

CLINITEK Status Connect Installation and Setup



In-Service Training

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Training Agenda

- System overview
- Setting up the analyzer
- Customizing Setup



Note: This information applies only to the CLINITEK Status Connect System with the latest version of software version 2.6.2/2.4.2.0. Sample interference notes features are not available in the U.S.

What is the Clinitek Status Connect System?

- Automated POC urinalysis analyzer with a broad testing menu
 - ✓ Routine urinalysis, albumin-to-creatinine ratio, protein-to-creatinine ratio and hCG pregnancy test
- Automates the timing and result interpretation for routine urinalysis tests, kidney checks and hCG pregnancy tests
- Auto-Checks® features identify test strip type, perform strip integrity check for humidity overexposure – prevents testing with unvalidated test strips and strips compromised by humidity over-exposure
- Automatically transmits data to DMS/LIS or EMR





System Overview

CLINITEK Status Connect System Overview

The CLINITEK Status® Connect System is a portable, easy to use analyzer. It is designed to read only Siemens Urinalysis test strips and Clinitest® hCG tests.

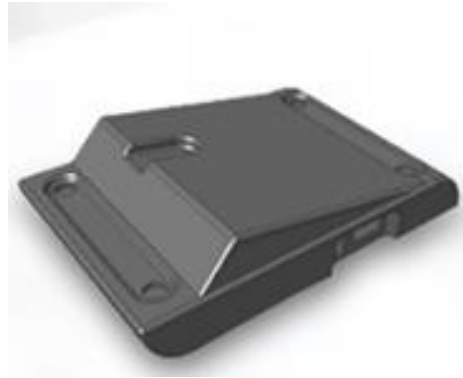
- Measures the following in urine: Albumin, Bilirubin, Blood (Occult), Creatinine, Glucose, Ketone, Leukocytes, Nitrite, pH, Protein, Protein-to-Creatinine Ratio, Albumin-to-Creatinine Ratio, Specific Gravity, Urobilinogen, and human Chorionic Gonadotropin (hCG)
- These measurements are used to assist diagnosis in the following areas: Kidney function, Urinary tract infections, Metabolic disorders (such as diabetes mellitus), Liver function, and Pregnancy





Setting up the Analyzer

CLINITEK Status Connect System Configuration



CLINITEK Status®+ Urine
Chemistry Analyzer

CLINITEK Status Connector Base

CLINITEK Status
Connect System
Includes Barcode

CLINITEK Status+ Analyzer

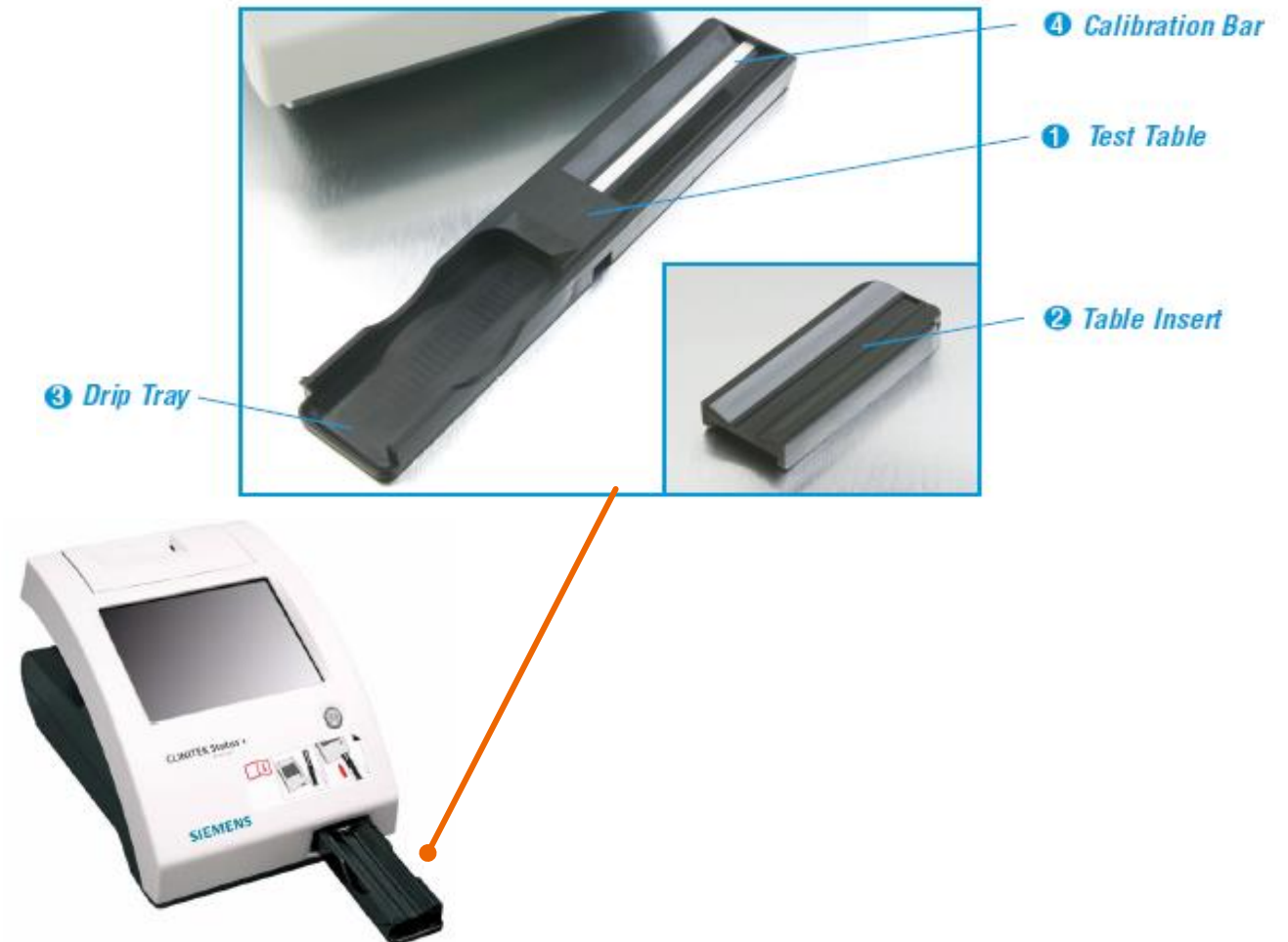
1. CLINITEK Status+ Analyzer
2. Power supply adaptor and AC power cord
3. Test table with calibration bar
4. Test table insert
5. Paper roll



