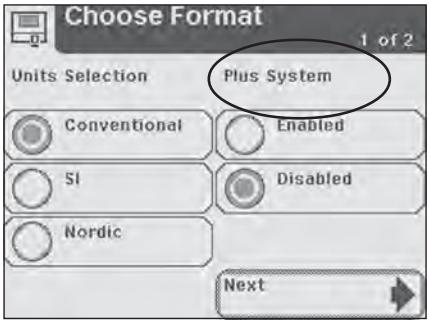


Choose Format
Screen 1 of 2
Units Selection – allows you to select the format in which you would like results by touching the round button next to the appropriate type of format.



NOTE: Nordic units are only available in English and Swedish. If you set the language to Chinese, this screen does not display, as only SI units are available in Chinese.

Plus System – select **Enabled** (on) if you wish to have results shown in the Plus System. You will also see in Appendix B that results can be recorded in the Plus System (which uses "+" symbols) instead of clinical units such as mg/dL (mmol/L). In some languages there is no difference between the normal system and the Plus System.



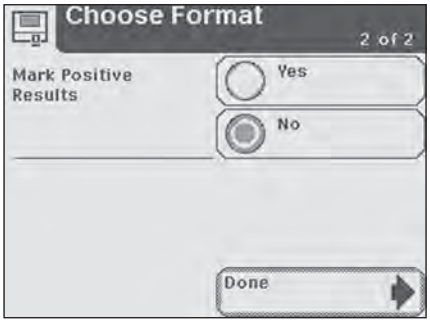
Screen 2 of 2

Mark Positive Results – allows you to choose whether positive results should be marked with an asterisk (see Appendix B for results to be shown as positive).

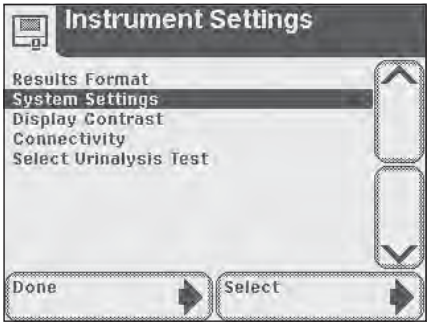
Touch the round button next to **Yes** to mark and record positive results. These will be marked on the display, on a printout and when the data is transferred to a host computer.

Touch **No** and positive results will not be marked.

Touch **Done** to enter your choice and return to ***Instrument Settings***.



System Settings
This allows selections regarding the printer, power and sound.

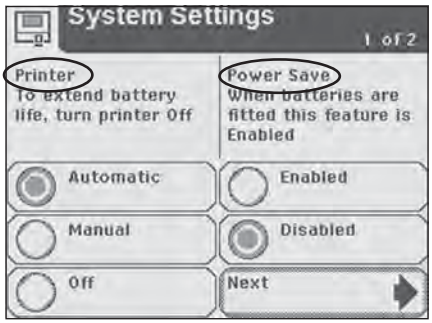


System Settings
Screen 1 of 2
Printer – allows you to select the preferred printing option by touching the round button.

Automatic – Results for each test will be printed automatically when the test is complete.

Manual – Test results will not be printed automatically. They can be printed by touching the **Print** selection area on the ***Results*** screen.

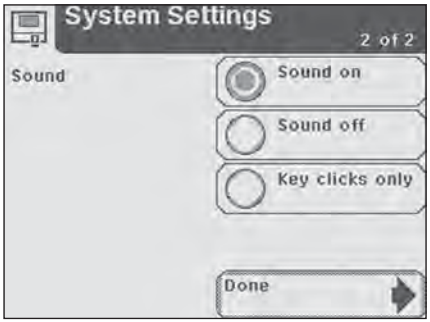
Off – Test results will not be printed.



Power Save – allows you to enable and disable this feature. If the instrument is powered from an electrical outlet and is not used for 5 minutes, you may choose to have the test table retract and the instrument power down. When it is powered by batteries, Power Save is always enabled and it will power down after 5 minutes of non-use. Touch the **Enabled** (on) to activate or **Disabled** (off) if the Power Save mode is not desired.

Screen 2 of 2

Sound – allows you to adjust the sound by highlighting and selecting a level.



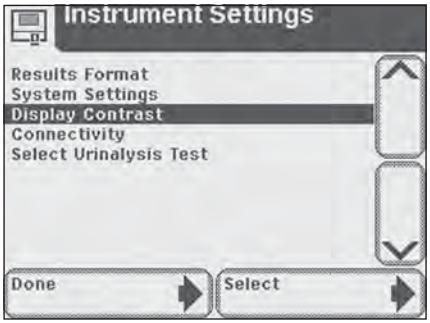
Sound on – The instrument will use a range of audible tones.

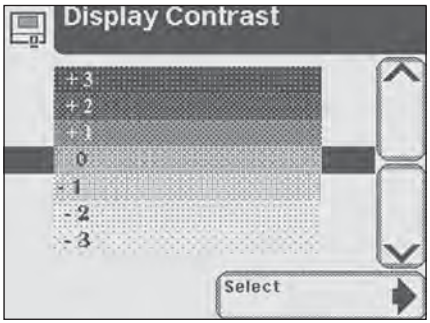
Sound off – No audible tones will be made by the instrument.

Key clicks only – Audible clicks will be heard when the user touches an active button or key.

Display Contrast

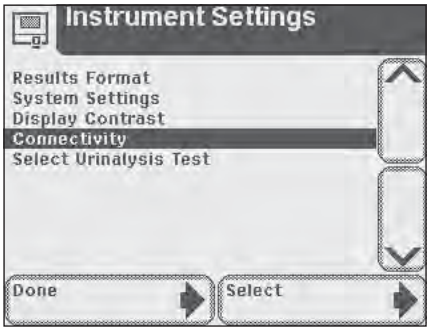
This allows the contrast of the display to be increased or decreased to suit the work area in which it is being operated. Use the up and down arrows to sample the contrast settings and touch **Select** to set and return to the ***Instrument Settings*** screen.





Connectivity

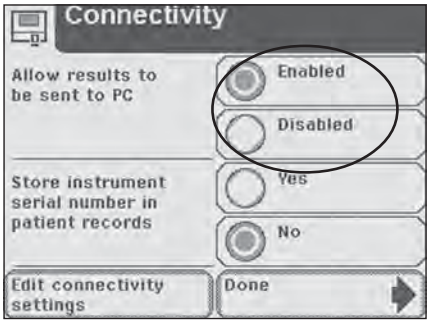
You can connect the instrument to a PC or host computer, or, if you have a Clinitek Status connector, to an LIS using an Ethernet or wireless network. If you are using the connector, refer to the *Clinitek Status Connect System Operator's Guide* for more information.



Allow results to be sent to PC

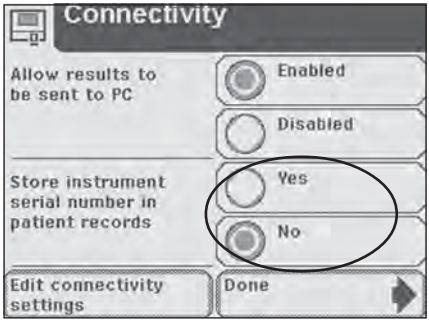
If enabled, the system automatically sends both new and recalled patient tests to a host or LIS.

To automatically send new and recalled patient results to the LIS or a PC directly connected to the system, touch **Enabled**.To prevent sending new and recalled patient results to the LIS or PC, touch **Disabled**.



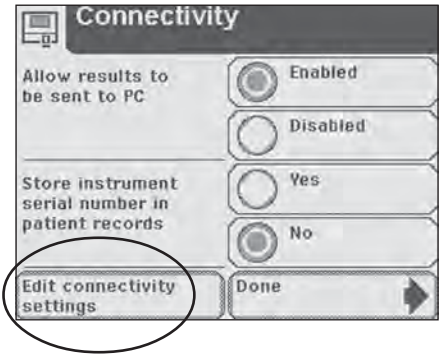
NOTE: If there is no connector, Siemens recommends setting the connector to Disabled setting. Setting the connector to the Enabled setting without a connector may prevent communication with an external system.

Store instrument serial number in patient records
Touch round button of either **Yes** or **No** depending on whether you choose to include the serial number of your Clinitek Status+ analyzer as part of the patient results sent to the computer**.**

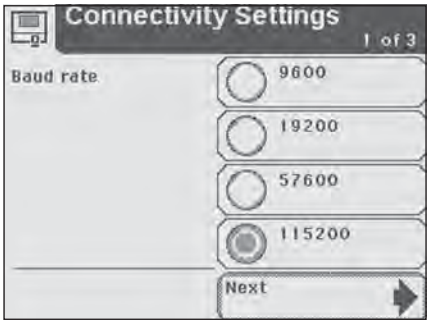


If you have enabled the upload capability, you will need to ensure that the connectivity settings are correct for the data transfer.

