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 un-validated test strips and strips compromised by humidity over-exposure
- Automatically transmits data to DMS/LIS or EMR

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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

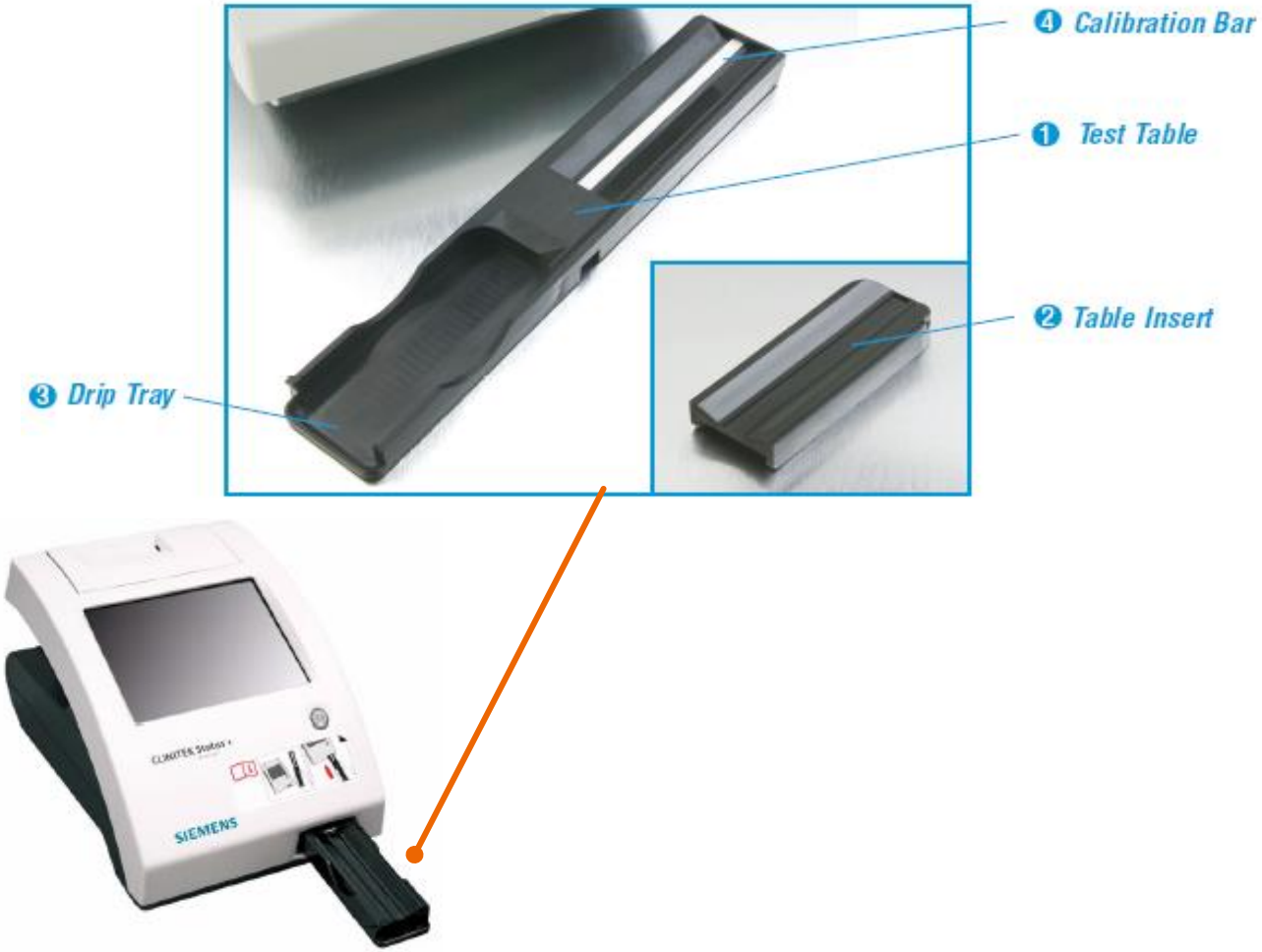
CLINITEK Status+ Analyzer

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

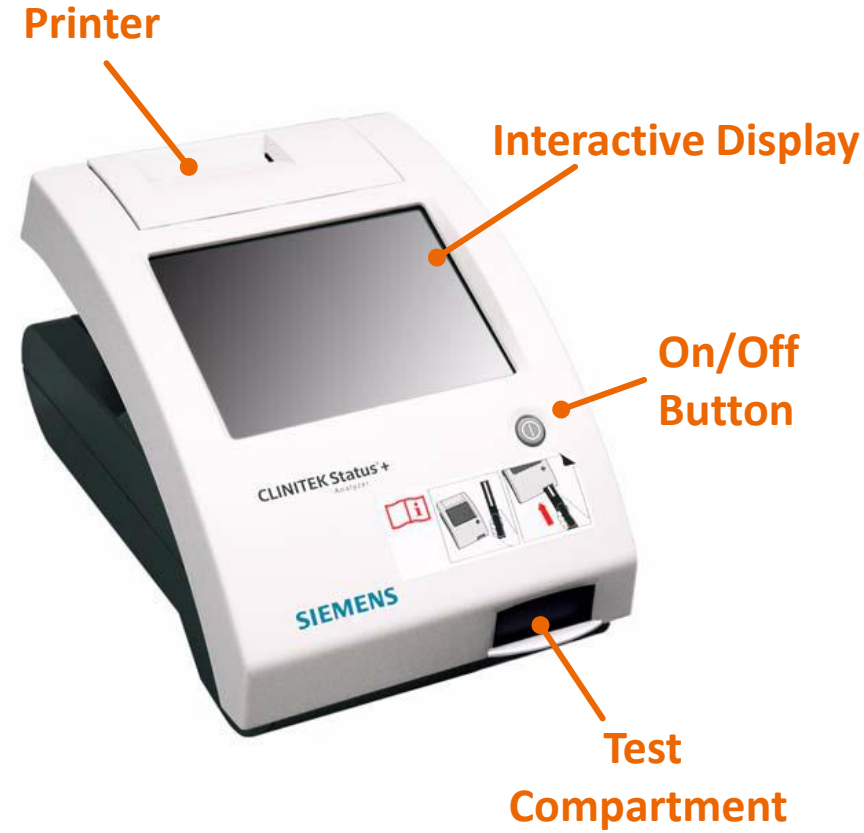
Test Table Overview and Set Up

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



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

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)

Loading the Printer Paper

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

1. Turn the back of the analyze 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

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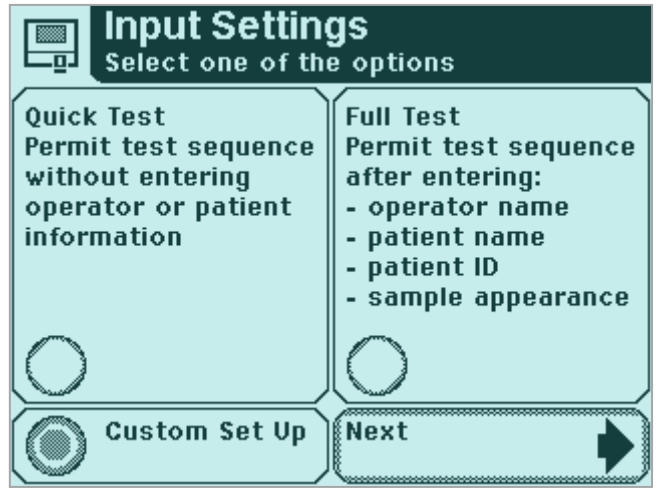
Customizing Setup

