CLINITEK Status®+

Semi-Automated Urinalysis Analyzer

Operator's Guide

10379682 (134798) Rev. D, 2021-04

CE

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The information in this operator's guide 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 the system is used in a manner differently than specified by Siemens Healthcare Diagnostics, the protection provided by the equipment may be impaired. See warning and hazard statements.

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1 Introduction

The introduction explains how to get started, unpack, and install your CLINITEK Status®+ analyzer. The introduction also includes an overview of the analyzer.

Intended Use

The CLINITEK Status+ Urine Chemistry Analyzer is a portable semi-automated, easy to use analyzer. It is designed to read only Siemens Healthcare Diagnostics Reagent Strips for Urinalysis and Clinitest® hCG tests.

This analyzer is intended for the semi-quantitative and qualitative type of measurement of the following in human 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 aid in assessment of conditions such as:

- Kidney disease
- Urinary tract infections
- Metabolic disorders (such as diabetes mellitus)
- Liver disease
- Pregnancy

Tests performed using the CLINITEK Status+ analyzer are intended for *in vitro* diagnostic (IVD) use only.

The CLINITEK Status+ analyzer is intended for professional use in near patient (point-of-care) facilities and centralized laboratory locations.

Summary and Explanation

The urinalysis strips also measure physical characteristics, including acid-base balance and urine concentration. Test results can be used along with other diagnostic information to rule out certain disease states and to determine if microscopic analysis is needed.

*Multistix PRO® urinalysis strips are ready to use upon removal from the bottle and the entire strip is disposable. The strips may be read visually, requiring no additional laboratory equipment for testing.

The strips can also be read on an instrument, using the CLINITEK® family of Urine Chemistry Analyzers and the appropriate software; Multistix PRO 11 Reagent Strips are for use on the CLINITEK 500 and CLINITEK Advantus® Analyzers only. The CLINITEK Status system automatically identify the strip being tested, using the ID bands near the handle of the strip. Contact your product representative for further information.

Multistix PRO urinalysis strips are for *in vitro* diagnostic use.

*Product availability varies by country

Getting Started

This section provides information about how to unpack and install your CLINITEK Status+ analyzer.

Unpacking the Clinitek Status+ Analyzer

The CLINITEK Status+ analyzer is delivered in 1 carton.

To unpack your CLINITEK Status+ analyzer, perform the following steps:

1. Carefully remove the contents of the shipping carton.

   Note Retain the shipping carton and packing materials, which offer the best protection against damage if you need to ship the analyzer.

2. Inspect the carton and contents for visible signs of damage.

   If the analyzer appears damaged, immediately file a complaint with the carrier.

3. Remove each wrapping and verify that you have the following items (see *Figure 1-1*):

   - CLINITEK Status+ analyzer
   - Power supply adaptor and AC power cord

Note If the power cord is not the style you need, contact your local technical support provider. See *Appendix B, Support Information*.

- Test table

CAUTION
Do not touch the white calibration bar on the test table. Damage to the calibration bar could affect the test results.

- Test table insert

Note If you use a urinalysis strip that has 4 or fewer test pads, such as Uristix® 4 reagent strips, use a short test table insert. You need to order the short test table insert separately from the analyzer (see *Appendix C, Orderable Supplies*).

- Paper roll

Note You also can print on label stock. For information about how to order label rolls, see *Appendix C, Orderable Supplies*.

- Depending on the analyzer model you received, you also could have a Warranty Registration Card, Unpack and Installation Guide, and Quick Reference Card.

Figure 1-1: Clinitek Status+ Analyzer Components

1	Clinitek Status+ Analyzer
2	Power supply adaptor and AC power cord (Figure shows US version)
3	Test table with calibration bar
4	Test table insert
5	Paper roll

Assembling the Clinitek Status+ Analyzer

After you unpack the analyzer components, you can assemble and connect them.

To assemble the Clinitek Status+ Analyzer components, perform the following steps:

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

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

CAUTION
The electromagnetic environment should be evaluated prior to operation of the device. Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g., unshielded intentional RF sources), as these can interfere with the proper operation. This equipment complies with the emission and immunity requirements of the IEC 61326 series.

2. Connect the appropriate end of the power cord into the power inlet socket located on the back of the analyzer (see *Figure 1-2*).

Figure 1-2: Assembling the Clinitek Status+ Analyzer

1	Serial port
2	Power cord

Connect the other end of the power cord into an AC electrical wall outlet.

CAUTION
Use only the power supply adapter included with the analyzer. A different power supply adapter might damage the analyzer.

Inserting the Batteries (optional)

To power the Clinitek Status+ Analyzer by batteries (optional), perform the following steps:

1. Place the analyzer on its side.
2. Remove the battery cover on the bottom of the analyzer by pressing down on the tab and pulling out the cover.

3. Place 6 new alkaline AA-size batteries into the battery compartment.
4. Place the battery cover back on the compartment and turn the analyzer back on its base.

CAUTION
Do not use batteries in the analyzer, if you attach the analyzer to a CLINITEK Status connector. Leaving the batteries in the battery compartment may corrode the batteries.

Inserting the Test Table and Test Table Insert

To insert the test table and test table insert, perform the following steps:

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

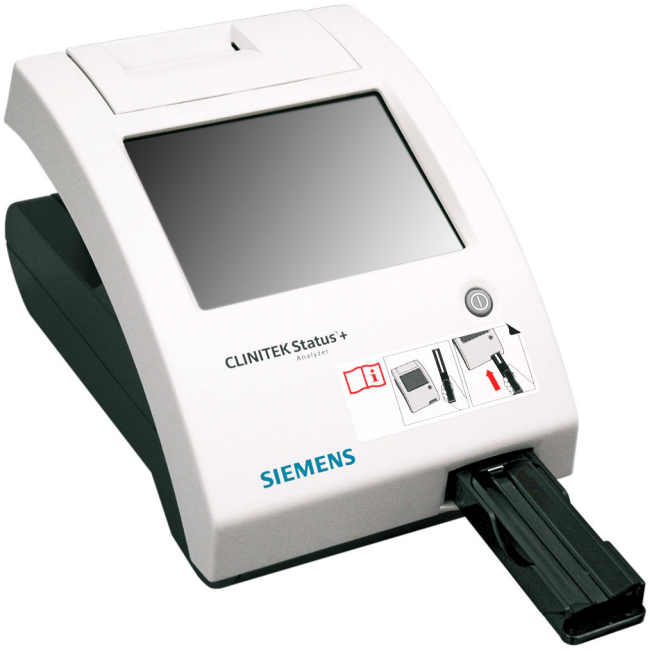
CAUTION
Do not push the test table fully into the analyzer. The test table may become jammed and prevent the use of the analyzer.

Do not touch the white calibration bar on the test table. Damage to the calibration bar could affect the test results.

3. Place the test table insert into the test table (see *Figure 1-3*).

Note The test table insert adapts for use with a Siemens urinalysis strip or an hCG cassette. Use one side for a strip test and the other side for a cassette test.

Figure 1-3: The Test Table and Test Table Insert



Connecting the Analyzer to a Computer

To connect the analyzer to a computer, perform the following steps:

1. Purchase a 9-pin null modem serial cable from your local technical support provider or distributor. See *Appendix B, Support Information*.
2. Connect the serial cable to the serial port located on the back of the analyzer.
3. Connect the other end of the serial cable to the back of the computer.

Note If you want to connect the analyzer to a CLINITEK Status connector, follow the instructions in the *CLINITEK Status Connect Unpacking and Installation Guide* and the *CLINITEK Status Connect System Operator's Guide, Section 6, System Configuration*.

When you connect the analyzer to CLINITEK Status connector, you can use wired (Ethernet) or wireless network connectivity, Quality Control, increased security, bar-code scanning, and additional features with the CLINITEK Status+ analyzer.

The CLINITEK Status connector provides standard wired and wireless connectivity of the CLINITEK Status+ analyzer to your LAN, LIS, HIS, or EMR. The connector also allows for centralized control of all satellite Point of Care (POC) CLINITEK Status+ analyzers. For details, see the *CLINITEK Status Connect System Operator's Guide*.

CAUTION
Do not use batteries in the analyzer, if you attach the analyzer to a CLINITEK Status connector. If you leave the batteries in the battery compartment, the batteries may corrode.

Loading the Printer Paper

The analyzer uses ordinary thermal paper as provided, or label stock. For more information about ordering supplies, see *Appendix C, Orderable Supplies*.

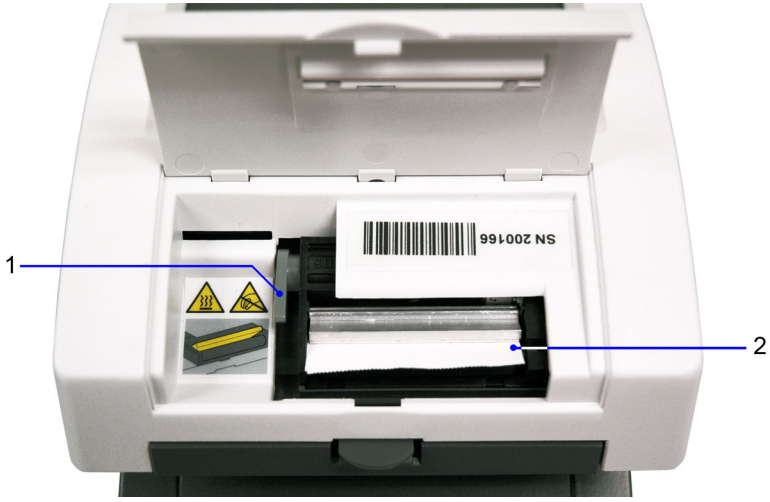
To load the printer paper or label roll, perform the following steps:

1. With the back of the analyzer facing you, 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 the cover.
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 the wall and through the printer until you have approximately 10 cm (or 4 inches) of paper through the printer.

6. Feed the edge of the paper through the printer cover.
7. Push the paper holding arm down in the closed position (see *Figure 1-4*).
8. Close the paper roll and printer covers by clicking them into position.

Note By default, the analyzer automatically prints the test results. To disable the automatic print function, see Section 7, *System Configuration*, *Changing the System Settings*, page 107.

Figure 1-4: Printer Paper Compartment



1	Paper holding arm
2	Printer paper

Powering On/Off

If you power on the analyzer for the first time, the Start Up Wizard prompts you through a set-up procedure. Also, you must enter a startup code when you use the analyzer for the first time.

To power on the analyzer, perform the following steps:

1. Press the on/off button on the front of the analyzer.

   The analyzer runs a diagnostic test each time you power on the analyzer.

   If this is the first time you powered on the analyzer, the Start Up Wizard displays and prompts you to select a region.

2. Select a region.

   Note If your region does not display in the list, select **Other**.

   The **Authorization Code** screen displays.

3. For the start up code, enter **2664**.

   Note If you enter an incorrect start-up code, the `Incorrect Authorization Code` error message displays. Select **No** to return to the **Authorization Code** screen and enter **2664**.

To power off the analyzer, perform the following steps:

1. Before you power off the analyzer, always ensure that no strip or cassette is on the test table and that the table and insert are clean.
2. Press the on/off button for at least 2 seconds.

   The analyzer pulls in the test table. If no strip or cassette is on the test table, the test table door closes and the analyzer powers off.

   If a strip or cassette is still on the test table, the analyzer pushes out the test table and powers off. The test table remains out.

To pull the test table into the analyzer, power on the analyzer, remove the strip or cassette on the test table, and then power off the analyzer.

CAUTION

Do not push the test table fully into the analyzer. The test table might become jammed and prevent the use of the analyzer.

Hardware Overview

The CLINITEK Status+ analyzer consists of the following hardware components:

- Display
- Test table
- Printer
- Connections and power
- Memory card slot

Display

You interact with the CLINITEK Status+ analyzer through an integrated touch screen display. The touch screen displays messages, options, and requests for information. You respond by selecting a button or an area on the screen (see *Figure 1-5*).

CAUTION
Do not use anything hard or pointed on the touch screen. It might damage the screen.

Note If you run a CLINITEK Status+ analyzer with a CLINITEK Status connector, you can use a handheld bar-code reader to enter information into the analyzer.

Figure 1-5: Touch Screen Display

Test Table

All testing takes place on the test table.

1. Place the strips or the cassette on the test table insert.

   Note If you use a urinalysis strip that has 4 or fewer test pads, such as Uristix 4 reagent strips, use a short test table insert. You need to order the short test table insert separately from the analyzer (see *Appendix C, Orderable Supplies*).

2. The analyzer pulls in the test table partially for calibration and then pulls in the test table completely to read and test the strip or cassette.

3. When the test finishes, the test results display on the screen.

4. You can transfer the test results to a computer by using the RS-232 serial port on the back of the analyzer.

   If you run a CLINITEK Status+ analyzer with a CLINITEK Status connector, you can transfer the test results through a wireless or wired Ethernet connection.

Printer

An internal thermal printer prints the test results.

Connections and Power

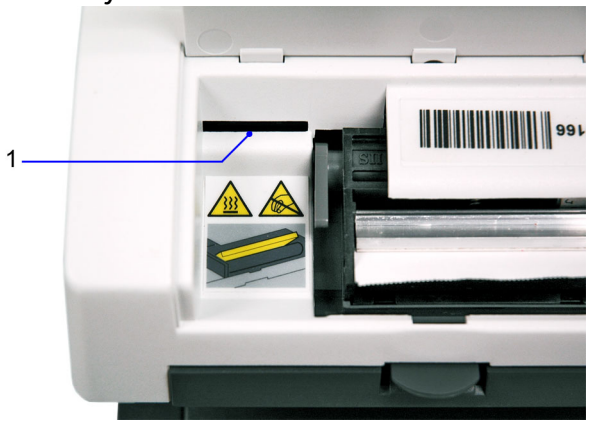
Connect the analyzer into an electrical outlet to use on a benchtop, or use batteries so you can freely move the analyzer from one testing site to another.

Memory Card Slot

The memory stores the analyzer software, operating parameters, settings you select, up to 950 patient test results, and 200 authorized operators. The information is stored in the memory, whether the analyzer is powered on or off.

You can update the software by inserting a memory card into the slot under the printer cover (see *Figure 1-6*).

Figure 1-6: Memory Card Slot



1	Memory Card Slot

Note If you run a CLINITEK Status+ analyzer with a CLINITEK Status connector, you can alternatively insert a memory stick into the USB port on the back of the Status connector.

Software Overview

The CLINITEK Status+ analyzer user interface consists of a touch screen with an onscreen alphanumeric keyboard.

Touch Screen

Use the **Select Ready** screen to configure the analyzer, run tests, recall results, and navigate to any point in the software (see *Figure 1-7*).

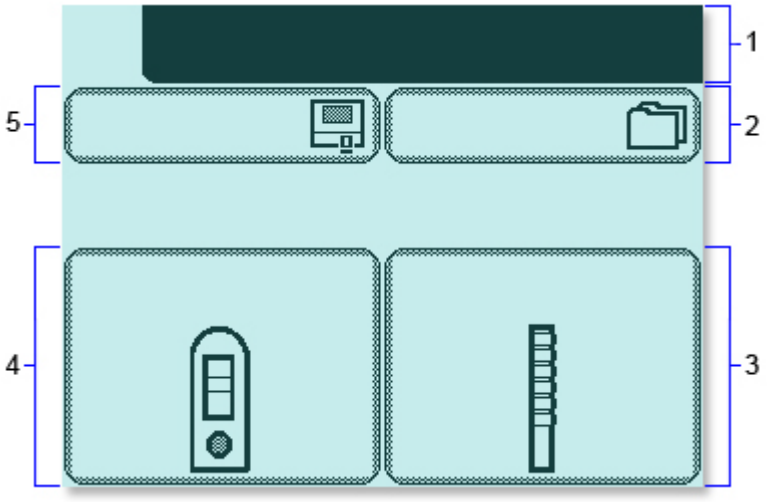
The **Select Ready** screen contains the following elements:

- **Title bar** Contains the current screen name, date, and time.
- **Selection area** Includes Instrument Set Up, Recall Results, Cassette Test, and Strip Test.

For a complete list of icons with their descriptions, see *Appendix E, Symbols*.

Note Depending on the screen that displays, when the analyzer is idle for a period of time, the analyzer returns to the **Select Ready** screen.

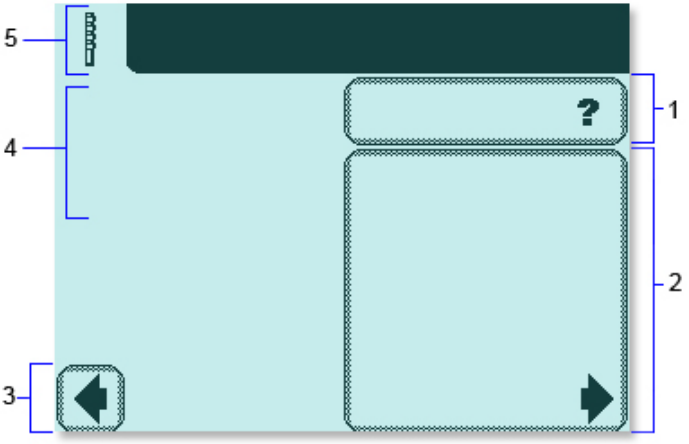
Figure 1-7: Select Ready Screen



1	Title bar
2	Recall Results
3	Strip Test
4	Cassette Test
5	Instrument Set Up

Each subsequent screen can display an icon in the upper left corner to indicate an analyzer mode or action (see *Figure 1-8*). For example, the battery icon indicates that the analyzer is powered by batteries. A screen also can display buttons, instructions, alert messages, and error messages.

Figure 1-8: Screen Elements

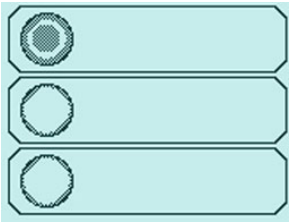
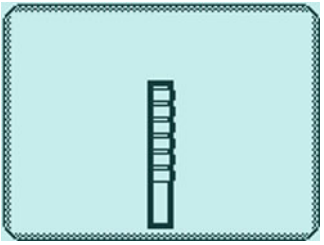


1	Help
2	Selection Area
3	Button
4	Instructions
5	Icon

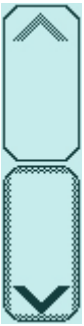
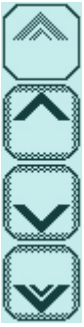
Tap the screen lightly in a selection area or button to select an option or button, or to navigate in a list of items.

CAUTION
Do not use anything hard or pointed on the touch screen. It might damage the screen.

