

Operator's Guide

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CE

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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 Overview

This section covers the following topics:

- Intended Use
- System Overview
- Hardware Overview
- Software and User Interface Overview
- Operating Sequence

Intended Use

The CLINITEK Novus® Automated Urine Chemistry analyzer is a fully automated urinalysis instrument for clinical laboratory use. The CLINITEK Novus Analyzer is intended to read Siemens Healthcare Diagnostics CLINITEK Novus cassettes, as well as determine urine specific gravity and urine clarity.

The CLINITEK Novus cassettes are intended for the semi-quantitative measurement of the following parameters in urine: albumin, bilirubin, blood (occult), creatinine, glucose, ketone (acetoacetic acid), leukocytes, nitrite (qualitative), pH, protein, color, urobilinogen,, albumin-to-creatinine ratio, and protein-to-creatinine ratio.

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

- Carbohydrate metabolism (such as diabetes mellitus)
- Kidney function
- Liver function
- Metabolic disorders
- Urinary tract infection

For *in vitro* diagnostic use.

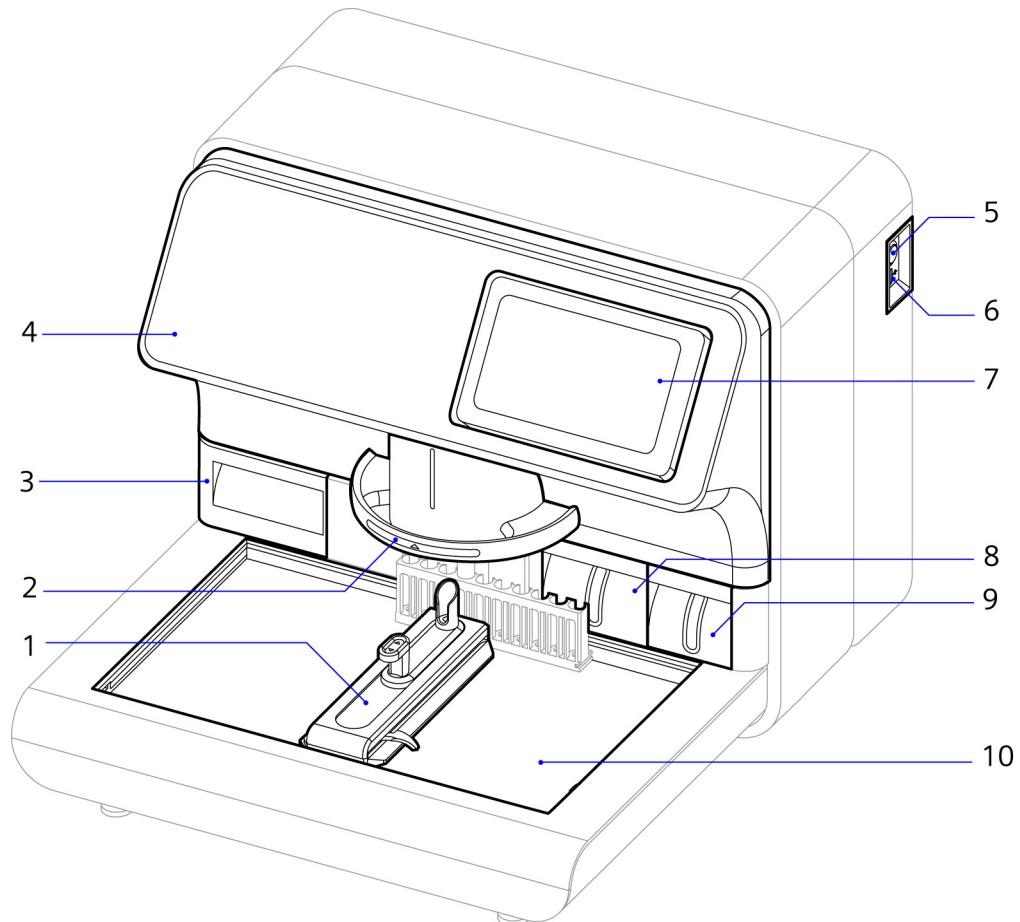
System Overview

The CLINITEK Novus Analyzer reads the color and intensity of the test pads and converts the results into clinically meaningful units. See *Tables of Results*, page 224.

The system operates in the following way:

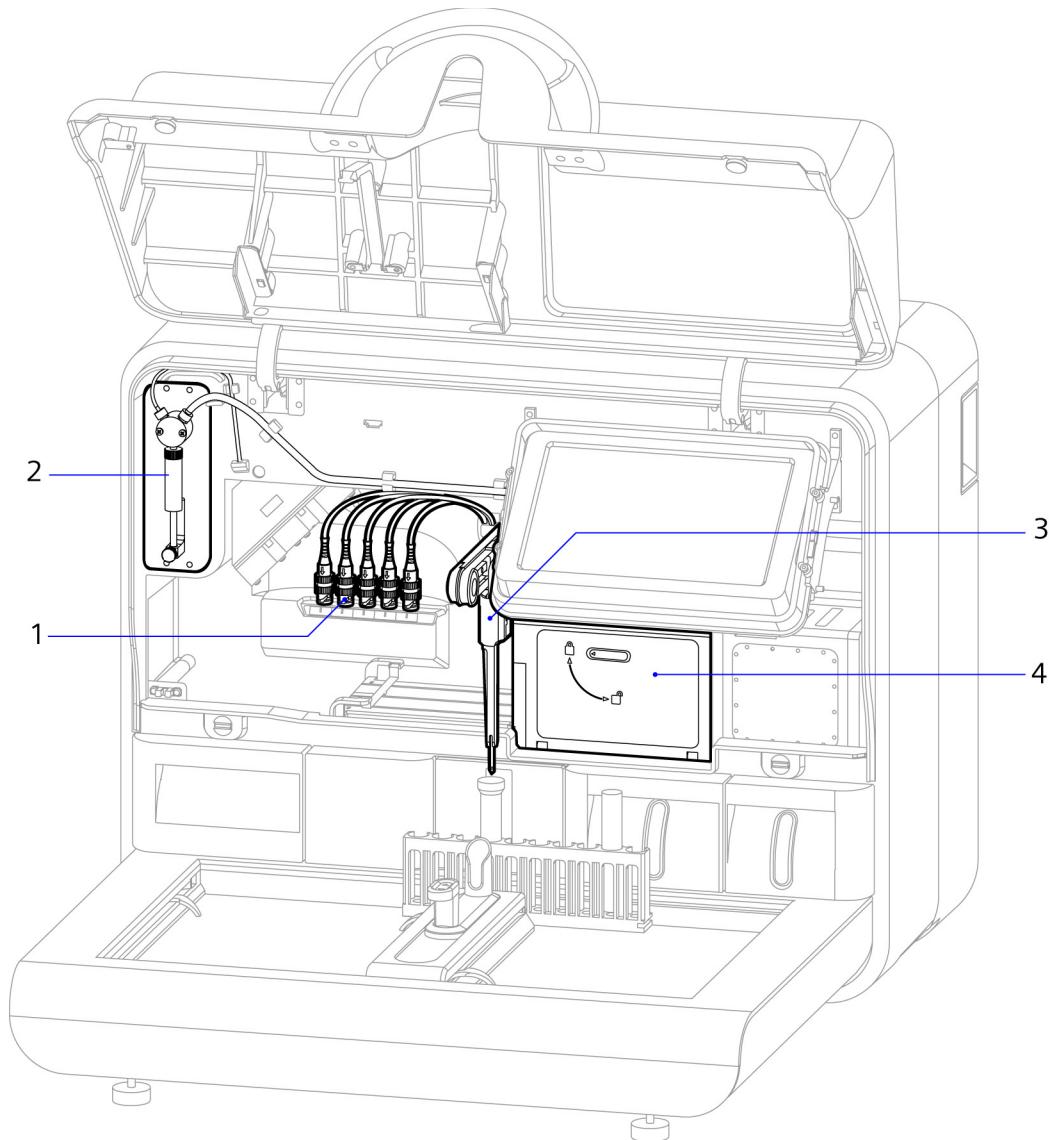
- To test the samples, the optical system has a color digital camera that records an image of a set of test pads, and then analyzes the color and intensity of the light reflected from a reacted test pad. The concentration of each analyte is measured by the color change that develops when a sample is deposited on a test pad.
- The electronic design and automated features enable the system to perform tests on each sample at a rate of 15 seconds per sample.
- To calibrate the system, use the solutions in the CLINITEK Novus Analyzer Calibration Kit. The kit contains 3 solutions for calibrating the SG sensor, and 1 solution for calibrating the clarity. The system uses 1 of the 3 calibrators to calibrate certain test pads. As part of the calibration, the system performs a cleaning cycle and dry pad calibration. The system uses 9 test sets during calibration.
- To ensure quality throughout the entire testing process, read about your laboratory quality assurance program.
- To prepare the samples for testing, load the sample tubes that you want to test into the racks, each of which holds 10 tubes. You can place up to 20 racks on the rack handler, with 10 racks to the right and 10 racks to the left of the STAT island. A minimum of 2 mL of urine is required for testing.

Figure 1-1: CLINITEK Novus Analyzer, Front Exterior View



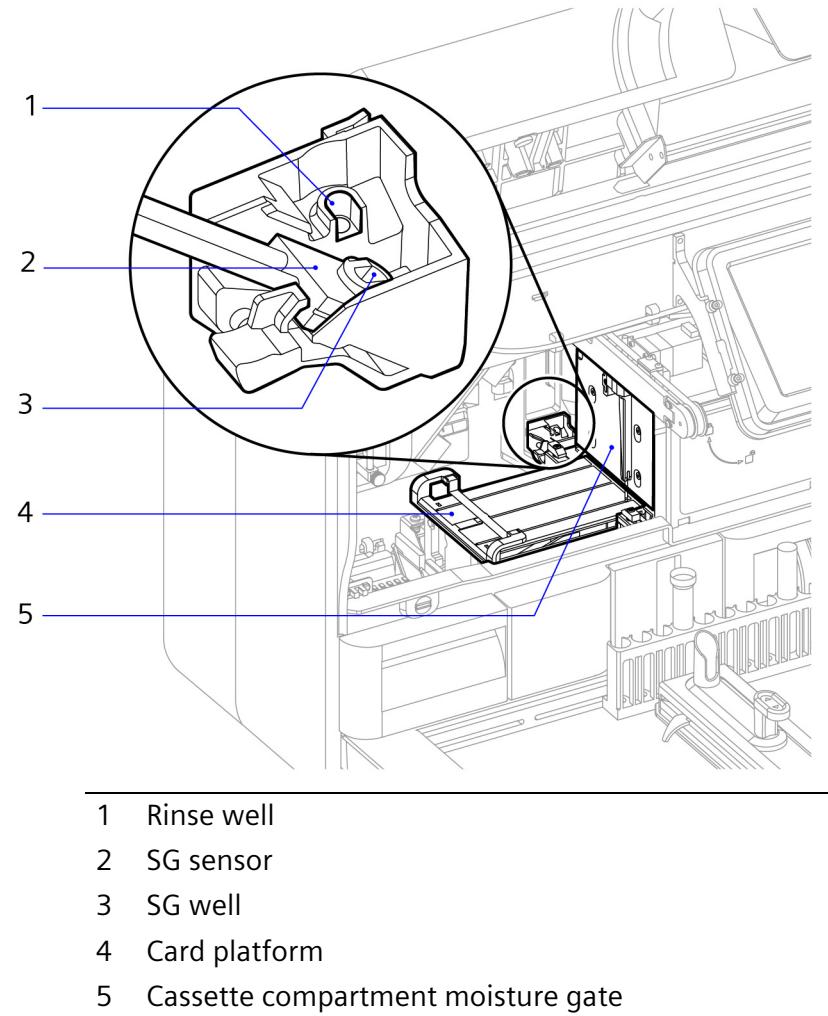
-
- | | |
|----|-------------------|
| 1 | STAT island |
| 2 | Cover handle |
| 3 | Card waste drawer |
| 4 | System cover |
| 5 | On button |
| 6 | USB port |
| 7 | Display |
| 8 | Waste drawer |
| 9 | Rinse drawer |
| 10 | Rack handler |
-

Figure 1-2: CLINITEK Novus Analyzer, Front Interior Right View



-
- 1 Sensor cables
 - 2 Syringe
 - 3 Pipette
 - 4 Cassette compartment door
-

Figure 1-3: CLINITEK Novus Analyzer, Front Interior Left View



Hardware Overview



CAUTION

The CLINITEK Novus analyzer must be connected to an Uninterruptible Power Supply (UPS).

The CLINITEK Novus Analyzer contains several major hardware components.

Rack Handler

The rack handler consists of the following components:

- Loading and unloading areas

- STAT island and STAT holder
- Sampling area

The rack handler transports the racks of tubes with samples to the pipette. Use the platform on the right and left side of the STAT island for loading and unloading racks, respectively. The loading area is on the right side and the unloading area is on the left side (*Figure 1-4*). The rack moves to the sampling area for the pipette to aspirate the samples in the tubes.

For information about the **Rack Circulation** setting, see *Configuring the Basic Settings*, page 187.

The racks move through the rack handler, by a rack pusher on each side of the rack for forward movement, and by another rack pusher at the end of the rack for side-to-side movement.

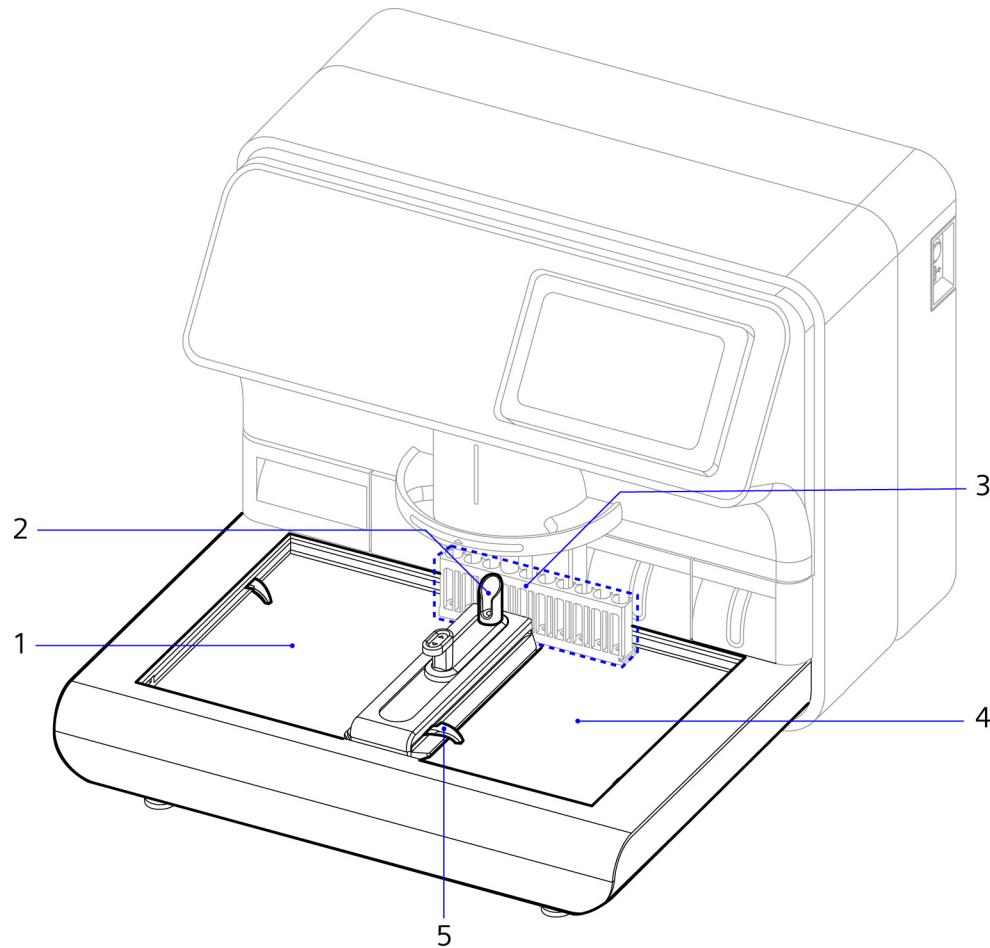
The rack handler has the following sensors:

- **Rack presence sensor** The rack presence sensor is a rectangular window behind the STAT island (toward the system), across from the optic window, which detects the presence of a rack in the sampling area.
- **Rack travel sensors** The rack travel sensors are 4 rectangular windows, 1 near each corner of the rack handler. These sensors detect when the rack is at the end of its travel path on the rack handler.
- **Rack error sensor** The rack error sensor is a rectangular window in front of the STAT island (closest to you), which detects a misplaced rack in front of the STAT island.

The STAT island contains a STAT holder that holds a single sample tube for processing in STAT mode.

Note If you connect the CLINITEK Novus Analyzer to a sediment system, you must use the appropriate connected rack handlers for rack transport.

Figure 1-4: Rack Handler



-
- 1 Unloading area
 - 2 STAT holder
 - 3 Sampling area
 - 4 Loading area
 - 5 Rack pusher
-

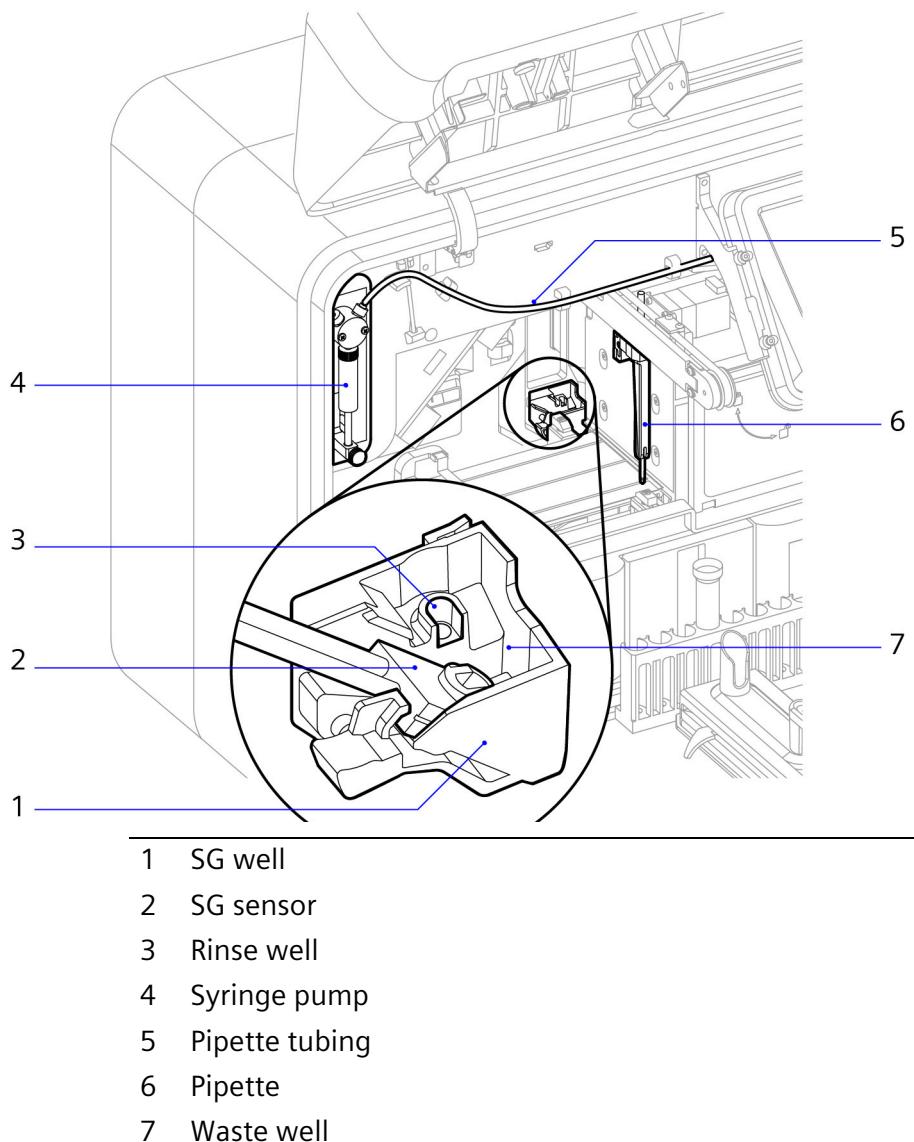
Pipette and Fluidic Systems

Note The analyzer rehydrates the SG well every 15 minutes to prevent drying of the fiber optic.

For each sample, the pipette and fluidic systems work in the following way:

1. The rack moves to the sampling area and positions the tube under the pipette. The pipette moves down into tube and senses the sample level. The pipette detects a low volume sample but does not detect non-ionic solutions such as distilled or deionized water.

Figure 1-5: Pipette System



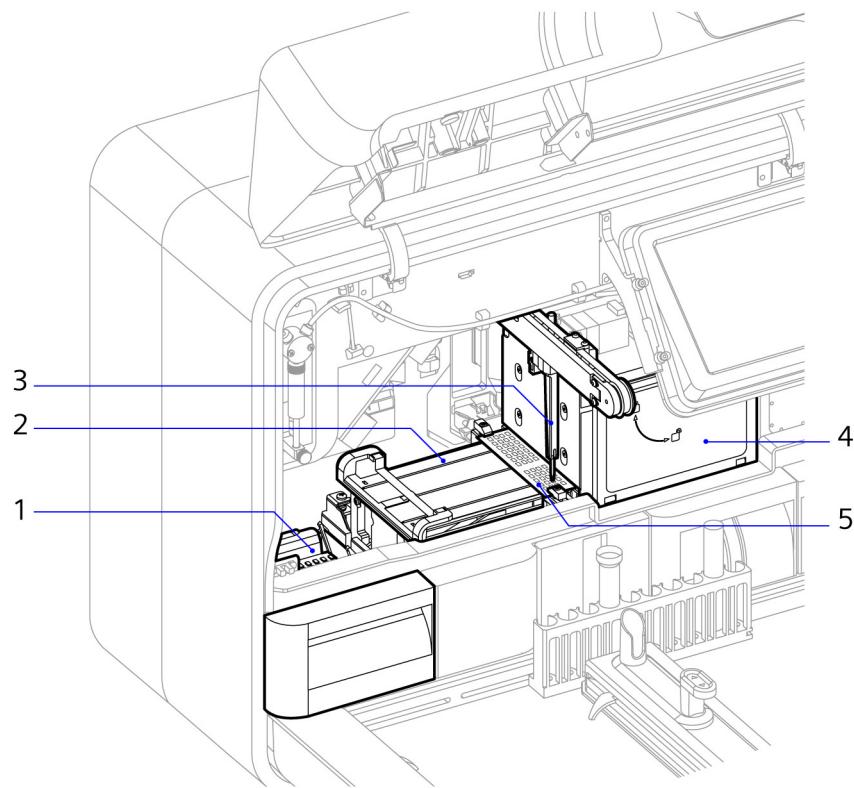
2. The syringe pump aspirates a small amount of the sample into the pipette and pipette tubing.

3. The pipette moves into position above the first test pad. The syringe pump dispenses a specific amount of the sample on each test pad, and into the SG well to determine the SG and clarity. The volume dispensed is specific to each pad type.
4. After the dispensing finishes, the pipette moves to the SG sensor, where the pipette dispenses the volume required for SG and clarity measurements, and then dispenses the remainder of the sample into the waste well.
5. The pipette dispenses the rinse solution into the rinse well to ensure complete rinsing of the pipette, and then rinses the SG well.

Card Handler

The card handler transports the test cards from the cassette to the card platform (*Figure 1-6*).

1. Each test card is positioned beneath the pipette, where a precise volume of sample is dispensed.
2. The camera records an image of the set of test pads.
3. After all of the test pads have been used, the card moves into the card waste drawer.

Figure 1-6: Card Handler

-
- 1 Card waste drawer
 - 2 Card platform
 - 3 Pipette
 - 4 Cassette compartment
 - 5 Test card
-

Rinse and Waste Systems

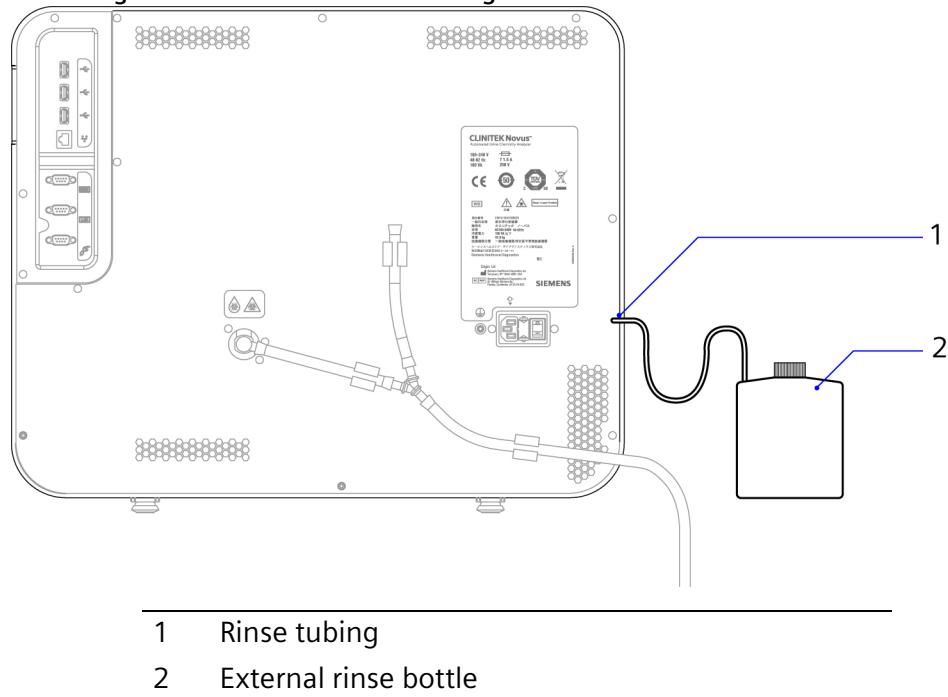
The system handles the rinse solution, liquid waste, and used test cards (*Figure 1-7*).

Rinse System

The system uses a rinse solution prepared by adding 2 mL of CLINITEK Novus Rinse Additive to 1000 mL of distilled or deionized water. The 1-liter rinse bottle holds sufficient rinse solution for the use of 1 full cassette. Change the rinse solution as directed in the rinse solution instructions for use.

An external rinse bottle connection is available and optional. Your Siemens Service Representative can connect the rinse solution tubing to a non-pressurized, external rinse bottle. The external rinse tubing connects to the syringe and continues through a hole on the right side of the connector panel to the external rinse bottle.

Figure 1-7: External Rinse Tubing

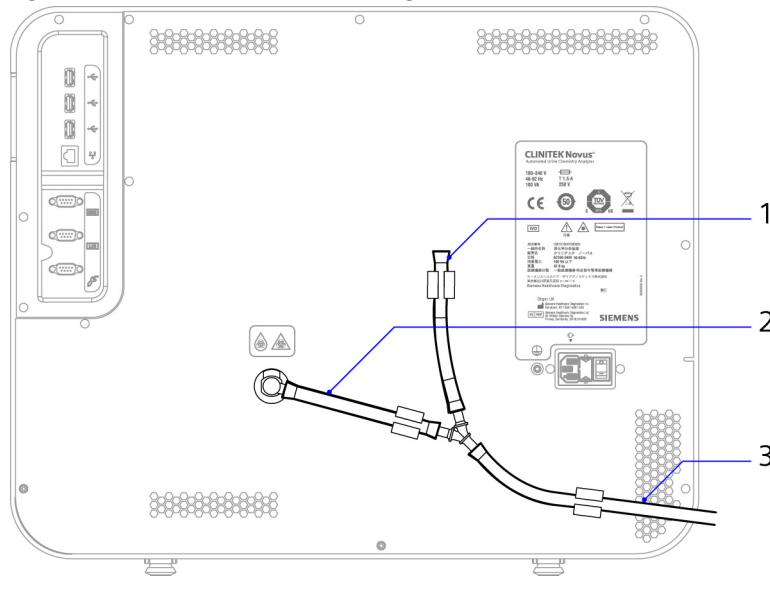


Waste System

The liquid waste drains into the internal waste bottle, which allows you easy access to emptying the liquid waste.

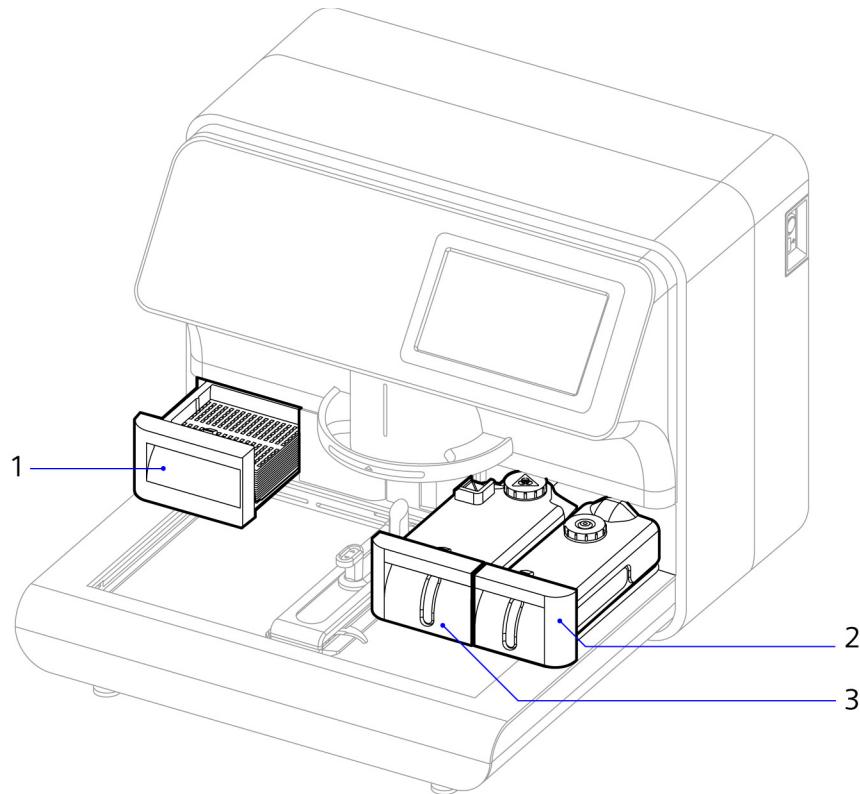
The liquid waste could drain through optional tubing to an external waste bottle or external drain. The external waste tubing connects from the SG well to the external drain port on the back panel. The waste tubing is on the left, the vent tubing is in the middle, and the waste tubing on the right connects to the external drain.

Figure 1-8: External Waste Tubing



-
- 1 Vent tubing
 - 2 Waste tubing
 - 3 Waste tubing to external drain
-

When a test card is completely used, the system pushes the card into the card waste drawer. The drawer can hold up to 1 full cassette of cards.

Figure 1-9: Rinse and Waste Systems

-
- 1 Card waste drawer
 - 2 Rinse bottle
 - 3 Waste bottle
-

Detection Systems

Table 1-1: Detection Sensors

Sensor	Description
System cover	Detects if the system cover is open or closed.
Cassette compartment moisture gate	Detects if the cassette compartment moisture gate is open or closed.
Cassette compartment door	Detects if the cassette compartment door is locked or unlocked.
Rinse bubble	Continually checks for bubbles in the rinse tubing.

Sensor	Description
Rinse Bottle Presence	Detects whether the rinse bottle is present, if the system is configured for internal rinse.
Rinse Bottle Level	Detects the level of rinse solution in the rinse bottle, if the system is configured for internal rinse.
Waste Bottle Presence	Detects whether the waste bottle is present.
Waste Bottle Level	Detects the level of liquid in the waste bottle, if the system is configured for internal waste.
Card Waste Drawer Presence	Detects if the card waste drawer is present, if the system is configured for internal waste.
Card Waste Drawer Level	Detects if the card waste drawer is full or empty.
Cassette Presence	Detects if the cassette is present.
Humidity	Checks the relative humidity inside the cassette compartment.
Temperature	Checks the temperature inside the system.
STAT in Place	Detects if the STAT holder is in place (toward the system) for testing a STAT sample.
Pipette Crash	Detects if the pipette crashed.
Rack Presence	Detects the presence of a rack in the sampling area.
Rack Error	Detects a rack that is incorrectly positioned in front of the STAT island (closest to you).
Rack Travel	These 4 sensors (in, out, right, and left) detect when the rack is at the end of its travel path on the rack handler.

Sensor	Description
Internal barcode reader	<p>Scans the barcode labels on the tubes and detects the following tube conditions:</p> <ul style="list-style-type: none"> • A tube is in place in the rack. If no tube is in place, the rack moves to the next tube slot. • A tube is capped. If the tube is capped, the system alerts you, skips that sample, and moves the next tube into place, or stops processing, depending on the Workflow option you select (see <i>Operations Settings</i>, page 190). In the patient results summary, the results display for all samples, including the skipped samples. You also can display only the results that contain errors, such as a skipped sample.
Level	<p>Located on the pipette. It determines the liquid level in each tube. This ensures that the pipette is submerged to a specific depth in the sample.</p>

Internal Barcode Reader

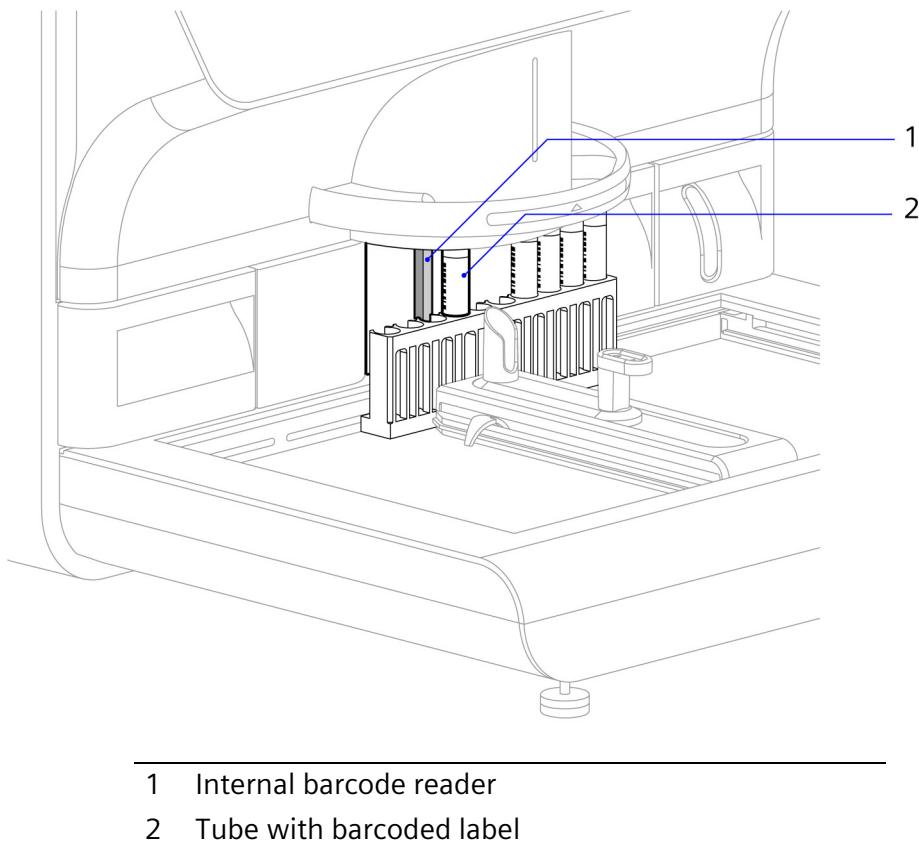
The internal barcode reader scans the barcode labels on the sample tubes in the racks, enabling positive sample identification (*Figure 1-10*). The barcode reader scans the barcode label immediately before the system analyzes the sample in the tube. For details on configuring the barcode reader, see *Table 7-3, Sample Settings*.

Note The internal barcode reader does not scan the barcode label for a tube you place in the STAT holder.

The internal barcode reader recognizes the following user-configurable barcode types (symbologies) to read sample IDs:

- Code 128
- Codabar (NW-7)
- Code 93
- Code 39, with or without check digit
- Interleaved 2 of 5 (I 2 of 5), with or without check digit

Figure 1-10: Internal Barcode Reader



Handheld Barcode Reader (Optional)

Optionally, in addition to the internal barcode reader, you can use a handheld barcode reader to perform the following tasks:

- Read the sample ID on the barcoded, labeled sample tubes in the racks instead of manually entering data using the onscreen keyboard.
- Read a control lot, calibrator lot, expiration date for Siemens controls and calibrators, operator ID, or comments instead of entering them using the onscreen keyboard.

The handheld barcode reader recognizes the following user-configurable barcode types (symbologies) to read sample IDs:

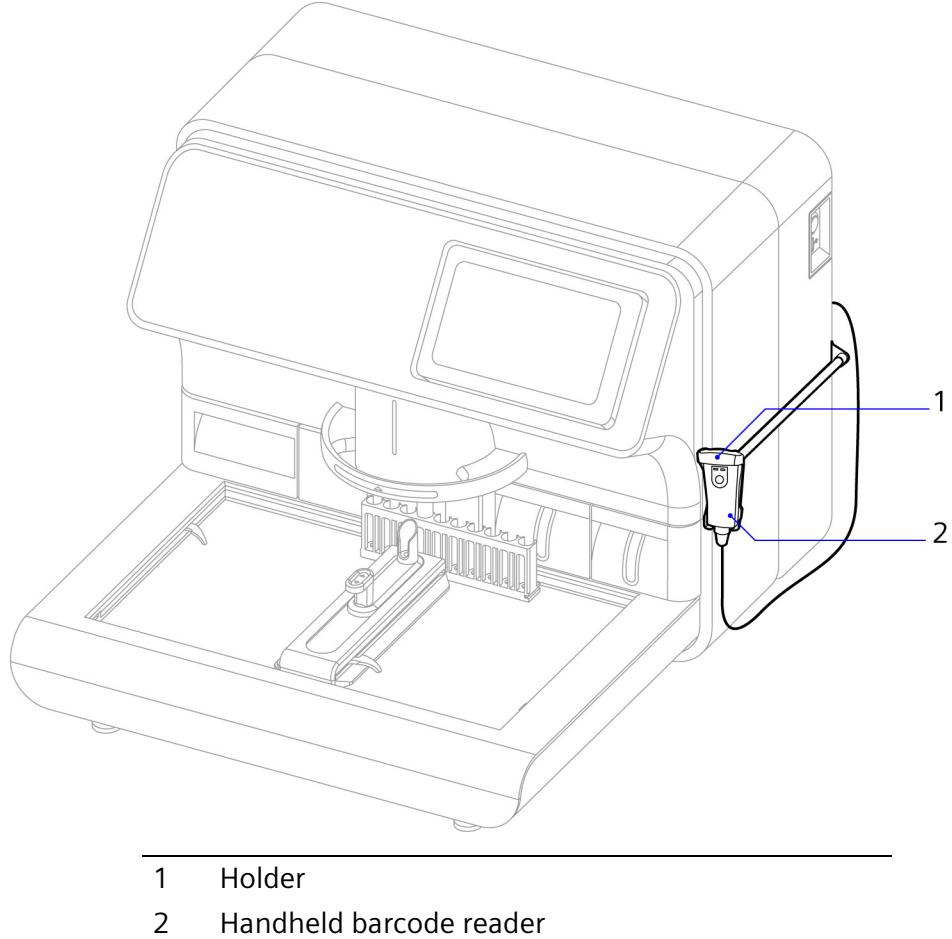
- Code 128
- Codabar (NW-7)
- Code 93
- Code 39, with or without check digit
- Interleaved 2 of 5 (I 2 of 5), with or without check digit

You can purchase a handheld barcode reader from your local technical support provider. When a Siemens Service Representative installs the system, they can also install and configure the handheld barcode reader.

If you purchase a handheld barcode reader after installation, install it according to the installation instructions provided with it. You must configure the barcode reader. The internal barcode reader and the handheld barcode reader can be configured to read different barcode types. For details on configuring the barcode reader, see *Table 7-3, Sample Settings*.

The optional handheld barcode reader has a holder that mounts to the analyzer. For details about installing the holder, see the instructions in the CLINITEK Novus Barcode Reader Installation Kit.

Figure 1-11: Handheld Barcode Reader Holder



SG and Clarity Measurement

A fiber optic refractive index method determines the specific gravity. Light transmits through a specially shaped fiber optic onto which the system dispenses the sample. The SG sensor measures the amount of light passing through the fiber optic at one end. The closer the refractive index of the sample is to that of the fiber optic, the more light is lost from the optic. Because the refractive index is proportional to specific gravity, the light measured at the end of the fiber optic loop correlates to the specific gravity of the sample.

The SG sensor measures the refractive index of the rinse solution between each sample as a reference value, compensating for the temperature and light source variations. The SG sensor also determines the clarity by measuring the transmission and scattering of the light that passes through the sample.

When the system is not processing samples, it dispenses rinse solution into the SG sensor every 15 minutes. This hydration step ensures that sample residues do not dry in the SG sensor. Dried residue influences the accuracy of subsequent SG readings until you clean the SG well. For this reason, you must leave the system powered on at all times.

Connector Panel

The connector panel is located at the back of the system on the upper left side, as you look at the system from the back (*Figure 1-11*). The panel contains several ports and a connector.

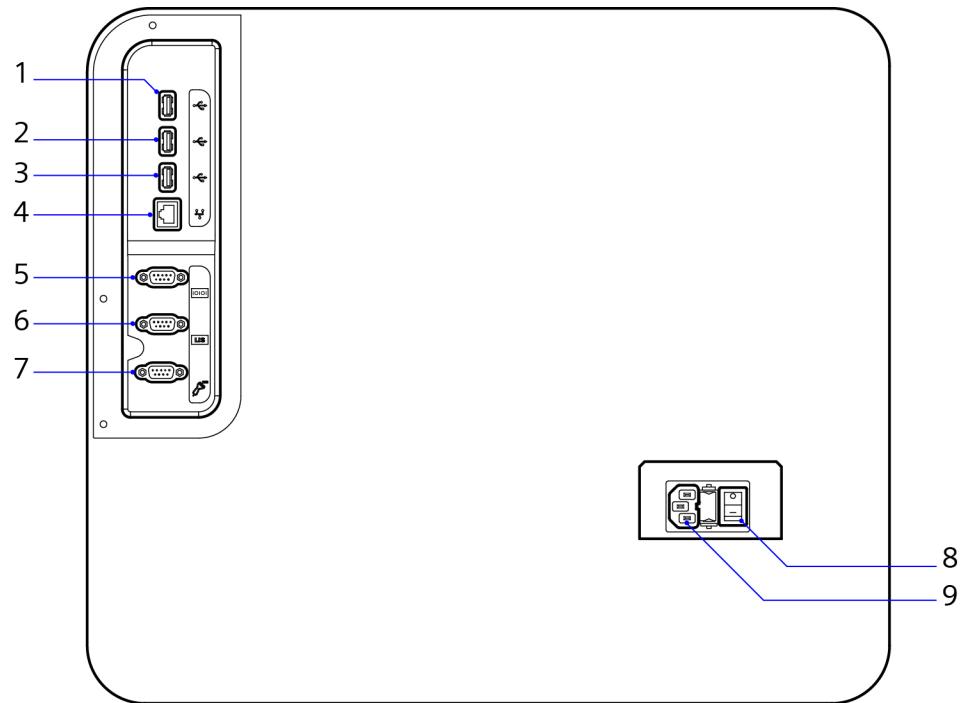
- **3 USB ports.**
 - Connect to a printer.
 - Insert an FAT32 formatted USB stick.

Note The system provides a USB port on the right side of the system beneath the On button. Use this USB port to copy and restore data and install software with an FAT32 formatted USB memory stick. After you insert an FAT32 formatted USB memory stick, the system ignores any additional sticks that you insert in a different USB port. Verify the formatting of your USB stick on a computer workstation prior to use with the CLINITEK Novus analyzer.

- **Ethernet port** Connects to the LIS and to the Remote Services server.
- **3 serial ports** Connect to a universal sample handler, LIS, and optional, handheld barcode reader.
- **Power receptacle** The electrical power cord connects to the power receptacle at the back of the system, on the lower right side.

The power switch is located to the right of the power receptacle. Siemens Healthcare Diagnostics strongly recommends that you keep the power switch at the on position all of the time. If you power off the system for longer than 1 hour, prime the pump, as explained in *Priming the Pump*, page 92. Leave the system powered on for at least 1 hour to rehydrate the SG well before you resume operation.