Customize Set-up – Select Test Mode

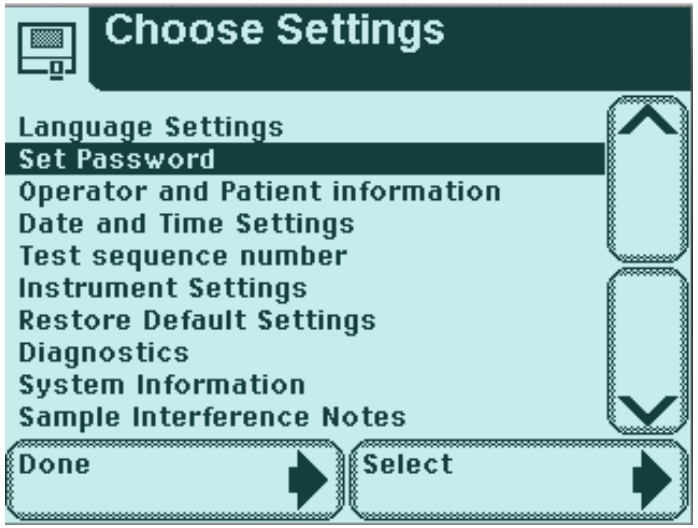
- Select the testing mode that best fits your site needs.
- There are three modes to select from:
  - ✓ Quick test – does not require any patient operator data to be entered
  - ✓ Full test – requires operator, patient and other fixed data to be entered
  - ✓ Custom



Path: Select Instrument Set Up > Operator and Patient Information

Customize Set-up – Set Password

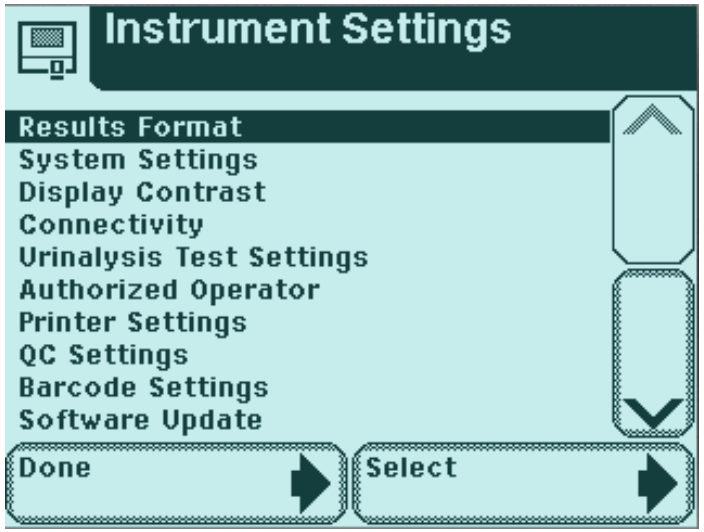
- If the site requires supervisor(s) to be the only ones who can modify system settings, a system password should be programmed.
- The analyzer defaults to not having a system password and is open for all to make system changes.
- The system password differs from the operator ID.
- Operator IDs can be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