The CLINITEK Status+ analyzer provides several screen elements: option, area, button, arrow, and double arrows.

Screen Element	Example	Description
Option		Round option buttons display on screens where you select an option. The option button with a filled circle is the current selection. For example, **Sound on**, **Sound off**, and **Key clicks only** are instrument setup options. To change your selection, select an option button with an unfilled circle. The newly selected circle (round option button) is highlighted. In the example, the **Sound on** option is selected.
Selection Area		Selection areas enclosed in boxes on the screen indicate functions that you can select. Select a boxed area to activate that function. For example, **Strip Test**. An area varies in size. For example, the boxes on the **Select Ready** screen are large areas.

Screen Element	Example	Description
Button		Several buttons display at the bottom of the screens, which include **Select** and **Done**. To navigate the screens, the analyzer displays left and right arrow buttons. To move to the previous screen, select **Previous** (left arrow). To move to the next screen, select **Next** (right arrow).

Screen Element	Example	Description
Arrow		Select the up and down arrows on the right side of the screen to scroll through the items in a list and highlight an item on the left side of the screen. Select the **Select** button to confirm your selection and move to the next screen. When an arrow is highlighted, you can use it to scroll. When an arrow is dimmed, you are viewing the first item or last item in the list, and cannot scroll beyond that page. **Note** When an item in a list displays a highlighted bar, you can select that item.
Double Arrows		When double arrows display on the screen, you select these arrows to move to the top or bottom of the page. When a double arrow is highlighted, you can use it to scroll. When a double arrow is dimmed, you are viewing the first page or last page of the list, and cannot move beyond that page.

Entering Information

Some options require you to enter information. For example, the analyzer prompts you to enter an Operator ID, Patient Name, and Patient ID. Depending on how you set up your analyzer, an alphabetic or numeric keyboard displays on the screen.

To switch between the onscreen keyboards, follow these steps:

- To display the numeric keyboard, select **123**.
- To display the alphabetic keyboard, select **ABC**.

To specify which onscreen keyboard you want to display by default, use the **Keypad Priority** option, as explained in Section 7, *System Configuration*, *Custom Set Up*, page 96.

Note By default, some screens display an alphabetic or numeric keyboard, and override the keyboard default you specify.

If you run a CLINITEK Status+ analyzer with a CLINITEK Status connector, you can connect a handheld bar-code reader to the analyzer, and scan information for some values.

You also can connect a keyboard to the analyzer, where the analyzer recognizes only the keyboard input equivalent to the alphabetic and numeric characters on the onscreen keyboards. For example, to enter a name, number, or birth date, select the alphabetic or numeric characters on the keyboard. Those selections display in the data entry box.

Note When you switch between the alphabetic and numeric onscreen keyboards, the analyzer retains the values in the data entry box on both keyboard screens.

For most data entry boxes, you can enter a minimum of 6 and a maximum of 63 characters, depending on the type of entry. An audible tone sounds when you exceed the maximum number of characters.

After you finish entering the information, select **Enter** (from either onscreen keyboard).

2 Operations

Materials Provided

CLINITEK Status+ Analyzer

Special Materials Required (Not Provided)

Item	Description
*	Siemens Reagent Strips for Urinalysis
10310483 (1364)	Chek-Stix® Combo Pak Control Strips for Urinalysis
10310618	Clinitest® hCG Cassettes

* Contact your local technical support provider for the configuration available in your country.

Before You Begin

Before running a test:

- You should test fresh urine samples within 2 hours of collection.
- Make sure you have enough urine to cover all of the test pads on the strip.
- Refrigerated urine samples must be brought to the room temperature (20-30°C).
- Do not change any of the analyzer's default settings.
- Check that the test table and table insert are clean.

  Note You should clean the test table and table insert weekly or more frequently to maintain the analyzer.

You can perform a Quick Test or a Full Test with a urinalysis strip or an hCG cassette. Place a strip or a cassette on the test table. The analyzer calibrates and begins testing.

Note You can configure the Quick Test or Full Test, as explained in Section 7, *System Configuration*, *Setting up Operator and Patient Information*, page 95.

With a Full Test, enter the Operator Name, and Patient Name, and Patient ID from the analyzer display. If you run a CLINITEK Status+ analyzer with a CLINITEK Status connector, enter the information from a bar-code reader.

Note You cannot cancel a test before the analyzer finishes the test.

View and print the test results that display on the screen.

Performing a Urinalysis Strip Quick Test

When you place a urinalysis strip on the test table, the analyzer calibrates and starts to perform the analysis. Perform the following procedure to test a strip.

BIOHAZARD
Wear personal protective equipment. Use universal precautions. For recommended precautions when you work with biohazardous materials, see *Appendix A, Safety Information*.

Preparing a Urinalysis Strip Quick Test

Before you perform a urinalysis strip Quick Test, prepare the analyzer and the strip.

For more information about the use and storage of urinalysis strips, see the urinalysis strip instructions for use insert.

Note An ID band is a white or colored area near the handle of a Siemens urinalysis strip. CLINITEK Microalbumin and Multistix PRO urinalysis strips contain a colored ID band. The analyzer reads the ID band to identify the strip type. Therefore, you do not need to select the strip type from a menu.

To prepare a urinalysis strip Quick Test, perform the following steps:

Note If you use a reagent strip that has 4 or fewer test pads, such as Uristix 4 reagent strips, use a short test table insert. You need to order the short test table insert separately from the analyzer (see *Appendix C, Orderable Supplies*).

1. On the **Select Ready** screen, select **Strip Test**.

2. If you enabled lot information with Instrument Set Up, enter the strip lot number and expiration date, as follows. Otherwise, go to step 3.
    - To use the last strip number and begin the test, select **Use Last Lot**.
    - To enter new strip data, select **Enter new lot and expiration**. Enter the strip lot number and select **Enter**. Use the arrow keys to enter the strip expiration date and select **Enter**.
3. Make sure the reagent strip holder faces upward in the test table insert.
4. Have the urinalysis strip and paper towel ready.

Running a Urinalysis Strip Quick Test

When you run a urinalysis strip Quick Test, the analyzer calibrates and then analyzes the strip.

To run a urinalysis strip Quick Test, perform the following steps:

Note After you select **START**, you have 8 seconds to dip the reagent strip in the urine sample and place the strip in the test table channel.

1. Select **START**.

    The **Prepare Test** screen displays steps on how to perform the test. A timer displays the amount of time remaining that you have to complete the task.

    Note To display the strip testing steps on the screen, select **Help**.

2. Dip the reagent strip in the urine sample and wet all the pads.

    The ID band provides auto-strip identification to ensure that the analyzer reports the correct strip configuration when you perform a urinalysis test. The analyzer also performs a strip integrity check for exposure to humidity.

    Note Be sure to use the proper dipping technique.

3. Immediately remove the strip from the urine.
4. Drag the edge of the strip against the side of the sample container as you remove it.

5. Blot the edge of the strip on a paper towel to remove the excess urine.
6. Place the reagent strip in the test table channel with the test pads facing up.
7. Slide or push the strip to the end of the channel. Do not touch the pads on the strip.
    - After the 8-second countdown ends, the analyzer pulls in the test table and strip, and then calibrates.

    Note Each time you run a test, the analyzer calibrates.

CAUTION

Do not push or pull the test table because the calibration might fail or the movement might cause might cause table positioning errors.

Do not move or bump the table while the analyzer calibrates. The calibration might fail.

- After the calibration finishes, the analyzer starts analyzing the strip, and the **Analyzing** screen displays.
- A timer counts down the time remaining in the strip analysis process. After the countdown ends, the analyzer displays the first page of the test results on the **Results** screen.
- The results display on the screen for 2 minutes. Then, the display returns to the **Select Ready** screen.
- The test table and strip move out of the analyzer.

Note If you set up the analyzer to print the test results automatically, the **Printing** screen displays until the printout finishes. If you set up the analyzer with a connection to a PC, the analyzer sends the test results to the PC.

Viewing the Urinalysis Strip Quick Test Results

The first page of test results display on the **Results** screen. You can view additional pages of the test results and sample interference notes on the **Results** screen.

To view additional pages of the urinalysis strip Quick Test results and the sample interference notes, perform the following steps:

1. Select **More** to view the remaining test results.

   If you use reagent strips with an ID band, you can view sample interference notes for this test.

2. Select **Notes** to view the sample interference notes, if the analyzer generated them for the test.

   The **Interference notes** screen displays up to 5 sample interference notes.

   Note If you disable the **Sample Interference Notes** setting in Instrument Set Up, or the analyzer does not generate sample interference notes, the **Notes** button does not display. If you run a test with this feature disabled, the analyzer does not generate notes at the time of the actual test. If you enable the **Sample Interference Notes** setting, and then recall the test results, the analyzer generates notes for this patient test.

3. Select the up and down arrows to scroll through the notes.
4. Select **Done** to return to the main **Results** screen.

Viewing Sample Interference Notes

Sample interference notes inform you about the test results that can be affected by components detected in the urine sample. By default, sample interference notes display and print. To set up sample interference notes, see Section 7, *System Configuration*, *Setting up Sample Interference Notes*, page 119.

Depending on the strip and sample, sample interference notes could include the following statements:

- 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.

Printing the Urinalysis Strip Quick Test Results

Print the urinalysis strip Quick Test results manually or automatically, or send the results to a computer.

To print the urinalysis strip Quick Test results manually, perform the following steps:

Select **Print** to print the test results.

- The date, time, test sequence number, and test results display on the printout.
- For Color and Clarity, the value is **Not Entered**.
- If the results are positive, an asterisk (*****) displays next to the results, only if you selected **Mark positive results** in Instrument Set Up.
- Depending on the configuration settings, the test results printout could include any of the following information:
- Date
- Time
- Test number
- Results
- Sample interference notes (if enabled in Instrument Set Up)

For instructions on how to set up the analyzer so that you can print the results automatically or send the results to a computer, see Section 7, *System Configuration*, *Changing the Connectivity Settings*, page 110.

Completing the Urinalysis Strip Quick Test

Complete the Quick Test for one strip or continue testing one strip at a time, until you finish testing all the strips you want to analyze.

To complete the urinalysis strip Quick Test, perform the following steps:

1. Remove the used urinalysis strip from the test table, and dispose of it according to your standard laboratory procedures.
2. Wipe the table insert, if necessary (see Section 4, *Maintenance*, *Weekly Cleaning of the Test Table and Test Table Insert*, page 57).

3. Report the results to a laboratory supervisor or physician.
4. Select **Done** to complete the test.

   The results display on the screen for 2 minutes. Then, the **Prepare Test** screen displays, ready for you to prepare the next strip Quick Test.

Performing an hCG Cassette Quick Test

With an hCG cassette Quick Test, when you place the hCG cassette on the test table, the analyzer calibrates and starts to perform the analysis. Perform the following tasks to run an hCG cassette Quick Test.

BIOHAZARD
Wear personal protective equipment. Use universal precautions. For recommended precautions when you work with biohazardous materials, see *Appendix A, Safety Information*.

Preparing a Cassette Quick Test

Note For more information about the use and storage of test cassettes, see the Clinitest hCG cassette test instructions for use insert.

CAUTION
Bring the test cassette and urine sample to room temperature 20° to 30°C (68° to 86°F) before you run a test. The wrong temperature could cause inaccurate test results.

To prepare a cassette Quick Test, perform the following steps:

1. On the the **Select Ready** screen, select **Cassette Test**.
2. If configured, enter the cassette lot number and expiration date:
   - To use the last cassette number and begin the test, select **Use Last Lot**.
   - To enter new cassette data, select **Enter new lot and expiration**. Enter the cassette lot number and select **Enter**. Use the arrow keys to enter the cassette expiration date and select **Enter**.

3. On the **Test Type** screen, select **Clinitest hCG cassette**.

   The **Prepare Test** screen displays.

   Note To display the cassette testing steps on the screen, select **Help**.

4. Position the test table insert in the test table for a cassette test.
5. Remove the test cassette from the foil package and place the cassette on the test table.

Running a Cassette Quick Test

To run the test, you have 8 seconds to perform the following steps:

Note After you select **START**, you have 8 seconds to draw the urine sample into the pipette and add the urine sample into the well on the cassette. For instructions on how to use the cassette, see the cassette instructions for use insert.

1. Select **START**.

   The **Prepare Test** screen displays steps on how to perform the test. A timer displays the amount of time remaining to complete the task.

2. Draw the urine sample to the line marked on the pipette (approximately 0.2 mL).
3. Add the entire contents of the pipette into the sample well of the test cassette.

   After the 8-second countdown ends, the analyzer pulls in the test table and cassette, and then calibrates.

Note Each time you run a test, the analyzer calibrates.

CAUTION

Do not push or pull the test table because the calibration might fail or the movement might cause table positioning errors.

Do not move or bump the table while the analyzer calibrates. The calibration might fail.

After the calibration finishes, the analyzer starts analyzing the cassette, and the **Analyzing** screen displays.

A timer counts down the time remaining in the cassette analysis process. After the countdown ends, the analyzer displays the test results on the **Results** screen.The test table and cassette move out of the analyzer.

Note If you set up the analyzer to print the test results automatically, the **Printing** screen displays until the printout finishes. If you set up the analyzer with a connection to a PC, the analyzer sends the test results to the PC.

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 reports it sooner. If the result is borderline, then you should retest with a new sample in 48 to 72 hours. For complete instructions on test results, see the Clinitest hCG cassette test instructions for use insert.

For instructions on how to set up the analyzer so that you can print the results automatically or send the results to a computer, see Section 7, *System Configuration*, *Changing the Connectivity Settings*, page 110.

Viewing the Cassette Quick Test Results

The test results display on the **Results** screen. Select **Done** to return to the main **Results** screen.

Printing the Cassette Quick Test Results

Print the cassette Quick Test results manually or automatically, or send the results to a computer.

To print the cassette Quick Test results manually, select **Print**.

The test results printout includes the following information:

- Cassette type
- Lot number, if configured
- Lot expiration date, if configured
- Test date
- Test time
- Test number
- Results

For instructions on how to set up the analyzer so you can print the results automatically or send the results to a computer, see Section 7, *System Configuration*.

Completing the Cassette Quick Test

Complete the testing for one cassette or continue testing one cassette at a time until you finish testing all the cassettes you want to analyze.

To complete the cassette Quick Test, perform the following steps:

1. Remove the used cassette from the test table, and dispose of it according to your standard laboratory procedures.
2. Wipe the table insert, if necessary (see Section 4, *Maintenance*, *Weekly Cleaning of the Test Table and Test Table Insert*, page 57).
3. Report the results to a laboratory supervisor or physician.
4. Select **Done** to complete the test.

   The results display on the screen for 2 minutes. Then, the display returns to the **Select Ready** screen.

Performing a Urinalysis Strip Full Test

With a urinalysis strip full test, you can enter an Operator Name, Patient Name, and Patient ID. When you place the strip on the test table, the analyzer calibrates and starts to perform the analysis. Perform the following procedures to test a strip.

BIOHAZARD
Wear personal protective equipment. Use universal precautions. For recommended precautions when you work with biohazardous materials, see *Appendix A, Safety Information*.

Entering Operator and Patient Information

Enter or select an operator name, patient name, and patient ID.

To enter operator and patient information, perform the following steps:

1. On the **Select Ready** screen, select **Strip Test**.
2. On the **Operator Name** screen, to enter the operator name, perform the following steps:
   - Only if configured, if you are the last operator, select **Last Operator**.
   - If you are a new operator:

   a. Select **Enter New Operator**.

   b. Enter your name (a maximum of 13 characters) on the **Enter Operator Name** screen.

   c. Select **Enter**.

   For more information about how to use the keyboard, see Section 1, *Introduction*.

   You also can enter the Operator Name from a computer keyboard, or if you run the analyzer with the CLINITEK Status connector, scan it from a bar-coded label using the handheld bar-code reader.
3. On the **Patient Information** screen, to enter the patient information, perform the following steps:

- To enter a previous patient:

a. Select **Recall Patient**.

b. Scroll through the patient name list.

   The most recently performed test displays at the top of the list.

c. Highlight the patient name and select **Select**.

Note The patient name list displays up to 200 patients in chronological order. When the list reaches 200 patients, the analyzer deletes the oldest name from the list. You cannot retrieve the deleted name.

- To enter a new patient:

a. Select **Enter New Patient**.

b. Enter the patient name (maximum of 20 characters) on the **Enter Patient Name** screen.

c. Select **Enter**.

   You also can enter the patient name from a computer keyboard.

   If you run a CLINITEK Status+ analyzer with a CLINITEK Status connector, you can scan the patient name from a bar-coded label using the handheld bar-code reader.

4. Enter the patient ID (maximum of 13 characters) on the **Enter Patient ID** screen, and select **Enter**.

Preparing a Urinalysis Strip Full Test

Before you run a urinalysis strip Full Test, prepare the strip and the analyzer.

To prepare a urinalysis strip Full Test, perform the following steps:

Note If you use a reagent strip that has 4 or fewer test pads, such as Uristix 4 reagent strips, use a short test table insert. You need to order the short test table insert separately from the analyzer (see *Appendix C, Orderable Supplies*).

1. If you enabled lot information with Instrument Set Up, enter the strip lot number and expiration date, as follows; otherwise, go to step 2.

- To use the last strip number and begin the test, select **Use Last Lot**.
- To enter new strip data, select **Enter new lot and expiration**. Enter the strip lot number and select **Enter**. Use the arrow keys to enter the strip expiration date and select **Enter**.

2. Make sure the reagent strip holder faces upward in the test table insert.
3. Have the urinalysis strip and paper towel ready.

Running a Urinalysis Strip Full Test

When you run a urinalysis strip Full Test, the analyzer calibrates and then analyzes the strip.

To run a urinalysis strip Full Test, perform the following steps:

Note After you select **START**, you have 8 seconds to dip the reagent strip in the urine sample and place the strip in the test table channel.

1. Select **START**.

   The **Prepare Test** screen displays steps on how to perform the test. A timer displays the amount of time remaining to complete the task.

   Note To display the strip testing steps on the screen, select **Help**.

2. Dip the reagent strip in the urine sample and wet all the pads.

   The ID band allows auto-strip identification to ensure that the analyzer reports the correct strip configuration when you perform a urinalysis test.

   Note Be sure to use the proper dipping technique.

3. Immediately remove the strip from the urine.
4. Drag the edge of the strip against the side of the sample container as you remove it.
5. Blot the edge of the strip on a paper towel to remove the excess urine.
6. Place the reagent strip in the test table channel with the test pads facing up.

