CLINITEK Status®
Connect System

Operator's Guide

(For U.S. Only)

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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.

1 Introduction

The CLINITEK Status® connector is intended for use with the CLINITEK Status+ analyzer. The connector allows network connectivity and centralized control of all the satellite Point of Care (POC) CLINITEK Status+ analyzers. The connector communicates with remote Hospital and Laboratory Information Systems (HIS/LIS) and interfaces with Electronic Medical Records (EMR).

The CLINITEK Status connector and CLINITEK Status+ analyzer together are the CLINITEK Status Connect system.

This operator's guide provides information about setting up and using functionality provided by the connector. For complete information about using the CLINITEK Status+ analyzer, see the *CLINITEK Status+ Analyzer Operator's Guide*.

The connector includes the following key features:

- Centralized control
- Communication with an LIS
- Bar-code scan to easily enter data
- Operator management and security
- Password protection
- Improved data management
- Quality control (QC) lockout
- QC reminder
- Communication through the Ethernet or a wireless connection
- Recall patient and QC records
- Copy Setup configuration using a USB memory stick
- Customized urine colors

Hardware Overview

The hardware consists of the following components:

- User interface
- Network connectivity

- Memory
- Bar-code scanner (optional)

User Interface

The CLINITEK Status connector connects to the CLINITEK Status+ analyzer by attaching the units and connecting them with two short cables. The connector includes 2 Universal Serial Bus (USB) 2.0 ports, 1 Ethernet (RJ45) port, and 3 Serial (RS-232) ports.

You can connect a USB memory stick, external printer, Ethernet device, and handheld bar-code scanner to the system using the interface connections. You can use an optional handheld bar-code scanner or external keyboard to enter operator, patient, and cassette and strip information into the system, instead of entering information using the keyboard screens.

Network Connectivity

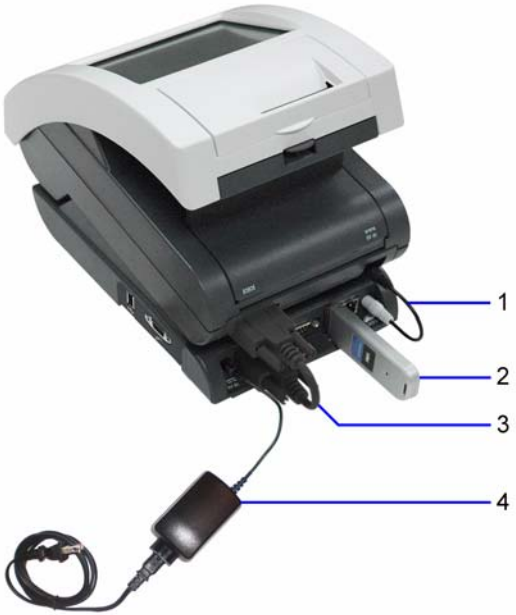
The CLINITEK Status connector supports bi-directional communication with an external LIS and Ethernet, or wireless network connectivity.

The connector supports the 802.11b and 802.11g wireless specifications by connecting a wireless card to the rear USB port.

Standard wired connectivity is available by using the supplied Ethernet cable and the RJ45 port.

You also can send CSV-formatted results to an LIS or PC using the serial (RS-232) port on the back of the connector.

Figure 1-1: Network Connections and Power Cord



1. 7.6-cm (3-inch) DC power cable
2. Optional wireless card
3. 15.2-cm (6-inch) RS-232 cable
4. Power supply adaptor with AC power cord

Memory

The CLINITEK Status+ analyzer operating system, software, and settings are stored in the onboard, non-volatile, EEPROM memory. You can insert a USB memory stick into the USB port on the connector to copy configuration information. You can then insert the USB memory stick into another CLINITEK Status connector and copy the configuration setup to the new system.

Note You cannot import data from a spreadsheet into the system.

Optional Bar-code Scanner

The connector also supports importing certain information using an optional bar-code scanner. When a screen prompts for patient information, operator ID and name, or QC control and level, you can use the bar-code scanner to enter the information.

Figure 1-2: Bar Code of Patient Information

Software Overview

The CLINITEK Status Connect system provides an easy-to-navigate user interface. For complete information about using the CLINITEK Status+ analyzer, see the *CLINITEK Status+ Analyzer Operator's Guide*.

Analyzer Overview

This section provides a quick reference on navigating and using the CLINITEK Status+ analyzer user interface screens, entering information, test modes, and setting a password. For complete information about using the CLINITEK Status+ analyzer, see the *CLINITEK Status+ Analyzer Operator's Guide*.

Navigating the Screens

The CLINITEK Status+ analyzer screens display messages, instructions, and options to which you respond by selecting or touching the appropriate area on the screen. Each screen has an icon, title bar, and one or more touch-sensitive active areas. To select any item, touch the appropriate area on the screen.

The icon indicates the area in which you are working: Strip Test, Cassette Test, Instrument Set Up, Recall Results, or QC.

For screen symbols, see *Appendix F, Symbols*, *User Interface*, page 85.

The system provides 3 types of touch-sensitive areas:

- **Option buttons** Option buttons typically appear on screens that require a selection among several items. The button with a filled circle is the current selection. Some screens allow more than one selection.
- **Selection areas** Selection areas are text or symbols on the screen enclosed in boxes of varying sizes. To activate that function, touch any area within the box.
- **Scroll arrows** Scroll arrows are the up and down arrows on the right side of the screen. Touch the arrows to scroll through the list of information on the left side of the screen. After the information on the left side of the screen is highlighted, select the appropriate button at the bottom of the screen. If double scroll arrows display on the screen, use these arrows to navigate to the top or bottom of the page.

Entering Information

When the screen prompts you to enter information, an alphabetic or numeric keyboard displays on the screen. To toggle between the alphabetic and numeric keyboards, select either **A B C** or **1 2 3** at the top left part of the screen. When you finish entering information, select **Enter** at the bottom of the screen.

Setting Test Mode

The CLINITEK Status+ analyzer allows you to set up patient tests in 3 modes: Quick, Full, or Custom. When the CLINITEK Status+ analyzer is set to Quick Test, the system does not display prompt for patient or operator information. In Full Test, the system displays prompts for operator and patient information. Custom Test allows you to set which options are prompted and displayed in results.

Setting the Password

The CLINITEK Status+ analyzer default is to have the password disabled. You can set the password through Instrument Settings. One password allows all users who know it to modify system settings. The password differs from the Operators ID list in that you can permit individual operators to perform patient tests, QC tests, recall results, and modify system settings. If both the password and Operator ID are enabled, the system prompts only for the Operator ID. For more information about Operator IDs, see *Section 2, Operations, Managing the Operators List*, page 17.

2 Operations

This section describes how to use the CLINITEK Status connector with the CLINITEK Status+ analyzer. For complete information about using the analyzer, see the *CLINITEK Status+ Analyzer Operator's Guide*.

The connector allows the system to connect to a Local Area Network (LAN) and supports several external devices. The connector includes two USB ports, three serial RS-232 ports, and one Ethernet RJ45 port.

The USB ports allow for software upgrades, copying configuration setup, wireless network connectivity, and external keyboard use. The RS-232 ports are used to send data to Laboratory Information Systems (LIS) and support an optional bar-code scanner. The RJ45 port provides network connectivity for communication with remote systems.

Getting Started

This section explains how to set up the CLINITEK Status Connect system for the first time using the Start-Up Wizard. For unpacking and installing instructions, see *Section 6, System Configuration*.

Using the Start-Up Wizard

After you connect the instrument and connector, and turn the system on, the instrument completes self-checking and the **Start-Up Wizard** screen displays. Use the Start-Up Wizard to set the basic functionality including the language, current date and time, and unit convention.

To set the basic functionality with the Start-Up Wizard:

1. On the **Select Language** screen, use the arrow keys to select your language.
2. Select **Select**.

   The next **Start-Up Wizard** screen displays.
3. Select **Next**.

   The **Set Date & Time** screen displays.
4. Use the arrow keys to set the month, day, year, and time.

5. Select **Next**.

   The **Input Settings** screen displays.

6. Select **Quick Test** or **Full Test**.

   For descriptions of the Quick and Full tests, see the *CLINITEK Status+ Analyzer Operator's Guide*.

7. Select **Next**.

   The **Select Urinalysis Test** screen displays.

8. Use the arrow keys to select a Siemens reagent strip.

9. Select **Next**.

   The **Choose Results Format** screen displays.

10. Select the **Conventional**, **SI**, or **Nordic** unit.

    Note Nordic units are available only in English and Swedish. SI units are available only in Chinese. If you set the language to Chinese, the **Choose Results Format** screen does not display.

11. To return to the **Select Ready** screen:

    a. Select **Next**.

       The **Confirmation** screen displays.

    b. Select **Next**.

       The **Select Ready** screen displays.

To enable the connector functionality, see *Enabling the Connector*, page 17.

Note If you reset the system defaults, the connector resets to **Enabled**.

Getting to the Select Ready Screen

The **Select Ready** screen displays after system initialization. The **Select Ready** screen is the starting point to run urine strip tests, cassette tests, QC tests, and to recall data or modify system settings.

When you turn the power on, the system initializes and the **Select Ready** screen displays. After you modify the system settings or run tests, you might need to select **Done** several times to return to the **Select Ready** screen.

Enabling the Connector

To enable the connector to communicate with the CLINITEK Status+ analyzer:

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

   The **Choose Settings** screen displays.

2. Use the arrow keys to select **Instrument Settings**.
3. Select **Select**.

   The **Instrument Settings** screen displays.

4. Use the arrow keys to select **Connectivity**.
5. Select **Select**.

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

6. To enable communication between the instrument and the connector, select **Enabled**.

   To prevent communication, select **Disabled**.

   You can edit the connectivity settings if the connector is Disabled.

   Note If you do not run your analyzer with a connector, Siemens recommends setting the connector to the **Disabled** setting. Setting the connector to the **Enabled** setting without a connector might prevent communication with an external system.