Customized Setup Review

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Result Format

Connectivity

Urinalysis Test Setting

Authorized Operator

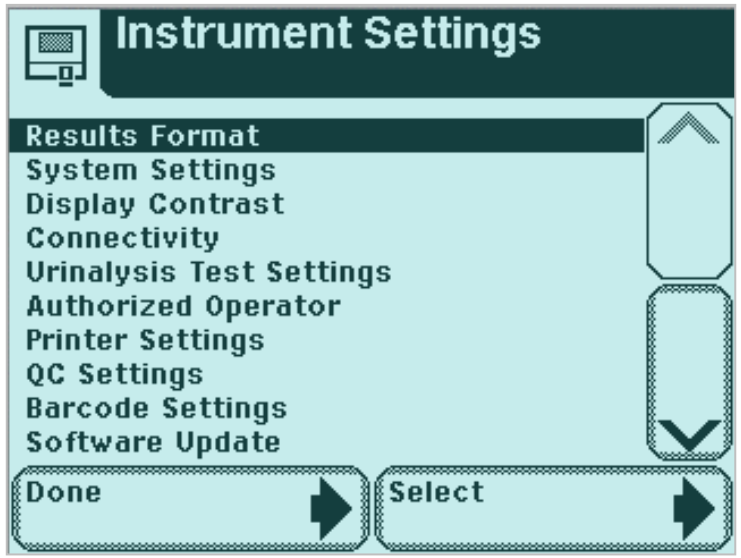
Printer Setting

QC Setting

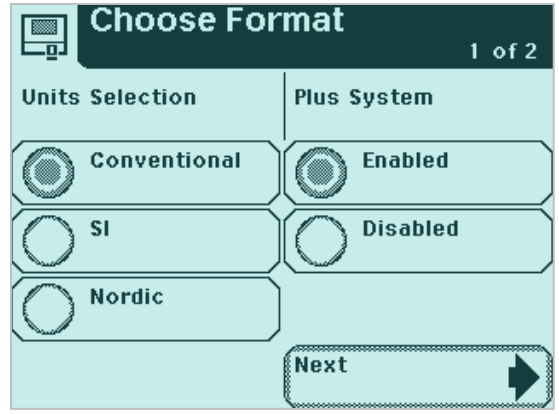
Barcode Setting

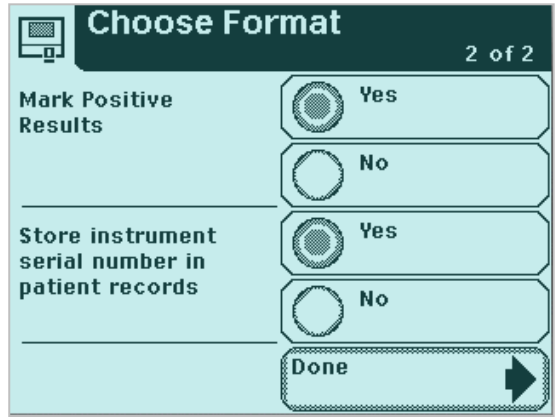
Select Results Format

- 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



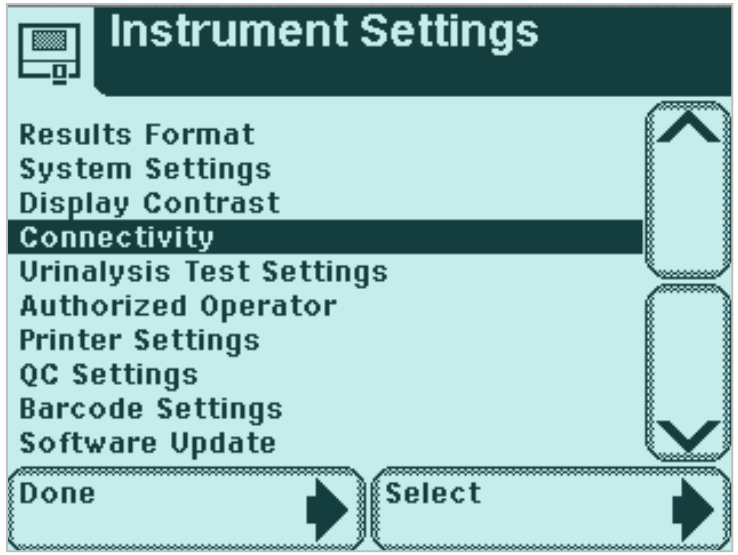
Path: Select Instrument Set Up > Instrument Settings > Results Format