7. Slide or push the strip to the end of the channel. Do not touch the pads on the strip.

   After the 8-second countdown ends, the analyzer pulls in the test table and strip, and then calibrates.

   Note Each time you run a test, the analyzer calibrates.

CAUTION
Do not push or pull the test table because the calibration might fail or the movement might cause table positioning errors.

Do not move or bump the table while the analyzer calibrates. The calibration might fail.

After the calibration finishes, the analyzer starts analyzing the strip, and the **Analyzing** screen displays.

Selecting the Appearance of the Urine Sample

While the analyzer analyzes the strip, a **Select Appearance** screen displays.

To select the appearance of the urine sample, perform the following steps:

1. Visually observe the urine sample and determine the appropriate color and clarity.
2. Select the urine sample color and clarity:
   - If the urine sample is yellow and clear, select **Yellow and Clear**.
   - If the urine sample is not yellow and clear, select **Other**, and select a color. Next, select a **Clarity** option and select **Next**.

   A time indicator on the **Select Appearance** screen counts down the time remaining in the analysis of the strip. The analyzer displays either of the following screens:

   - **Analyzing** if the strip is still being analyzed.

- **Results** if analyzing the strip is complete.

A timer counts down the time remaining in the strip analysis process. After the countdown ends, the analyzer displays the first page of the test results on the **Results** screen.

The results display on the screen for 2 minutes. Then, the display returns to the **Select Ready** screen.

The test table and strip move out of the analyzer.

Note If you set up the analyzer to print the test results automatically, the **Printing** screen displays until the printout finishes. If you set up the analyzer with a connection to a PC, the analyzer sends the test results to the PC.

Viewing the Urinalysis Strip Full Test Results

The first page of test results display on the **Results** screen. You can view additional pages of the test results and sample interference notes (if configured) on the **Results** screen.

To view additional pages of the urinalysis strip Full Test results and the sample interference notes, perform the following steps:

1. Select **More** to view the remaining test results.

   If you use reagent strips with an ID band, you can view sample interference notes for this test.

2. Select **Notes** to view the sample interference notes, if the analyzer generated them for the test.

   The **Interference notes** screen displays up to 5 sample interference notes.

   Note If you disable the **Sample Interference Notes** setting in Instrument Set Up, or the analyzer does not generate sample interference notes, the **Notes** button does not display. If you run a test with this feature disabled, the analyzer does not generate notes at the time of the actual test. If you enable the **Sample Interference Notes** setting, and then recall the test results, the analyzer generates notes for this patient test.

3. Select the up and down arrows to scroll through the notes.
4. Select **Done** to return to the main **Results** screen.

Printing the Urinalysis Strip Full Test Results

Print the urinalysis strip Full Test results manually or automatically, or send the results to a computer.

To print the urinalysis strip Full Test results manually, select **Print** to print the test results.

The test results printout includes the following information:

- Patient name and Patient ID
- Urinalysis strip type
- Lot number, if configured
- Lot expiration date, if configured
- Test date
- Test time
- Operator
- Test number
- Color
- Clarity
- Results (If the results are positive, an asterisk (*) displays next to the results, only if you selected Mark Positive Results in Instrument Set Up.)
- Sample interference notes (if enabled in Instrument Set Up)

For instructions on how to set up the analyzer so that you can print the results automatically or send the results to a computer, see Section 7, *System Configuration*, *Changing the Connectivity Settings*, page 110.

Completing the Urinalysis Strip Full Test

Complete the testing for one strip or continue testing one strip at a time, until you finish testing all the strips you want to analyze.

To complete the urinalysis strip Full Test, perform the following steps:

1. Remove the used urinalysis strip from the test table, and dispose of it according to your standard laboratory procedures.
2. Wipe the table insert, if necessary (see Section 4, *Maintenance*, *Weekly Cleaning of the Test Table and Test Table Insert*, page 57).

3. Report the results to a laboratory supervisor or physician.
4. Select **Done** to complete the test and return to the **Select Ready** screen.
5. Select **Done** to return the **Strip Test Prepare** screen.

   You are ready to start the next test. If you completed your testing, select **Back** to return to the **Select** screen.

Performing an hCG Cassette Full Test

With an hCG cassette full test, you can enter an Operator Name, Patient Name, and Patient ID. When you place a cassette on the test table, the analyzer calibrates and starts to perform the analysis. Perform the following procedures to test a cassette.

BIOHAZARD
Wear personal protective equipment. Use universal precautions. For recommended precautions when you work with biohazardous materials, see *Appendix A, Safety Information*.

Entering Operator and Patient Information

Enter or select an operator name, patient name, and patient ID.

To enter operator and patient information, perform the following steps:

1. On the **Select Ready** screen, select **Cassette Test**.
2. On the **Operator Name** screen, to enter the operator name, perform the following steps:
   - Only if configured, if you are the last operator, select **Last Operator**.
   - If you are a new operator:

   a. Select **Enter New Operator**.
   b. Enter your name (maximum of 13 characters) on the **Enter Operator Name** screen.

c. Select **Enter**.

For more information about how to use the keyboard, see Section 1, *Introduction*, *Entering Information*, page 28.

You also can enter the operator name from a computer keyboard. If you run a CLINITEK Status+ analyzer with a CLINITEK Status connector, you can scan the operator name from a bar-coded label using the handheld bar-code reader.

3. On the **Patient Information** screen, enter the patient information:

   - To look up a previous patient, select **Recall Patient**. Scroll through the patient name list. The most recently performed test displays at the top of the list. Highlight the patient name and select **Select**.

   Note The patient name list displays up to 200 patients in chronological order. When the list reaches 200 patients, the analyzer deletes the oldest name from the list. You cannot retrieve the deleted name.

   - To enter a new patient, select **Enter New Patient**, and enter the patient name (maximum of 20 characters) on the **Enter Patient Name** screen. Then, select **Enter**.

   You also can enter the Patient Name from a computer keyboard.

   If you run a CLINITEK Status+ analyzer with a CLINITEK Status connector, you scan the patient name from a bar-coded label using the handheld bar-code reader.

4. Enter the patient ID (maximum of 13 characters) on the **Enter Patient ID** screen, and select **Enter**.

Preparing a Cassette Full Test

Note For more information about the use and storage of test cassettes, see the Clinitest hCG cassette test instructions for use insert.

CAUTION
Bring the test cassette and urine sample to room temperature 20° to 30°C (68° to 86°F) before you run a test. The wrong temperature could cause inaccurate test results.

To prepare a cassette Full Test, perform the following steps:

1. On the the **Select Ready** screen, select **Cassette Test**.
2. If configured, enter the cassette lot number and expiration date:
   - To use the last cassette number and begin the test, select **Use Last Lot**.
   - To enter new cassette data, perform the following steps:
   a. Select **Enter new lot and expiration**.
   b. Enter the cassette lot number and select **Enter**.
   c. Use the arrow keys to enter the cassette expiration date and select **Enter**.
3. On the **Test Type** screen, select **Clinitest hCG cassette**.

   The **Prepare Test** screen displays.

   Note To display the cassette testing steps on the screen, select **Help**.
4. Position the test table insert in the test table for a cassette test.
5. Remove the test cassette from the foil package and place the cassette on the test table.

Running a Cassette Full Test

To run the test, you have 8 seconds to perform the following 2 steps:

Note After you select **START**, you have 8 seconds to draw the urine sample into the pipette and add the urine sample into the well on the cassette.

1. Select **START**.

   The **Prepare Test** screen displays steps on how to perform the test. A timer displays the amount of time remaining to complete the task.
2. Draw the urine sample to the line marked on the pipette (approximately 0.2 mL).

   For instructions on the cassette, see the cassette instructions for use insert.

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

   After the 8-second countdown ends, the analyzer pulls in the test table and cassette, and then calibrates.

   Note Each time you run a test, the analyzer calibrates.

CAUTION
Do not push or pull the test table because the calibration might fail or the movement might cause table positioning errors.

Do not move or bump the table while the analyzer calibrates. The calibration might fail.

After the calibration finishes, the analyzer starts analyzing the cassette, and the **Analyzing** screen displays.

The analyzer displays either of the following screens:

- **Analyzing** If the cassette is still being analyzed.
- **Results** If analyzing the cassette has been completed.

A timer counts down the time remaining in the cassette analysis process. After the countdown ends, the analyzer displays the test results on the **Results** screen.

The results display on the screen for 2 minutes. Then, the display returns to the **Select Ready** screen.

The test table and cassette move out of the analyzer.

Note If you set up the analyzer to print the test results automatically, the **Printing** screen displays until the printout finishes. If you set up the analyzer with a connection to a PC, the analyzer sends the test results to the PC.

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 reports it sooner. If the result is borderline, then you should retest with a new sample in 48 to 72 hours. For complete instructions on test results, see the Clinitest hCG cassette test instructions for use insert.

For instructions on how to set up the analyzer so that you can print the results automatically or send the results to a computer, see Section 7, *System Configuration*, *Changing the Connectivity Settings*, page 110.

Viewing the Cassette Full Test Results

The test results display on the **Results** screen. Select **Done** to return to the main **Results** screen.

Printing the Cassette Full Test Results

Print the cassette Full Test results manually or automatically, or send the results to a computer.

To print the cassette Full Test results manually, select **Print**.

The test results printout includes the following information:

- Patient name and Patient ID
- Lot number, if configured
- Lot expiration date, if configured
- Test date
- Test time
- Operator
- Test number
- Results

Completing the Cassette Full Test

Complete the testing for one cassette or continue testing one cassette at a time until you finish testing all the cassettes you want to analyze.

To complete the cassette Full Test, perform the following steps:

1. Remove the used cassette from the test table, and dispose of it according to your standard laboratory procedures.
2. Wipe the table insert, if necessary (see Section 4, *Maintenance*, *Weekly Cleaning of the Test Table and Test Table Insert*, page 57).
3. Report the results to a laboratory supervisor or physician.
4. Select **Done** to complete the test.
5. Select **Back** to return to the **Select Ready** screen.

Note Keep the calibration bar clean to ensure accurate hCG results. For details about cleaning the calibration bar, see *Cleaning the White Calibration Bar*, page 51.

3 Calibration & QC

This chapter covers calibration and quality control (QC).

Calibration Overview

The CLINITEK Status+ analyzer calibrates automatically before each measurement. The analyzer calibrates by reading the white calibration bar at the appropriate wavelengths to ensure accurate test results (see *Figure 3-1*).

Figure 3-1: Calibration Bar

The calibration bar was tested on a reference spectrophotometer. By calibrating the reference spectrophotometer with the National Institute of Standards and Technology (NIST) traceable calibrators, Siemens can show traceability to NIST.

Note Keep the calibration bar clean to ensure accurate results. For details about cleaning the calibration bar, see the next section on *Cleaning the White Calibration Bar*.

Cleaning the White Calibration Bar

For the CLINITEK Status+ analyzer to perform as intended and provide reliable test results, the white calibration bar on the test table needs to be clean and not discolored. With normal use, the white calibration bar should not become dirty or discolored.

BIOHAZARD
Wear personal protective equipment. Use universal precautions. For recommended precautions when you work with biohazardous materials, see *Appendix A, Safety Information*.

To clean the white calibration bar, perform the following steps:

1. Remove the insert from the test table.
2. Remove the test table by pulling it slowly out of the analyzer.
3. Drain the drip tray, if necessary.
4. Examine the white calibration bar on the test table for dirt or discoloration.

CAUTION
Do not touch the calibration bar while you examine it or after you clean it. Your fingerprints or lint on the bar could cause unreliable test results. When you examine the white calibration bar, do it carefully under good lighting.

5. If the white calibration bar appears clean and unmarked, perform the following steps:
   a. Place the test table into the analyzer by holding the table at the end opposite the white calibration bar, with the white calibration bar facing upward.
   b. Push the test table firmly but slowly, just over halfway into the analyzer.

CAUTION
Do not push the test table fully into the analyzer. The test table might jam and prevent you from using the analyzer.

   c. Place the test table insert.

6. If the white calibration bar is dirty or discolored, perform the following steps:

   a. Wet a new cotton-tipped stick or lint-free cloth with distilled water and gently wipe and clean the calibration bar.

CAUTION

Do not scratch the white calibration bar. Marks and stains could cause inaccurate test results, especially for hCG tests. Severe marks could cause errors.

Do not use solvents of any kind to clean the bar. They could destroy the bar.

   b. Allow the calibration bar to air dry.

   c. Inspect the surface for dust, foreign material, scratches, or scuffs.

      If you cannot completely clean the calibration bar or if the bar still has marks, order a new test table. Contact your Siemens representative.

   d. Place the test table, as described in step 5.

Quality Control Overview

Quality Control (QC) testing helps ensure that the urinalysis strips and cassettes are reacting correctly and that the analyzer is accurately reading them. QC also helps detect errors that result from user techniques.

QC should be performed in accordance with local, state, and federal guidelines.

This chapter provides only a general overview of quality control testing. To run quality control, follow the instructions in the quality control instructions for use product insert.

If you run a CLINITEK Status+ analyzer with a CLINITEK Status connector, you can configure QC testing with reminder prompts and the lockout feature. For more information about the QC configuration settings, see the *CLINITEK Status Connect System Operator's Guide*.

Urinalysis Strip Quality Control Testing

Test negative and positive controls when you first open a new bottle. Water should NOT be used as a negative control. Each laboratory should establish its own goals for adequate standards of performance. For information about control manufacturers, contact the Siemens Customer Service Department.

Run QC tests to ensure reagent storage integrity; train new users; confirm test performance; and when patient's clinical conditions or symptoms do not match the results. Also, run QC tests per your laboratory procedures. Liquid ready-to-use controls are available. Do not use water as a negative control. For recommendations and technical questions, call your local technical support provider or distributor, or visit siemens-healthineers.com/poc.

Compare QC results to the QC manufacturer's acceptable results list. If the QC results are not acceptable, do not test the patient samples until you solve the problem. Repeat QC tests until you have acceptable results.

For expected values for each analyte, see the quality control instructions for use product insert.

hCG Cassette Quality Control Testing

Each test includes two procedural controls, which indicate that sufficient sample was added for capillary flow to occur and the correct procedural technique was used. If the analyzer detects a failure of either of these two procedural controls, an error is reported and the test must be repeated.

Run QC tests to ensure reagent storage integrity; train new users; confirm test performance; and when patient's clinical conditions or symptoms do not match the results. Also, run QC tests per your laboratory procedures. Liquid ready-to-use controls are available. Do not use water as a negative control. For recommendations and technical questions, call your local technical support provider, or visit siemens-healthineers.com/poc.

Compare QC results to the QC manufacturer's acceptable results list. If the QC results are not acceptable, do not test the patient samples until you solve the problem. Repeat QC tests until you have acceptable results.

Quality Control Troubleshooting

If the control results fall outside the values stated in the product instructions for use insert, try any of the following corrective actions:

- Use a fresh strip out of a bottle or a fresh cassette out of a package and repeat the QC test.
- Use a fresh bottle of strips or fresh package of hCG cassettes to repeat the quality control procedure.
- Use a fresh control solution and repeat the quality control procedure.
- If you use lyophilized controls, prepare the control solution using a fresh bottle of control product.

For more troubleshooting information, see Section 5, *Troubleshooting*, or contact your local technical support provider for assistance.

4 Maintenance

Clean the test table and table insert weekly or more frequently, if necessary, to maintain the analyzer for the following reasons:

- Ensure that the analyzer operates properly
- Provide accurate test results
- Prevent contamination
- Avoid bacterial growth

Siemens recommends that you check the calibration bar for cleanliness weekly, and when you clean the test table. Also, check the calibration bar for cleanliness if you remove a strip from inside the analyzer. Clean the calibration bar, only if needed.

BIOHAZARD
Wear personal protective equipment. Use universal precautions. For recommended precautions when you work with biohazardous materials, see *Appendix A, Safety Information*.

Weekly Cleaning of the Test Table and Test Table Insert

Clean the test table and test table insert on a weekly basis or more frequently if necessary, to ensure test result accuracy and prevent contamination and bacterial growth.

To clean the test table and test table insert, perform the following steps:

1. Remove the test table by pulling it slowly out of the analyzer.
2. Lift the table insert to remove it from the test table.
3. Drain the drip tray, if necessary.
4. Wet a cotton-tipped stick with water and thoroughly scrub the test table and table insert, except for the white calibration bar.
5. Rinse both sides of the table insert and test table under running water.

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

CAUTION
Do not to scratch the white calibration bar. Marks and stains could cause inaccurate test results, especially for hCG tests. Severe marks can cause errors.

7. Examine the white calibration bar on the test table for dirt or discoloration.

CAUTION
Do not touch the calibration bar while you examine it or after you clean it. Your fingerprints or lint on the bar could cause unreliable test results. When you examine the white calibration bar, do it carefully under good lighting.

- If the white calibration bar appears clean and unmarked, go to step 9.
- If the bar appears dirty or discolored, clean the calibration bar, as described in *Cleaning the White Calibration Bar*, page 58.

8. Insert the test table, pushing it in more than halfway into the analyzer.

CAUTION
Do not push the test table fully into the analyzer. The test table might jam and prevent you from using the analyzer.

9. Insert the table insert.

Cleaning the White Calibration Bar

For the CLINITEK Status+ analyzer to perform as intended and to provide reliable test results, the white calibration bar on the test table needs to be clean and not discolored.

Siemens recommends that you check the calibration bar for cleanliness weekly, and when you clean the test table. Also, check the calibration bar for cleanliness if you remove a strip from inside the analyzer. Clean the calibration bar, only if needed.

BIOHAZARD
Wear personal protective equipment. Use universal precautions. For recommended precautions when you work with biohazardous materials, see *Appendix A, Safety Information*.

To clean the white calibration bar, perform the following steps:

1. Remove the insert from the test table.
2. Remove the test table by pulling it slowly out of the analyzer.
3. Drain the drip tray, if necessary.
4. Examine the white calibration bar on the test table for dirt or discoloration.

CAUTION
Do not touch the calibration bar while you examine it or after you clean it. Your fingerprints or lint on the bar could cause unreliable test results. Examine the white calibration bar carefully under good lighting.

5. If the white calibration bar appears clean and unmarked, perform the following steps:
    a. Re-insert the test table into the analyzer by holding the table at the end opposite the white calibration bar, with the white calibration bar facing upward.
    b. Push the test table firmly but slowly, just over halfway into the analyzer.

CAUTION
Do not push the test table fully into the analyzer. The test table might jam and prevent you from using the analyzer.

    c. Insert the test table insert.

6. If the white calibration bar appears dirty or discolored, perform the following steps:

   a. Wet a new cotton-tipped stick or lint-free cloth with distilled water and gently wipe and clean the calibration bar.