7. Select **Previous**.
8. Select **Done** twice to return to the **Select Ready** screen.

Managing the Operators List

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

The CLINITEK Status+ analyzer stores 700 operators. The Clinitek Status Analyzer stores 20 operators.

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

CAUTION
Do not change the Operator ID setting after you set the Operator ID and Operator Name settings. If you change the Operator ID setting, the system deletes all the patient results.

Setting up the Operator IDs

To set up the operator IDs, perform the following steps:

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

   The **Choose Settings** screen displays.

2. Use the arrow keys to select **Instrument Settings**.
3. Select **Select**.

   The **Instrument Settings** screen displays.

4. Use the arrow keys to select **Authorized operator**.
5. Select **Select**.

   The **Authorized operator** screen displays.

6. Select an authorized operator access option:

   a. To permit access only by authorized operators, select **Enabled**. To add at least 1 operator, see the next section, *Adding the Operator IDs*.

   b. To allow all operators access to the system, select **Disabled**. Select **Done** 3 times to return to the **Select Ready** screen.

CAUTION
Do not power down the system if the instrument uses the operator list sent by the LIS. If the connector loses power, the system deletes the operator names.

Note The operator list sent by the LIS overwrites the operator list you enter through the CLINITEK Status+ analyzer.

Adding the Operator IDs

To add operator IDs:

Note The operator list sent by the LIS overwrites the operator list you enter through the CLINITEK Status+ analyzer.

1. On the **Authorized operator** screen, select **Add operator**.
2. Enter the new **Operator ID**.

   Note To enter text, use the alpha keyboard (**ABC**). To enter numbers, select **123**.
3. Select **Enter**.

   The **Authorized Operator** screen displays with the Operator ID and which functions the operator can perform.
4. To edit this Operator ID, select **Edit**.
5. To edit which functions this Operator ID can access, select **Edit**.

   The **Authorized Operator-Operator access screen 1 of 2** displays.
6. Enable or disable the following operator access options:
   - To allow this operator to run patient tests, select **Enabled**. To prevent patient tests, select **Disabled**.
   - To allow this operator to run QC tests, select **Enabled**. To prevent QC tests, select **Disabled**.
7. Select **Next**.

   The **Authorized Operator-Operator access screen 2 of 2** displays.
8. Enable or disable the following operator access options:
   - To allow this operator to recall results, select **Enabled**. To prevent recall results, select **Disabled**.
   - To allow this operator to set up the instrument, select **Enabled**. To prevent instrument setup, select **Disabled**.

9. To return to the **Select Ready** screen:
    a. Select **Done** twice.

       The **Authorized Operator-Operators list** screen displays.
    b. Select **Exit**.
    c. Select **Done** 3 times to return to the **Select Ready** screen.

Viewing, Printing, Deleting, and Editing the Operator IDs

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

Note If you delete the entire operator list, ensure that the Authorized Operators setting is Disabled. For details about adding an operator, see *Adding the Operator IDs*, page 19.

To delete, edit, view, and print the operators list:

1. To delete the entire operators list:
    a. On the **Authorized operator** screen, select **Delete operators list**.

       The **Delete operators list** caution screen displays.
    b. Select a delete option:
        - To delete, select **Yes**. Go to step 5.
        - To keep the operators list, select **No**. The **Authorized operator** screen displays.
2. To edit or view the operators list:
    a. On the **Authorized operator** screen, select **View operators list**.

       The **Authorized Operator-Operators list** screen displays.
    b. Use the arrow keys to select the operator you want to delete or edit.
3. To delete or edit an operator:
    - To delete that operator, select **Delete entry**.
    - To edit or delete that operator, select **Select**.

      The **Authorized operator** screen displays.

- To add an operator, see *Adding the Operator IDs*, page 19.

4. To print all the operators, select **Print**.

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

5. To return to the **Select Ready** screen:

   a. To return to the **Authorized operator** screen, select **Exit**.

   b. Select **Done** 3 times.

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

Scanning the Patient Information

You can require operators to only enter patient information with the bar-code scanner and not allow operators to manually enter patient information.

To require patient information entry only by scanning, perform the following steps:

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

   The **Choose Settings** screen displays.

2. Use the arrow keys to select **Operator and Patient Information**.

3. Select **Select**.

   The **Input Settings** screen displays.

4. Select **Custom Set Up**.

5. Select **Next**.

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

6. Select **Next**.

   The **Custom Settings-Patient Information screen 2 of 5** displays.

7. Select **Bar code reader settings**.

   The **Patient Information** screen displays.

8. Select a bar-code reader setting:

- To require entry of patient information only by bar-code scanner, select **Enabled**.
- To permit entry of patient information by either bar-code scanner or manually, select **Disabled**.

9. To return to the **Select Ready** screen:
   a. Select **Done**.

      The **Custom Settings Patient Information screen 2 of 5** displays.
   b. Select **Next** 4 times.
   c. Select **Done** twice to return to the **Select Ready** screen.

Managing the Urine Colors

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

Setting and Customizing Urine Colors

You can select from 1 of 10 instrument-provided colors and add up to 4 customized colors to the patient test results.

To include instrument-provided colors, perform the following steps:

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

   The **Choose Settings** screen displays.
2. Use the arrow keys to select **Operator and Patient information.**
3. Select **Select**.

   The **Input Settings** screen displays.
4. Select **Custom Set Up**.
5. To navigate to the **Sample Appearance-Select Colors** screen:
   a. Select **Next**.

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

b. Select **Next** 3 times.

   The **Custom Settings-Sample Appearance screen 4 of 5** displays.

c. Select **Edit colors**.

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

6. To select colors, select a button for the color you want.

   To remove a selected color, select that color button again.

7. Select **Next**.

   The **Sample Appearance-Select colors screen 2 of 3** displays.

8. To select colors, select a button for the color you want.

9. To return to the **Select Ready** screen:

   a. Select **Next**.

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

   b. Select **Next** 3 times.

      The **Input Settings-Confirmation** screen displays.

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

Adding Customized Colors

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

1. On the **Sample Appearance-Select colors screen 3 of 3**, select **Enter custom color 1** (**2**, **3**, or **4**) corresponding to each custom color.

2. Enter the custom color (maximum of 10 characters).

   Note To enter text, use the alpha keyboard (**ABC**). To enter numbers, select **123**.

3. Select **Enter**.

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

CAUTION
Do not edit a custom color that already exists. The system would delete all the patient results.

If a custom color exists, the **Sample Appearance** screen displays.

- Select **Yes**, to edit that custom color and delete all records.
- Select **No**, to return to the **Sample Appearance Select Colors screen 3 of 3**.

4. Select **Next** 3 times.

   The **Input Settings-Confirmation** screen displays.

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

Entering the Urine Color and Clarity during the Test Cycle

While a strip test is in progress, you can select one of the instrument-provided or custom urine colors and clarity options for a urine sample. You can select the standard option of Yellow for urine color and Clear for clarity.

Note The Entering urine color and clarity option is available only in Full Test or Custom mode.

To enter the urine color and clarity:

1. On the **Select Appearance-Test in progress** screen, during a patient test, select a urine color and clarity option:
   - To select the standard option, select **Yellow and Clear**. Go to step 8.
   - To select a urine color and clarity, select **Other**.

     If you selected **Other**, the **Select Appearance-Test in progress screen 2 of 4** displays.
2. Select a color for the urine sample from the options displayed.
3. Select **Next**.

   The **Select Appearance-Test in progress screen 3 of 4** displays.
4. If you want a different color for the urine sample, select a color from the options displayed.

   Note You can select only one color for a urine sample.
5. Select **Next**.

   The **Select Appearance-Test in progress screen 4 of 4** displays.

6. Select the clarity of the urine sample.
7. Select **Next**.

   While the test is in progress, the **Analyzing-In progress** screen displays followed by the **Results** screen.
8. Select **Done** to return to the **Select Ready** screen.

Managing the Strip Lot Number and Expiration Date

You can enter the strip lot number and expiration date and associate this information with each patient record. After entered, the information is retained for the next test, or you can enter a new lot number and expiration date. You can also enter strip information using the optional bar-code scanner.

You can set the instrument to prompt for new strip information or use the information from the last strip before each patient test.

Setting the Strip Information Prompt

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

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

   The **Choose Settings** screen displays.
2. Use the arrow keys to select **Instrument Settings**.
3. Select **Enter**.

   The **Instrument Settings** screen displays.
4. Use the arrow keys to select **Urinalysis Test Settings**.
5. Select **Select**.

   The **Urinalysis Test Settings** screen displays.
6. Select **Next**.

   The **Urinalysis Test** screen displays.

7. Select a prompt option:
   - To prompt for strip information before each test, select **Enabled**.
   - To bypass a prompt to enter strip information before each test, select **Disabled**.
8. Select **Done** 3 times to return to the **Select Ready** screen.

Entering the Strip Lot Number and Expiration Date

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

Note For more information about the strip lot number and expiration date, see the *CLINITEK Status+ Analyzer Operator's Guide*.

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

   The **Strip** screen displays.
2. Select a strip lot number and expiration date option:
   - To use the last strip number and begin the test, select **Use Last Lot**.
   - To enter new strip data, select **Enter new lot and expiration**.

   The **Strip Lot** screen displays.
3. Enter the strip lot number.

   Note To enter text, use the alpha keyboard (**ABC**). To enter numbers, select **123**.
4. Select **Enter**.

   The **Strip Expiration** screen displays.
5. Use the arrow keys to indicate the strip expiration date.
6. Select **Enter**.

   The **Prepare Test** screen displays.
7. Select **Start**.

3 Quality Control

Quality Control (QC) testing helps assure that the reagent strips and cassettes are reacting correctly and that the instrument is accurately reading them. It can also help detect errors resulting from user techniques.

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

Note You cannot send QC results through the serial port to a host computer or LIS.

To ensure quality throughout the entire testing process, read about your laboratory quality assurance program. For information about recalling or deleting QC records, see Section 5, *File Management*, *Managing Patient and System Information*, page 45.