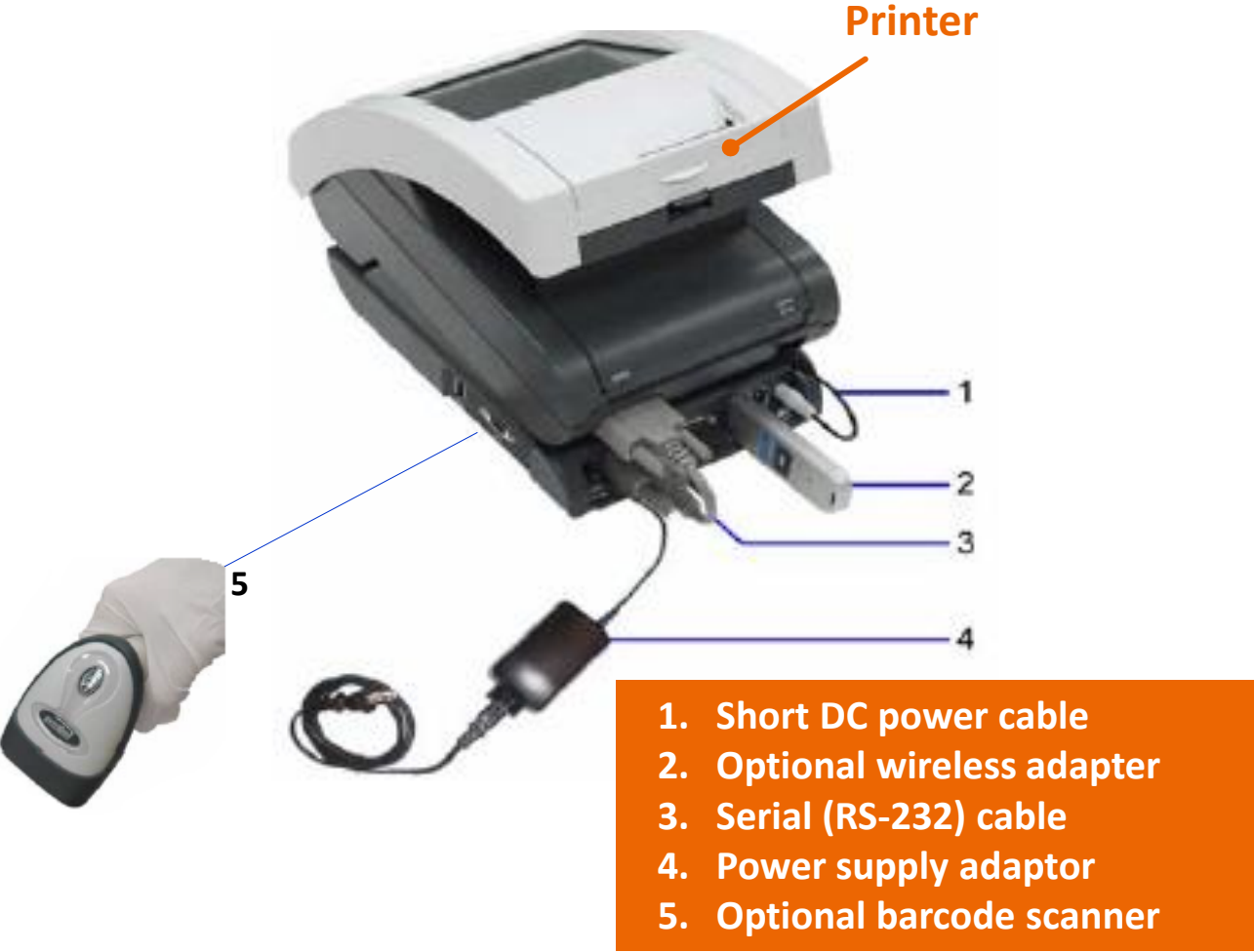
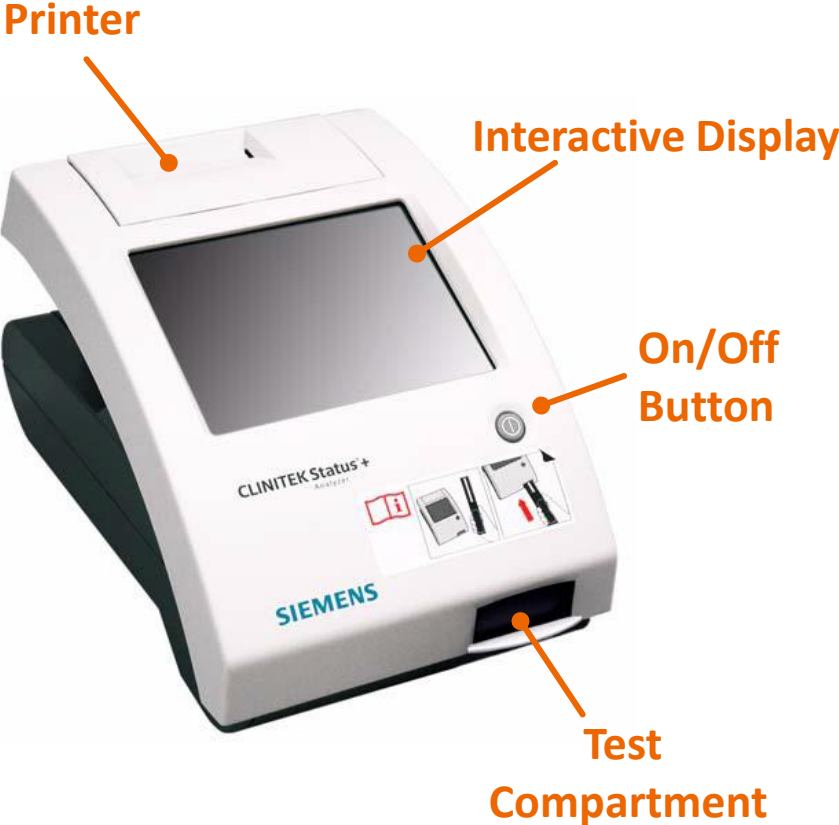
Test Table Overview and Set Up

Inserting the test table is only done during set up or when cleaning the test table:

1. Insert the test table into the analyzer
2. Hold the tray by the Drip Tray end
3. Do not touch the calibration bar – careful not to scratch or soil as this will impact performance
4. With the calibration bar facing upwards push the test tray into the analyzer just over halfway
5. Do not force the tray table as it may become jammed (The analyzer will automatically pull in the tray when the power is turned on)
6. Place the Table Insert onto the Drip Tray



CLINITEK Status Connect System Overview



Clinitek Status Connector Overview

- Adding the connector platform provides the following:
 - ✓ Barcode scanning for entry of patient and operator IDs, test strip, cassette and QC material lot number and expiration dating
 - ✓ Interfacing to data management systems and network via Ethernet
 - ✓ Bi-directional functionality such as operator ID downloading and remote QC lock out
 - ✓ QC mode for QC lock out and separate database for QC testing data
 - ✓ Wireless capability (if site access points are compatible)



Connector

Loading the Printer Paper

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

1. Turn the back of the analyzer to face you
2. Pull on the tab to open the printer cover
3. Open the paper roll compartment
4. Lift the paper holding arm into the open, upright position
5. Insert a new paper roll - it should unroll from underneath and roll toward the compartment wall
6. Feed the paper up along the wall and through the printer until 4 inches of paper feeds through
7. Feed the edge of the paper through the printer cover
8. Push the paper holding arm down in the closed position (if this step is missed the printer will not print)
9. Close both covers by clicking into place



1 Paper holding arm

2 Printer paper

Powering Analyzer On/Off

If you power on the analyzer for the first time, the Start Up Wizard will guide the set-up procedure:

1. Press the on/off button on the front of the analyzer
 - Analyzer performs automatic checks when powered on

To power off the analyzer, perform the following steps:

1. Ensure that no strip or cassette is on the test table and that the table and insert are clean
2. Hold the on/off button down for at least 2 seconds
3. Analyzer pulls in the test table and will turn off
 - If the test table hasn't been cleared of test strip or cassette, it will be pushed out by the analyzer and powered off
 - To power off and have the tray stored inside the analyzer, power back on, clear the test strip or cassette and power off





Customizing Setup

Customize Set-up – Select Test Mode

- Select the testing mode that best fits your site needs.
- There are three modes to select from:
 - ✓ Quick test – does not require any patient operator data to be entered
 - ✓ Full test – requires operator, patient and other fixed data to be entered
 - ✓ Custom

The image shows a screenshot of the 'Input Settings' screen. At the top, there is a dark header with the title 'Input Settings' and the instruction 'Select one of the options'. Below this, there are three main selection areas, each with a radio button and a description:

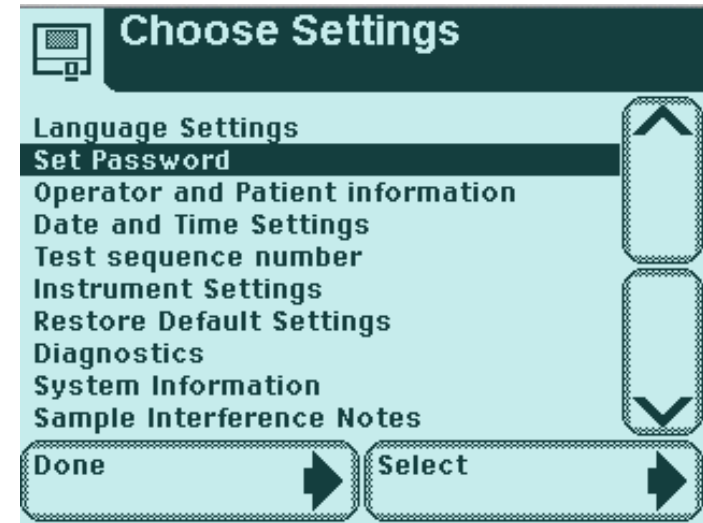
- Quick Test**: Permit test sequence without entering operator or patient information. This option is currently selected, indicated by a filled radio button.
- Full Test**: Permit test sequence after entering:
 - operator name
 - patient name
 - patient ID
 - sample appearanceThis option has an empty radio button.
- Custom Set Up**: This option also has an empty radio button.