CAUTION

Do not scratch the white calibration bar. Marks and stains could cause inaccurate test results, especially for hCG tests. Severe marks can cause errors.
Do not use solvents of any kind to clean the calibration bar. They could destroy the bar.

   b. Allow the calibration bar to air dry.

   c. Inspect the surface for dust, foreign material, scratches, or scuffs.

      If you cannot completely clean the calibration bar or if the bar has scratches, order a new test table. Contact your Siemens representative.

   d. Insert the test table and table insert, as described in step 5.

Disinfecting the Test Table and Table Insert

Disinfect the test table and the test table insert as necessary, following your lab guidelines. Use a recommended disinfection solution for the following reasons:

- Prevent contamination
- Prevent bacterial growth
- Avoid damage to the test table and insert

CAUTION

Do not autoclave the test table or the insert because it would destroy them.

To disinfect the test table and the table insert, perform the following steps:

1. Prepare one of the following solutions in a tall, narrow container (such as an empty Multistix® bottle) to a depth of about 10 cm (or 4 inches):
   - **Presept, Cidex, Theracide, or Amphyl solution** prepare according to the product directions.
   - **Household Bleach (5% sodium hypochlorite)** use as full strength or dilute with water to as much as 1:20 (mix 5 mL bleach with 95 mL water for a total of 100 mL).
   - **Isopropyl Alcohol (70% to 85%)** use as full strength.

CAUTION
Any solutions other than the ones mentioned might damage the test table and the table insert.

2. Remove the table insert from the test table.
3. Remove the test table by pulling it slowly out of the analyzer.
4. Drain the drip tray, if necessary.
5. Place the table insert and test table into the solution, with the white calibration bar on the test table above the liquid level.

CAUTION
Be sure the cleaning solution does not come in contact with the white calibration bar. Cleaning solution can discolor or damage the calibration bar.

6. Soak the test table and the table insert for a minimum of 2 minutes and a maximum of 10 minutes.

CAUTION
Do not soak the test table and the table insert longer than 10 minutes. You could damage them.

7. Rinse the test table and the table insert thoroughly with water.

CAUTION
Rinse away all the solution residue, as any remaining solution might affect the reagent pad chemistries.

8. Dry the test table and the table insert thoroughly with a soft cloth, except for the white calibration bar.
9. Insert the test table and the table insert in the analyzer, as described in *Weekly Cleaning of the Test Table and Test Table Insert*, page 57.

Cleaning the Outside of the Analyzer

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

BIOHAZARD
Wear personal protective equipment. Use universal precautions. For recommended precautions when you work with biohazardous materials, see *Appendix A, Safety Information*.

To clean the outside of the analyzer, perform the following steps:

1. Power off the analyzer 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.

CAUTION
Do not use any type of solvent, oil, grease, silicone spray, or lubrication on the analyzer.
Do not spray glass cleaner directly onto the screen.
Do not use laboratory wipes, such as Kimwipes, because they might scratch the screen.
Prevent liquid from entering inside the printer compartment. You could damage the analyzer or the printer.

3. Disinfect the display with the same solution you use for the test table, as described in *Disinfecting the Test Table and Table Insert*, page 60.
    a. Wipe the solution on the display and let it remain for 10 minutes.
    b. Wipe the display with a clean cloth dampened with water.
    c. Dry the display with a clean cloth.

Changing the Batteries

The CLINITEK Status+ analyzer allows you to run approximately 100 tests from a set of batteries. To achieve this, the Power Save feature is always activated when you power the analyzer by batteries.

Note The test result printout might be lighter when you use batteries to power the analyzer.

If you do not use the analyzer in 3 minutes when it is battery-powered, it automatically powers off.

When you power the analyzer by batteries, a battery power icon displays near the title bar. The icon contains up to 4 vertical bars to indicate the amount of power left in the batteries.

When the batteries run low, the testing continues, but a `Low battery` message displays on the **Select Ready** screen.

Note If you do not change the batteries and the power level becomes too low to power the analyzer, a `Critical low battery` message displays. You cannot run a test until you replace the batteries.

CAUTION
Do not operate the analyzer with batteries, if you send data through a serial port, or to an LIS. The data might become corrupted.

The CLINITEK Status+ analyzer uses 6 AA-size batteries.

CAUTION
Do not use batteries in the analyzer, if you run a CLINITEK Status+ analyzer with a CLINITEK Status connector. Be sure to remove the batteries because they could leak and damage the analyzer and the connector.

To change the batteries, perform the following steps:

1. Remove the test table by pulling it slowly out of the analyzer.
2. Drain the drip tray, if necessary.
3. Place the analyzer on its side.
4. Remove the battery cover on the bottom of the analyzer:
    a. Press down on the tab.
    b. Pull out the battery cover.
5. Replace the batteries:
    a. Remove the current batteries.
    b. Place 6 new AA-size batteries into the analyzer.
6. Insert the battery cover.
7. Turn the analyzer back onto its base.
8. Insert the test table and table insert.

5 Troubleshooting

If an operational or analyzer problem occurs, in most cases, an error number with an explanation of the problem displays on the **Select Ready** screen. If a problem persists, write down the error number that displays and contact your local technical support provider for assistance.

If you think a Siemens urinalysis strip or an hCG cassette is causing the problem, see its product insert for troubleshooting information.

After an error occurs, if you power off the analyzer, be sure to retest the sample that was in progress. When you power on the analyzer, restart the test.

Error Messages

Error messages display to help you when the CLINITEK Status+ analyzer detects an issue that needs your attention. The type of error message depends on the importance of the problem and the mode in which you use the analyzer. The error messages include the following types:

- Errors that disable the analyzer
- Errors that require correction
- Advisory error messages
- Results alerts

Note For a list of errors and advisory messages and how to correct them, see *Errors and Advisory Messages*, page 66.

Errors That Require Correction

Certain errors must be corrected to enable testing. These errors do not prevent you from using other analyzer functions. An error message displays with a corrective action. Perform the corrective action to enable testing.

Advisory Error Messages

An advisory error message is of less importance, and displays on the **Select Ready** screen the next time the **Select Ready** screen displays. When you perform the corrective action, the analyzer removes the message from the screen.

If more than one advisory error occurs, when you clear the first advisory error message, the analyzer displays the next advisory error message.

Results Alert

If an error occurs during testing and the test cannot continue because of the error, a message displays on the **Results Alert** screen. The results alert error message provides details about the error and shows that the test was cancelled. The analyzer pushes out the test table so that you can remove the urinalysis strip or cassette.

Errors and Advisory Messages

The following table contains the error codes and descriptions, with their probable causes and corrective actions.

Note If you cannot troubleshoot an error, contact your local technical support provider or distributor, as described in *Appendix B, Support Information*.

Error Code	Error Message	Action
E01	Low battery power	The battery level is too low to power the analyzer. Replace the batteries by using any of the following instructions: On the screen, select **Error Report** to view the instructions. See Section 4, *Maintenance*, *Changing the Batteries*, page 63. Change the Power Save setting to extend the battery life. For details, see *Section 7, System Configuration*, *Changing the System Settings*, page 107.
E02	Failure of calibration data	Contact your local technical support provider or distributor.
E03, E04, E05, E06, E07, E08, E21, E22, E90, E91, E92 or E93	Failure of computer software	Contact your local technical support provider or distributor.
E10 or E48	Loss of test results	1. Power off the analyzer by pressing the on/off button for 2 seconds. 2. Power on the analyzer by pressing the on/off button. 3. Repeat the test.

Error Code	Error Message	Action
E11	Failure of test table	The test table is positioned improperly. 1. Make sure that the test table is in place. 2. Move the test table in or out of the analyzer slightly to reposition the test table. 3. If the error remains, with the analyzer powered on, disconnect the power cord from the back of the analyzer and connect it back in. Press the on/off button to power on the analyzer. 4. If the error remains with the test table in place, contact your local technical support provider or distributor. See *Appendix B, Support Information*, *Technical Assistance*, page 132.
E12	Failure of LED	An LED light source failed. Contact your local technical support provider or distributor.
E20	Failure of clock	Contact your local technical support provider or distributor.

Error Code	Error Message	Action
E23	Low battery power	When the battery level becomes too low to power the analyzer, error code E01 displays. Replace the batteries by using any of the following instructions: • On the screen, select **Error Report** to view the instructions. • See Section 4, *Maintenance*, *Changing the Batteries*, page 63. Change the Power Save setting to extend the battery life. For details, see Section 7, *System Configuration*, *Changing the System Settings*, page 107.
E24	No printer paper	Replace the printer paper by using any of the following instructions: • On the screen, select **Error Report** to view the instructions. • Lift the printer paper compartment cover to view the instructions inside. • See Section 1, *Introduction*, *Loading the Printer Paper*, page 15.
E25, E64, or E65	Failure of automatic calibration	Clean the calibration bar. If the error remains after cleaning, order a new test table. Contact your local technical support provider or distributor.

Error Code	Error Message	Action
E27	Setup failure	1. Power off the analyzer by pressing the on/off button for 2 seconds. 2. Power on the analyzer by pressing the on/off button.
E28	Printer error	1. Lift the printer cover. 2. Push the paper holding arm back into position. For the location of the paper holding arm, see Section 1, *Introduction*, *Loading the Printer Paper*, page 15.
E50	Incorrect strip type or tilted strip	**Note** For ID band urinalysis strips, skip step 1. 1. Ensure that the strip type you selected in Instrument Set Up is the type you use (see Section 7, *System Configuration*, *Changing the Urinalysis Test Settings*, page 112). 2. Verify that you correctly placed the strip on the test table insert. If you used the correct type of strip and you correctly placed the strip on the test table insert, check the analyzer operation by running either of the following tests: ○ Test a yellow and clear sample. ○ Run a Chek-Stix QC test (see Section 3, *Calibration & QC*).
E52	Invalid barcode	Repeat the test using the correct Siemens cassette.

Error Code	Error Message	Action
E53	Strip Test selected but cassette detected	Repeat the test using the Cassette Test routine (see Section 2, *Operations*, *Performing an hCG Cassette Quick Test*, page 35).
E54	Cassette Test selected but strip detected	Repeat the test using the Strip Test routine (see Section 2, *Operations*, *Performing a Urinalysis Strip Quick Test*, page 30).
E56	Incorrect size test table	Repeat the test using the correct test table (see Section 2, *Operations*, *Performing a Urinalysis Strip Quick Test*, page 30).
E57	Missing strip or cassette	Repeat the test and ensure that you correctly position the strip or cassette on the test table (see Section 2, *Operations*, *Performing a Urinalysis Strip Quick Test*, page 30 or *Performing an hCG Cassette Quick Test*, page 35).
E58	Misplaced strip	1. Repeat the test and ensure that you correctly position the strip on the test table (see Section 2, *Operations*, *Performing a Urinalysis Strip Quick Test*, page 30). 2. If the error remains, examine the test table insert to ensure that the small, white line located near the tip of the strip (on the strip side of the insert) is present and not damaged. 3. If this line is damaged, contact your local technical support provider or distributor.

Error Code	Error Message	Action
E59	Inverted strip positioned on the test table	Repeat the test with a fresh strip and ensure that the strip is correctly positioned on the test table (see Section 2, *Operations*, *Preparing a Urinalysis Strip Quick Test*, page 30).
E60	Tilted strip	Repeat the test with a fresh strip and ensure that the strip is correctly positioned on the test table (see Section 2, *Operations*, *Preparing a Urinalysis Strip Quick Test*, page 30).
E61	Dry strip	Repeat the test with a fresh strip and ensure that the strip has been in contact with the sample (see Section 2, *Operations*, *Preparing a Urinalysis Strip Quick Test*, page 30).
E62	Light Ingress	Too much light is reflecting on the analyzer. Move the analyzer to a location with lower lighting. Contact your local technical support provider or distributor.
E63	Failure to find end of strip	Repeat the test with a fresh strip and ensure that the strip is correctly positioned on the test table (see Section 2, *Operations*, *Preparing a Urinalysis Strip Quick Test*, page 30).

Error Code	Error Message	Action
E67 or E68	Sampling Error	A sample flow issue with the cassette test might have been detected. One or more test indicator lines might be missing or indiscernible from the background, or you applied insufficient or excess sample to the cassette. Ensure you correctly fill the pipette and dispense the correct volume of sample into the well of the cassette (see Section 2, *Operations*, *Running a Cassette Quick Test*, page 36). If the error occurs with a highly colored or visibly bloody or viscous sample, collect a fresh sample and repeat the test. If the error occurs with quality control testing, consider using a different control solution product.
E69	Strip quality problem	When the analyzer performed a quality check, the strip quality failed. The quality check detects whether the strip was compromised due to humidity exposure. Also, some commercially available quality controls and patient samples that are highly pigmented or have very high leukocyte levels might falsely cause this error. 1. Remove the defective strip and discard. 2. Repeat the test with a fresh strip that meets the quality requirements.

Troubleshooting the Analyzer Operation

The following table contains the analyzer operation icons that can display near the title bar on the **Select Ready** screen when an operation issue occurs.

Icon	Description	Action
	Low Battery Power	Displays on the **Select Ready** screen, indicating that the battery power level is low. An advisory message also displays when the battery power level is low. The power level decreases while the testing continues. If the battery level falls too low to power the analyzer, you cannot run a test until you replace the batteries. • Replace the batteries. For instructions, see Section 4, *Maintenance*, *Changing the Batteries*, page 63.
	No Printer Paper	Displays on the **Print Help** button on the **Select Ready** screen, indicating that the printer is out of paper or a label roll. An advisory message also displays. • Replace the empty paper or label roll with a new one, as instructed in Section 1, *Introduction*, *Loading the Printer Paper*, page 15.

Icon	Description	Action
	No Connector	Displays only if you run a CLINITEK Status+ analyzer with a CLINITEK Status connector. Indicates that the analyzer is not connected to the connector. You had enabled the Instrument Settings, Connectivity Platform setting but the analyzer cannot communicate with the connector platform. The cables on the analyzer and the connector are not connected physically, a cable broke, or the connector platform stopped working. • Check the connectors and cables. • If the connectors physically connect the analyzer to the connector platform and the cables are not broken, call your local technical support provider or distributor.
	No Remote Connection	Displays only if you run a CLINITEK Status+ analyzer with a CLINITEK Status connector. Indicates that the wired (Ethernet) or wireless connection between the analyzer and the server on a remote computer does not exist. The remote connection issue could be caused by the Ethernet card, network host PC, or server software.

The following table contains the issues that can occur when you operate the analyzer.

Description	Action
Display shows dashes	Dashes in a field indicate where you disabled a an option. Dashes also display when you exclude urinalysis tests for chemistries from the test results. You can write the information on the blank lines in the test result printout, if needed.
Test table movement is irregular or slow	Heavy buildup of dried urine on the test table. • Clean the test table and insert as described in Section 4, *Maintenance*, *Weekly Cleaning of the Test Table and Test Table Insert*, page 57. Low battery power. • Replace the batteries as described in Section 4, *Maintenance*, *Changing the Batteries*, page 63.

Calling for Assistance

If your CLINITEK Status+ analyzer displays corrective actions for a detected problem, carry out the instructions provided before you call for assistance. If your actions do not correct the problem or the instructions do not display, contact your local technical support provider or distributor.

Technical Support

When you call for assistance about an error message, have the following items ready. These items help the technical support representative work on the issue as quickly as possible.

- Error number
- Completed problem list (see *Problem List*, page 77)

For technical support provider or distributor contact information, see *Appendix B, Support Information*, *Technical Assistance*, page 132.

Customer Support

For customer support, contact your local technical support provider or distributor. For contact information, see *Appendix B, Support Information*, *Technical Assistance*, page 132.

Problem List

Complete the following form. Have it ready when you speak to your local technical support provider or distributor.

Clinitek Status+ Analyzer Problem List

Serial Number _____

Installation Date _____

Software Version _____

	YES	NO
1. Have you reviewed the error messages on pages *67-73*?	☐	☐
2. Record any error messages that display. _____ _____ _____		
3. Does the test table move out to the "load" position when the analyzer is first turned on?	☐	☐
4. If Question #3 is NO, then answer the following questions:		
• Is the power cord connected to 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 Ready** screen or the **Results** screen as expected?	☐	☐

Clinitek Status+ Analyzer Problem List		
6. Does the test table move into and out of the analyzer?	☐	☐
7. Does a quality control solution give the expected result?	☐	☐
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: _____ _____ _____ _____ _____		

6 File Management

The system stores the following information:

- System configuration settings
- Up to 950 patient test results

Note When the results list reaches 950 patient tests, the analyzer deletes the oldest test from the list. You cannot recall the deleted test.

You can perform the following tasks with the results:

- Recall, search, and view the patient test results
- Automatically send all the test results or individual test results to a computer (if connected)
- Automatically sends the test results to a computer while you test the sample and when you recall results (if configured, and if connected)
- Print all the test results or individual test results
- Delete the test results

If you connect the analyzer to a computer through a serial port, you can send the test results to the host computer. You also can set up the analyzer to automatically transfer the test results to the computer each time the analyzer completes a test. For information about connecting your analyzer to a computer, see Section 1, *Introduction*, *Connecting the Analyzer to a Computer*, page 14.

If you run a CLINITEK Status+ analyzer with a CLINITEK Status connector, see the *CLINITEK Status Connect System Operator's Guide*.

Recalling the Patient Test Results

You can search for the patient test results by patient name or patient ID, or by date. You also can view all the results, and print the patient test results you want.

To search for and recall the patient test results, perform the following steps:

1. At the **Select Ready** screen, select **Recall Results**.

   The **Recall Options** screen displays.

2. Select **Recall Patient Tests** or **QC Tests**.

   Note The QC feature is available only with a CLINITEK Status connector. For details, see the *CLINITEK Status Connect System Operator's Guide*.

   The **Recall Options** screen displays.

3. Select **Patient Tests** (default), if necessary, and select **Next**.

4. Search for the results in either of the following ways, or view all the results by skipping to step 5.

   To search by patient name or patient ID, perform the following steps:

   a. Select **Search for name or ID**.

   b. Enter the patient name or patient ID and select **Enter**.

   To search by date, perform the following steps:

   a. Select **Search by date**.

   b. Enter the earliest date by using the scroll arrows.

   c. Enter the latest date by using the scroll arrows.

   d. Select **Select**.

5. Select **View all results**.

   The **Recall Results Search Results** screen displays with the stored patient results, arranged in chronological order. The most recent test results display at the top and the oldest test result displays at the bottom of the list. The most recent test result is highlighted in the list.

   The first page of the patient test results display. If the test results display on more than one page, the **More** button displays. Select **More** to view additional pages of test results.