Touch **Edit Connectivity Settings** and a series of 3 screens for ***Connectivity Settings*** will allow you to edit the settings.

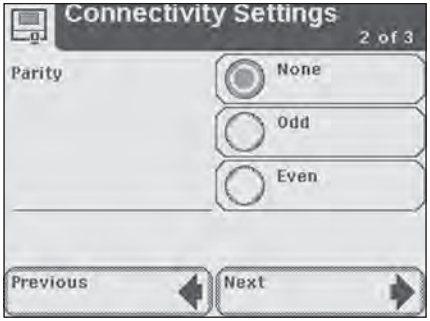


Connectivity Settings
Screen 1 of 3
Baud rate – Touch a round button to select the correct Baud rate and **Next** to move to the next screen.



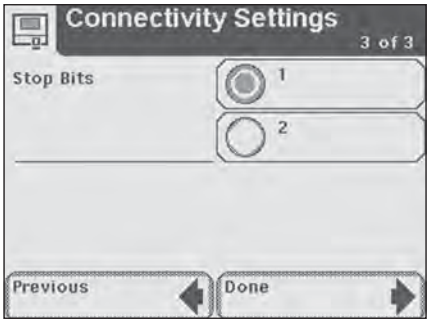
Screen 2 of 3

Parity rate – Touch a round button to select the correct Parity rate and **Next** to move to the next screen.



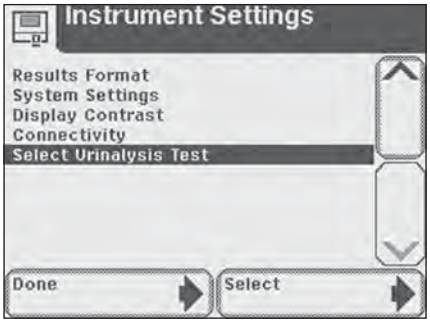
Screen 3 of 3

Stop Bits – Touch a round button to select the number of Stop Bits.

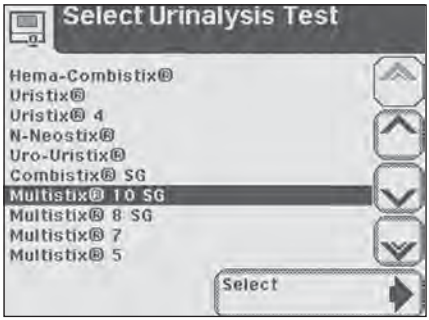


Select Urinalysis Test

This displays a list of some of the Siemens Healthcare Diagnostics urinalysis strips which can be used with the Clinitek Status+ analyzer.



Use the up and down arrows to scroll through the list until the type of strip you want to use is highlighted. Touch **Select** to confirm and return to the ***Instrument Settings*** screen.

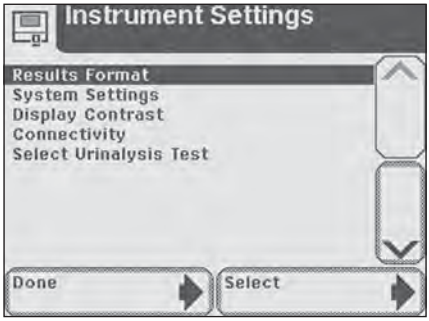


⚠ **Do not use any reagent strip product other than what is shown on the display. Using the wrong Reagent Strip will give you incorrect results.**

Some strips do not appear on the list (e.g., Clinitek® Microalbumin 2). The analyzer will automatically identify them through the color ID band on the strip.

*You do not need to select a type of Clinitest® immunoassay cassette within **Instrument Set Up**.*

Touch **Done** repeatedly to return to the main ***Select*** screen.



Edit Reported Chemistries

This section describes how to include or exclude urinalysis tests from the reported results. Tests include GLU, BIL, KET, SG, BLO, pH, PRO, URO, NIT, LEU, ALB, and CRE. The default is all tests are reported and the button is filled.

To set up tests for urinalysis, perform the following steps:

1. At the *Select Ready* screen, touch **Instrument Set Up**.
   The *Choose Settings* screen displays.
2. Use the arrow keys to select **Instrument Settings**.
3. Touch **Select**.
   The *Instrument Settings* screen displays.
4. Use the arrow keys to select **Urinalysis Test Settings**.
5. Touch **Select**.
   The *Urinalysis Test* screen displays.
6. Touch **Edit reported chemistries**.
   The *Reported Chemistries* screen 1 of 2 displays.
7. To remove a selected test from reported results, touch the button for that test.
   To include a test in reported results, touch that test's button again.
8. Touch **Next** to advance to the next screen.
   The *Reported Chemistries* screen 2 of 2 displays.
9. Touch the button for the test you want to remove.
   Touch the button again to include that test.
10. Touch **Done**.
11. Touch **Next**.
12. Touch **Done** 3 times to return to the *Select Ready* screen.

The reported results selection applies to all strip types.

Authorized Operator

This section describes how to set up use of operator IDs and add, edit, or delete the list of operator IDs. When enabled, the system permits only allowed operators to perform patient tests, QC tests (when using the connector), recall results, or modify system settings. Operators gain access by entering their ID.

The Clinitek Status+ analyzer stores 700 operators.

NOTE: The Operator ID is never printed or displayed with patient results. If you wish to associate the Operator's Name with patient results, enable Operator Name in *Custom Settings-Operator* screen 1 of 5.

⚠ **CAUTION**
Once the Operator ID and Operator Name settings are made, do not change the Operator ID setting. If you change the Operator ID setting, all patient results are erased.

Setting Operator IDs

To set up operator IDs, perform the following steps:
1. At the *Select Ready* screen, touch **Instrument Set Up**. The *Choose Settings* screen displays.
2. Use the arrow keys to select **Instrument Settings**.
3. Touch **Select**. The *Instrument Settings* screen displays.

4. Use the arrow keys to select **Authorized Operator**.
5. Touch **Select**.
   The *Authorized operator* screen displays.
6. To permit access only by authorized operators, touch **Enabled**.
   To allow all operators access to the system, touch **Disabled**.
7. If you selected **Enabled**, see *Adding Operator IDs* below to add at least one operator.
   If you selected **Disabled**, touch **Done** 3 times to return to the *Select Ready* screen.

⚠ CAUTION
If the instrument uses the operator list sent by the LIS, do not power down the system. If the connector loses power, the operator names are erased.

NOTE: The operator list sent by the LIS overwrites an operator list entered via the analyzer.

Adding Operator IDs

To add operator IDs, perform the following steps:
1. At the *Authorized operator* screen, touch **Add operator**.
2. Enter the new Operator ID.
   Use the alpha keyboard to enter text.
   To enter numeric text, touch **123**.
3. Touch **Enter**.
   The *Authorized Operator* screen displays indicating the Operator ID and which functions the operator can perform.
4. To edit this Operator ID, touch **Edit**.

5. To edit which functions this Operator ID can access, touch **Edit**.
   The *Authorized Operator-Operator access* screen 1 of 2 displays.
6. To allow this operator to run patient tests, touch **Enabled**.
   To prevent patient tests, touch **Disabled**.
7. To allow this operator to run QC tests, touch **Enabled**.
   To prevent QC tests, touch **Disabled**.
8. Touch **Next**.
   The *Authorized Operator-Operator access* screen 2 of 2 displays.
9. To allow this operator to recall results, touch elect **Enabled**.
   To prevent recall results, touch **Disabled**.
10. To allow this operator to set up the instrument, touch **Enabled**.
    To prevent instrument setup, touch **Disabled**.
11. Touch **Done** twice.
    The *Authorized Operator-Operators list* screen displays.
12. Touch **Exit**.
13. Touch **Done** 3 times to return to the *Select Ready* screen.

Viewing, Editing, Printing, and Deleting Operator IDs

You can view, print, or delete the entire operator list or edit individual operators.

NOTE: If you delete the entire operator list, ensure that authorized operators is Disabled. See *Setting Operator IDs* above.

At the *Authorized operator* screen, perform the following steps:

1. To delete the entire operators list, touch **Delete operators list**. The *Delete operators list* caution screen displays.
2. To delete, touch **Yes**.
   To keep the operators list, touch **No**.
   If you selected **No**, the *Authorized operator* screen displays.
   If you selected **Yes**, go to Step 8.
3. To edit or view the operators list, touch **View operators list**.
   The *Authorized Operator-Operators list* screen displays.
4. Use the arrow keys to select the operator you want to delete or edit.
5. To delete that operator, touch **Delete entry**.
   To edit or delete that operator, touch **Select**.
   The *Authorized operator* screen displays.
   Refer to *Adding Operator IDs* above, Step 6.
6. To print all operators, touch **Print**.