You should run quality controls when:

- Determined by your laboratory procedures at regular intervals.
- Using a new shipment of reagents or cassettes.
- Using a new lot number of reagent or cassettes.
- Opening a new bottle of reagents.
- Test results are in doubt.
- Training new operators.

CAUTION
Ensure that the QC setup includes all analytes you measure in your location. Otherwise, QC testing coverage may not be complete.

Managing the QC Tests

A CLINITEK Status+ analyzer can store up to 200 QC test results. A CLINITEK Status analyzer can store up to 50 QC test results.

You can run QC tests for strips or cassettes at any time or when a QC test is due based on a schedule you set. When a QC test is due, the **QC** button on the **Select Ready** screen displays the type of test (strip or cassette) that is due.

- To run a QC test at any time, select **QC Test** on the **Select Ready** screen and see *Running a QC Strip Test*, page 36 or *Running a QC Cassette Test*, page 38.
- To run a QC test when it is due, select **QC Test Strip (or Cassette) due** on the **Select Ready** screen and see *Running a QC Strip Test*, page 36 or *Running a QC Cassette Test*, page 38.

You can manage QC tests in the following ways:

- Set the instrument to lock out patient tests when a required QC is due.
- Set whether the instrument or operator determines if QC results pass or fail.
- Set the instrument to allow patient tests when a reminder QC is due.
- Set the instrument to lock out testing any patient sample until all QC control results are within the acceptable range. If a control result is out of range, troubleshoot the system, correct any problems identified, and run the controls again. When control results are within the acceptable range, you can test and report patient samples as usual.

Setting up the QC Strip Tests

You can set QC strip tests and define their type, frequency, and pass or fail ranges. You can set required or reminder QC tests, frequency and schedule, and the number of control levels for each QC.

Using the QC Set Up features, you can set whether the instrument or operator determines QC pass or fail results. If the instrument determines pass or fail, it compares the QC results to the ranges you specified in QC Setup. Or, you can have the operator determine the QC test pass or fail after viewing the results.

Accessing the QC Strip Set Up

To access the QC Set Up procedure for strip tests, perform the following steps:

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

   The **Choose Settings** screen displays.

2. Use the arrow keys to select **Instrument Settings**.
3. Select **Select**.

   The **Instrument Settings** screen displays.
4. Use the arrow keys to select QC Settings.
5. Select **Select**.

   The **QC Settings** screen displays.
6. For QC strip test, select Set Up.

   The **QC Settings-Strip test screen 1 of 3** displays.

Setting the QC Strip Tests Options

To set the QC strip tests, perform the following steps:

1. Select a QC strip test option:
   - To allow QC prompts, select **Enabled**.
   - To prevent QC prompts, select **Disabled**.
2. Select a required or reminder option:
   - To require QC tests when they are due and not permit patient tests, select **Required**.
   - To permit patient tests even if a QC test is due, select **Reminder**.
3. Select **Next**.

   The **QC Settings-Strip test screen 2 of 3** displays.
4. Select a QC pass or fail option:
   - To have the instrument determine QC pass or fail, select **Instrument**.
   - To have the operator determine QC pass or fail, select **Operator**.

   Note If you selected to have the operator determine pass or fail, you do not need to define the QC strip test controls and set the QC strip test pass or fail ranges. However, you must use the strip selected in the **Urinalysis Test Settings** screen, a color-banded strip, or an IR-banded strip. You can only run one QC level for each QC test; additional levels require an additional QC test.

5. Select a QC test fail option:
   - To permit patient tests if the QC test fails, select **Yes**.
   - To prevent patient tests if the QC test fails, select **No**.
6. Select **Next**.

   The **QC Settings-Strip test screen 3 of 3** displays.

Defining the QC Strip Test Controls

To define QC strip test controls, perform the following steps:

1. To set the number of levels to complete a QC test, select **1**, **2**, or **3**.
2. For each control set in step 1, select the corresponding **Control Level, 1**, **2**, or **3**.

   For example, if you set 2 controls, you must define Control Level 1 and Control Level 2.

   The **Control Level 1-Strip test** screen displays.
3. To enter the first control level name:
   a. Select **Enter name of control**.

      The **Name of Control** screen displays.
   b. Enter the name of this control.

   Note To enter text, use the alpha keyboard (**ABC**). To enter numbers, select **123**.

   c. Select **Enter**.

      The **Control Level 1-Strip test** screen displays.
4. To enter the second control level name:
   a. Select **Enter name of level**.

      The **Name of Level** screen displays.
   b. Enter the name of this level.
   c. Select **Enter**.

      The **Control Level 1-Strip test** screen displays.

5. To select the strip type:
   a. Select **Select strip type**.

      The **QC Strip Type-Select strip for this QC level** screen displays.
   b. Use the arrow keys to select the strip type.
   c. Select **Select**.

      The **Control Level 1-Strip test** screen displays.

Setting QC Strip Test Pass or Fail Ranges

To set QC strip test pass or fail ranges, perform the following steps:

1. Select **Set pass ranges**.

   The **QC Level 1-Tests and pass ranges screen 1 of 3** displays.
2. To set the glucose pass range, select the **GLU** option.
3. Select the corresponding **Pass range** button.

   The **QC Level 1-Set pass range for GLU** screen displays.
4. Use the arrow keys to indicate the following values:
   - Lowest acceptable clinical values for glucose.
   - Highest acceptable clinical values for glucose.
5. Select **Set**.

   The **QC Level 1-Tests and pass ranges screen 1 of 3** displays.
6. Enter the pass ranges for glucose, ketone, blood, bilirubin, specific gravity, pH, protein, nitrite, albumin, urobilinogen, leukocytes, and creatinine, as directed in steps 2–5.

   Select **Next** to advance through all 3 screens.

   Note Each test is included in the QC if the corresponding button is filled. Each test is excluded if the corresponding button is blank. If you do not select an option, that parameter is disabled for the QC test.

   When you complete entering pass ranges for the tests, the **QC Level 1-Tests and pass ranges screen 3 of 3** displays.

7. Select **Done**.

   The **Control Level 1-Strip test** screen displays.

8. Select **Done**.

   The **QC Settings-Strip test screen 3 of 3** displays.

9. If necessary, repeat defining the QC strip test controls for the next control level.

10. After you define all the QC levels, select **Done**.

    The **QC Settings** screen displays.

Setting the QC Strip Schedule

To set the QC strip test schedule, perform the following steps:

1. For QC strip test, select **Interval**.

   The **QC Settings-Set QC schedule for strip tests** screen displays.

   To schedule QC tests by hours:

   a. Select the **Hours** option.
   b. Use the arrow keys to indicate the number of hours between QC tests.
   c. Select **Done** 3 times to return to the **Select Ready** screen.

   To schedule QC tests by days:

   a. Select the **Days** option.
   b. Use the arrow keys to indicate the number of days between QC tests.

2. If you selected Days, select **Set QC time**.

   The **QC Settings-Set QC time for strip tests** screen displays.

3. Select the **1**, **2**, or **3** option for the number of QC tests per day.

4. Use the arrow keys to indicate time of day for each test.

5. To return to the **Select Ready** screen:

   a. Select **Set**.

      The **QC Settings-Set QC schedule for strip test** screen displays.

b. Select **Done**.

   The **QC Settings** screen displays.

c. Select **Done** 3 times.

Setting Up QC for Cassette Tests

This section describes how to set QC for hCG cassette tests and define their type, frequency, and pass/fail ranges. You can set required or reminder QC tests, frequency and schedule, and the number of control levels for each QC.

Using the QC Set Up features, you can set whether the instrument or operator determines QC pass or fail results. If the instrument determines pass/fail, it compares the QC results to ranges you specified in the QC Set Up procedure. Or, you can have the operator determine QC test pass/fail after viewing the results.

Accessing the QC Cassette Set Up

To access the QC Set Up procedure for cassette tests, perform the following steps:

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

   The **Choose Settings** screen displays.

2. Use the arrow keys to select **Instrument Settings**.
3. Select **Select**.

   The **Instrument Settings** screen displays.

4. Use the arrow keys to select **QC Settings**.
5. Select **Select**.

   The **QC Settings** screen displays.

6. For the QC cassette test, select **Set Up**.

   The **QC Settings-Cassette test screen 1 of 3** displays.

Setting the QC Cassette Tests

To set the QC cassette tests, perform the following steps:

1. Select a QC cassette option:
   - To allow QC prompts, select **Enabled**.

- To prevent QC prompts, select **Disabled**.

2. To require QC tests when they are due and not permit patient tests, select **Required**.

   To permit patient tests even if a QC test is due, select **Reminder**.

3. Select **Next**.

   The **QC Settings-Cassette test screen 2 of 3** displays.

4. Select a QC pass or fail option:

   - To have the instrument determine QC pass or fail, select **Instrument**.
   - To have the operator determine QC pass or fail, select **Operator**.

   Note If you selected to have the operator determine pass or fail, you do not need to define the QC cassette test controls.

5. Select a QC test failure option:

   - To permit patient tests if the QC test fails, select **Yes**.
   - To prevent patient tests if the QC test fails, select **No**.

6. Select **Next**.

   The **QC Settings-Cassette test screen 3 of 3** displays.

Defining the QC Cassette Test Controls

To define the QC cassette test controls, perform the following steps:

1. To set the number of levels to complete a QC test, select **1** or **2**.
2. For each control set in Step 1, select the corresponding **Control Level**, **1** or **2**.

   For example, if you set 2 controls, you must define Control Level 1 and Control Level 2.

   The **Control Level 1-Cassette test** screen displays.

3. To enter the first control level name:

   a. Select **Enter name of control**.

      The **Name of Control** screen displays.

   b. Enter the name of this control.

Note To enter text, use the alpha keyboard (**ABC**). To enter numbers, select **123**.

c. Select **Enter**.

The **Control Level 1-Cassette test** screen displays.

4. To select a control level type:
   - To set the control level as positive, select **Positive**.
   - To set the control level as negative, select **Negative**.
5. Select **Done**.