6. Select the up and down arrow keys to scroll through the results.
7. To print all the results, select **Print All**.

   Any information you entered for a patient displays on the printout.

8. Select **Back > Done** to return to the **Select Ready** screen.

To view and print individual patient test results, perform the following steps:

1. Highlight the result you want to recall.
2. Select **Select** to view the result details.
3. Select **Print** to print the result.
4. When you finish viewing the result, select **Done**.

   The **Select Test Results** screen displays.

5. Select **Back > Done** to return to the **Select Ready** screen.

Sending All the Test Results to a Computer

You can send all the test results to a PC or host computer.

To send all the test results to a computer, perform the following steps:

1. Verify that you connected the analyzer to a PC or a host computer.
2. Display the search results on the screen (see *Recalling the Patient Test Results*, page 80).
3. Select **Send all data**.

To automatically send the test results to a PC, host computer, or Laboratory Information System (LIS), enable a Connectivity setting, as explained in Section 7, *System Configuration*.

Note After you set the analyzer to transmit the results automatically, the **Send all data** button remains enabled. If you inadvertently select **Send all data**, the system transmits all data contained in the system memory, and might duplicate the patient records on the host computer or LIS.

Sending Individual Test Results to a Computer

To send individual test results to a computer, perform the following steps:

1. Enable the **Allow results to be sent to PC** option in Instrument Set Up.
2. On the **Select Ready** screen, select **Recall Results**.

   The **Recall Options** screen displays.
3. Select **Recall Results**.

   The **Recall Results Search Results** screen displays with the stored patient results.
4. Using the scroll arrows, scroll down to highlight the patient record and then select **Select**.

   The system resends the data.
5. To return to the **Select Ready** screen, select **Done > Back > Done**.

Deleting Patient Results

You can delete all the patient test results for any of the following reasons:

- Download the results to a host computer
- Move the analyzer from one site to another
- Send the analyzer for repair
- Protect patient confidentiality and comply with HIPAA regulations
- Discard the analyzer

Note The QC feature is available only with a CLINITEK Status connector. For details, see the *CLINITEK Status Connect System Operator's Guide*.

To delete the patient test results, perform the following steps:

CAUTION
Before you delete any test results, be sure that the loss of the test results is acceptable. If you did not send the test results to a host computer or printer, Siemens recommends that you perform those tasks before you delete the results. Keep in mind, the system erases the results from the database, and you can no longer recall them.

1. On the **Select Ready** screen, select **Recall Results**.

   The **Recall Options** screen displays.

2. Select **Delete Records**.

   The system displays a confirmation message.

3. Select **Yes**.

7 System Configuration

You can configure your CLINITEK Status+ analyzer to suit your workplace requirements. If you do not customize any configuration settings, the system uses the default configuration settings.

- For instructions on how to unpack and install your CLINITEK Status+ analyzer, see *Section 1, Introduction*.
- If you have a CLINITEK Status connector, and need instructions on how to configure the connector, see the *CLINITEK Status Connect System Operator's Guide, Section 6, System Configuration*.

Default Settings

You can view and print the system configuration settings, as explained in *Viewing and Printing the System Configuration Settings*, page 127. The following table contains the system configuration options with their default settings for English (US).

Note For CLINITEK Status connector system configuration settings, see the *CLINITEK Status Connect System Operator's Guide, Section 6, System Configuration*.

Configuration Option	Default Setting
Allow Results to be Sent to PC	Enabled
Authorized Operator	Disabled
Bar-code Reader	Disabled
Chemistries Reported	• Strip: ALB, BIL, BLO, CRE, GLU, KET, LEU, NIT, pH, PRO, SG, URO • Cassette: hCG
Custom Field	Disabled
Date Format	MM-DD-YY
Display Contrast	0 (zero)
Include Patient Name or Patient ID in Results	Patient Name
Input Settings	Quick Test

Configuration Option	Default Setting
Keyboard Priority	Alphabetic
Language	English
Last Operator Name	Disabled
Lot information for strip and cassette	Disabled
Mark Positive Results	No
Network Type	Serial connection
Operator Name	Disabled
Parity	None
Password	Disabled (Password protection is not set.)
Patient ID	Disabled
Patient Name	Disabled
Plus System	Disabled
Power Save	Disabled
Printer	Internal, Automatic
QC Strip	• QC test prompts – Disabled • Type of prompt – Required • QC confirmed by – Instrument • QC Strip Lock-out – No • Tests per QC – 2 • Test Interval – Days • Hours – 8 • Days –1 • Number of Shifts – 3 • QC Times – 06:00, 14:00, 22:00 For details about the QC control level default settings, print the system configuration settings, see *Viewing and Printing the System Configuration Settings*, page 127.

Configuration Option	Default Setting
QC Cassette	• QC test prompts – Disabled • Type of prompt – Required • QC confirmed by – Instrument • QC Cassette Lock-out – Enabled • Tests per QC – 2 • Test Interval – Days • Hours – 8 • Days – 1 • Number of Shifts – 3 • QC Times – 06:00, 14:00, 22:00 For details about the QC control level default settings, print the system configuration settings, see *Viewing and Printing the System Configuration Settings*, page 127.
Results Format Units Selection	Conventional
Results Printout	• Custom information, internal notes, operator name, patient name, patient ID, serial number, urine color, urine clarity – Enabled • Header – Disabled
Sample Appearance	None
Sample Interference Notes	Enabled
Serial Port Connectivity	• Enabled • Baud rate – 57600 • Parity – None • Stop Bits – 1
Serial Number Stored in Patient Records	No
Software Upload	Enabled
Sound	On
Strip Type	Multistix 10 SG

Configuration Option	Default Setting
System Settings	Printer – Automatic
Test Type	Quick Test
Test Sequence Number	0001
Time Format	12 hour
Urine Colors	Light Yellow, Yellow, Dark Yellow, Amber, Brown, Red, Orange, Pink Green, Blue, Other
Urine Colors Customized	None

If you connect a CLINITEK Status+ analyzer to a CLINITEK Status connector, the following configuration options are available.

Configuration Option	Default Setting
Bar-code reader	Disabled
Connectivity Platform	Disabled
Network connection	Serial connection
QC Cassette Level	1 – Positive 2 – Negative
QC Strip	• QC Test Prompts – Disabled • Type of Prompt – Required • QC Confirmed by – Instrument • QC Strip Lock-Out – No • Tests per QC – 2 • Test Interval – Days • Hours – 8 • Days – 1 • Number of Shifts – 3
QC Times	• Shift 1 – 06:00 • Shift 2 – 14:00 • Shift 3 – 22:00

Configuration Option	Default Setting
Wired connectivity	• Connectivity – Disabled • IP Configuration – DHCP • Gateway – No • Comms Protocol – POCT1 • Host – None For details about the gateway default settings, print the system configuration settings, see *Viewing and Printing the System Configuration Settings*, page 127.
Wireless connectivity	• Connectivity – Disabled • Security – Disabled • Authentication – Open system • IEEE 802. 1X – Disabled • Pre-shared Key – Disabled • WEP Key Index – 1 • WPA Encryption – TKIP • IP Configuration – DHCP • Gateway – No • Comms Protocol – POCT1 For details about the gateway default settings, print the system configuration settings, see *Viewing and Printing the System Configuration Settings*, page 127.

Changing the System Configuration Settings

You can change the default system configuration settings to customize the system for your point of care needs.

To change the system configuration settings, perform the following steps:

1. On the **Select Ready** screen, select **Instrument Set Up**.

   If password protection is enabled, the **Enter Password** screen displays. Type a password. The characters you enter display as asterisks. Select **Enter**.

   The **Choose Settings** screen displays.

2. Use the up and down arrows to scroll through the list and highlight a setting.
3. Select **Select**.
4. Make your changes to the settings.
5. Select **Done** until the **Select Ready** screen displays.

Changing the Language Settings

You can specify the language you want for your system. The following languages are available:

- English
- Deutsch
- Français
- Italiano
- Español
- Svenska
- Japanese
- Chinese

To change the Language Settings, perform the following steps:

1. On the **Select Ready** screen, select **Instrument Set Up**.
2. On the **Choose Settings** screen, select **Language Settings**.

3. Use the up and down arrows to scroll through the languages and highlight the language you want.
4. Select **Select**.

   A confirmation message displays.

CAUTION
If you change the language, the system deletes all the test results in the current language.
If you want to continue using the same language, select **No**. The **Choose Settings** screen displays.

5. Select **Yes**.
6. Select **Done**.

7. If you changed the language, the system changes the default values for several settings.

   The following table contains the default settings for English (US), French, German, and Italian.

Setting	English (US)	French	German	Italian
Password Required	Disabled	Disabled	Disabled	Disabled
Date Format	mm-dd-yyyy	dd-mm-yyyy	dd-mm-yyyy	dd-mm-yyyy
Time Format	12 hour	24 hour	24 hour	24 hour
Operator Name entry	Disabled	Disabled	Disabled	Disabled
Last Operator button display	Disabled	Disabled	Disabled	Disabled
Patient ID entry	Disabled	Disabled	Disabled	Disabled
Patient Name entry	Disabled	Disabled	Disabled	Disabled
Custom data entry	Disabled	Disabled	Disabled	Disabled
Keyboard Priority	Alpha	Alpha	Alpha	Alpha
Units selection	Conventional	SI	Conventional	SI
Plus System	Disabled	Disabled	Disabled	Disabled
Mark Positives	Disabled	Disabled	Disabled	Disabled
Default Strip	Multistix 10 SG	Multistix 10 SG	Multistix 10 SG	Multistix 10 SG
Color & Clarity entry required	None	None	None	None
Display results by Patient Name or Patient ID	Patient Name	Patient Name	Patient Name	Patient Name

Setting	English (US)	French	German	Italian
Output of instrument serial number with results data	Disabled	Disabled	Disabled	Disabled
Power Save	Disabled	Disabled	Disabled	Disabled
Printer	Automatic	Automatic	Automatic	Automatic
Sound	Enabled	Enabled	Enabled	Enabled

The following table contains the default settings for Spanish, Swedish, Japanese, and Chinese.

Setting	Spanish	Swedish	Japanese	Chinese
Password Required	Disabled	Disabled	Disabled	Disabled
Date Format	dd-mm-yyyy	dd-mm-yyyy	yyyy-mm-dd	dd-mm-yyyy
Time Format	12 hour	24 hour	24 hour	12 hour
Operator Name entry	Disabled	Disabled	Disabled	Disabled
Last Operator button display	Disabled	Disabled	Disabled	Disabled
Patient ID entry	Disabled	Disabled	Disabled	Disabled
Patient Name entry	Disabled	Disabled	Disabled	Disabled
Custom data entry	Disabled	Disabled	Disabled	Disabled
Keyboard Priority	Alpha	Alpha	Alpha	Alpha
Units selection	SI	SI	JCCLS	SI
Plus System	Disabled	Disabled	Disabled	Disabled
Mark Positives	Disabled	Disabled	Disabled	Enabled
Default Strip	Multistix 10 SG	Multistix 7	Uro-Hema-Combistix SG-L	Multistix 10 SG

Setting	Spanish	Swedish	Japanese	Chinese
Color & Clarity entry required	None	None	None	None
Display results by Patient Name or Patient ID	Patient Name	Patient Name	Patient Name	Patient Name
Output of instrument serial number with results data	Disabled	Disabled	Disabled	Disabled
Power Save	Disabled	Disabled	Disabled	Disabled
Printer	Automatic	Automatic	Automatic	Automatic
Sound	Enabled	Enabled	Enabled	Enabled

Setting and Removing a Password

You can set a password to protect the Instrument Set Up settings. After you set a password, you cannot make changes to the Instrument Set Up settings until you enter the password. You can remove the password.

To set a password, perform the following steps:

1. On the **Select Ready** screen, select **Instrument Set Up**.
2. On the **Choose Settings** screen, select **Set Password**.
3. Enter a password using the alphabetic and/ or numeric onscreen keyboards (maximum of 12 characters).

   If you change your mind and do not want to enter a password, select the left arrow key (Back) on the alphabetic keyboard. The **Choose Settings** screen displays.

   Note Be sure to keep a record of the password so that you can access Instrument Set Up. If you lose your password, call your local technical support provider or distributor.
4. Select **Enter**.
5. Select **Done**.

To remove a password, perform the following steps:

1. On the **Select Ready** screen, select **Instrument Set Up**.

2. Enter the password.
3. On the **Choose Settings** screen, select **Remove Password**.

   The **Set Password** option displays in the **Choose Settings** menu. You no longer need a password to gain access to Instrument Set Up.
4. Select **Done**.

Setting up Operator and Patient Information

The operator and patient information settings provide the following options:

- Quick Test
- Full Test
- Custom Set Up

Quick Test

When you run a Quick Test, the system runs the test and assigns a sequential test number that displays when the results display or print.

Note You cannot enter patient and operator information with a Quick Test.

To select a Quick Test, perform the following steps:

1. On the **Select Ready** screen, select **Instrument Set Up**.
2. On the **Choose Settings** screen, select **Operator and Patient Information**.
3. Select **Quick Test**.

   The system assigns a sequence number to the test but does not let you enter patient and operator information. To enter patient and operator information, see *Full Test*, page 96 and *Custom Set Up*, page 96.
4. Select **Next**.
5. Select **Done**.

Full Test

By default, when you run a Full Test, the system prompts you to enter operator, patient, and sample appearance information.

However, if you need to set the prompt for a Full Test, perform these steps:

1. On the **Select Ready** screen, select **Instrument Set Up**.
2. On the **Choose Settings** screen, select **Operator and Patient Information**.
3. Select **Full Test**.
4. Select **Next**.
5. Select **Done**.

Custom Set Up

You can select any of the following custom settings:

- Operator name
- Alphabetic or numeric keypad priority
- Patient name
- Patient ID
- Bar-code reader
- Patient name or patient ID in the Results list
- Last operator's name displayed
- Sample appearance
- Custom field for frequently used information, such as Physician Name

To customize the patient, operator, and sample appearance information, perform the following steps:

1. On the **Select Ready** screen, select **Instrument Set Up**.
2. Select **Custom Set Up**.
3. Select **Next**.

   The **Custom Settings 1 of 5** screen displays.

4. Select the settings you want. Select **Next** or **Previous** to navigate through the screens.

Custom Setting	Description
Screen 1 of 5	
Operator Name	• **Enabled** prompts you to enter an operator name when you run a test. • **Disabled** (default) does not prompt you to enter an operator name when you run a test.
Keypad priority	• **Numeric** during data entry, displays the numeric keyboard as the first keyboard. • **Alphabetic** (default) during data entry, displays the alphabetic keyboard as the first keyboard.
Screen 2 of 5	
Patient Name	• **Enabled** prompts you to enter a patient name when you run a test. • **Disabled** (default) does not prompt you to enter a patient name when you run a test.

Custom Setting	Description
Patient ID	• **Enabled** prompts you to enter a patient ID when you run a test. • **Disabled** (default) does not prompt you to enter a patient ID when you run a test. The system stores up to 950 patient test results. When the patient test results list contains 950 patient tests (or the maximum amount for your system), the system deletes the oldest test from the list. You cannot recall a deleted test result. **Note** If you disable **Patient Name** and **Patient ID**, the system displays a sequential test number with the test results.
Bar-code reader settings	1. Select **Barcode Reader Settings**. 2. Enable or disable the bar-code reader: ○ **Enabled** requires you to enter a patient name and patient ID only by bar-code reader. ○ **Disabled** (default) allows you to enter a patient name and patient ID by bar-code reader, or by the onscreen keyboard. 3. Select **Done** to return to the **Custom Settings Patient Information, page 2 of 5** screen.

Custom Setting	Description
Screen 3 of 5	
Choose which to show in Results list	• **Patient Name** (default) displays the patient name in the results list. • **Patient ID** Displays the patient ID in the results list.
Last Operator's Name displayed	• **Enabled** displays the last operator name when the system prompts you to enter an operator name, during a strip or cassette test. • **Disabled** (default) does not display the last operator name when the system prompts you to enter an operator name, during a strip or cassette test.
Screen 4 of 5	
Choose which to record during a strip test	• **Color and Clarity** displays and prints the urine sample color and clarity for a strip test. • **Color only** displays and prints the urine sample color for a strip test. • **Clarity only** displays and prints the urine sample clarity for a strip test. • **None** (default) does not display or print the urine sample color or clarity for a strip test.

Custom Setting	Description
Screen 5 of 5	
Custom Field	• **Enter Custom Field** allows you to create a label for a custom field. For example, if you create a label, PHYSICIAN, the system displays the prompt `Enter Patient Information PHYSICIAN`. Then, you would enter the physician name. • **Enabled** displays the custom field when you run a test. • **Disabled** (default) does not display the custom field when you run a test. To create a custom field name, perform the following steps: 1. Select **Enter Custom Field**. The **Enter Custom Field** screen displays with a keyboard. 2. Use the keyboard to enter a custom field name. 3. Select **Enter** to return to the **Custom Settings** screen.

The **Input Settings-Confirmation** screen displays the custom settings.

5. Select **Done** twice to return to the **Select Ready** screen.

Setting up the Urine Color and Clarity

You can configure the urine color and clarity for the urinalysis strip patient test results in the following ways:

- Set the system to prompt you for the urine color, clarity, or both.
- Edit the urine color.
- Customize the urine color.

Note You can set a prompt for the urine color and clarity only with the **Custom Set Up** option.

Edit and Customize Urine Colors

You can select from 10 urine colors and customize up to 4 urine colors for the patient test results.

To edit the urine colors, perform the following steps:

1. On the **Select Ready** screen, select **Instrument Set Up**.
2. On the **Choose Settings** screen, select **Operator and Patient Information**.
3. On the **Input Settings** screen, select **Custom Set Up**. Select **Next**.
4. On the **Custom Settings-Operator 1 of 5** screen, select **Next** 3 times.
5. On the **Custom Settings-Sample Appearance 4 of 5** screen, select **Edit colors**.

   The **Sample Appearance-Select colors 1 of 3** screen displays.

Urine Color Option	Description
Screen 1 of 3	
• Light yellow • Yellow • Dark yellow • Amber • Brown • Red	By default, all colors are selected. • Select a selected color to exclude it. • Select a color to include it. • Select **Next** to display the **Sample Appearance-Select colors 2 of 3** screen.
Screen 2 of 3	
• Orange • Pink • Green • Blue • Other	By default, all colors are selected. • Select a selected color to exclude it. • Select a color to include it. • Select **Next** to display the **Sample Appearance-Select colors 3 of 3** screen.