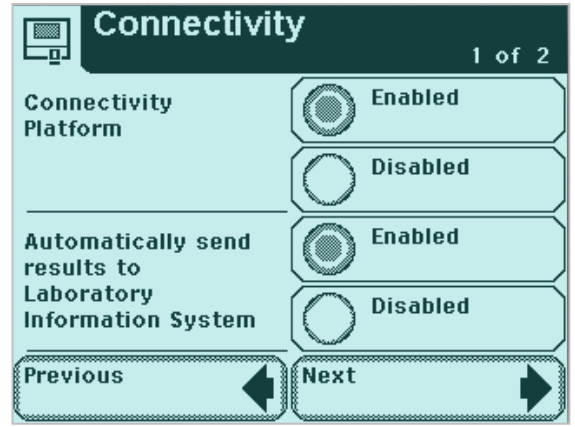




Select Connectivity Set Up

- 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



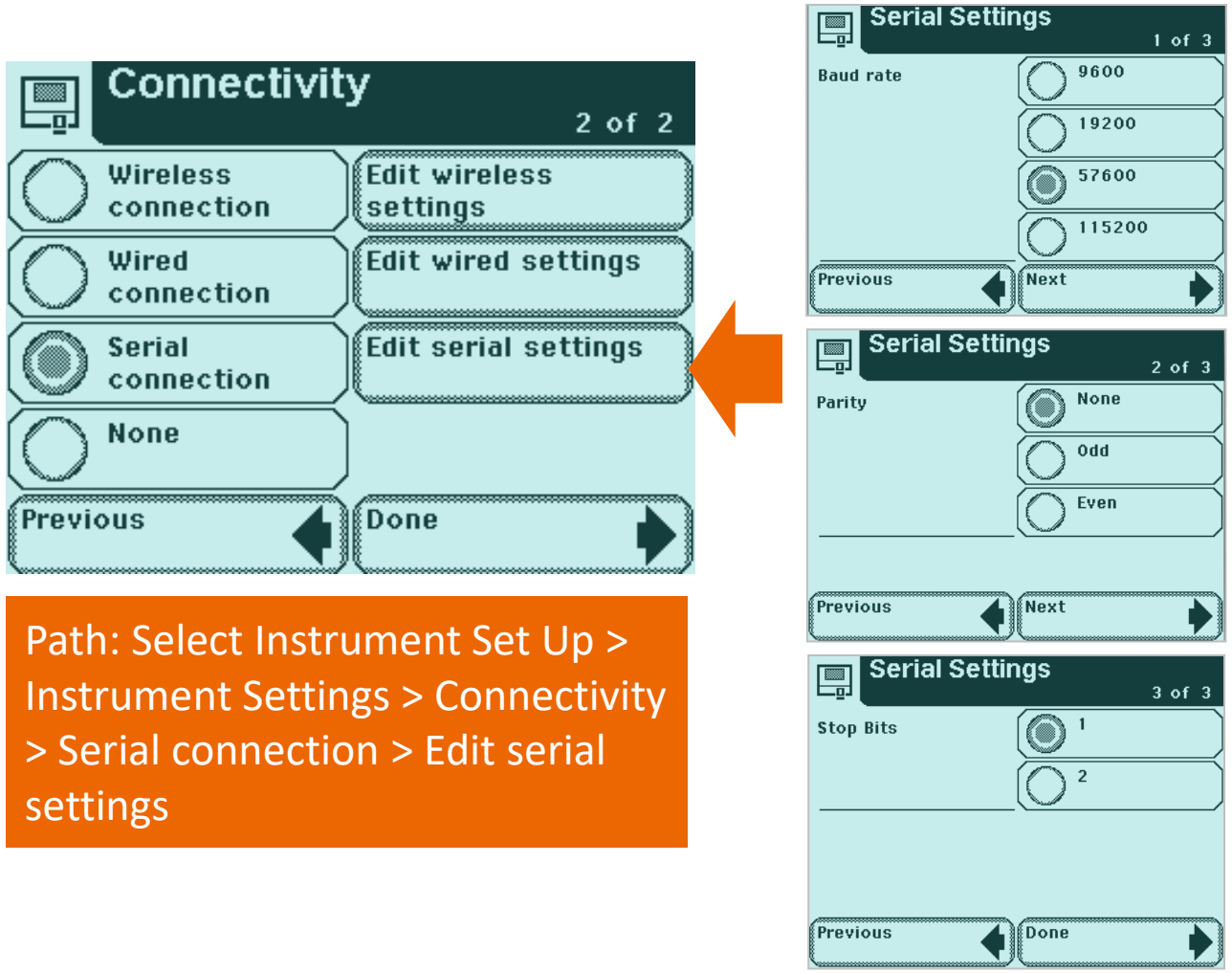


Path: Select Instrument Set Up > Instrument Settings > Connectivity

Select Connectivity Options - Serial Connection Set Up

- For connecting the analyzer serially, follow these steps.

  Note: serial connections will be uni-directionally only.