   The **QC Settings-Cassette test screen 3 of 3** displays.
6. If necessary, repeat defining QC cassette test controls for the next control level.
7. After you define all the QC levels, select **Done**.

   The **QC Settings** screen displays.

Setting a QC Cassette Test Schedule

To set the QC cassette test schedule, perform the following steps:

1. For QC cassette test, select **Interval**.

   The **QC Settings-Set QC schedule for cassette test** screen displays.
2. Schedule the QC tests:
   - To schedule QC tests by hours, select the **Hours** option and use the arrow keys to indicate the number of hours between QC tests. Go to step 7.
   - To schedule QC tests by days, select the **Days** option and use the arrow keys to indicate the number of days between QC tests.
3. If you selected Days, select **Set QC time**.

   The **QC Settings-Set QC time for cassette test** screen displays.
4. Select the **1**, **2**, or **3** option for the number of QC tests per day.
5. Use the arrow keys to indicate time of day for each test.

6. Select **Set**.

   The **QC Settings-Set QC schedule for cassette tests** screen displays.

7. Select **Done**.

   The **QC Settings** screen displays.

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

Running a QC Strip Test

Note Prepare the controls according to the manufacturer's instructions.

This section describes how to run a QC strip test when it is due and for one QC level. Repeat the procedure if more than one QC level is set.

To perform a QC strip test when due, perform the following steps:

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

   The **QC Test** screen displays.

2. Select **QC Strip Test Required**.

   - If the instrument is set to determine pass/fail, the **Control Lot** screen displays. Go to step 5.
   - If the operator is set to determine pass/fail, the **Name of Control** screen displays.

3. To enter the control information:

   a. Enter the control name and select **Enter**.

      Note To enter text, use the alpha keyboard (**ABC**). To enter numbers, select **123**.

      The **Name of Control Level** screen displays.

   b. Enter the control level and select **Enter**.

      The **Control Lot** screen displays.

   c. Enter the control lot and select **Enter**.

      The **Control Expiration** screen displays.

   d. Use the arrow keys to indicate the control lot expiration date and select **Enter**.

      The **Strip Lot** screen displays.

4. To enter the strip information:
   a. Enter the strip lost and select **Enter**.
      The **Strip Expiration** screen displays.
   b. Use the arrow keys to indicate the strip expiration date.
   c. Select **Enter**.

   The **Prepare Test** screen displays.

   If needed, see the *CLINITEK Status+ Analyzer Operator's Guide*.
5. Select **Start**.

   The **Results** screen displays.

   Note When the instrument is set to determine pass/fail, if the test results pass, the **Results-QC Test: Pass** screen displays. If the test results fail, the **Results-QC Test: Fail** screen displays.
6. To print the results, select **Print**.
7. To navigate the results:
   - To view the next page, select **More**.
   - To return to the previous page, select **Back**.
8. Select **Done**.

   The **QC Test-Select PASS or FAIL** screen displays.
9. To select a pass or fail option:
   - To pass the test, select **QC PASS**.
   - To fail the test, select **QC FAIL**.
10. Select **Done**.

    The **QC Test-Results Summary** screen displays.

    Note Depending on the instrument configuration, you cannot run the patient tests until the QC tests pass.
11. To repeat a failed QC test, select **Repeat failed QC test**.

12. Select **Done** to return to the **Select Ready** screen.

CAUTION
If you set more than 1 QC test control level, such as negative and positive, be sure to run all control levels within 10 minutes of each other. Otherwise, the CLINITEK Status+ analyzer times out and the QC fails. Any successful QC does not count.

Running a QC Cassette Test

This section describes how to run a QC cassette test when it is due and for one QC level. Repeat the procedure if more than one QC level is set.

To perform a QC cassette test when due, perform the following steps:

1. Prepare the controls according to the manufacturer's instructions.
2. On the **Select Ready** screen, select **QC Test Cassette test due**.

   The **QC Test** screen displays.
3. Select **QC Cassette Test Required**.
   - If the instrument is set to determine pass/fail, the **Control Lot** screen displays. Go to step 5.
   - If the operator is set to determine pass/fail, the **Enter Control Name** screen displays.
4. To enter the control information:
   a. Enter the name of this control and select **Enter**.

      Note To enter text, use the alpha keyboard (**ABC**). To enter numbers, select **123**.

      The **Enter Control Level** screen displays.
   b. Enter the control level and select **Enter**.

      The **Control Lot** screen displays.
   c. Enter the control lot and select **Enter**.

      The **Control Expiration** displays.
   d. Use the arrow keys to indicate the control lot expiration date and select **Enter**.

      The **Cassette Lot** screen displays.

5. To enter the cassette lot information:

   a. Enter the cassette lot number and select **Enter**.

      The **Cassette Expiration** screen displays.

   b. Use the arrow keys to indicate the control lot expiration date. and select **Enter**.

      The **Prepare Test** screen displays.

6. Select **Start**.

   If needed, see the *CLINITEK Status+ Analyzer Operator's Guide*.

   The **Results** screen displays.

   Note When the instrument is set to determine pass/fail, if the test results pass, the **Results-QC Test: Pass** screen displays. If the test results fail, the **Results-QC Test: Fail** screen displays.

7. To print the results, select **Print**.

8. To navigate the pages:

   - To view the next page, select **More**.
   - To return to the previous page, select **Back**.

9. Select **Done**.

   The **QC Test-Select PASS or FAIL** screen displays.

10. To select a pass or fail option:

    - To pass the test, select **QC PASS**.
    - To fail the test, select **QC FAIL**.

11. Select **Done**.

    The **QC Test-Results Summary** screen displays.

    Note Depending on instrument configuration, patient tests cannot be run until the QC tests pass.

12. To repeat a failed QC test, select **Repeat failed QC test**.

13. Select **Done** to return to the **Select Ready** screen.

CAUTION
If you set more than 1 QC test control level, such as negative and positive, be sure to run all control levels within 10 minutes of each other. Otherwise, the CLINITEK Status+ analyzer times out and the QC fails. Any successful QC does not count.

Managing the QC Results

This section describes how to add notes to the QC test results and print the QC strip or cassette results:

1. To run a QC test, see *Running a QC Strip Test*, page 36 or *Running a QC Cassette Test*, page 38.
2. On the **Results-QC Test** screen, select **Add QC notes**.

   The **QC Test-Add QC notes** screen displays.
3. Enter notes about this QC test.

   Note To enter text, use the alpha keyboard (**ABC**). To enter numbers, select **123**.
4. Select **Enter**.

   The **Results-QC Test** screen displays.
5. To print the results, select **Print**.
6. Select **Done** to return to the **Select Ready** screen.

   Note You can only add QC test notes immediately after you run a test.

Quality Control Errors

If the control results are outside the values stated in the package insert, try using a new control solution. If the new solution fails again, contact the manufacturer. For more information, see the quality control and urinalysis strip or cassette instructions for use.

The following table lists possible sources of error and suggested corrective action.

Cause	Corrective Action
Incorrect analyzer setup.	If using a reagent strip, verify that the reagent strip used corresponds to the reagent strip selected. Repeat the control procedure.
Improper technique.	Carefully repeat the control procedure. See the *CLINITEK Status+ Analyzer Operator's Guide*, as needed.
Deterioration of the reagent strip/cassette test areas due to exposure to light, ambient moisture, or heat.	Use a fresh bottle of reagent strips or pack of cassettes to repeat the quality control procedure. If fresh reagent strips or cassettes fail to give results within the expected values, proceed to the next possible cause.
Deterioration of the control solution.	Use a fresh control solution to repeat the quality control procedure. If fresh solution fails to give results within the expected values, proceed to the next possible cause.
Deterioration of the quality control product.	Prepare control solution using a fresh bottle of control product. Repeat the quality control procedure. If the fresh control solution fails to give results within the expected values, proceed to the next possible cause.
CLINITEK Status+ analyzer malfunction.	If you cannot successfully complete the quality control procedure, an analyzer malfunction or reagent strip problem may exist. Check the calibration bar for dust, dirt, or scratch marks, or contact Technical Support at 877-229-3711 for assistance.

4 Troubleshooting

If an operational or system problem occurs, an error code or message may display on the screen with an explanation of the problem. If the problem persists, record the error code, and contact Technical Support at 877-229-3711 for assistance.

If you turn the system off, you must retest the sample that was in process when the error occurred.

Depending on the configuration, the following messages may display and require action to continue:

- Not all required QC levels were run.

  Exiting now will cause the QC test to fail.
- The QC test has failed.

  Patient tests cannot be run until a QC test is passed.
- Disabling authorized operators will cause all stored data to be deleted.
- Operator is not authorized to access this area.
- Deleting records will clear the selected stored data.
- Editing this custom color will cause all stored data to be deleted.
- At least one color must be enabled.
- The authorized operator list is full.

  You must delete some operators before you can add more.
- Copying the set up to the memory stick will delete all stored data.
- It is not possible to copy Set Up.

  The software versions do not match.
- The software versions detected are not compatible. Install new software or notify your local representative.

5 File Management

A CLINITEK Status+ analyzer may contain up to 950 patient test and 200 QC test results, and up to 700 authorized operators.

A CLINITEK Status analyzer may contain up to 200 patient test and 50 QC test results, and up to 20 authorized operators.

Note If the LIS sends the Operators List to the system, Operator Names are not retained if the system loses power. The LIS must resend the list.

Managing Patient and System Information

You can recall or delete patient or QC results. You can recall all patient data or QC tests or search the results by ID or date. You can also delete all patient and QC results stored on the instrument.

Recalling Patient or QC Results

To recall the patient or QC results, perform the following steps:

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

   The **Recall Options** screen displays.

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

   The **Recall Results** screen displays.

4. Select a search option:
   - To search patient tests, select **Patient tests**.
   - To search QC tests, select **QC tests**.
5. Select **Next**.

   The **Recall Results** screen displays.