Urine Color Option	Description
Screen 3 of 3 • Custom color 1 • Custom color 2 • Custom color 3 • Custom color 4	**Note** If you edit a custom color that already exists, the system deletes all the patient test results. To customize a urine color, perform the following steps: 1. Select **Enter custom color 1, 2, 3,** or **4** that corresponds to Custom Color 1, 2, 3, or 4. 2. Enter a custom color name. **Note** A color name can have a maximum of 10 characters. 3. Select **Enter**. The **Sample Appearance-Select colors screen 3 of 3** displays. If a custom color exists, the **Sample Appearance alert** screen displays. 4. Select an option: • Select **Yes** to edit the custom color and delete all the records. • Select **No** to return to the **Sample Appearance Select Colors 3 of 3** screen. To delete a custom color, perform the following steps: 1. Select **Edit custom color 1, 2, 3,** or **4** that corresponds to Custom Color 1, 2, 3, or 4. 2. Select backspace to delete each letter in the custom color name. 3. Select **Enter**.

6. Select **Next** 3 times to display the **Input Settings-Confirmation** screen.
7. Select **Done** twice to return to the **Select Ready** screen.

Changing the Date and Time

The date and time display on the **Select Ready** screen in the title bar. The system includes the date and time with the test results in the format you specify, on the display and the printout.

To change the date and time, perform the following steps:

1. On the **Select Ready** screen, select **Instrument Set Up**.
2. On the **Choose Settings** screen, select **Date and Time Settings**.
3. On the **Set Date & Time** screen, use the up and down arrows to adjust the date and time.
4. Select **AM** or **PM** if you want the 12-hour time format.
5. Select **Set**.
6. Select **Done**.

To change the date and time format, perform the following steps:

1. On the **Select Ready** screen, select **Instrument Set Up**.
2. On the **Choose Settings** screen, select **Date and Time Settings**.
3. On the **Set Date & Time** screen, select **Choose Format**.
4. On the **Choose Format** screen, select a date format.
5. Select a time format.

   Note If you select the 24-hour format, the AM and PM selections are not available.
6. Select **Done** to return to the **Set Date & Time** screen.

   The date and time display in the format you selected.
7. Select **Set** to confirm your choices and return to the **Choose Settings** screen.
8. Select **Done** to return to the **Select Ready** screen.

Resetting the Test Sequence Number

The test sequence numbers run from 0001 to 9999. You can reset the test sequence number to start at 0001 for the next test.

To reset the test sequence number, perform the following steps:

1. On the **Select Ready** screen, select **Instrument Set Up**.
2. On the **Choose Settings** screen, select **Test sequence number**.

   The **Sequence Number** screen shows the next test number.
3. Select **Reset to 0001**.
4. Select **Done** twice to return to the **Select Ready** screen.

Changing the Instrument Settings

The instrument settings control the way the system displays information and operates.

The instrument settings include the following options:

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

To change the instrument settings, perform the following steps:

1. On the **Select Ready** screen, select **Instrument Set Up**.
2. On the **Choose Settings** screen, select **Instrument Settings**.
3. On the **Instrument Settings** screen, select an option.
4. Select **Next** or **Previous** to move forward and backward through the screens.
5. When you finish, select **Done**.

Changing the Results Format

You can display and print the test results in different formats. You also can specify whether you want to include the instrument serial number with the results.

You can select any of the following results formats:

- Normal System
  - Conventional
  - SI (Systéme International)
  - Nordic units
- Plus System
- Mark positive results with an asterisk (*)
- Store the instrument serial number in the patient records

To change the results format, perform the following steps:

1. On the **Select Ready** screen, select **Instrument Set Up**.
2. On the **Choose Settings** screen, select **Instrument Settings**.
3. On the **Instrument Settings** screen, select **Results Format**.

   The **Choose Format 1 of 2** screen displays.

   Note If you set the language to Chinese, the **Choose Format 1 of 2** screen does not display.

4. Select the results format options.

Results Format Option	Description
Screen 1 of 2	
Units Selection	• Conventional (default) • SI (Systéme International) • Nordic **Note** Nordic units are available only in English and Swedish. SI units are available only in Chinese. If you set the language to Chinese, the **Choose Format 1 of 2** screen does not display.
Plus System	• **Enabled** displays the test results in the Plus System. Results that you record in the Plus System use plus (+) symbols instead of clinical units, such as mg/dL. **Note** For some languages, the Normal System and the Plus System test results are the same, as shown in *Appendix D, Specifications*, *Tables of Results*, page 137. • **Disabled** (default) displays the test results in the Normal System, not in the Plus System.

5. Select **Next**.

   The **Choose Format 2 of 2** screen displays.

6. Select the results format options.

Results Format Option	Description
Screen 2 of 2	

Mark Positive Results	• **Yes** displays an asterisk (*) next to the positive results on the screen, a printout, and when you transfer the data to a host computer. For more information, see *Appendix D, Specifications*, *Tables of Results*, page 137. • **No** (default) does not mark the positive results.
Store instrument serial number in patient records	• **Yes** stores the analyzer serial number in the patient records to identify the analyzer. • **No** (default) does not store the analyzer serial number in the patient records.

7. Select **Done** 3 times to return to the **Select Ready** screen.

Changing the System Settings

The System Settings let you change the following options:

- Printer
- Power Save mode
- Sound

To change the System Settings, perform the following steps:

1. On the **Select Ready** screen, select **Instrument Set Up**.
2. On the **Choose Settings** screen, select **Instrument Settings**.
3. On the **Instrument Settings** screen, select **System Settings**.

4. On the **System Settings** screen, perform the following steps:
    a. Select the **System Settings** options.

System Settings Option	Description
Screen 1 of 2	
Printer	• **Automatic** (default) prints the results for each test automatically after you complete the test. • **Manual** does not print the test results automatically. Select **Print** on the **Results** screen to print the test results. This option extends the battery life. • **Off** the test results do not print. This option extends the battery life. You might want to select the **Off** option, when the printer runs out of printer paper, while you send data to the LIS or host computer, or if you want to reduce the noise level in the laboratory.

System Settings Option	Description
Power Save	• **Enabled** activates Power Save mode. If you power the system from an electrical outlet and the system remains idle for 5 minutes, the system pulls in the test table and powers down. If you power the system by batteries, Power Save is always activated. After the system remains idle for 5 minutes, it powers down. • **Disabled** (default) deactivates Power Save mode if you power the system from an electrical outlet.
Screen 2 of 2	
Sound	• **Sound on** (default) plays a range of audible tones when you select an area, button, or key on the screen. Also, a tone sounds if you have a problem performing a task. Sounds range from a single beep to a click. • **Sound off** does not play any audible tones. • **Key clicks only** sounds an audible click when you select an active button or key on the screen.

b. Select **Next**.

c. When you finish, select **Done** 3 times to return to the **Select Ready** screen.

Changing the Display Contrast

You can increase or decrease the display contrast to suit your work area and lighting where you operate the system. A higher contrast level makes the screen easier to read. The contrast levels range from the darkest at +3 to the lightest at -3. The default contrast level is 0.

To change the display contrast, perform the following steps:

1. On the **Select Ready** screen, select **Instrument Set Up**.
2. On the **Choose Settings** screen, select **Instrument Settings**.
3. On the **Instrument Settings** screen, select **Display Contrast**.
4. On the **Display Contrast** screen, use the up and down arrows to view each contrast setting.
5. When you find the contrast setting you want, select **Select**.
6. Select **Done** twice to return to the **Select Ready** screen.

Changing the Connectivity Settings

You can connect the analyzer to a PC or host computer through a serial port. If you have a Status connector, you can connect the analyzer to an LIS using a wired (Ethernet) or wireless network, or send data through the serial port. To change the connectivity settings for the connector, see the *CLINITEK Status Connect System Operator's Guide*.

Selecting the Connectivity Settings

To select the connectivity settings, perform the following steps:

1. On the **Select Ready** screen, select **Instrument Set Up**.
2. On the **Choose Settings** screen, select **Instrument Settings**.
3. On the **Instrument Settings** screen, select **Connectivity**.

   The **Connectivity 1 of 2** screen displays.

4. Select the connectivity options.

Connectivity Option	Description
Screen 1 of 2	
Connectivity Platform	• **Enabled** allows communication between the analyzer and the connector. • **Disabled** (default) prevents communication between the analyzer and the connector.
Allow results to be sent to PC	• **Enabled** (default) allows the analyzer to send the test results to a PC. • **Disabled** prevents the analyzer from sending the test results to a PC. **Note** If you do not use a CLINITEK Status connector, Siemens recommends that you select **Disabled**.

5. Select **Next**.

   The **Connectivity 2 of 2** screen displays.

6. Select **Serial Connection**.

7. Select **Edit serial settings**, and select the following options:

   a. For **Baud** rate, select **9600**, **19200**, **57600**, or **115200**.

   b. Select **Next**.

   c. For **Parity**, select **None**, **Odd**, or **Even**.

   d. Select **Next**.

   e. For **Stop Bits**, select **1** or **2**.

8. Select **Done** 4 times to return to the **Select Ready** screen.

Changing the Urinalysis Test Settings

The Urinalysis Test Settings include the following options:

- Siemens urinalysis strip that you want to use with the CLINITEK Status+ analyzer
- Strip lot number and expiration date
- Tests that you want to report

Note You do not need to select a type of Clinitest immunoassay cassette.

Changing the Urinalysis Strip

To change the urinalysis strip, perform the following steps:

1. On the **Select Ready** screen, select **Instrument Set Up**.
2. On the **Choose Settings** screen, select **Instrument Settings**.
3. On the **Instrument Settings** screen, select **Urinalysis Test Settings**.
4. On the **Urinalysis Test** screen, select a urinalysis strip.

CAUTION
Do not use any urinalysis strip product other than the Siemens strips that are on the list. Using the wrong urinalysis strip gives you incorrect results.

Note Some Siemens strips are not on the list of strips, such as CLINITEK Microalbumin and Multistix PRO. The system identifies them through the color ID band on the strip. Other Siemens strips include a white ID band that identifies the strip type.

5. Select **Next**.
6. Select **Done** 3 times to return to the **Select Ready** screen.

Changing the Lot Number and Expiration Date Prompt Setting

By default, for a Full Test, the system prompts you to enter the strip lot number and expiration date, and associate this information with each patient record. You can select whether you want to enter a new lot number and expiration date, or use the lot information from the previous test.

Note When you set the prompt for strip lot information, the system also allows you to enter the cassette lot information before you run a cassette test.

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

1. On the **Select Ready** screen, select **Instrument Set Up**.
2. On the **Choose Settings** screen, select **Instrument Settings**.
3. On the **Instrument Settings** screen, select **Urinalysis Test Settings**.
4. On the **Urinalysis Test** screen, select **Next**.
5. On the second **Urinalysis Test** screen, for **Enter strip lot number and expiration date before each test**, select one of the following options:
    - **Enabled** (default) prompts you to enter the strip or cassette lot number and expiration date before each test.
    - **Disabled** does not display a prompt to enter strip or cassette lot number and expiration date before each test.
6. Select **Done** 3 times to return to the **Select Ready** screen.

Editing the Reported Chemistries

By default, the system reports all chemistries in the test results: GLU, BIL, KET, SG, BLO, pH, PRO, URO, NIT, LEU, ALB, and CRE. You can include or exclude chemistries from the test results. The reported chemistries you select apply to all Siemens strip types.

To edit the reported chemistries, perform the following steps:

1. On the **Select Ready** screen, select **Instrument Set Up**.
2. On the **Choose Settings** screen, select **Instrument Settings**.
3. On the **Instrument Settings** screen, select **Urinalysis Test Settings**.
4. On the **Urinalysis Test** screen, select **Edit reported chemistries**.
5. On the **Reported Chemistries 1 of 2** screen, change the reported chemistries. By default, all chemistries are selected.
    - Select a chemistry to include it.

- Select a selected chemistry to exclude it.

6. Select **Next** to display the **Reported Chemistries 2 of 2** screen, which contains the rest of the chemistries.
   - Select a chemistry to include it.
   - Select a selected chemistry to exclude it.
7. To return to the **Select Ready** screen, perform the following steps:
   a. Select **Done**.
   b. Select **Next**.
   c. Select **Done** twice.

Setting up the Authorized Operators

The CLINITEK Status+ analyzer stores 700 operators. You can authorize operators to perform certain tasks, where they gain access to the system by entering their name to perform those tasks. You can add, edit, and delete authorized operators.

Note When you enable the Instrument Set Up password, you restrict access to Instrument Set Up for only those operators who know the password. If you enable the Authorized Operator setting and the Instrument Set Up password, the operator name has priority over the Instrument Set Up password.

Enable or Disable Authorized Operators

To enable or disable authorized operators, perform the following steps:

1. On the **Select Ready** screen, select **Instrument Set Up**.
2. On the **Choose Settings** screen, select **Instrument Settings**.
3. On the **Instrument Settings** screen, select **Authorized Operator**.
4. On the **Authorized Operator** screen, for **Authorized operators only**, select an option:
   - To permit access only by authorized operators, select **Enabled**.

- To allow all operators to gain access to the system without entering their name, select **Disabled**.

CAUTION
After you add an operator, if you enable or disable the Authorized Operator setting, the system deletes all the patient test results.

5. Select one of the following options:
   - If you selected **Enabled**, add at least 1 operator, as explained in *Add an Operator*, page 115.
   - If you selected **Disabled**, select **Done** 3 times to return to the **Select Ready** screen.

   Note If the CLINITEK Status+ analyzer loses power, the system retains the operator IDs.

Add an Operator

You can add up to 700 operators.

Note If you do not add any authorized operators and no operators display in the list, be sure to return to the **Select Ready** screen. That way, the system disables the Authorized Operator setting and you can continue to gain access to the system.

To add an operator, perform the following steps:

1. On the **Select Ready** screen, select **Instrument Set Up**.
2. On the **Choose Settings** screen, select **Instrument Settings**.
3. On the **Instrument Settings** screen, select **Authorized Operator**.
4. On the **Authorized operator** screen, select **Add operator**.
5. On the **Operator ID** screen, enter an operator name.
6. Select **Enter**.

   The **Authorized Operator** screen displays, indicating the operator name and which functions the operator can perform.

Note By default, the operator name does not print or display with the patient test results. If you want to include an operator name with the patient test results, see *Custom Set Up*, page 96.

CAUTION
After you add an operator, if you enable or disable the Authorized Operator setting, the system deletes all the patient test results.

7. Select **Done 3** times to return to the **Select Ready** screen.

Edit the Authorized Operator Functions

When you set up authorized operators, they can perform the following tasks:

- Run patient tests
- Run QC tests (with a Status connector)
- Recall results
- Modify System Settings

To edit the authorized operator functions for an operator, perform the following steps:

1. On the **Select Ready** screen, select **Instrument Set Up**.
2. On the **Choose Settings** screen, select **Instrument Settings**.
3. On the **Instrument Settings** screen, select **Authorized Operator**.
4. On the **Authorized Operator** screen, select **View operators list**.
5. On the **Authorized Operator – Operators list** screen, scroll to and highlight the operator name you want to edit, and select **Select**.
6. On the **Authorized operator** screen, in the Operator ID functions area, select **Edit**.

   The **Authorized Operator-Operator access 1 of 2** screen displays.
7. Select the authorized operator options, select **Next**.

   The **Authorized Operator-Operator access 2 of 2** screen displays.

8. Select the authorized operator options.

Authorized Operator Option	Description
Screen 1 of 2	
Patient test	• **Enabled** (default) lets the operator run patient tests. • **Disabled** prevents the operator from running patient tests.
QC test	• **Enabled** lets the operator run QC tests. • **Disabled** prevents the operator from running QC tests.
Screen 2 of 2	
Recall results	• **Enabled** lets the operator recall results. • **Disabled** prevents the operator from recalling results.
Instrument set up	• **Enabled** lets the operator set up the system. • **Disabled** prevents the operator from setting up the system.

9. To return to the **Select Ready** screen, perform the following steps:
   a. Select **Done** twice.
   b. On the **Authorized Operator-Operators list** screen, select **Exit**.
   c. Select **Done** 3 times.

View, Edit, Print, and Delete Operators

You can perform the following tasks for the authorized operators:

- View the operators list

- Edit an operator name
- Delete an operator
- Print the operators list
- Delete the operators list

To view the operators list, perform the following steps:

1. Select **View operators list**.

   The authorized operators display.

2. Use the scroll arrows to view the operators in the list.

To edit an operator name, perform the following steps:

1. On the **Authorized Operator-Operators list** screen, select an operator.
2. On the **Authorized operator** screen, select **Edit**.
3. Change the operator name.
4. Select **Done**.

To delete an operator, perform the following steps:

1. On the **Authorized Operator-Operators list** screen, select an operator.
2. Select **Delete entry**.
3. Select **Yes** to confirm the deletion.

   Note To add an operator, see *Add an Operator*, page 115.

To print all operators, perform the following steps:

Select **Print**.

The system prints only the first 100 operators, and in alphabetical order.

Note You can print the operators on an external printer but only if you connect the CLINITEK Status+ analyzer to a CLINITEK Status connector.

To delete all operators in the list, perform the following steps:

1. On the **Authorized operator** screen, select **Delete operators list**.

   The **Delete operators list caution** screen displays.

2. Select **Yes**.

   Note If you want to keep the operators list, select **No**. The **Authorized operator** screen displays.

   The system deletes all the operators in the list and disables the Authorized Operator setting.

Setting up Sample Interference Notes

Sample interference notes inform you about test results that can be affected by components detected in the urine sample. By default, sample interference notes display and print.

Depending on the strip and sample, sample interference notes could include the following statements:

- 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.

To set up sample interference notes, perform the following steps:

1. On the **Select Ready** screen, select **Instrument Set Up**.
2. On the **Choose Settings** screen, select **Instrument Settings**.
3. On the **Instrument Settings** screen, select **Sample Interference Notes**.
4. On the **Notes Settings** screen, perform the following steps:
   - To include sample interference notes, select **Enabled** (default).
   - To exclude sample interference notes, select **Disabled**.
5. Select **Done** twice.

Changing the Printer Settings

You can customize the printed test results by including or excluding the following printout options. By default, all printout options are enabled except the **Custom Header** option, which is disabled. You also need to configure the printout options.