Figure 1-12: Connector Panel



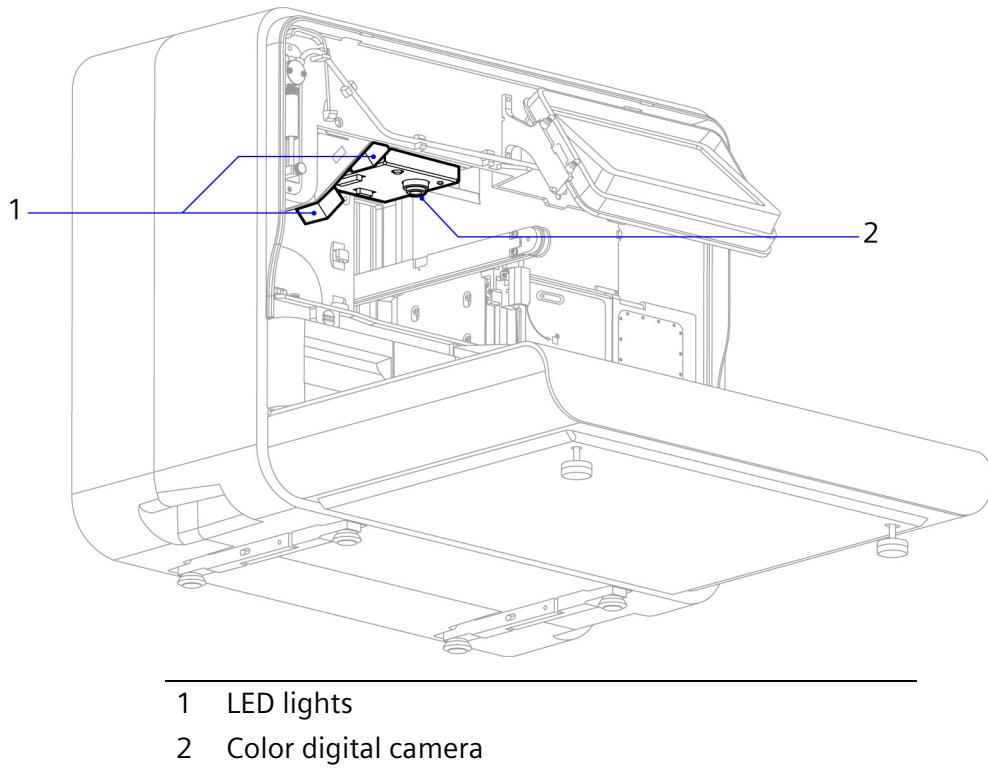
-
- 1 USB port
 - 2 USB port
 - 3 USB port
 - 4 Ethernet port
 - 5 Serial port universal sample handler
 - 6 Serial port LIS
 - 7 Serial port optional handheld barcode reader
 - 8 Power switch
 - 9 Power receptacle
-

Optical System

The optical system (*Figure 1-13*) includes a color digital camera that captures images with a resolution of 1 megapixel (1400 x 750 pixels).

1. The camera electronically analyzes the color and intensity of light that reflects from a reacted test area.
2. An LED light source illuminates the card platform and test card.
3. After the pipette dispenses a sample on a row of test pads, the camera records an image of those test pads.
4. The card advances so that the next set of test pads aligns under the pipette transport, and the camera records the next image.
5. The system uses multiple images to analyze the reacted test areas.
6. The card moves into the card waste drawer.

Figure 1-13: Optical System



Display

The integrated touch screen display shows the software user interface with words or objects. You interact with the touch screen display to select a menu item, button, or options on the screen. The touch screen displays messages, options, and requests for information.



CAUTION

Do not use anything hard or pointed on the touch screen, such as a pen or pencil tip. It might damage the screen.

You can use the stylus provided in the CLINITEK Novus Accessory Kit, your finger, or a pencil eraser to select items on the screen.

The display allows you to adjust the tilt angle of the screen. You can tilt the display up to 15 degrees back or forward. Consider tilting the display to reduce glare and reflections on the screen, or so that the screen is perpendicular to your line of sight.

An arrow appears in each corner on the frame of the display. You press the arrows to tilt the display to the angle you want.

To tilt the display:

- Press firmly on the up arrows in the upper-left and upper-right corners to move the top of the display back.
- Press firmly on the down arrows in the lower-left and lower-right corners to move the bottom of the display back.

Software and User Interface Overview

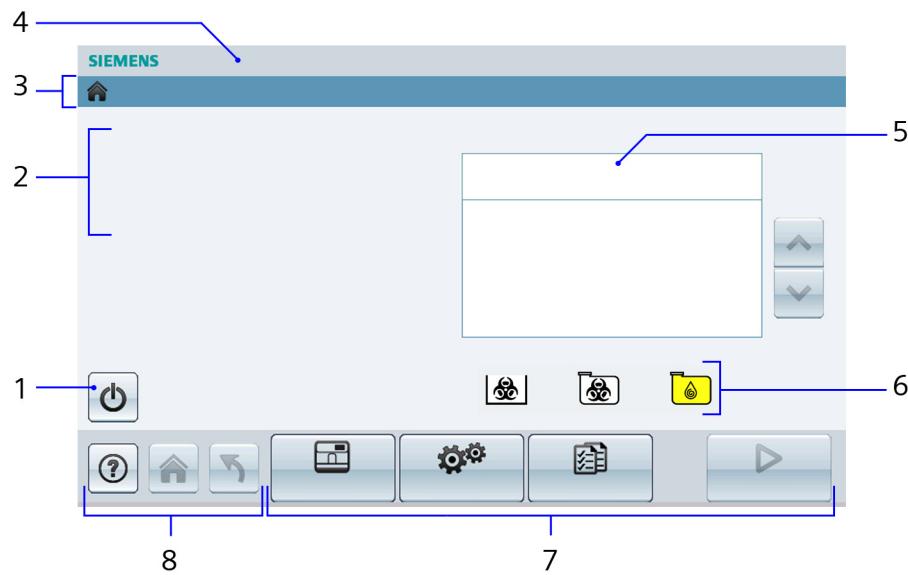
For the CLINITEK Novus Analyzer user interface (UI) navigation map, see *Appendix H, User Interface (UI) Navigation Map*.

Exploring the Home Screen

The CLINITEK Novus Analyzer user interface consists of a touch screen with an alphanumeric screen keyboard. The analyzer displays a **Home** screen (*Figure 1-14*) that contains menus, messages, and instructions, as described in *Table 1-2*. From the **Home** screen, you can perform system and management tasks, set up the system, recall the results, and perform a patient test. The system continually updates the system status in the Status log.

By default, a screen saver displays a message on the **Home** screen and dims the screen after a specified period of inactivity to extend the life of the screen. To activate the screen, select anywhere on the screen.

Figure 1-14: Home Screen



-
- 1 Off button
 - 2 Cassette Status
 - 3 Title bar
 - 4 Status bar
 - 5 Status log
 - 6 Waste and rinse status
 - 7 System function bar
 - 8 Navigation bar
-

Table 1-2: Home Screen Elements

Element	Description
Status bar	<p>Displays the following system status indicators:</p> <ul style="list-style-type: none">• Ready The system is ready to perform a patient or control test.• Not Ready The system is not ready to perform a patient or control test until you perform a task (such as clean or calibrate). To display the details for performing a patient, control, or calibration test, or cleaning the SG well, select the yellow alert messages in the Status log.• Processing The system is performing a patient, control, or calibration test.
Title bar	<p>Displays the current screen name, date, and time. Multiple screen names indicate the path to the current screen location. For example, Home > Setup > Configuration.</p>
Cassette Status	<p>Shows the status of the loaded cassette:</p> <ul style="list-style-type: none">• Tests Remaining The number of tests remaining in the cassette that decreases with each test the system processes. A new cassette displays a total of at least 450 tests but could display up to 464 tests. When no tests remain in the cassette, the Tests Remaining number is 0. You can test 450 to 464 samples, depending on how many tests a new cassette contains, including calibrators and controls.• Cassette Cassette type: CLINITEK Novus 10 Urinalysis Cassette or CLINITEK Novus PRO 12 Urinalysis Cassette.• Cassette Lot Lot of the cassette.

Element	Description
Cassette Status	<ul style="list-style-type: none"> Onboard Stability The amount of usage time available on the cassette. After you load a cassette, a countdown of cassette validity will begin. When the countdown reaches 0 days, the remaining life displays in hours. When the onboard stability time ends, load a new cassette. Next Sample The sequence number for the next patient sample. The system assigns a unique sequential identification number for every test you process. A patient sequence number for the ASTM and HL7 interface protocols includes a prefix of 0–9. For example, 0–00001 or 5–00002. The prefix and test sequence are configurable numbers. For details, see <i>Sequence Number Setting</i>, page 211. Next STAT The sequence number for the next STAT sample. The STAT sequence number uses a prefix of S and reverts back to S-00001 for ASTM and HL7 every 24 hours. To reset the STAT Reset Time setting, see <i>Operations Settings</i>, page 190.
Load List	<p>If you configured your system to load the sample IDs from the LIS, the Load List button displays beneath the Cassette Status list. The number of sample IDs in the load list displays beneath the Load List button.</p> <p>If you connect the CLINITEK Novus Analyzer to a system that uses a universal sample handler or a sediment system, the CLINITEK Novus analyzer does not support a load list. The Load List button does not display.</p>
Off button	Shuts down the software and powers off the hardware. To power off the system completely, you press the power switch on the connector panel to the off position.

Element	Description
Status log	<p>Displays the system status, and error and warning messages. The system continually updates the log.</p> <p>When the system displays the Not Ready status in the Status bar, a yellow warning message displays in the log. The message prompts you to perform a task that makes the system ready for testing.</p> <p>When more than 4 messages are in the status log, scroll buttons on the right of the screen become visible. When the messages fill more than 1 page, a page number indicator displays above the scroll buttons. For example, 1 of 3.</p>
Waste and Rinse Status	<p>Indicates if the card waste drawer is full or empty, and the percentage full for the waste and rinse bottles.</p>
Navigation bar	<ul style="list-style-type: none"> • Help Displays the online Help screens. • Home Returns to the Home screen. • Back Returns to the previous screen.
System Function bar	<p>Displays on the Home screen and with menus.</p> <ul style="list-style-type: none"> • System Calibrate, perform a control test, load or unload a cassette, clean the SG well, prime the pump, perform diagnostics, change the System Management settings, and replace or adjust the hardware. • Setup Change the Date, Time, Volume, Rack Circulation, and Brightness settings. Configure the Operations, Sample, Analyte, and Device settings. • Results Recall and delete results for the patient, control, calibration, and last group of patient tests. • Start Perform a patient test.

Entering Information

Some options require you to enter information, such as entering patient data. An alphanumeric keyboard displays on the screen so that you can enter or edit the alphanumeric data.

The onscreen keyboard consists of a label, text box, alphabetic and numeric buttons, and action command buttons to accept or cancel the entry. The characters you enter through the onscreen keyboard display in the text box. After you finish entering the information, select **Enter**. To cancel the entry, select **Cancel**.

Also, you can use the optional, handheld barcode reader to enter information. The barcode reader icons display to the right of the data entry box on the onscreen keyboard:

- **Enabled barcode reader** Use the handheld barcode reader.
- **Disabled barcode reader** Cannot use the handheld barcode reader because it was either disabled or not connected to the serial port on the connector panel.

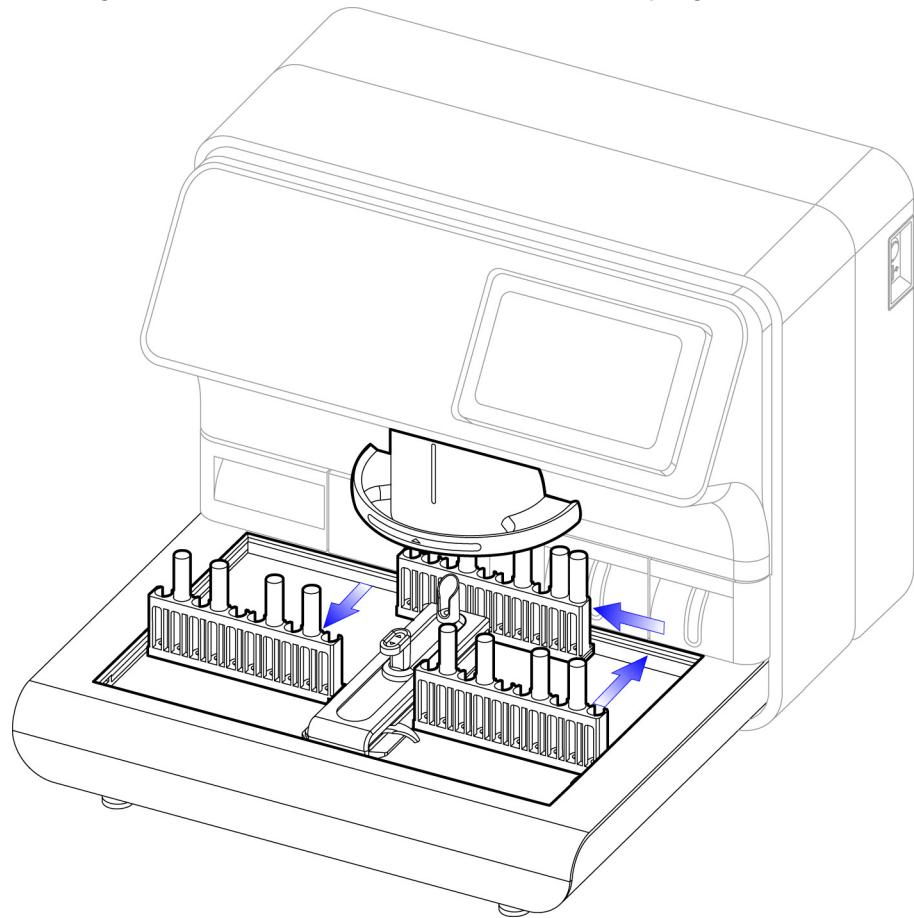
To use the handheld barcode reader, when the onscreen keyboard displays, scan the barcode label. The system enters the data in the text box and selects **Enter**. With a successful scan, the handheld barcode reader projects a green light on the target barcode, and beeps. With a failed scan, the handheld barcode reader projects a red light on the target barcode.

Operating Sequence

The CLINITEK Novus Analyzer software and hardware system sequence includes the following major steps for processing the samples:

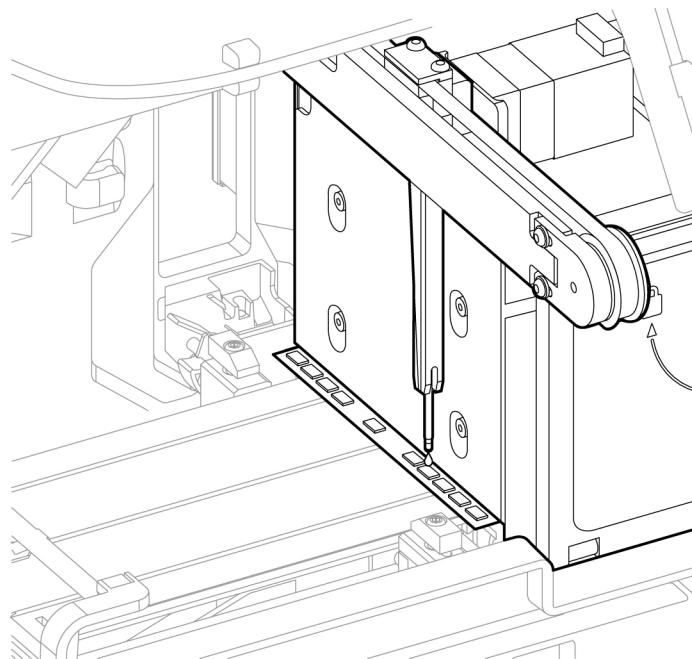
1. The rack handler moves the rack to position the first tube in the sampling area. The internal barcode reader scans the label on the tube.

Figure 1-15: Rack Handler Moves Rack to the Sampling Area



2. The system advances the test card to move the set of test pads to the dispense position.
3. The pipette moves to the aspirate position and aspirates a small volume of the sample.
4. The pipette moves to the dispense position and dispenses the sample on the test pads, and then moves to the SG sensor and dispenses the sample into the SG sensor.

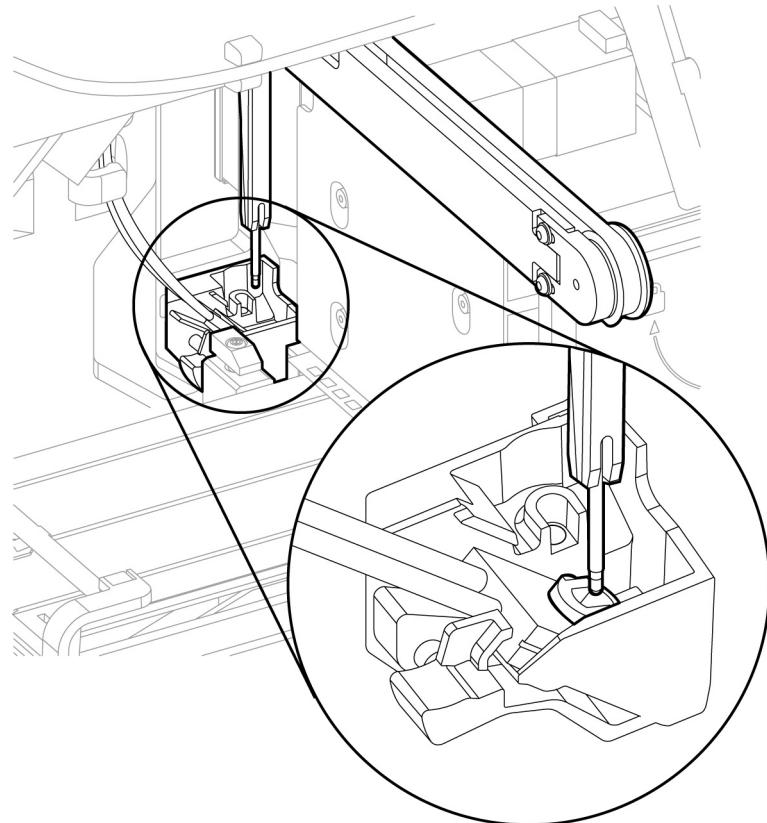
Figure 1-16: Pipette Dispensing Sample on Pads



5. The test card advances so that a new set of test pads is in position for the next sample. The camera records an image of the test card to analyze the results.

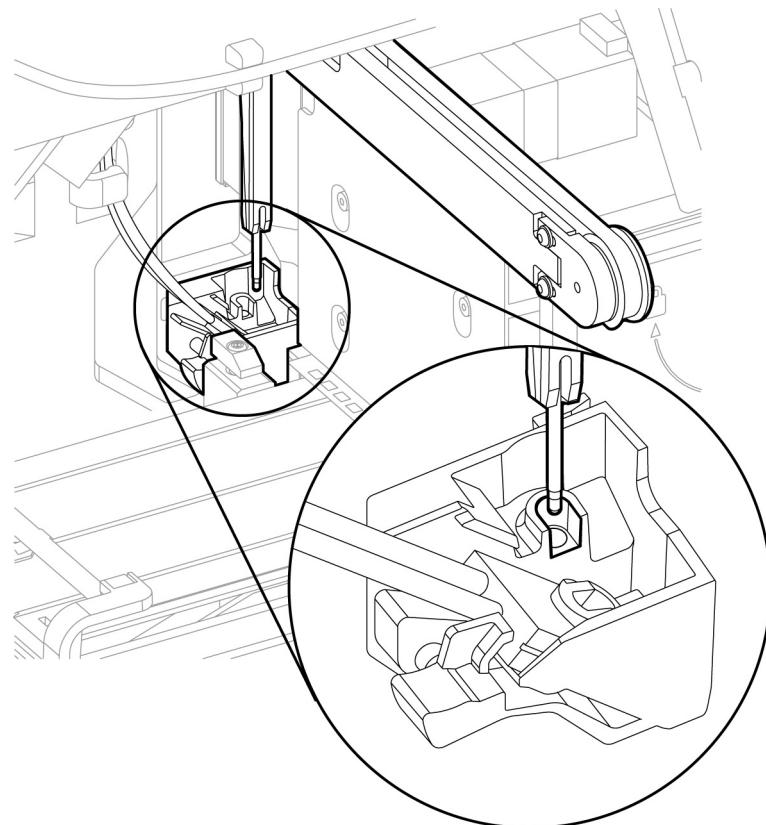
6. The pipette dispenses the remaining sample into the SG well.

Figure 1-17: Pipette Dispenses Remaining Sample into the SG Well



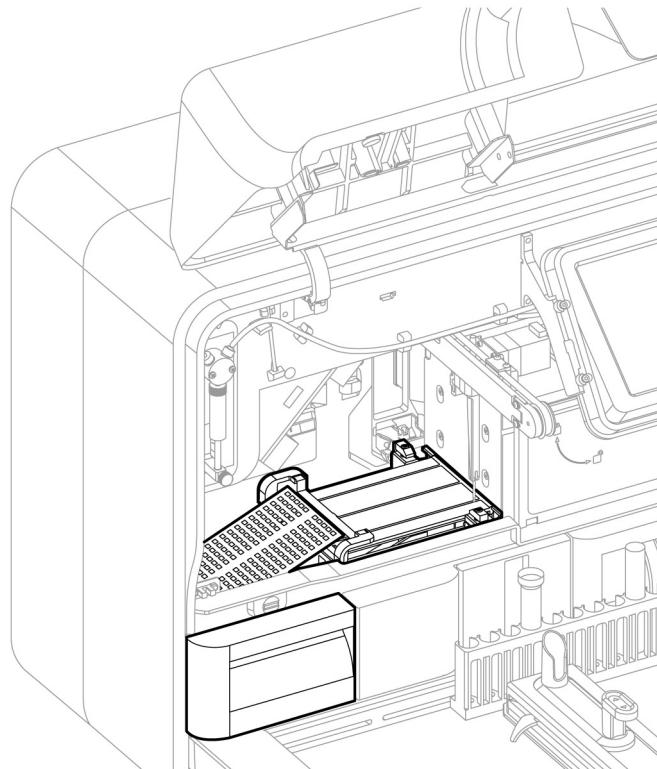
7. The pipette moves to the rinse well to rinse the inside and outside of the pipette, and then the pipette rinses the SG well.

Figure 1-18: Pipette Rinses in the Rinse Well



8. The system repeats steps 1–7 to process all the samples. After all of the test pads on a card have been used, the card moves into the card waste drawer.

Figure 1-19: Test Card Moves into the Card Waste Drawer



2 System Operation

This section covers the following topics:

- Powering the system On and Off
- Working with a Cassette
- Testing the Patient Samples and Working With the Results
- Testing a STAT Sample and Working With the Results
- Disposing of Rinse and Waste

Powering the System On and Off

Use the procedures to power the system on and off.

Powering the System On

Keep the power switch in the On position all of the time. If you power off the system for longer than 1 hour, prime the pump, as explained in *Priming the Pump*, page 92. Leave the system powered on for at least 1 hour to rehydrate the SG well before you resume operation.



CAUTION

The CLINITEK Novus analyzer must be powered on, even when the system is not processing samples, in order to hydrate the specific gravity (SG) well with rinse solution every 15 minutes.

The hydration ensures that the sample residues do not dry in the SG well and contaminate the fiber optics. Dried residue influences the accuracy of subsequent SG readings until you clean the SG well.

If the CLINITEK Novus analyzer has been powered off for more than 1 hour, prime the pump, as explained in *Priming the Pump*, page 92. Leave the system powered on for at least 1 hour to rehydrate the SG well before you resume operation.

To power on the system, follow these steps:

1. Ensure the system is connected to an Uninterruptible Power Supply (UPS).
2. If the system was powered off completely, at the back, lower left side of the system, press the power switch to the on position.
3. On the right side of the system, press the On button.

- The system performs a self-test while the screen is blank for approximately 45 seconds.
- The system loads the software while displaying the product name, software version, and copyright information.
- The **Home** screen displays.
- The **Status** bar displays the **Ready** mode indicator.

The **Status** bar might display the **Not Ready** mode indicator.

Warning messages might display in the **Status log**. For example, the cassette is not present, the cassette has a low quantity of tests remaining, or the onboard stability of the cassette expired. Also, you might be prompted to calibrate the system.

Note If powering the system on after a power loss greater than 10 minutes, the onboard stability of the cassette may be jeopardized. See the **Caution** statement for *Unloading and Loading a Cassette*, page 44.

Powering the System Off



CAUTION

Do not power off the system unless it is absolutely necessary. Siemens strongly recommends that you keep the power switch in the on position all of the time.

1. On the **Home** screen, select the **Off** button.
2. Select **Yes**.
The system shuts down the software and powers off the system.
3. At the back of the system, press the power switch to the off position.
The system is completely powered off.

Note For optimal performance, Siemens recommends that the instrument remain powered off for a minimum of 10 seconds before powering on.

Working with a Cassette

Siemens offers the following urinalysis cassettes for testing samples:

- **CLINITEK Novus 10 Urinalysis Cassette** A cassette that contains 16 sets of 10 test pads per card for the following tests: bilirubin, blood (occult), color, glucose, ketone (acetoacetic acid), leukocytes, nitrite, pH, protein, and urobilinogen. See the instructions for use.

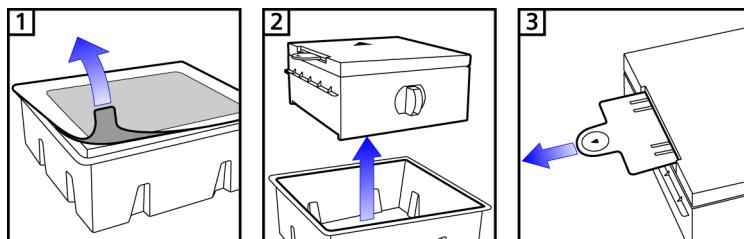
- **CLINITEK Novus PRO 12 Urinalysis Cassette** A cassette that contains 16 sets of 12 test pads per card with the same 10 sets of test pads as the CLINITEK Novus 10 cassette, and 4 additional tests, albumin, creatinine, protein-to-creatinine ratio, and albumin-to-creatinine ratio. See instructions for use.

Opening a New Cassette



CAUTION

Do not open a cassette if you do not intend to load it within 10 minutes. Humidity causes the test pads to deteriorate. For accurate test results, discard the cassette if it was exposed for more than 10 minutes, and open a new one.

Figure 2-1: Opening a New Cassette

-
- 1 Use the foil tab to peel the foil seal off the tray.
 - 2 Remove the cassette from the tray.
 - 3 Pull the shipping card out of the cassette.
-

**CAUTION**

Do not use test cards that might fall out of the cassette. Dispose of them. If test cards fall out of the cassette, the amount of cards in the cassette would be less than the system card count. An error would occur when the system expects a card to advance onto the card platform, and the card is not there because it no longer exists in the cassette.

To ensure that cards do not fall out of the cassette, open the cassette and immediately load it into the system. Do not move the cassette or flip it upside down.

Unloading and Loading a Cassette

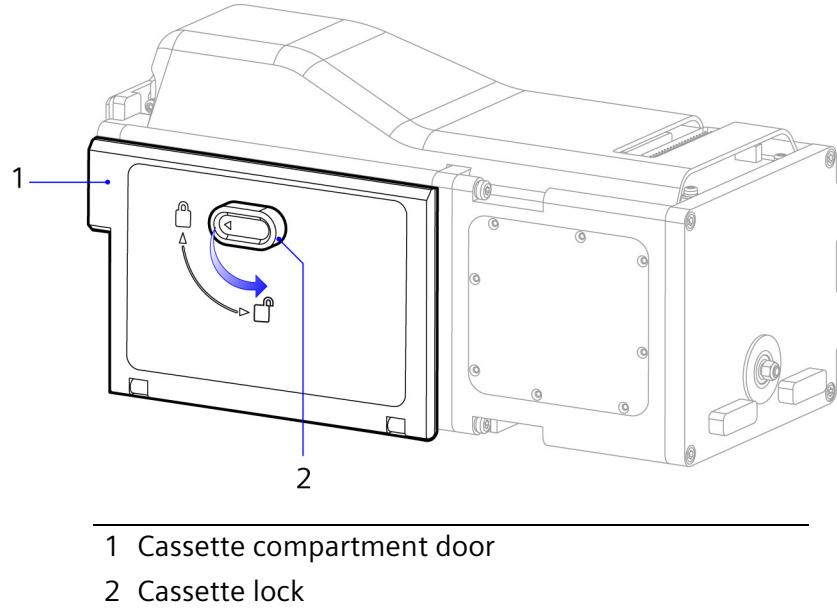
**CAUTION**

Do not leave the cassette compartment moisture gate open for longer than 10 minutes when a cassette is in the compartment. Humidity causes the test pads to deteriorate. If the system displays a message that the cassette is invalid, or if the cassette compartment moisture gate has been opened for 10 minutes or more, replace the cassette. The system will inform you if the cassette is invalid and will not process tests until a valid cassette is loaded.

1. Select **System > Load & Unload**.
2. If a cassette is already loaded in the cassette compartment, to confirm unloading the cassette, select **Yes**.
The cassette compartment moisture gate will open. If a test card is on the card platform, the system ejects the card. The moisture gate will remain open until the cassette compartment door is unlocked and re-locked.
3. When prompted, open the system cover.

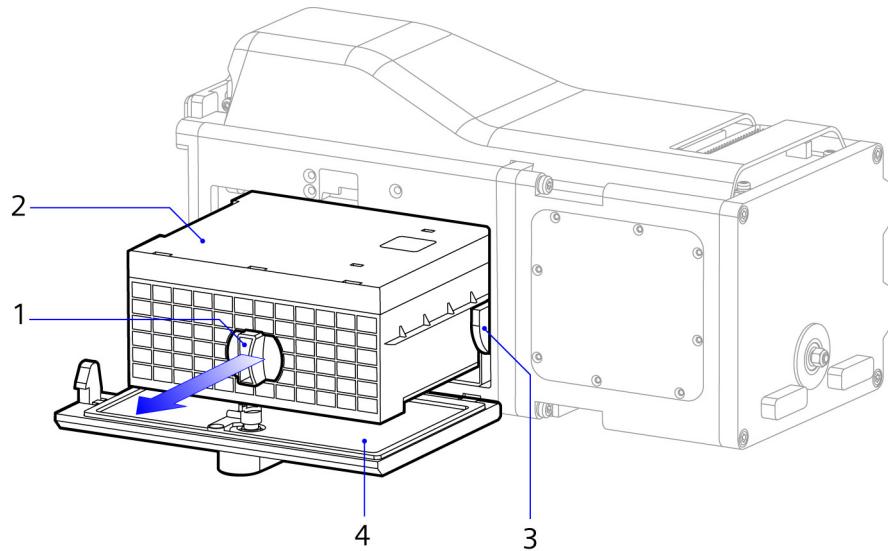
4. To unlock the cassette compartment door, turn the lock counterclockwise, and then open the door.

Figure 2-2: Unlocking the Cassette Compartment Door



5. Hold the cassette by its handle in the front, and slide the cassette toward you on the cassette compartment rails.

Figure 2-3: Unloading the Cassette



-
- 1 Cassette handle
 - 2 Cassette
 - 3 Cassette compartment rail
 - 4 Cassette compartment door
-

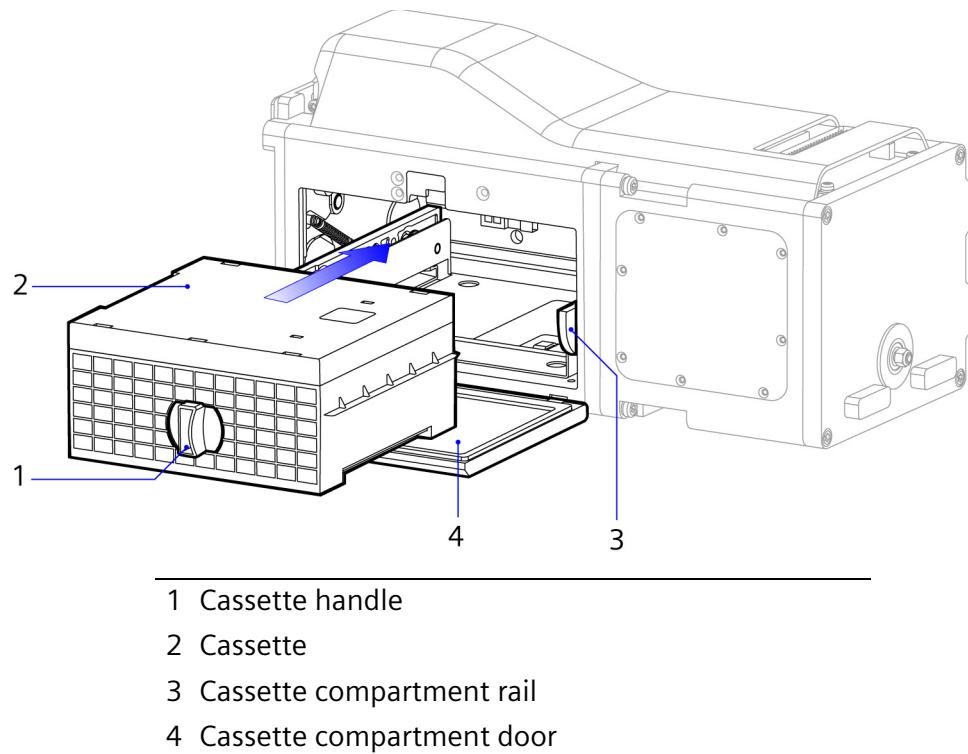


CAUTION

Do not use any test cards that fall out of the cassette. Dispose of them.

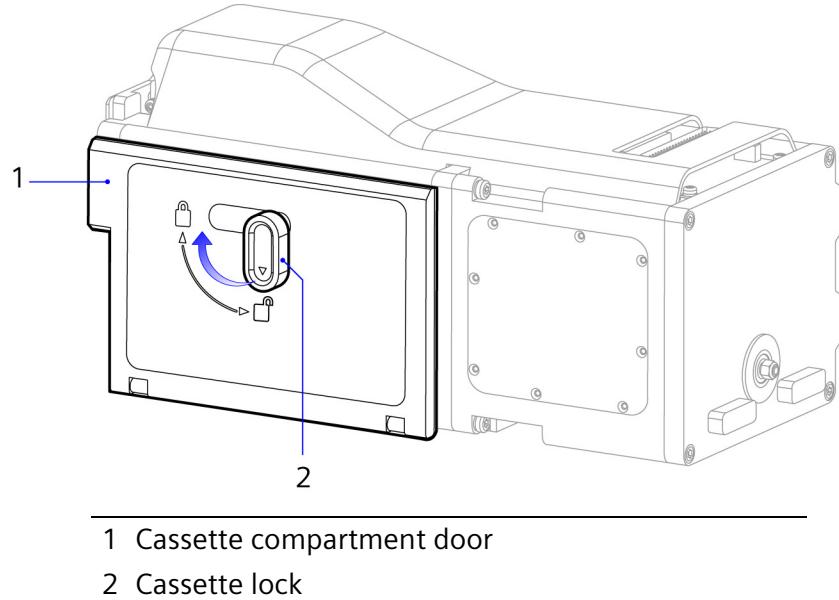
6. To load the new cassette, hold the cassette by its handle in the front, and slide the cassette into the cassette compartment using the rails as your guide.

Figure 2-4: Loading the New Cassette



7. Close the cassette compartment door and turn the lock clockwise to lock the door.

Figure 2-5: Locking the Cassette Compartment Door



8. Close the system cover.

The system reads the lot number and expiration date from the cassette.

Testing the Patient Samples

The system is ready to perform a test when the **Home** screen displays **Ready** in the **Status** bar and the **Start** button is enabled.

Before you start each new test, perform the following tasks:

- Prepare the samples
- Place the racks on the rack handler

Preparing the Samples



BIOHAZARD

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



WARNING

Do not test urine samples that are visibly mucoid or foamy on the system. To test these samples, pour off or pipette a sample that is free from mucous or foam. For samples that are visibly bloody, collect another sample.

Note With unpreserved samples, for the most accurate results, test within 2 hours of collection.

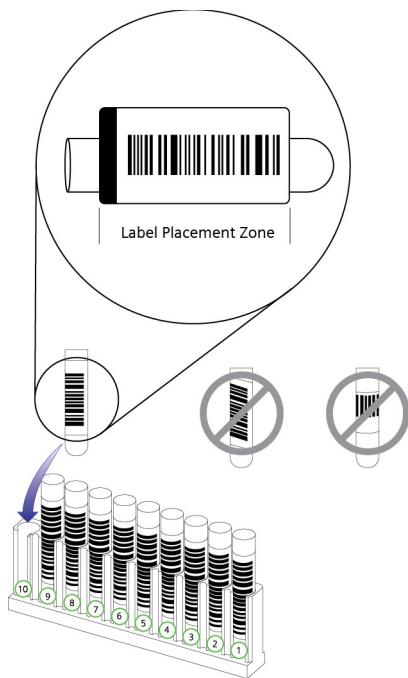
1. Allow the samples to reach room temperature if they were refrigerated.
2. Mix each sample thoroughly.
3. Pour 2 mL of each sample into a labeled sample tube.



CAUTION

- Do not process the tubes with misaligned barcode labels. Be sure that the barcode label is placed vertically and straight (not skewed) on the tube. A misaligned label might result in barcode reading problems (*Figure 2-6*).
 - Ensure that the quality of the barcode label is acceptable. The ideal 1D barcode label must have clean and clear straight lines with high contrast between the light and dark areas. Label quality can interfere with correct scanning.
 - Avoid using labels with a highly laminated surface or with poorly printed barcodes, such as those with broken areas, smudges, or other irregularities. Environmental factors, such as exposure to dampness and ultraviolet light, can also damage the barcodes during storage or use.
 - Do not process the tubes with multiple barcode labels. The barcode reader can read only 1 barcode, not multiple barcodes on a tube.
 - To avoid labeling errors when you enter sample IDs manually, keep the handheld barcode reader enabled and use it to scan the barcode labels.
-
4. Place the specimen label on the test tube such that the text and barcode are legible from left to right (from cap to tube bottom) as shown in *Figure 2-6* .

Figure 2-6: Placing Barcode Labels on a Tube



5. Load the tubes of patient samples into the racks:
 - a. Place each tube in the rack so that the barcode shows through the open side of each tube slot in the rack (*Figure 2-6*).
 - b. Ensure that the tubes are properly seated in the racks.
Tubes that are improperly seated in the racks can interfere with the pipette movement.

Note If you use wide-mouth tubes, place them in every other tube slot in the rack, as shown in *Figure 3-2, Wide-Mouth Tubes in Every Other Slot in Rack*.

The system stops processing if it detects an empty rack. Load the tubes starting with position 1 in each rack. The system processes the samples from left to right, starting in position 1 in the rack. This loading method ensures higher efficiency in processing the samples.

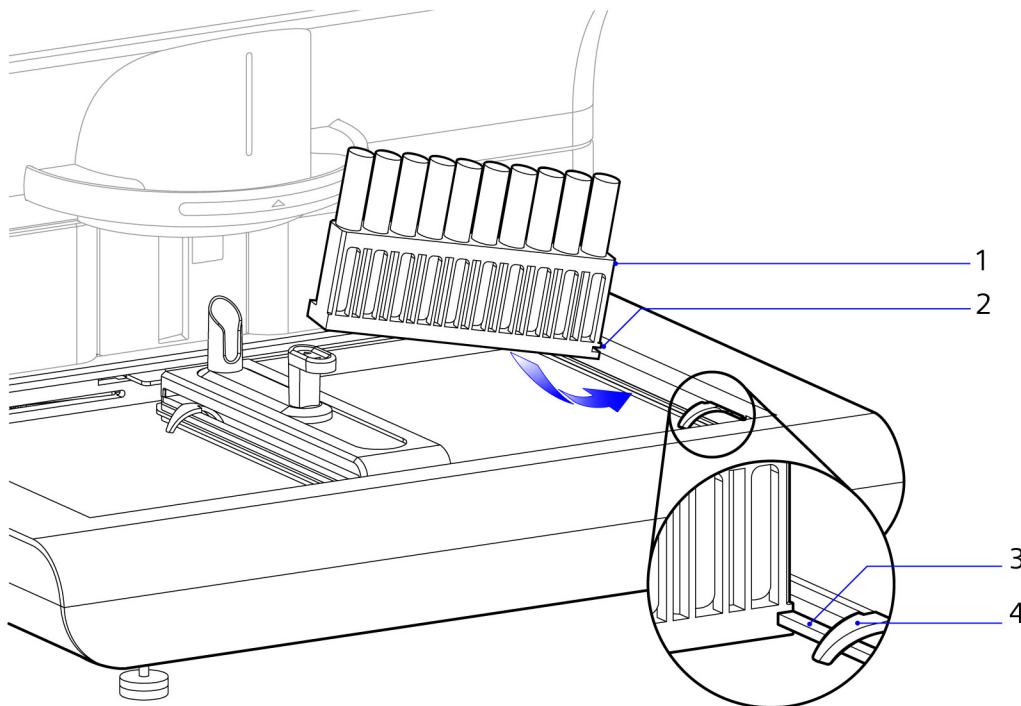
If you leave more than 1 slot between tubes or place only 1 tube in a rack, the processing efficiency decreases.

Placing the Racks on the Rack Handler

1. Place the racks on the loading area of the rack handler with the open side of each tube slot in the rack facing toward the system.

2. Tilt the rack at an angle to the right, and align the rack slot on the bottom, right side of the rack, sliding it into the retaining rail.

Figure 2-7: Placing the Racks on the Rack Handler



-
- 1 Rack
 - 2 Rack slot
 - 3 Retaining rail
 - 4 Rack pusher
-



CAUTION

Do not load more than 10 racks on either side of the rack handler.
Do not place a rack in front of or behind the STAT island, or immediately in front of the card waste drawer in the unloading area.

Working with the Load List

The load list can contain a maximum of 200 sample IDs. The transmission of additional sample IDs is refused when 200 have been received or when you start testing patient samples.

You can send multiple batches and add them to the same load list, when the system is not processing patient, calibration, or control samples, providing that the total number of sample IDs does not exceed 200.

Note Sample IDs that have been accepted by the system are not affected.



CAUTION

Do not add more than 200 sample IDs to a load list. If the LIS sends a load list with more than 200 sample IDs, the system rejects all sample IDs in the load list request.

When testing samples contained in the load list, do not test any other samples. If no sample IDs are in the load list, the testing does not start.

The system assigns the load-listed sample IDs to the first rack of samples tested by the system. If a sample rack contains fewer samples than the number of sample IDs in the load list, the remainder of the load list is held until the system tests the next rack of samples. At that time, the system assigns the remaining sample IDs.



WARNING

Do not place the sample tubes in the rack in a different order from the sample IDs in the load list. If you do, the system does not test the correct samples. Be sure to place the tubes in the rack that matches the order of the sample IDs in the load list.

If you use a load list as the source for sample IDs, place the tubes in the rack in the exact order in which the sample IDs appear in the load list.

Note You can run STAT tests. However, observe whether the LIS allows the receipt of STAT records in the middle of a load-listed run. The system sends STAT results to the LIS immediately when they are available, if you enable **STAT** in the **Host Data** setting.

To configure the system to use a load list, see *Sample and Controls Settings*, page 193.

You can view, print, and delete the load list.

1. On the **Home** screen, select **Load List**.

The system displays 10 sample IDs per page with the following information:

- **Received** The date and time the most recent sample ID was received from the LIS.
- **Count** The number of sample IDs in the load list.
- **Load Entry Number** The number of the sample ID entry in the list.
- **Sample ID** The sample IDs for the samples.

2. To print the load list, select **Print**

3. To delete the load list, select **Delete**, if enabled.

4. If you enabled the **System Access, Data Delete** setting, enter the password.

Performing a Patient Test

Note If you use a load list as the source for sample IDs, the system receives the load list of sample IDs from the LIS to identify the samples.