NOTE: The system prints the first 100 operators listed alphabetically.

7. To return to the *Authorized operator* screen, touch **Exit**.
8. Touch **Done** 3 times to return to the *Select Ready* screen.

NOTE: Enabling the instrument password restricts access to Instrument Setup to those who know the password. If both Operator ID and password are enabled, the Operator ID has priority.

Printer Settings

This section describes how to customize the printed test results.

Customizing the Printout

You can customize the test results printout by including or excluding:

- Operator name
- Patient name
- Patient ID
- Instrument serial number
- Urine color
- Urine clarity
- Up to 2 header lines of customized alphanumeric text

To customize the printout, perform the following steps:

1. At the *Select Ready* screen, touch **Instrument Set Up**. The *Choose Settings* screen displays.
2. Use the arrow keys to select **Instrument Settings**.
3. Touch **Select**. The *Instrument Settings* screen displays.
4. Use the arrow keys to select **Printer Settings**.
5. Touch **Select**. The *Printer Settings-Included in print-out* screen 1 of 4 displays.
6. To select options, for example Operator Name, Serial Number, Patient Name, or Patient ID to include in the printout, touch the option button.

To remove a selected option, touch that option button again.

7. Touch **Next**.
   The *Printer Settings-Included in print-out* screen 2 of 4 displays.
8. To select options, for example, Color, Clarity, or Custom Information to include in the printout, touch the option button.
   To remove a selected option, touch that option button again.
9. Select **Next**.
   The *Printer Settings-Set Up Custom Header* screen 3 of 4 displays.
10. To include a custom header in the printout, touch **Enabled**.
    To exclude a custom header, touch **Disabled**.
11. To edit or create line 1 of a custom header, touch **Enter Line 1**.
    The *Custom Header* screen displays.
12. Enter custom header text.
    Use the alphabetic keyboard to enter text.
    To enter numeric text, touch **123**.
13. Touch **Enter**.
    The *Printer Settings-Set Up Custom Header* screen 3 of 4 displays.
14. To edit or create line 2 of a custom header, touch **Enter Line 2**.

NOTE: Each custom header line accepts up to 24 alphanumeric characters.

15. Touch **Next**.
    The *Printer Settings* screen 4 of 4 displays.
16. To print to the internal printer, touch **Internal printer**.
    To print to an external printer, touch **External printer**.
17. If you selected **Internal printer**, to print sample interference notes, touch **Enabled**.
    To disable printing sample interference notes, touch **Disabled**.

NOTE: If you select External printer, sample interference notes are automatically sent to the printer.

18. Touch **Done** 3 times to return to the *Select Ready* screen.

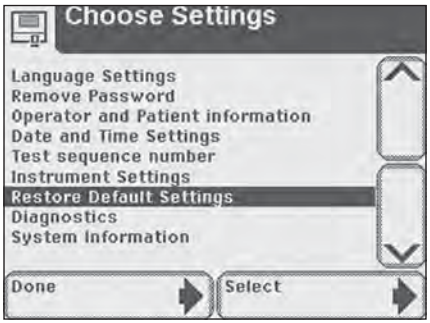
NOTE: To use an external printer, you must connect and enable the Clinitek Status connector.

Quality Control

For QC instructions, refer to the *Clinitek Status Connect System Operator's Guide*.

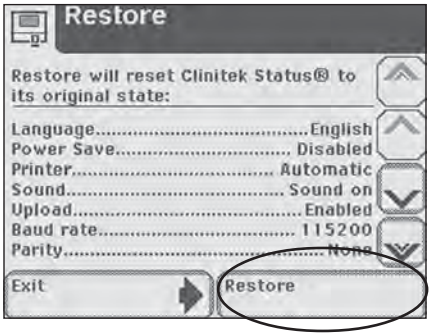
Restore Default Settings

This option lists the analyzer's original settings.

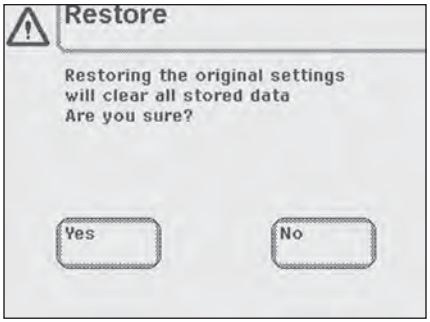


Use the up and down arrows to view the default settings.

Touch **Restore** in order to return the analyzer to the settings listed.



Touch **Yes** to confirm your decision or **No** to maintain the current settings of your analyzer. You will then return to the ***Restore*** screen. Select **Exit** to return to ***Choose Settings***.



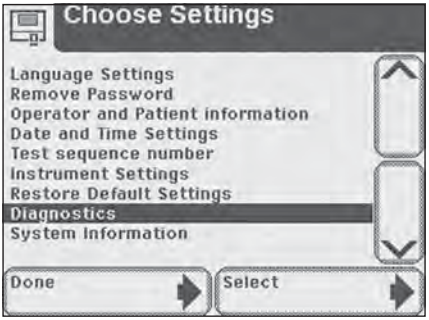
⚠ **When the original settings are restored, all results and patient data will be deleted from the memory.**

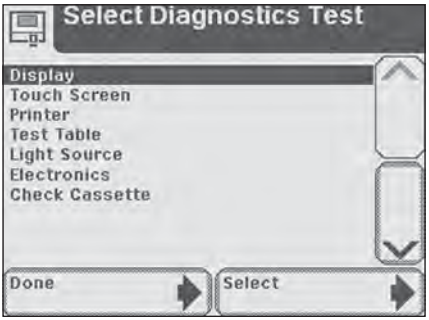
Diagnostics

This option lists 7 diagnostic tests which can be conducted.

- Display
- Touch Screen
- Printer
- Test Table
- Light Source
- Electronics
- Check Cassette

⚠ **These diagnostics tests should only be conducted when instructed by your local representative. The representative will lead you through the test procedures (see Appendix A for Local Technical Support Providers and Distributors).**





Sample Interference Notes

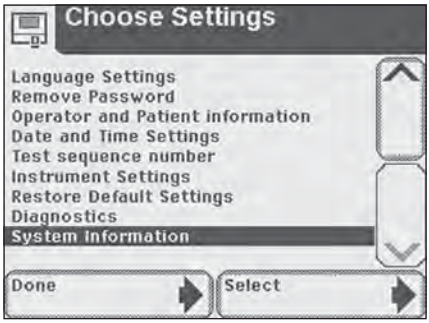
To include Sample Interference Notes, perform the following steps:

1. At the *Select* screen, touch **Instrument Set Up**.
   The *Choose Settings* screen displays.
2. Use the arrow keys to select **Sample Notes**.
3. Touch **Select**.
   The *Notes Settings* screen displays.
4. To enable Sample Interference Notes, touch **Enabled**.
   To disable Sample Interference Notes, touch **Disabled**.
5. Touch **Done** twice to return to the *Select* screen.

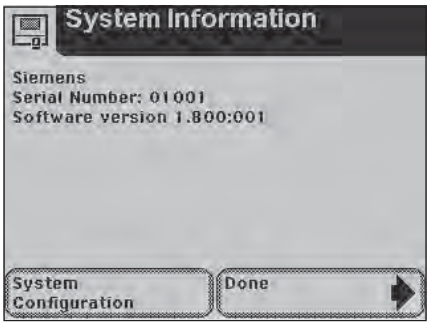
5 Instrument Set Up

System Information

This screen has information about your analyzer.

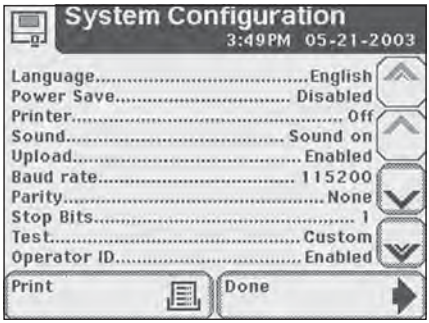


Touch ***System Configuration*** to view details of the current system configuration. This screen will show the current settings for all the items which can be changed within the ***Input Settings*** and ***Instrument Settings*** screens. Scroll through the list using the up and down arrows to view the details and print the information if required.



> *If the printer paper roll needs replacing, **Print** will be disabled and you will be able to select **Help** to view instructions on replacing the printer paper (if you require further instruction see page 1 5, Loading the Printer Paper or Label Roll).*

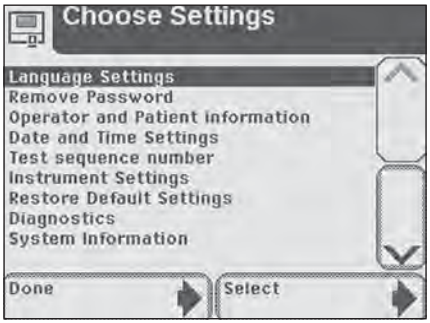
Select **Done** once to return to ***System Information*** screen and a second time to return to ***Choose Settings*** screen.