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

You also can specify the following printer options:

- Enable or disable an external printer
- Enable or disable the internal printer
- Print sample interference notes

To customize the printout, perform the following steps:

1. On the **Select Ready** screen, select **Instrument Set Up**.
2. On the **Choose Settings** screen, select **Instrument Settings**.
3. On the **Instrument Settings** screen, select **Printer Settings**.
4. On the **Printer Settings Included in print-out, 1 of 4** screen, select or clear any of the following options:
    - Operator Name
    - Patient Name
    - Serial Number
    - Patient ID
5. Select **Next**. On the **Printer Settings Included in print-out, 2 of 4** screen, select or clear any of the following options:
    - Color
    - Clarity
    - Custom Information (Up to 2 header lines of customized alphanumeric text)
6. Select **Next.**
7. On the **Printer Settings Included in print-out, Set Up Custom Header, 3 of 4** screen, perform the following steps:
    - Select **Enabled** to include the custom header in the printout.

Note By default, the custom header is disabled. However, if you enter information for the header, the system enables the custom header printout option.

- Select **Enter Line 1** and enter the information for the first line of the custom header.
- Select **Enter Line 2** and enter the information for the second line of the custom header.

Note Enter up to 24 alphanumeric characters for each header line.

8. Select **Next**. On the **Printer Settings Printer options 4 of 4** screen, select or clear any of the following options:

   Note To use an external printer, connect and enable the Status connector.

   - To print to an external printer, select **External printer**.

   Note If you select **External printer**, sample interference notes print automatically.

   - To print to the internal printer, select **Internal printer** (default).
   - If you select Internal printer and want to print sample interference notes, select **Enabled** for the **Print notes on internal printer** option.
   - To disable printing sample interference notes, select **Disabled**.

9. Select **Done 3** times to return to the **Select Ready** screen.

Changing the Quality Control Settings

The Quality Control settings display but they are disabled. If you run the CLINITEK Status+ analyzer with a CLINITEK Status connector, the Quality Control settings are available. For instructions on how to set up the Quality Control settings, see the *CLINITEK Status Connect System Operator's Guide*.

Restoring the Default Settings

You can restore the original settings (see *Default Settings*, page 85) for the system.

Note The CLINITEK Status+ analyzer configuration settings include settings that apply when you run an analyzer with a CLINITEK Status connector.

To restore the default settings, perform the following steps:

1. On the **Select Ready** screen, select **Instrument Set Up**.
2. On the **Choose Settings** screen, select **Instrument Settings**.
3. On the **Instrument Settings** screen, select **Restore Default Settings**.
4. On the **Restore** screen, scroll up and down to view the default settings.
5. Select **Restore** to return the system to the settings in the Restore list.
6. Select **Yes** to confirm your decision.

   Note Select **No** to maintain the current settings and return to the **Restore** screen.
7. Select **Exit**.

CAUTION
When the system restores the original settings, the system deletes all results and patient data.

Updating the Analyzer Software

Periodically, Siemens adds new features and makes improvements to the CLINITEK Status+ analyzer software. These software updates are available on a memory card that you insert beneath the printer cover.

To upgrade the analyzer software, perform the following steps:

CAUTION
Ensure you have printed or recorded the most recent patient results before you perform the software upgrade because the upgrade process deletes all patient records and all patient test results in the system. For more information about recall results, see Section 6, *File Management*.

1. If the CLINITEK Status+ analyzer is on, press the on/off power button until the analyzer powers off.

   The test table retracts.

2. Prepare the analyzer:

   a. Ensure the CLINITEK Status+ analyzer connects to external power and not battery power.

CAUTION
Do not use battery power when you upgrade the software. If you do, the software installation might fail.

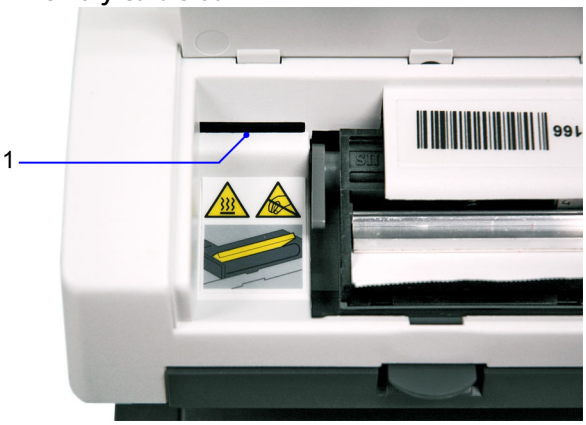
   b. Do not power on the analyzer.
   c. Turn the analyzer so that the back of the analyzer faces you.
   d. Lift the printer cover.

CAUTION
Do not use gloves when you insert or remove the memory card. Using gloves can result in electrostatic damage to the card.

Ensure you wear gloves as required by your facility to perform other tasks.

3. Insert the memory card (label side up, arrow facing the slot) into the memory card slot to the left of the printer mechanism, until the card stops and then clicks (see *Figure 7-1*).

Figure 7-1: Memory Card Slot



1	Memory Card Slot

4. Power on the analyzer by pressing the on/off power button.
   - The analyzer beeps repeatedly in a low tone for up to 90 seconds.
   - The **System Test in progress** screen displays briefly.
   - The test table extends.
   - The **Software Update** screen displays.
5. Select **Install Software**.

CAUTION

Do not remove the memory card or disconnect the unit from the power supply during an upgrade. If you do, the installation fails.

A blank screen displays for up to 3 minutes during the following installation process:

- The analyzer beeps repeatedly in a low tone for up to 75 seconds.
- Next, you hear 1 longer beep.

- Then, you hear repeated beeps at a higher tone for up to 2 minutes.

When the installation finishes, the analyzer performs the following operations:

- The screen displays the message, `Performing a System Diagnostic Test`.
- The test table retracts and extends.
- The **Software Update** screen displays a message that the software was successfully installed.

6. Select **Done**.

   If you upgrade from software Version 1.x, the system displays the message `E27, Set Up Failure`. Clear the error message by continuing with the steps in the next section on how to complete the software upgrade.

   Note The E27 message indicates that a significant change was made to the system database and occurs with a successful software upgrade from software Version 1.x.

To complete the software upgrade, perform the following steps:

1. Press the on/off power button until the analyzer powers off.

   The test table retracts.

2. Remove the memory card from the memory card slot.

CAUTION

Do not leave the memory card in the slot after you finish the upgrade. If you do, the system deletes all sample results and performs an unnecessary upgrade each time you power on the analyzer.

3. Close the printer cover.
4. Power on the analyzer.

Running Diagnostics

You can run the following diagnostics on the analyzer:

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

CAUTION
Do not run the Check Cassette diagnostics on your own. Run the Check Cassette diagnostic tests only when your local technical support provider or distributor asks you to do so. The representative will lead you through the test procedure. For local technical support providers and distributors, see *Appendix B, Support Information*.

To run the diagnostics, perform the following steps:

1. On the **Select Ready** screen, select **Instrument Set Up**.
2. On the **Choose Settings** screen, select **Instrument Settings**.
3. On the **Instrument Settings** screen, select **Diagnostics**.
4. On the **Select Diagnostics Test** screen, select a diagnostic test
5. Select **Select**.
6. Read the onscreen instructions.
7. Select **Run Test**.
8. Select **Done** twice.

Viewing the System Information

You can view the following system information:

- Serial number
- Software version

To view the system information, perform the following steps:

1. On the **Select Ready** screen, select **Instrument Set Up**.
2. On the **Choose Settings** screen, select **Instrument Settings**.
3. On the **Instrument Settings** screen, select **System Information**.

   The **System Information** screen displays with the serial number and software version.

Viewing and Printing the System Configuration Settings

You can view and print the system configuration settings.

Note If you run an analyzer with a CLINITEK Status connector, you can copy the configuration settings to and from a memory stick. For more information, see the *CLINITEK Status Connect System Operator's Guide, Section 6, System Configuration*.

To view and print the system configuration settings, perform the following steps:

1. On the **Select Ready** screen, select **Instrument Set Up**.
2. On the **Choose Settings** screen, select **Instrument Settings**.
3. Select **System Configuration**.

   The **System Configuration** screen displays with the current system configuration details for the options you can change through **Input Settings** and **Instrument Settings**.
4. Scroll through the list to view the details.
5. Select **Print** to print the system configuration information.

   Note If you need to replace the printer paper roll, the **Print** option is disabled. For instructions on replacing the printer paper, select **Help** or see *Introduction*, page 7, *Loading the Printer Paper*, page 15.
6. Select **Done** twice.

Appendix A: Safety Information

Read the following safety information for your protection in the laboratory.

Protecting Yourself from Biohazards

The established guidelines for handling laboratory biohazards are 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 these safety guidelines 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, blood products, and other body fluids.

Recognizing Sources of Contamination

When you handle potentially infectious agents, keep in mind the following major sources of contamination:

- Hand-to-mouth contact
- Hand-to-eye contact
- Direct contact with superficial cuts, open wounds, and other skin conditions that might permit absorption into subcutaneous skin layers
- Splashes or aerosol contact with skin and eyes

Preventing Contamination

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

- Wear gloves while servicing parts of the analyzer 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 analyzer 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 pipette 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.

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 B: Support Information

This appendix provides the technical support information for your CLINITEK Status+ analyzer.

Installation Details

Please record the following information and keep this sheet in your laboratory for future reference.

Date of Installation _____

Serial Number _____

Limitations of Liability

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

For warranty service, contact your local technical support provider for assistance, instructions, repair, or replacement of this instrument.

Legal Information

To contact a legal representative for Siemens Healthcare Diagnostics in the European community, contact the Siemens Authorized Representative.

Disposal of the Analyzer

The instrument must be treated as biological contaminated hazardous waste. Proper disposal of old instruments (including its plastic parts, electrical components) prevents potential negative consequences for the environment and human health. All electrical and electronic products and other components of the analyzer should be disposed of separately from the municipal waste system. Final disposal must be organized in a way that does not endanger waste handlers. As a rule, such equipment must be sterile before it is passed for final disposal. For more information about disposal of such product, please contact your city office, waste disposal service, or your local safety officer.

Training

This guide describes the proper use and operation of the system. System operators and administrators should familiarize themselves with the applicable sections in the manual prior to conducting testing to assure safe and effective use of the system. As training requirements for this device vary by country and region, make sure you follow any training in accordance with local, federal, or country laws and regulations. If you require further information about training in the use of this product, contact your local Siemens Healthineers representative.

Technical Assistance

Call for assistance if the following circumstances occur:

- An error message continues to display after you perform the steps as described on the screen and in Section 5, *Troubleshooting*.
- You need additional assistance about an analyzer problem.
- The problem is beyond the scope of this guide.
- You cannot solve the problem and an analyzer failure is apparent.

Our local technical support providers are available to help you. Before calling, please complete the *Problem List*, page 77. Make a photocopy of the list first. This information helps your local technical support provider to identify the probable cause of the problem.

To order supplies or replacement parts, or to obtain service, contact your local technical support provider or visit siemens-healthineers.com/poc

According to EU regulation 2017/746, any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the EU Member State in which the user and/or patient is established.

Origin GB
Siemens Healthcare Diagnostics Inc.
511 Benedict Avenue
Tarrytown, NY 10591-5097 USA

Siemens Healthcare Diagnostics
Manufacturing Ltd.
Chapel Lane
Swords, Co. Dublin, Ireland
siemens-healthineers.com/poc

Appendix C: Orderable Supplies

This appendix contains the supplies you can order from your local technical support representative.

Supplies and Optional Equipment

The following supplies and optional equipment are available for your CLINITEK Status+ analyzer. Contact your local technical support representative to order the supplies.

Supplies

Product Description	*SMN*
Siemens Reagent Strips for Urinalysis	*
Chek-Stix Combo Pak Control Strips for Urinalysis	10310483 (1364)
Chek-Stix Positive Control Strips for Urinalysis	10310482 (1360)
Clinitest hCG Cassettes	10310618
Thermal Printer Paper (5 rolls)	10314709
Label paper (5 rolls)	10324219

* Contact your local technical support provider for the configuration available in your country.

Optional Equipment **

- CLINITEK Status Connector (Non Wi-Fi and Wi-Fi)
- Handheld bar-code reader (for use only with the CLINITEK Status Connector)

** Contact your local technical support provider for the configuration available in your country.

Replacement Parts

Replacement parts are available for your CLINITEK Status+ analyzer. Contact your local technical support representative to order the following parts:

Description	*SMN*
Power Supply - US	10378632
Power Supply - UK	10378633
Power Supply - European	10378634

Description	*SMN*
Test Table	10309067
Table Insert - Short/ 8 cm (3 1/4 inches)	10309069
Table Insert - Long/11 cm (4 1/2 inches))	10309068

Documentation

The following documentation is available for your CLINITEK Status+ analyzer. Contact your local technical support representative to order any documentation.

Description	*Part Number*
Clinitek Status+ analyzer (This guide) - (printed manual, multiple languages available)	10379682
Clinitek Status+ analyzer multilingual CD	10704099
CLINITEK Status+ Quick Reference Card (printed manual, multiple languages available)	10379696
LIS Interface Guide	10492286

Appendix D: Specifications

This appendix contains the analyzer specifications and tables of results.

Analyzer Specifications

This appendix summarizes the design specifications for the CLINITEK Status+ analyzer and provides summary tables of test results from the CLIA waiver and the physician office studies.

Analyzer Dimensions

Dimension	Value
Depth	272 mm (10.7 inches)
Width	171 mm (6.7 inches)
Height	158 mm (6.2 inches)
Weight	1.66 kg (3.65 lb) CLINITEK Status+ analyzer only (unpacked, without batteries or power supply)

Environmental Specifications

Specification	Value
Ambient Operating Temperature Range	18° to 30°C (64° to 86°F)
Ambient Operating Humidity Range	18% to 80% Relative Humidity (non-condensing)
Optimum Operating Temperature Range	22° to 26°C (72° 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. For example, at temperatures under 22°C (72°F), urobilinogen and leukocyte results might decrease, and at temperatures above 26°C (79°F), increase.
Altitude	2000 m (6562 ft)
Pollution Degree	2

Electrical Requirements

Requirement	Value
Power	9V DC, 7.2 VA
Battery Powered Operation	Size 6 AA alkaline batteries

Safety Standards

The CLINITEK Status+ analyzer is classed as a Class A computing device in accordance with Part 15 of the 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.

Safety Certifications

For safety certifications information, see the Declaration of Conformity (DoC). Contact your local technical support provider for the DoC.

Electromagnetic Compatibility (EMC)

For electromagnetic compatibility (EMC) information, see the Declaration of Conformity (DoC). Contact your local technical support provider for the DoC.

IT Security

See the product's Security White Paper and MDS2 for additional information about specifications for software, hardware, network characteristics, and security controls. This technical information is not part of the operator guide, and is intended for the information technology or security professional. Security White Paper and MDS2 can be found at siemens-healthineers.com/poc or contact your local technical service provider.

Tables of Results

The analyzer displays and prints the test results for reagent strips and cassettes in the following formats:

- English Units, Conventional
- English Units, International (SI)
- English Nordic Units, Nordic Plus System

English, Units – Conventional

If you select English Conventional unit of measurement, the reagent strip and cassette tests display the following results.

Reagent Strip Tests

The following table contains the test, abbreviation, units, Normal System results, and Plus System results for English Conventional units for reagent strips.

The results shown in the shaded areas are marked as positives, if you enabled Mark Positive Results in Instrument Set Up. They are marked by asterisks when displayed and printed, and when the CLINITEK Status+ analyzer transfers the data to a host computer.

Table D-1: English Units – Conventional, Reagent Strips

Test	Abbreviation	Units	Reported Results			
			Normal System		Plus System	
Glucose	GLU	mg/dL	Negative	500	Negative	2+
			100	>=1000	Trace	3+
			250		1+	
Glucose (CLINITEK Microalbumin 9)	GLU	mg/dL	Negative	500	Negative	2+
			100	1000	Trace	3+
			250	>=2000	1+	4+

Test	Abbreviation	Units	Reported Results				
			Normal System			Plus System	
Bilirubin	BIL	-	Negative		Moderate	Negative	2+
			Small		Large	1+	3+
Ketone	KET	mg/dL	Negative		40	Negative	2+
			Trace		80	Trace	3+
			15		>=160	1+	4+
Specific Gravity	SG	-	<=1.005		1.020	No Difference	
			1.010		1.025		
			1.015		>=1.030		
Occult Blood	BLO	-	Negative		Small	Negative	1+
			Trace-lysed		Moderate	Trace-lysed	2+
			Trace-intact		Large	Trace-intact	3+
pH	pH	-	5.0	6.5	7.5	No Difference	
			5.5	7.0	8.0		
			6.0	7.5	8.5		

Test	Abbreviation	Units	Reported Results			
			Normal System		Plus System	
Protein (Multistix PRO) (CLINITEK Microalbumin 9)	PRO	mg/dL	Negative 15 30	100 300	Negative Low 1+	2+ 3+
Protein (All other reagent strips)	PRO	mg/dL	Negative Trace 250	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	

Test	Abbreviation	Units	Reported Results		
			Normal System		Plus System
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
Albumin: Creatinine (CLINITEK Microalbumin 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

Test	Abbreviation	Units	Reported Results		
			Normal System		Plus System
Protein: Creatinine (CLINITEK Microalbumin 9)	P:C	mg/g	Normal Dilute Normal 300 Abnormal 1500 Abnormal	3000 Abnormal >=5000 Abnormal	No Difference

Cassette Test

The following table contains the test, abbreviation, units, Normal System results, and Plus System results for English Conventional units for cassettes.

Table D-2: English, Units – Conventional, Cassette

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

English Units – International (SI)

If you select English International (SI) unit of measurement, the reagent strip and cassette tests display the following results.

Reagent Strip Tests

The following table contains the test, abbreviation, units, Normal System results, and Plus System results for English SI units for reagent strips.

The results shown in the shaded areas are marked as positives, if you enabled Mark Positive Results in Instrument Set Up. They are marked by asterisks when displayed, when printed, and when the CLINITEK Status+ analyzer sends the data to a host computer.