1. Verify that the **Status** bar displays the **Ready** status.

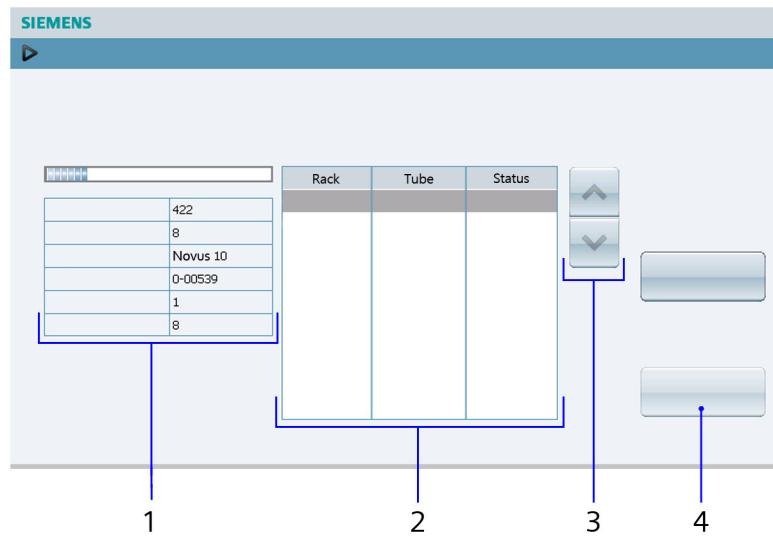
Note If you use a load list as the source for sample IDs, and the load list is empty, the **Start** button is not available. The **Status** bar shows the **Not Ready** indicator.

2. Select **Start**.

The system processes the samples, as explained in *Operating Sequence*, page 34.

Patient Test Progress

The **Patient Test Progress** screen displays. The system continually updates the progress for each sample you test.

Figure 2-8: Patient Test Progress Screen

- 1 Patient test progress area
- 2 Patient status area
- 3 Status navigation area
- 4 STAT button

The patient status area displays the tests by rack and tube number with their status, starting with the most recent test.

Status Item	Description
Rack	The rack number of the sample.
Tube	The tube number of the sample.
Status	<ul style="list-style-type: none">• Completed The sample was completed.• Low volume The volume of sample in the tube is too low.• Dispense error The system could not dispense the sample.• Tube error The tube is capped or too high.

Patient Test Completion

The system finishes processing the samples.

The results display on the **Patient Results** screen, as explained in *Viewing the Patient Results*, page 56.

The **Patient Missing Data** screen displays for the following reasons:

- If you selected **Sample Handler** as the sample source, and the internal barcode reader could not read the barcode label or sample ID.
- If you selected the **Color Reporting** or **Report Clarity** option to manually enter the color or clarity values.
- If you selected the **Manual** option for the **Sample Source** setting.
- If you enabled the **Patient Comments** setting.

You must enter the missing data so that the system can complete processing those samples. See *Entering the Missing Data*, page 61.

If an error occurs during a patient test, see Section 5, *Troubleshooting*. If an error persists, call your local technical service provider.

If an error occurs that stops the testing process, the rack handler stops processing the samples and ejects the rack the system is processing. If you enabled the **Rack Circulation** and **Circulation Stop** settings, the rack handler counts and resets the number of racks to be tested. To avoid retesting racks, remove them. For more information about rack handler errors that stop the testing process, *Recovering from Rack Handler Errors*, page 122.



CAUTION

If you use load lists as the source for sample IDs, and if testing stops, verify whether the **Stop on Error** setting is enabled or disabled. Based on the **Stop on Error** setting, use the following steps to perform a corrective action.

If **Stop on Error** is enabled, the system stops when it detects a low volume sample or capped tube sample. This sample remains on the load list and would be the first sample for the next group of tests. Remove all completed samples from the last rack the system processed and position the sample in the first rack you want to test in the next group of tests.

If **Stop on Error** is disabled, the system skips the low volume sample or capped tube sample and continues testing. These samples are removed from the load list and displayed as errors at the end of the testing. If you want to correct the sample problem and retest those samples, obtain an updated load list that includes those samples. Before you test those samples, rearrange the order of them in the rack as defined by the load list.

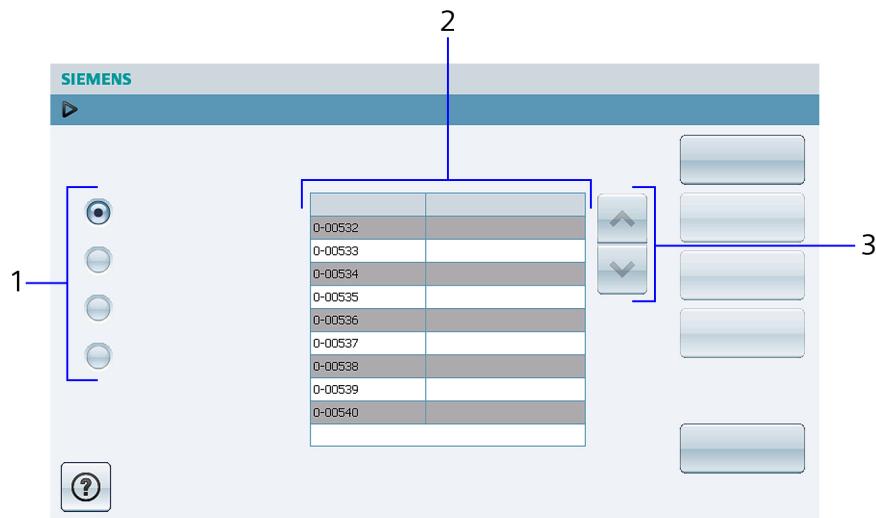
The system stops processing the samples based on certain conditions or errors, as explained in *Troubleshooting Error Messages*, page 128.

Viewing the Patient Results

After the system finishes processing the samples, and if necessary, you had entered the missing data (*Entering the Missing Data*, page 61), the **Patient Results** screen displays a summary of the results (*Figure 2-9*).

You can specify the type of results you want to display in the patient results summary, such as all of the results, or only the results identified with sieve or errors.

Figure 2-9: Patient Results Screen



1. To display all results or results by type, select an option:
 - **All** Displays all of the patient test results.
 - **Sieve** Displays the patient test results that match the sieve criteria, confirmatory or microscopic.
 - **Error** Displays the patient tests that had errors.
 - **Send Error** Displays only when the system could not send the patient test results to the LIS, and if you configured the **Host Data** setting to send the results automatically to the LIS.

The summary displays 10 samples per page with their sequence number and status, starting with the most recent samples.

Summary Item	Description
Seq. No.	The sequence number of the sample.
Status	<p>The status of a sample that is identified by its sequence number:</p> <ul style="list-style-type: none">• Completed The sample was completed.• Low volume The volume of sample in the tube is low.• Dispense error The system could not dispense the sample.• Tube error The tube is capped or too high.• Microscopic The sample was completed and met the microscopic sieve criteria.• Confirmatory The sample was completed and met the confirmatory sieve criteria.• Sieve The sample was completed and met both the microscopic and confirmatory sieve criteria.

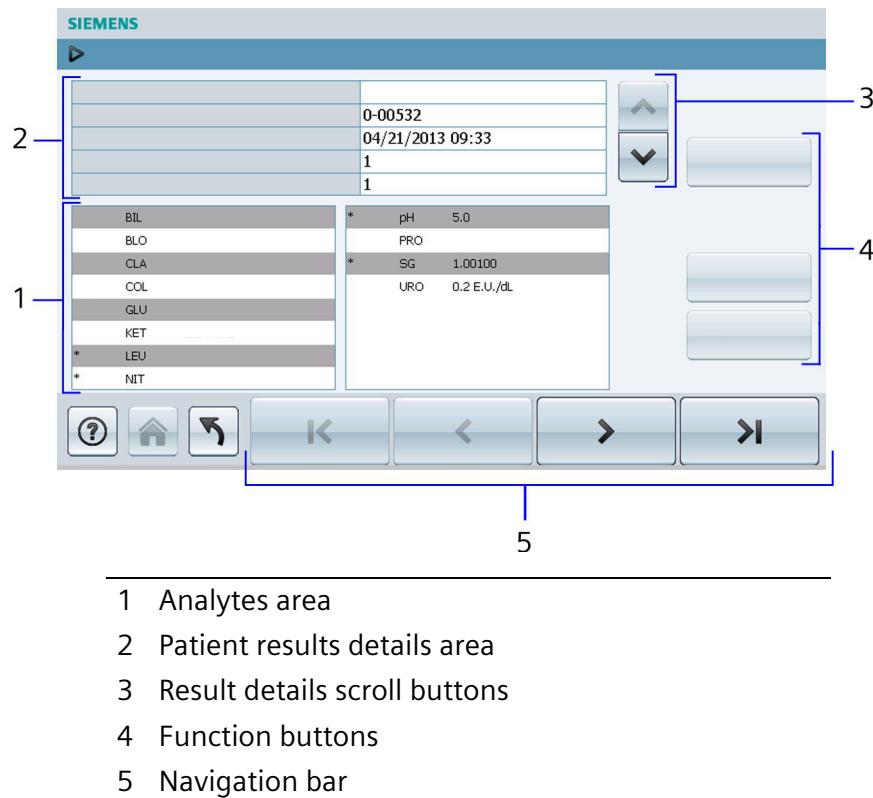
2. Use the scroll arrows to navigate the summary.
3. To view the details, print the summary or the details, or send the summary to the LIS, select a function button.

Viewing the Patient Result Details

1. On the Patient Result Details screen, select View.

The detailed results for the first sample display.

Figure 2-10: Patient Result Details Screen



2. Use the scroll buttons to the right of the summary to navigate the list.
3. Read the information in the analytes area.

For information on the results, see *Tables of Results*, page 224. If the system cannot determine a valid analyte value, a result value of **Error** displays for the analyte.

A symbol represents an analyte flag, which displays next to an analyte for a sample that meets the following criteria:

Table 2-1: Analyte Flags

Symbol	Description
^	Range adjusted
#	Sieve
*	Abnormal
†	Sample quality

4. To display patient comments, print the details, or send the details to the LIS, select a function button.

Finishing the Tests and Testing the Next Group



BIOHAZARD

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

1. After the system finishes processing the last sample, ensure that the system sent all of the results to the printer or LIS.
2. Remove the racks from the rack handler.
3. Wipe any spills on the rack handler immediately.
Note Moisture underneath the racks can prevent the racks from moving properly, and can cause rack jams.
4. Load the new racks of samples.

5. To begin testing the next group of samples, select **Start**.
-

**CAUTION**

The CLINITEK Novus analyzer must be powered on, even when the system is not processing samples, in order to hydrate the specific gravity (SG) well with rinse solution every 15 minutes.

The hydration ensures that the sample residues do not dry in the SG well and contaminate the fiber optics. Dried residue influences the accuracy of subsequent SG readings until you clean the SG well.

If the CLINITEK Novus analyzer has been powered off for more than 1 hour, prime the pump, as explained in *Priming the Pump*, page 92. Leave the system powered on for at least 1 hour to rehydrate the SG well before you resume operation.

Entering the Missing Data

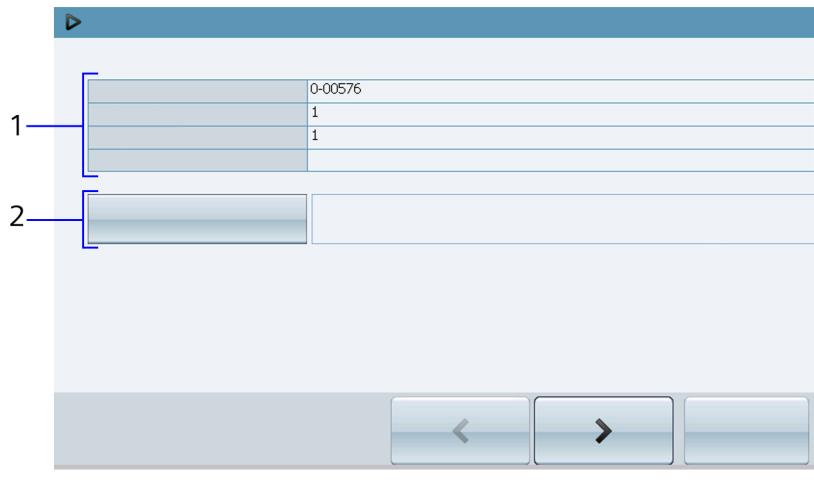
**WARNING**

To prevent incorrect results displayed onscreen, printed, or sent to the LIS, which are associated with incorrect sample IDs or other incorrect data, carefully verify the sample ID or data you enter manually before you proceed. Or keep the handheld barcode reader enabled and use it to scan the barcode labels to enter sample IDs.

If you enabled the **Sample** settings for sample ID, color, clarity, or patient comments, you can enter any of that data on the **Patient Missing Data** screen. The sample IDs and comments are optional and the system can complete a test without that data.

1. Read the current sample data at the top of the **Patient Missing Data** screen.

Figure 2-11: Patient Missing Data Screen



1 Patient results details area

2 Missing data area

The top section of the **Patient Missing Data** screen contains the patient results details. Up to 3 types of missing data could display with a button and a yellow box. After you enter the data in the yellow box, the box color changes to white.

2. Enter or select the missing data.

Missing Data	Procedure
Sample ID	<ol style="list-style-type: none">1. Select Sample ID.2. Using the screen keyboard or the handheld barcode reader, enter a sample ID (up to 20 characters).3. Select Enter.
Color & Clarity	<ol style="list-style-type: none">1. Select Color & Clarity.2. Select a color.3. Select a clarity.4. Select Save.
Clarity	<ol style="list-style-type: none">1. Select Clarity.2. Select a clarity.3. Select Save.

Color	<ol style="list-style-type: none">1. Select Color.2. Select a color.3. Select Save.
Comments	<p>Displays the first 32 characters of each comment you enter. The system assigns each comment a number, 1–4. For example, if you select Comment 1 and enter Overnight collection, the system displays 1:Overnight collection for Comment 1.</p> <ol style="list-style-type: none">1. Select Comments.2. Select a comment button: Comment 1, Comment 2, Comment 3, or Comment 4.3. Enter a comment (maximum of 40 characters) and select Enter.4. Select Save.

3. To navigate the samples with missing data, use the **Navigation** bar.
4. When you complete entering the missing data, select **Done**.

The results display on the **Patient Results** screen. For details, see *Viewing the Patient Results*, page 56.

Testing a STAT Sample

You can test a STAT sample only while you perform patient testing. The system pauses the patient sample tests to allow the STAT sample to be run and then displays the STAT results to be viewed, printed, or transmitted. The patient sample tests will resume when you exit the STAT test screen.

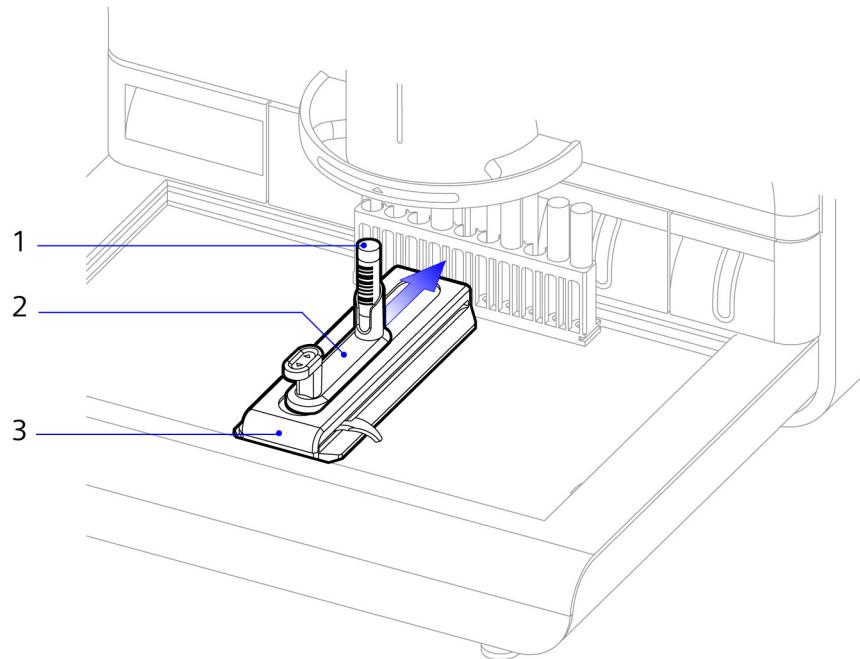
When you test a STAT sample, the system assigns a STAT sequence number to the STAT sample. For the ASTM and HL7 interface protocols, the STAT sequence number format is S-NNNNN, where S represents STAT, followed by a hyphen (-), and 5 numbers. For example, S-83942.

Performing a STAT Test

The system assigns a STAT sequence number.

1. If necessary, pull the holder toward you in the STAT island until it stops.
2. Place the tube in the STAT holder.
3. Push the holder toward the system until it stops in the STAT island.

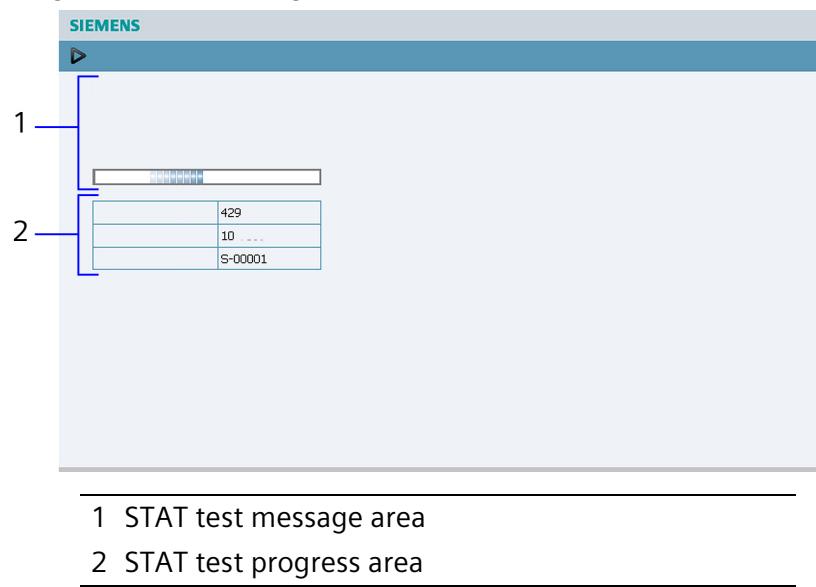
Figure 2-12: Tube in the STAT Holder



-
- 1 Tube
 - 2 STAT holder
 - 3 STAT island
-

4. On the **Patient Progress** screen, to start the STAT sample test, select **STAT**.

Figure 2-13: STAT Progress Screen



Note The internal barcode reader does not scan the barcode label for a tube you place in the STAT holder.

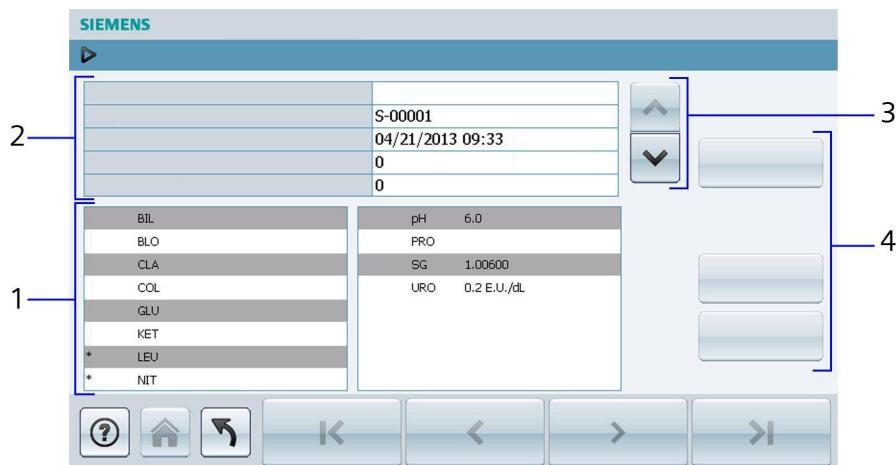
5. After the system finishes aspirating and dispensing the STAT sample, pull the STAT holder toward you and remove the STAT tube.
6. Optionally, navigate to the missing data screen to scan the STAT sample barcode label with the handheld barcode reader.

If patient data (sample ID, color, clarity, or patient comments) is missing, the **Patient Missing Data** screen displays. You can enter the missing data, as explained in *Entering the Missing Data*, page 61. After you enter the missing data, the **STAT Results** screen displays.

Viewing the STAT Result

1. Read the result details at the top of the **STAT Result Details** screen.

Figure 2-14: STAT Result Details Screen



-
- 1 Analytes area
 - 2 STAT result details area
 - 3 Result details scroll buttons
 - 4 Function buttons
-

2. Read the information in the analytes area.

A symbol represents an analyte flag, which displays next to an analyte for a sample that meets the following criteria:

Table 2-2: Analyte Flags

Symbol	Description
^	Range adjusted
‡	Sieve
*	Abnormal
†	Sample quality

3. To display patient comments, print the details, or send the details to the LIS, select a function button.

Disposing of Rinse and Waste

Laws and regulations enacted to protect the environment and to encourage resource conservation require the disposal of hazardous and biohazardous wastes in a specified manner.

Some of the wastes from the CLINITEK Novus analyzer can be classified as hazardous or biohazardous wastes. The laboratory is responsible to determine the laws and regulations applicable to their facility, and to dispose of wastes accordingly. If required to sample system wastes and effluent to evaluate compliance with applicable regulations, your laboratory should contact a local licensed waste disposal firm for assistance.

Handle and dispose of human samples, control materials, and all of the test cards in accordance with the prevailing regulations and guidelines of agencies with jurisdiction over the laboratory. For details about special precautions for handling CLINITEK Novus cassettes, calibrators, and controls, see the product label and Material Safety Data Sheets. Material Safety Data Sheets are available from Siemens.

Emptying and Filling the Rinse Bottle

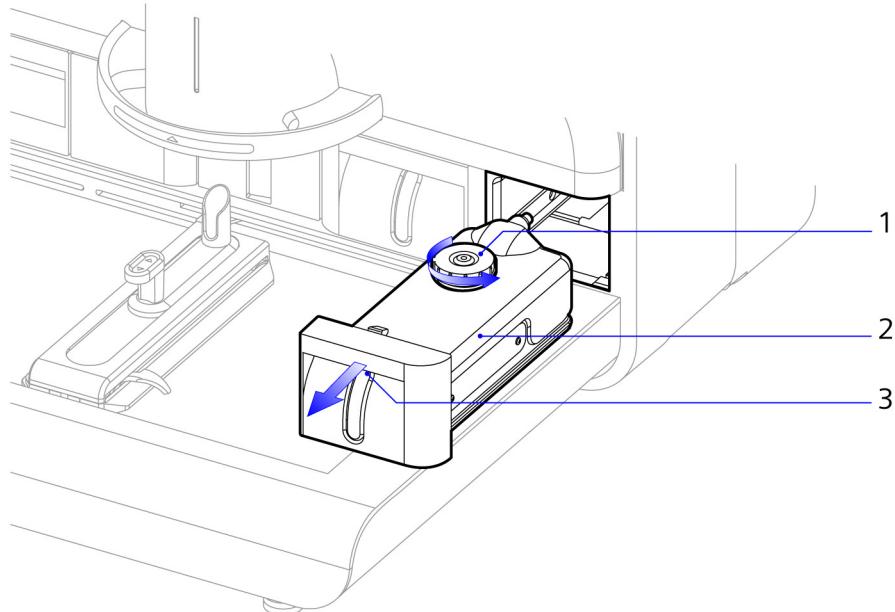
The internal rinse bottle holds rinse solution for 1 full cassette. The rinse level indicator on the **Home** screen displays the percentage full, in 20% increments, for the rinse bottle. When only 20% remains, the system will inform you.

An external rinse bottle connection is optional. For details, contact your local technical support provider.

Emptying and Filling the Internal Rinse Bottle

1. Remove the racks from the rack handler.
2. To release the latch, press latch forward and pull the rinse drawer toward you. Slide the drawer all the way out of the slot.
3. Turn the rinse bottle cap counterclockwise and remove it.

Figure 2-15: Removing the Rinse Drawer



-
- 1 Cap
 - 2 Rinse bottle
 - 3 Latch
-

4. Empty the remaining rinse solution from the rinse bottle.
Note Dispose of the rinse solution according to your laboratory guidelines.
5. Fill the rinse bottle:
 - a. Fill the rinse bottle with 1000 mL of distilled or deionized water.
 - b. Add 2 mL of CLINITEK Novus Rinse Additive.
 - c. Swirl the bottle gently 6 times to mix.
 - d. Place the cap back on the rinse bottle and turn it clockwise, making it finger tight.
 - e. Wipe off the rinse bottle to dry it.
6. Slide the rinse drawer back into the slot until the drawer is fully closed and latched.
7. Prime the pump, as explained in *Priming the Pump*, page 92.

Emptying and Filling an External Rinse Bottle

Check the level of the external rinse bottle periodically to ensure the bottle is full. The system does not prompt you to fill the external rinse bottle. When 20% of the rinse solution remains, refill the external rinse bottle.

1. Disconnect the rinse solution tubing from the external rinse bottle.
2. Empty the remaining rinse solution from the rinse bottle.
3. Dispose of the rinse solution according to your laboratory procedures.
4. To fill the rinse bottle, use a ratio of 500 mL of distilled or deionized water to 1 mL of CLINITEK Novus Rinse Additive. For example, 2000 mL of distilled or deionized water to 4 mL of rinse additive.
5. Swirl the bottle gently to mix.
6. Reconnect the tubing.
7. Prime the pump, as explained in *Priming the Pump*, page 92.

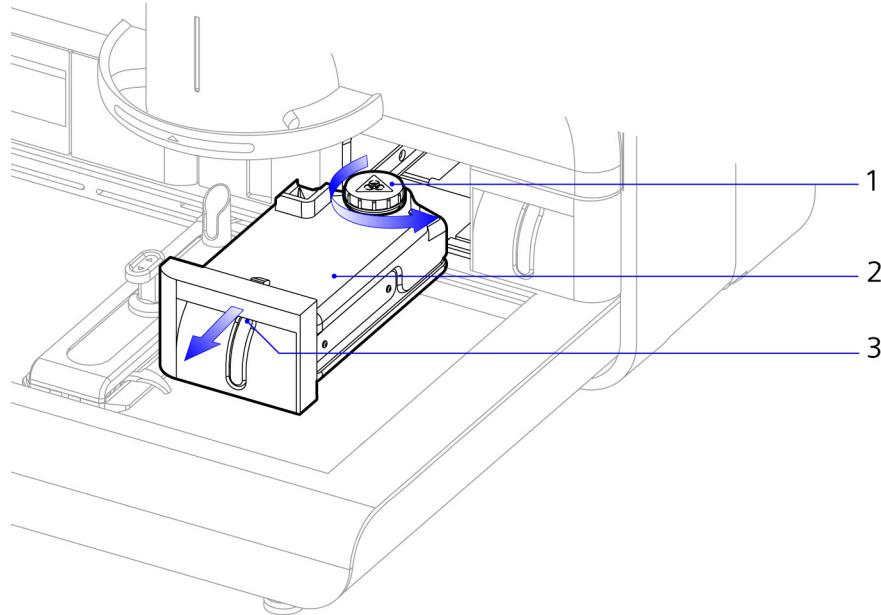
Emptying the Internal Waste Bottle

The internal waste bottle holds the liquid waste for 1 full cassette. The waste level indicator on the **Home** screen displays the percentage full in increments of 20% only for the internal waste bottle.

When the internal waste bottle is 80% full, a warning message displays. At 100% full, you cannot perform any tests.

1. Remove the racks from the rack handler.
2. To release the latch, press latch and pull the waste bottle drawer toward you. Slide the drawer all the way out of the slot.
3. Turn the bottle cap counterclockwise and remove it.

Figure 2-16: Removing the Waste Drawer



-
- 1 Cap
 - 2 Waste bottle
 - 3 Latch
-

4. Empty the liquid waste from the bottle.



BIOHAZARD

Dispose of the liquid waste according to your laboratory and biohazard guidelines.

5. Place the cap back on the waste bottle and turn it clockwise, making it finger tight.
6. Wipe off the waste bottle to dry it.
7. Slide the waste drawer back into the slot until the drawer is fully closed and latched.

Emptying the External Waste Bottle

Check the level of the external waste bottle periodically to avoid an overflow. The system does not prompt you to empty the external waste bottle. Empty the external waste bottle when it is 80% full.



BIOHAZARD

Dispose of the liquid waste according to your laboratory and biohazard guidelines.

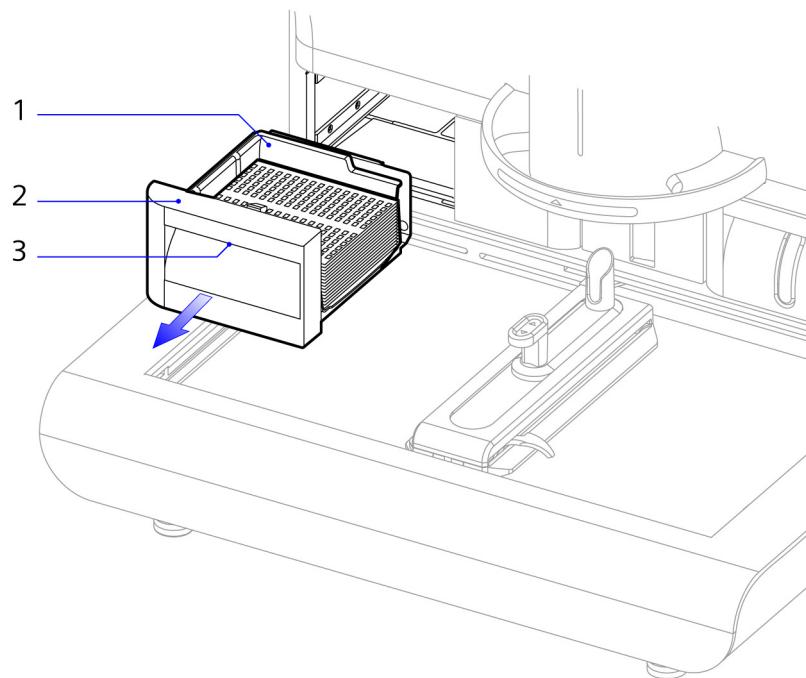
1. Disconnect the tubing from the external waste bottle.
2. Empty the remaining waste from the waste bottle.
3. Wipe off the waste bottle to dry it.
4. Reconnect the tubing.

Emptying the Card Waste Drawer

The used test cards slide into the card waste drawer and holds the test cards for 1 full cassette.

The system detects when the card waste drawer is full or empty.

1. Remove the racks from the rack handler.
2. To release the latch, press the latch and pull the card waste drawer toward you. Slide the drawer all the way out of the slot.

Figure 2-17: Removing the Card Waste Drawer

-
- 1 Internal liner
 - 2 Card waste drawer
 - 3 Latch
-

**BIOHAZARD**

Dispose of the used test cards according to your laboratory and biohazard guidelines.

3. Empty the cards into a biohazard container.
The drawer has an open side on the right, which allows you to easily empty it.
4. To clean the card waste drawer, follow these steps:
 - a. Remove the internal liner (*Figure 2-17*).
 - b. Press the ridges of the liner on the bottom of the drawer.
 - c. Lift up the liner and slide it out of the drawer.
 - d. Clean the liner with isopropyl alcohol.
5. Replace the internal liner into the card waste drawer.
6. Slide the drawer into the slot until the drawer is fully closed and latched.

3 Calibration and Quality Control

This section covers the following topics:

- Calibrating the System
- Performing a Quality Control Test

Calibrating the System

You can calibrate the system at any time.

Calibration is required under the following conditions:

- You load another cassette with the same lot but did not calibrate the system within the last 24 hours. The **Status** bar displays **Not Ready**.
- You load a new cassette lot. The **Status** bar displays **Not Ready**.
- The system displays error messages requiring you to calibrate the system. The **Status** bar displays **Not Ready**.
- You enable the **Report Clarity** setting and the last calibration did not include clarity reporting.
- You upgrade the software.
- You replace the pipette, SG sensor, or syringe.
- You restore old data from a backup.

Preparing to Calibrate the System

Before you calibrate the system, have the following items available:

- **Sample Tubes** For tube specifications, contact your local technical support provider.
- **CLINITEK Novus Calibration Kit** CAL #1, #2, #3, and #4. CAL #4 is also available separately.

- **Tube of Bleach** Use bleach with a sodium hypochlorite concentration of 5.25%, which cleans the SG well. Use a fresh tube of bleach solution each day.

**CAUTION**

Do not use bleach that is stronger than 5.25% sodium hypochlorite because it damages the SG sensor.

If the concentration of sodium hypochlorite is higher than 5.25%, dilute the bleach with distilled water. For example, if the bleach is 6% sodium hypochlorite, add 0.75 mL of water to 5 mL of the 6% bleach and swirl to mix gently.

1. Prepare the tubes of calibration and cleaning solutions, as follows:
 - a. Pour at least 2 mL of 5.25% sodium hypochlorite into a properly labeled sample tube.
You can reuse this tube throughout the day as needed without discarding it. However, the tube must always contain at least 2 mL.
 - b. Pour at least 3 mL of each calibration solution (from the Calibration Kit) into the properly labeled sample tubes (1 tube per solution) for CAL #1, #2, #3, and optionally, CAL #4.

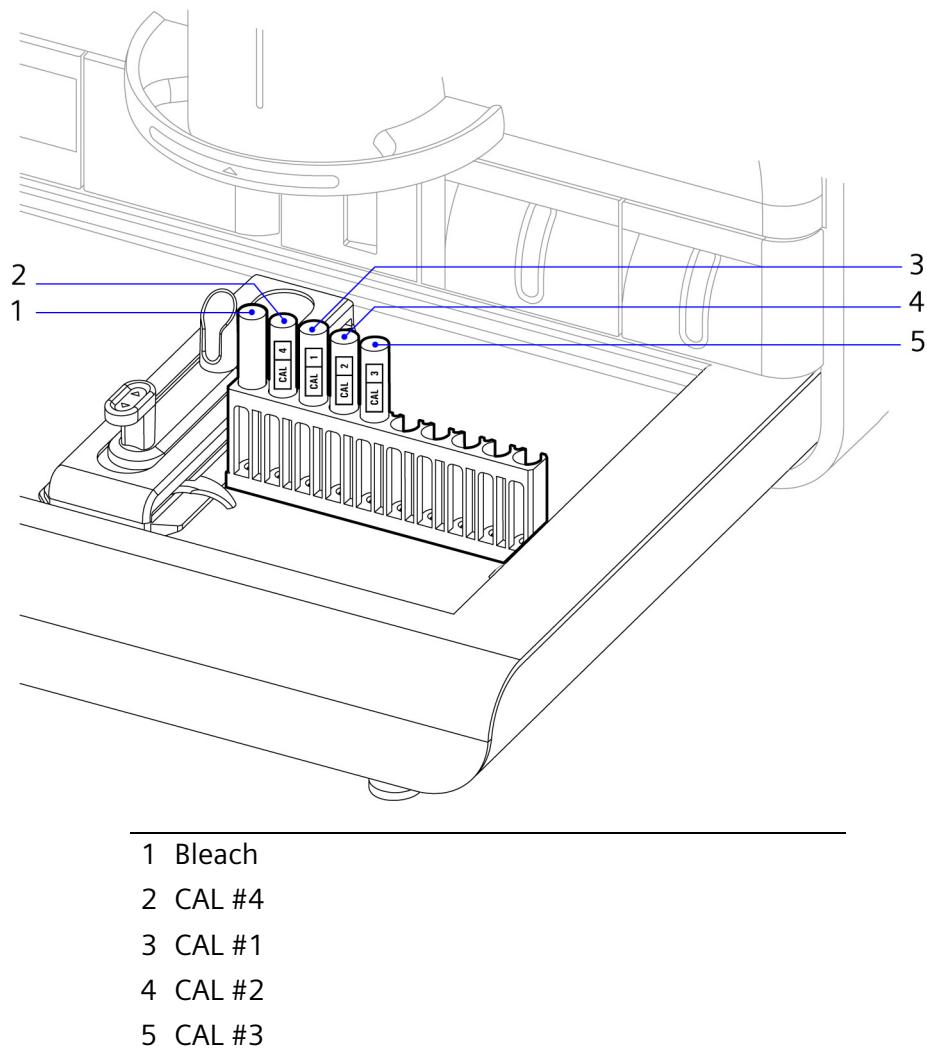
Note If you disable the **Report Clarity** setting, and use a CLINITEK Novus 10 cassette, you do not need to use CAL #4 for calibration.

 - c. Allow all of the solutions to equilibrate to room temperature before you use them.
2. If you enable the **Report Clarity** setting, place the calibrators in the rack in the following order:
 - **1st Test Position** Bleach
 - **2nd Test Position** CAL #4
 - **3rd Test Position** CAL #1
 - **4th Test Position** CAL #2
 - **5th Test Position** CAL #3

If you disable the **Report Clarity** setting, and use a CLINITEK Novus 10 cassette, you do not need to use CAL #4. Place the calibrators in the rack in the following order:

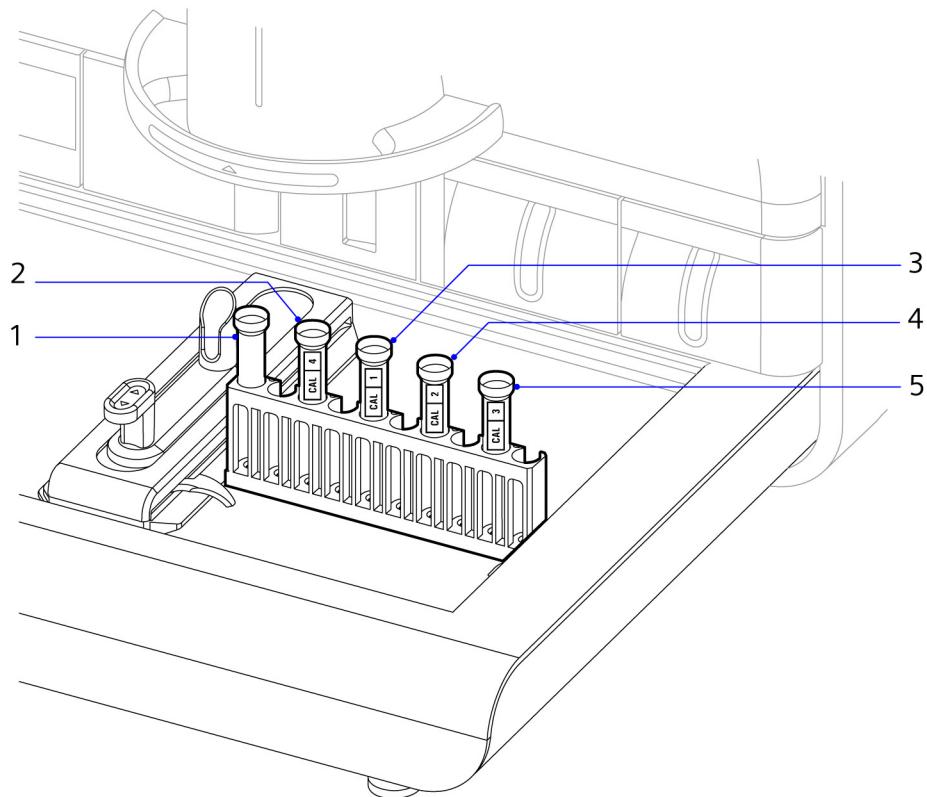
- **1st Test Position** Bleach
 - **2nd Test Position** CAL #1
 - **3rd Test Position** CAL #2
 - **4th Test Position** CAL #3
3. Place the rack in the loading area on the right side of the rack handler, with the open side of each tube slot in the rack facing the system (*Figure 3-1*).

Figure 3-1: Preparing for Calibration with Report Clarity Enabled



Note If you use wide-mouth tubes, place them in every other tube slot in the rack.

Figure 3-2: Wide-Mouth Tubes in Every Other Slot in Rack



-
- 1 Bleach
 - 2 CAL #4
 - 3 CAL #1
 - 4 CAL #2
 - 5 CAL #3
-

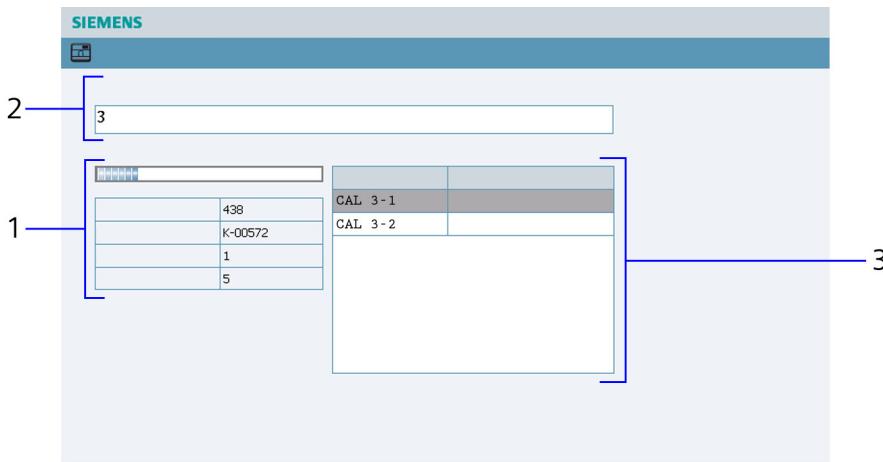
Performing a Calibration Test

Note If you use 3 calibrators, the system uses 7 test sets for calibration. If you use 4 calibrators, the system uses 9 test sets for calibration. Ensure that at least 7 or 9 test sets are remaining on the cassette.

1. Select **System > Calibration**.
2. Perform 1 of the following tasks:
 - If the lots are correct, select **Next**.
 - If you want to change the lots, go to step 3.
 - If you want to add new lots, go to step 4.
3. To change the lots, follow these steps:
 - a. Select a **Change** button.
 - b. Select a lot.
4. To add new lots, follow these steps:
 - a. Select a **Change** button
 - b. Select **Add**.
 - c. Enter a lot.
 - d. Select an expiration date.
5. Select **Next**.
6. Select **Start**.

The rack handler moves the rack into position for testing, beginning with the cleaning cycle for 3 minutes.

The **Calibration Progress** screen displays. The system continually updates the calibration status and performs a calibration in 4 minutes.

Figure 3-3: Calibration Progress Screen

-
- 1 Calibration progress area
 - 2 Calibration message area
 - 3 Calibration results summary
-

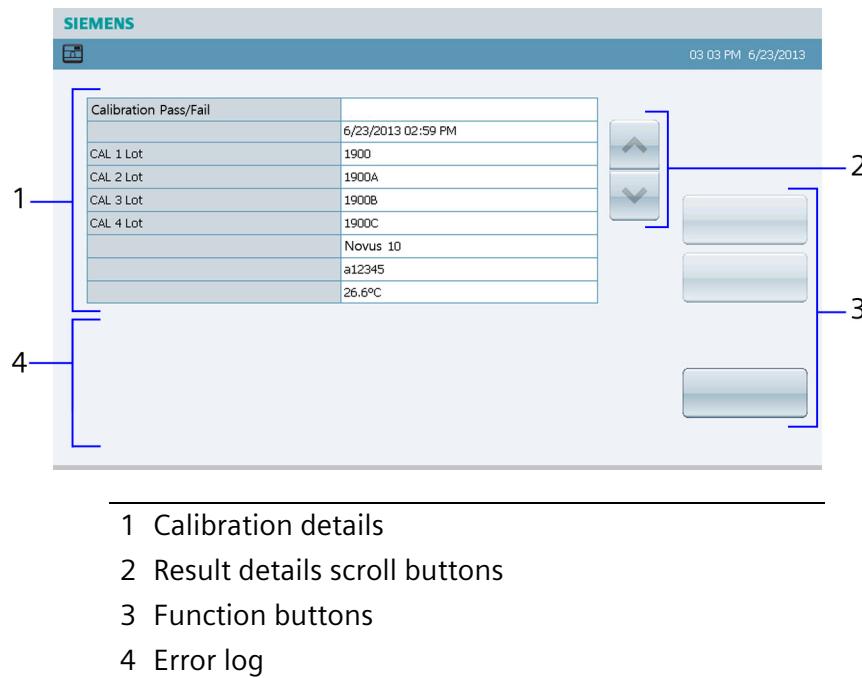
A calibration sequence number consists of the prefix (K), a hyphen (-), and 5 numbers. For example, K-00001.

Note The calibration must be successful to perform patient tests. If an error occurs during calibration or the calibration failed, see *Troubleshooting a Failed Calibration*, page 123.