At the bottom right, there is a 'Next' button with a right-pointing arrow.

Path: Select Instrument Set Up
> Operator and Patient
Information

Customize Set-up – Set Password

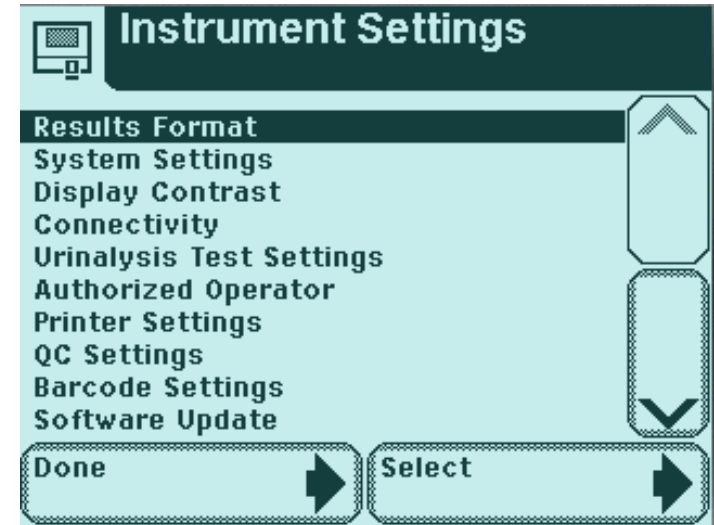
- If the site requires supervisor(s) to be the only ones who can modify system settings, a system password should be programmed.
- The analyzer defaults to not having a system password and is open for all to make system changes.
- The system password differs from the operator ID.
- Operator IDs can be added and supervisor can set individual operator access.



Path: Select Instrument Set Up
> Set Password

Customize Set-up

- Instrument set up allows for customization and standardization of running your urinalysis program.
- Review each area to select your settings:
 - ✓ Results format – units and flagging
 - ✓ Connectivity – define connectivity settings
 - ✓ Urinalysis test setting – handling of lot and expiration dating
 - ✓ Authorized operators – to set up operator access and lock out
 - ✓ Printer settings – define printing requirements
 - ✓ QC settings – define QC testing needs
 - ✓ Barcode setting



Path: Select Instrument Set Up
> Instrument Settings

Result
Format

Connectivity

Urinalysis
Test
Setting

Authorized
Operator

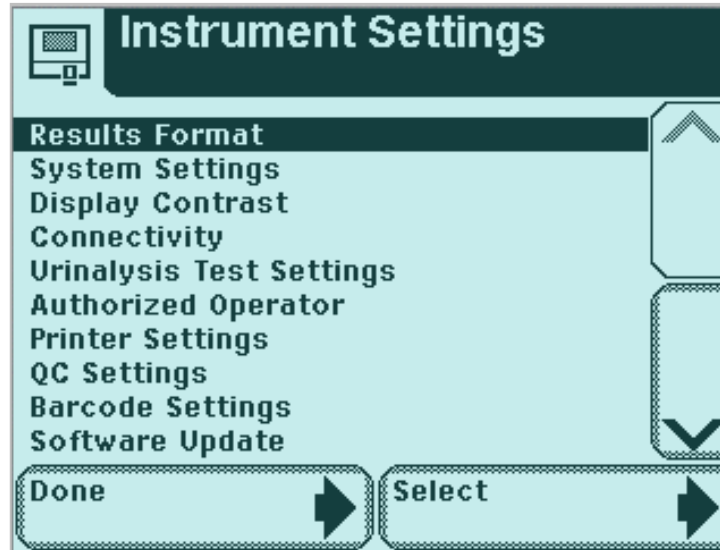
Printer
Setting

QC
Setting

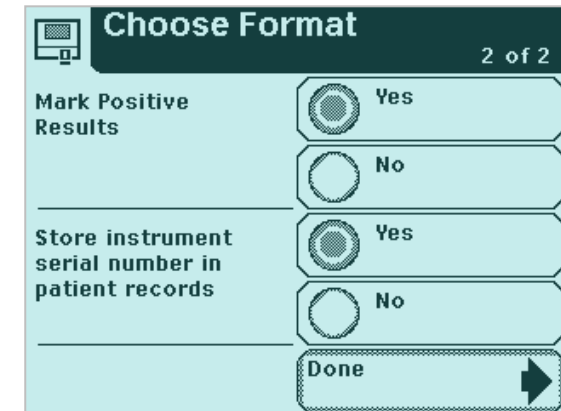
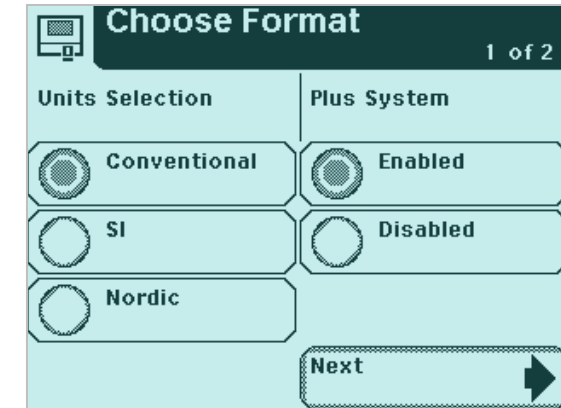
Barcode
Setting

Select Results Format

- Select units for reported results
- Determine if Plus system for results are required
- Determine if positive results should be flagged
- Determine if analyzer serial number should be recorded with each result

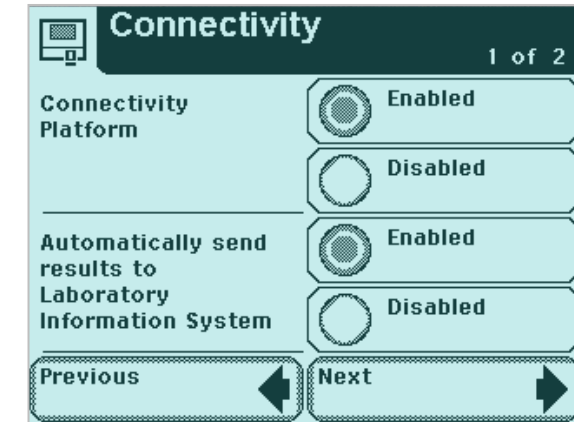
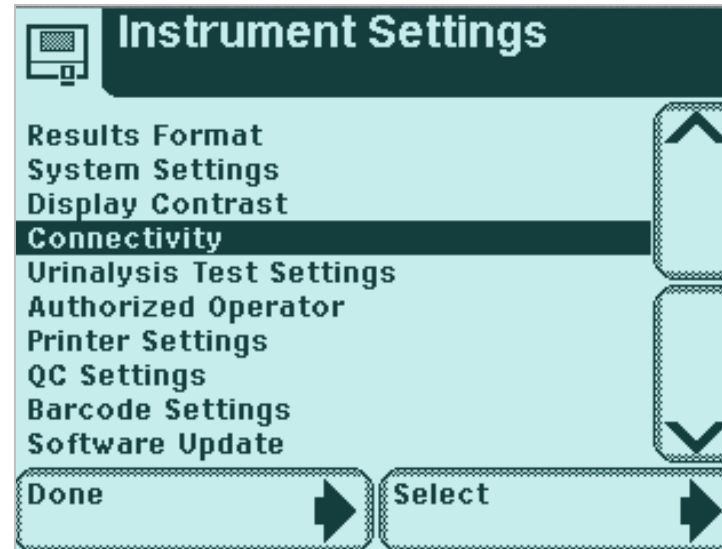


Path: Select Instrument Set Up > Instrument Settings > Results Format



Select Connectivity Set Up

- Enable connectivity platform if interfacing the analyzer to data management systems/LIS or EMR
- Connector must be enabled for barcode scanning and QC management features
- Determine if results need to be automatically transmitted after testing



Path: Select Instrument Set Up >
Instrument Settings > Connectivity

Select Connectivity Options - Serial Connection Set Up

- For connecting the analyzer serially, follow these steps.