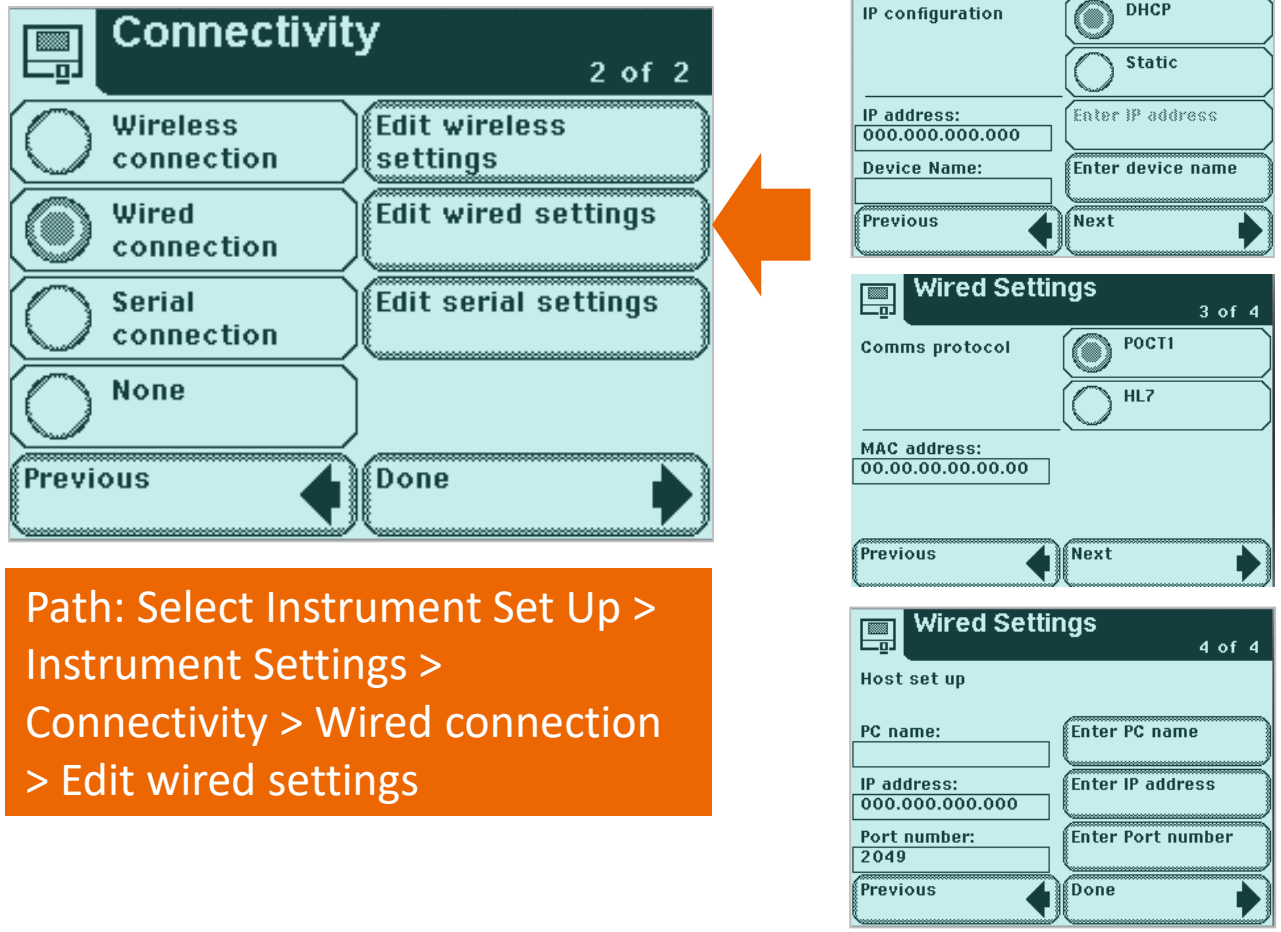


Path: Select Instrument Set Up > Instrument Settings > Connectivity > Serial connection > Edit serial settings

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.