5 Instrument Set Up

System Information

This completes the settings and choices within **Instrument Set Up**. Touch **Done** to return to the main ***Select*** screen.

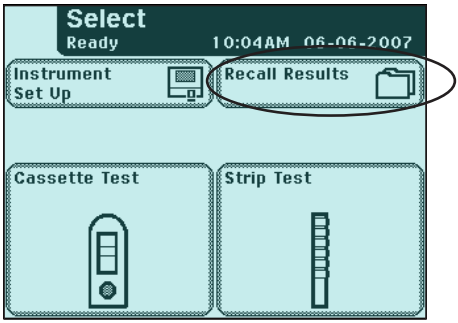


6 Recall Results

Patient Results

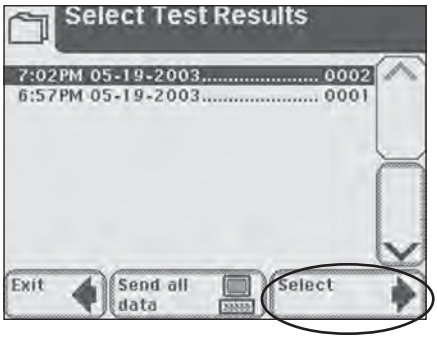
Patient Results

Recall results enables you to search, view, and print patient test results. These results are stored on the analyzer. If you are using the Clinitek Status connector, you can also recall QC results.



At the ***Select*** Screen, touch **Recall Results** button.

The next screen displayed is ***Select Test Results***.



The test results are in chronological order. The most recent test result is displayed at the top of the screen and is highlighted.

Use the up and down arrow keys to scroll through the list of patient tests and highlight the patient you would like to recall.

To view details of a patient result, touch the **Select** button.

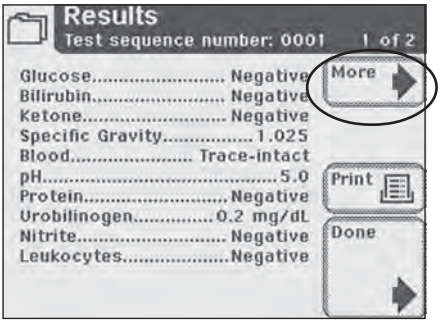
The results will automatically be sent to the connected computer if this option is set up in the analyzer.

If you require further instruction regarding how to set up the analyzer so the results are automatically sent to a computer see Section 5, Instrument Set Up.

6 Recall Results

Patient Results

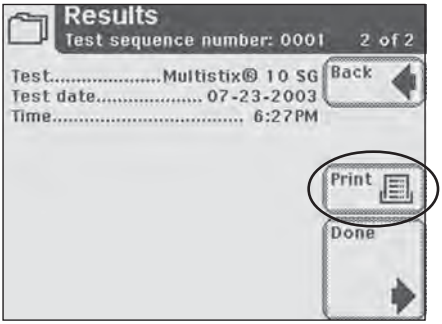
The first page of the patient's results is displayed on the screen.



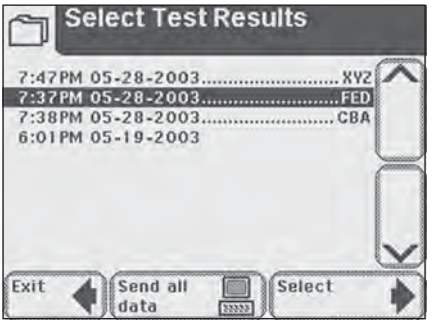
If more than one page of results exists for the patient, then the **More** button will be present on the screen.

If you would like to print the results, touch the **Print** button. Any information that was entered in regard to the patient will be included on the printout.

When you are finished viewing the patient's results, touch **Done**.



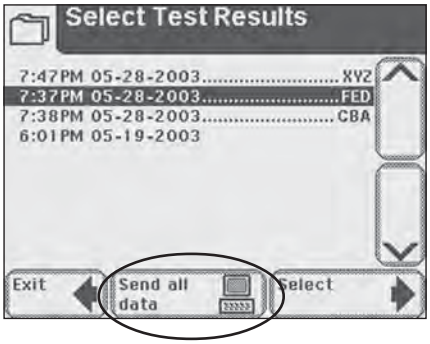
You will return to the ***Select Test Results*** screen. Press **Exit** to return to the main ***Select*** screen.



Sending Data to a PC

*To send data to a computer; if a computer has been connected to the analyzer, all results can be sent to the computer by touching the **Send all data** button.*

If you are using a Clinitek Status connector, refer to the *Clinitek Status Connect System Operator's Guide*.



7 Troubleshooting

General Information
Your Clinitek Status®+ analyzer will operate properly if you follow the directions for using and cleaning the instrument.

Error Messages
Error messages will be displayed to help you when the Clinitek Status+ analyzer detects something which needs your attention. The format of this advisory information depends upon the importance of the problem and the mode in which the instrument is being used.

> *To correct an error, see the List of Errors and Advisory Messages located at the end of this section.*

Errors which Disable the Instrument
If the error is one which prevents the instrument from being used, all selection areas on the screen will be disabled. Taking the corrective action shown will remove the error alert screen and allow you to use the instrument.

Other Errors
There are certain errors which need to be corrected to enable testing of samples but do not prevent other instrument functions from being used. You will need to carry out the corrective action to enable testing.

Advisory Messages
Errors of less importance will be presented via a message on the main ***Select*** screen when this screen is next displayed. When you have taken corrective action, the message will be removed from the display. If more than one of this class of error occurs, clearing one message will enable the next to be displayed in order of importance to a user.

Results Alert
If an error occurs during testing and the test cannot continue because of the error, this will be presented via the ***Results Alert*** screen. This will provide details of the error and show that the test has been cancelled. The test table will be extended so that the urinalysis strip or Clinitest® cassette can be removed.

7 Troubleshooting

Battery Power Icon

The battery icon indicates the power level of the battery. Power can be reduced while testing continues, with an advisory message displayed on the main ***Select*** screen. If battery level falls too low to power the analyzer, all selection areas on the display will be disabled until the batteries are replaced (if you require detailed instructions regarding how to change the batteries see Section 9, Cleaning and Maintenance).

Paper-out Icon

A paper-out icon appears in the top of the title bar when the printer paper/label roll needs replacing. An advisory message will be displayed on the main ***Select*** screen. Replace with new paper or label roll as instructed in Section 1, Loading the Printer Paper or Label Roll.

Dashes in Displays

Dashes are displayed in the ***Results*** screens and on printouts when no text has been entered for a field enabled in **Instrument Set Up**.

Dashes may appear next to Color and Clarity on test result printouts. This occurs when the instrument is powered by batteries. Color and Clarity are selected in the **Instrument Set Up**, but no selections have been recorded on the ***Select Appearance*** screens before time-out.

The time-out on these screens is designed to ensure that battery life is preserved. The Color and Clarity description may be added to the printout in writing if needed.

Irregular or Slow Movement of Test Table

If movement of the test table is irregular or slow, this may be caused by:

a) heavy buildup of dried urine on the test table. Clean the test table and insert as described in Section 9, Periodic Cleaning of Test Table.

b) low battery power. Replace the batteries as described in Section 9, Cleaning and Maintenance.

7 Troubleshooting

Calling for Assistance
If your Clinitek Status+ analyzer is displaying corrective actions for a detected problem, please carry out the displayed instructions before calling for assistance. If this does not correct the problem or no instructions are displayed, contact your local technical support provider (for contact information please see Appendix A, Local Technical Support Providers and Distributors).

If you are calling for assistance with a displayed error, please have the following items ready (this will assist your local representative to deal with your inquiry as quickly as possible).

a) Error number
b) Completed Problem Checklist (found at the end of this section).

For customer support, please contact your local technical support provider or distributor (for contact information please see Appendix A, Local Technical Support Providers and Distributors).

Warranty
Your Clinitek Status+ analyzer has a one-year warranty period. This warranty is designed to protect you from the cost associated with repairing systems that exhibit malfunctions due to defects in materials and/or workmanship during the warranty period.

The warranty period commences from the date that the instrument is received at your location. Use the Warranty Registration Card provided with the instrument to register your warranty.

To obtain assistance during the warranty period, please contact your local technical support provider or distributor.