Note: serial connections will be uni-directionally only.

Connectivity 2 of 2

<input type="radio"/> Wireless connection	Edit wireless settings
<input type="radio"/> Wired connection	Edit wired settings
<input checked="" type="radio"/> Serial connection	Edit serial settings
<input type="radio"/> None	

Previous Done

Path: Select Instrument Set Up > Instrument Settings > Connectivity > Serial connection > Edit serial settings

Serial Settings 1 of 3

Baud rate

<input type="radio"/> 9600
<input type="radio"/> 19200
<input checked="" type="radio"/> 57600
<input type="radio"/> 115200

Previous Next

Serial Settings 2 of 3

Parity

<input checked="" type="radio"/> None
<input type="radio"/> Odd
<input type="radio"/> Even

Previous Next

Serial Settings 3 of 3

Stop Bits

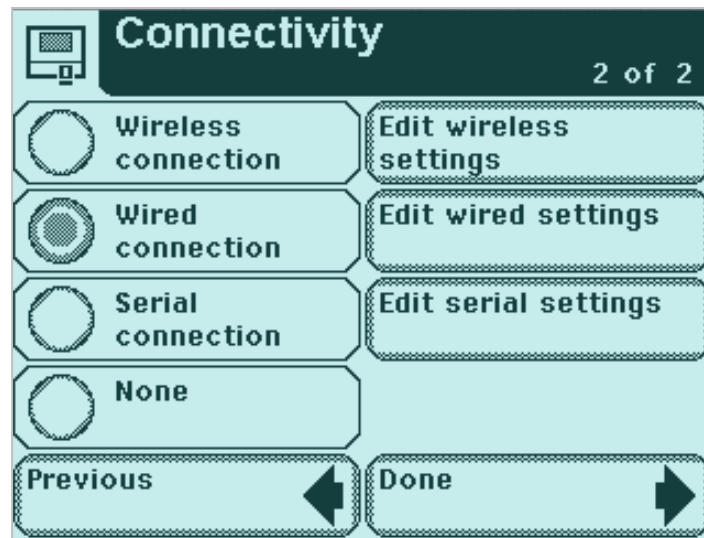
<input checked="" type="radio"/> 1
<input type="radio"/> 2

Previous Done

Select Connectivity Options – Wired Connection Set Up

- For connecting the analyzer with a wired connection, follow these steps.

Note: wired connections will be bi-directional allowing commands, operator lists and instrument set-ups to be sent down to the analyzer.

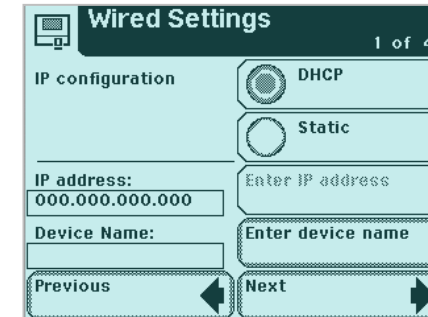


Connectivity 2 of 2

<input type="radio"/> Wireless connection	Edit wireless settings
<input checked="" type="radio"/> Wired connection	Edit wired settings
<input type="radio"/> Serial connection	Edit serial settings
<input type="radio"/> None	

Previous Done

Path: Select Instrument Set Up > Instrument Settings > Connectivity > Wired connection > Edit wired settings



Wired Settings 1 of 4

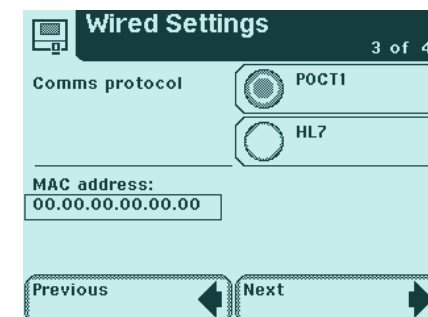
IP configuration

☒ DHCP ☐ Static

IP address: 000.000.000.000 Enter IP address

Device Name: Enter device name

Previous Next



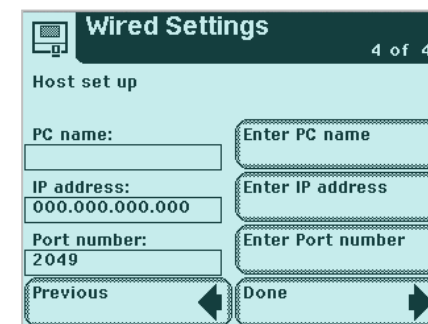
Wired Settings 3 of 4

Comms protocol

☒ POCT1 ☐ HL7

MAC address: 00.00.00.00.00.00

Previous Next



Wired Settings 4 of 4

Host set up

PC name: Enter PC name

IP address: 000.000.000.000 Enter IP address

Port number: 2049 Enter Port number

Previous Done

Select Connectivity Options - Wireless Connection Set Up

- For connecting the analyzer with a wired connection, follow these steps.

Note: wired connections will be bi-directional allowing commands, operator lists and instrument set-ups to be sent down to the analyzer.

Connectivity 2 of 2

<input type="radio"/> Wireless connection	Edit wireless settings
<input checked="" type="radio"/> Wired connection	Edit wired settings
<input type="radio"/> Serial connection	Edit serial settings
<input type="radio"/> None	
Previous	Done

Wireless Settings

Security: ☒ Disabled, ☐ WEP, ☐ WPA PSK, ☐ WPA2 PSK

MAC address: 00.00.00.00.00.00

Previous Next

Wireless Settings
Disabled

☒ DHCP ☐ Static

SSID: Enter SSID

IP address: 000.000.000.000 Enter IP address

Device Name: Enter device name

Previous Next

Path: Select Instrument Set Up > Instrument Settings > Connectivity > Wireless connection > Edit wireless settings

Select Connectivity Options - Selecting Wireless Network

- For connecting the analyzer with a wireless, work with Siemens representative to determine if all access points at the site are compatible with the system.
- If the system will be compatible, follow these steps.

Note: wireless connections will be bi-directional allowing commands, operator lists and instrument set-ups to be sent down to the analyzer.