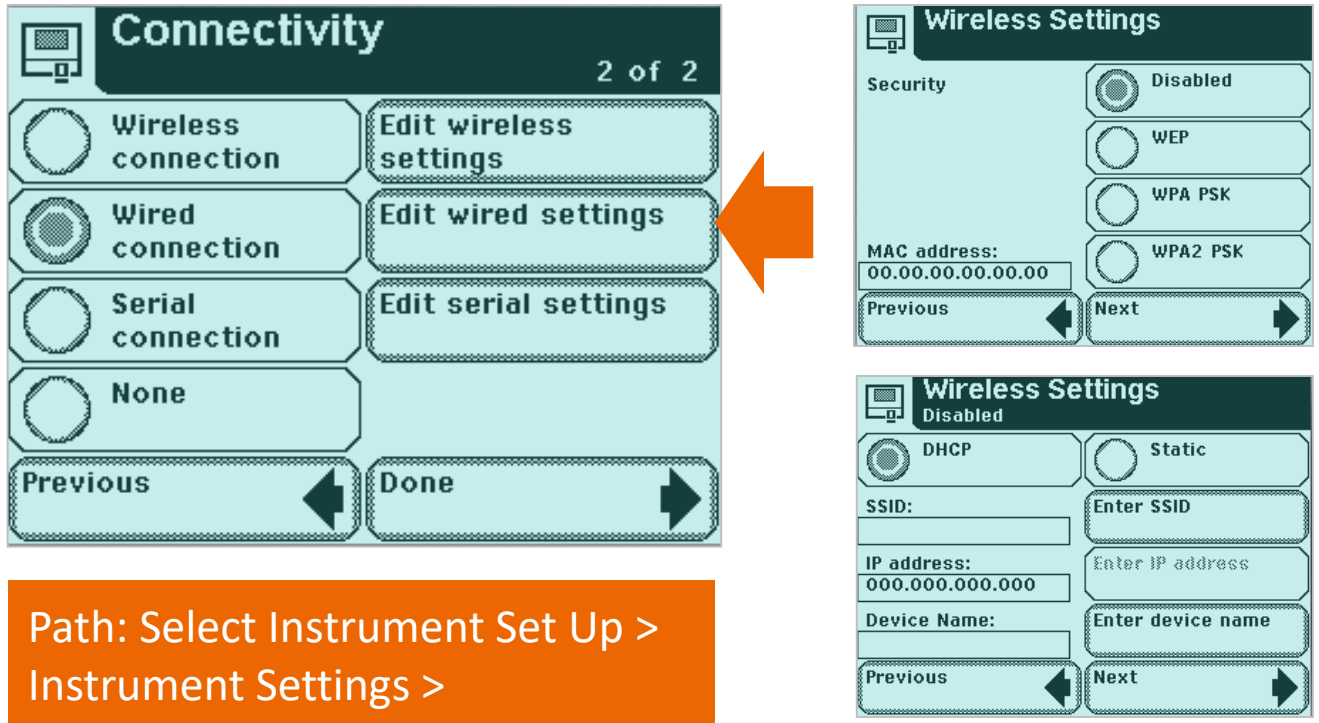


Path: Select Instrument Set Up > Instrument Settings > Connectivity > Wired connection > Edit wired settings

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.