Table D-3: English, Units – International SI, Reagent Strips

Test	Abbreviation	Units	Reported Results			
			Normal System		Plus System	
Glucose	GLU	mmol/L	Negative	28	Negative	2+
			5.5	>=55	Trace	3+
			14		1+	
Glucose (CLINITEK Microalbumin 9)	GLU	mmol/L	Negative	28	Negative	2+
			5.5	55	Trace	3+
			14	>=110	1+	4+

Test	Abbreviation	Units	Reported Results			
			Normal System		Plus System	
Bilirubin	BIL	–	Negative	Moderate	Negative	2+
			Small	Large	1+	3+
Ketone	KET	mmol/L	Negative	3.9	Negative	2+
			Trace	7.8	Trace	3+
			1.5	>=15.6	1+	4+
Specific Gravity	SG	–	<=1.005	1.020	No Difference	
			1.010	1.025		
			1.015	>=1.030		
Occult Blood	BLD	Ery/µL	Negative	Ca 25	Negative	1+
			Trace-lysed	Ca 80	Trace-lysed	2+
			Trace-intact	Ca 200	Trace-intact	3+
pH	pH	–	5.0	8.0	No Difference	
			6.5			
			5.5	8.5		
			7.0			
			6.0	>=9.0		
			7.5			

Test	Abbreviation	Units	Reported Results			
			Normal System		Plus System	
Protein (Multistix PRO) (CLINITEK Microalbumin 9)	PRO	g/L	Negative 0.15 0.3	1.0 3.0	Negative Low 1+	2+ 3+
Protein (All other reagent strips)	PRO	g/L	Negative Trace 0.3	1.0 >=3.0	Negative Trace 1+	2+ 3+
Urobilinogen	UBG	µmol/L	3.2 16 33	66 >=131	No Difference	
Nitrite	NIT		Negative	Positive	No Difference	
Leukocytes	LEU	Leu/µL	Negative Ca 15 Ca 70	Ca 125 Ca 500	Negative Trace 1+	2+ 3+
Albumin	ALB	mg/L	10 30	80 150	No Difference	

Test	Abbreviation	Units	Reported Results		
			Normal System		Plus System
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 (CLINITEK Microalbumin 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

Test	Abbreviation	Units	Reported Results		
			Normal System		Plus System
Protein: Creatinine (CLINITEK Microalbumin 9)	P:C	mg/mmol	Normal Dilute Normal 33.9 Abnormal 170 Abnormal	339 Abnormal >=566 Abnormal	No Difference

Cassette Test

The following table contains the test, abbreviation, units, Normal System results, and Plus System results for SI units for cassettes.

Table D-4: English, Units – International SI, Cassette.

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

English Nordic, Units – Nordic Plus System

If you select English Nordic unit of measurement, the reagent strip and cassette tests display the following results.

Reagent Strip Tests

The following table contains the test, abbreviation, units, Normal System results, and Plus System results for Nordic units for reagent strips.

The results shown in the shaded areas are marked as positives, if you enabled Mark Positive Results in Instrument Set Up. They are marked by asterisks when displayed, when printed, and when the CLINITEK Status+ analyzer sends the data to a host computer.

Table D-5: English Nordic, Units – Nordic Plus System, Reagent Strips

Test	Abbreviation	Units	Reported Results			
			Normal System		Plus System	
Glucose	GLU	–	Negative	3+	Negative	2+
			1+	4+	Trace	3+
			2+		1+	
Glucose (CLINITEK Microalbumin 9)	GLU	–	Negative	3+	Negative	2+
			1+	4+	Trace	3+
			2+	5+	1+	4+

Test	Abbreviation	Units	Reported Results				
			Normal System			Plus System	
Bilirubin	BIL	–	Negative		2+	No Difference	
			1+		3+		
Ketone	KET	–	Negative		3+	Negative	2+
			1+		4+	Trace	3+
			2+		5+	1+	4+
Specific Gravity	SG	–	<=1.005		1.020	No Difference	
			1.010		1.025		
			1.015		>=1.030		
Occult Blood	BLD	–	Negative		1+	No Difference	
			+/-		2+		
			+/- Intact		3+		
pH	pH	–	5.0	6.5	8.0	No Difference	
			5.5	7.0	8.5		
			6.0	7.5	>=9.0		

Test	Abbreviation	Units	Reported Results			
			Normal System		Plus System	
Protein (Multistix PRO) (CLINITEK Microalbumin 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	UBG	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	

Test	Abbreviation	Units	Reported Results		
			Normal System		Plus System
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 (CLINITEK Microalbumin 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

Test	Abbreviation	Units	Reported Results		
			Normal System		Plus System
Protein: Creatinine (CLINITEK Microalbumin 9)	P:C	mg/mmol	Normal Dilute Normal 33.9 Abnormal 170 Abnormal	339 Abnormal >=566 Abnormal	No Difference

Cassette Test

The following table contains the test, abbreviation, units, Normal System results, and Plus System results for Nordic units for cassettes.

Table D-6: English Nordic Units – Nordic Plus System, Cassette

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

System Overview and Principles

Description of Optical System

The optical system consists of:

- six light emitting diodes (LEDs)
- a light guide
- a mirror
- a lens
- a detector

Light from the LEDs travels along the light guide and is reflected off the calibration bar, strip or cassette onto the mirror.

The light 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.

These are processed by the instrument's microprocessor and converted into clinically meaningful results.

Instrument 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 the instrument is powered by batteries.

Urinalysis Sequence

Each time a urinalysis strip is read, the instrument first positions the test table correctly and checks the electronics and signals.

It then takes reference readings off the white calibration bar on the test table. The reference readings are taken at six wavelengths and used to calculate the sample readings.

The table and test strip are pulled into the instrument where the correct placement of the test strip is confirmed. The table then moves completely into the instrument closing the shutter. The test table positions strip pads in the read area.

All test pads are read simultaneously at all six wavelengths. The analyzer's optical system images the entire strip, all reagent pads at once.

The light reflected from the test pad at specific wavelengths 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 test and reference readings are then used to determine presence and/or amount of each constituent in the urine sample.

Appendix E: Symbols

This appendix provides the symbols for the analyzer and packaging.

Analyzer and Labeling Symbols

The analyzer and labeling symbols are in the following locations:

- CLINITEK Status+ analyzer documentation
- CLINITEK Status+ analyzer exterior
- Power supply provided with the analyzer
- Carton in which the analyzer was delivered
- Urinalysis strips and cassettes supplies that you use with the analyzer

Analyzer and Packaging Symbols

This following table contains the symbols that appear on the exterior of the CLINITEK Status+ analyzer, the power supply provided with the analyzer, the carton in which the analyzer was delivered, and the urinalysis strips and cassettes supplies that you use with the analyzer.

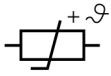
Symbol	Description
	Direct current input supply
	Double insulated product or transformer may also identify class 2 equipment (power supply only)
	Instrument is safety tested by TUV SUD, a national certification body, for conformity to global markets, including Canada, US, and Europe.
	CE Mark
	Device for near patient testing
	Manufacturer
	European authorized representative

Symbol	Description
	Power on/off button
	Caution, consult accompanying documents
	*In vitro* diagnostic medical device
	Consult instructions for use
	Caution, temperature hazard, hot surface
	Caution for handling electrostatic sensitive devices to avoid causing a hazard to the product
	Contains sufficient for (n) tests
	Use by YYYY-MM
	Batch code
	Keep away from sunlight and heat
	Do not reuse a reagent

Analyzer Symbols

This following table contains the symbols on the exterior of the CLINITEK Status+ analyzer and the carton in which the analyzer is delivered.

Symbol	Description
	Serial port
	This analyzer contains certain toxic or hazardous substances or elements. The environmental protection use period for this analyzer is 50 years. The analyzer can be used safely during its environmental protection use period. The analyzer should be recycled immediately after its environmental protection use period has expired.
	Temperature limitation (18–30° C)
	Catalog number
	Serial number
	Biohazard
	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 the RESY packaging standards
	Keep this way up
	Fragile, handle with care

Symbol	Description
	Keep dry
	VDE Testing and Certification Institute – Germany
	Manufacturer's mark (FWHK) and manufacturing location (Hong Kong)
	Manufacturer's mark (FWGB) 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
	Risk of electric shock.

Display Icons

This following table contains the icons that display on the screen.

Symbol	Name	Description
	Instrument Set Up	Allows you to set up the analyzer to suit your needs.
	Strip Test	Runs a test with a urinalysis strip (such as Multistix 10SG) urinalysis test and displays the strip test results.

Symbol	Name	Description
	Cassette Test	Runs a test with a cassette (Clinitest hCG) test and displays the cassette test results.
	Results Recall	Recalls results from the analyzer memory.
	Printer	Prints results.
	Data Transfer to Personal Computer	Displays the individual data and test results that the CLINITEK Status+ analyzer transfers to a PC.
	Alert	Alerts you to an error message.
	Battery Power	Displays a maximum of four bars, indicating the battery power level of a a battery powered analyzer.
	Low Battery Power	Displays fewer than three bars, indicating the battery power level of a a battery powered analyzer is low.
	Paper Out	Displays when you need to replace the printer paper or label roll.
	Connector	Indicates that the analyzer is connected to the CLINITEK Status connector.
	No Connector	Displays only if you run a CLINITEK Status+ analyzer with a CLINITEK Status connector. Indicates that the CLINITEK Status+ analyzer is not connected to the CLINITEK Status connector.

Symbol	Name	Description
	Connectivity	Displays only if you run a CLINITEK Status+ analyzer with a CLINITEK Status connector. Indicates that the CLINITEK Status+ analyzer is connected to the CLINITEK Status connector, Connectivity is enabled, and the system is connected to the LIS.
	No Connectivity	Displays only if you run a CLINITEK Status+ analyzer with a CLINITEK Status connector. Indicates that the CLINITEK Status system is not connected to the wired (Ethernet) or wireless connection between the analyzer and the server on a remote computer.

Appendix F: Glossary

The glossary contains hardware and software terms and acronyms.

Hardware Terms

The following table defines hardware terms commonly used on the CLINITEK Status+ analyzer.

Term	Definition
bar code	Encoded information that is read by an optical scanner.
calibration bar	The white calibration bar (on the test table) that provides traceable calibration.
cassette	A Clinitest hCG reagent cassette for pregnancy test use.
check cassette	A system diagnostic cassette that simulates a reacted test area.
CLINITEK Status+ analyzer	The CLINITEK Status analyzer with increased memory and additional features.
CLINITEK Status Connect system	The CLINITEK Status+ analyzer attached to the CLINITEK Status connector.
connector	The CLINITEK Status connector platform where you can attach the CLINITEK Status+ analyzer.
display	The LCD that displays the software user interface.
Ethernet port	The port where a network Ethernet cable is inserted.
external bar-code reader	An optional bar-code scanner that is connected to the RS232 port on the connector. Used to enter data.
external printer	An optional printer is connected to the CLINITEK Status Connect system, only when you connect the CLINITEK Status+ analyzer to the CLINITEK Status connector.
hardware	The physical components of the analyzer.

Term	Definition
instrument	The CLINITEK Status+ analyzer.
memory card	An electronic storage device that stores the analyzer software.
onboard printer	The internal paper roll printer.
onboard printer cover	The portion of the case that opens and closes to cover the on-board printer.
power cord	The cord that connects the analyzer to an electrical outlet.
power switch	The switch that turns the analyzer on and off.
serial connector	An RS232 connection used to transfer data between the analyzer and a PC.
test table	The plastic case that holds the test table insert.
test table insert	The plastic case that holds either the cassette or urinalysis strip for testing.
touch screen	The LCD display that lets the operator select controls on the screen.
USB port	The ports where USB cables are inserted.
urinalysis strip	A Siemens urinalysis strip with test pads for *in vitro* diagnostic use.

Software Terms

The following table defines software terms commonly used on the CLINITEK Status+ analyzer.

Term	Definition
alert message	A message that conveys information to the operator about the analyzer.
alphanumeric	Data comprised of alphabetic and numeric characters.
audio alert	Sounds emitted by the analyzer to draw the operator's attention to the analyzer.

Term	Definition
authorized operator	Operators who can perform certain tasks, where they gain access to the analyzer by entering their operator ID to perform those tasks.
auto-check	Performs automatic strip quality checks and provides results in about 1 minute.
automatic strip identification	Automatically identifies an ID band strip type with no need to select it from a menu.
baud rate	The speed of data transmission in bits per second (bps) between the analyzer and a remote device.
calibration	The analyzer reads the white calibration bar at the appropriate wavelengths to ensure accurate test results.
cancel	To end a sequence or an operation.
comment	A notation the operator enters for a QC test result.
configuration	System hardware and software settings that adjust or configure some aspect of the analyzer.
conventional unit	Unit of measurement for test results.
control	Objects that display on the software UI that the operator can manipulate. Buttons, boxes, and optionbuttons are examples of controls. Solution containing a known level of analytes.
countdown	A numeric display that indicates the amount of time left in an operation.
Custom set up	Patient, operator, and sample appearance custom settings.
data entry	The act of entering data such as a patient or operator ID into the analyzer.
data entry box	A software UI object which displays the data that the operator entered.

Term	Definition
default setting	A value defined and preset by Siemens.
delete	A function an operator uses to remove an object, such as test results or an authorized operator, from the system database.
diagnostic screen	A software UI screen which enables the operator to perform a system diagnostic test when troubleshooting the analyzer.
disabled	The state when a software feature or function, such as a configuration setting, is not available.
enabled	The state when a software feature or function, such as a configuration setting, is available.
error	An event that prevents the analyzer from operating as expected.
error code	A number displayed by the analyzer to communicate the occurrence of an error to the operator.
export	To copy setup data from the analyzer to a removable data storage device.
Full Test	A strip or cassette test where the operator is prompted to enter patient and operator information.
help	Information presented to the operator to assist them with the completion of a task or operation.
Help screen	The screen that displays the help information to the operator.
humidity check	Detects if the strip is exposed to humidity and if so, displays an error message.
icon	An graphical depiction of a control in the software UI.
import	To copy setup data from a removable data storage device to the analyzer.

Term	Definition
keyboard	A software UI display (alphabetic or numeric) that the operator uses to type information.
laboratory information system	Laboratory computer system that you can connect to the analyzer. Abbreviation: LIS.
Menu screen	A software UI screen that displays a list of commands and one or more command buttons for the operator to select.
Normal System	Provides a negative result or a value for a positive result.
notifications message	A message that conveys information about the analyzer to the operator.
navigation	The act of moving between the screens that comprise the analyzer software UI.
navigation button	A software UI button control that when selected, brings the operator to a different software UI screen.
parity	A serial communication setting that verifies whether the data has been transmitted accurately.
Plus System	Provides plus symbols (+) for a result. The more plus symbols, the higher the result. For example, 2 + represents two plus symbols (++) and 3+ represents three plus symbols (+++).
power supply	Electronic component of the analyzer that converts the AC voltages in the power line to the DC voltages inside the analyzer.
prompt	Questions, instructions, or commands that help the operator complete the current task.
quality control	A process that ensures the operator is following the procedure to obtain accurate test results. Abbreviation: QC.
Quick Test	A strip or cassette test where the analyzer does not prompt you to enter patient or operator information.

Term	Definition
ready	The state when the analyzer is available to perform tests.
recall	To access data such as test results stored on the analyzer.
restore	To restore the analyzer setup to the default settings.
required entry	A data entry box that must have data entered into it.
sample interference notes	Informs the user when appropriate about test results that can be affected by components detected in the same urine sample.
screen	The display area that contains the controls the operator selects when operating the analyzer. The analyzer software UI contains screens, prompts, messages, and other operating information.
screen title	A text label that typically displays in the upper left corner of a screen which serves as a label for that screen.
Select Ready screen	The software UI screen that displays when the system completes the startup process. All software UI navigation begins from the Select Ready screen.
settings	The areas of the software user interface where you can configure the analyzer.
Settings screen	A software UI screen which enables the operator to adjust or configure some aspect of the analyzer.
SI units	An abbreviation for Systéme International, a unit of measure.
software	Computer instructions that generate and carry out commands to control the system operation.

Term	Definition
startup code	If your software provides sample interference notes, the Start-Up wizard prompts you to enter a startup code.
Start-Up Wizard	A wizard that steps you through a quick setup procedure when you power on the analyzer for the first time.
stop bits	The number of bits that maintain synchronization between the system and a remote device during data transmission.
test result	Measured reportable values displayed to the operator at the end of a test sequence.
test sequence	A series of software UI screens that guides the operator through the tasks required to perform a test on a sample.
Title bar	The area along the top of software UI screens where the location icon and title display.
troubleshooting	Determining the cause of a system or test performance problem.
user interface	The system software screens where the operator interacts. Abbreviation: UI.

Acronyms

The following table defines acronyms commonly used on the CLINITEK Status+ analyzer.

Acronym	Full Title
ALB	Albumin
ASTM	American Society for Testing and Measurement
BIL	Bilirubin
BLO	Occult Blood
CRE	Creatinine
CSV	Comma Separated Values

Acronym	Full Title
DC	Direct Current
DHCP	Dynamic Host Configuration Protocol
DMS	Data Management System
DNS	Domain Name Server
EHR	Electronic Health Record
EMR	Electronic Medical Record
GLU	Glucose
hCG	Human Chorionic Gonadotrophin
HIS	Hospital Information System
HL7	Health Level 7 (protocol)
IP	Internet Protocol
KET	Ketone
LAN	Local Area Network
LEU	Leukocyte
LIS	Laboratory Information System
NIST	National Institute of Standards and Technology
NIT	Nitrite
pH	Hydrogen ion concentration
PC	Personal Computer
POCT	Point of Care Testing (protocol)
PRO	Protein
QC	Quality Control
SG	Specific Gravity
SI	Systéme International
SN	Serial Number
UI	User Interface
URO	Urobilinogen
USB	Universal Serial Bus
VA	Volt Amp

Revision History

10379682 Rev.D

Chapter/Appendix	Description of Change
Table of contents	Added headings “Materials Provided”, “Special Materials Required (Not Provided)”, “Before You Begin”, “Disposal of Analyzer”, “Technical Assistance”, “Training”, “IT Security”, and “System Overview and Principles”.
Introduction	Updated section “Intended Use” with information about type of measurement, automation, testing population, IVD symbol, and clinical conditions. Updated section “Summary and Explanation” with product availability information. Added electromagnetic caution statement in section “Assembling the Clinitek Status+ Analyzer”.
Operations	Added section “Materials Provided”, “Special Materials Required (Not Provided)”, and “Before You Begin”.
Appendix A: Support Information	Added section “Disposal of the Analyzer” and “Training”. Updated section heading “Technical Assistance” and added “EUDAMED” statement and information about adverse incident to the user in that section.
Appendix C: Orderable Supplies	Added part numbers to the respective supply items in section “Supplies and Optional Equipment”, “Replacement Parts”, and “Documentation”.
Appendix D: Specifications	Added section “IT Security” and “System Overview and Principles”.

Chapter/Appendix	Description of Change
Appendix E: Symbols	Added “Device for near patient testing” symbol with description and updated the “CE Mark” description. Updated “Serial number” and “Catalog number” symbols.
*	Updated web address to “siemens-healthineers.com/poc”. Updated the device description to “CLINITEK Status+ Semi-Automated Urinalysis Analyzer” in front page.

* Indicates the changes are common and not included in any particular sections of this Operator’s Guide.

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