7. After the system moves the rack to the left side of the rack handler, remove the rack.

Viewing the Calibration Results

The **Calibration Results** screen shows the results details. If the calibration fails, the **Calibration Error Log** displays error messages beneath the calibration details. See *Troubleshooting a Failed Calibration*, page 123.

Figure 3-4: Calibration Results Screen

Working with Calibration Results

To delete or print the details, or send the details to the LIS, select a function button.

Performing a Quality Control Test

Perform a quality control test after calibration according to your laboratory practices.

The system can run both Siemens and non-Siemens controls. To configure the system to run Siemens controls, to run non-Siemens controls, to name the controls, to enable control comments, or to configure the control limit checks, see *Sample and Controls Settings*, page 193 and *Configuring the Sample Settings for Control Samples*, page 198. The factory-default configuration is none.

Preparing for a Control Test

You can configure the system to run at least 1 or as many as 3 control tests in a single run.

Note You must configure the controls settings for the number of controls you are running. You can test up to 3 controls in a single control run.



CAUTION

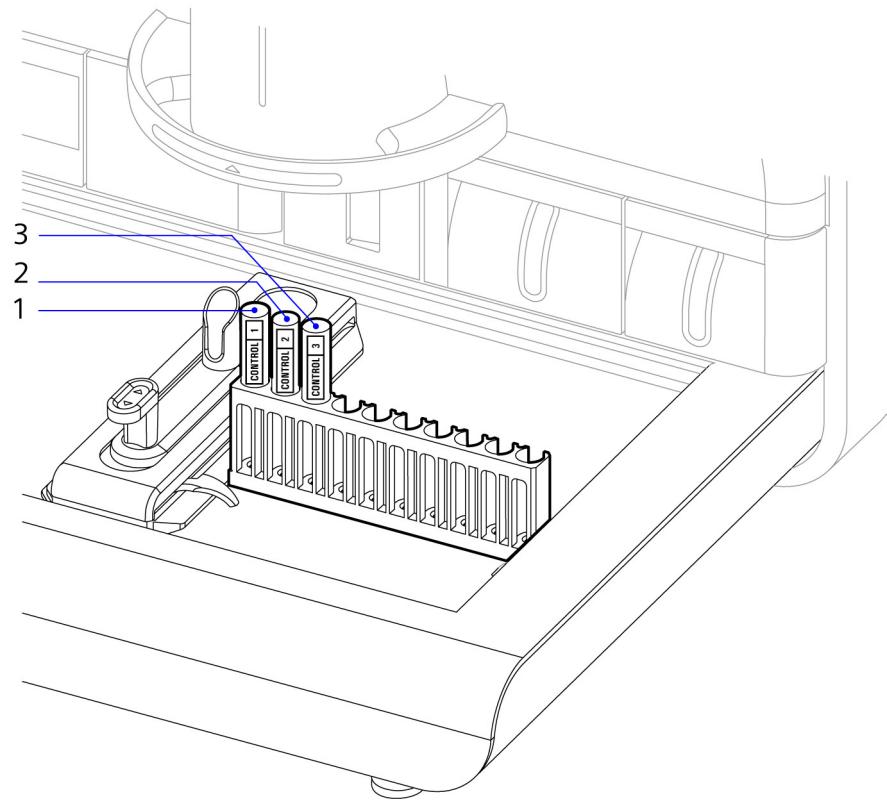
Do not place the tubes with control solutions in incorrect rack positions. If you do, the system processes those samples anyway. The control results would be incorrect.

1. Pour at least 2 mL of each appropriate, commercially available control into properly labeled tubes, following their instructions for use.
2. Place up to 3 tubes of control solution into a rack in the following positions:
 - **Control 1** Position 1
 - **Control 2** Position 2
 - **Control 3** Position 3

Note If you use wide-mouth tubes, place them in every other tube slot in the rack, as shown in *Figure 3-2, Wide-Mouth Tubes in Every Other Slot in Rack*.

To change the placeholder names for the controls, see *Configuring the Sample Settings for Control Samples*, page 198.

3. Place the rack on the right side of the rack handler, with the open side of each tube slot in the rack facing the system (*Figure 3-5*).

Figure 3-5: Preparing for a Control Test

1 Control 1

2 Control 2

3 Control 3

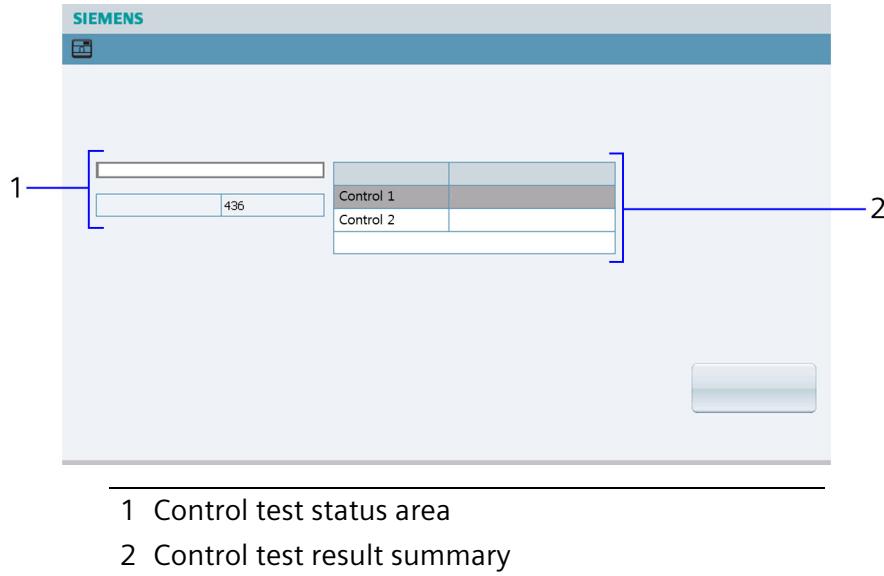
Performing a Control Test

You can run at least 1 or as many as 3 controls in a single run. You can configure the system to run up to 3 control samples at one time. For details to configure the controls, control names, or control limit checks, see to *Sample and Controls Settings*, page 193 and *Configuring the Sample Settings for Control Samples*, page 198.

If you analyze 3 control samples consecutively (with no other urine samples in between the samples in the rack for control testing), clean the SG well immediately after you test the 3rd control, and before you test any patient samples or additional controls.

1. Select **System > Control**.
2. Verify the onscreen control lots are correct.
 - If the control lots are correct, select **Next**, and go to step 4.
 - To change or add control lots, continue to step 3.
3. To change or add control lots, perform these steps:
 - a. Select the **Change** button that corresponds with the control you wish to change or add.
 - b. Select **Add**.
 - c. Enter the control lot, select **Enter**.
 - d. Enter the control lot expiration date, select **Enter**.
4. Select **Next**.

Figure 3-6: Control Test Progress Screen

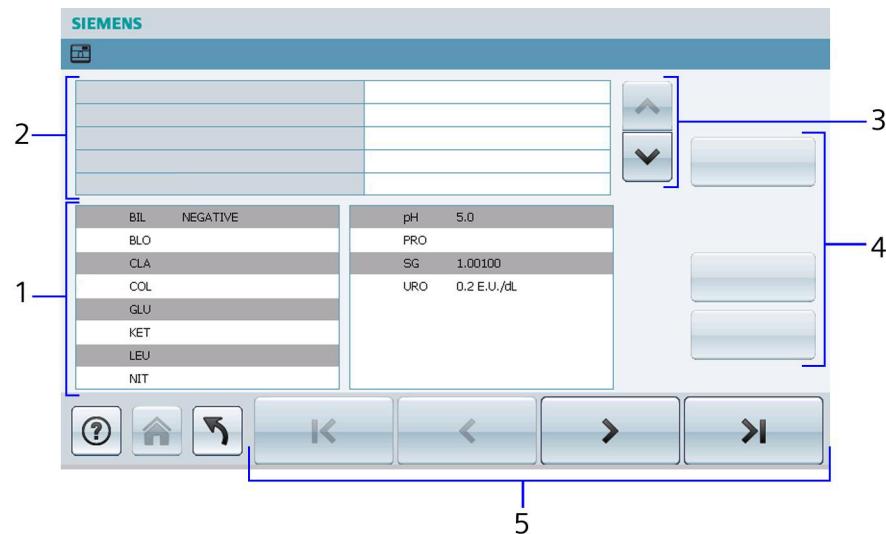


The system tests each control once. A control sequence number consists of the prefix (C), a hyphen (-), and 5 numbers. For example, C-00011.

5. After the rack moves to the left side of the rack handler, remove the rack.

Viewing the Control Test Results

Figure 3-7: Control Results Details Screen



- 1 Analytes area
- 2 Control results details area
- 3 Results details scroll buttons
- 4 Function buttons
- 5 Navigation bar

For additional details on control test results functions, see *Viewing the Control Results*, page 178.

1. Use the scroll buttons to navigate the details at the top of the **Control Result Details** screen.
2. To navigate the results, use the **Navigation** bar.
3. Read the information in the analytes area.

A symbol represents an analyte flag, which displays next to an analyte for a sample that meets the following criteria:

Table 3-1: Control Analyte Flags

Symbol	Description
^	Range adjusted
‡	Sieve
*	Out of expected range
†	Sample quality

4. To display control comments, graph the result, print the result or send the result to the LIS, select a function button.

For details about troubleshooting a failed control test, see *Troubleshooting Quality Control*, page 125.

Note You can change the default control limit check settings and define reporting limits. If changed from default, the system will flag control results with an (*) asterisk, if reported outside of the user-defined control limits, and prevent further samples from being run until the quality control test has passed. For details on configuring the control limit checks, see *Configuring the Sample Settings for Control Samples*, page 198.

Entering the Missing Data

1. Read the current sample data at the top of the **Control Missing Data** screen.
2. Select a **Comments** button.

The system displays the first 32 characters of each comment you enter. The system assigns each comment a number, 1–2. For example, if you select **Comment 1** and enter **Overnight collection**, the system displays **1:Overnight collection** in the **Comments** box.

3. Select a **Comment** button.
4. Enter a comment (up to 40 characters).
5. Select **Save**.
6. To navigate the samples with missing data, use the navigation buttons on the **Navigation** bar.
7. To enter the missing data for each sample, repeat steps 2–5.

8. Select **Done**.

Graphing the Control Results

You can graph the control results by control name and analyte.

1. Select **Results**.
2. Select **Control**.
3. To graph all control results, select **All Results**. To graph specific analytes, select 1 or more analytes, then select **Enter**.
4. To graph specific controls, select 1 or more controls to graph, then select **Enter**.

To set the graph lower and upper range values, to print control results, or to graph additional control results, select a function button.

For details on configuring the control results graphs, see *Working with the Control Graphs*, page 180.

4 Maintenance

This section covers the following topics:

- Maintenance Guidelines
- Disinfecting the System
- Performing Daily and Periodic Maintenance
- Replacing the Hardware (Pipette, SG Sensor, and Syringe)
- Adjusting the Hardware
- Performing System Management Tasks

Maintenance Guidelines



BIOHAZARD

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

The CLINITEK Novus analyzer requires minimal maintenance. Use the following general maintenance guidelines to ensure proper maintenance:

- Handle the system with care.
- Avoid prolonged exposure to excessive humidity or extreme temperatures.
- Keep the exterior of the system free of dust and residue by wiping it periodically with a cloth dampened with water or mild detergent.
- Keep the display screen clean by gently wiping it with a lint-free cloth dampened with water or 70% isopropyl alcohol.
- Do not use any kind of spray cleaners because the aerosol might enter and damage the optical system.
- Leave the system powered on at all times. The system rehydrates the SG well every 15 minutes to prevent drying of the fiber optic.

**CAUTION**

The CLINITEK Novus analyzer must be powered on, even when the system is not processing samples, in order to hydrate the specific gravity (SG) well with rinse solution every 15 minutes.

The hydration ensures that the sample residues do not dry in the SG well and contaminate the fiber optics. Dried residue influences the accuracy of subsequent SG readings until you clean the SG well.

If the CLINITEK Novus analyzer has been powered off for more than 1 hour, prime the pump, as explained in *Priming the Pump*, page 92. Leave the system powered on for at least 1 hour to rehydrate the SG well before you resume operation.

- Keep the cover and drawers closed at all times (except when required by a procedure you perform) to prevent dust and debris from entering the optical system and to ensure proper rehydration of the SG well.

**CAUTION**

Do not allow the system to be idle for an extended period without first emptying the waste bottle. If the system is going to be idle for several days, be sure to empty the waste bottle before the idle period to prevent excessive bacterial growth in the bottle. If the system has been powered off for longer than 1 hour, prime the pump (see *Priming the Pump*, page 92). Leave the system powered on for at least 1 hour to rehydrate the SG well before you resume operation.

A maintenance log template is provided in *Appendix F, Maintenance Log*. Copy this log template every month, and use it as a record of your CLINITEK Novus analyzer maintenance.

Disinfecting the System

Disinfection might be required on several parts of the system, such as the rack handler, card platform, display, sensor windows, and racks.

Disinfect the system components by using 70% isopropyl alcohol or a solution of 10% bleach and 90% water.

**BIOHAZARD**

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

**CAUTION**

Do not use aerosol disinfectant products outside or inside the system because they might damage the optical system and wet the components you do not clean.

Do not use bleach as a disinfectant for the optic windows and camera because it can adversely affect them.

1. Wipe the system components (rack handler, card platform, display, sensor windows, and racks) with a cloth moistened with disinfectant solution, or spray a cloth or hand towel with the aerosol disinfectant.
2. Wait the appropriate length of time for the solution, as noted by the manufacturer.
3. Wipe off the component with water and dry it.

Performing Daily Maintenance

Clean the SG well daily to maintain the system for the following reasons:

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

Daily maintenance includes the following tasks:

- Cleaning the rack handler
- Cleaning the SG well
- Emptying the waste bottle (see *Emptying the Internal Waste Bottle*, page 69)

Cleaning the Rack Handler

Clean the rack handler as needed to maintain the system for the following reasons:

- Ensure that the system operates properly.

- Ensure smooth movement of the racks.
- Avoid bacterial growth.



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 rack handler, use a germicidal wipe on the loading and unloading areas.

Cleaning the SG Well

The cleaning cycle takes about 3 minutes to process. The system cleans the SG well as part of the calibration procedure. You also can clean the SG well under the following circumstances:

- At any time other than during calibration
- Daily
- When the system prompts you to clean the SG well

The system prompts you to clean the SG well when 24 hours have elapsed since the last cleaning. The system does not begin testing until you clean the SG well.



BIOHAZARD

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



CAUTION

Do not use bleach that is stronger than 5.25% sodium hypochlorite because it damages the SG sensor.

If the concentration of sodium hypochlorite is higher than 5.25%, dilute the bleach with distilled water. For example, if the bleach is 6% sodium hypochlorite, add 0.75 mL of water to 5 mL of the 6% bleach and mix gently.

1. Pour at least 2 mL of household bleach (5.25% sodium hypochlorite) into a sample tube, labeled **Bleach**.
2. Place the tube of bleach in the 1st test position in a rack.
3. Place the rack in the loading area of the rack handler.
4. Select **System > Clean SG Well**.

5. Select **Start**.

After the system finishes cleaning, a message displays informing you that the cleaning cycle is complete.

Performing Periodic Maintenance

Perform the following maintenance tasks on an as-needed basis:

- Priming the pump
- Cleaning the card platform
- Cleaning the moisture gate
- Cleaning the card grippers
- Cleaning the racks
- Cleaning the rack sensors
- Cleaning the pad sensor

Priming the Pump

Priming the syringe pump with rinse solution is necessary under the following conditions:

- When you refill the rinse.
- If air bubbles appear in the rinse line.
- When an error message informs you to prime the pump.

Select **System > Prime Pump**.

Note If the system has been powered off for longer than 1 hour, prime the pump. Then leave the system powered on for at least 1 hour to rehydrate the SG well before you resume operation.

Cleaning the Card Platform

If a large amount of sample or other liquid spills on the card platform, clean it. Check the card platform for residue, as needed.

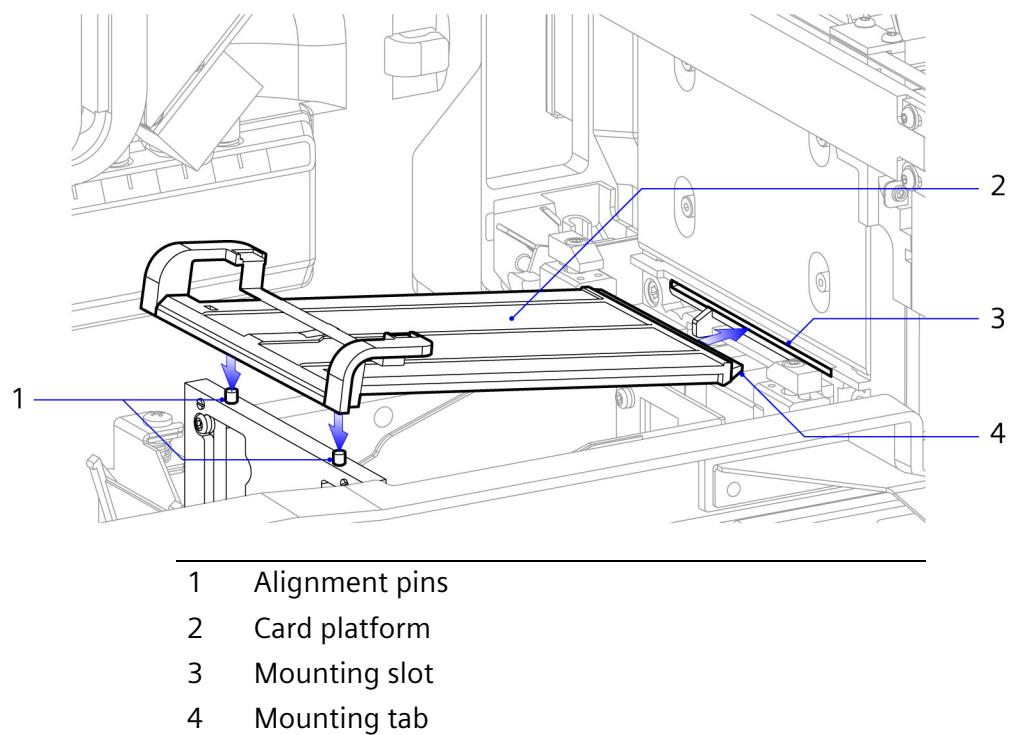


BIOHAZARD

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

1. To eject any cards, select **System > Diagnostics > Hardware Tests > Card Handler**.
2. Pull up the left side of the card platform and slide it to the left.
3. Clean the platform with 70% isopropyl alcohol, or 10% bleach, or another disinfecting solution.
4. To insert the platform, slide the mounting tab on the right side of the platform into the mounting slot beneath the card gate (*Figure 4-1*).
5. Push down on the left side of the card platform and snap the platform holes into the alignment pins.

Figure 4-1: Inserting the Card Platform



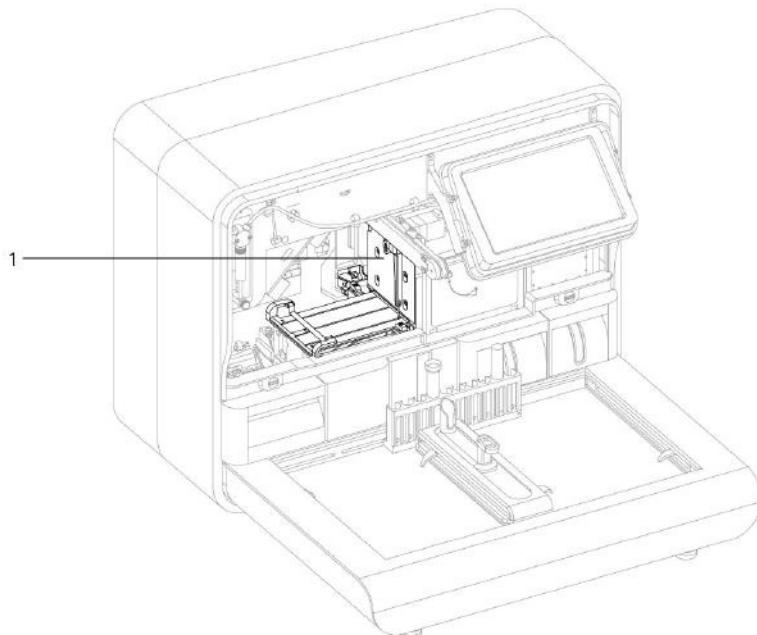
Cleaning the Moisture Gate

Follow this procedure on a weekly basis to keep the moisture gate clean.

Note It is recommended that you perform this task when no cassette is loaded.

1. Wipe the outer side (facing the card platform) using a lint-free cloth dampened with deionized water.

Figure 4-2: Cleaning the moisture gate



1 Cassette compartment moisture gate

2. Clean the bottom edge of the moisture gate and its mating edge with a lint-free cloth dampened with deionized water.

Note Perform this step only when unloading and loading a cassette. During this time, the moisture gate will open to allow sufficient time to clean the edges.

3. When finished, dry the area, and then load the new cassette.

Note The cassette compartment door should be left open no longer than 10 minutes. The cleaning should take no longer than 1-2 minutes to perform.

Cleaning the Card Grippers

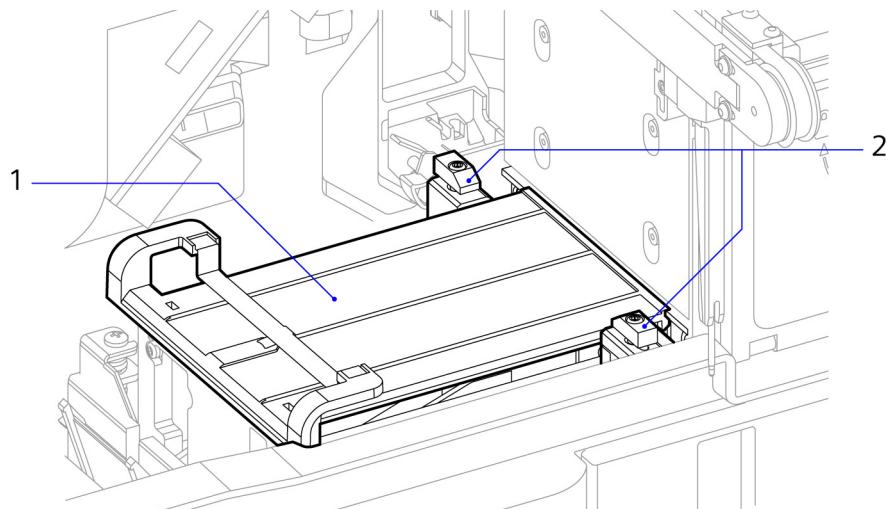


BIOHAZARD

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

1. Check the 2 card grippers on the right side of the card platform for debris.
2. Clean the card grippers with 70% isopropyl alcohol.

Figure 4-3: Card Grippers



1 Card platform

2 Card grippers

Cleaning the Racks



BIOHAZARD

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

1. Use a mild detergent on the racks.
2. Rinse the racks with water.
3. Dry the racks carefully with a soft, lint-free cloth.

Cleaning the Rack Pushers and Sensors

The rack handler contains sensors and pushers that you must clean periodically to prevent rack jams and operating problems. See *Rack Handler*, page 13.

Whenever you see residue on any of the rack sensors or rack pushers, clean them.



BIOHAZARD

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

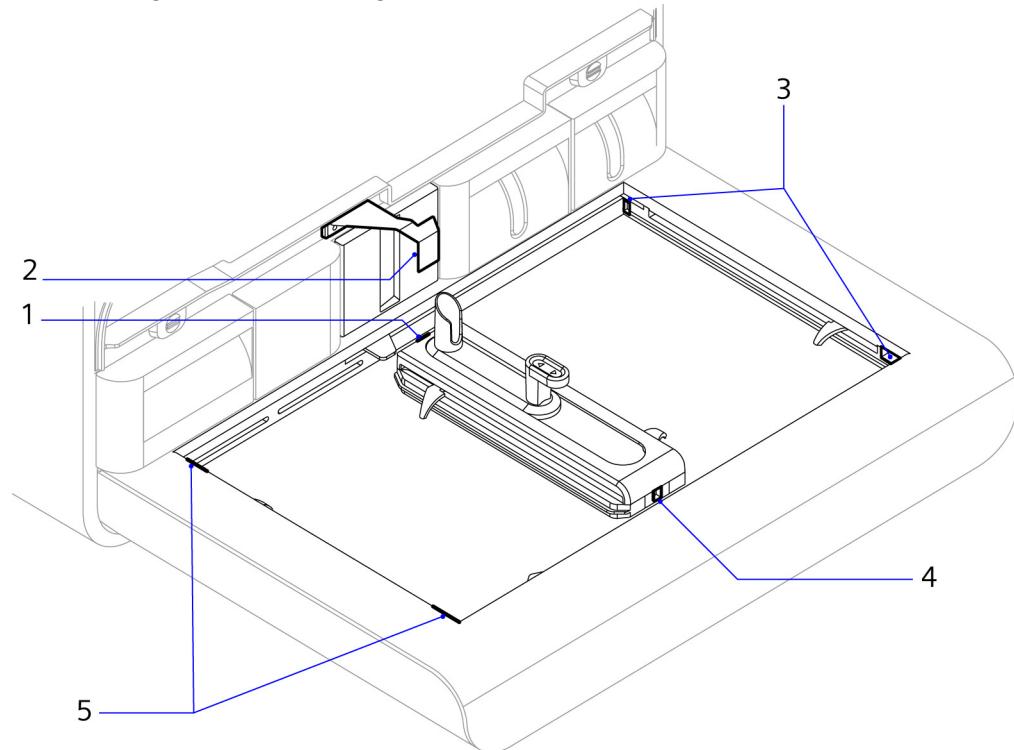
1. Clean the rack pushers with a germicidal wipe.
2. Dampen a long, fiber-free, optical-grade swab with water.

CAUTION

Do not leave any residue on the plastic surfaces.

3. Gently wipe each sensor.

Figure 4-4: Cleaning the Rack Sensors



-
- 1 Rack presence sensor
 - 2 Barcode reflector
 - 3 In and right rack travel sensors
 - 4 Rack error sensor
 - 5 Out and left rack travel sensors
-

4. Use compressed air to remove the dust and dry the sensors.

Cleaning the Pad Sensor

The pad sensor is located on the left side of the cassette compartment, just above the ramp. Clean the pad sensor and remove the card dust in the cassette compartment if a card jam error occurs or once a year.

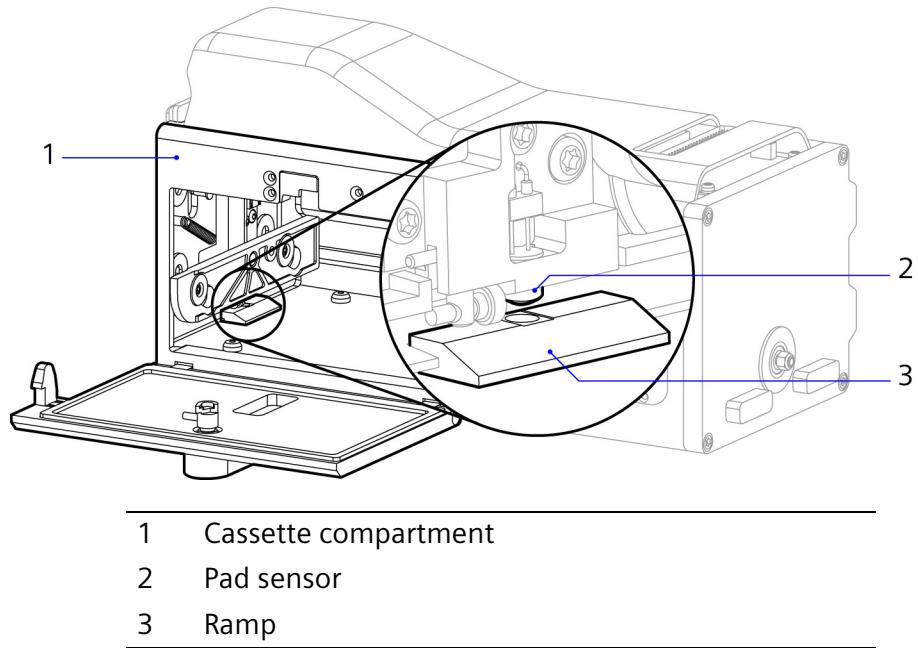


BIOHAZARD

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

Spray the pad sensor with compressed air.

Figure 4-5: Pad Sensor



Making Minor Repairs

You can make minor repairs on the CLINITEK Novus analyzer. You must understand the hardware replacement procedures completely before you attempt them. Perform the procedures with care.

For any repairs other than those given in this section, and for information on service for your system, see *Appendix B, Warranty and Support Information*.

A CLINITEK Novus Accessory Kit is included with your system.



CAUTION

Do not handle the CLINITEK Novus analyzer roughly. It is a precision system and must be handled accordingly. The system and the rack handler are heavy and requires 2 people to move the system. Rough handling of the system disturbs internal calibrated optics and electronics or causes other damage. Always handle the system with care.

Cleaning the Barcode Readers

The internal barcode reader and handheld barcode reader require very little routine care. However, the optic window of the internal barcode reader and barcode reflector might have a buildup of urine residue.

Each month, or when you notice any residue, clean and disinfect the optic window and barcode reflector.

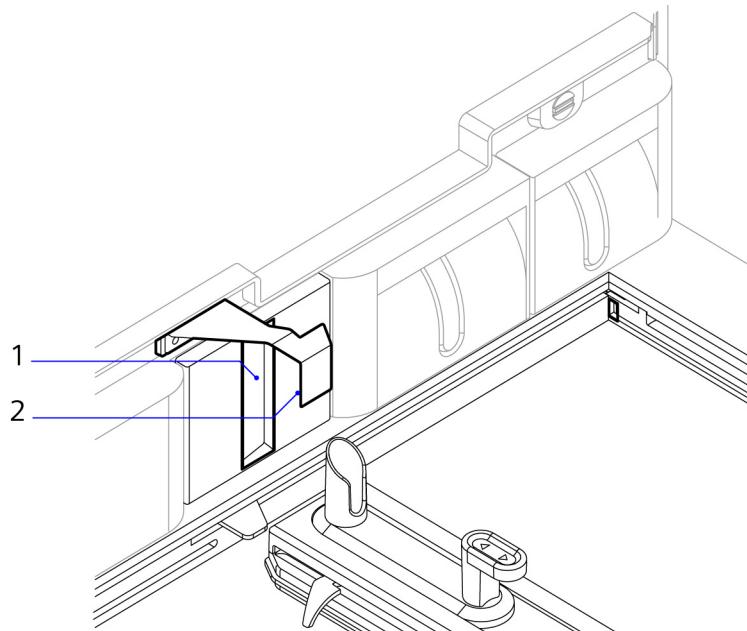


BIOHAZARD

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

1. Wipe the optic window and its case with a soft cloth dampened with 70% isopropyl alcohol until all of the residue is gone.
2. Dry the optic window with a soft cloth.
3. Wipe the barcode reflector with a soft cloth dampened with 70% isopropyl alcohol until all of the residue is gone.
4. Dry the barcode reflector with a soft cloth.

Figure 4-6: Internal Barcode Reader Components



1 Optic window

2 Barcode reflector

Replacing the Hardware

You can replace the following hardware components:

- Pipette
- SG Sensor
- Syringe

Replacing the Pipette

The Pipette Replacement Assistant steps you through the process of removing the old pipette and installing the new pipette with onscreen instructions. Follow the onscreen directions, and read the following instructions for complete information.

Note Before beginning the replacement, Siemens recommends placing an absorbent wipe or towel on the rack infeed area to absorb any rinse solution that may exit the pipette tube during replacement.

Removing the Old Pipette



BIOHAZARD

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

1. Remove the racks from the rack handler.
2. Select **System > Diagnostics > Replace or Adjust > Replace Pipette**.

The Pipette Replacement Assistant displays the on screen instructions.



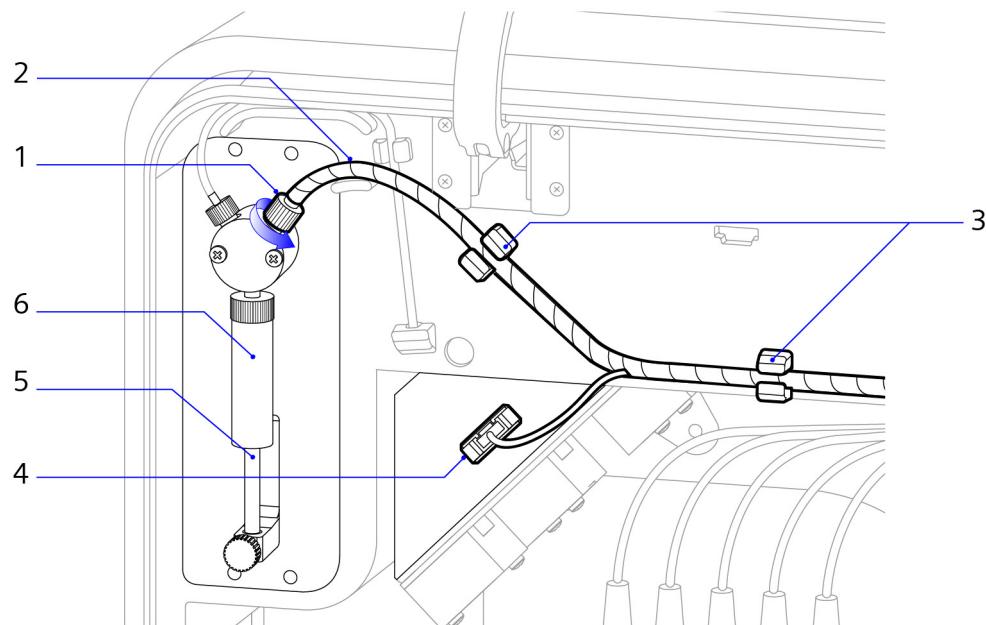
CAUTION

Be sure that nothing is blocking the path of the pipette.

3. Select **Replace**.

The pipette moves to the replacement position.

4. After the pipette stops moving, as indicated on screen by the Assistant, open the cover and locate the pipette system, and then select **Next**.
5. Remove the pipette tubing by unscrewing the finger nut from the syringe valve.
6. Disconnect the level sensor connector, and then select **Next**.
7. Remove the tubing from the clips on the wall of the system, and then select **Next**.

Figure 4-7: Preparing to Remove the Pipette

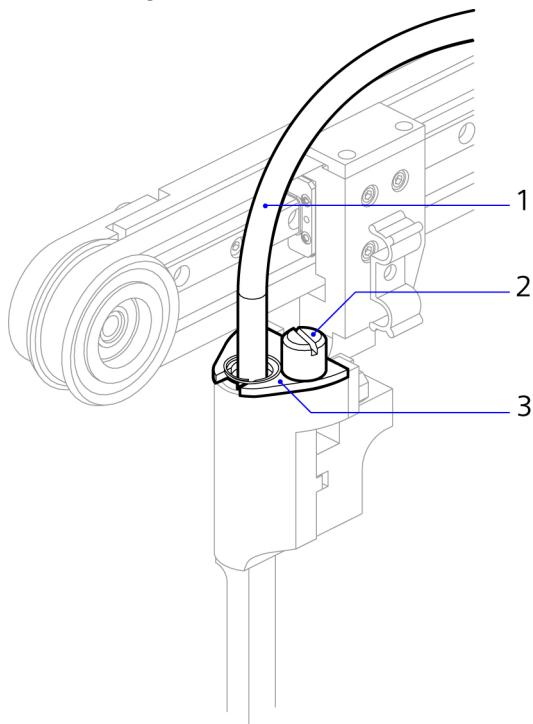
-
- 1 Finger nut
 - 2 Pipette tubing
 - 3 Clips
 - 4 Level sensor connector
 - 5 Plunger
 - 6 Syringe
-

8. Remove the pipette by loosening the screw on the top bracket.

**CAUTION****PINCH HAZARD**

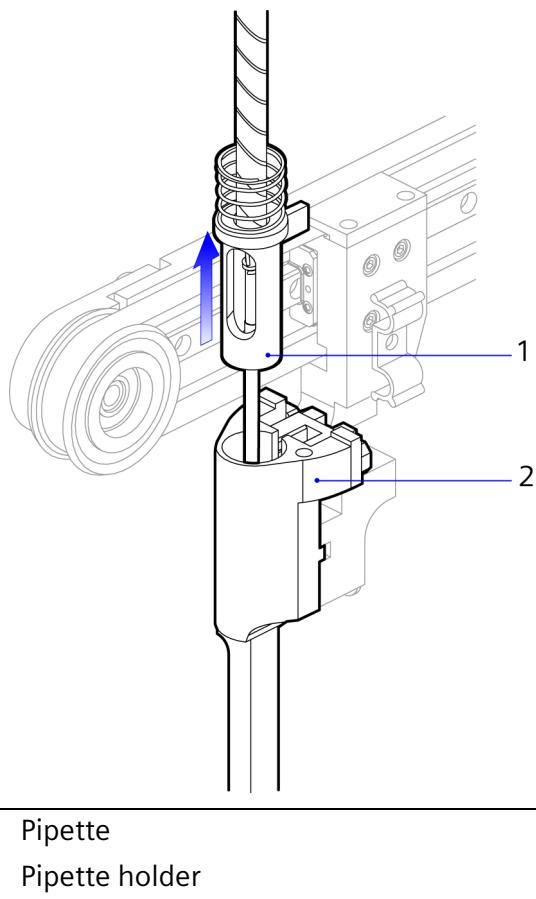
Use caution when working around the plunger and syringe. Ensure that nothing is blocking the path of the plunger and syringe.

Figure 4-8: Loosening the Thumb Screw



-
- 1 Pipette tubing
 - 2 Thumb screw
 - 3 Top bracket
-

9. Remove the bracket and lift the pipette up from the holder, and then select **Next**.

Figure 4-9: Removing the Pipette

1 Pipette

2 Pipette holder

Installing a New Pipette



BIOHAZARD

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

1. Remove the new pipette assembly (included in the CLINITEK Novus Accessory Kit) from the plastic container.
2. Remove the large outer shield, and then carefully remove the small inner shield, pulling down from the top of the pipette.



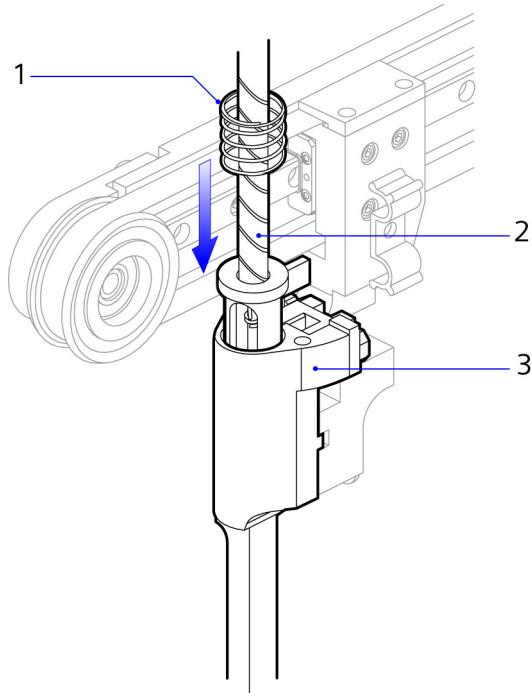
CAUTION

Be sure the tip does not touch the holder as you insert the pipette.

The pipette tip is fragile and easily damaged. Do not handle the tip or allow the assembly to drop on its end.

3. Install the new pipette by sliding it into the slot, with the tab facing away from you.
4. Slide the spring downward into the slot.

Figure 4-10: Inserting the New Pipette



-
- | | |
|---|----------------|
| 1 | Spring |
| 2 | Pipette |
| 3 | Pipette holder |
-

5. Insert the bracket and tighten the thumb screw, and then select **Next**.
6. Press the tubing into the clips on the wall, and then select **Next**.
7. Connect the level sensor connector, with the tab facing up, and then select **Next**.
8. Insert the pipette tubing by screwing the finger nut into the syringe valve until it clicks, and then select **Done**.
The pipette moves to the home position. The system primes the pump.
9. Adjust the pipette depth after pipette replacement, as explained in the procedure *Adjusting the Pipette Depth*, page 114.
10. Verify the pipette replacement, as explained in the next section, *Verifying the Pipette Replacement*.

Verifying the Pipette Replacement



CAUTION

PINCH HAZARD

Use caution when working around the plunger and syringe. Ensure that nothing is blocking the path of the plunger and syringe.

1. Add at least 2 mL of saline solution to a tube and insert the tube in a rack on the rack handler.
2. Select **System > Diagnostics > Hardware Tests > System Sequence**.
3. Open the system cover.
4. Select **Start**, and then watch the pipette dispense the saline on the test pads.
If the pipette dispensed the drop on the card platform or between the pads, check that you properly installed the pipette. If you cannot resolve the problem, contact your local technical support provider.
5. Close the cover.
6. Discard the old pipette assembly in a biohazard container.
7. Recalibrate the system, as described in Section 3, *Calibration and Quality Control*.

Replacing the SG Sensor

The SG Sensor Replacement Assistant steps you through the process of removing the old SG sensor and installing the new SG sensor with onscreen directions. Follow the onscreen directions, and read the following instructions for complete information.

Removing the Old SG Sensor



BIOHAZARD

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

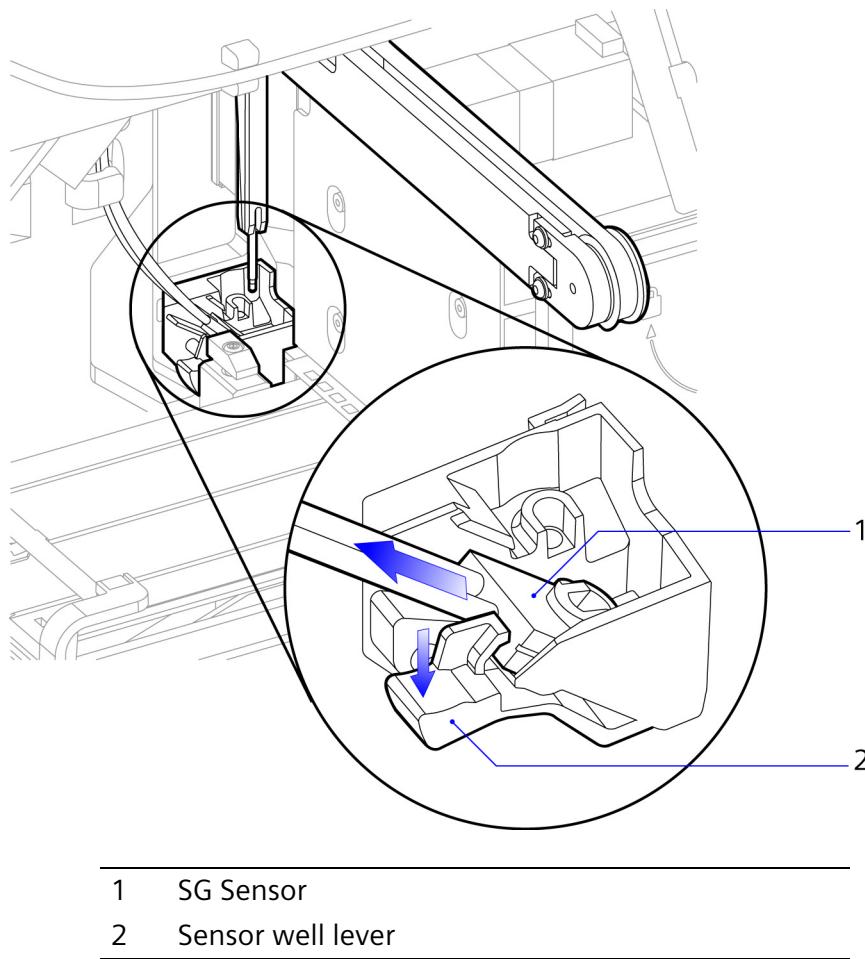
1. Remove the racks from the rack handler.

2. Select **System > Diagnostics > Replace or Adjust > Replace SG Sensor.**

The SG Sensor Replacement Assistant displays the first of 9 screens of instructions.