Clinitek Status+ Analyzer: **List of Errors and Advisory Messages**		
Error Code	**Description**	**Action**
E01	Low battery power	Replace the batteries: a) To view instructions on the display, touch the Error Report selection area, or b) To use the instructions in this manual, see page 9 7, *Changing Batteries*.
E02	Failure of calibration data	Contact your local representative (contact information is given in Appendix A).
E10 or E48	Loss of test results	1. Switch the instrument off by pressing the on/off button for 2 seconds. 2. Switch the instrument on again by pressing the on/off button. 3. Repeat the test.
E11	Failure of test table	1. Make sure that the test table is in place. Move the test table in or out of the instrument slightly to reposition the test table. 2. If the error remains, with the instrument powered on, unplug the power cord from rear of instrument and plug back in. Turn instrument on by pressing the gray power button. 3. If the error remains with the test table in place, contact your local representative (contact information is given in Appendix A).
E12	Failure of LED	Contact your local representative (contact information is given in Appendix A).
E20	Failure of clock	Contact your local representative (contact information is given in Appendix A).
E23	Low battery power	Replace the batteries: a) To view instructions on the display, touch the Error Report selection area, or b) To use the instructions in this manual, see page 1 2, *Installing Batteries* and/or page 9 7, *Changing Batteries*. If the battery level becomes too low to power the instrument, Error Code E01 will be displayed.
E24	No printer paper	Replace the printer paper a) See instructions on the inside of the printer paper compartment cover, or b) To view instructions on the display, touch the Error Report selection area, or c) To use the instructions in this manual, see page 1 4, *Loading the Printer Paper or Label Roll.*

Error Code	Description	Action
E25, E64 or E65	Failure of automatic calibration	Clean the calibration strip. If the error remains after cleaning, contact your local representative (contact information is given in Appendix A).
E27	Set Up failure	1. Switch the instrument off by pressing the on/off button for 2 seconds. 2. Switch the instrument on again by pressing the on/off button.
E28	Printer error	Lift the printer cover and push the paper holding arm back into position (see page 1 5, *Loading the Printer Paper or Label Roll* for location of paper holding arm).
E50	Incorrect strip type or tilted strip	Ensure that the strip type selected in Instrument Set Up is being used (see 5 24, *Select Urinalysis Test*). Check that the strip is placed correctly on the test table insert. If the correct type of strip is being used and the strip is placed correctly, check the instrument operation by running another test using: a) a yellow and clear sample, or b) Chek Stix® (see page 8 1, *Quality Control Testing*).
E52	Invalid barcode	Repeat the test using the correct Siemens cassette.
E53	Strip Test selected but cassette detected	Repeat the test using the Cassette Test routine (see page 4 6 or 4 19).
E54	Cassette Test selected but strip detected	Repeat the test using the Strip Test routine (see page 4 1 or 4 11).
E56	Incorrect size test table	Repeat the test using the correct test table (see page 4 1).
E57	Missing strip or cassette	Repeat the test ensuring that the strip or cassette is positioned on the test table (see page 4 1 or 4 6 for strip or cassette testing).

Error Code	Description	Action
E58	Misplaced strip	Repeat the test ensuring that the strip is correctly positioned on the test table (see page 4 3). If error remains and you are testing a urine dip strip, examine the test table insert to insure that the small, white line located near the tip of the strip (on strip side of insert) is present and not damaged. If this line is damaged or missing contact your local representative (contact information is given in Appendix A).
E59	Inverted strip positioned on the test table	Repeat the test ensuring that the strip is correctly positioned on the test table (see page 4 3).
E60	Tilted strip	Repeat the test ensuring that the strip is correctly positioned on the test table (see page 4 3).
E61	Dry strip	Repeat the test ensuring that the strip has been in contact with the sample (see page 4 2).
E62	Light Ingress	Contact your local representative (contact information is given in Appendix A).
E63	Failure to find end of strip	Repeat the test ensuring that the strip is correctly positioned on the test table (see page 4 3).
E67 or E68	Insufficient sample	A sample flow issue with the cassette test may have been detected. One or more of the test indicator lines may be missing or indiscernible from the background, or not enough sample was applied to the cassette. Repeat the test ensuring the pipette is correctly filled and the correct volume of sample is dispensed into the well of the cassette (see page 4 8).
E69	Strip quality problem	When performing the quality check, the strip quality failed. This means that the strip was not shipped or stored in the proper humidity, temperature, or light conditions. 1. Remove the defective strip and discard. 2. Repeat the test ensuring the strip meets quality requirements. 3. Repeat the test using a new test strip.

Error Code	Description	Action
E03, **E04**, **E05**, **E06**, **E07**, **E08**, **E21**, **E22**, **E90**, **E91**, **E92** or **E93**	Failure of computer software	Contact your local representative (contact information is given in Appendix A).

Clinitek Status+ Analyzer: **Problem Checklist**

Serial Number _____

Installation Date_____

	YES	NO
1. Have you reviewed the error messages on pages 7-4 to 7-7?	☐	☐
2. Please record any error messages that have been displayed: _____ _____ _____		
3. Does the test table move out to the "load" position when the analyzer is first turned on?	☐	☐
4. If Question #3 is NO –		
▪ Is the power cord plugged into a live electrical outlet, into the transformer, and then into the analyzer?	☐	☐
▪ If using batteries, are they fully charged and correctly placed in the analyzer?	☐	☐
5. Does the display show the ***Select*** screen or the ***Results*** screen as expected?	☐	☐
6. Does the test table move into and out of the analyzer?	☐	☐
7. Does a quality control solution give the expected result?	☐	☐

	YES	NO
8. Is the name of the Siemens Healthcare Diagnostics urinalysis strip or Clinitest immunoassay cassette shown on the display the same as the product being used?	☐	☐
9. Does the display or printout show the correct test names and expected results?	☐	☐
10. Is the white calibration bar on the test table dirty, scratched, or damaged?	☐	☐

11. Additional problem observations, please describe:

_____
_____
_____
_____
_____

8 Quality Control Testing

If you are using a Clinitek Status connector, refer to the *Clinitek Status Connect System Operator's Guide*.

Quality Control for Urinalysis Strip Testing

Test negative and positive controls whenever a new bottle of reagent strips is first opened.

Water should **NOT** be used as a negative control. Contact your Siemens representative for additional information on performing QC testing.

> *Refer to the quality control product insert for expected values for each analyte.*

Quality Control for Cassette Testing

It is recommended that quality control specimens be used with each new reagent box opened.

Water should **NOT** be used as a negative control. Contact your Siemens representative for additional information on performing QC testing.

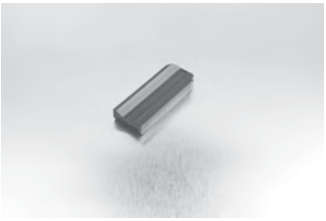
> ***hCG*** *Please refer to the Clinitest® hCG cassette test package insert for the appropriate quality control material.*

9 Cleaning and Maintenance

Cleaning

Cleaning

The test table insert and the test table should be kept clean if the analyzer is to operate properly.



⚠ **Do not autoclave the test table or test table insert.**

BIOHAZARD Wear personal protective equipment. Use universal precautions. Refer to *Appendix H* for recommended precautions when working with biohazardous materials.

Routine Cleaning of Test Table Insert

1 Remove insert and thoroughly clean.

2 Rinse both sides of the table insert under running water.

3 Dry and replace insert.

Periodic Cleaning of Test Table when Required

1 Remove the test table by pulling it slowly out of the analyzer. Lift the test table insert from the test table, drain the drip tray if necessary.

2 Wet a cotton-tipped stick with water and carefully clean test table (except for white calibration bar).

3 Dry the test table thoroughly (except for the white calibration bar) with a soft cloth or lint-free tissue.

⚠ Care should be taken not to scratch the white calibration bar. Instructions for cleaning the white calibration bar are given later in this section.

4 Reinsert the test table into the analyzer by holding the table at the end opposite the white calibration bar, with the white calibration bar facing upwards. Push the test table firmly but slowly, just over halfway into the analyzer.

⚠ Do not push the test table fully into the analyzer as the test table may become jammed and prevent the use of the analyzer.

5 Replace the test table insert.

9 Cleaning and Maintenance

Cleaning

Disinfecting the Test Table and Insert

1 Prepare one of the following solutions in a tall, narrow container (e.g., empty Multistix® bottle) to a depth of about 4 inches (10 cm):

- **Presept**, **Cidex**, **Theracide** and **Amphyl** solutions - prepare according to product directions.

- **Household Bleach** (5% sodium hypochlorite) – this can be used either full strength or dilute with water to as much as 1:20 (i.e., mix 5 mL bleach with 95 mL water for a total of 100 mL).