Wireless Settings
Disabled

☒ DHCP ☐ Static

SSID: i Enter SSID

IP address: 000.000.000.000 Enter IP address

Device Name: Enter device name

Previous Next

Path: Select Instrument Set Up > Instrument Settings > Connectivity > Wireless connection > Edit wireless settings

Wireless Settings
Disabled

i Connected
DetectedNetwork2 Disconnected
DetectedNetwork3 Disconnected
DetectedNetwork4 Disconnected
DetectedNetwork5 Disconnected

Signal

Back Connect Next

Wireless Settings
Disabled

Host set up

PC name: Enter PC name

IP address: 000.000.000.000 Enter IP address

Port number: 2049 Enter Port number

Previous Next

Wireless Settings
Disabled

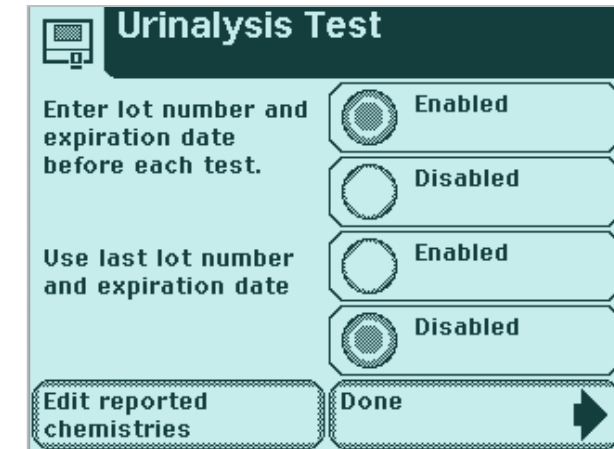
Comms protocol ☒ POCT1 ☐ HL7

Previous Done



Select Urinalysis Testing Options

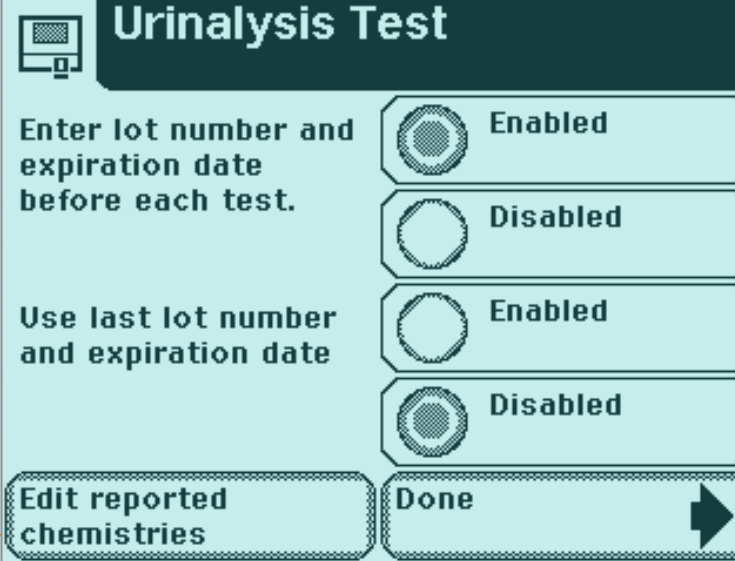
- Determine if lot and expiration dating for test strips is required to be recorded with each patient test and enable function.
- Determine if last lot number is acceptable or if site will require this information to be scanned in with each test.



Path: Select Instrument Set Up >
Instrument Settings > Urinalysis Test
Settings

Select Reported Chemistries

- System default is to report all chemistries.
- System can be customized to select chemistries to repress or not report.



Urinalysis Test

Enter lot number and expiration date before each test.

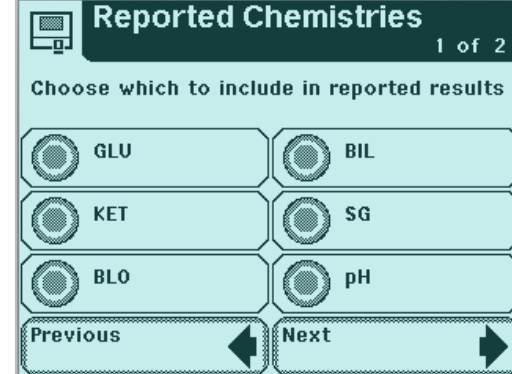
Use last lot number and expiration date

☒ Enabled
☐ Disabled

☐ Enabled
☒ Disabled

Edit reported chemistries **Done**

Path: Select Instrument Set Up > Instrument Settings > Urinalysis Test Settings



Reported Chemistries 1 of 2

Choose which to include in reported results

☒ GLU ☒ BIL

☒ KET ☒ SG

☒ BLO ☒ pH

Previous **Next**



Reported Chemistries 2 of 2

Choose which to include in reported results

☒ PRO ☒ URO

☒ NIT ☒ LEU

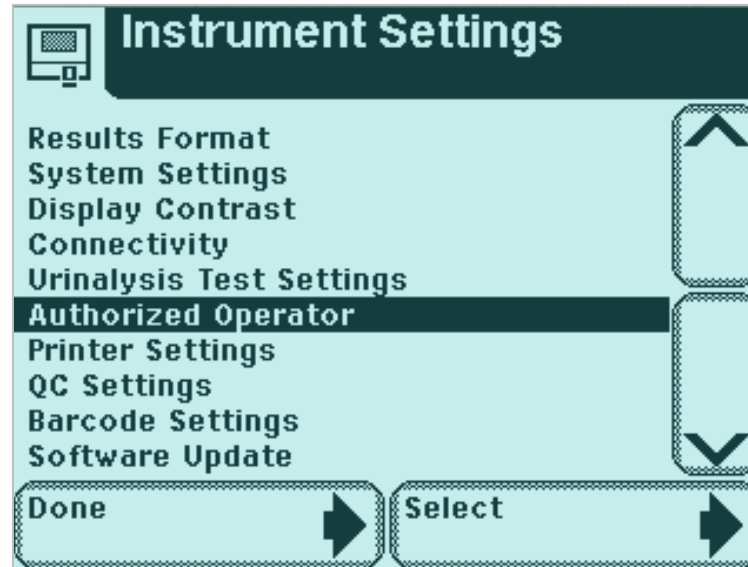
☒ ALB ☒ CRE

Previous **Done**

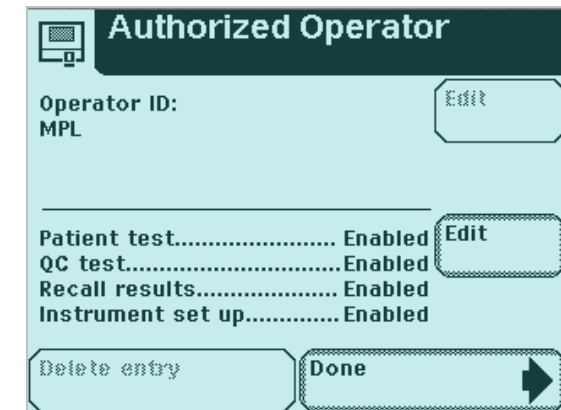


Set Up Authorized Operators

- Set up authorized operators.
- For each operator, set up:
 - ✓ operator ID
 - ✓ access level



Path: Select Instrument Set Up > Instrument Settings > Authorized Operator



Set Up Authorized Operator Access

- Set up authorized operators.
- For each operator, set up:
 - ✓ operator ID
 - ✓ access level