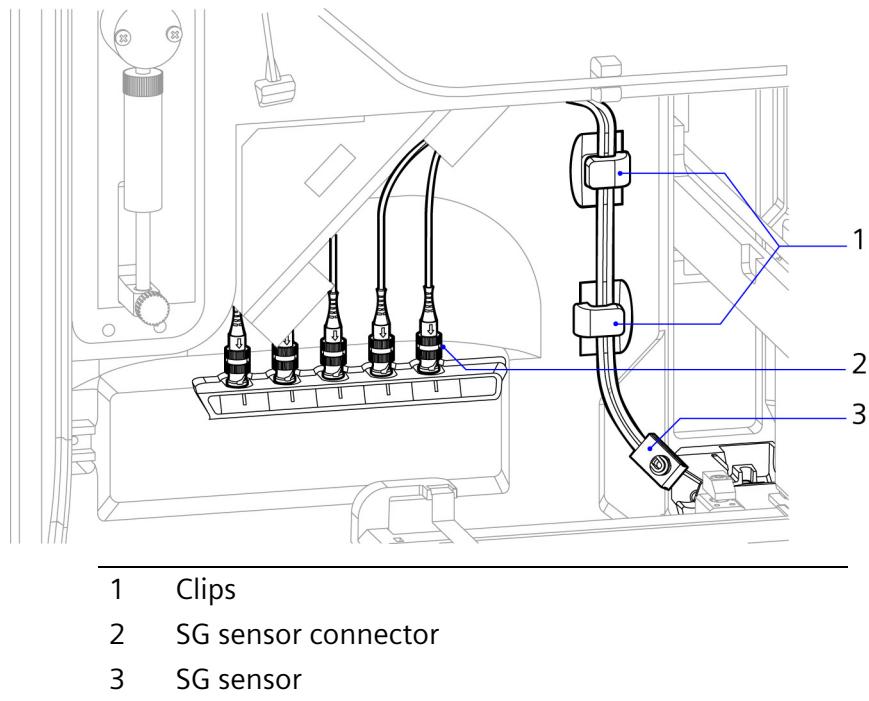
3. Select **Replace.**
4. Open the cover and locate the SG well behind the right corner of the card platform, and then select **Next.**
5. Remove the SG sensor by holding down the sensor well lever and pulling the SG sensor out, and then select **Next.**

Figure 4-11: Removing the SG Sensor



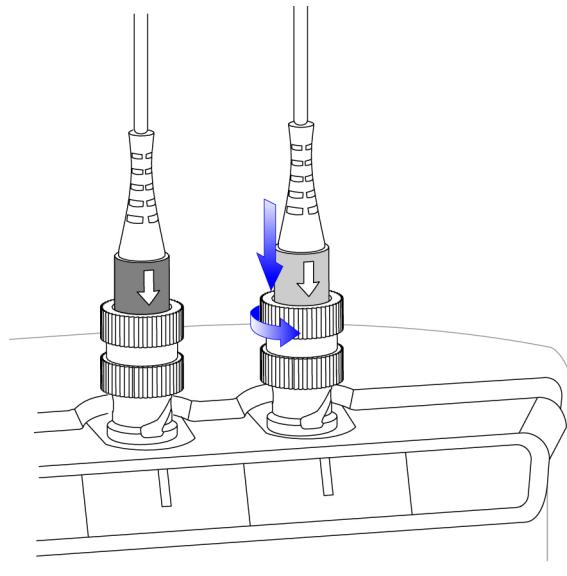
6. Unhook the SG sensor cables from the clips on the wall of the system, and then select **Next.**
7. Locate the 5 color-coded SG sensor connectors to the left and above the card platform.

Figure 4-12: Unhooking the SG Sensor Cables



8. Remove the connectors, starting at one end and working to the opposite end:
 - a. Push the connector down.
 - b. Turn the collar counterclockwise $\frac{1}{4}$ -turn.
 - c. Lift the connector.

Figure 4-13: Removing a Connector



9. After you remove all of the connectors, select **Next**.

Installing a New SG Sensor

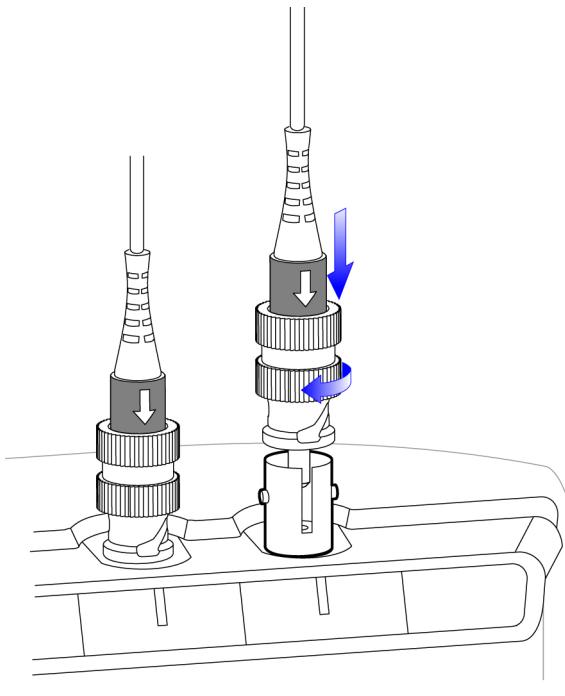


BIOHAZARD

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

1. Install the new SG sensor by sliding the SG sensor (facing up) into the sensor well (*Figure 4-11*), until you hear a click, and then select **Next**.
2. Hook the SG sensor cables by holding the sensor connectors in one hand, while hooking each sensor cable to the clips, and then select **Next**.
3. Attach the connectors, starting at one end and working to the opposite end:
 - a. Holding the connector collar, align the tab to the slot in its matching color socket.
 - b. Push the collar down and turn it clockwise $\frac{1}{4}$ -turn.
 - c. To ensure the connector is locked, gently try to lift the connector.

Figure 4-14: Attaching a Connector



4. Select **Done**.
5. Close the cover.
6. Discard the old SG sensor in a biohazard container.
7. Wait 1 hour while the system is hydrating the SG sensor.
8. After complete hydration, calibrate the system.

Replacing the Syringe

The Syringe Replacement Assistant steps you through the process of removing the old syringe and installing the new syringe with onscreen directions. Follow the onscreen directions, and read the following instructions for complete information.

Removing the Old Syringe

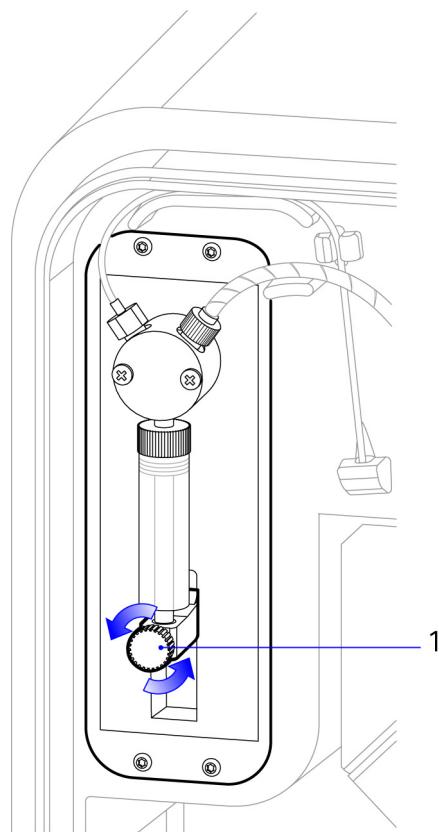


BIOHAZARD

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

1. Remove the racks from the rack handler.
2. Select **System > Diagnostics > Replace or Adjust > Replace Syringe**.
The Syringe Replacement Assistant displays the first of 5 screens of instructions.
3. Select **Replace**.
4. Open the cover, locate the syringe, and then select **Next**.
5. Loosen the plunger screw counterclockwise from the syringe pump arm at the bottom of the syringe, and then select **Next**.

Figure 4-15: Removing the Syringe

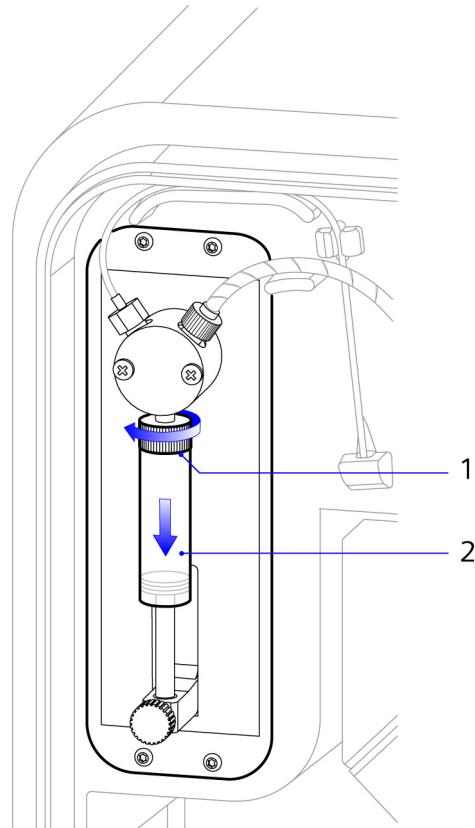


1 Plunger screw

6. To move the syringe pump arm down, select **OK**.

7. Remove the syringe:
 - a. Turn the syringe valve screw clockwise to loosen the syringe from its fitting on the syringe valve and remove the syringe.
 - b. Set aside the syringe.

Figure 4-16: Removing the Syringe



-
- 1 Syringe valve screw
 - 2 Syringe
-

8. Select **Next**.

Installing a New Syringe



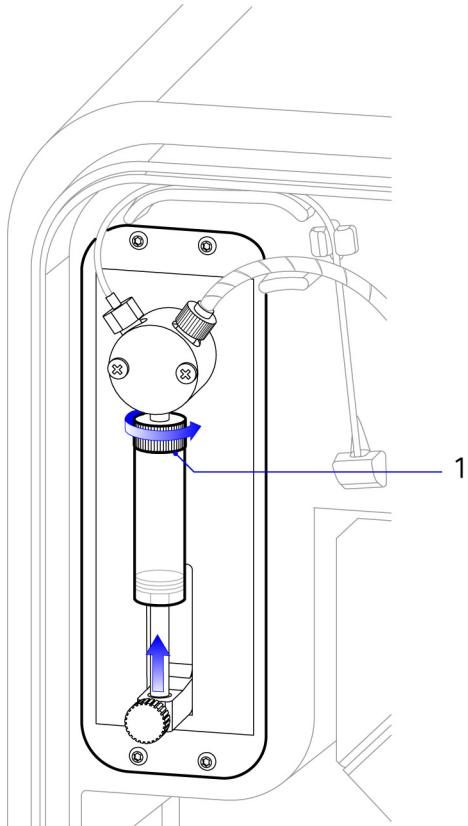
BIOHAZARD

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

1. Obtain a new syringe (included in the CLINITEK Novus Accessory Kit) and remove it carefully from its box.

2. Install the new syringe by screwing it into the syringe valve counterclockwise, and then select **Next**.

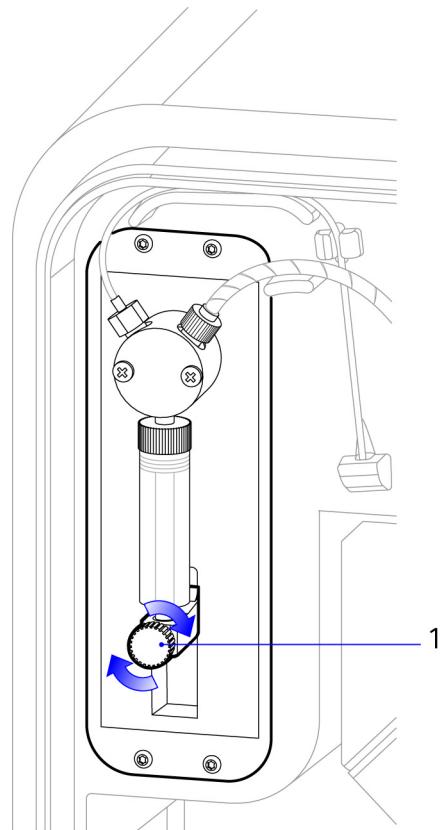
Figure 4-17: Installing the New Syringe



1 Syringe valve

3. To move the syringe pump arm up, select **OK**.
4. Tighten the plunger screw clockwise into the syringe pump arm, and then select **Done**.

Figure 4-18: Tightening the Plunger Screw



1 Plunger screw

5. After the system primes the pump, close the cover.
6. Discard the old syringe in an appropriate container.
7. Recalibrate the system, as described in Section 3, *Calibration and Quality Control*.

Adjusting the Hardware

You can adjust the following hardware components:

Touch screen You can calibrate the touch screen to ensure that the point of contact from your finger or a stylus is positioned correctly on the screen.

Pipette depth Initially, the pipette depth is set during installation. After you replace the pipette, adjust the pipette depth for when it moves down into a tube to avoid damaging the pipette. A crash sensor on the pipette stops the pipette from crashing down to the bottom of the tube.

Calibrating the Touch Screen

1. Select **System > Diagnostics > Replace or Adjust > Touch Screen Calibration.**
2. Select the cross-hair in the center of the screen.
3. Repeat selecting the cross-hair as it moves to each corner of the screen.
4. Repeat steps 3 and 4 if the cross-hair still displays.

When the cross-hair disappears, the **Replace or Adjust** menu displays and the calibration is complete.

If the calibration test does not end, call your local technical support service provider.

Adjusting the Pipette Depth

During installation of the system, the Siemens Service Representative sets the pipette depth.

After you replace the pipette, adjust the pipette depth so that it moves down into a tube without crashing or damaging the pipette. Activation of the crash sensor on the pipette stops the pipette from moving further down to the bottom of the tube and crashing.

1. Place an empty, dry tube in the first position in a rack on the rack handler.
2. Select **System > Diagnostics > Replace or Adjust > Adjust Pipette Depth.**
3. Select **Start.**

The system performs the following tasks:

- Moves the sample tube to the sampling area.
- Moves the pipette out to the sampling position.
- Moves the pipette down slowly until it discovers the bottom of the tube.

A message displays informing you that the pipette depth process is complete.

4. Select **Exit.**

Note If you are adjusting the pipette depth after installation of a new pipette, verify the pipette replacement with the procedure, *Verifying the Pipette Replacement*, page 105.

Performing System Management Tasks

You can perform the following system management tasks:

- Install the software
- Back up the settings and the data
- Restore the settings and the data
- Set the automatic backup time
- Reset the system defaults
- View the system information

Installing the Software

Note When you update the software, the system deletes the calibration results. Siemens recommends that you print the calibration results or send them to the LIS before you update the software.

1. Select **System > System Management > Install Software**.
2. Insert the software USB memory stick in a USB port.

Note The system recognizes only 1 USB memory stick that you insert. If you insert one USB memory stick in a USB port, and insert another USB memory stick in a different USB port, the system ignores the additional stick. You can remove a USB memory stick and replace it with a different stick.

3. Select **Start**.
 4. To confirm the current and new version numbers of the software, select **Yes**.
 5. After the system finishes installing the software, select **Restart**.
- Note** When prompted, remove the software USB memory stick.
6. To view the software version, select **System > About the System**.

Backing up the Settings and the Data

The storage capacity on the internal SD card is 100 megabytes.

Back up the system settings and the patient, control, and calibration data to an FAT32 formatted USB memory stick.

Note When you back up the settings and the data, you can restore the settings to the same system or a different system. You can restore the data only to the same system.

1. Select **System > System Management > Back Up**.

2. Insert an FAT32 formatted USB memory stick in a USB port.

Note The system recognizes only 1 USB memory stick that you insert. If you insert a USB memory stick in a USB port, and insert another USB memory stick in a different USB port, the system ignores the additional stick. You can remove a USB memory stick and replace it with a different stick.

3. Select **Start**.
4. After the system finishes backing up the system settings and the patient, control, and calibration data, select **Exit**.
5. When prompted, remove the software USB memory stick.

Restoring the System Settings

You can restore the system settings from a backup that was stored on a USB memory stick, to the same system from where you backed up the settings.

Note When you restore the system settings, the system deletes the patient, control, and calibration data in the system database.

1. Select **System > System Management > Restore Settings**.
2. Insert the USB memory stick (that contains the system settings) in a USB port.

Note The system recognizes only 1 USB memory stick that you insert. If you insert a USB memory stick in a USB port, and insert another USB memory stick in a different USB port, the system ignores the additional stick. You can remove a USB memory stick and replace it with a different stick.

3. Select **Start**.

Note When prompted, remove the software USB memory stick.

Restoring the System Settings and Data

You can restore the system settings, and the patient data and control data from a backup that was stored on a USB memory stick, to the same system from where you backed up the settings or to a different system.

You can restore the patient, control, and calibration data only to the same system from where you backed it up.

1. Select **System > System Management > Restore Data**.
2. Insert the USB memory stick (that contains the system settings and data) in a USB port.

Note The system recognizes only 1 USB memory stick that you insert. If you insert a USB memory stick in a USB port, and insert another USB memory stick in a different USB port, the system ignores the additional stick. You can remove a USB memory stick and replace it with a different stick.

3. Select **Start**.

Note When prompted, remove the software USB memory stick.

Setting the Automatic Backup Time

The internal SD card stores the system settings, and patient, control, and calibration data. The automatic backup is used only internally by the software.

By default, the system backs up the system settings and the patient, control, and calibration data every 24 hours. You can specify the time for an automatic backup to occur.

1. Select **System > System Management > Set Auto Backup**.
2. Select a time in hours and minutes, and AM or PM (if enabled).
3. Select **Save**.

Resetting the System to the Default Settings

When the CLINITEK Novus analyzer is sent from the factory, all of the system settings are set to the default values. You can reset the current system settings to the system default settings except for the language settings (see *Operations Settings*, page 190).

When you call for technical support, the representative might ask you to reset the system to the default settings.



CAUTION

Do not reset the system to the system default settings if you want to retain the patient and control data. If you reset the system to the system default settings, the system deletes the patient and control data.

1. Select **System > System Management > Reset System Defaults**.
2. To confirm, Select **Yes**.
The system restarts and restores the default settings.
3. Calibrate the system, as describe in *Calibrating the System*, page 73.

Viewing the System Information

To view the system information, select **System > About the System**. The system information displays, as described in *Table 4-1*.

Table 4-1: System Information

Item	Description
Software Revision	The current version of the software.
Firmware Revision	The current version of the firmware.
JADAK Revision	The current version of the JADAK firmware.
Service Date	The date of the last service performed on the system.
System Serial Number	The serial number for the system.
Exposure Adjustment Date	The date of the last Exposure Adjustment.
Total Tests run	The total number of tests performed on the system.
Novus 10–Test Run	The total number of tests performed from a CLINITEK Novus 10 cassette.
Novus 12–Test Run	The total number of tests performed from a CLINITEK Novus PRO 12 cassette.
Calibration Tests	The total number of calibration tests performed on the system.
Control Tests	The total number of control tests performed on the system.
Patient Tests	The total number of patient tests performed on the system.

5 Troubleshooting

This section covers the following topics:

- Performing General Troubleshooting
- Viewing the Sensor Status
- Troubleshooting Warnings, Failures, and Errors
- Cleaning Sample Spills on the Rack Handler
- Contacting your Technical Support provider
- Using the Pre-Service Checklist
- Performing Hardware Diagnostic Tests

Performing General Troubleshooting

As with all systems, errors might occur with the analyzer. Some errors require the system to adjust the hardware, after which the system can continue to operate. Other errors require your intervention. The system displays warning and error messages so that you can prevent or troubleshoot errors.

The warning and error messages provide a brief explanation of the problem detected, and detailed information about the corrective action or solution to correct the problem. In some cases, an error code also displays at the beginning of an error message. For example, E102 A syringe pump operation error occurred.

Viewing the Sensor Status

The analyzer has sensors that continuously monitor the status of the electronic components of the system. View the sensor status to determine if you need to troubleshoot the system. For a complete list of sensors, see *Detection Systems*, page 21.

Select **System > Diagnostics > Sensor Status**.

Each sensor name with its status displays. The status could include any of the following descriptions:

- Closed or Open
- Locked or Unlocked
- Detected or Not Detected
- Present or Not Present
- Full or Not Full

- Crashed or Not Crashed

Troubleshooting Warnings in the Status Log

The Status log displays warning messages, which help you troubleshoot the system and prevent errors, as described in *Table 5-1*.

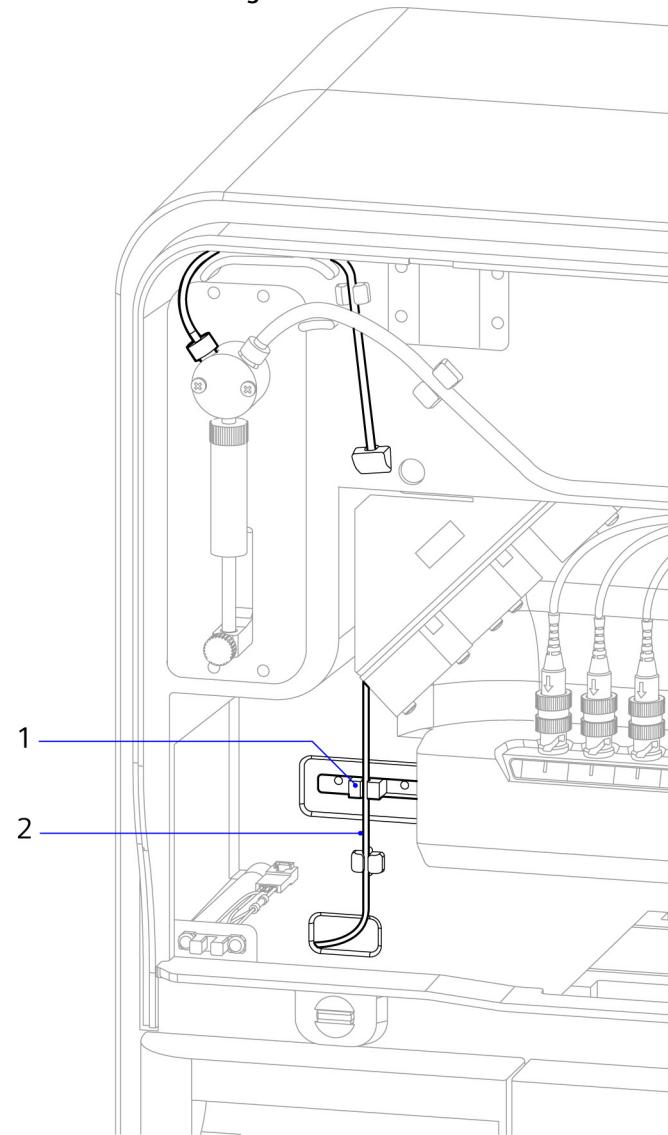
Table 5-1: Warning Messages in the Status Log

Color	Indication
Yellow	A yellow warning message requires you to take an action. Example: The cassette is empty. To troubleshoot a yellow warning message, perform these steps: <ol style="list-style-type: none">1. To view the details of a yellow warning message, select the message in the Status log.2. Read the details of the message.3. Select OK.4. Perform the corrective action steps provided in the details.
White	A white warning message indicates that a warning condition exists. Example: The number of tests remaining is low.

Troubleshooting Rinse Errors

Ensure that no kinks or bends occur in the rinse tubing of the external rinse bottle. Air bubbles could occur in the rinse tubing. The rinse bubble sensor detects the air bubbles and displays an error message that the rinse solution is not detected. To clear the air bubbles, prime the pump.

Figure 5-1: Rinse Tubing



-
- 1 Rinse bubble sensor
 - 2 Straight rinse tubing
-

Recovering from Rack Handler Errors

If the rack handler detects an error, the system handles the error in the following way, if possible:

- The system finishes processing the sample it started testing but stops processing new samples and moves the rack to the unloading area.
 - An error message with a number displays.
 - An error alert sounds.
1. Determine the reason for the error, and correct it, if possible.
See *Troubleshooting Error Messages*, page 128.
 2. On the **Patient Results** or **Patient Missing Data** screen, select **View** and navigate to the last patient result.
 3. Note the tube position in the rack of the last sample the system processed.
 4. Move all of the racks out of the sampling and loading area.
 5. If the system did not finish testing all of the samples in a rack, remove the samples that the system already processed.
 6. Move the rack that the system did not finish testing to the first position in the loading area so that the system continues testing the samples where it left off.
 7. Position the remaining racks on the rack handler, depending on the **Rack Circulation** setting you selected.
The Status bar displays **Ready**.
 8. Start a new test for the samples that the system did not process.

Cleaning Sample Spills on the Rack Handler

- If a small amount of sample spills on the rack handler, perform these steps:
 - Clean the loading and unloading areas with a mild detergent and dry with a soft cloth.
 - Run the rack handler hardware test.
 - If the test passes, continue testing the samples.
 - If the test fails, clean the rack sensors with a damp, lint-free, optical-grade swab. Repeat the rack handler hardware test.

- If a large amount of sample spills on the rack handler, and possibly seeped into the rack sensors, perform these steps:
 - Clean the loading and unloading areas with a mild detergent and dry with soft cloth.
 - Clean the rack sensors with a damp, lint-free, optical-grade swab.
 - Perform the rack handler hardware test to ensure that the rack handler is working properly.

Troubleshooting a Failed Calibration

- If a calibration stops because of hardware errors, see *Troubleshooting Error Messages*, page 128.
- If a calibration fails, read the probable causes with the suggested corrective actions in *Table 5-2* to troubleshoot the problem.

For further assistance, contact your local technical service provider (see *Appendix B, Warranty and Support Information*).

Table 5-2: Troubleshooting Calibration

Probable Cause	Corrective Action
The calibrator lots have expired.	Use fresh calibrators and recalibrate the system.
The cassette lot has expired.	Load a new cassette and calibrate the system.

Probable Cause	Corrective Action
The calibrators are in the wrong order in the rack.	<p>If you enable the Report Clarity setting, and you use a 10- or 12-test set, or if you disable the Report Clarity setting, and you use a 12-test set, place the calibrators in the rack in the following order:</p> <ul style="list-style-type: none">• 1st Test Position Bleach• 2nd Test Position CAL #4• 3rd Test Position CAL #1• 4th Test Position CAL #2• 5th Test Position CAL #3 <p>If you disable the Report Clarity setting, and you use a 10-test set, you do not need to use CAL #4. Place the calibrators in the rack in the following order:</p> <ul style="list-style-type: none">• 1st Test Position Bleach• 2nd Test Position CAL #1• 3rd Test Position CAL #2• 4th Test Position CAL #3
The CLINITEK Novus analyzer is malfunctioning.	Contact your local technical service provider.

Troubleshooting Quality Control

If you use CLINITEK Novus Control Solutions, they should produce the values stated in the instructions for use for the CLINITEK Novus Positive and Negative Control Strips.

- If a control test stops because of hardware errors, see *Troubleshooting Error Messages*, page 128.
- If the results for either of the control solutions fall outside of the ranges assigned to the control, read the probable causes with corrective actions in the specified order in *Table 5-3*.

For further assistance, contact your local technical service provider. See *Appendix B, Warranty and Support Information*.

Table 5-3: Troubleshooting Quality Control

Probable Cause	Corrective Action
1. The control lot has expired.	Prepare a fresh control solution and retest the control.
2. The CLINITEK Atlas Control Strips expired.	Use a fresh bottle of CLINITEK Atlas Control Strips and prepare a fresh control solution. Test the fresh control solution.
3. The CLINITEK Atlas Control Solutions have expired.	Use a fresh bottle of CLINITEK Atlas Control Strips and prepare a fresh control solution. Test the fresh control solution.
4. The cassette lot has expired.	Load a new cassette and calibrate the system as prompted, and then retest the control solution.
5. The CLINITEK Novus analyzer is malfunctioning.	Contact your local technical service provider.

Troubleshooting the Internal Barcode Reader

You can use the test barcode labels included with the internal barcode reader to verify the operation of the reader. Two sheets of barcode test labels are provided in the CLINITEK Novus Accessory Kit. Each sheet contains all 4 symbologies, with and without check digits. These test barcode labels are of a known quality, printed in accordance with the internal barcode reader specifications.

To test the internal barcode reader with the test barcode labels, select **System > Diagnostics > Hardware Tests > Barcode Readers > Internal**.

If hardware errors occur, see *Troubleshooting Error Messages*, page 128.

To troubleshoot the internal barcode reader, read the probable causes with corrective actions in the specified order in *Table 5-4*.

If you have internal barcode reader problems that cannot be resolved, contact your local technical service provider for assistance.

Table 5-4: Troubleshooting the Internal Barcode Reader

Probable Cause	Corrective Action
1. The barcode labels are improperly positioned on the tubes, or the tubes are not positioned properly in the rack.	Rotate the tube slightly to ensure that the barcodes show completely through the open side of each tube slot in the rack. Try to read the label again. If the problem persists, remove the label and replace it with a new barcode label vertically on the tube (<i>Figure 2-6</i>).
2. A tube has multiple barcode labels.	Remove the labels and replace them with 1 barcode label.
3. The narrow bar width is too small.	Reprint the labels according to the guidelines in the Caution on page 49.
4. The barcode length is too long.	Reprint the labels according to the guidelines in the Caution on page 49.
5. The height of the barcode is too short.	Reprint the labels according to the guidelines in the Caution on page 49.
6. The background reflection is too high or low in the barcode reader reflector.	Check the height of the tubes to ensure that they meet the height specifications of 100–106 mm.

Probable Cause	Corrective Action
7. The labels have poor quality barcodes.	If the internal barcode reader cannot consistently read the labels, apply a test barcode label (from the CLINITEK Novus Accessory Kit) with the format you use to a new sample tube. Perform the barcode hardware test. If the barcode reader can read the test barcode labels, the quality of your labels might be suspect.
8. The barcode reader is malfunctioning.	If the internal barcode reader cannot read the test label, the reader itself is suspect. Contact your local technical service provider.

Troubleshooting the Handheld Barcode Reader

You can use the test labels included with the handheld barcode reader to verify the operation of it. Two sheets of test barcode labels are provided in the CLINITEK Novus Accessory Kit. Each sheet contains all 4 symbologies, with and without check digits. These test labels are of a known quality, printed in accordance with the handheld barcode reader specifications.

To test the handheld barcode reader with the test barcode labels, select **System > Diagnostics > Hardware Tests > Barcode Readers > Handheld**.

To troubleshoot the handheld barcode reader, read the probable causes with corrective actions in the specified order in *Table 5-5* .

- If hardware errors occur, see *Troubleshooting Error Messages*, page 128.
- If you have handheld barcode reader problems that cannot be resolved, contact your local technical service provider for assistance.

Table 5-5: Troubleshooting the Handheld Barcode Reader

Probable Cause	Corrective Action
1. The barcode labels are improperly positioned on the tubes, which might cause reading problems.	Hold the tube or place it in a rack and scan the entire barcode.
2. A tube has multiple barcode labels.	Remove the labels and replace them with 1 barcode label.

Probable Cause	Corrective Action
3. The narrow bar width is too small.	Reprint the labels according to the guidelines in the Caution on page 49.
4. The barcode length is too long.	Reprint the labels according to the guidelines in the Caution on page 49.
5. The height of the barcode is too short.	Reprint the labels according to the guidelines in the Caution on page 49.
6. The labels have poor quality barcodes.	If the handheld barcode reader cannot consistently read the labels, apply a test barcode label with the format you use to a new sample tube. Perform the barcode hardware test. If the reader can read the test labels, the quality of your labels might be suspect.
7. The barcode reader is not connected properly.	Verify that the barcode reader is connected properly to the serial port on the connector panel.
8. The barcode reader is malfunctioning.	If the handheld barcode reader cannot read the test label, the reader itself is suspect. Contact your local technical service provider.

Troubleshooting Error Messages

The system can display 2 types of error messages:

- With an error code, for example,

E650 - A card jam error occurred.

Perform the card handler test by selecting System > Diagnostics > Hardware Tests > Card Handler.

If the error persists, contact your local technical support provider.

- Without an error code, for example,

The card waste drawer is full.

Error Messages with Error Codes

To troubleshoot error messages with error codes, look up the error number and error message in *Table 5-6* to find the probable cause and corrective action.

Table 5-6: Troubleshooting the Error Messages with Error Codes

Error Code and Message	Corrective Action
E99 - An undefined error occurred.	Contact your local technical support provider to report this error.
E100 - A pump hardware error occurred.	Perform the fluidic system test by selecting System > Diagnostics > Hardware Tests > Fluidic . If the error persists, contact your local technical support provider.
E102 - A syringe pump operation error occurred.	Perform the fluidic system test by selecting System > Diagnostics > Hardware Tests > Fluidic . If the error persists, contact your local technical support provider.
E103 - A syringe pump communication error occurred.	Perform the fluidic system test by selecting System > Diagnostics > Hardware Tests > Fluidic . If the error persists, contact your local technical support provider.
E150 - A pipette up-down motor hardware error occurred.	Perform the fluidic system test by selecting System > Diagnostics > Hardware Tests > Fluidic . If the error persists, contact your local technical support provider.
E152 - A pipette up-down motor homing error occurred.	Perform the fluidic system test by selecting System > Diagnostics > Hardware Tests > Fluidic . If the error persists, contact your local technical support provider.
E153 - A pipette up-down motor move error occurred.	Perform the fluidic system test by selecting System > Diagnostics > Hardware Tests > Fluidic . If the error persists, contact your local technical support provider.

Error Code and Message	Corrective Action
E154 - A pipette up-down motor stall error occurred.	<p>Perform the fluidic system test by selecting System > Diagnostics > Hardware Tests > Fluidic.</p> <p>If the error persists, contact your local technical support provider.</p>
E155 - A pipette crash occurred.	<p>Ensure that the tube is properly placed in the rack. Adjust the pipette depth.</p> <p>Inspect the pipette for damage by moving it with the Pipette Replacement Assistant. Select Next 3 times without performing the actions, and select OK.</p> <p>Perform a system sequence test with the system cover open. Ensure that the pipette dispenses the sample properly.</p> <p>Calibrate.</p> <p>If the error persists, contact your local technical support provider.</p>
E200 - A pipette in-out motor hardware error occurred.	<p>Perform the fluidic system test by selecting System > Diagnostics > Hardware Tests > Fluidic.</p> <p>If the error persists, contact your local technical support provider.</p>
E202 - A pipette in-out motor homing error occurred.	<p>Perform the fluidic system test by selecting System > Diagnostics > Hardware Tests > Fluidic.</p> <p>If the error persists, contact your local technical support provider.</p>
E203 - A pipette in-out motor move error occurred.	<p>Perform the fluidic system test by selecting System > Diagnostics > Hardware Tests > Fluidic.</p> <p>If the error persists, contact your local technical support provider.</p>
E204 - A pipette in-out motor stall error occurred.	<p>Perform the fluidic system test by selecting System > Diagnostics > Hardware Tests > Fluidic.</p> <p>If the error persists, contact your local technical support provider.</p>

Error Code and Message	Corrective Action
E270 - A rinse bottle level sensor error occurred.	Contact your local technical support provider to report this error.
E271 - An error occurred in the rinse bottle level sensor.	Contact your local technical support provider to report this error.
E310 - A waste bottle level sensor error occurred.	Contact your local technical support provider to report this error.
E311 - An error occurred in the waste bottle level sensor.	Contact your local technical support provider to report this error.
E350 - A pipette depth error occurred.	Fluid was detected in the sample tube when you adjusted the pipette depth. Use an empty, dry tube and restart the process.
E400 - An error occurred in the card handler pusher motor.	Perform the card handler test by selecting System > Diagnostics > Hardware Tests > Card Handler . If the error persists, contact your local technical support provider.
E402 - An error occurred in the card handler.	Perform the card handler test by selecting System > Diagnostics > Hardware Tests > Card Handler . If the error persists, contact your local technical support provider.
E403 - An error occurred in the card handler.	Perform the card handler test by selecting System > Diagnostics > Hardware Tests > Card Handler . If the error persists, contact your local technical support provider.
E450 - A hardware error occurred in the card handler gate.	Perform the card handler test by selecting System > Diagnostics > Hardware Tests > Card Handler . If the error persists, contact your local technical support provider.
E452 - A homing error occurred in the card handler gate.	Perform the card handler test by selecting System > Diagnostics > Hardware Tests > Card Handler . If the error persists, contact your local technical support provider.
E453 - A move error occurred in the card handler gate.	Perform the card handler test by selecting System > Diagnostics > Hardware Tests > Card Handler . If the error persists, contact your local technical support provider.

Error Code and Message	Corrective Action
E500 - An error occurred in the card handler.	Perform the card handler test by selecting System > Diagnostics > Hardware Tests > Card Handler . If the error persists, contact your local technical support provider.
E502 - An error occurred in the card handler.	Perform the card handler test by selecting System > Diagnostics > Hardware Tests > Card Handler . If the error persists, contact your local technical support provider.
E503 - An error occurred in the card handler.	Perform the card handler test by selecting System > Diagnostics > Hardware Tests > Card Handler . If the error persists, contact your local technical support provider.
E550 - An error occurred in the card handler.	Perform the card handler test by selecting System > Diagnostics > Hardware Tests > Card Handler . If the error persists, contact your local technical support provider.
E552 - An error occurred in the card handler.	Perform the card handler test by selecting System > Diagnostics > Hardware Tests > Card Handler . If the error persists, contact your local technical support provider.
E553 - An error occurred in the card handler.	Perform the card handler test by selecting System > Diagnostics > Hardware Tests > Card Handler . If the error persists, contact your local technical support provider.
E600 - A general error occurred in the test pad detector.	Contact your service representative to report this error.
E601 - An error occurred in the test pad detector.	Contact your service representative to report this error.
E602 - An error occurred in the test pad detector.	Contact your service representative to report this error.
E650 - A card jam error occurred.	Perform the card handler test by selecting System > Diagnostics > Hardware Tests > Card Handler . If the error persists, contact your local technical support provider.
E651 - A card load error occurred.	Perform the card handler test by selecting System > Diagnostics > Hardware Tests > Card Handler . If the error persists, contact your local technical support provider.

Error Code and Message	Corrective Action
E800 - A general error occurred in the image processor.	<p>Calibrate the system by selecting System > Calibration. If the error persists, contact your local technical support provider.</p>
E801 - A camera error occurred in the image processor.	<p>Perform the optical test by selecting System > Diagnostics > Hardware Tests > Optical > Imaging. If the optical test passes, calibrate the system by selecting System > Calibration. If the error persists, contact your local technical support provider.</p>
E802 - An I2C error occurred in the image processor.	<p>Perform the optical test by selecting System > Diagnostics > Hardware Tests > Optical > Imaging. If the optical test passes, calibrate the system by selecting System > Calibration. If the error persists, contact your local technical support provider.</p>
E803 - An error occurred in the image processor.	<p>Calibrate the system by selecting System > Calibration. If the error persists, contact your local technical support provider.</p>
E804 - A lamp error occurred in the image processor.	<p>Open the system cover. Perform the optical imaging test by selecting System > Diagnostics > Hardware Tests > Optical > Imaging. Verify all 4 lamps turn on during the test. Close the system cover and repeat the optical imaging test. If the optical imaging test passes, calibrate the system by selecting System > Calibration. If the error persists, contact your local technical support provider.</p>
E900 - A communication error occurred between the processors.	<p>Restart the system. If the error persists, contact your local technical support provider.</p>

Error Code and Message	Corrective Action
E901 - An error occurred in the dual port memory.	Restart the system. If the error persists, contact your local technical support provider.
E902 - A timeout error occurred between the processors.	Restart the system. If the error persists, contact your local technical support provider.
E1000 - An error occurred in the rack handler.	Remove any jammed racks or other objects from the rack handler. Perform the rack test by selecting System > Diagnostics > Hardware Tests > Rack . If the error persists, contact your local technical support provider.
E1002 - An error occurred in the rack handler.	Remove any jammed racks or other objects from the rack handler. Perform the rack test by selecting System > Diagnostics > Hardware Tests > Rack . If the error persists, contact your local technical support provider.
E1003 - An error occurred in the rack handler.	Remove any jammed racks or other objects from the rack handler. Perform the rack test by selecting System > Diagnostics > Hardware Tests > Rack . If the error persists, contact your local technical support provider.
E1004 - An error occurred in the rack handler.	Remove any jammed racks or other objects from the rack handler. Perform the rack test by selecting System > Diagnostics > Hardware Tests > Rack . If the error persists, contact your local technical support provider.
E1050 - An error occurred in the rack handler.	Remove any jammed racks or other objects from the rack handler. Perform the rack test by selecting System > Diagnostics > Hardware Tests > Rack . If the error persists, contact your local technical support provider.
E1052 - An error occurred in the rack handler.	Remove any jammed racks or other objects from the rack handler. Perform the rack test by selecting System > Diagnostics > Hardware Tests > Rack . If the error persists, contact your local technical support provider.

Error Code and Message	Corrective Action
E1053 - An error occurred in the rack handler.	Remove any jammed racks or other objects from the rack handler. Perform the rack test by selecting System > Diagnostics > Hardware Tests > Rack . If the error persists, contact your local technical support provider.
E1054 - An error occurred in the rack handler.	Remove any jammed racks or other objects from the rack handler. Perform the rack test by selecting System > Diagnostics > Hardware Tests > Rack . If the error persists, contact your local technical support provider.
E1100 - An error occurred in the rack handler.	Remove any jammed racks or other objects from the rack handler. Perform the rack test by selecting System > Diagnostics > Hardware Tests > Rack . If the error persists, contact your local technical support provider.
E1102 - An error occurred in the rack handler.	Remove any jammed racks or other objects from the rack handler. Perform the rack test by selecting System > Diagnostics > Hardware Tests > Rack . If the error persists, contact your local technical support provider.
E1103 - An error occurred in the rack handler.	Remove any jammed racks or other objects from the rack handler. Perform the rack test by selecting System > Diagnostics > Hardware Tests > Rack . If the error persists, contact your local technical support provider.
E1104 - An error occurred in the rack handler.	Remove any jammed racks or other objects from the rack handler and perform the rack test by selecting System > Diagnostics > Hardware Tests > Rack . If the error persists, contact your local technical support provider.
E1150 - An error occurred in the rack handler.	Remove any jammed racks or other objects from the rack handler and perform the rack test by selecting System > Diagnostics > Hardware Tests > Rack . If the error persists, contact your local technical support provider.

Error Code and Message	Corrective Action
E1152 - An error occurred in the rack handler.	<p>Remove any jammed racks or other objects from the rack handler and perform the rack test by selecting System > Diagnostics > Hardware Tests > Rack.</p> <p>If the error persists, contact your local technical support provider.</p>
E1153 - An error occurred in the rack handler.	<p>Remove any jammed racks or other objects from the rack handler and perform the rack test by selecting System > Diagnostics > Hardware Tests > Rack.</p> <p>If the error persists, contact your local technical support provider.</p>
E1154 - An error occurred in the rack handler.	<p>Remove any jammed racks or other objects from the rack handler and perform the rack test by selecting System > Diagnostics > Hardware Tests > Rack.</p> <p>If the error persists, contact your local technical support provider.</p>
E1200 - A data error occurred in the internal barcode reader.	<p>Restart the system. Perform the internal barcode reader test by selecting System > Diagnostics > Hardware Tests > Barcode Readers > Internal.</p> <p>If the error persists, contact your local technical support provider.</p>
E1201 - An error occurred in the internal barcode reader.	<p>Restart the system. Perform the internal barcode reader test by selecting System > Diagnostics > Hardware Tests > Barcode Readers > Internal.</p> <p>If the error persists, contact your local technical support provider.</p>
E1202 - The internal barcode reader needs calibration.	<p>Your local technical support provider needs to calibrate the internal barcode reader. Contact your local technical support provider.</p>
E1300 - No rack handler was detected.	<p>Restart the system.</p> <p>If the error persists, contact your local technical support provider.</p>
E1400 - A jam error occurred in the rack handler.	<p>Remove any jammed racks or other objects from the rack handler. Perform the rack test by selecting System > Diagnostics > Hardware Tests > Rack.</p> <p>If the error persists, contact your local technical support provider.</p>

Error Code and Message	Corrective Action
E1402 - Too many racks were found on the rack handler.	Remove the excess racks from the rack handler. Restart processing the tests. If the error persists, contact your local technical support provider.
E1403 - A rack load error occurred.	Remove the racks in front of and behind the STAT island. If the error persists, contact your local technical support provider.
E1404 - An error occurred in the rack handler.	Remove any jammed racks or other objects from the rack handler. Ensure that the rack handler is level and nothing is preventing a rack from reaching the left end of the rack handler. If the error still persists, contact your local technical support provider.
E1405 - An error occurred in the rack handler.	Remove any jammed racks or other objects from the rack handler. Ensure that the rack handler is level and nothing is preventing a rack from reaching the right end of the rack handler. If the error still persists, contact your local technical support provider.
E1500 - A universal sample handler error occurred.	Clear the error on the universal sample handler. See the universal sample handler documentation. If the error persists, contact your local technical support provider.
E1501 - An error occurred in the universal sample handler.	Clear the error on the universal sample handler. See the universal sample handler documentation. If the error persists, contact your local technical support provider.
E1601 - A time tolerance error occurred in the test processor.	Restart the system. If the error persists, contact your local technical support provider.
E1750 - An SG sensor error occurred.	Restart the system, and then calibrate. If the error persists, contact your local technical support provider.