  ⚠ **Rinse away all bleach residue, as remaining bleach will affect several of the reagent pad chemistries.**

- **Isopropyl Alcohol** (70% to 85%) - this can be used full strength.

⚠ **Any solutions other than those listed above may damage the test table and insert.**

2 Place the insert and/or test table into the solution, making sure the white calibration bar on the test table remains above the liquid level.

⚠ **Be sure the solution does not come in contact with the white calibration bar. Do not cover the container while the test table is soaking.**

3 Soak the table and insert for a minimum of 2 minutes and maximum of 10 minutes. Do not soak longer than 10 minutes.

4 Rinse the test table and insert thoroughly with water.

5 Dry with a soft cloth and replace test table and table insert in the analyzer (as described on the previous page).

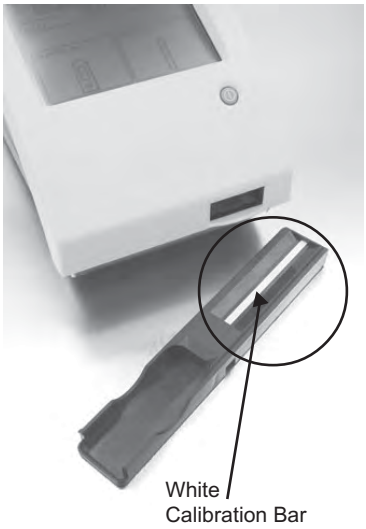
9 Cleaning and Maintenance

Cleaning

To enable your Clinitek Status®+ analyzer to perform as intended and provide reliable test results, it is recommended that you regularly check the white calibration bar on the test table, and always check it after a strip jam.

In normal use, the white calibration bar should not become dirty or discolored.

BIOHAZARD Wear personal protective equipment. Use universal precautions. Refer to *Appendix H* for recommended precautions when working with biohazardous materials.



Cleaning the White Calibration Bar

1 Remove the insert from the test table.

2 Remove the test table by pulling it slowly out of the analyzer.

3 Check the white calibration bar on the test table for dirt or discoloration.

4 If the white calibration bar is clean and unmarked, replace the table into the analyzer by holding the table at the end opposite the white calibration bar, with the white calibration bar facing upwards. Push the test table firmly but slowly, just over half way into the analyzer.

⚠ **Do not push the test table fully into the analyzer as the test table may become jammed and prevent the use of the analyzer.**

5 Replace the test table insert.

6 If the white calibration bar is dirty or discolored, gently wipe and clean it with a new cotton-tipped stick or lint-free cloth wetted with distilled water.

⚠ **Care should be taken not to scratch the white calibration bar. Solvents of any kind must not be used to clean the bar.**

7 Allow the calibration bar to air dry and then inspect the surface for dust, foreign material, scratches or scuffs. If the calibration bar cannot be cleaned or is still marked, obtain a new test table.

8 Reinsert the test table as described earlier in point 4.

9 Cleaning and Maintenance

Cleaning

Always keep the outside of the Clinitek Status+ analyzer clean and free of dust.

BIOHAZARD Wear personal protective equipment. Use universal precautions. Refer to *Appendix H* for recommended precautions when working with biohazardous materials.

1 Turn the analyzer off by pressing the on/off button for 2 seconds.

2 Wipe the outside (including the display) with a damp (not wet) cloth and a mild detergent.

⚠ **Do not use any type of solvent, oil, grease, silicone spray, or lubrication on the analyzer.**

⚠ **Do not spray the glass cleaner directly onto the screen. Do not use laboratory wipes, such as Kimwipes, since they may scratch the screen.**

⚠ **Care should be taken to avoid liquid from entering the printer compartment.**

The display may be disinfected using the same solutions as for the test table (see earlier in this section). Wipe the solution on and allow to remain for 10 minutes. Wipe clean using a clean cloth dampened with water, then dry.

Changing Batteries

Battery-Powered Operation
The Clinitek Status+ analyzer is designed to let you carry out the maximum number of tests (approximately 100) from a set of batteries. To achieve this, the Power Save feature is always activated when the instrument is powered by batteries.

If the instrument is not used in 5 minutes when battery-powered, it will automatically power down.

A battery power icon will be shown in the top right corner of the title bar when the analyzer is being powered by batteries. The number of segments displayed represents the amount of power remaining in the batteries.

When power is reduced but testing can continue, an advisory message will be displayed on the main ***Select*** screen.

NOTE: The printout may be lighter if the analyzer is using battery power.

> ⚠ **If you do not change the batteries and the level becomes too low to power the analyzer, the error will become critical and all selection areas on the screen will be disabled until the batteries are replaced.**

9 Cleaning and Maintenance

Changing Batteries

Remove the test table from the analyzer. Next, place the analyzer on its side and remove the battery cover by pressing down on the tab and pulling out. Remove current batteries. Place 6 new AA-size batteries into the analyzer. Replace the battery cover and turn the instrument back onto its base.

Appendix A: Local Technical Support Providers and Distributors

Legal Information

To contact the legal representative for Siemens Healthcare Diagnostics within the European community, contact the Siemens Authorized Representative. To order supplies or replacement parts, or to obtain service, contact your local technical support provider.

Siemens Healthcare Diagnostics Authorized Representative
Siemens Healthcare Diagnostics Ltd.
Sir William Siemens Sq.
Frimley, Camberley, GU16 8QD UK

Origin: UK

Siemens Healthcare Diagnostics Inc.
Tarrytown, NY 10591-5097 USA

EC REP

Siemens Healthcare Diagnostics Ltd.
Sir William Siemens Sq.
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511 Benedict Avenue
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Australia

シーメンスヘルスケア・ダイアグノスティクス株式会社
東京都品川区東五反田 3－20－14
Siemens Healthcare Diagnostics

輸入

www.siemens.com/diagnostics

Appendix B: Tables of Results

Table 1 **English – Conv.**
Units – Conventional

Reagent Strip Tests

Test	Abbreviation	Units	Reported Results	
			Normal System	Plus System
Glucose	GLU	mg/dL	Negative 100 250 500 >=1000	Negative Trace 1+ 2+ 3+
Glucose (CT Malb 9*)	GLU	mg/dL	Negative 100 250 500 1000 >=2000	Negative Trace 1+ 2+ 3+ 4+
Bilirubin	BIL		Negative Small Moderate Large	Negative 1+ 2+ 3+
Ketone	KET	mg/dL	Negative Trace 15 40 80 >=160	Negative Trace 1+ 2+ 3+ 4+
Specific Gravity	SG		<=1.005 1.010 1.015 1.020 1.025 >=1.030	No Difference
Occult Blood	BLO		Negative Trace-lysed Trace-intact Small Moderate Large	Negative Trace-lysed Trace-intact 1+ 2+ 3+
pH	pH		5.0 6.5 8.0 5.5 7.0 8.5 6.0 7.5 >=9.0	No Difference
Protein (Multistix PRO®) (CT Malb 9*)	PRO	mg/dL	Negative 15 30 100 300	Negative Low 1+ 2+ 3+
Protein (All other urinalysis strips)	PRO	mg/dL	Negative Trace 30 100 >=300	Negative Trace 1+ 2+ 3+
Urobilinogen	URO	E.U./dL	0.2 1.0 2.0 4.0 >=8.0	No Difference
Nitrite	NIT		Negative Positive	No Difference
Leukocytes	LEU		Negative Trace Small Moderate Large	Negative Trace 1+ 2+ 3+
Albumin	ALB	mg/L	10 30 80 150	No Difference
Creatinine	CRE	mg/dL	10 50 100 200 300	No Difference
Albumin: Creatinine (Clinitek Microalbumin 2)	A:C	mg/g	<30 Normal 30 – 300 Abnormal >300 High Abnormal	No Difference

Test	Abbreviation	Units	Reported Results		
			Normal System		Plus System
Albumin: Creatinine (CT Malb 9*)	A:C	mg/g	Normal Dilute <30 Normal	30-300 Abnormal >300 High Abnormal	No Difference
Protein: Creatinine (Multistix PRO)	P:C	mg/g	Normal Dilute Normal 150 Abnormal	300 Abnormal >500 Abnormal	No Difference
Protein: Creatinine (CT Malb 9*)	P:C	mg/g	Normal Dilute Normal 300 Abnormal 1500 Abnormal	3000 Abnormal >=5000 Abnormal	No Difference

Cassette Test

Test	Abbreviation	Reported Results		
		Normal System		Plus System
Human Chorionic Gonadotropin	hCG	hCG Negative Borderline hCG level Test fresh sample in 48-72 hours	hCG Positive	No Difference

The results shown in shaded areas will be marked as positives, if “mark positive results” is selected in **Instrument Set Up**. They will be marked by asterisks when displayed, when printed and when the data is transferred to a host computer.