Authorized Operator

Operator ID: MPL Edit

Patient test..... Enabled Edit

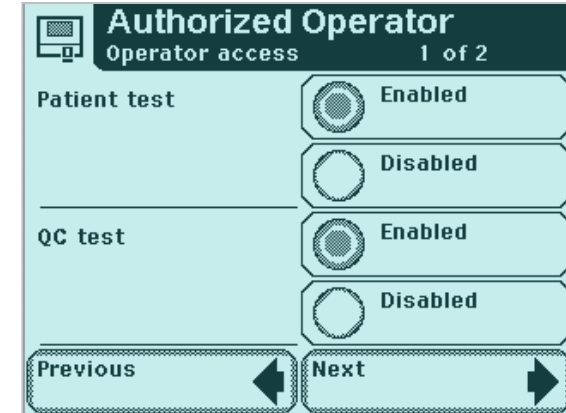
QC test..... Enabled

Recall results..... Enabled

Instrument set up..... Enabled

Delete entry Done

Path: Select Instrument Set Up > Instrument Settings > Authorized Operator



Authorized Operator
Operator access 1 of 2

Patient test Enabled

Disabled

QC test Enabled

Disabled

Previous Next



Authorized Operator
Operator access 2 of 2

Recall results Enabled

Disabled

Instrument set up Enabled

Disabled

Previous Done

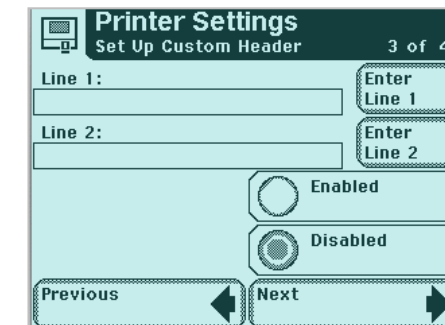
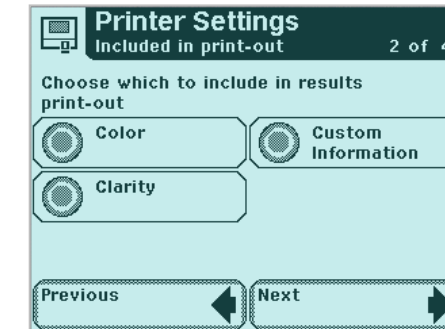
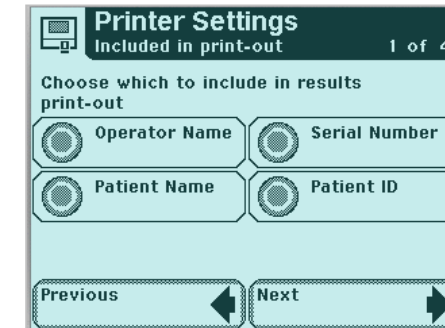


Select On-board Printer Settings

- Select information to include on print-out with each test result:
 - ✓ Operator name
 - ✓ Patient name
 - ✓ Patient ID
 - ✓ Serial number
 - ✓ Color
 - ✓ Clarity
 - ✓ Custom information
 - ✓ Customer headers



Path: Select Instrument Set Up > Instrument Settings > Printer Settings



Define Printer Options

- Select printer type – internal or external.
- If customer notes to be printed with each result, select Enabled.

The screenshot shows a 'Printer Settings' screen with a dark header bar containing a printer icon, the title 'Printer Settings', the subtitle 'Printer options', and the page indicator '4 of 4'. Below the header, there are two radio button options: 'External printer' (unselected) and 'Internal printer' (selected). Below these, there is a section for 'Print notes on internal printer' with two radio button options: 'Enabled' (selected) and 'Disabled' (unselected). At the bottom, there are two buttons: 'Previous' with a left arrow and 'Done' with a right arrow.

Path: Select Instrument Set Up >
Instrument Settings > Printer
Settings

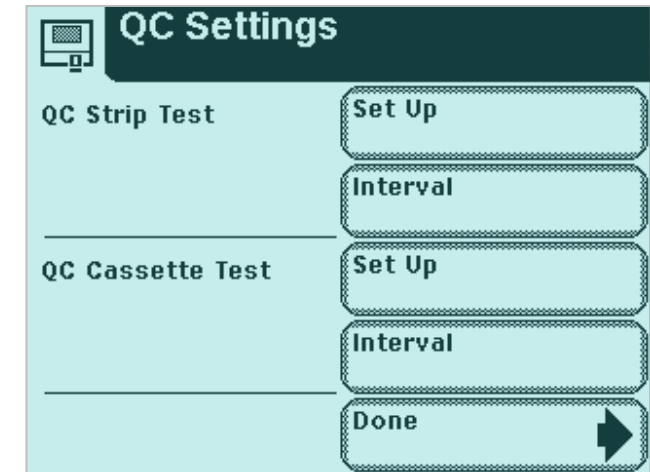


Customize – Quality Control (QC) Set Up

- Define QC set up and testing intervals for urine test strips and hCG cassette test.

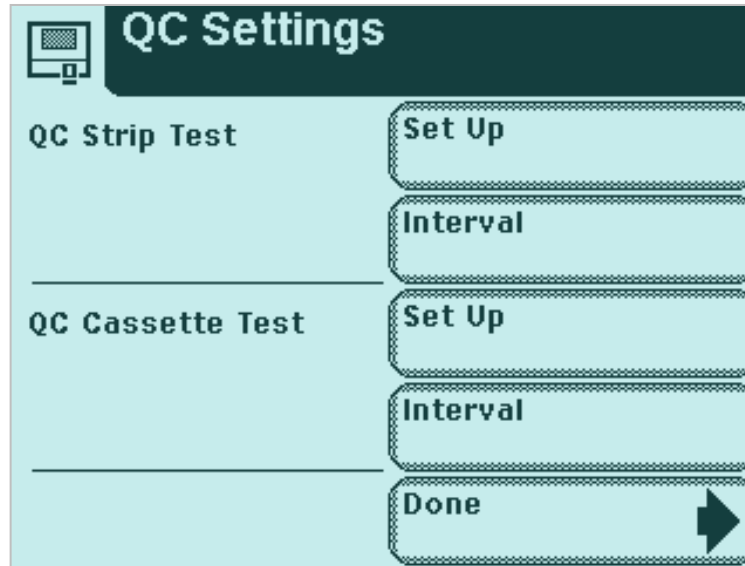


Path: Select Instrument Set Up >
Instrument Settings > QC Settings



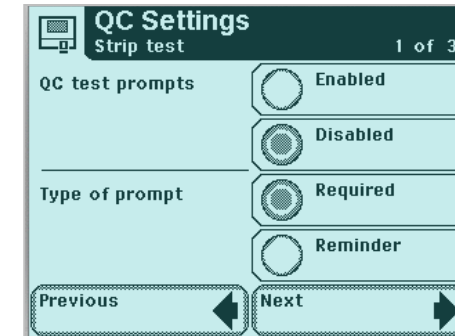
Customize – QC Strip Set Up

- Select Set Up for QC Strip time and define:
 - ✓ Enable prompting for QC tests
 - ✓ Define the desired prompt level: required or reminder.
 - ✓ Select if pass/fail flagged by analyzer or operator.
 - ✓ Select test lock out if QC fails.

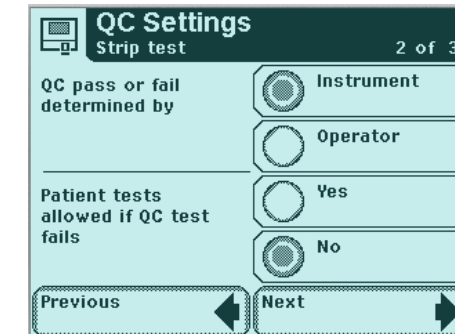


The image shows a menu titled "QC Settings" with a computer icon. It contains two main sections: "QC Strip Test" and "QC Cassette Test". Each section has three options: "Set Up", "Interval", and "Done". The "Set Up" option for "QC Strip Test" is highlighted with a dashed border.

Path: Select Instrument Set Up >
Instrument Settings > QC Settings



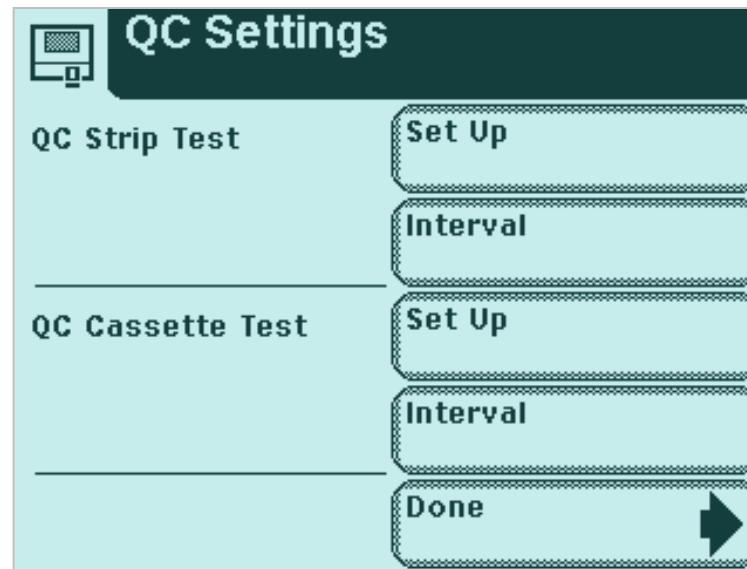
The image shows a screen titled "QC Settings" with a computer icon and "Strip test" below it. It is labeled "1 of 3". It contains two sections: "QC test prompts" with "Enabled" and "Disabled" radio buttons, and "Type of prompt" with "Required" and "Reminder" radio buttons. The "Required" radio button is selected. At the bottom are "Previous" and "Next" buttons with arrows.