Error Code and Message	Corrective Action
E1751 - A read error occurred in the SG sensor.	<p>Remove the SG sensor. Inspect it for particles and debris, and remove the debris delicately to avoid damaging the sensor. Soak the sensor in 5.25% bleach for no longer than 5 minutes. Rinse carefully and thoroughly with deionized water. Restart the system.</p> <p>If the error persists, contact your local technical support provider.</p>
E1752 - A lamp error occurred in the SG sensor.	<p>Restart the system, and then calibrate.</p> <p>If the error persists, contact your local technical support provider.</p>
E1753 - A read error occurred in the clarity sensor.	<p>Restart the system, and then calibrate.</p> <p>If the error persists, contact your local technical support provider.</p>
E1754 - A lamp error occurred in the clarity sensor.	<p>Restart the system, and then calibrate.</p> <p>If the error persists, contact your local technical support provider.</p>
E1800 - A sensor error occurred.	<p>View the sensor error status by selecting System > Diagnostics > Sensor Status.</p> <p>Contact your local technical support provider to report this error.</p>
E1810 - A hygrometer sensor error occurred.	<p>Contact your local technical support provider to report this error.</p>
E1820 - A temperature sensor error occurred.	<p>Contact your local technical support provider to report this error.</p>
E1830 - A test pad error occurred. The testing stopped.	<p>The system detected multiple test pad errors on the test card and ejected the card into the card waste drawer. The results for the processed samples display. Restart the testing for the unprocessed and remaining samples.</p> <p>If the error persists, contact your local technical support provider.</p>
E1840 - A P1 write error occurred in the SD storage.	<p>Perform the SD storage test by selecting System > Diagnostics > Hardware Tests > SD Storage.</p> <p>If the error persists, contact your local technical support provider.</p>

Error Code and Message	Corrective Action
E1841 - A P1 read error occurred in the SD storage.	Perform the SD storage test by selecting System > Diagnostics > Hardware Tests > SD Storage . If the error persists, contact your local technical support provider.
E1842 - An error occurred in the SD storage.	Perform the SD storage test by selecting System > Diagnostics > Hardware Tests > SD Storage . If the error persists, contact your local technical support provider.
E1843 - An error occurred in the SD storage.	The free space is low on the P1 SD card. Contact your local technical support provider to report this error.
E1844 - A P1 SD card error occurred in the SD storage.	The P1 SD card needs to be replaced. Contact your local technical support provider to report this error.
E1850 - A P2 write error occurred in the SD storage.	Perform the SD storage test by selecting System > Diagnostics > Hardware Tests > SD Storage . If the error persists, contact your local technical support provider.
E1851 - A P2 read error occurred in the SD storage.	Perform the SD storage test by selecting System > Diagnostics > Hardware Tests > SD Storage . If the error persists, contact your local technical support provider.
E1852 - An error occurred in the SD storage.	Perform the SD storage test by selecting System > Diagnostics > Hardware Tests > SD Storage . If the error persists, contact your local technical support provider.
E1853 - An error occurred in the SD storage.	The free space is low on the P2 SD card. Contact your local technical support provider to report this error.
E1854 - A P2 SD card error occurred in the SD storage.	The P2 SD card needs to be replaced. Contact your local technical support provider to report this error.
E1860 - A general error occurred in the RFID tag.	Perform the RFID test by selecting System > Diagnostics > Hardware Tests > RFID . If the error persists, contact your local technical support provider.

Error Code and Message	Corrective Action
E1863 - An error occurred in the RFID tag.	<p>Repeat the test on the same cassette, and then on a different cassette.</p> <p>If the error persists, contact your local technical support provider.</p>
E1864 - An invalid data error occurred in the RFID tag.	<p>The data on the cassette RFID tag is corrupted. Unload the cassette and load a new one.</p> <p>Contact your local technical support provider to report this error.</p>
E1865 - No RFID tag was found on the cassette.	<p>The system does not detect an RFID tag on the cassette. Unload the cassette and load a new one.</p>
E1880 - The P2 microprocessor failed to start.	<p>Restart the system.</p> <p>If the error persists, contact your local technical support provider.</p>
E1890 - An error occurred in the handheld barcode reader.	<p>Verify that the handheld barcode reader is connected properly. Perform a handheld barcode reader test by selecting System > Diagnostics > Hardware Tests > Barcode Readers > Handheld. Scan the barcode label.</p> <p>If the error persists, repeat the test and scan the test barcode labels.</p> <p>If the error still persists, contact your local technical support provider.</p>
E1900 - A data corruption error occurred.	<p>Restart the system.</p> <p>If the error persists, contact your local technical support provider.</p>
E1901 - An I/O error occurred in the data file.	<p>Perform the SD storage test by selecting System > Diagnostics > Hardware Tests > SD Storage.</p> <p>If the error persists, contact your local technical support provider.</p>
E1903 - A read error occurred in the database.	<p>Restart the system.</p> <p>If the error persists, contact your local technical support provider.</p>
E1904 - A write error occurred in the database.	<p>Restart the system.</p> <p>If the error persists, contact your local technical support provider.</p>
E1905 - No data record was found.	<p>Restart the system.</p> <p>If the error persists, contact your local technical support provider.</p>

Error Code and Message	Corrective Action
E1906 - An invalid database version error occurred.	<p>The database version is incompatible with the current software.</p> <p>Contact your local technical support provider to report this error.</p>
E1907 - The database was restored from the backup.	<p>The database failed to open and was restored from the backup. Any data collected since the last daily automatic backup was lost.</p> <p>If the error persists, contact your local technical support provider.</p>
E1908 - The database was restored.	<p>The database failed to open and was not restored from the backup. All of the data and the settings were lost. To restore your data from the most recent USB backup, select System > System Management > Restore Data.</p> <p>Contact your local technical support provider to report this error.</p>
E1909 - The system does not restore data from a different Novus system.	<p>You can restore the data only on the CLINITEK Novus system where it was backed up. You can restore the settings from a different CLINITEK Novus system.</p>
E1980 - A file open error occurred in the USB memory stick.	<p>The system could not open or create a file on the USB memory stick. Repeat the USB port test on a different USB memory stick by selecting System > Diagnostics > Hardware Tests > USB Port.</p> <p>If the error persists, contact your local technical support provider.</p>
E1981 - A write error occurred in the USB memory stick.	<p>The system could not write the data to the USB memory stick. Repeat the USB port test on a different USB memory stick.</p> <p>If the error persists, contact your local technical support provider.</p>
E1982 - A read error occurred in the USB memory stick.	<p>The system could not read the data on the USB memory stick. Repeat the USB port test on a different USB memory stick.</p> <p>If the error persists, contact your local technical support provider.</p>

Error Code and Message	Corrective Action
E1983 - An error occurred in the USB memory stick.	<p>The test data that the system read did not match the data that was written in the USB port test. Repeat the USB Port Test with a different USB memory stick. Select System > Diagnostics > Hardware Tests > USB Port.</p> <p>If the error persists, contact your local technical support provider.</p>
E2000 - A serial hardware error occurred.	<p>Restart the system. To ensure connectivity, perform the LIS Connectivity test by selecting System > Diagnostics > Hardware Tests > LIS Connectivity.</p> <p>If the error persists, contact your local technical support provider.</p>
E2001 - A send error occurred.	<p>Verify the LIS connection by performing the LIS Connectivity test. Select System > Diagnostics > Hardware Tests > LIS Connectivity. Check all of the port connections and the LIS status.</p> <p>If the error persists, contact your local technical support provider.</p>
E2050 - An Ethernet hardware error occurred.	<p>Check all of the port connections and the LIS status. Restart the system. To ensure connectivity, perform the LIS connectivity test by selecting System > Diagnostics > Hardware Tests > LIS Connectivity.</p> <p>If the error persists, contact your local technical support provider.</p>
E2052 - The system could not connect to the LIS.	<p>Ensure that the LIS connectivity settings on the system and the LIS match, the LIS is connected to the LIS port on the system, and the LIS is powered on. To ensure connectivity, perform the LIS connectivity test by selecting System > Diagnostics > Hardware Tests > LIS Connectivity.</p> <p>If the error persists, contact your local technical support provider.</p>
E2053 - The device host name is invalid.	<p>If the error persists, contact your local technical support provider.</p>

Error Code and Message	Corrective Action
E2100- No printer was detected.	<p>Check the printer connections and the power. To ensure that the printer is working properly, select System > Diagnostics > Hardware Tests > Print. If the error persists, contact your local technical support provider.</p>
E2101- A printer error occurred.	<p>The print job did not complete. Clear all errors at the printer, and check the connections and the power. To ensure that the printer is working properly, select System > Diagnostics > Hardware Tests > Print. If the error persists, contact your local technical support provider.</p>
E4006 - A CAL 3 PRO error occurred.	<p>The response of the Protein reagent to CAL 3 is out of range. Verify the order of the calibrators in the rack and repeat calibration by selecting System > Calibration. If the error persists, contact your local technical support provider.</p>
E4009 - A CAL 3 GLU error occurred.	<p>The response of the Glucose reagent to CAL 3 is out of range. Verify the order of the calibrators in the rack and repeat calibration by selecting System > Calibration. If the error persists, contact your local technical support provider.</p>
E4015 - Errors occurred while checking the humidity.	<p>The leukocyte reagent has deteriorated from exposure to humidity. Load a new cassette, and then perform calibration by selecting System > Calibration. If the error persists, contact your local technical support provider.</p>
E4016 - A dispense error occurred.	<p>Check the sample quality, and the integrity and alignment of the pipette. Repeat calibration by selecting System > Calibration. If the error persists, contact your local technical support provider.</p>

Error Code and Message	Corrective Action
E4200 - A calibration error occurred in the SG LED.	<p>Verify that the SG sensor is properly connected and hydrated.</p> <p>Inspect the pipette for damage (see <i>Pipette and Fluidic Systems</i>, page 15).</p> <p>Verify that the external waste bottle is draining properly. Calibrate.</p> <p>If the error persists, soak the sensor in 5.25% bleach for no longer than 5 minutes. Rinse carefully and thoroughly with deionized water. Calibrate.</p> <p>If the error still persists, contact your local technical support provider.</p>
E4201 - A clarity LED calibration error occurred.	<p>Verify that the SG sensor is properly connected and hydrated.</p> <p>Inspect the pipette for damage (see <i>Pipette and Fluidic Systems</i>, page 15).</p> <p>Verify that the external waste bottle is draining properly. Calibrate.</p> <p>If the error persists, soak the sensor in 5.25% bleach for no longer than 5 minutes. Rinse carefully and thoroughly with deionized water. Calibrate.</p> <p>If the problem persists, replace the SG sensor and calibrate.</p> <p>If the error still persists, contact your local technical support provider.</p>

Error Code and Message	Corrective Action
E4202 - A CAL 4 scatter value too small error occurred.	<p>The scatter value of CAL 4 is too small compared to the clear solutions.</p> <p>Verify that the SG sensor is properly connected and hydrated.</p> <p>Inspect the pipette for damage by moving it with the Pipette Replacement Assistant. Select Next 3 times without performing the actions, and select OK.</p> <p>Ensure that the pipette dispenses the sample properly by performing a system sequence test with the system cover open.</p> <p>Verify that the external waste bottle is draining properly.</p> <p>Calibrate.</p>
E4203 - A CAL 4 scatter signal too small error occurred.	<p>The scatter value of CAL 4 is too small compared to other calibrators.</p> <p>Verify that the SG sensor is properly connected and hydrated.</p> <p>Inspect the pipette for damage by moving it with the Pipette Replacement Assistant. Select Next 3 times without performing the actions, and select OK.</p> <p>Ensure that the pipette dispenses the sample properly by performing a system sequence test with the system cover open.</p> <p>Verify that the external waste bottle is draining properly.</p> <p>Calibrate.</p>
E4204 - A CAL 4 electrical scatter signal error occurred.	<p>The CAL 4 electrical scatter signal is below the expected range. The electrical signal level of the scatter measurement is below the minimum acceptable value.</p> <p>Repeat calibration.</p> <p>If the error persists, contact your local technical support provider.</p>

Error Code and Message	Corrective Action
E4205 - A CAL 4 electrical scatter signal error occurred.	<p>The CAL 4 electrical scatter signal is above the expected range. The electrical signal level of the scatter measurement is greater than the maximum acceptable value.</p> <p>Repeat calibration.</p> <p>If the error persists, contact your local technical support provider.</p>
E4206 - A CAL 1 and 3 mean SG value difference error occurred.	<p>The SG signal difference between CAL 1 and CAL 3 is too small.</p> <p>Verify the calibrators are not expired. If expired, replace them, and then calibrate.</p> <p>If the error persists, replace the SG sensor, and then calibrate.</p> <p>If the error still persists, contact your local technical support provider.</p>
E4207 - A CAL 2 and 3 mean SG value difference error occurred.	<p>The SG signal difference between CAL 2 and CAL 3 is too small. Verify the calibrators are not expired. If expired, replace them, and then calibrate.</p> <p>If the error still persists, contact your local technical support provider.</p>
E4208 - A clarity error occurred during calibration.	<p>A clarity error occurred during calibration. The precision of the scatter measurement of the rinse is poor.</p> <p>Verify that the SG sensor is properly connected and hydrated.</p> <p>Inspect the pipette for damage by moving it with the Pipette Replacement Assistant. Select Next 3 times without performing the actions, and select OK.</p> <p>Ensure that the pipette dispenses the sample properly by performing a system sequence test with the system cover open.</p> <p>Calibrate.</p> <p>If the error persists, contact your local technical support provider.</p>

Error Code and Message	Corrective Action
E4209 - An clarity error occurred during calibration.	<p>The average measurement of the rinse clarity transmission signal during calibration is out of range.</p> <p>Verify that the SG sensor is properly seated and hydrated.</p> <p>Inspect the pipette for damage by moving it with the Pipette Replacement Assistant. Select Next 3 times without performing the actions, and select OK.</p> <p>Ensure that the pipette dispenses the sample properly by performing a system sequence test with the system cover open.</p> <p>Calibrate.</p> <p>If the error persists, contact your local technical support provider.</p>
E4210 - A poor precision of the clarity transmission error occurred.	<p>The precision of the clarity transmission measurements on the rinse is poor.</p> <p>Verify that the SG sensor is properly connected and hydrated.</p> <p>Inspect the pipette for damage by moving it with the Pipette Replacement Assistant.</p> <p>Ensure that the pipette dispenses the sample properly by performing a system sequence test with the system cover open.</p> <p>Verify that the external waste bottle is draining properly.</p> <p>Calibrate.</p> <p>If the problem persists, replace the SG sensor and calibrate.</p>

Error Code and Message	Corrective Action
E4211 - A CAL 4 scatter precision error occurred.	<p>The precision of the CAL 4 scatter is poor. Verify that the SG sensor is properly connected and hydrated.</p> <p>Inspect the pipette for damage by moving it with the Pipette Replacement Assistant. Select Next 3 times without performing the actions, and select OK.</p> <p>Ensure that the pipette dispenses the sample properly by performing a system sequence test with the system cover open.</p> <p>Verify that the external waste bottle is draining properly.</p> <p>Calibrate.</p> <p>If the error persists, contact your local technical support provider.</p>
E4403 - An out of range error occurred in the crop origin.	Adjust the mechanical alignment of the camera and repeat the optical calibration.
E4404 - An exposure/white balance error occurred.	<p>The average RGB signal is out of range after the system adjusted the exposure/white balance.</p> <p>Verify that all 4 LED lights illuminate when you turn them on.</p> <p>Check the illumination assembly for dirt and debris and clean, if necessary.</p> <p>Repeat the optical calibration.</p>
E4405 - An overall image uniformity error occurred.	<p>The uniformity of illumination over the entire field of view is out of range.</p> <p>Check the illumination assembly for dirt and debris and clean, if necessary.</p> <p>Verify that all 4 LED lights illuminate when you turn them on.</p> <p>Repeat the optical calibration.</p>
E4406 - An image error occurred in the camera.	<p>The camera recorded an image with the LED lights off, which indicates a possible light leak.</p> <p>Check the system cover and the back panel to ensure they are completely closed and properly secured.</p> <p>Repeat the optical calibration.</p>

Error Code and Message	Corrective Action
E4407 - An error occurred during the camera alignment.	<p>The upper left alignment of the camera to the card is out of range.</p> <p>Check the mechanical alignment of the camera.</p> <p>Check if the card is properly aligned and repeat the optical alignment.</p>
E4408 - An error occurred during the camera alignment.	<p>The upper right alignment of the camera to the card is out of range.</p> <p>Check the mechanical alignment of the camera.</p> <p>Check if the card is properly aligned and repeat the optical alignment.</p>
E4409 - A uniformity error occurred in the column image.	<p>The column image uniformity is poor along the test column.</p> <p>Check if the illumination assembly is free of dirt and debris.</p> <p>Verify that all 4 LED lights illuminate when they turn on.</p> <p>Repeat the optical calibration.</p>
E4410 - A red-green difference error occurred.	<p>Check if the illumination assembly is free of dirt and debris.</p> <p>Verify that all 4 LED lights illuminate when they turn on.</p> <p>Repeat the optical calibration.</p>
E4411 - A blue-green difference error occurred.	<p>Check if the illumination assembly is free of dirt and debris.</p> <p>Verify that all 4 LED lights illuminate when they turn on.</p> <p>Repeat the optical calibration.</p> <p>If the error persists, contact your local technical support provider.</p>
E4412 - A range error occurred in the LED drive current.	<p>The illumination adjustment cannot be completed within the acceptable limits of the drive current.</p> <p>Check if the illumination assembly is free of dirt and debris.</p> <p>Verify that all 4 LED lights illuminate when they turn on.</p> <p>Repeat the optical calibration.</p>

Error Code and Message	Corrective Action
E4413 - Shutter Width Exceeded Maximum Value Failure	<p>The Exposure Adjustment test failed because the shutter width exceeded the maximum allowable value.</p> <p>Verify that the LEDs are working and camera is not obstructed. To reset the camera to the default settings, select Reset and the repeat the exposure adjustment test.</p>
E4420 - The dark test failed. Too many bad pixels were found.	<p>Inspect the system cover and connector panel to ensure they are completely closed and properly secured. Repeat the exposure adjustment. If the failure persists, inspect the camera and LED lights.</p>
E4600 - A positional calibration factor difference error occurred.	<p>The difference in the image uniformity adjustments from the previous calibrations is large.</p> <p>Repeat calibration up to 3 times.</p> <p>If the error persists, contact your local technical support provider.</p>
E4601 - An average RGB out of range dark test error occurred.	<p>The image taken with the illumination off indicates a light leak.</p> <p>Ensure the system cover and the back panel are completely closed and properly secured.</p> <p>To clear the error, perform the optical_imaging test. Select System > Diagnostics > Hardware Tests > Optical > Imaging.</p> <p>If the error persists, contact your local technical support provider.</p>
E4602 - An RGB standard deviation dark test error occurred.	<p>The image taken with the illumination off indicates a light leak.</p> <p>Check the system door and the back panel to ensure they are completely closed and properly secured.</p> <p>To clear the error, perform the optical imaging test by selecting System > Diagnostics > Hardware Tests > Optical > Imaging.</p> <p>If the error persists, contact your local technical support provider.</p>

Error Code and Message	Corrective Action
E4603 - A pixels out of range dark test error occurred.	<p>Check the system cover and the back panel to ensure they are completely closed and properly secured.</p> <p>To clear the error, perform an optical test by selecting System > Diagnostics > Hardware Tests > Optical > Imaging.</p> <p>If the error persists, contact your local technical support provider.</p>
E4604 - A positional calibration factor out of range error occurred.	<p>Repeat calibration by selecting System > Calibration.</p> <p>If the error persists, contact your local technical support provider.</p>
E4605 - An insufficient positional calibration data error occurred.	<p>If the error persists, contact your local technical support provider.</p>
E4606 - An exposure change error occurred.	<p>The system detected the exposure change during sample testing. The illumination or the camera exposure setting has changed since the last calibration.</p> <p>Calibrate by selecting System > Calibration.</p> <p>If the error persists, contact your local technical support provider.</p>
E4700 - A clarity measurement error occurred.	<p>The precision of recent scatter measurements in the rinse solution is poor.</p> <p>Verify that the SG sensor is properly connected and hydrated.</p> <p>Inspect the pipette for damage by moving it with the Pipette Replacement Assistant. Select Next 3 times without performing the actions, and select OK.</p> <p>Ensure that the pipette dispenses the sample properly by performing a system sequence test with the system cover open.</p> <p>Verify that the external waste bottle is draining properly.</p> <p>Calibrate.</p> <p>If the problem persists, replace the SG sensor.</p> <p>Calibrate.</p>

Error Code and Message	Corrective Action
E4800 - A humidity exposure error occurred.	<p>Discoloration of the leukocyte reagent indicates it has deteriorated from exposure to humidity. The system did not use this test and did not test this sample. Repeat the test.</p> <p>If the error persists, load a new cassette.</p> <p>If the error still persists, contact your local technical support provider.</p>
E4801 - A test pad dispense error occurred.	<p>The pipette did not dispense enough of the sample on 1 or more test pads. Inspect the pipette for damage by moving it with the Pipette Replacement Assistant. Select Next 3 times without performing the actions, and select OK. Ensure that the pipette dispenses the sample properly by performing a system sequence test with the system cover open.</p> <p>If the problem persists, replace the SG sensor. Calibrate.</p>
E4900 - A pre-test ambient light error occurred.	<p>The image taken with the illumination off indicates a light leak.</p> <p>Check the system cover and the back panel to ensure they are completely closed and properly secured.</p> <p>Repeat the patient test.</p> <p>If the error persists, perform an optical test by selecting System > Diagnostics > Hardware Tests > Optical > Imaging.</p> <p>If the error still persists, contact your local technical support provider.</p>

Error Code and Message	Corrective Action
E4901 - A pre-test SG rinse outlier error occurred.	<p>Verify that the SG sensor is properly connected and hydrated. Inspect the pipette for damage by moving it with the Pipette Replacement Assistant. Select Next 3 times without performing the actions, and select OK.</p> <p>Ensure that the pipette dispenses the sample properly by performing a system sequence test with the system cover open.</p> <p>Verify that the external waste bottle is draining properly and that the Rinse Solution was made properly. Clean.</p> <p>If the problem persists, replace the SG sensor and calibrate. If the error persists, contact your local technical support provider.</p>

Error Messages without Error Codes

To troubleshoot error messages without error codes, look up the error message in *Table 5-7* to find the system behavior and corrective action.

For further assistance, contact your local technical service provider (see *Appendix B, Warranty and Support Information*).

Table 5-7: Troubleshooting the Error Conditions

Error Condition	System Behavior	Corrective Action
<ul style="list-style-type: none"> • The tube is capped. • The tube contains a low volume sample. 	<p>If you enable the Stop on Error setting, the system stops processing the samples.</p> <p>If you disable the Stop on Error setting, the system skips the sample and continues processing the remaining samples.</p>	<p>See <i>Troubleshooting the Internal Barcode Reader</i>, page 125.</p> <p>For a low volume sample, verify that the sample volume is 2 mL.</p> <p>For details about the Stop on Error option, see <i>Operations Settings</i>, page 190.</p>

Error Condition	System Behavior	Corrective Action
<ul style="list-style-type: none"> • No tests remain in the cassette. • The rinse bottle is empty. • The waste bottle is full. • The card waste drawer is full. • The patient database storage is full. • The system cover is open. 	The system stops processing the samples.	<ol style="list-style-type: none"> 1. Perform the task that clears the error. 2. If applicable, on the Patient Results or Patient Missing Data screen, select View and navigate to the last patient result. 3. Note the tube position in the rack of the last sample the system processed. 4. To avoid retesting racks, remove them. 5. To restart the testing, see <i>Recovering from Rack Handler Errors</i>, page 122.
If errors occur in the following hardware: <ul style="list-style-type: none"> • Barcode readers • Card handler • Fluidic • LIS connectivity • Optical • Rack handler • RFID • SD storage • Touch screen • USB port 	The system stops processing the samples.	Perform a hardware test to clear an error, and then restart the testing. If the error persists, contact your local technical support provider.
If errors occur for the following reasons: <ul style="list-style-type: none"> • Interprocessor communication • Test processor 	The system stops processing the samples.	Contact your local technical support provider to report this error.

Inspecting the Pipette

Some error messages prompt you to inspect the integrity and alignment of the pipette tip. Use the Pipette Replacement Assistant to inspect the pipette.

Note Before you proceed, be sure to close the cover.

1. Remove all of the racks on the rack handler.
2. Select **System > Diagnostics > Replace or Adjust > Replace Pipette**.
3. Select **Replace**, and then select **Next** 3 times without performing the actions.

A message displays informing you that the system is ready to move the pipette.

4. To move the pipette forward (toward you) and down, select **OK**.
5. After the pipette stops moving, open the system cover and locate the pipette system.
6. To determine if the translucent pipette tip is frayed, crushed, or bent, place a piece of dark colored paper behind the pipette tip, and observe.
7. To inspect all of the sides of the pipette tip, use a flashlight.
8. To advance to the end of the Pipette Replacement Assistant, perform these steps:
 - a. Select **Next** 4 times.
 - b. Select **Done**.

If you cannot determine any pipette damage from the inspection, perform a sample cycle test:

1. Select **System > Diagnostics > Hardware Tests > System Sequence**.
2. If the system cover is closed, open it.
3. Follow the onscreen instructions.
4. Observe the pipette as it dispenses the sample on the test pads for any irregularities such as dispensing sample on areas other than the test pads.
5. Select **OK**.
6. Select **Exit**.

If you still cannot determine any pipette damage, calibrate by selecting **System > Calibration**.

If the problem persists, contact your local technical support provider.

Working with Error Logs

To analyze and determine how to correct operator and system errors, you can view and print the errors in the error log. The error log information can help your local technical service provider or a Siemens Service Representative help you possibly fix the issues.

1. Select **System > Diagnostics > Logs > Error Log**.

A list of errors in the log displays. For each error message, the list contains the date and time, error code, and error message.

2. To navigate the error list, use the scroll arrows.
3. To view the details of an error message, perform these steps:
 - a. Select an error message in the error log.
 - b. Read the details
 - c. Select **OK**.
4. To print the errors, perform 1 of the following tasks:
 - To print all of the errors, select **Print All**.
 - To print the 10 most recent errors from the log, select **Print Last 10**.
5. Select **Exit**.

Exporting the Event Logs

The system creates 1 event log per day and stores up to 15 event logs.

You can export the event logs to help your local technical service provider or a Siemens Service Representative troubleshoot and diagnose system problems.

1. Select **System > Diagnostics > Logs > Event Log**.

A list of daily event logs displays. For each event log, the file name includes the date in the following format: Novus_YYYYMMDD. For example, Novus_20140204.log.

2. Navigate to the event log you want and select it.
3. Export the event log:
 - a. Insert an FAT32 formatted USB memory stick in a USB port.

Note The system recognizes only the first USB memory stick that you insert. If you insert more than 1 USB memory stick, the system ignores the additional sticks.

- b. Select **Export**.
4. When prompted, remove the USB memory stick.
5. Select **Exit**.

Contacting Your Technical Support Provider

Contact your local technical support provider when any of the following situations occur:

- If the error message continues to display after you perform the steps in the onscreen instructions.
- If you cannot correct the problem after you perform the hardware tests (see *Performing Hardware Diagnostic Tests*, page 160) or use the troubleshooting information in this section.
- If additional assistance is required concerning a system problem.
- If you cannot isolate the problem or it is beyond the scope of this manual.

Before you call for assistance, use the Pre-Service Checklist, as explained in the next section, *Using the Pre-Service Checklist*.

The results from the hardware tests can help your local technical service provider determine the cause of an error or system problem.

Contact your local technical support provider for information and assistance.

Using the Pre-Service Checklist

- Before you call for system service, collect only the information stated in the Pre-Service Checklist that relates to your system problem.
- Complete only the section related to your system problem. The checklist is organized in alphabetical order by hardware and software categories.
- Use the checklist to help your local technical support provider identify the probable cause of your system malfunction and resolve it.

CLINITEK Novus Analyzer Pre-Service Checklist		Yes	No
What is the software version? (Select System > About the System.) _____			
Calibration and Quality Control			
1. If you cannot complete calibration or if you obtain incorrect control results, answer the following questions:	<input type="checkbox"/>	<input type="checkbox"/>	
Has the cassette been removed from the system for any amount of time?	<input type="checkbox"/>	<input type="checkbox"/>	
Have the calibrator solutions passed their expiration dates?	<input type="checkbox"/>	<input type="checkbox"/>	
Have the bottles of control strips passed their expiration dates or have the control solutions passed their use life (8 hours)?	<input type="checkbox"/>	<input type="checkbox"/>	
2. Did you perform the system sequence test? Select System > Diagnostics > Hardware Tests > System Sequence . Did the test pass or fail? _____ Answer the questions for the system sequence test in the Patient Testing section, question #1.	<input type="checkbox"/>	<input type="checkbox"/>	
Internal Barcode Reader			
1. If tube detection errors occur, answer the following questions:			
Has the optic window of the internal barcode reader been cleaned?	<input type="checkbox"/>	<input type="checkbox"/>	
What is the JADAK version? (Select System > About the System.) _____	<input type="checkbox"/>	<input type="checkbox"/>	
2. Did you perform the internal barcode reader test? Select System > Diagnostics > Hardware Test > Barcode Readers > Internal . Follow the onscreen instructions. Did the test pass or fail? _____	<input type="checkbox"/>	<input type="checkbox"/>	
Optical			
1. Do the LED lights illuminate brightly when you perform a system sequence test? Place 1 tube of saline solution in position 1 in a rack on the rack handler. Open the system cover. Select System > Diagnostics > Hardware Tests > System Sequence to test all 4 LED lights.	<input type="checkbox"/>	<input type="checkbox"/>	
2. Did you perform the optical test? Select System > Diagnostics > Hardware Tests > Optical > Imaging . Did the test pass or fail? _____	<input type="checkbox"/>	<input type="checkbox"/>	
Patient Testing			
1. Did you perform the system sequence test? Open the system cover. Select System > Diagnostics > Hardware Tests > System Sequence . Did the test pass or fail? _____	<input type="checkbox"/>	<input type="checkbox"/>	
Did the rack handler move the rack to the sampling area?	<input type="checkbox"/>	<input type="checkbox"/>	
Did the card handler advance the card by 1 set of test pads?	<input type="checkbox"/>	<input type="checkbox"/>	
Did the pipette move to the sampling area?	<input type="checkbox"/>	<input type="checkbox"/>	
Did the pipette aspirate and dispense the sample successfully?	<input type="checkbox"/>	<input type="checkbox"/>	
Did all 4 LED lights illuminate?	<input type="checkbox"/>	<input type="checkbox"/>	
Did the rack handler move the rack to the unloading area?	<input type="checkbox"/>	<input type="checkbox"/>	
2. Are the control test results correct?	<input type="checkbox"/>	<input type="checkbox"/>	

CLINITEK Novus Analyzer Pre-Service Checklist		Yes	No
3. Do error or warning messages display in the Status log when you test the patient or control samples?		<input type="checkbox"/>	<input type="checkbox"/>
4. If so, what are they? (List the error number and description.) _____		<input type="checkbox"/>	<input type="checkbox"/>
Printer, LIS, Handheld Barcode Reader			
1. Is an external device being used? If so, what is the device? _____		<input type="checkbox"/>	<input type="checkbox"/>
2. Is the printer and/or LIS connected and powered on?		<input type="checkbox"/>	<input type="checkbox"/>
3. If your printer is connected to a USB port, did you perform the USB port test? Select System > Diagnostics > Hardware Test > USB Port . Did the test pass or fail? _____		<input type="checkbox"/>	<input type="checkbox"/>
4. Is the printer properly printing the test results? Perform the printer hardware test. Select System > Diagnostics > Hardware Test > Printer . Did the test pass or fail? _____		<input type="checkbox"/>	<input type="checkbox"/>
5. Did you select the correct settings for sending data? (See <i>Devices Settings</i> , page 205.)		<input type="checkbox"/>	<input type="checkbox"/>
6. Is the LIS receiving the correct data? Do the results correspond with the screen?		<input type="checkbox"/>	<input type="checkbox"/>
Did you perform the LIS connectivity test? Select System > Diagnostics > Hardware Test > LIS Connectivity . Did the test pass or fail? _____		<input type="checkbox"/>	<input type="checkbox"/>
7. Is the handheld barcode reader working properly?		<input type="checkbox"/>	<input type="checkbox"/>
8. Did you perform the handheld barcode reader test? Select System > Diagnostics > Hardware Test > Barcode Readers > Handheld . Follow the onscreen instructions. Did the test pass or fail? _____		<input type="checkbox"/>	<input type="checkbox"/>
9. What is the JADAK version? (Select System > About the System .) _____		<input type="checkbox"/>	<input type="checkbox"/>
Rack Handler			
1. Did you clean the loading and unloading areas, rack sensors, racks, and rack pushers? (See <i>Cleaning the Rack Pushers and Sensors</i> , page 96.)		<input type="checkbox"/>	<input type="checkbox"/>
2. Did you perform the rack hardware test? Select System > Diagnostics > Hardware Tests > Rack . Did the test pass or fail? _____		<input type="checkbox"/>	<input type="checkbox"/>
Startup			
1. Restart the system. Do the CLINITEK Novus analyzer screen and Home screen display in 45 seconds?		<input type="checkbox"/>	<input type="checkbox"/>
2. If the answer to question #1 is No, is the system plugged into a live AC electrical outlet?		<input type="checkbox"/>	<input type="checkbox"/>
3. Is the onscreen keyboard operating properly? If not, perform the touch screen calibration test. Select System > Diagnostics > Hardware Test > Touch Screen .		<input type="checkbox"/>	<input type="checkbox"/>
Waste and Rinse Systems			
1. If you use internal rinse and waste bottles, do the waste and rinse level indicators on the Home screen match the level of the internal rinse and waste bottles?		<input type="checkbox"/>	<input type="checkbox"/>
2. Is the external waste bottle full?		<input type="checkbox"/>	<input type="checkbox"/>
3. Did you add CLINITEK Novus Rinse Additive to the distilled or deionized water?		<input type="checkbox"/>	<input type="checkbox"/>

Performing Hardware Diagnostic Tests

You can perform hardware diagnostic tests on the system components, as described in *Table 5-8*.

Table 5-8: Hardware Tests

Hardware Test	Description
Touch screen	Checks the touch screen for dead spots.
Barcode readers	Checks the internal and handheld barcode readers to determine if they work properly.
Printer	Prints a test report so that you can determine if the printer works properly.
LIS connectivity	Determines if the LIS (host computer) and the system can communicate, and tests the configuration.
USB port	Checks the USB storage functionality of both USB ports.
RFID reader	Checks the Radio Frequency Identification (RFID) tag read and write functionality.
Optical system	Checks if the optical system is working properly, displays an image so that you can determine the focus quality, and if the 4 LED lights are working.
Fluidic system	Checks the fluid dispenser and recovers motor position errors.
Rack handler	Checks the rack handler and recovers motor position errors.
Card handler	Allows you to home the test card transport system, test the card handler motors, and verify that the sensors work.
System Sequence	Checks the aspiration and dispense functions for a sample, including the optical, fluidic, card handler, and rack handler systems.
SD storage	Checks the functionality and capacity of both Secure Digital (SD) cards, P1 and P2.

1. Select **System > Diagnostics > Hardware Tests**.
2. If prompted, enter a password.
3. Select a hardware test.

4. Perform the steps, as described in *Table 5-9* .
5. Select **Exit**.
6. If a test fails, repeat the test.
7. If the test fails again, contact your local technical support provider.

Table 5-9: Hardware Tests

Test	Procedure
Touch screen	<p>1. Select Touch Screen.</p> <p>2. Select Start. A screen keyboard displays 48 buttons, which allows you to select each button to test whether the touch screen works for that area.</p> <p>3. Select each of the 48 buttons on the screen keyboard in 90 seconds. If you select all of the buttons in 90 seconds, the keyboard screen closes. A message displays indicating that the test passed. Select OK. If you do not select all of the 48 buttons in 90 seconds, the keyboard screen closes. A message displays indicating that the test failed. Select OK.</p>
Barcode reader (handheld)	<p>1. Select Barcode Readers > Handheld.</p> <p>2. Scan a barcode using the handheld barcode reader. If the scan is successful, the scanned barcode displays in the list. Up to 5 scanned barcodes display in the list at 1 time. For each barcode you scan, the system adds the scanned barcode to the top of the list. The previously scanned barcodes move down in the list. The list can contain up to 100 barcodes. If the scanned barcode exceeds the maximum length, the data truncates on the right. If the scan fails, the scanned barcode does not display in the list and an error message displays.</p> <p>3. To clear the barcodes in the list, select Clear Data.</p>

Test	Procedure
Barcode reader (internal)	<ol style="list-style-type: none">1. Select Barcode Readers > Internal.2. Select Start.3. Read the onscreen instructions. The system tests the cap and tube detection of the internal barcode reader. If the internal barcode reader recognizes an empty tube without a cap in the first position in a rack and a capped tube in the second position in the same rack, the test passed. If the internal barcode reader does not recognize an empty tube without a cap in the first position in a rack and a capped tube in the second position in the same rack, the test failed. <p>Note If the tubes have barcodes, the barcode data displays in the Test Result box. If the tubes do not have barcodes, the test does not fail.</p>
Printer	<ol style="list-style-type: none">1. Verify that you enabled the Printer setting.2. Select Printer.3. Select Start. If the printer test passed, the system prints a test printer report. If the printer test failed, the report does not print and an error message displays.

Test	Procedure
LIS connectivity	<p>1. Select LIS Connectivity. To transmit the result test, select Send Result Test. To transmit a debug message for the result test, select Send Debug Message. To save the result test and debug message, insert an FAT32 formatted USB stick.</p> <p>2. Select Start. The test uses the current LIS settings to transmit a message to the LIS, and wait for a reply. If the system receives a reply from the LIS, the test passed. If the LIS does not respond or a communication error occurs, the test failed.</p>
USB port	<p>1. Insert a USB memory stick in a USB port. The system recognizes only the first USB memory stick that you insert. If you insert more than 1 USB memory stick, the system ignores the additional sticks.</p> <p>2. Select USB Port.</p> <p>3. Select Start. The system performs the following tasks: Creates a file. Writes the file to the USB memory stick. Opens the file on the USB memory stick. Verifies that the content of the new file matches the file on the USB memory stick. If the USB port test is successful, a message displays informing you that the test passed. If the USB port test fails, an error message displays in the Test Result box.</p> <p>4. Select Exit.</p> <p>5. When prompted, remove the USB memory stick.</p>

Test	Procedure
RFID	<p>1. Select RFID. 2. Select Start.</p> <p>The system performs the following tasks: Attempts to detect a cassette. Attempts to write and read data to and from the test area on the RFID tag in the cassette. If the RFID test passed, a message displays informing you that the test passed. If the RFID test failed, an error message displays in the Test Result box.</p>
Optical Imaging	<p>Note Do not open the system cover. If you do, the test fails.</p> <p>1. Select Optical > Imaging. 2. Select Start.</p> <p>The camera records a dark image without the flash. The system analyzes the data and checks if the image reference results are within acceptable limits for the image.</p> <p>3. Observe the pipette opening in the system cover to see the LED lights flashing, as the camera records a light image with the flash. The system analyzes the data and checks if the image reference results are within acceptable limits for the image. If the image results are within acceptable limits, the test passed. The system displays an image of the card platform, and 1 or more sets of test pads, if a card is on the platform. If hardware errors occur or the images are outside of acceptable limits, the test failed.</p>

Test	Procedure
Optical LED	<p>Note This test can only be conducted when the system cover is open.</p> <ol style="list-style-type: none"> 1. Select Optical > LED. 2. Open the system cover and locate the 4 LED lamps inside of the instrument. 3. Select Start. 4. Observe the 4 LED lamps during the test. To begin the test, select Start. <p>If all 4 LED lamps turned on during the test, the test passed.</p> <p>If 1 or more LED lamps did not turn on during the test, the test failed. Report the failure to your local technical support provider.</p>
Fluidic	<ol style="list-style-type: none"> 1. Select Fluidic. 2. Select Start. <p>The test re-homes all of the components in the fluidic system, primes the pump, and then performs a rinse cycle.</p> <p>If the test re-homed the fluidic system without any errors, the test passed.</p> <p>If the system cannot re-home the fluidic system, the test failed. An error message displays in the Test Result box.</p>
Rack handler	<ol style="list-style-type: none"> 1. Select Rack Handler. 2. Select Start. <p>The test re-homes all of the components in the rack handler and consolidates the racks to test the rack mechanisms.</p> <p>If the test re-homed the rack handler and completed without any errors, the test passed.</p> <p>If the system cannot re-home the rack handler, an error message displays in the Test Result box.</p>

Test	Procedure
Card handler	<ol style="list-style-type: none">1. Select Card Handler.2. Select Start. The test homes and exercises all of the motors. If a test card is on the card platform, the system ejects the card. If the test homed the card handler and completed without any errors, the test passed. If the system cannot home the card handler, the test failed. An error message displays in the Test Result box.

Test	Procedure
System Sequence	<p>1. Add at least 2 mL of saline solution to a tube and insert the tube in a rack on the rack handler.</p> <p>2. Select System Sequence.</p> <p>3. Select Start.</p> <p>4. To observe the tasks that the system performs to aspirate and dispense a sample, open the system cover.</p> <p>Positions a tube in the sampling area.</p> <p>Moves the pipette out and aspirates the sample from the tube.</p> <p>Moves out a card and dispenses the sample on the pads.</p> <p>Cleans the pipette.</p> <p>Ejects the rack.</p> <p>Takes an image of the test pads.</p> <p>If the test completed without any errors, the test passed.</p> <p>If an error message displays in the Test Result box, the test failed.</p>
SD storage	<p>1. Select SD Storage.</p> <p>2. Select Start.</p> <p>The test verifies that the SD card can read and write data and verifies the capacity of the SD card. The read and write verification creates a file, writes to it, and reads what is written to verify it. The capacity verification checks if the total storage space is adequate.</p> <p>If the test completed without any errors, the test passed.</p> <p>If an error message displays in the Test Result box, the test failed.</p>

6 Results and File Management

This section covers the following topics:

- Recalling the Patient, Control, and Calibration Results
- Recalling the Last Patient Test Results
- Deleting Results

Recalling the Patient Results

1. Select **Results > Patient**.
2. If prompted, enter a password.
3. Select the search criteria.

Search Criteria	Procedure
Date range	<ol style="list-style-type: none">1. Select Date Range.2. Select a start date.3. Select an end date.4. Select Enter.
Sample ID	<ol style="list-style-type: none">1. Select Sample ID.2. To search for 1 sample ID, enter the complete sample ID from the screen keyboard or from a barcode label with the handheld barcode reader.3. To search for a group of sample IDs, enter only the numbers that all of the records in the group have in common, with a percent sign (%). For example, if you enter 1250%, the system recalls only the results with a sample ID that begins with 1250.4. Select Enter.
Cassette lot number	<ol style="list-style-type: none">1. Select Cassette Lot Number.2. Enter a cassette lot. If you do not know the entire number, enter a partial number with a percent sign (%). For example, if you enter 125%, the system recalls only the lots that begin with 125.3. Select Enter.

Search Criteria	Procedure
Operator ID	<ol style="list-style-type: none">1. Select Operator ID.2. Enter an operator ID. If you do not know the entire name, enter a partial name with a percent sign (%). For example, if you enter Smi%, the system recalls only the lots that begin with Smi.3. Select Enter.
All results	Select All Results .
Abnormal results	Select Abnormal .
Confirmatory sieve	Select Confirmatory Sieve .
Microscopic sieve	Select Microscopic Sieve .