6. Search for the results in any of the following ways:
   - To search for patient tests by a patient name or patient ID, or to search for QC tests by operator ID, select **Search by name or ID**. Go to Step 7.
   - To search by date, select **Search by date**. Go to step 9.

7. To retrieve all the results, select **View all results**. Go to step 11.

   Enter the patient or QC test search criteria:

   - To recall patient test results, enter a patient name or a patient ID.
   - To recall QC test results, enter an operator ID.

   Note To enter text, use the alpha keyboard. To enter numbers, select **123**.

8. Select **Enter**. Go to step 11.
9. Select a date range.
10. Select **Search**.

    The **Recall Results-Search Results** screen displays.

11. To view or print the retrieved records, follow these steps:

    - To print all the records retrieved, select **Print all**.

    Note Printing all the records may take a long time.

    - To send all the records retrieved to an external system, select **Send all**.

    Note If you select **Send all**, but no data exists to send, a screen with the message `No data to send` displays.

    - To select an individual record, use the arrow keys to select the record. Select **Select**.

12. To search again, select **Back**.

    The **Recall Options** screen displays.

13. Select **Done** to return to the **Select Ready** screen.

Deleting Records

You can delete all patient and QC results stored on the instrument.

To delete the patient and QC results, perform the following steps:

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

   The **Recall Options** screen displays.

2. Use the arrow keys to select **Delete Records**.

3. Select **Select**.

   The **Delete Records** screen displays.

4. Select an option:

   - Select **Yes** to delete all records and return to the **Select Ready** screen.
   - Select **No** to return to the **Recall Options** screen.

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

6 System Configuration

This section provides detailed unpack and installation instructions for the CLINITEK Status connector. Follow the installation steps carefully to ensure proper installation, operation, and service.

CAUTION
Do not drop or handle the system roughly, which can disturb internal calibrated optics and electronics or cause other damage. Always handle the system with care.

Place the CLINITEK Status Connect system in a location specific for avoiding extreme temperature variations. Avoid proximity to open windows, direct sunlight, ovens, hot plates, open burners, radiators, and dry ice baths. Do not place the system on the same bench as a source of vibration. Provide bench space large enough to allow free air circulation around the system.

Note If you run analyzer software version 1.9 or lower, upgrade the software to the latest version. For more information about the software upgrade instructions, see the Software Upgrade Kit.

Recording the Warranty Information

1. Locate the serial number.

   The instrument serial number is located under the printer cover. The connector serial number is on the bottom of the connector.

2. Print the Pre-service Checklist, and the warranty information in *Appendix A, Support Information*.

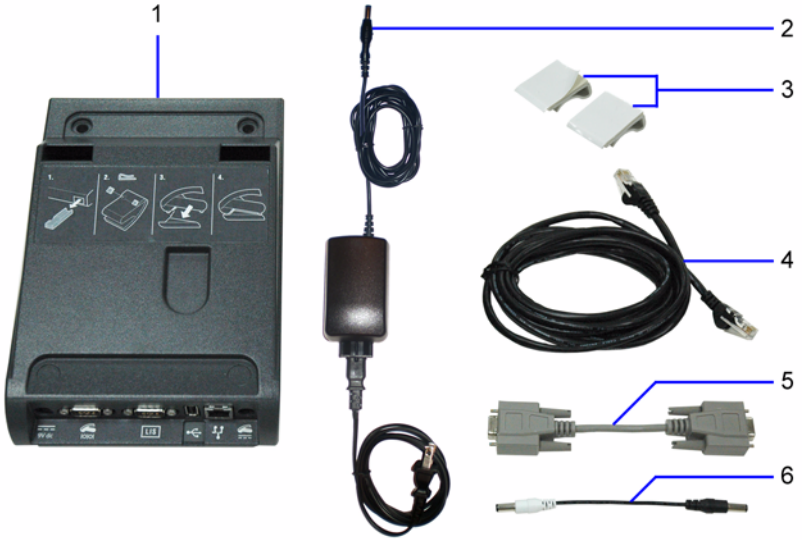
3. Write the installation date and serial number in the spaces provided on the Pre-service Checklist, and in the warranty information printout.

Unpacking the Connector

The CLINITEK Status connector is delivered in one shipping carton.

1. Carefully remove the contents of the shipping carton.
2. Inspect the carton and contents for visible signs of damage. If damage to the connector exists, immediately file a complaint with the carrier.
3. Ensure all the items in the following list are included in the package:
   - CLINITEK Status connector
   - 2 plastic clips
   - Power supply adaptor and AC power cord
   - Documentation CD
   - Quick Reference Guide, English
   - *CLINITEK Status Connect System Operator's Guide*, English
   - Ethernet cable
   - 15.2-cm (6-inch) Serial (RS-232) cable
   - 7.6-cm (3-inch) DC power cable
4. Retain the connector shipping carton and packing materials, which offer the best protection against damage if you need to ship the connector.

Figure 6-1: Hardware Package Contents



1. Connector
2. Power supply adaptor
3. Plastic clips
4. Ethernet cable
5. 15.2-cm (6-inch) Serial (RS-232) cable
6. Short DC power cable

Installing the Connector

To install the connector, perform the following steps:

1. See the diagram on the CLINITEK Status connector to physically attach the instrument to the connector.
2. Remove the test table from the instrument.

CAUTION
Do not touch the white calibration bar. Damage to the calibration bar may affect test results.

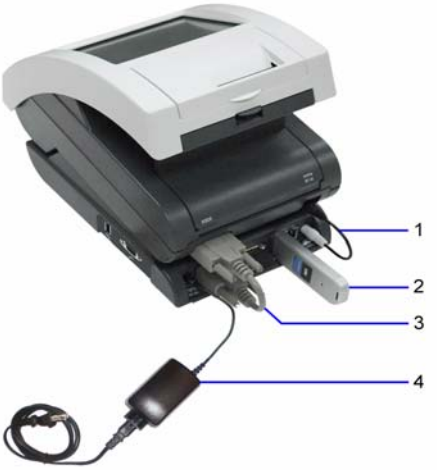
3. After ensuring the instrument is unplugged from the main power supply, fasten the instrument into the slots of the connector as shown on the diagram.

   You have 2 options for securing the units to each other:

   a. Use the clips to secure the instrument to the connector.
   b. Use only the cables mentioned in step 4 and step 5.

CAUTION
Use caution if moving the system. The two units are not securely attached and might separate.

Figure 6-2: Connections



1. Short DC power cable
2. Optional wireless card
3. Serial (RS-232) cable
4. Power supply adaptor

4. Connect the 15.2-cm (6-inch) Serial (RS-232) cable to the instrument and connector as shown in *Figure 6-2* (3).
5. Connect the white plug of the 7.6-cm (3-inch) DC power cable to the connector and the black plug to the instrument as shown *Figure 6-2* (1).

6. Select a network connectivity option:
    a. Insert an optional wireless card into the rear USB port shown in *Figure 6-2* (2).
    b. Insert the Ethernet network cable into the RJ45 port and connect the other cable end to a LAN socket.
7. Connect the power supply adaptor to the connector and then to an AC electrical wall outlet *Figure 6-2* (4).
    a. If the software version on your instrument is ≥ 2.0, proceed to step 8 below.
    b. If you run analyzer software version 1.9 or lower, upgrade the software to the latest version. For more information about the software upgrade instructions, see the Software Upgrade Kit.
8. To turn the instrument on, press the on/off button.
9. After system initialization, the **Start-Up Wizard** screen displays. The Start-Up Wizard allows you to set basic system functionality, as explained in Section 2, *Operations*, *Using the Start-Up Wizard*, page 15.

Installing the Optional Bar-code Scanner

Connect the bar-code scanner to the serial RS-232 port on the side of the connector before powering on the system. If the system is on, power it off, connect the bar-code scanner, and then turn the system on. For more information, see *Appendix D, Bar-code Scanner*.

Starting the Connect System

After you properly installed the system, press the on/off button on the instrument to start the system. The screen displays the following information:

- Model Name
- Software Version
- Copyright Information

Start Up Tests

After you turn the power on, a message displays explaining that the system is starting up. The system performs hardware functionality tests to verify that the internal optics and the mechanical system are operating correctly.

Verifying that the System is Ready

The instrument displays the current date and time and verifies that no errors occurred. If no errors occurred, the **Select Ready** screen displays and the system is ready.

Configuring the Connector

To use the functionality provided by the connector, you must enable it to operate with the instrument.

To enable the connector to communicate with the CLINITEK Status+ analyzer, perform the following steps:

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

   The **Choose Settings** screen displays.

2. Use the arrow keys to select **Instrument Settings**.
3. Select **Select**.

   The **Instrument Settings** screen displays.

4. Use the arrow keys to select **Connectivity**.
5. Select **Select**.

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

6. Select a communication option:
   - To enable communication between the instrument and the connector, select **Enabled**.
   - To prevent communication, select **Disabled**.
7. Select **Next**.
8. Select **Done** 3 times to return to the **Select Ready** screen.

For details about connecting to a network or LIS, see the following information:

- *Managing Network Connectivity*, page 56
- *Appendix E, Computer Interface (LIS)*
- *CLINITEK Status Connect System Interface Specification*

Copying Configuration Settings

Using a memory stick, you can copy configuration settings from one instrument and then copy the same settings to multiple instruments.

To copy configuration settings, perform the following steps:

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

   The **Choose Settings** screen displays.
2. Use the arrow keys to select **System Information**.
3. Select **Select**.

   The **System Information** screen displays.
4. Select **System Configuration**.

   The **Configuration Settings** screen displays.
5. Select **Copy set up**.

   The **Copy Set Up** screen displays.
6. Select a copy option:
   - To copy the configuration settings from this instrument to a memory stick, select **Copy to memory stick**.
   - To copy the configuration settings from a memory stick to this instrument, select **Copy from memory stick**.

CAUTION

Copying Set Up configuration to an instrument deletes all stored data on the instrument.

Copying Set Up configuration to a USB memory stick deletes an existing configuration file on the memory stick.