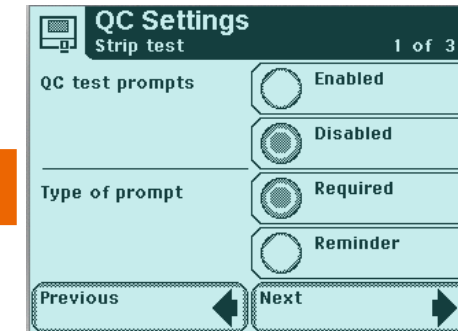
The image shows a screen titled "QC Settings" with a computer icon and "Strip test" below it. It is labeled "2 of 3". It contains two sections: "QC pass or fail determined by" with "Instrument" and "Operator" radio buttons, and "Patient tests allowed if QC test fails" with "Yes" and "No" radio buttons. The "Instrument" and "No" radio buttons are selected. At the bottom are "Previous" and "Next" buttons with arrows.

Customize – QC Strip Set Up

- Select Set Up for QC Strip time and define:
 - ✓ Enable prompting for QC tests
 - ✓ Define the desired prompt level: required or reminder.
 - ✓ Select if pass/fail flagged by analyzer or operator.
 - ✓ Select test lock out if QC fails.



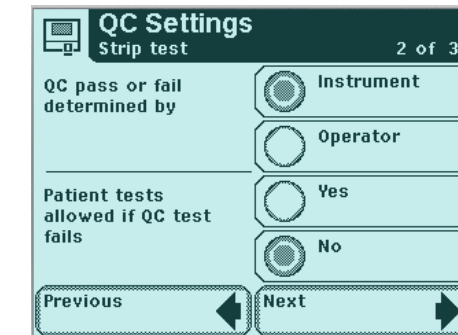
The main 'QC Settings' menu is displayed. It has a dark header with a monitor icon and the title 'QC Settings'. Below the header, there are two sections: 'QC Strip Test' and 'QC Cassette Test'. Each section has three buttons: 'Set Up', 'Interval', and 'Done' (with a right arrow). An orange arrow points from the 'Set Up' button under 'QC Strip Test' to the detailed settings screen on the right.



This is the first screen of the 'QC Settings Strip test' configuration. It has a dark header with a monitor icon, the title 'QC Settings Strip test', and '1 of 3'. The settings include:

- 'QC test prompts' with radio buttons for 'Enabled' (selected) and 'Disabled'.
- 'Type of prompt' with radio buttons for 'Required' (selected) and 'Reminder'.

At the bottom are 'Previous' and 'Next' navigation buttons with arrows.



This is the second screen of the 'QC Settings Strip test' configuration. It has a dark header with a monitor icon, the title 'QC Settings Strip test', and '2 of 3'. The settings include:

- 'QC pass or fail determined by' with radio buttons for 'Instrument' (selected) and 'Operator'.
- 'Patient tests allowed if QC test fails' with radio buttons for 'Yes' and 'No' (selected).

At the bottom are 'Previous' and 'Next' navigation buttons with arrows.

Path: Select Instrument Set Up >
Instrument Settings > QC Settings

Define the QC Testing Protocol

- Select the number of levels of QC to test.
- Define the :
 - ✓ Name of level
 - ✓ Strip type for QC testing
 - ✓ Set the pass ranges – high and low levels for each parameter

The screen is titled "QC Settings" with a sub-header "Strip test" and a page indicator "3 of 3". It is divided into two main sections. The left section, "Number of levels to complete QC test", features three circular buttons labeled 1, 2, and 3. The right section, "Define control levels", contains two rectangular buttons labeled "Control level 1" and "Control level 2". At the bottom, there are "Previous" and "Done" buttons with left and right arrows respectively.

Path: Select Instrument Set Up >
Instrument Settings > QC Settings

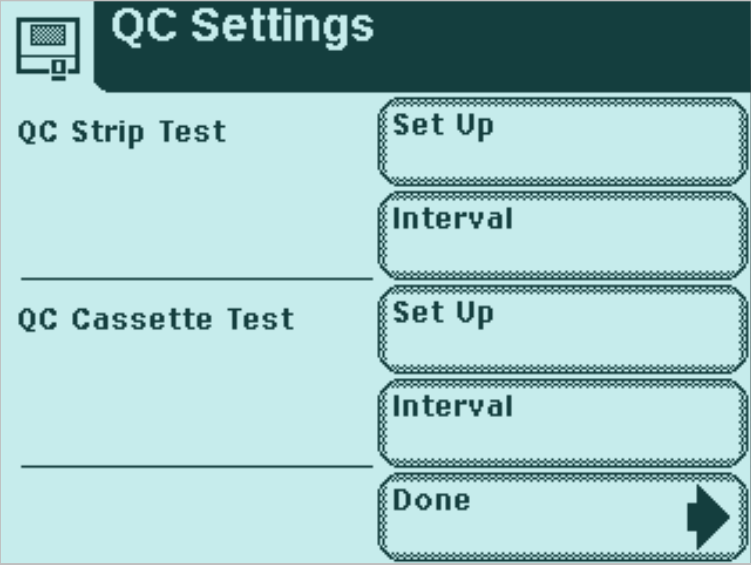
The screen is titled "Control Level 1" with a sub-header "Strip test" and a page indicator "3 of 3". It contains several input fields: "Control:" with the value "CHEK-STIX", "Level:" with the value "NEGATIVE", and "Strip:" with the value "Multistix® 10 SG". To the right of these fields are three buttons: "Enter name of control", "Enter name of level", and "Select strip type". Below these are two more buttons: "Set pass ranges" and "Done". At the bottom, there are "Previous" and "Done" buttons with left and right arrows respectively.

The screen is titled "Control level 1" with a sub-header "Tests and pass ranges" and a page indicator "1 of 3". It displays a list of tests: GLU, KET, BLO, and BIL. Each test has a corresponding "Pass range" button. At the bottom, there are "Previous" and "Next" buttons with left and right arrows respectively.

The screen is titled "Control Level 1" with a sub-header "Set pass range for GLU". It is divided into two columns: "Set lowest value" and "Set highest value". Both columns show a "Negative" value and two arrows (up and down) for adjustment. At the bottom, there are "Previous" and "Set" buttons with left and right arrows respectively.

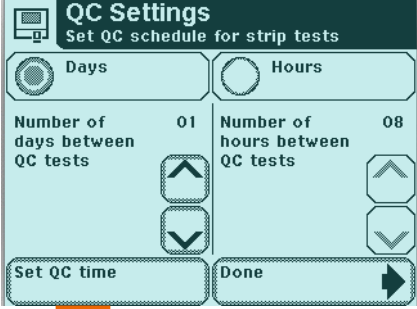
Customize – QC Testing Interval

- Define the testing frequency:
 - ✓ You can select days if you want to test daily
 - ✓ You can specify a time of day for QC to be run
 - ✓ You can define a testing time buffer, if you select a certain time of day – this will allow testing to be performed before or after a specified time
 - ✓ User hours if QC is required more than once per day per your site guidelines

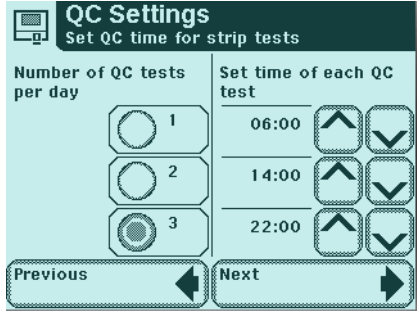


The screen displays the 'QC Settings' menu. It has two main sections: 'QC Strip Test' and 'QC Cassette Test'. Each section has three buttons: 'Set Up', 'Interval', and 'Done'. The 'Done' button for the 'QC Cassette Test' section has a right-pointing arrow.