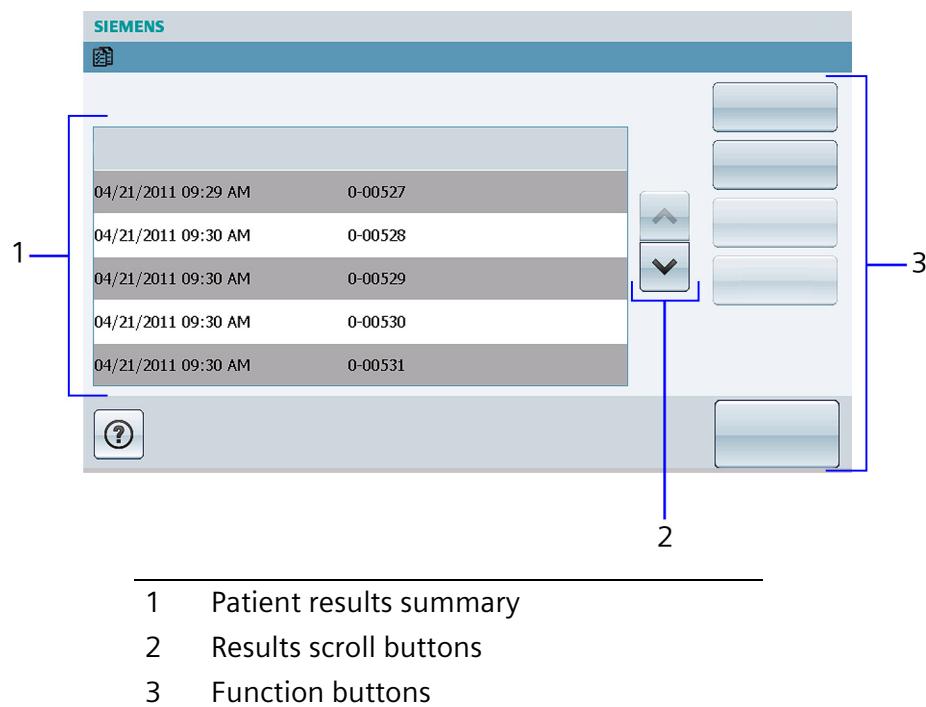
Search Criteria	Procedure
Sequence number by range	<ol style="list-style-type: none">1. Select Seq. No.2. Select Range Start.3. Select Change.4. Select Patient or STAT.5. Enter the lowest sequence number in the group of results you want to recall, and select Enter. For a patient sequence number, enter a prefix (0–9), a hyphen (-), and 5 numbers. For example, 0-45892. For a STAT sequence number, enter 5 numbers. For example, S-12345.6. Select Change.7. Select Patient or STAT.8. Enter the highest sequence number in the group and select Enter. To recall only 1 result, enter the same number for the Start and End sequence numbers. To recall a group of patient and STAT results, enter the lowest patient sequence number and highest STAT sequence number in the group. For example, 1-00030 to S-00825.9. Select Enter. The system searches for the results with the same prefix from the lowest to the highest sequence number, inclusive.

Search Criteria	Procedure
Sequence number by the lowest to the highest number	<ol style="list-style-type: none">1. Select Seq. No.2. Select Lowest Number  Start.3. Select Patient or STAT.4. Enter the lowest start sequence number in the group of results you want to recall. For a patient sequence number, enter a prefix (0–9), a hyphen (-), and 5 numbers. For example, 0-45892. For a STAT sequence number, enter 5 numbers. For example, S-12345.5. Select Enter. The system searches for the results with the same prefix (patient or STAT) from the lowest to the highest sequence number, inclusive.

Viewing the Patient Results

The **Results Patient** screen displays the number of results that meet the search criteria, along with the results that meet the search criteria. The most recent results display at the top of the patient results summary.

Figure 6-1: Results Patient Screen



Working with Patient Results

1. To navigate the patient results summary, select a scroll arrow.
2. The function buttons allow you to perform various tasks with the patient results. To view, delete all, print all, send all patient results to the LIS, or export patient results to a USB stick, select the corresponding function button.

Note To export patient data, insert an FAT32 formatted USB stick and select **Export**.

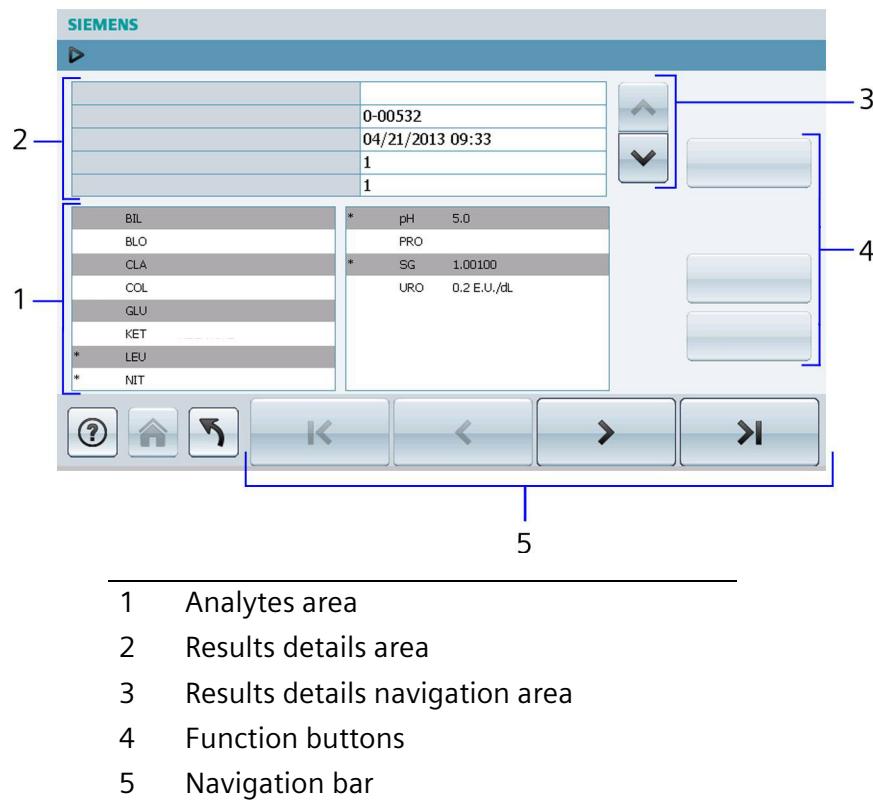
Note For details about deleting results, see *Deleting Results*, page 185.

Viewing the Patient Result Details

1. Select a patient result in the summary.
2. Select **View**.

- To navigate the details, select a scroll button.

Figure 6-2: Results Patient Details Screen



- Read the information in the analytes area.

A symbol represents an analyte flag, which displays next to a sequence number for a sample that meets the following criteria:

Table 6-1: Patient Sample Analyte Flags

Symbol	Description
^	Range adjusted
‡	Sieve
*	Abnormal
†	Sample Quality

- To navigate the results, use the **Navigation bar**.
- To display patient comments, delete or print results, or send results to the LIS, select a function button.

Note The database can hold up to 7500 patient records. Exporting the entire database will take 15 minutes.

Exporting the Patient Results

You can export the patient results as a tab-delimited text file to an FAT32 formatted USB memory stick.

1. Select **Results > Sample > Export**.
2. Insert an FAT32 formatted USB memory stick in a USB port.

Note The system recognizes only the first USB memory stick that you insert. If you insert more than 1 USB memory stick, the system ignores the additional sticks.

3. Select **Export**.
4. Select **OK**.
5. When prompted, remove the USB memory stick.

You can copy the data from the text file to a worksheet or database to perform data analysis.

Recalling the Control Results

1. Select **Results > Control**.
2. If prompted, enter a password.
3. Select the search criteria.

Search Criteria	Procedure
Date range	<ol style="list-style-type: none">1. Select Date Range.2. Select a start date.3. Select an end date.4. Select Enter.
Control lot	<ol style="list-style-type: none">1. Select Control Lot.2. Enter a control lot. If you do not know the entire number, enter a partial number with a percent sign (%). For example, if you enter 125%, the system recalls only the lots that begin with 125.3. Select Enter.

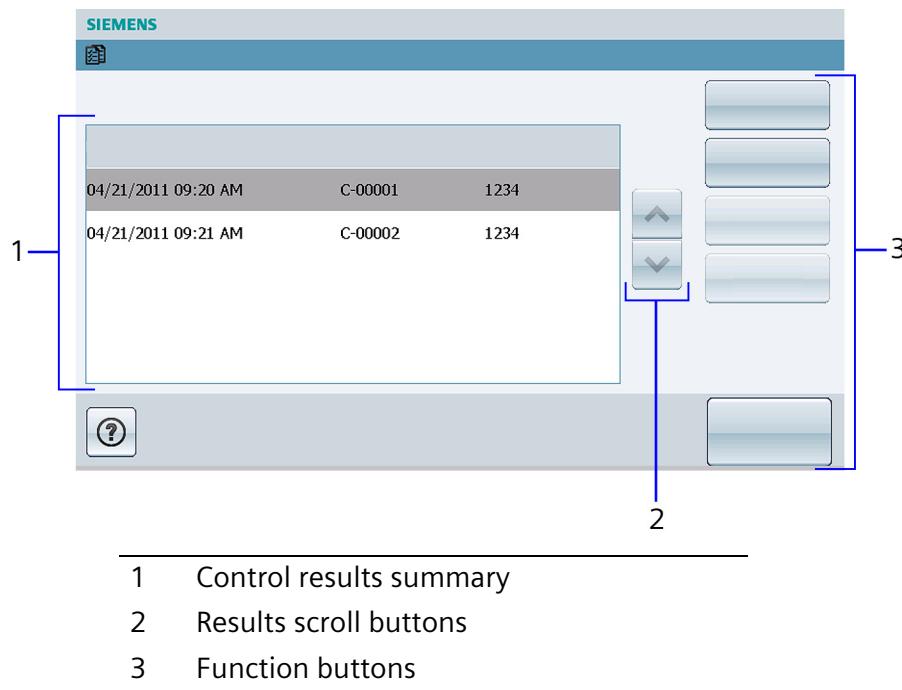
Search Criteria	Procedure
Cassette lot	<ol style="list-style-type: none">1. Select Cassette Lot.2. Enter a cassette lot.3. Select Enter.
Operator ID	<ol style="list-style-type: none">1. Select Operator ID.2. Enter an operator ID. <p>Note If you do not know the entire name, enter a partial name with a percent sign (%). For example, if you enter Smi%, the system recalls only the lots that begin with Smi.</p> <ol style="list-style-type: none">3. Select Enter.
All results	Select All Results .

Search Criteria	Procedure
Sequence number by range	<p>1. Select Seq. No.</p> <p>2. Select Range Start.</p> <p>3. Select Change.</p> <p>4. Enter the lowest sequence number of the group of results you want to recall, and select Enter. For a control sequence number, enter 5 numbers. For example, C-45892.</p> <p>5. Select Change.</p> <p>6. Enter the highest sequence number in the group, and select Enter.</p> <p>7. Select Enter. The system searches for the results with the same prefix from the lowest to the highest sequence number, inclusive.</p> <p>Note To recall only 1 result, enter the same number for both the Start and End sequence numbers.</p>
Sequence number by the lowest to the highest number	<p>1. Select Seq. No.</p> <p>2. Select Lowest Number Start.</p> <p>3. Enter the lowest start sequence number of the group of results you want to recall. For a control sequence number, enter 5 numbers. For example, C-45892.</p> <p>4. Select Enter. The system searches for the results with the same prefix from the lowest to the highest sequence number, inclusive.</p>

Viewing the Control Results

The **Results Control** screen displays the number of results that meet the search criteria, along with the results that meet the search criteria. The most recent results display at the top of the control results summary.

Figure 6-3: Results Control Screen



Working with Control Results

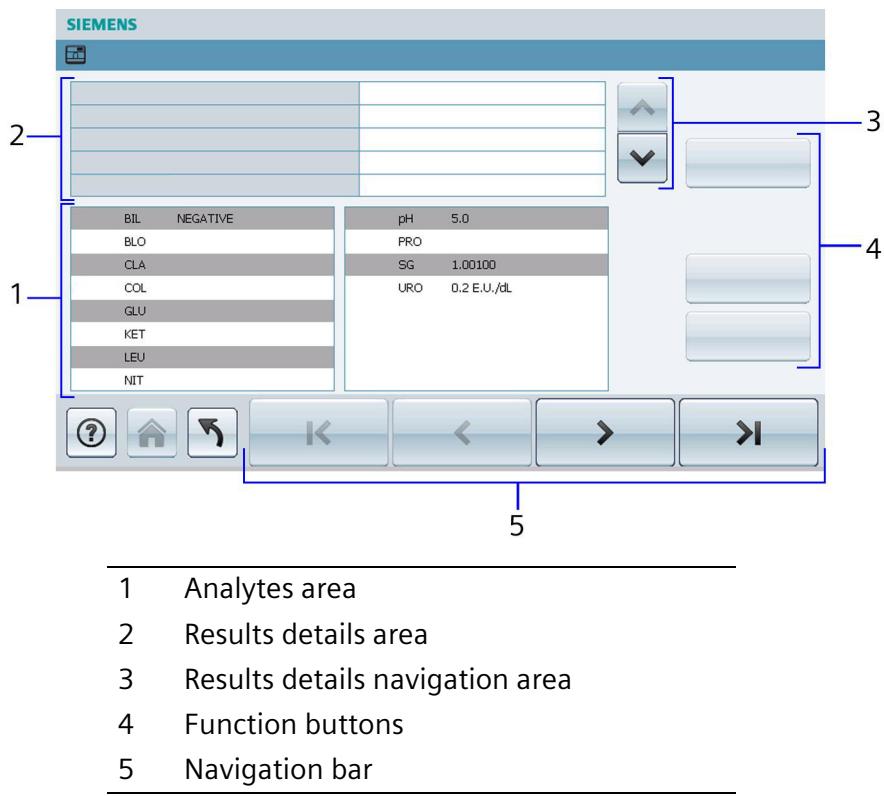
1. To navigate the summary, select a scroll arrow.
2. To view, delete all or print all results, graph all results, or send all results to the LIS, select a function button.

Note For details about deleting results, see *Deleting Results*, page 185.

Viewing the Control Result Details

1. Select a result in the control results summary.
2. Select **View**.
3. To navigate the details, select a scroll button.

Figure 6-4: Results Control Details Screen



4. Read the information in the analytes area.

A symbol represents an analyte flag, which displays next to a sequence number for a sample that meets the following criteria:

Table 6-2: Control Sample Analyte Flags

Symbol	Description
^	Range adjusted
‡	Sieve
*	Out of Expected Range
†	Sample Quality

5. To navigate the results, use the **Navigation** bar.
6. To display control comments, delete results, graph results, print results, or send the results to the LIS, select a function button.

Graphing the Control Results

You can graph the control results by the following categories, which will appear as onscreen buttons:

- Date range
- Control lot
- Cassette lot
- Operator ID
- All results

1. Select **Results > Control**.
2. Select a category.
3. Select **Graph**.
4. Select 1 or more analytes that you want to graph. A check mark beside the analyte indicates that it is selected. Each analyte will appear on its own graph.
5. Select **Enter**.
6. Select 1 or more controls that you want to graph.
7. Select **Enter**.

Working with the Control Graphs

After you have created a control graph, you can adjust the Y-axis range, and print 1 or all of the graphs.

Note The values on the Y axis are the decode values for that particular analyte and are not significant. However, the graph can be used for QC trending purposes.

To adjust the Y-axis range for a graph:

1. Select **Range**.
2. To change the minimum or maximum, select **Change**.
3. Enter the value, then select **Enter**.

To print a single graph, select **Print** or to print all graphs, select **Print All**.

Exporting the Control Results

You can export the control results as only a tab-delimited text file to an FAT32 formatted USB memory stick.

1. Select **Results > Control > Export**.
2. Insert an FAT32 formatted USB memory stick in a USB port.

Note The system recognizes only the first USB memory stick that you insert. If you insert more than 1 USB memory stick, the system ignores the additional sticks.

3. Select **Export**.
4. Select **OK**.
5. When prompted, remove the USB memory stick.

You can copy the data from the text file to a worksheet or database to perform data analysis.

Recalling the Calibration Results

1. Select **Results > Calibration**.
2. If prompted, enter a password.
3. Select the search criteria.

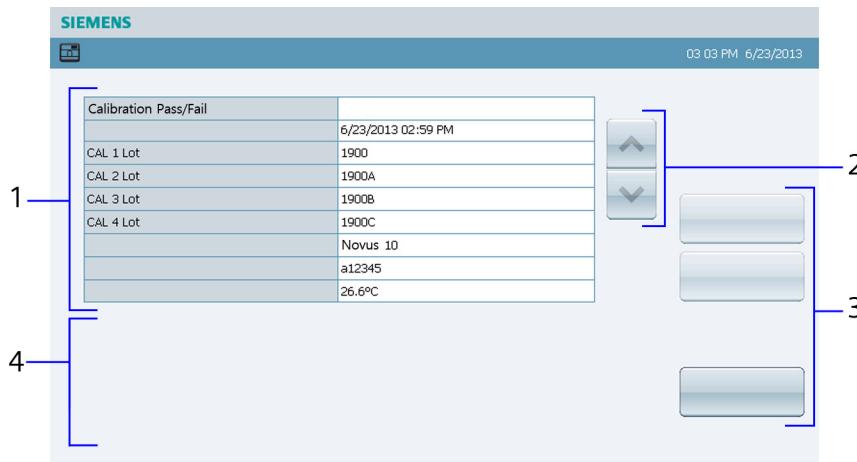
Search Criteria	Procedure
Date range	<ol style="list-style-type: none">1. Select Date Range.2. Select a start date.3. Select an end date.4. Select Enter.
Calibrator lot	<ol style="list-style-type: none">1. Select Calibrator Lot.2. Enter a calibrator lot. If you do not know the entire number, enter a partial number with a percent sign (%). For example, if you enter 125%, the system recalls only the lots that begin with 125.3. Select Enter.
Cassette lot	<ol style="list-style-type: none">1. Select Cassette Lot.2. Enter a cassette lot. If you do not know the entire number, enter a partial number with a percent sign (%). For example, if you enter 125%, the system recalls only the lots that begin with 125.3. Select Enter.

Search Criteria	Procedure
Operator ID	<ol style="list-style-type: none"> 1. Select Operator ID. 2. Enter an operator ID. If you do not know the entire name, enter a partial name with a percent sign (%). For example, if you enter Smi%, the system recalls only the lots that begin with Smi. 3. Select Enter.
All results	Select All Results .

Viewing the Calibration Results

The **Results Calibration** screen displays the number of results that meet the search criteria, along with the results that meet the search criteria. The most recent results display at the top of the calibration results summary.

Figure 6-5: Results Calibration Screen



-
- 1 Calibration results summary
 - 2 Results scroll buttons
 - 3 Function buttons
 - 4 Calibration error log
-

Working with Calibration Results

1. To navigate the summary, select a scroll arrow.
2. If the calibration failed, read the error messages in the error log beneath the calibration results details.
3. To delete all or print all results, or send all results to the LIS, select a function button.

Note For details about deleting results, see *Deleting Results*, page 185.

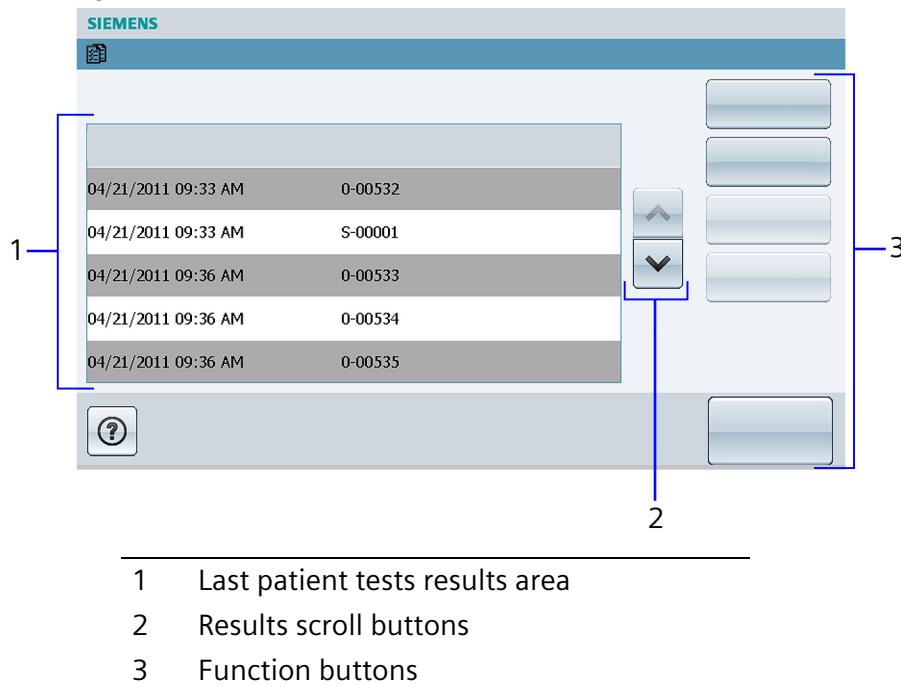
Recalling the Last Patient Tests Results

You can recall the results for the last group of patient samples you tested, based on the criteria you specify.

1. Select **Results > Last Patient Tests**.
2. If prompted, enter a password.
3. Select the search criteria, as explained in *Recalling the Patient Results*, page 169.

Viewing the Last Patient Tests Results

The **Results Last Patient Tests** screen displays the number of results that meet the search criteria, along with the results that meet the search criteria. The most recent results display at the top of the last patient tests results summary.

Figure 6-6: Results Last Patient Tests Screen

Working with the Last Group of Patient Tests

1. To navigate the summary, select a scroll arrow.
2. To view, delete all or print all results, or to send all results to the LIS, select a function button.

Note For details about deleting results, see *Deleting Results*, page 185.

Viewing the Result Details of the Last Patient Tests

1. Select a patient result in the last group of patient test results.
2. Select **View**.
3. To navigate the details, select a scroll button.

4. Read the analyte information in the analytes area.

A symbol represents an analyte flag, which displays next to a sequence number for a sample that meets the following criteria:

Table 6-3: Analyte Flags

Symbol	Description
^	Range adjusted
‡	Sieve
*	Abnormal

5. To navigate the results, use the **Navigation** bar.
6. To delete or print results, or send results to the LIS, select a function button.

Note For details about deleting results, see the next section, *Deleting Results*.

Deleting Results

Note To protect your data from unwanted deletion, enable the **Data Delete** setting. The system prompts you to enter a password before you can delete results. See *System Access Settings*, page 210.

The system stores the following maximum number of results:

- **Patient results** 7500
- **Calibration results** 200
- **Control results** 400

You can free up space for new results in the following ways:

- Delete 1 or more results that you recalled.
- Delete all of the patient results.
- Enable the **Delete Results** setting for the system to delete the oldest result (*Operations Settings*, page 190).

To delete results, follow these steps:

1. Select **Results > Delete**.
2. If you enabled the **Data Delete** setting, enter a password.
3. Select the type of results you want.
4. Select **Yes**.

7 System Configuration

This section contains information about configuring basic and advanced settings. The Siemens Service Representative has already set up your system according to your current local and laboratory usage. You might need to reconfigure the system on an as-needed basis.

For the basic settings, you do not need a password.

As a supervisor, you can restrict access to menus by configuring the advanced system settings. You would be prompted to enter a password to access those menus.

Configuring the Basic Settings

You can configure the following basic system settings without a password:

- **Date** Changes the date for the system clock.
- **Time** Changes the time for the system clock.
- **Volume** Adjusts the volume of the system speaker, which alerts you to error and warning messages.
 - **Off** Turns the system speaker off.
 - **Level 1** Low audible volume.
 - **Level 2** Medium audible volume.
 - **Level 3** High audible volume.
- **Brightness** Changes the brightness of the screen from a low level of 1 to a high level of 20.
- **Rack** If your system uses a rack and not a universal sample handler, you can enable or disable the rack circulation on the rack handler.
 - **Enable** When enabled, load the racks on both the right and left sides. The racks move from the loading area through the sampling area to the unloading area in a counterclockwise direction. Simultaneously, the racks on the opposite side move from the unloading area to across the front of the rack handler to the loading area. The system processes the racks that started in the loading area first, and the racks that started in the unloading area last. You can end the processing by placing an empty rack in the unloading area. The system always stops testing when it detects an empty rack.

- **Disable** When disabled, the racks move only from the loading area (right side) to the unloading area (left side).

The first rack moves into the sampling area. After the system tests all of the samples, the rack moves to the left and the second rack moves into position.

This process continues until 10 racks have accumulated in the unloading area (left side), at which time the system stops processing. The system always stops testing when it detects an empty rack.

- **Circulation Stop** When you enable rack circulation, you also can select the **Circulation Stop** option, whereby the system counts the racks.

The system counts the number of racks on each side of the rack handler before processing begins. The system stores the count in memory as the maximum number of racks the system is going to process.

When the rack circulation function begins, the racks move across the front of the rack handler from the left side to the right. Processing stops after the stored number of racks has been processed. The system always stops testing when it detects an empty rack.

To configure the basic settings, follow these steps:

1. Select **Setup**.
2. Select a basic setting.
3. Perform the steps as described in *Table 7-1* .

Table 7-1: Basic Settings

Configuration Setting	Procedure
Date	<ol style="list-style-type: none"> 1. Select Date. 2. Select a date format: MM/DD/YY, DD.MM.YYYY, or YYYY.MM.DD. 3. Enter or select the month, day, and year. 4. Select Save.
Time	<ol style="list-style-type: none"> 1. Select Time. 2. Select a time format: 12-hour or 24-hour. 3. Enter or select hours and minutes. 4. If you selected 12-hour, select AM or PM. 5. Select Save.
Volume	<ol style="list-style-type: none"> 1. Select Volume. 2. Select Disable or a volume level: Low, Medium, or High. 3. Select Save.
Brightness	<ol style="list-style-type: none"> 1. Select Brightness. 2. Select a brightness level from 1-20. 3. Select Save.
Rack Circulation	<ol style="list-style-type: none"> 1. Select Rack. 2. For the rack circulation option, select Enable or Disable. 3. For the Circulation Stop Method option, select Rack Count, if necessary. 4. Select Save.

Configuring the Advanced Settings

The advanced settings allow you to configure the system.

Note If you restricted access to the **Configuration** menu by enabling the **System Setup** setting, the system prompts you to enter a password to change the advanced settings.

- **Operations** Configures the interface protocol, results language and units, STAT reset time, delete results mode, screen saver message and timeout, low number of tests warning with the number of tests remaining, and workflow. The Setup Assistant steps you through configuring the system setup at 1 time instead of selecting the settings individually.
- **Sample** Sets the sample source, color reporting, color names, clarity reporting, clarity range, patient comments, controls, control checks, control names, and control comments.
- **Analyte** Allows you to select the analytes reported, analyte order, analyte ranges, normal ranges, SG precision, abnormal results marking, and sieve options.
- **Devices** Configures the LIS port, transmitted data, print format, handheld barcode reader, and remote services.
- **System Access** Enables or disables password protection for the Diagnostics, System Setup, Data Recall, and Data Delete menus. You can specify if the system prompts for an operator ID before performing a test. If you restrict access to any of the menus, you can change the user password.
- **Sequence Number** Changes the sequence number for the next patient test.

Operations Settings

Configure the following operations settings to customize the test results and operational tasks:

- **Interface Protocol** Allows you to send the results to the LIS in either of 2 protocols: ASTM (American Society of Testing Materials) and HL7 (Health Level 7). See *ASTM Software Interface*, page 222 and *HL7 Software Interface*, page 223. For the reported values available in both interface protocols, see the results tables in *Appendix D, Specifications*.
- **Languages & Units** Specifies the language for the system and the units (**Conventional**, **Conventional with Plus System**, **SI**, and **SI with Plus System**) to display the results.
The test name abbreviations and the units in which the system displays the results depend on the language and units you select. See the results tables in *Appendix D, Specifications*.
- **STAT Reset Time** Specifies the time (for example, 10:00 AM) for when the system resets the next STAT sequence number to S-00001, which occurs every 24 hours. You can customize the STAT reset time to fit the work flow in your laboratory.

- **Delete Results** Deletes the oldest patient, calibration, or control result to free up space for the new result when the database is full (**Automatic**) or allows you to delete the results to free up space for the new results (**Manual**).
- **Screen Saver** Dims the screen after a specified period of inactivity to extend the life of the screen. You can display a default or custom screen saver message.
- **Low Test Warning** Enables or disables the warning message for a low number of tests remaining. If enabled, you can select the number of tests that would cause a low test warning message to display. For example, select a number between 1 and 200.
- **Workflow** Allows you to select the **Stop on Error** option to stop processing the patient samples when the system detects an error. An error could be caused by a tube with a low volume sample or a capped tube. If you do not select the **Stop on Error** option, when the system detects an error for the sample, the system skips the sample and does not test it. The system continues processing the remaining samples.
- **Setup Assistant** Steps you through configuring the system setup instead of selecting the settings individually.

To configure the operations settings, follow these steps:

1. Select **Setup > Configuration > Operations**.
2. Perform the steps as described in *Table 7-2* .

Table 7-2: Operations Settings

Configuration Setting	Procedure
Interface Protocol	<ol style="list-style-type: none">1. Select Interface Protocol.2. Select an interface protocol.3. Select Save.
Languages & Units	<ol style="list-style-type: none">1. Select Languages & Units.2. Select a language.3. Select a unit for the results.4. Select Save.
STAT Reset Time	<ol style="list-style-type: none">1. Select STAT Reset Time.2. Select a time in hours and minutes.3. For the 12-hour time format, select AM or PM.4. Select Save.

Configuration Setting	Procedure
Delete Results	<ol style="list-style-type: none"> 1. Select Delete Results. 2. Select Automatic or Manual. 3. Select Save.
Screen Saver	<ol style="list-style-type: none"> 1. Select Screen Saver. 2. Select Default or Custom Message. 3. If you select Custom Message, select Change. Enter a message in the Screen Saver Message box with up to 20 characters. 4. To change the screen saver timeout, select a time interval in minutes. The timeout range is from 10 to 30 minutes in increments of 1 minute. 5. Select Save.
Low Test Warning	<ol style="list-style-type: none"> 1. Select Low Test Warning. 2. Select Enable or Disable. 3. If you enable the setting, you can specify a low test warning threshold with a range between 1 and 200 tests. For example, if you set the low test warning to 10 tests, the system alerts you when 10 tests remain on the cassette. 4. Select Save.
Workflow	<ol style="list-style-type: none"> 1. Select Workflow. 2. Select the Stop on Error option, if necessary. 3. Select Save.

Setup Assistant

The Setup Assistant steps you through configuring the system setup at 1 time instead of selecting the settings individually. You can set up the language, results output, system operations, and connectivity options.

1. Select **Setup > Configuration > Operations > Setup Assistant**.
2. Select a language and the results units, and then select **Next**.

Note When you change the language, the system changes the results units.

3. Select a date format and set the date, and then select **Next**.
4. Select a time format and set the time, and then select **Next**.
5. Select an interface protocol, and then select **Next**.
 - Select the LIS settings. Select an LIS port or disable it.
 - To change the **Ethernet** or the **Serial** port settings, select **Change**, and enter the values. See *Devices Settings*, page 205.
6. Select **Next**:
7. Select the test results and the test data you want to send to the LIS, and then select **Next**.
8. Select the printer and print settings.
 - Enable or disable the printer.
 - Select a page orientation.

The page orientation applies only to the Patient Results and the Control Results reports. All other reports print only in the portrait orientation.
 - To add or change a report header, select **Change**. For example, enter your hospital or laboratory name.
9. Select **Save**.

Sample and Controls Settings

Configure the following sample settings to customize the identification, description, and physical analysis for the urine samples:

- **Sample Source** Handles the source of the sample IDs. The **Disable** option disables using the sample IDs. The **Manual** option lets you enter the sample IDs after the system finishes processing the samples. The **Sample Handler** option receives the sample IDs from the rack handler or universal sample handler. If you use the rack handler, the internal barcode reader reads the sample IDs. If you use the universal sample handler, it reads the sample IDs.

If you select **Sample Handler**, and use the rack handler (not the universal sample handler), configure the barcode reader settings, as explained in *Table 7-3, Sample Settings*. The **Load List** option receives the sample IDs from the LIS.

Note To avoid labeling errors when you enter sample IDs manually, keep the handheld barcode reader enabled and use it to scan the barcode labels.

- **Color Reporting** Reports the color of a patient sample. The Report Color option lets you enable or disable the Color Reporting setting. The Determine Color option lets the system detect the color values (Automatic) or lets you enter the color values (Manual). The Abnormal Colors option lets you select the colors that you want to assign as abnormal.
- **Color Names** Allows you to assign a name to each color level.
- **Report Clarity** Enables or disables reporting the clarity of a patient sample. You can let the system set the clarity values (Automatic) or you can enter the clarity values (Manual).
- **Clarity Range** Allows you to adjust the range for the clarity thresholds. For clear to cloudy, and cloudy to turbid, select from -100% to +100%. If you select **Manual** for the **Report Clarity** option, the system does not adjust the clarity range.

Note Before you adjust the ranges, analyze a statistically significant number of samples that cover all of the reporting levels to be changed (Clear, Cloudy, Turbid). After you adjust the range, analyze the same samples again to verify the new performance.

Good laboratory practice requires that all control and proficiency samples be tested in an identical manner to that used for testing routine samples. Control ranges for the internal quality assurance program should be established by the individual laboratory when using adjusted ranges.

If you adjust the clarity ranges, the performance characteristics stated by the manufacturer for clarity are no longer valid. Validation of the new ranges and expected results become your responsibility.

- **Patient Comments** Specifies whether you can enter notes for the patient results. If enabled, you can add up to 4 patient comments. For example, the sample delivery method or work shift.
- **Controls** Allows you to select or add controls to be used in a control run.
- **Control Limit Checks** Allows you to enable or disable Control Limit Checking. If enabled, you can modify the expected analyte ranges.
- **Control Names** Specifies the control names for non-Siemens controls.
- **Control Comments** Specifies whether you can enter notes about the control results. If enabled, you can add up to 2 control comments. For example, whether the control test results were within the limits, or the work shift.

Configuring the Sample Settings for a Patient Sample

To configure the sample settings for a patient sample, follow these steps:

1. Select **Setup > Configuration > Sample**.
2. Perform the steps as described in *Table 7-3* .

Table 7-3: Sample Settings

Configuration Setting	Procedure
Sample Source	<p>1. Select Sample Source.</p> <p>2. Select an option:</p> <ul style="list-style-type: none"> Disable Disables using the sample IDs. Manual Allows you to enter the sample IDs after the system finishes processing the samples. Sample Handler Receives the sample IDs from the rack handler or universal sample handler. Load List Receives the sample IDs from the LIS. <p>3. If you select Manual or Sample Handler, you can change the Barcode Type that the barcode reader will recognize.</p> <p>If you select the radio button beside Multiple Selection, you can select 1 or more barcode types. A check mark beside the barcode type indicates that it is selected.</p> <p>If you select the radio button beside Single Selection, the barcode reader will only recognize the 1 2 of 5 barcode type, with or without check digit. A check mark beside the barcode type indicates that it is selected.</p> <p>4. If you select Manual or Sample Handler, you can change the Ignore Leading Characters, and Ignore Trailing Characters.</p> <p>Select Change to change the values, and then select Enter.</p> <p>After you make all of the changes, select Enter.</p>

Configuration Setting	Procedure
	<p>5. If you select Load List, select Change, and then enable or disable the deletion of the load list.</p> <p>Note This option is not available when the system is connected to a urine sediment analyzer.</p> <p>6. Select Save.</p>
Color Reporting	<ol style="list-style-type: none"> 1. Select Color Reporting. 2. For the Report Color option, select Enable or Disable. 3. For the Determine Color option, select Automatic or Manual. 4. For the Abnormal Color Levels option, select the colors you want to assign as abnormal. 5. Select Save.
Color Names	<ol style="list-style-type: none"> 1. Select Color Name. 2. Select Change. 3. Enter the color name. 4. Select Enter. 5. If you want to return to the system default settings for the color names, select Reset. 6. Select Save.
Report Clarity	<ol style="list-style-type: none"> 1. Select Report Clarity. 2. For the Report Clarity option, select Enable or Disable. 3. For the Determine Clarity option, select Automatic or Manual. 4. Select Save.

Configuration Setting	Procedure
Clarity Range	<ol style="list-style-type: none"> 1. Select Clarity Range. 2. For the Clear to Cloudy option, increase or decrease the percentage by selecting the left or right arrow. 3. For the Cloudy to Turbid option, increase or decrease the percentage by selecting the left or right arrow. 4. If you want to return to the default system clarity ranges, select Reset. 5. Select Save.
Patient Comments	<ol style="list-style-type: none"> 1. Select Patient Comments. 2. For the Patient Comments option, select Enable or Disable. 3. If you select Enable, to enter a patient comment, select Change. 4. Enter the comment. For example, Overnight collection. 5. Select Enter. 6. If you want to display the placeholder text (for example, Comment 1 or Comment 2) instead of the comment you entered, select Reset. 7. Select Save.

Configuring the Sample Settings for Control Samples

To configure the operations settings for controls, follow these steps:

1. Select **Setup > Configuration > Sample**.
2. Perform the steps as described in *Table 7-4* .

Table 7-4: Control Settings

Configuration Setting	Procedure
Controls	<ol style="list-style-type: none">1. Select Controls.2. Beneath the desired sample, select Change.3. To set the control for a sample, select the desired control.4. Select Enter, repeat as needed for up to 3 total controls.5. When finished, select Save.
Control Checks	<p>To disable Control Checks,</p> <ol style="list-style-type: none">1. Select Disable.2. Select Save. <p>To enable Control Checks:</p> <ol style="list-style-type: none">1. Select Enable.2. Select a control from the list on the left of the screen, then select Change.3. Select an analyte to change, then set the lower and upper limits. Repeat for all necessary analytes.4. When finished with the analytes, select Enter.5. Select Save.6. To return to the default control limits, select Reset and then select Save. <p>Note Control data stored on the instrument is deleted when the ranges are adjusted.</p>

Configuration Setting	Procedure
Control Names	<ol style="list-style-type: none"> 1. Select Control Name. 2. To change a control name, select Change. 3. Enter a control name. 4. Select Enter. 5. Select Save. 6. If you want to display the placeholder text (for example, Control 1 or Control 2) instead of the control name text you entered, select Reset and then select Save.
Control Comments	<ol style="list-style-type: none"> 1. Select Control Comments. 2. For the Control Comments option, select Enable or Disable. 3. To enter a control comment, select Change. 4. Enter the comment. For example, the work shift. 5. Select Enter. 6. Select Save. 7. If you want to display the placeholder text (for example, Comment 1 or Comment 2) instead of the comment you entered, select Reset and then Select Save.

Analyte Settings

Configure the following analyte settings to select the analytes, analyte order, ranges, specific gravity precision, abnormal results marking, and sieve options:

- **Analytes List** Specifies the analytes you want to display, print, or send to the LIS.
- **Analyte Order** Specifies the order in which you want to report the analytes.

- **Ranges** Adjusts the sensitivity of each reporting level for most tests by changing the range of values that is assigned to each level. You can set the upper and lower limit for a range.

By adjusting the upper limit of a level, the system reports a greater or lesser sensitivity of results at that level. Conversely, the system reports a lesser or greater sensitivity of specimens at the next higher level.

- For the CLINITEK Novus 10 cassette, you can adjust protein but you cannot adjust the levels for color, pH, SG, creatinine, and P:C.
- For the CLINITEK Novus PRO 12 cassette, you cannot adjust the levels for color, pH, SG, protein, albumin, creatinine, A:C, and P:C.

To indicate that an analyte range was adjusted, a caret (^) displays next to the analyte in the analyte area on a results screen.

Note Before you adjust the ranges, analyze a statistically significant number of samples that cover all of the reporting levels to be changed (Clear, Cloudy, Turbid). After you adjust the range, analyze the same samples again to verify the new performance.

Good laboratory practice requires that all control and proficiency samples be tested in an identical manner to that used for testing routine samples. Control ranges for the internal quality assurance program should be established by the individual laboratory when using adjusted ranges.

If you adjust the clarity ranges, the performance characteristics stated by the manufacturer for clarity are no longer valid. Validation of the new ranges and expected results become your responsibility.

Note If you adjust the **Ranges**, the existing patient and control data will be deleted.

- **Normal Ranges** Allows you to select the analyte ranges you want to designate as normal. The system flags the results as abnormal if the results value is not within the normal range. For pH and SG, you can set the upper and lower limit for a normal range. For the rest of the analytes, you can set only the upper limit, while the first level in the list of options defaults to the lower limit.
- **SG Precision** Allows you to select the precision (0.001, 0.005) for reporting the specific gravity results.

Note If you adjust the **SG Precision**, the existing patient and control data will be deleted.

- **Abnormal Flags** Enables or disables indicating the abnormal patient results that are outside the expected values with an asterisk (*).

- **Sieve** Enables or disables using sieve criteria, which could help identify the samples for confirmatory testing or microscopic examination.
Note If you adjust the **Sieve** criteria, the existing patient and control data will be deleted
- **Sieve Flags** Enables or disables indicating the sieve patient results that are outside of the expected values with a double dagger (#).

To configure the analyte settings, follow these steps:

1. Select **Setup > Configuration > Analyte**.
2. Perform the steps as described in *Table 7-5* .

Table 7-5: Analyte Settings

Configuration Setting	Procedure
Analytes List	<ol style="list-style-type: none">1. Select Analytes List. The analytes display in alphabetical order, with the exception of A:C and P:C, which display at the end of the list.2. Select the analytes you want to report in the results.3. Select Save.

Configuration Setting	Procedure
Analyte Order	<ol style="list-style-type: none">1. Select Analyte Order. By default, all of the analytes display in alphabetical order, with the exception of A:C and P:C, which display at the end of the list.2. Select the analyte you want as the first in the order, which displays the number 1.3. To undo the last analyte you selected, select the Undo button.4. Select additional analytes in the order you want. The corresponding order number for each analyte displays.5. To update the order for the analytes, select Update. The system updates the analyte order by displaying the analytes with their respective numbers in contiguous order. The analytes you did not select display after the selected ones in their original order. The system does not report those analytes.6. To save the analyte order, select Save.

Configuration Setting	Procedure
Ranges	<p>1. Select Ranges. You can adjust the following analytes: BIL, BLO, GLU, KET, LEU, NIT, and PRO.</p> <p>2. Select an analyte in the Analyte list. The range for the analyte displays in the Range list. If no adjustment was made, the range displays 0%.</p> <p>3. Select Change. For example, you can adjust the following ranges:</p> <ul style="list-style-type: none"> Negative: Trace Trace: 30 mg/dL 30 mg/dL: 100 mg/dL 100 mg/dL: \geq3 00 mg/dL <p>4. For each range, increase or decrease the percentage by selecting the left and right arrows. For example, if you adjust the range for Trace:30 mg/dL, a negative (-) or positive number displays next to the percentage.</p> <p>Positive adjustment If you increase the range, the sensitivity of the results for the first level of the pair increases. The sensitivity of the results at the second level decreases.</p> <p>Negative adjustment If you decrease the range, the sensitivity of the results for the first level of the pair decreases. The sensitivity of the results at the second level increases.</p> <p>If you increase the range to 100%, the system does not report the next level in the pair.</p> <p>If you decrease the range to -100%, the system does not report the previous level in the pair.</p>

Configuration Setting	Procedure
Ranges	<p>5. Select Enter. 6. Select Save. 7. To return to the default range of 0% for an analyte, select Reset and then select Save.</p> <p>To indicate that an analyte range was adjusted, a caret (^) displays next to the analyte in the analyte area on a results screen.</p>
Normal Ranges	<p>1. Select Normal Ranges. 2. Select an analyte in the list. 3. Select a normal range for the analyte. 4. Select Save. 5. To return to the default normal range, select Reset and then select Save.</p>
SG Precision	<p>1. Select SG Precision. 2. Select 0.001 or 0.005. 3. Select Save.</p>
Abnormal Flags	<p>1. Select Abnormal Flags. 2. Select Enable or Disable. 3. Select Save.</p>
Sieve	<p>1. Select Sieve. 2. Select Enable or Disable. 3. If you enable the sieve setting, select the analytes for Confirmatory and Microscopic. 4. Select Save.</p>

Devices Settings

Configure the following devices settings to set up the LIS port, data transmission, handheld barcode reader, and printer options:

- **Communication Port** Allows you to select the network settings for an Ethernet or a serial port, or disable the port.
For the network information, contact your local technical support provider.
- **Host Data** Specifies the types of results and data you want to send to the LIS.