* Clinitek Microalbumin 9

Table 2 English – S.I.
Units – International (S.I.)

Reagent Strip Tests

Test	Abbreviation	Units	Reported Results	
			Normal System	**Plus System**
Glucose	GLU	mmol/L	Negative 28 5.5 >=55 14	Negative 2+ Trace 3+ 1+
Glucose (CT Malb 9*)	GLU	mmol/L	Negative 28 5.5 55 14 >=110	Negative 2+ Trace 3+ 1+ 4+
Bilirubin	BIL		Negative Moderate Small Large	Negative 2+ 1+ 3+
Ketone	KET	mmol/L	Negative 3.9 Trace 7.8 1.5 >=15.6	Negative 2+ Trace 3+ 1+ 4+
Specific Gravity	SG		<=1.005 1.020 1.010 1.025 1.015 >=1.030	No Difference
Occult Blood	BLD	Ery/µL	Negative Ca 25 Trace-lysed Ca 80 Trace-intact Ca 200	Negative 1+ Trace-lysed 2+ Trace-intact 3+
pH	pH		5.0 8.0 6.5 5.5 8.5 7.0 6.0 >=9.0 7.5	No Difference
Protein (Multistix PRO®) (CT Malb 9*)	PRO	g/L	Negative 1.0 0.15 3.0 0.3	Negative 2+ Low 3+ 1+
Protein (All other reagent strips)	PRO	g/L	Negative 1.0 Trace >=3.0 0.3	Negative 2+ Trace 3+ 1+
Urobilinogen	UBG	µmol/L	3.2 66 16 >=131 33	No Difference
Nitrite	NIT		Negative Positive	No Difference
Leukocytes	LEU	Leu/µL	Negative Ca 125 Ca 15 Ca 500 Ca 70	Negative 2+ Trace 3+ 1+
Albumin	ALB	mg/L	10 80 30 150	No Difference
Creatinine	CRE	mmol/L	0.9 17.7 4.4 26.5 8.8	No Difference
Albumin:Creatinine (Clinitek Microalbumin 2)	A:C	mg/mmol	<3.4 >33.9 Normal High Abnormal 3.4 – 33.9 Abnormal	No Difference
Albumin:Creatinine (CT Malb 9*)	A:C	mg/mmol	Normal Dilute Abnormal <3.4 >33.9 Normal High 3.4-33.9 Abnormal	No Difference

Test	Abbreviation	Units	Reported Results		
			Normal System		Plus System
Protein: Creatinine (Multistix PRO)	P:C	mg/mmol	Normal Dilute Normal 17.0 Abnormal	33.9 Abnormal >56.6 Abnormal	No Difference
Protein: Creatinine (CT Malb 9*)	P:C	mg/mmol	Normal Dilute Normal 33.9 Abnormal 170 Abnormal	339 Abnormal >=566 Abnormal	No Difference

Cassette Test

Test	Abbreviation	Reported Results		
		Normal System		Plus System
Human Chorionic Gonadotropin	hCG	hCG Negative Borderline hCG level Test fresh sample in 48-72 hours	hCG Positive	No Difference

The results shown in shaded areas will be marked as positives, if “mark positive results” is selected in **Instrument Set Up**. They will be marked by asterisks when displayed, when printed and when the data is transferred to a host computer.

* Clinitek Microalbumin 9

Table 3 English – Nordic
Units – Nordic Plus System

Reagent Strip Tests

Test	Abbreviation	Units	Reported Results	
			Normal System	**Plus System**
Glucose	GLU		Negative 1+ 2+ 3+ 4+	Negative Trace 1+ 2+ 3+
Glucose (CT Malb 9*)	GLU		Negative 1+ 2+ 3+ 4+ 5+	Negative Trace 1+ 2+ 3+ 4+
Bilirubin	BIL		Negative 1+ 2+ 3+	No Difference
Ketone	KET		Negative 1+ 2+ 3+ 4+ 5+	Negative Trace 1+ 2+ 3+ 4+
Specific Gravity	SG		<=1.005 1.010 1.015 1.020 1.025 >=1.030	No Difference
Occult Blood	BLD		Negative +/- +/- Intact 1+ 2+ 3+	No Difference
pH	pH		5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0	No Difference
Protein (Multistix PRO®) (CT Malb 9*)	PRO		Negative Low 1+ 2+ 3+	No Difference
Protein (All other reagent strips)	PRO		Negative +/- 1+ 2+ 3+	Negative Trace 1+ 2+ 3+
Urobilinogen	URO	µmol/L	3.2 16 33 66 >=131	No Difference
Nitrite	NIT		Negative Positive	No Difference
Leukocytes	LEU		Negative 1+ 2+ 3+ 4+	Negative Trace 1+ 2+ 3+
Albumin	ALB	mg/L	10 30 80 150	No Difference
Creatinine	CRE	mmol/L	0.9 4.4 8.8 17.7 26.5	No Difference
Albumin: Creatinine (Clinitek Microalbumin 2)	A:C	mg/mmol	<3.4 Normal 3.4 – 33.9 Abnormal >33.9 High Abnormal	No Difference
Albumin: Creatinine (CT Malb 9*)	A:C	mg/mmol	Normal Dilute <3.4 Normal 3.4-33.9 Abnormal >33.9 High Abnormal	No Difference
Protein: Creatinine (Multistix PRO)	P:C	mg/mmol	Normal Dilute Normal 17.0 Abnormal 33.9 Abnormal >56.6 Abnormal	No Difference
Protein: Creatinine (CT Malb 9*)	P:C	mg/mmol	Normal Dilute Normal 33.9 Abnormal 170 Abnormal 339 Abnormal >=566 Abnormal	No Difference

Cassette Test

Test	Abbreviation	Units	Reported Results		
			Normal System		Plus System
Human Chorionic Gonadotropin	hCG		hCG Negative Borderline hCG level Test fresh sample in 48 72 hours	hCG Positive	No Difference

The results shown in shaded areas will be marked as positives, if “mark positive results” is selected in **Instrument Set Up**. They will be marked by asterisks when displayed, when printed and when the data is transferred to a host computer.

* Clinitek Microalbumin 9

Appendix C: Specifications

Power Required
110V AC ± 20%, 45 - 65 Hz (US only)
220V AC ± 20%, 45 - 65 Hz (Europe only)
240V AC ± 20%, 45 - 65 Hz (UK only)
100V - 240V AC ± 20%, 45 - 65 Hz (with in-line lead)

Battery Powered Operation
Size 6 AA alkaline batteries

Dimensions
Depth - 272 mm (10.7 inches)
Width - 171 mm (6.7 inches)
Height - 158 mm (6.2 inches)

Weight
Clinitek Status®+ instrument only (unpacked, without batteries or power supply) – 1.66 kg (3.65 lb)

Ambient Operating Temperature Range
18°C to 30°C (64°F to 86°F)

Ambient Operating Humidity Range
18% to 80% Relative Humidity (non-condensing)

Optimum Operating Temperature Range
22°C to 26°C (72°F to 79°F)

Optimum Operating Humidity Range
35% to 55% Relative Humidity (non-condensing)
Optimum ranges insure that the reagent results are optimized for performance. At temperatures under 22°C (72°F), urobilinogen and leukocyte results may be decreased, and at temperatures above 26°C (79°F), increased.

Altitude: 2000 m (6562 ft)

Installation Category: II

Pollution Degree: 2

Instrument Memory
950 Patient test results
200 Patient details (Patient's Name and/or Patient Identification)

Safety Standards
The Clinitek Status+ analyzer is classed as a Class A computing device in accordance with Part 15 of FCC Rules.

NOTE: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. The equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

The instrument is listed by the Underwriters' Laboratories (UL) and the Canadian Standards Association (CSA) as certified and complies with the safety standards specified in UL 61010A-1 and CSA-C22, No. 1010.1.

The instrument complies with the protection requirements of EN 61010-1, EN 50082-1 January 1992, EN 50081-1 January 1992, and the safety specifications of IEC 61010-1 A2 1995.

The instrument is certified as meeting the EMC requirements and safety specifications of the In Vitro Diagnostic Directive (98/79/EC).