Note To copy Set Up, the software versions of the instrument from which you are copying, and the software version of the instrument to which you are copying, must match.

7. Select **Copy Set Up**.
   - If successful, the **Copy Set Up** succeeded screen displays. Select **OK**.
   - If unsuccessful, the **Copy Set Up** caution screen displays. Select **Retry** to try again or **Exit**.

Managing Network Connectivity

This section describes how to set and edit network connectivity options and set the communications protocol used to interface with your LIS. When the instrument and connector are connected, you can connect to a Local Area Network (LAN) via the RJ45 port or via an optional wireless card plugged into the rear USB port. The CLINITEK Status connector supports the HL7 or POCT1A communication protocol. You can also send data in CSV format using the rear serial port.

For serial connectivity settings and requirements including baud rate, parity, and start/stop bits, see the *CLINITEK Status+ Analyzer Operator's Guide*. For additional information, see the *CLINITEK Status Connect System Interface Specification*.

Connecting to the LAN

To connect the system to the LAN, perform the following steps:

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

   The **Choose Settings** screen displays.
2. Use the arrow keys to select **Instrument Settings**.
3. Select **Select**.

   The **Instrument Settings** screen displays.
4. Use the arrow keys to select **Connectivity**.
5. Select **Select**.

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

6. To enable communication between the instrument and the connector, select **Enabled**.

   To prevent communication, select **Disabled**.

7. To automatically send new and recalled patient results to the LIS or a PC directly connected to the system, select **Enabled**.

   To prevent sending new and recalled patient results to the LIS or PC, select **Disabled**.

8. Select **Next**.

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

9. Use one of the following options for network connectivity:

   - To connect to the LAN using the Ethernet cable, select **Wired connection**, select **Edit wired settings**, and see *Connecting to the LAN, Wired Settings*, page 57.
   - To connect to the LAN using the wireless card, select **Wireless connection**, select **Edit wireless settings**, and see *Connecting to the LAN, Wireless Settings*, page 60.
   - To connect to an external computer system using the serial connection, select **Serial connection**, and see the *CLINITEK Status+ Analyzer Operator's Guide*.
   - For no connectivity, select **None**.

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

    Note If you do not run your analyzer with a connector, Siemens Healthcare Diagnostics recommends setting the connector to **Disabled** setting. Setting the connector to **Enabled** setting without a connector may prevent communication with an external system.

    Note You can edit connectivity settings if the connector is disabled.

Connecting to the LAN, Wired Settings

Before you configure the wired settings, ensure the system is connected to the LAN with the supplied Ethernet cable. For details about the LAN settings, see *Connecting to the LAN*, page 56.

To connect to the LAN using an Ethernet cable, perform the following steps:

1. On the **Connectivity screen 2 of 2**, select **Wired connection** and select **Edit wired settings**.

   The **Wired Settings screen 1 of 4** displays.

   Note As needed, consult with your Network Administrator before entering the information.

2. Select an IP address option:

   - To use the Dynamic Host Configuration Protocol to assign a dynamic IP address, select **DHCP**. Go to step 4.
   - To manually enter a static IP address, select **Static**. To edit or create the IP address, select **Enter IP address**, and enter the IP address. Go to step 4.

3. To edit or create the device name, select **Enter device name**.

   Note To enter text, use the alpha keyboard (**ABC**). To enter numbers, select **123**.

4. Select **Enter**.

   The **Wired Settings screen 1 of 4** displays.

5. Select **Next**.

   The **Wired Settings screen 2 of 4** displays.

6. Select a Gateway option:

   To use a Gateway:

   a. Select **Yes**.
   b. To edit or create the Gateway address, select **Enter Gateway address**.
   c. Enter a gateway address.
   d. Select **Enter**.

   To bypass a Gateway, select **No**. Go to step 8.

7. To edit or create the Subnet mask:

   a. Select **Enter Subnet mask**.

      The **Subnet mask** screen displays.

b. Select **Enter**.

The **Wired Settings screen 2 of 4** displays.

c. Select **Next**.

The **Wired Settings screen 3 of 4** displays.

8. Select a communication protocol:

- To use the POCT1 communication protocol, select **POCT1**.
- To use the HL7 communication protocol, select **HL7**.

Note If you select POCT1, the **Enter Patient Information** screen displays when running a strip test, even in Quick Test mode.

9. Select **Next**.

The **Wired Settings screen 4 of 4** displays.

10. To edit or create the Host PC name, follow these steps:

a. Select **Enter PC name**.

The **PC name** screen displays.

b. Enter the PC name.

c. Select **Enter**.

11. To edit or create the Host IP address, follow these steps:

a. Select **Enter IP address**.

The **IP address** screen displays.

b. Enter the IP address.

c. Select **Enter**.

12. To edit or create the Host port number, follow these steps:

a. Select **Enter Port number**.

The **Port number** screen displays.

b. Edit or create the Host port number.

c. Select **Enter**.

The **Wired Settings screen 4 of 4** displays.

13. Select **Done**.

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

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

Connecting to the LAN, Wireless Settings

Before you configure the wireless settings, ensure a wireless card is connected to the rear USB port. For details about the LAN settings, see *Connecting to the LAN*, page 56.

To connect to the LAN using the wireless card, perform the following steps:

1. On the **Connectivity screen 2 of 2** screen, select **Wireless connection** and select **Edit wireless settings**.

   The **Wireless Settings** screen displays.

Note As needed, consult with your Network Administrator before entering information.

2. Select a security option:
   - To bypass the security settings, select **Disabled**.
   - To use WEP, select **WEP**.
   - To use WPA, select **WPA**.
   - To use WPA PSK, select **WPA PSK**.
3. Select **Next**.
   - If you selected **Disabled**, go to *Host Setup*, page 63.
   - If you selected **WEP**, go to *WEP Security*, page 60.
   - If you selected **WPA**, go to *WPA Security*, page 61.
   - If you selected **WPA PSK**, go to *WPA Security*, page 61.

WEP Security

1. Select an authentication option:
   - To use an open system, select **Open system**. To use the IEEE 802.1X specification, select **IEEE 802.1X**.
   - To use a shared key, select **Shared key**.
   - To use a pre-shared key, select **Pre-shared key**.
2. Select **Next**.

3. To enter a WEP key for WEP encryption, follow these steps:
   a. Select **Enter WEP key**.
      The **Enter WEP key** screen displays.
   b. Enter the WEP key.
   c. Select **Enter**.
4. To enter a key index for WEP encryption, follow these steps:
   a. Select **Enter key index**.
      The **Enter key index** screen displays.
   b. Select an index.
   c. Select **Set**.
5. Select **Next**.
6. Go to *IP Address*, page 62.

WPA Security

1. Select a WPA encryption option:
   - To use TKIP WPA encryption, select **TKIP**.
   - To use AES WPA encryption, select **AES**.
2. Select **Next**.
   - If you selected **WPA**, go to *IP Address*, page 62.
   - If you selected **WPA PSK**, and **TKIP** in step 1, go to *IP Address*, page 62.
   - If you selected **WPA PSK**, and **AES** in step 1, to set the WPA network key, select **WPA PSK Network key**.

   The **WPA PSK Network key** screen displays.
3. Enter the WPA PSK network key.
4. Select **Enter**.

   The **WPA PSK Network key** screen displays.
5. Select **Next**.
6. Go to *IP Address*, page 62.

IP Address

1. Select an IP address option:
   - To use the Dynamic Host Configuration Protocol to assign a dynamic IP address, select **DHCP**. Go to step 4.
   - To manually enter a static IP address, select **Static**.
2. Continue to set up the DHCP or Static option:

   If you selected **DHCP**, to edit or create the device name, follow these steps:

   a. Select **Enter device name**.

      The **Device Name** screen displays.

   b. Enter the device name.

   c. Select **Enter**.

   If you selected **Static**, to edit or create the IP address,

   a. Select **Enter IP address**.

      The **IP address** screen displays.

   b. Enter the IP address.

   c. Select **Enter**.
3. To edit or create the SSID, follow these steps:

   a. Select **Enter SSID**.

      The **Enter SSID** screen displays.

   b. Enter the SSID.

   c. Select **Enter**.
4. When you complete the settings, select **Next**.

   The system attempts to connect to a wireless network.

   - If connected, select **Next**. Go to *Host Setup*, page 63.
   - If not connected, the `Network not detected` message displays. Select **OK**.
5. Select a detected wireless network.

6. Select **Connect**.
    - If connected, select **Next**. Go to *Host Setup*, page 63.
    - If not connected, contact your Network Administrator.

Host Setup

1. To edit or create the Host PC name, follow these steps:
    a. Select **Enter PC name**.
    The **PC name** screen displays.
    b. Enter the PC name.
    c. Select **Enter**.
2. To edit or create the Host IP address, follow these steps:
    a. Select **Enter IP address**.
    The **IP address** screen displays.
    b. Enter the IP address.
    c. Select **Enter**.
3. To edit or create the Host port number, follow these steps:
    a. Select **Enter Port number**.
    The **Port number** screen displays.
    b. Enter the port number.
    c. Select **Enter**.
4. When you complete the settings, select **Next**.
5. Select a communication protocol:
    - To use the POCT1 communication protocol, select **POCT1**.
    - To use the HL7 communication protocol, select **HL7**.

    Note If you select POCT1, the **Enter Patient Information** screen displays when running a strip test, even in Quick Test mode.
6. Select **Done**.

    The **Connectivity screen 2 of 2** displays.
7. Select **Done** 3 times to return to the **Select Ready** screen.

Managing Printout Settings

This section describes how to customize the printed test results. For other printer settings, see the *CLINITEK Status+ Analyzer Operator's Guide*.

Customizing the Printout

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

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

To customize the printout, perform the following steps:

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

   The **Choose Settings** screen displays.

2. Select **Instrument Settings** and select **Select**.

   The **Instrument Settings** screen displays.

3. Select **Printer Settings** and select **Select**.

   The **Printer Settings-Included in print-out screen 1 of 4** displays.