- **Handheld Barcode Reader** Enables or disables the handheld barcode reader, change the barcode type, select leading and trailing characters, and test whether the handheld barcode reader works properly.
If you change the Sample Source setting, the system applies those settings to the internal and handheld barcode readers.
- **Print** Enables or disables the printer, changes the page orientation (Portrait or Landscape), and adds or changes the report header.
- **Remote Services** Allows a service representative to gain remote access to your CLINITEK Novus analyzer upon your agreement. The service representative can view your screen, perform tasks on your system, and troubleshoot and diagnose problems.

To configure the devices settings, follow these steps:

1. Select **Setup > Configuration > Devices**.
2. Perform the steps as described in *Table 7-6* .

Table 7-6: Devices Settings

Configuration Setting	Procedure
Communication Port	<p>1. Select Communication Port. 2. To select a communication port, select Ethernet or Serial. 3. To change the port settings, select Change. 4. To disable the LIS port, select Disable.</p> <p>Ethernet Settings</p> <p>1. Select Ethernet. 2. Select Change for each barcode type. 3. Change the values for the following options and select Enter.</p> <p>Device Host Name The network name of the CLINITEK Novus analyzer.</p> <p>LIS Address The address or name of the LIS.</p> <p>IP Port Number The port number of the LIS.</p> <p>IP Address Type The IP address type for the CLINITEK Novus analyzer, such as DHCP or Static. If you select DHCP, the DHCP server supplies the IP address information. If you select Static, go to step 4.</p> <p>4. Enter the following Static IP address information:</p> <p>MAC Address The address of the Ethernet hardware. You do not have to enter it.</p> <p>IP Address The address of the analyzer.</p> <p>Subnet Mask The subnet mask number.</p> <p>Default Gateway The address of the default gateway.</p> <p>DNS Server Address The address of the DNS server.</p> <p>5. Select Save.</p>

Configuration Setting	Procedure
Communication Port	<p>Serial Settings</p> <ol style="list-style-type: none"> 1. If you select Serial, to change the settings, select Change. 2. To change the baud rate for transmission, select Change, select a baud rate, and select Enter. 3. Change the values for the following options: Data Bit The number of data bits (7 or 8). Parity The parity of the transmission (Odd, Even, or None). Stop Bits The number of stop bits for transmission (One or Two). 4. Select Enter. 5. Select Save.
Host Data	<ol style="list-style-type: none"> 1. Select Host Data. 2. Select the type of results you want to send to the LIS: Patient, STAT, Control, and Calibration. 3. Select the type of data you want to send to the LIS: Color, Clarity, and Rack & Tube. 4. Select Save.
Handheld	<ol style="list-style-type: none"> 1. Select Handheld. 2. For the handheld barcode reader option, select Enable or Disable. <p>Scan Data Settings</p> <ol style="list-style-type: none"> 1. To select a barcode type for scanning data, select Change. 2. Select a barcode type and select Enter. 3. Select Save.

Configuration Setting	Procedure
Handheld	<p>Scan Sample ID Settings</p> <ol style="list-style-type: none"> 1. To change the values for scanning sample IDs, select Change. 2. To change the barcode type, select Change, select a barcode type, and select Enter. 3. To select the number of leading characters to ignore, select Change, enter a value, and select Enter. 4. To select the number of trailing characters to ignore, select Change, enter a value, and select Enter. 5. Select Enter. 6. Select Save. <p>Scan Test</p> <p>Note If you select Disable or Load List for the Sample Source setting, the Test Sample ID button is not available.</p> <ol style="list-style-type: none"> 1. To test a sample ID, select Test Sample ID, and scan the barcode label with the barcode reader within 10 seconds. The sample ID displays in the box at the bottom of the screen. 2. To test other data, select Test Data, scan the barcode with the barcode reader within 10 seconds. The test data displays in the box at the bottom of the screen.
Print	<ol style="list-style-type: none"> 1. Select Print. 2. For the Printer option, select Enable or Disable. 3. For the page Orientation option, select Portrait or Landscape (for only a patient or control results report). 4. To enter a report header, select Change, enter the header, and select Enter. For example, your hospital or laboratory name. 5. Select Save.

Configuration Setting	Procedure
Remote Services	<ol style="list-style-type: none"> 1. Select Remote Services. 2. For the Remote Services option, select Enable or Disable. 3. If you select Enable, enter an IP address and port number to connect to the remote service. You can obtain the IP address and port number from the service representative. 4. Select Save.

System Access Settings

Configure the following system access settings to enable or disable password protection. You can specify whether to prompt for an operator ID, and change the user password.

- **Restrict Access** Allows you to restrict access to performing diagnostics, using system setup, recalling results, and deleting data by prompting for a password. The password protects the Diagnostics, System Setup, Data Recall, and Data Delete menus.
- **User Password** If you restrict access to any menus, you can change the user password. The user password allows you to change the advanced settings if they were password-protected, and gain access to the menus you restricted.

Note If you do not define a user password, you can use the system password. The system password allows you to change the advanced settings if they were password-protected, and gain access to the menus you restricted. To obtain the system password, contact your local technical support provider.

- **Enable** Allows you to enable or disable prompting the operator to enter an operator ID before performing a patient, control, or calibration test. An operator ID has up to 10 letters and numbers, including spaces. For example, Smith1 or Smith 2.

To configure the devices settings, follow these steps:

1. Select **Setup > Configuration > System Access**.
2. Perform the steps as described in *Table 7-7* .

Table 7-7: System Access Settings

Configuration Setting	Procedure
Restrict Access	<p>1. Select 1 or more of the following options:</p> <ul style="list-style-type: none"> • Customer Diagnostics • System Setup • Data Recall • Data Delete <p>A check mark in a check box indicates that you selected the option.</p> <p>2. Select Save.</p>
User Password	<p>Note If you restricted access to any menus, the user password option displays.</p> <ol style="list-style-type: none"> 1. Select Change. 2. Enter a user password. 3. Select Enter. 4. Select Save.
Enable	<p>1. Select Prompt for Operator ID.</p> <p>A check mark in the check box indicates that you enabled the option.</p> <p>2. Select Save.</p>

Sequence Number Setting

The system assigns a unique sequential identification number to every sample you process. The sequence number is based on the interface protocol you select.

You can change the sequence number for the next patient test. The system displays the next sequential unused sample sequence number.

The test sequence number format is based on the interface protocol you select. The ASTM and HL7 format are N-NNNNN where the first N represents a prefix number (0–9), followed by a hyphen (-), and 5 numbers (0–9). For example, 1-39425.

1. Select **Setup > Configuration > Sequence Number**.
2. Select **Change**.
3. Enter the sequence number you want to start with.
4. Select **Enter**, then select **Save**.

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 a dilution of 10% bleach and 90% water.
- 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.

Protecting Yourself from the Card Detection Laser

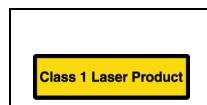
The CLINITEK Novus analyzer contains an integrated card detection laser.

Only Siemens trained field service personnel should perform procedures related to the laser assembly.

Laser Safety Classification

During normal operation, with all of the protective housings in place, the CLINITEK Novus analyzer is classified as CDRH Class 1 and EN 60825-1 Class 1 (Figure A-1).

Figure A-1: EN 60825-1 Class Label



Laser Safety Classification of the Card Detection Laser

The laser safety classification for the integrated card detection laser is CDRH Class 3B and EN 60825-1 Class 3B.

Table A-1: Class 3B Laser Specifications

Characteristic	Specification
Maximum Power Output	2 mW
Wavelength	850 nm
Pulse Duration	Continuous Wave (cw)
Units of Beam Divergence	2°



LASER WARNING

Only trained field service personnel should perform procedures related to laser assemblies.

Appendix B: Warranty and Support Information

This appendix provides the warranty technical support information for your CLINITEK Novus analyzer.

Warranty Information

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

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

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

Installation Details

Record the following information and keep it 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.

When to Contact Technical Support

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 Pre-Service Checklist, page 157. Make a photocopy of the list first. This information helps your local technical support provider identify the probable cause of the problem.

To order supplies or replacement parts, or to obtain service, contact your local technical support provider at 877-229-3711 or visit www.siemens.com/poc.

Information for Technical Assistance

To provide system information that you may need when you call for technical assistance, see the *Installation Details*, page 217 and *Using the Pre-Service Checklist*, page 157.

For technical assistance, contact your local technical support provider.

Made in UK



Siemens Healthcare Diagnostics Inc.
511 Benedict Avenue
Tarrytown, NY 10591-5097 USA
www.siemens.com/poc



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

Appendix C: Supplies

Startup Supplies

With a new instrument installation, your CLINITEK Novus Analyzer will include additional startup supplies. A list of some startup supplies can be found in *Table C-1*. This list is subject to change without notice. Some items may not be commercially available in all markets. Contact your local technical support provider for a complete list of supplies.

Table C-1: CLINITEK Novus Startup Supplies

Item	Part Number
Cord Set	10319275
Cord Set, Europe, Molded Plug	10323672
Cord Set, UK, 3 PIN 5A Plug	10323838
Sample Clips	10698402
Sample Racks	10698401
Syringe Assembly	10698452

Ordering Supplies and Replacement Parts

A list of some as-needed, orderable supplies can be found in *Table C-2*. This list is subject to change without notice. Some items may not be commercially available in all markets. Contact your local technical support provider for a complete list of supplies and replacement parts that you can order for the CLINITEK Novus analyzer.

In the United States, you can order replacement parts directly from:

Order Services
Siemens Healthcare Diagnostics Inc.
115 Norwood Park South
Norwood, MA 02062

or call toll free:

1-800-255-3232

Outside of the United States, contact your local technical service provider.

Table C-2: CLINITEK Novus Orderable Supplies

Item	Part Number
Card Drawer Assembly	10698535
Cassette Storage Box Kit	10844209
CLINITEK Atlas Negative CTRL	10311135
CLINITEK Atlas Positive CTRL	10311124
CLINITEK Novus 10 Urinalysis Cassette	10634643
CLINITEK Novus 10 Urinalysis Cassette, Japan	10697847
CLINITEK Novus PRO 12 Urinalysis Cassette	10634644
CLINITEK Novus Calibrator	10697753
CLINITEK Novus PRO 12 Urinalysis Cassette, Japan	10697848
Cord Set	10319275
Cord Set, Europe, Molded Plug	10323672
Cord Set, UK, 3 PIN 5A Plug	10323838
External Printer	10484585
External Rinse Kit	10714228
Fuse 1,25 amp (1.5A)	10698434
Handheld Barcode reader	10698414
Pipette Probe Assembly	10698435
Rack Handler	10698466
Rinse Additive	10697754
Run-Out Table Assembly	10844094
Sample Clips	10698402
Sample Racks	10698401
SG Sensor	10698455
Syringe Assembly	10698452
Universal Power Supply	10340710
Wash Drawer Assembly	10698457
Waste Drawer Assembly	10698456

Appendix D: Specifications

This appendix covers the following topics:

- Electrical and system specifications
- Environmental specifications
- Tables of results

Electrical and System Specifications

The following table contains the electrical and system specifications for the CLINITEK Novus analyzer.

Item	Specification
Voltage required	System 100-240 VAC 48–62 Hz The CLINITEK Novus analyzer has been manufactured and inspected as a 120 VAC system. Before it is used at any voltage other than 120 VAC, the system power cord, fuse, or rating label must be changed in order to comply with the specific requirements of each country.
Maximum Power Input	100 VA (system)
Dimensions	Depth — 68.6 cm (27 inches) Width — 63.5 cm (25 inches) Height — 53.3 cm (21 inches)
Weight	42 kg (93 lb)
Decibel Rating	60 dB (in a 20 x 20 ft room with no more than 40 dB background noise)
Recommended Minimum Bench Area	Width — 78.7 cm (31 inches) Depth — 71.1 cm (28 inches)
Recommended Clearance Above Bench	71.1 cm (28 inches)
Ambient Operating Temperature Range	18–30°C (64–86°F)
Ambient Operating Humidity Range	20–80% relative humidity

Item	Specification
Throughput	15 seconds per sample 240 samples per hour
Sample Tube Requirements	Style — Lipless Width — 16 mm (0.63 inches) Height — 95–106 mm (3.74–4.17 inches)
Calibration	A 3-point calibration, including baseline adjustment for each test pad, clarity, and the SG measurement to ensure optimal performance.
Performance of Specific Gravity Test	Clinical studies have shown at least 90% of results to be within 0.005 of the TS Meter readings.
Linearity of SG Refractometer	Results are linear through 1.045 when compared to the TS Meter. SG values up to 1.099 will be reported. However, measurements greater than 1.045 may be less accurate.
Performance of Clarity Test	Clinical studies have shown good agreement between results obtained visually and by the system.
Limitation of Clarity Results	Particulate material might settle out of the urine sample before the systemal clarity reading. Therefore, the clarity results from the CLINITEK Novus analyzer might not show exact agreement with visual clarity readings for freshly mixed samples.
ASTM Software Interface	Conforms to NCCLS LIS1-A1 (formerly ASTM E1381), Standard Specification for Low Level Protocol to Transfer Messages between Clinical Laboratory Instruments and Computer Systems and NCCLS LIS2 A2 (formerly ASTM E1394), Specification for Transferring Information Between Clinical Laboratory Instruments and Information Systems.

Item	Specification
HL7 Software Interface	Conforms to HL7 Messaging Standard version 2.5, An Application Protocol for Electronic Data Exchange in Healthcare Environments.
System Safety Design	The system operates safely under the following conditions: <ul style="list-style-type: none"> • Indoor use only • Installation category II (IEC 1010) • Pollution degree 2 (IEC 1010) • Maximum altitude of 2000 meters (6560 feet)
Optimum Operating Conditions	Temperature range: 22–26°C (72–79°F) Relative humidity: 35–55%

Environmental Factors

Prolonged exposure to excessive humidity and temperature should be avoided. Temperature should be held relatively constant to obtain the highest degree of operating stability.

The ambient temperature range for operating the system is 18–30°C (64–86°F).

The ambient operating humidity range is 20–80% relative humidity.

Place the system where it is not subjected to extreme temperature variations. Avoid proximity to direct sunlight, open windows, ovens, hot plates, open burners, radiators, and dry ice baths. It should also be located away from any system that uses a high voltage or large current, including centrifuges, large refrigerators, and ovens. Do not use the system in an explosive atmosphere.

Place the system on a bench that has a firm, level surface, capable of supporting at least 45 kg (93 lb) of weight. The surface should have a slope of no more than 3° from horizontal in either direction.

Be sure the system is located near a power source that meets the electrical requirements (voltage and amperage) specified on the rating label on the back of the system. The power receptacle must be grounded and should be a clean, noise-free, dedicated line.

Tables of Results

The tables of results include conventional and Système International (SI), with and without the Plus System for the ASTM and HL7 interface protocols, in the CLINITEK Novus supported languages.

If the system cannot determine a valid analyte value, a result value of **Error** displays for the analyte.

Table D-1: Conventional Units—ASTM and HL7 Results

Test	Abbreviation	ASTM and HL7 Results	
		Conventional	Conventional with Plus System
Color	COL	Yellow Dark Yellow Orange Red Green Other	Yellow Dark Yellow Orange Red Green Other
Clarity	CLA	Clear Cloudy Turbid Sl. Cloudy ^a	Clear Cloudy Turbid Sl. Cloudy ^a
Glucose	GLU	Negative 100 mg/dL 250 mg/dL 500 mg/dL >=1000 mg/dL	Negative Trace 1+ 2+ 3+
Bilirubin	BIL	Negative Small Moderate Large	Negative 1+ 2+ 3+
Ketone	KET	Negative Trace 15 mg/dL 40 mg/dL 80 mg/dL >=160 mg/dL	Negative Trace 1+ 2+ 3+ 4+
Specific Gravity 0.005 Units	SG	<=1.005 1.010 1.015 1.020 1.025 >=1.030	<=1.005 1.010 1.015 1.020 1.025 >=1.030
Specific Gravity 0.001 Units	SG	1.000 to >=1.099 in 0.001 increments	1.000 to >=1.099 in 0.001 increments
Occult Blood	BLO	Negative Trace Small Moderate Large NHT	Negative Trace 1+ 2+ 3+ NHT

Test	Abbreviation	ASTM and HL7 Results	
		Conventional	Conventional with Plus System
pH	pH	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0
Protein (10-Test Set)	PRO	Negative Trace 30 mg/dL 100 mg/dL 300 mg/dL >=1000 mg/dL	Negative Trace 1+ 2+ 3+ 4+
Protein (12-Test Set)	PRO	Negative 15 mg/dL 30 mg/dL 100 mg/dL 300 mg/dL >=1000 mg/dL	Negative Low 1+ 2+ 3+ 4+
Albumin	ALB	10 mg/L 30 mg/L 80 mg/L 150 mg/L	10 mg/L 30 mg/L 80 mg/L 150 mg/L
Urobilinogen	URO	0.2 E.U./dL 1.0 E.U./dL 2.0 E.U./dL 4.0 E.U./dL >=8.0 E.U./dL	0.2 E.U./dL 1.0 E.U./dL 2.0 E.U./dL 4.0 E.U./dL >=8.0 E.U./dL
Nitrite	NIT	Negative Positive	Negative Positive
Leukocytes	LEU	Negative Trace Small Moderate Large	Negative Trace 1+ 2+ 3+
Creatinine	CRE	10 mg/dL 50 mg/dL 100 mg/dL 200 mg/dL >=300 mg/dL	10 mg/dL 50 mg/dL 100 mg/dL 200 mg/dL >=300 mg/dL
Protein: Creatinine	P:C	P Norm : C Dil Normal 300 mg/g 500 mg/g >=1500 mg/g	P Norm : C Dil Normal 300 mg/g 500 mg/g >=1500 mg/g
Albumin: Creatinine	A:C	A Norm : C Dil Normal 150 mg/g >=300 mg/g	A Norm : C Dil Normal 150 mg/g >=300 mg/g

a. Sl. Cloudy is a manually selected result option. It is not automatically reported by the system.

Table D-2: SI Units—ASTM and HL7 Results

Test	Abbreviation	ASTM and HL7 Results	
		SI	SI with Plus System
Color	COL	Yellow Dark Yellow Orange Red Green Other	Yellow Dark Yellow Orange Red Green Other
Clarity	CLA	Clear Cloudy Turbid Sl. Cloudy ^a	Clear Cloudy Turbid Sl. Cloudy ^a
Glucose	GLU	Negative 5.5 mmol/L 14 mmol/L 28 mmol/L ≥55 mmol/L	Negative Trace 1+ 2+ 3+
Bilirubin	BIL	Negative Small Moderate Large	Negative 1+ 2+ 3+
Ketone	KET	Negative Trace 1.5 mmol/L 3.9 mmol/L 7.8 mmol/L ≥15.6 mmol/L	Negative Trace 1+ 2+ 3+ 4+
Specific Gravity 0.005 Units	SG	<=1.005 1.010 1.015 1.020 1.025 ≥1.030	<=1.005 1.010 1.015 1.020 1.025 ≥1.030
Specific Gravity 0.001 Units	SG	1.000 to ≥1.099 in 0.001 increments	1.000 to ≥1.099 in 0.001 increments
Occult Blood	BLD	Negative Trace-Lysed Ca 25 Ery/µL Ca 80 Ery/µL Ca 200 Ery/µL Trace-Intact	Negative Trace-Lysed 1+ 2+ 3+ Trace-Intact
pH	pH	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 ≥9.0	5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 ≥9.0
Protein (10-Test Set)	PRO	Negative Trace 0.3 g/L 1.0 g/L 3.0 g/L ≥10.0 g/L	Negative Trace 1+ 2+ 3+ 4+

Test	Abbreviation	ASTM and HL7 Results	
		SI	SI with Plus System
Protein (12–Test Set)	PRO	Negative 0.15 g/L 0.30 g/L 1.0 g/L 3.0 g/L >=10.0 g/L	Negative Low 1+ 2+ 3+ 4+
Albumin	ALB	10 mg/L 30 mg/L 80 mg/L 150 mg/L	10 mg/L 30 mg/L 80 mg/L 150 mg/L
Urobilinogen	UBG	3.2 µmol/L 16 µmol/L 33 µmol/L 66 µmol/L >=131 µmol/L	3.2 µmol/L 16 µmol/L 33 µmol/L 66 µmol/L >=131 µmol/L
Nitrite	NIT	Negative Positive	Negative Positive
Leukocytes	LEU	Negative Ca 15 Leu/µL Ca 70 Leu/µL Ca 125 Leu/µL Ca 500 Leu/µL	Negative Trace 1+ 2+ 3+
Creatinine	CRE	0.9 mmol/L 4.4 mmol/L 8.8 mmol/L 17.7 mmol/L >=26.5 mmol/L	0.9 mmol/L 4.4 mmol/L 8.8 mmol/L 17.7 mmol/L >=26.5 mmol/L
Protein: Creatinine	P:C	P Norm : C Dil Normal 33.9 mg/mmol 56.6 mg/mmol >=170 mg/mmol	P Norm : C Dil Normal 33.9 mg/mmol 56.6 mg/mmol >=170 mg/mmol
Albumin: Creatinine	A:C	A Norm : C Dil Normal 17 mg/mmol >=33.9 mg/mmol	A Norm : C Dil Normal 17 mg/mmol >=33.9 mg/mmol

a. SI. Cloudy is a manually selected result option. It is not automatically reported by the system.

Appendix E: Symbols

This appendix provides the symbols for the analyzer and packaging with the meaning of each symbol.

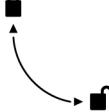
Analyzer and Packaging Symbols

The following table contains the system packaging symbols that can display on the exterior of the CLINITEK Novus analyzer or on the system packaging.

The symbols on the system provide you with the location of certain components and with warnings for proper operation.

The symbols on the system packaging provide you with other important information.

For information about the symbols that can display on the cassettes, controls, and calibrators, see the instructions for use.

Symbol	Description
	Place the tube in the STAT holder
	Lock and unlock the cassette compartment door
	Card waste drawer
	Waste drawer
	Rinse drawer
	On button
	USB port

Symbol	Description
	Serial port
	LIS port
	Direct current input supply
	Risk of electric shock
	Alternating current
	Instrument is safety tested by TUV SUD, a national certification body for conformity to global markets, including Canada, US, and Europe
	Product complies with the applicable directives of the European Union
	Legal manufacturer
	European authorized representative
	Caution, consult accompanying documents
	<i>In vitro</i> 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
	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.
	Use by YYYY-MM
	Catalog number
	Serial number

Symbol	Description
	Batch code
	Biohazard
	Pinch Hazard
	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
	Compliance with the RESY packaging standards
	Keep this way up
	Fragile, handle with care
	Keep dry
	Keep away from sunlight and heat
	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

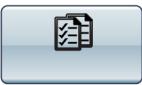
Symbols

Symbol	Description
	Laser
	Class 1 Laser Classification Label

Display Symbols

The following table contains the icons that display on the CLINITEK Novus analyzer screen.

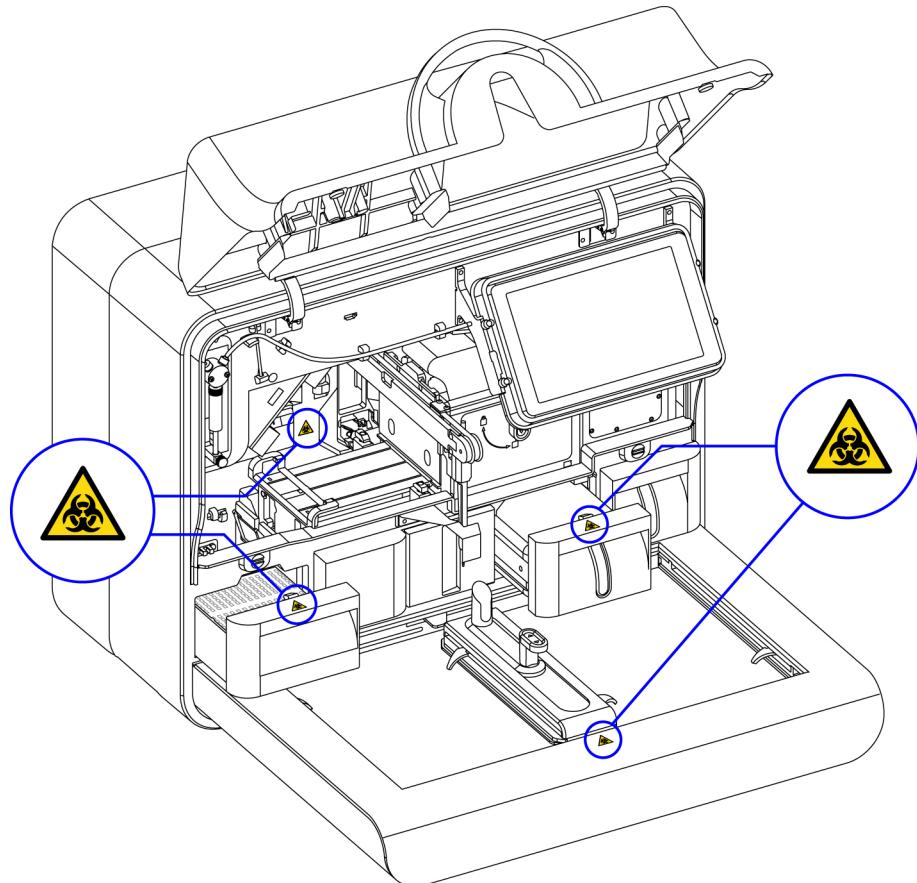
Symbol	Description
	Used for both Warning and Caution <ul style="list-style-type: none"> • A Warning indicates the risk of personal injury or loss of life. • A Caution indicates the possibility of loss of data or damage to or destruction of equipment.
	Warning or biohazard
	Off button
	Rinse level indicator
	Waste level indicator
	Card waste level indicator
	Handheld barcode reader enabled
	Handheld barcode reader disabled
	Remote services enabled
	System
	Setup

Symbol	Description
	Results
	Home
	Help
	Back
	Start
	First
	Last
	Previous
	Next

On System Symbols

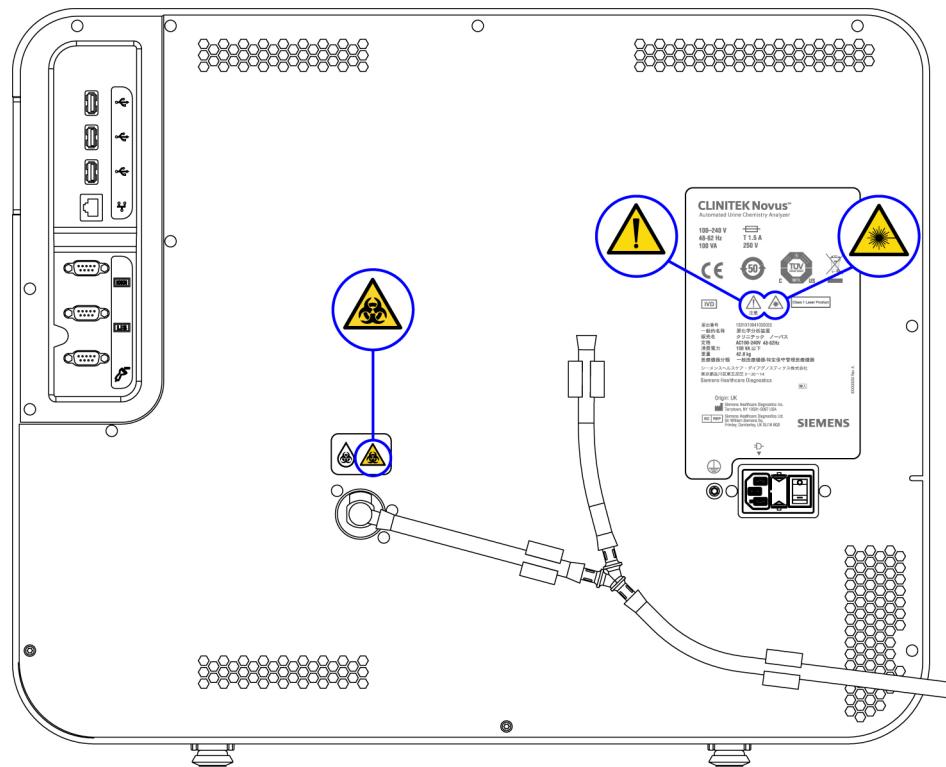
The following illustration provides the safety labels locations on the front of the analyzer.

Figure E-1: CLINITEK Novus Front View



The following illustration provides the safety labels locations on the back of the analyzer.

Figure E-2: CLINITEK Novus Back View



Appendix F: Maintenance Log

Use the Maintenance Log as a record of your CLINITEK Novus analyzer maintenance. Copy this log template and use it every month.

SIEMENS
CLINITEK Novus™
 Automated Urine Chemistry Analyzer

Maintenance Log

Month: _____ Year: _____

System Serial Number: _____

Reviewed by: _____

Daily Maintenance

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Check the cassette tests and rinse solution levels.																															
Empty the waste.																															
Clean the rack handler.																															
Clean the SG well.																															
Clean the racks.																															

Weekly Maintenance

	Week 1	Week 2	Week 3	Week 4	Week 5
Clean the moisture gate.					
Clean the rack pushers.					

As Needed Maintenance

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Disinfect the system.																															
Clean the barcode reader optic window.																															
Clean the rack sensors.																															
Clean the card grippers.																															
Clean the card platform.																															
Calibrate the system.																															
Replace the pipette.																															
Replace the syringe.																															
Calibrate the touch screen.																															
Adjust the pipette depth.																															
Prime the pump.																															

Appendix G: Glossary

The glossary contains hardware and software terms, and acronyms.

Hardware Terms

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

Term	Definition
barcode	Encoded information that is read by an optical scanner.
card handler	A transport system that moves a test card from the cassette compartment to the card platform, and then to the card waste drawer.
card platform	A platform where the test card remains while the pipette dispenses a urine sample and the camera records an image.
card waste drawer	A drawer that stores the used test cards.
cassette	A Siemens cassette that contains test cards with pads for <i>in vitro</i> diagnostic use, where the test reaction occurs.
cassette compartment	An area where you load and unload a cassette.
cassette compartment door	A door that provides access to the cassette compartment where you load and unload a cassette.
connector panel	Located at the back of the system on the upper left side and contains several ports and a connector.
display	The LCD monitor that displays the software user interface with words or objects, and tilts for easier viewing.
Ethernet port	The port where a network Ethernet cable is inserted.
fluidic system	The hardware that processes the samples: pipette, syringe pump, SG sensor, and SG well.
handheld barcode reader	An optional barcode scanner that is connected to the RS-232 port on the CLINITEK Novus analyzer. Used to enter data by scanning barcode labels.

Term	Definition
hardware	The physical components of the system.
internal barcode reader	A barcode scanner on the CLINITEK Novus analyzer. Used to enter data by scanning barcode labels. Detects whether a tube is in place in the rack, and if the tube is capped.
LED Fab#	Defines LED type that is installed on the system.
level sensor connector	A connector that connects the level sensor of the pipette to the system. The level sensor detects if the tip of the pipette is immersed in a sample.
LIS port	A port where you insert a cable to connect the LIS to the analyzer.
loading area	The platform on the right side of the rack handler for loading racks. If you enable the Rack Circulation setting, you can load and unload racks on both sides of the rack handler.
off button	The button on the left side of the Home screen that shuts down the software and powers off the hardware.
on button	The button on the right side of the system that powers on the system.
optical system	A color digital camera that captures an illuminated image of a set of test pads and analyzes the color and intensity of the light reflected from a reacted reagent area. The concentration of each analyte is measured by the color change developed when a urine sample is deposited on a porous pad containing dry reagent.
pipette	A hardware component that aspirates and dispenses the sample and hydrates the SG well.
pipette tubing	Connects the syringe valve to the pipette.
power switch	A button at the back of the system that powers the system on and off completely. Leave the power switch powered on at all times.

Term	Definition
printer	A printer device that is connected to the CLINITEK Novus analyzer.
rack	A sample rack. A device used to present tubes to the system. The rack contains space for up to 10 tubes.
rack handler	A platform on the right and left side of the STAT island for loading and unloading racks. The rack handler transports the racks of tubes with samples to the pipette. If you disable the Rack Circulation setting, the loading area is on the right side and the unloading area is on the left side. If you enable the Rack Circulation setting, you can load and unload racks on both sides of the rack handler.
rack pusher	A pusher moves a rack on the rack handler. A pusher is located on each side of the rack for forward movement, and another pusher is located at the end of the rack for side-to-side movement.
RFID tag	A radio frequency identification tag on a cassette that contains the information about the cassette to the analyzer.
rinse bottle	A bottle in the rinse drawer that stores the rinse solution.
rinse drawer	A drawer that contains the rinse bottle.
rinse well	The component where the pipette dispenses the rinse solution to rinse the pipette.
sampling area	An area on the rack handler where the pipette aspirates the samples in the tubes in racks.
sensor cables	The cables that connect the SG sensor connectors to the SG sensor.
serial connector	An RS-232 connection used to transfer data between the system and the LIS, optional handheld barcode reader, or a universal sample handler.
SG measurement	A fiber optic refractive index method that determines the specific gravity.
SG sensor	Measures the specific gravity and clarity of the urine sample.

Term	Definition
SG well	The component where the pipette dispenses the sample for the specific gravity and clarity measurements.
STAT holder	A holder in the STAT island for a single tube for processing a STAT test.
STAT island	The center of the rack handler that divides the loading and unloading areas, and contains the STAT holder.
syringe pump	A pump that aspirates the sample from the tube, dispenses the sample on the test card and in the SG well, and rinses the pipette at the SG well.
syringe valve	A valve on the syringe pump that switches between the sample and rinse for the pipette to aspirate a sample and rinse the SG well.
system	The CLINITEK Novus analyzer. The device and associated software used for analyzing urine.
system cover	Main door on the front side of the analyzer.
test card	A Siemens card with test pads for <i>in vitro</i> diagnostic use, where the test reaction occurs.
touch screen	The part of the LCD color display that allows you to select menu items, buttons, or options on the screen.
tray	A container that stores the cassette.
unloading area	The platform on the left side of the rack handler for unloading racks. If you enable the Rack Circulation setting, you can unload racks on both sides of the rack handler.
USB port	A port where you insert a USB cable to connect a printer or other devices to the analyzer.
waste bottle	A bottle in the waste drawer that stores the liquid waste.
waste drawer	A drawer that contains the waste bottle.

Software Terms

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

Term	Definition
alert message	An error or warning message that conveys information to the operator about the system.
alphanumeric	Data comprised of alphabetic and numeric characters.
analyte	A substance of unknown concentration in a sample.
assay	A generic term that refers to the chemical analysis for a specific analyte in a sample. Each assay possesses a unique test protocol. Also called test.
audio alert	Sounds emitted by the system to draw the operator's attention to the system, such as a beep.
baud rate	The speed of data transmission in bits per second (bps) between the system and a remote device.
calibration	The system analyzes the color response of the calibrators on the test pads to ensure accurate test results.
cancel	To end a sequence or an operation.
comment	A notation the operator enters for a patient or control test result.
configuration	System hardware and software settings that adjust or configure some aspect of the system.
context-sensitive help	Help information that pertains to a task or software user interface screen that is available when you select the screen in question. For example, when you select the Help button, the system displays information about the Home screen if you select it while viewing the Home screen.

Term	Definition
control	Objects that display on the software UI that the operator can manipulate. Buttons, boxes, and option buttons are examples of controls. Solution containing a known level of analytes. Used in quality control to confirm that the system can make reliable measurements.
conventional unit	Unit of measurement for test results.
data entry	The act of entering data, such as an operator ID into the system.
data entry box	A software UI object which displays the data that the operator entered.
default gateway	The IP address for the gateway you want your device to use to connect to your network.
default setting	A value defined and preset by Siemens.
delete	A function an operator uses to remove an object, such as test results.
device	Any hardware that performs a specific function such as a printer, LIS, or handheld barcode reader.
diagnostic	A system diagnostic test you perform to determine the status of or troubleshoot the system.
disabled	The state when a software feature or function, such as a configuration setting, is not available.
DNS	Domain Name Server. A computer connected to a network that translates the IP address for a device into a human-readable domain name.
enabled	The state when a software feature or function, such as a configuration setting, is available.
error	An event that prevents the system from operating as expected.
error code	A number displayed by the system to communicate the occurrence of an error to the operator.
Ethernet	International standard networking technology for wired devices.

Term	Definition
gateway	A routing device that passes traffic between subnets and networks.
Help screen	Information presented on the screen to an operator to assist them with the completion of a task or operation.
Home screen	The software UI screen that displays when the system completes the startup process. All software UI navigation begins from the Home screen.
interleaved 2 of 5	A barcode format. Abbreviation: I 2 of 5.
icon	A graphical depiction of a control in the software UI.
indicator	An icon on the screen that shows the status of a component, such as the waste and rinse status indicators.
interface protocol	The protocols that send the results to the LIS: ASTM (American Society of Testing Materials) and HL7 (Health Level 7).
IP address	Internet Protocol address. An identifier for a computer or device on a TCP/IP network.
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 system. Abbreviation: LIS.
last patient tests	The results from the last group of patient samples you tested.
MAC address	Media Access Control address. A unique value associated with a network adapter on a LAN.
menu screen	A software UI screen that displays a list of commands and 1 or more command buttons for the operator to select.
navigation	The act of moving between the screens that comprise the system software UI.
navigation button	A software UI button control that when selected, brings the operator to a different software UI screen.
Normal result	Provides a negative result or a value for a positive result.

Term	Definition
operator	A person who can perform patient and control tests, change general settings, and print and recall test results.
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 (+++).
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. Also called control. Abbreviation: QC.
ready	The state when the system is available to perform tests.
recall	To access data such as test results stored on the system.
remote services	A software service that allows a service representative to gain remote access to your CLINITEK Novus analyzer upon your agreement, where they can view your screen, perform tasks, and diagnose your system problems.
restore	To restore the settings and data that you backed up.
sample	A single aliquot of a patient, control, or calibrator specimen used for testing.
screen	The display area that contains the controls the operator selects when operating the system. The system software UI contains screens, prompts, messages, and other operating information.
service user	A special type of operator, who has access to service level functionality.
settings	The areas of the software user interface where you can adjust or configure the system.

Term	Definition
SI units	An abbreviation for Système International, a unit of measure.
software	Computer instructions that generate and carry out commands to control the system operation.
specimen	A quantity of material used for testing. See sample.
stop bits	The number of bits that maintain synchronization between the system and a remote device during data transmission.
supervisor	A special type of operator who can recall and delete data, change system settings, and install new software.
test	A diagnostic evaluation procedure. Also called assay.
test result	Measured reportable values displayed 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 a software UI screen that identifies the title of the screen.
troubleshooting	Determining the cause of a system or test performance problem.
upgrade	Software that you install to revise the software and hardware on the system.
user interface	The system software screens where the operator interacts. Abbreviation: UI.

Acronyms

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

Acronym	Full Title
A:C	Albumin-to-Creatinine ratio
ALB	Albumin
ASTM	American Society for Testing and Materials
BIL	Bilirubin

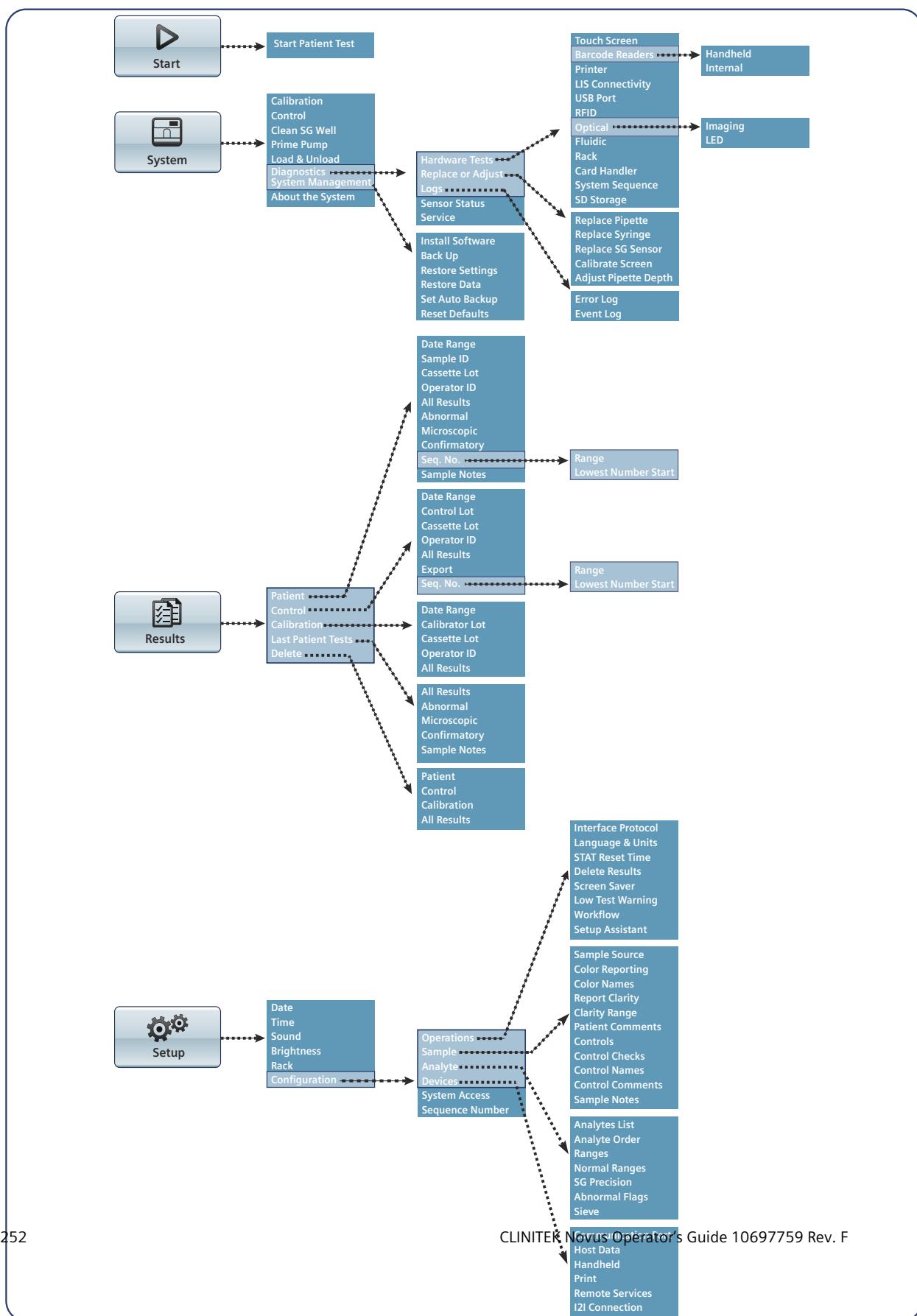
Acronym	Full Title
BLD	Occult Blood (SI)
BLO	Occult Blood (Conventional)
CFR	Code of Federal Regulations
CLA	Clarity
COL	Color
CRE	Creatinine
CSA	Canadian Standards Association
CSV	Comma Separated Values
DC	Direct Current
DHCP	Dynamic Host Configuration Protocol
DMS	Data Management System
DNS	Domain Name Server
EHR	Electronic Health Record
EMR	Electronic Medical Record
GLU	Glucose
HIS	Hospital Information System
HL7	Health Level 7 (protocol)
IEC	International Electrotechnical Commission
IP	Internet Protocol
KET	Ketone
LAN	Local Area Network
LEU	Leukocyte
LIS	Laboratory Information System
NHT	Non-Hemolyzed Trace
NIST	National Institute of Standards and Technology
NIT	Nitrite
P:C	Protein-to-Creatinine ratio
PC	Personal Computer
pH	Hydrogen ion concentration
POCT	Point of Care Testing (protocol)
PRO	Protein
QC	Quality Control
SG	Specific Gravity
SI	Système International
SN	Serial Number

Acronym	Full Title
UBG	Urobilinogen (SI)
UI	User Interface
URO	Urobilinogen (Conventional)
USB	Universal Serial Bus
VA	Volt Amp

Appendix H: User Interface (UI) Navigation Map

The UI navigation map can be used as a high-level tool to navigate through the CLINITEK Novus user interface. This map shows the most commonly used features, beginning with the function buttons on the home screen. This map does not show every menu, submenu, or softkey.

User Interface (UI) Navigation Map



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