Appendix D: Instrument Default Settings – English

Password
Password protection not set

Input Settings
Quick Test

Operator Name
Disabled

Keyboard Priority
Alphabetic

Entry of Patient's Name
Disabled

Entry of Patient ID
Disabled

Include Patient's Name or ID in Results
Patient's Name

Last Operator Name
Disabled

Sample Appearance
Disabled

Custom Data Entry
Disabled

Date Format
MM-DD-YYYY

Time Format
12 hour

Results Format
Units Selection
Conventional

Plus System
Disabled

Mark Positive Results
Disabled

System Settings
Printer
Automatic

Power Save
Disabled

Sound
On

Contrast Setting
0 (zero)

Connectivity
Allow Results to be Sent to PC
Enabled

Instrument Serial Number in Patient Records
Disabled

Baud Rate
115200

Parity
None

Stop Bits
1 (one)

Urinalysis Test Selected
Multistix® 10 SG

Sample Notes
Enabled

Authorized Operator
Disabled

Appendix E: System Overview & Principles

Description of Optical System
The optical system consists of six light emitting diodes, a light guide, a mirror, a lens and a detector. Light from the LEDs travels along the light guide and is reflected off the calibration bar, strip or cassette onto the mirror. It is then directed through an aperture on the lens, from where it is focused onto the detector. The light intensity detected is converted into electrical impulses, which are processed by the instrument's microprocessor and converted into clinically meaningful results.

When carrying out analysis on a urinalysis strip, the test table positions strip pads in the "read area". The light reflected at specific wavelengths (470 nm, 525 nm, 565 nm, 625 nm, 660 nm and 845 nm) from the test pad is dependent upon the degree of color change in the pad and is directly related to the concentration of the particular constituent in the urine. The analyzer's optical system images the entire strip (i.e., all reagent pads at once).

When using a Clinitest immunoassay cassette, the detector will scan the "read area" for the test, reference and control lines that form after urine has been applied. The reference and control lines will always form whereas the test line will only form if hCG is present in the sample.

Description of Internal Checks
When the analyzer is first turned *on*, the instrument performs a series of electronic, signal and memory checks, as well as ensuring there is sufficient battery voltage to operate the instrument (if powered by batteries).

Each time a urinalysis strip is read, the instrument positions the table correctly and checks the electronics and signals. It then takes reference readings off the white calibration bar on the test table. The readings are taken at all six wavelengths and are then used to calculate the sample readings.

The table and test strip are pulled into the instrument after the correct placement of the test strip is confirmed. The table then moves completely into the instrument closing the shutter. All test pads are read simultaneously at all six wavelengths. The test and reference readings are then used to determine presence and/or amount of each constituent in the urine sample.

Each time a cassette is read, the instrument positions the table correctly and checks the electronics and signals. It then takes reference readings of the white calibration bar on the test table. The readings are taken at two wavelengths (525 nm and 845 nm) and are then used to calculate the sample readings.

The table and cassette are pulled into the instrument where the presence of the cassette is confirmed. The table then pulls completely into the instrument closing the shutter and the cassette “read area” is scanned at two wavelengths. The test and references readings are then used to determine presence or absence of hCG the urine sample.

Differences between the Human Eye and Instrumental Optics

There are inherent differences between the colors that are perceived by the human eye and that are detected by any instrument optical system. The human eye is capable of detecting minute differences in shade and very small areas of color; whereas instrument optical systems are less sensitive to such small changes. Conversely, instrument optics are capable of detecting certain colors that are masked by or blended with other colors to the human eye.

For this reason, exact agreement between visual results and instrument results might not be found. However, agreement is generally within one visual color block or reported level and is equal to or better than the agreement between two visual readers.

Guidance and manufacturer's declaration – electromagnetic emissions		
The Siemens Clinitek Status® is intended for use in the electromagnetic environment specified below. The customer or the user of the Clinitek Status® should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The Clinitek Status® uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Clinitek Status® is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The Siemens Clinitek Status® is intended for use in the electromagnetic environment specified below. The customer or the user of the Clinitek Status should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70 % U_T (30% dip in U_T) for 25 cycles <5% U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0,5 cycle *40% U_T (60% dip in U_T) for 5 cycles 70 % U_T (30% dip in U_T) for 25 cycles <5% U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Clinitek Status requires continued operation during power mains interruptions, it is recommended that the Clinitek Status be powered from an uninterruptible power supply or a battery. *Note: Siemens should not provide the 100-240V supply for operation at 100V.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Not Applicable	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity

The Siemens Clinitek Status® is intended for use in the electromagnetic environment specified below. The customer or the user of the Clinitek Status should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Clinitek Status, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
			Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 80 MHz to 2,5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Clinitek Status is used exceeds the applicable RF compliance level above, the Clinitek Status should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Clinitek Status.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Siemens Clinitek Status®

The Clinitek Status is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Clinitek Status can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Clinitek Status as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to the frequency of transmitter m		
	150 kHz to 80 MHz $d=1.2\sqrt{P}$	80 kHz to 800 MHz $d=1.2\sqrt{P}$	800 MHz to 2,5 GHz $d=2.3\sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Appendix F: Training & Educational Materials

Chek-Stix® Positive and Negative control strips are available for use in your training program for routine urine strip testing (for supply information see Appendix A, Local Technical Support Providers and Distributors). Follow the package insert for instruction on preparation and testing.

Appendix G: Sample Interference Notes

Sample Interference Notes inform the user about test results that can be affected by components detected in the urine sample.

Depending upon the strip and sample, Sample Interference Notes include the following:

- High SG may cause falsely lowered GLU results.
- Elevated GLU may cause falsely lowered LEU results.
- Visibly bloody urine may cause falsely elevated PRO results.
- High SG may cause falsely lowered LEU results.
- High pH may cause falsely elevated PRO results.

Appendix H: Safety Information

Protecting Yourself from Biohazards

This information summarizes the established guidelines for handling laboratory biohazards. This summary is based on the guidelines developed by the Centers for Disease Control, the Clinical and Laboratory Standards Institute, and the Occupational Safety and Health Administration.

Use this summary for general information only. It is not intended to replace or supplement your laboratory or hospital biohazard control procedures.

By definition, a biohazardous condition is a situation involving infectious agents biological in nature, such as the hepatitis B virus, the human immunodeficiency virus, and the tuberculosis bacterium. These infectious agents may be present in human blood and blood products and in other body fluids.

The following are the major sources of contamination when handling potentially infectious agents:

- needlesticks
- hand-to-mouth contact
- hand-to-eye contact
- direct contact with superficial cuts, open wounds, and other skin conditions that may permit absorption into subcutaneous skin layers
- splashes or aerosol contact with skin and eyes

To prevent accidental contamination in a clinical laboratory, strictly adhere to the following procedures:

- Wear gloves while servicing parts of the system that have contact with body fluids such as serum, plasma, urine, or whole blood.
- Wash your hands before going from a contaminated area to a noncontaminated area, or when you remove or change gloves.
- Perform procedures carefully to minimize aerosol formation.
- Wear facial protection when splatter or aerosol formation are possible.
- Wear personal protective equipment such as safety glasses, gloves, lab coats or aprons when working with possible biohazard contaminants.

- Keep your hands away from your face.
- Cover all superficial cuts and wounds before starting any work.

  Dispose of contaminated materials according to your laboratory's biohazard control procedures.
- Keep your work area disinfected.
- Disinfect tools and other items that have been near any part of the system sample path or waste area with 10% v/v bleach.
- Do not eat, drink, smoke, or apply cosmetics or contact lenses while in the laboratory.
- Do not mouth pipet any liquid, including water.
- Do not place tools or any other items in your mouth.
- Do not use the biohazard sink for personal cleaning such as rinsing coffee cups or washing hands.

Do not recap, purposely bend, cut, break, remove from disposable syringes, or otherwise manipulate needles by hand. Needlestick injuries may result.

References

1. Centers for Disease Control. *Update: Universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus and other bloodborne pathogens in healthcare settings*. 1988. MMWR, 37:377-382, 387, 388.

2. Clinical and Laboratory Standards Institute (formerly NCCLS). *Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline - Third Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2005. CLSI Document M29-A3. [ISBN 1-56238-567-4].

3. Federal Occupational Safety and Health Administration. Bloodborne Pathogens Standard. 29 CFR 1910. 1030.

Appendix I: Clinitek Status®+ Intended Use and Indications for Use

The Clinitek Status®+ Urine Chemistry Analyzer is a portable easy to use analyzer. It is designed to read only Siemens Reagent Strips for Urinalysis and Clinitest® hCG tests.

This analyzer is intended for the measurement of the following in urine: Albumin, Bilirubin, Blood (Occult), Creatinine, Glucose, Ketone, Leukocytes, Nitrite, pH, Protein, Protein-to-Creatinine Ratio, Albumin-to-Creatinine Ratio, Specific Gravity, Urobilinogen, and human Chorionic Gonadotropin (hCG).

These measurements are used to assist diagnosis in the following areas:

- Kidney Function
- Urinary tract infections
- Metabolic disorders (e.g. diabetes mellitus)
- Liver Function
- Pregnancy

Tests performed using the Clinitek Status®+ Analyzer are intended for *in vitro* diagnostic use only.

The Clinitek Status®+ Analyzer is intended for near patient (point-of-care) facilities and centralized laboratory locations.

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