4. Customize the printout:

   a. Select any of the following options to include in the printout: Operator Name, Serial Number, Patient Name, or Patient ID

      Note To clear a selected option, select that option button again.

   b. Select **Next**.

      The **Printer Settings-Included in print-out screen 2 of 4** displays.

   c. Select any of the following options to include in the printout: Color, Clarity, or Custom Information.

Note To clear a selected option, select that option button again.

d. Select **Next**.

The **Printer Settings-Set Up Custom Header screen 3 of 4** displays.

5. Select a header option:
   - To include a custom header in the printout, select **Enabled**.
   - To exclude a custom header, select **Disabled**.
6. To edit or create the header for Line 1 or Line 2, perform these steps:
   a. Select **Enter Line 1** or **Enter Line 2**.

   The **Custom Header** screen displays.

   b. Enter the custom header text.

   Note Each custom header line accepts up to 24 alphanumeric characters.

   c. Select **Enter**.

   The **Printer Settings-Set Up Custom Header screen 3 of 4** displays.

   d. Select **Next**.

   The **Printer Settings screen 4 of 4** displays.
7. Select a printer option:
   - To print to the internal printer, select **Internal printer**.
   - To print to an external printer, select **External printer**.
8. Select **Done** 3 times to return to the **Select Ready** screen.

Appendix A: Support Information

Legal Information

For service, contact Technical Support at 877-229-3711.

Warranty Information

Installation Details

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

Date of Installation: _____

Serial Number: _____

Manufacturer's Warranty

For warranty information, contact your local Siemens service provider.

Support Information

Call for assistance if one of the following occurs:

- If the error message continues after performing the steps described on the screen.
- If additional assistance is required concerning a system problem.
- If the problem is beyond the scope of this guide.
- If the problem cannot be solved and a system failure is apparent.

Our local technical support providers are available to help you. Before calling, please complete the *Pre-service Checklist*, page 69. Make a photocopy of the checklist first. This information helps your local technical support provider to identify the probable cause of the problem.

To order supplies or replacement parts, or to obtain service, contact Technical Support at 877-229-3711 or visit www.siemens.com/diagnostics

For cleaning and disinfecting information, see the CLINITEK *Status+ Analyzer Operator's Guide*.

Addresses

www.siemens.com/diagnostics

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

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

Siemens Healthcare
Diagnostics Pty Ltd
885 Mountain Highway
Bayswater Victoria 3153
Australia

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

Pre-service Checklist

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

Date of Installation: _____

Serial Number: _____

Note After recording the information, make photocopies of this page to use before calling your local technical support provider.

1.	What is the version number of the software? To find this information: 1. Turn system power off. 2. Wait approximately 15 seconds. 3. Turn system power on. The software version displays after the initialization screen.	
2.	Are any error messages or warnings displayed? If so, what are they? List the error description and any numbers that display.	
3.	Have you performed the appropriate steps suggested on the display for the error being displayed?	
4.	Are the printer and host computer (LIS) connected and powered on?	
5.	Is the bar-code scanner working properly?	

Appendix B: Orderable Supplies

The orderable supplies have part numbers.

Note The part numbers are subject to change without notice.

Accessory Items

The following table lists the accessories available for the connector.

Part Number	Description
06502880	Bar-code Reader Kit
10376825	Wireless Card (USB)

Quality Control Supplies

The following table lists the QC supplies.

Part Number	Description
1360	Chek-Stix® Urinalysis Control Strips (Positive)
1364	Chek-Stix Combo Pak (Positive/Negative)

System Documentation

The following table lists the system documentation available for the connector.

Part Number	Description
10376827	English Quick Reference Guide
10376828	Multi-language Documentation CD
10378409	CLINITEK Status Connect System LIS Specification
10376829	Operator's Guide (English)
10376830	Operator's Guide (French)
10376831	Operator's Guide (German)
10376839	Operator's Guide (Italian)
10376832	Operator's Guide (Spanish)
10376838	Operator's Guide (Portuguese)
10376835	Operator's Guide (Danish)

Part Number	Description
10376833	Operator's Guide (Swedish)
10376834	Operator's Guide (Finnish)
10376840	Operator's Guide (Norwegian)
10376836	Operator's Guide (Japanese)
10376837	Operator's Guide (Chinese)
10376841	Operator's Guide (Dutch)
10376842	Operator's Guide (Polish)

Appendix C: Specifications

This appendix contains the CLINITEK Status connector specifications and tables of results.

Connector Specifications

This section summarizes the design specifications for the CLINITEK Status connector.

Note You cannot operate the instrument on battery power when using the connector.

Dimensions

The following table contains the dimensions of the CLINITEK Status connector.

Dimension	Value
Length	23.8 cm (9.357 inch)
Width	15.9 cm (6.252 inch)
Weight	0.62 kg (1.36 lbs)

Environmental Specifications

The following table contains the environmental specifications for the CLINITEK Status connector.

Specification	Value
Ambient Operating Temperature	18–30°C (41–104°F)
Operating Humidity	18–80% RH (non-condensing)
Indoor Use Only	For use at altitudes up to 2000 meters

Electrical Requirements

The following table contains the electrical requirements for the CLINITEK Status connector.

Requirement	Value
Electrical Rating	9V DC; 1.8A, 16.2VA
Safety	CLASSIFICATIONS: Type of protection = Class 3 product Pollution Degree 2. Over Voltage Category: Category 2 For use with the following plug-in power supply unit provided: • The direct plug-in of the power supply is considered as the disconnecting device. • Position the instrument so that you can easily reach the power cord plug to remove it from the wall socket, if needed.

Regulatory Specifications

The regulatory specifications include three categories:

- Electrical precautions
- Safety certifications
- Electromagnetic Compatibility (EMC)

Electrical Precautions

CAUTION
Use only the power supply adapter included with the unit.

Observe the following precautions when handling the system:

Connect the RS-232, USB, and Ethernet connectors to only SELV circuits.

External computing devices connected to the CLINITEK Status connector must comply with the standards UL 60950 for US, CAN/CSA-C22.2 No. 60950 for Canada, and IEC60950 for other countries.

Note This system was tested and complied with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This system generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions in the *CLINITEK Status Connect System Operator's Guide*, may cause harmful interference to radio communications.

Interference can occur in an installation. If the system causes harmful interference to radio or television reception, which can be determined by turning the equipment off and on, try to correct the interference using one or more of the following measures:

- Reorient or relocate the receiving antenna
- Increase the separation between the system and the receiver
- Connect the system into an outlet on a different circuit from the receiver
- Consult a dealer or experienced radio/TV technician for help

Safety Certifications

For information about safety certifications, see the Declaration of Conformity (DoC). For a DoC, contact Technical Support at 877-229-3711.

Electromagnetic Compatibility (EMC)

For information about electromagnetic compatibility (EMC), see the Declaration of Conformity (DoC). For a DoC, contact Technical Support at 877-229-3711.

Appendix D: Bar-code Scanner

You can use the bar-code scanner to input operator information including Operator ID, Operator Name, patient name, patient ID, QC control name, and QC level name.

The software in the bar-code scanner automatically distinguishes between bar-code formats.

Note You must connect the bar-code scanner to connector before powering the system on.

Installing the Optional Bar-code Scanner

1. Power the system off.
2. Connect the end of the cable to the serial RS-232 port on the side of the connector.
3. Press in firmly until the connection is secure.
4. Power the system on.

Testing the Optional Bar-code Scanner

Ensure that your external bar-code scanner has been correctly installed using the procedure in *Installing the Optional Bar-code Scanner*. Ensure that the bar-coded labels used in your laboratory comply with the specifications given later in this section.

Troubleshooting

It is important that the labels be printed to the required specifications. Reading errors may occur if any of the following conditions exist:

- The narrow bar width is too small.
- The bar-code length is too great.
- The height is too small.
- The scanner is held too far from the label.
- The background reflection is too high or low.

If the scanner does not consistently read your labels, apply a test label of the format being used to a new specimen tube and perform the Bar-code Test. If the scanner is able to read the test label, the quality of your labels may be suspect. If the test label cannot be read, the scanner itself is suspect.

If you cannot resolve problems, contact Technical Support at 877-229-3711 for assistance.

Specifications

Bar Code Formats

The connector's external bar-code scanner meets the requirements of ASTM E1466-92, *Standard Specification for Use of Bar Codes on Specimen Tubes in the Clinical Laboratory* (available from ASTM, 100 Barr Harbor Dr., West Conshohocken, PA 19428).

Bar Code Symbols and Labels

The connector accepts the data input of operator-entered information (Patient ID, Patient last name, Patient first name), Operator ID (Patient and Control), Comments (Patient and Control)), for the following bar code symbologies:

- Code 93 standard includes check digit
- Code 39 with optional check digit required
- Code 128 standard includes check digit
- Coda Bar without check digit

The following rules apply to data entered by the external bar-code scanner:

- Connector can read and display full ASCII character set.
- You can enter and display characters in lower case.
- Search to recall samples associated with the data entered by the external bar codes are not case sensitive.
- The connector serial number entry is supported in Code 128 intended for manufacturing entry.

The bar code symbols, and the labels themselves, must meet certain specifications, detailed below:

Bar Code Specification	Description
Number of Characters	One to 30 data characters. A maximum of 13 characters can be displayed, stored, and transmitted by the system.
Narrow Bar Width	0.15 mm to 0.51 mm (0.006 inches to 0.02 inches). It is better to be closer to the upper limit (0.51 mm/0.02 inches), as long as the entire bar code can be contained within the maximum length. This measurement affects both the symbol length and how far away from the label you can hold the handheld scanner. If the narrow bar width is at the minimum, the symbol length can be no greater than 90 mm (3.5 inches), including quiet zones, and the scanner can be held no more than 75 mm (3 inches) away.
Narrow to Wide Ratio	Must be within the specifications for the format being used. This is generally 2.0 to 3.0.
Symbol Length	Variable. See Narrow Bar Width for more information.
Quiet Zone	Minimum of 10 times the narrow bar width at each end of the symbol.
Symbol Height	Minimum of 10 mm (0.40 inches).
Total Size of Label	May be greater than the size of the symbol to allow for printing of human readable information. Printing of the specimen ID number in alphanumeric digits is strongly recommended.
Symbol Grade	Minimum grade of "C" as defined by ANSI X3.182-1990 (available from American National Standards Institute, 1430 Broadway, New York, NY 10018).
Wavelength of Light	630 nm (visible red LED).