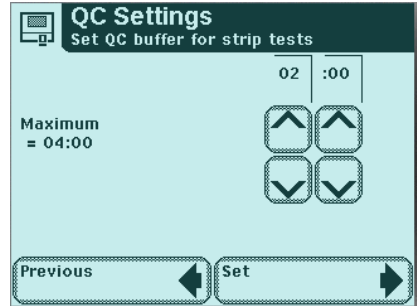
Path: Select Instrument Set Up > Instrument Settings > QC Settings



This screen is titled 'QC Settings' with the subtitle 'Set QC schedule for strip tests'. It has two radio buttons: 'Days' (selected) and 'Hours'. Below 'Days' are two numeric input fields: 'Number of days between QC tests' (set to 01) and 'Number of hours between QC tests' (set to 08). At the bottom are 'Set QC time' and 'Done' buttons.



This screen is titled 'QC Settings' with the subtitle 'Set QC time for strip tests'. It has two columns. The left column is 'Number of QC tests per day' with three radio buttons (1, 2, 3); the '3' button is selected. The right column is 'Set time of each QC test' with three time slots: 06:00, 14:00, and 22:00. Each time slot has up and down arrow buttons. At the bottom are 'Previous' and 'Next' buttons.



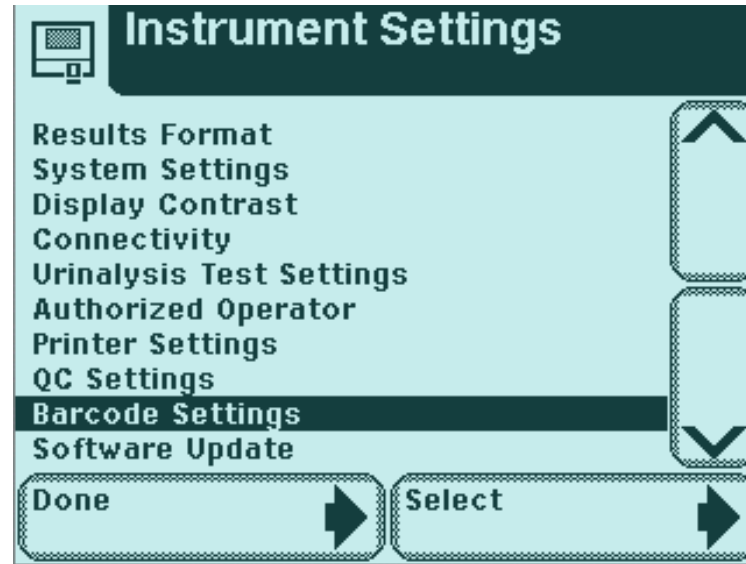
This screen is titled 'QC Settings' with the subtitle 'Set QC buffer for strip tests'. It has a 'Maximum' field set to 04:00. To its right are two numeric input fields for the buffer time, currently showing 02 and :00, with up and down arrow buttons. At the bottom are 'Previous' and 'Set' buttons.

In this example, the customer will run 3 QC tests per day. The first will be at 6:00 a.m. An eager operator can run QC within the 2 hour buffer. If they run at 4:00 a.m., this will count and they will not be prompted again at 6:00 a.m.



Define Barcode Settings

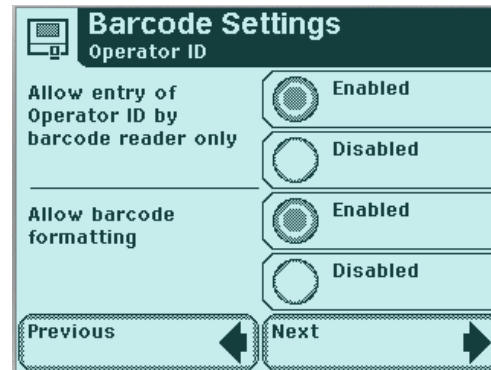
- Barcode settings can be defined for:
 - ✓ Operator ID
 - ✓ Patient ID
 - ✓ Control (Strip)
 - ✓ Control (Cassette)



Path: Select Instrument Set Up >
Instrument Settings > Barcode
Settings

Define Barcode Settings – Operator ID

- Choose if Operator ID should be entered only via barcode
- Define the barcode format for each:
 - ✓ Operator ID
 - ✓ Patient ID
 - ✓ Control (Strip)
 - ✓ Control (Cassette)
- Follow the screen sequence to set up for each of the data inputs above
- Use the leading and trailing feature to mask characters above the 13-character limit

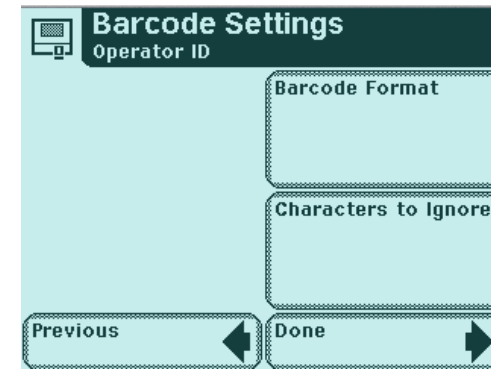


Barcode Settings
Operator ID

Allow entry of Operator ID by barcode reader only: ☒ Enabled ☐ Disabled

Allow barcode formatting: ☒ Enabled ☐ Disabled

Previous Next

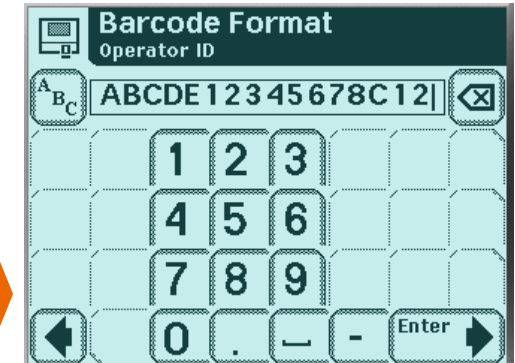


Barcode Settings
Operator ID

Barcode Format

Characters to Ignore

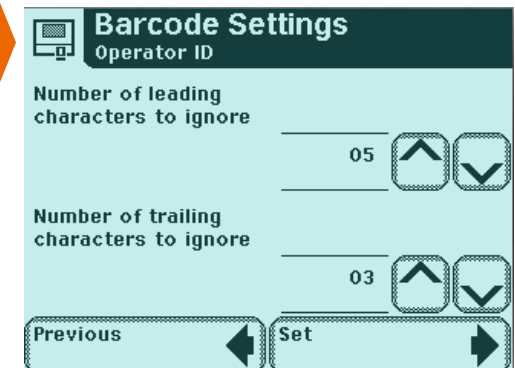
Previous Done



Barcode Format
Operator ID

ABC 123456789012

1 2 3
4 5 6
7 8 9
0 . - - Enter



Barcode Settings
Operator ID

Number of leading characters to ignore: 05

Number of trailing characters to ignore: 03

Previous Set

In this example, customer format is 16 characters – the customer only wants the numeric portion to be recorded “12345678”. Using the leading and trailing feature can help achieve this objective.



This training is a subset of the major custom features that can be set up.

Refer to the operators manual for more complete instructions and information.



Thank you!

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