Bar-Code Scanner Maintenance

CAUTION

Do not submerge the scanner in water. The scanner's housing is not water-tight.

Do not use laboratory wipes, because they may scratch the window.

Do not use any type of solvent, other then recommended solvents, to clean the scanner. Harsh chemicals can damage the finish or the window.

Clean the bar-code scanner window whenever it appears dirty or smeared:

- Wipe the scanner window with a soft cloth or facial tissue dampened with water, or an ethanol solution.
- If a detergent solution is used, rinse with a soft cloth or facial tissue dampened with water only.
- Clean the plastic case in the same manner.

Appendix E: Computer Interface (LIS)

You can connect the CLINITEK Status connector to a host computer or Laboratory Information System (LIS) using a serial, Ethernet, or wireless connection.

Note You can send only the patient test results through the serial port to a host computer or LIS, but not send the QC results.

For more information about the interface between the system and LIS, see the *CLINITEK Status Connect System Interface Specification*. Contact Technical Support at 877-229-3711 for additional information about programs to interface the connector to a computer or LIS.

Connection Specifications

Serial Connection

The serial transmission between the system and the host is established through the connector's rear serial port using a serial cable. For more information about the serial connections, see the *CLINITEK Status (Software Version 2.0 and Higher) LIS Interface Guide*.

Ethernet (Wired) Connection

The RJ45 port is used for TCP/IP transmission between the system and the network. The host listens for connections on the TCP/IP port and accepts the connection when the system tries to connect.

To connect from the Ethernet port to a 10/100BaseT network, use a standard straight-through CAT 5 cable.

Wireless Connection

The connector supports the 802.11b and 802.11g wireless network connectivity specifications. Connect the optional wireless card to the rear USB port on the connector for wireless transmission between the system and the network.

Communication Protocols

The CLINITEK Status Connect system can interface with an LIS using either the POCT1A or HL7 communication protocols. The POCT1A protocol supports bidirectional communication to allow the system to send and receive information from an LIS. The HL7 protocol supports unidirectional communication from the system.

CAUTION

Do not permit the LIS to download the Set Up Configuration file to the system without first backing up patient and QC records. Otherwise, the records are deleted.

The connector can also send CSV-formatted results to a host computer using the rear serial (RS-232) port.

Appendix F: Symbols

System and Packaging

This section describes the symbols that can display in the system documentation, the exterior of the CLINITEK Status+ analyzer or CLINITEK Status connector, or on the packaging.

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

For information about the symbols that can display on reagent packaging and labeling, see the related assay instruction for use package insert.

Symbol	Description
	• **Warning** Indicates the risk of personal injury or loss of life if operating procedures and practices are not correctly followed. • **Caution** Indicates the possibility of loss of data or damage to or destruction of equipment if operating procedures and practices are not strictly observed.
	Alerts you to a biohazard.
	Instrument is safety tested by TUV SUD, a national certification body, for conformity to global markets, including Canada, US, and Europe.
	Input electricity is alternating current.
	Input electricity is direct current.
	Location of a bar-code scanner port.
	Location of a serial port.
	Location of an Ethernet port.

Symbol	Description
	Location of the USB port.
	This electronic information product does not contain any toxic or hazardous substances or elements, and is green and environmental. This system can be recycled after being discarded and should not be casually discarded.
	Product has a temperature limitation range of 5° to 40°C.
	*In vitro* diagnostic device or an *in vitro* diagnostic medical device.
	Consult instructions for use.
	Product is fragile and you need to handle it with care.
	Keep the product dry.
	Do not spray any liquids in this area.
	Keep the product away from sunlight and heat.
	Temperature hazard.
	Observe precautions for handling electrostatic sensitive devices to avoid causing a hazard to the product.
	Follow the appropriate procedures for disposal of electrical and electronic equipment.
REF	Reference number for ordering a part or product.

Symbol	Description
SN	Serial number of a part or product.
Rev.	Revision letter of a part or product.
	Name and location of the product manufacturer.
	Date of manufacture of the product.
	Manufacturer's authorized representative within the European Community.
	Product or container should be oriented in the direction of the arrows.
	Product or container contains recycled material.
	Facilitates the recycling of corrugated materials. The number is licensed in Germany and printed on corrugated shippers.
	Product complies with the applicable directives of the European Union.

User Interface

This table describes the symbols that display on the system user interface.

Symbol	Feature	Description
	Connector	The CLINITEK Status+ analyzer is connected to the CLINITEK Status connector.
	No Connector	The CLINITEK Status+ analyzer is not connected to the CLINITEK Status connector.

Symbol	Feature	Description
	Connectivity	The CLINITEK Status+ analyzer is connected to the CLINITEK Status connector, Connectivity is enabled, and the system is connected to the LIS.
	No Connectivity	The CLINITEK Status+ analyzer is connected to the CLINITEK Status connector, Connectivity is enabled, but the system is not connected to the LIS.

Appendix G: Glossary

The glossary contains hardware and software terms and acronyms.

Hardware Terms

The following table defines hardware terms commonly used on the CLINITEK Status Connect system.

Term	Definition
Calibration Bar	The white calibration bar (on the test table) that provides traceable calibration.
Cassette	The Clinitest® hCG reagent cassette that is inserted into the instrument to perform pregnancy tests.
CLINITEK Status+ analyzer	The upgraded CLINITEK Status+ analyzer with increased memory.
CLINITEK Status Connect system	The CLINITEK Status+ analyzer and CLINITEK Status connector attached together.
Display	The LCD that displays the software user interface.
Ethernet Port	The port where a network Ethernet cable is inserted.
External Bar-Code Scanner	An optional bar-code scanner that is connected to the RS-232 port on the connector. Used to enter data.
Instrument	The CLINITEK Status+ analyzer.
Onboard Printer	The integrated roll printer.
Onboard Printer Cover	The portion of the case that opens and closes to cover the on-board printer.
Power Switch	The switch that turns the system on and off.
Power Cord	The cord that connects the system to an electrical outlet.
Serial Connector	An RS-232 connection used to transfer data between the system and host machine.
Test Table	The plastic case that holds either the cassette or urinalysis strip for testing.

Term	Definition
Touchscreen	The LCD display overlay which enables users to select controls on the display.
USB Port	The ports where USB cables are inserted.
Wired	Using the Ethernet cable to physically connect the connector to a LAN.
Wireless	Using the 802.11b or 802.11g specifications to connect the connector to a LAN.

Software Terms

The following table defines software terms commonly used on the CLINITEK Status Connect system.

Term	Definition
Alert Message	A message that conveys information about the system to the user.
Alphanumeric	Data comprised of alphabetic and numeric characters.
Audio Alert	Sounds emitted by the system to draw the operator's attention to the system.
Cancel	To end a sequence or operation.
Comment	A user-entered notation associated with a test result.
Control	Objects displayed on the software UI that the user can manipulate. Buttons, check boxes, and options are examples of controls.
	Solution containing a known level of analyte(s).
Countdown	A numeric display that indicates the amount of time left in an operation.
Data Entry	The act of entering data such as a patient or operator ID into the system.
Data Entry Box	A UI object which displays data that is entered by the operator.

Term	Definition
Diagnostic Screen	A UI screen which enables the operator to perform a system diagnostic test when troubleshooting the system.
Disabled	The state when a UI control, such as a button, is not available to be “touched” or “pressed” by an operator; Deselected option.
Enabled	The state when a software UI control, such as a button, is available to be “touched” or “pressed” by an operator; Selected option.
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.
Export	To copy data from the system to a removable data storage device.
Help	Information presented to the operator to assist them with the completion of a task or operation.
Help Screen	The screen used to display help information to the operator.
Icon	An image used to label a control.
Import	To copy data on to the system from a removable data storage device.
Menu Screen	A software UI screen that displays buttons to the operator for them to select from.
Notifications Message	A message that conveys information about the system to the user.
Navigation	The act of moving between the screens that comprise the system user interface.
Navigation Button	A software UI button control that when selected, brings the operator to a different UI screen.
Parity	A serial communication setting.
Ready	The state when the system is available to perform tests.

Term	Definition
Recall	To access data such as test results stored on the system.
Restore	The act of copying data back onto a system to restore it.
Required Entry	A data entry box that must have data entered into it.
Screen	The display area that contains the controls the operators select when operating the system. The system software UI comprises many screens.
Screen Title	A text label that typically appears in the upper left corner of a screen which serves as a label for that screen.
Select Ready Screen	The UI screen displayed when the start up is complete. All software UI navigation begins from this screen.
Settings Screen	A UI screen which enables the operator to adjust or configure some aspect of the system.
Supervisor	An operator who as been assigned supervisor access privileges on the system.
Test Result	Measured reportable values displayed to the operator at the end of a test sequence.
Test Sequence	A series of software UI screens that guides the operator through the tasks required to perform a test on a sample.
Title Bar	The area along the top of UI screens where the location icon and title appear.
UI; User Interface	The instrument software screens with which the user interacts.

Acronyms

The following table defines acronyms commonly used on the CLINITEK Status Connect system.

Acronym	Full Title
ASTM	American Society for Testing and Measurement
CSV	Comma Separated Values
DHCP	Dynamic Host Configuration Protocol
DNS	Domain Name Server
HIS	Hospital Information System
HL7	Health Level 7 (protocol)
IP	Internet Protocol
LAN	Local Area Network
LIS	Laboratory Information System
PC	Personal Computer
POCT	Point of Care Testing (protocol)
QC	Quality Control
SN	Serial Number
USB	Universal Serial Bus

Index

W