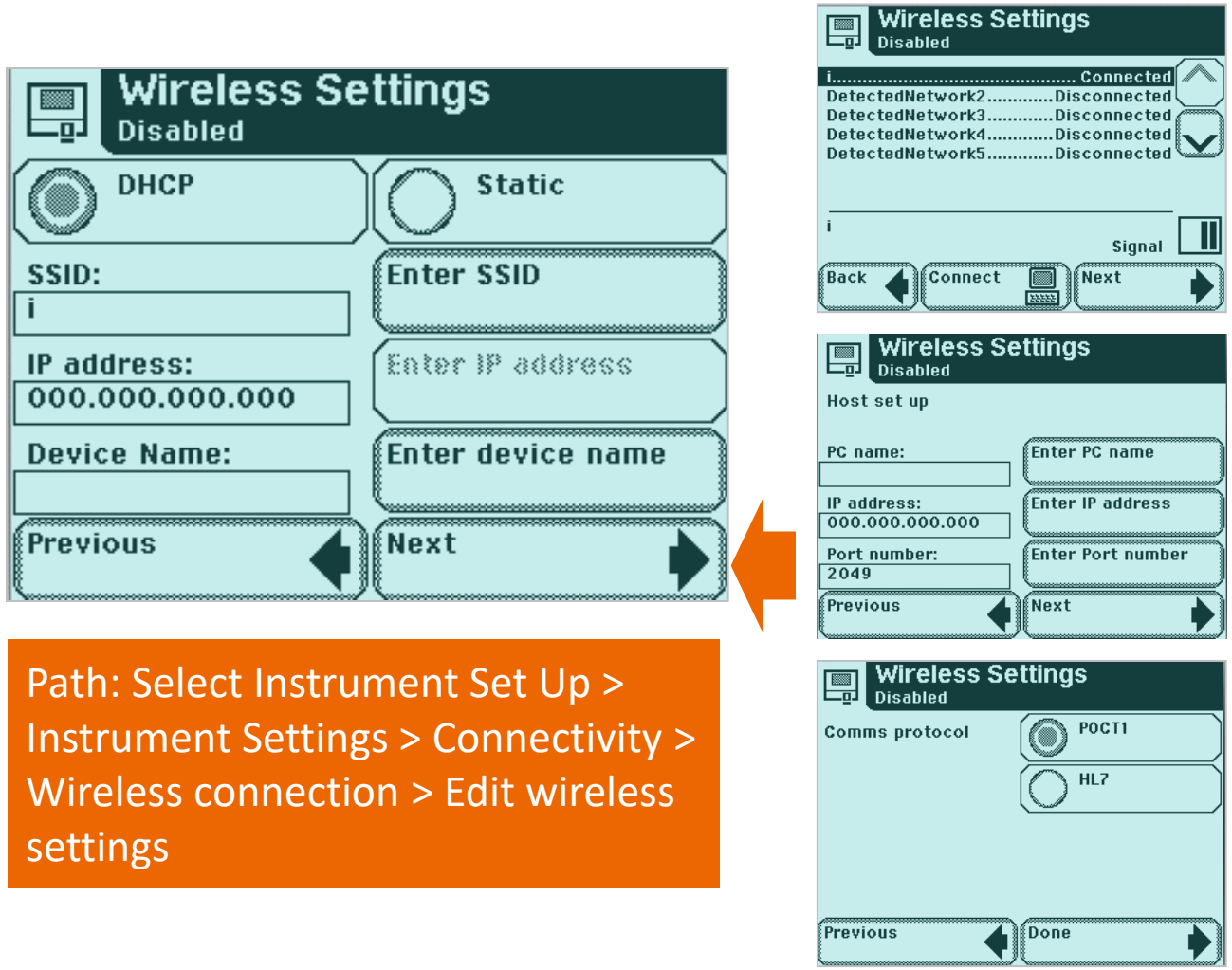


Path: Select Instrument Set Up > Instrument Settings > Connectivity > Wireless connection > Edit wireless settings

Select Connectivity Options - Selecting Wireless Network

- For connecting the analyzer with a wirelessly, 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.

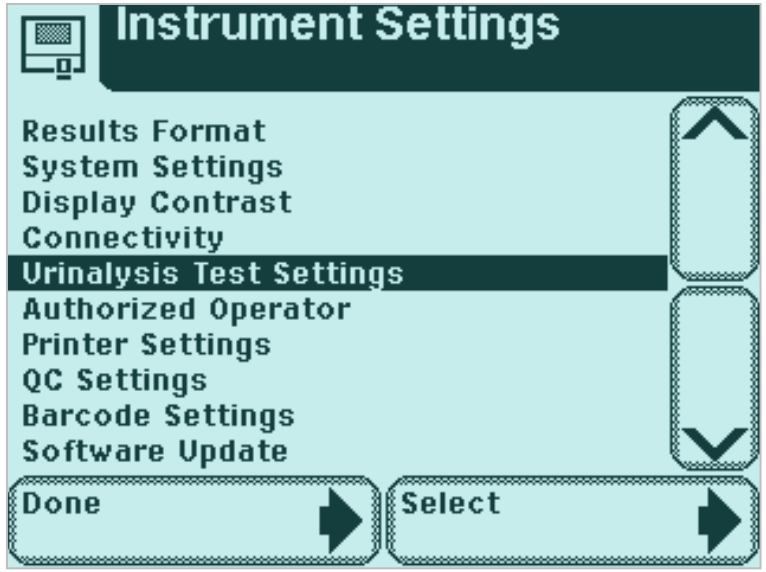
  Note: wireless connections will be bi-directional allowing commands, operator lists and instrument set-ups to be sent down to the analyzer.

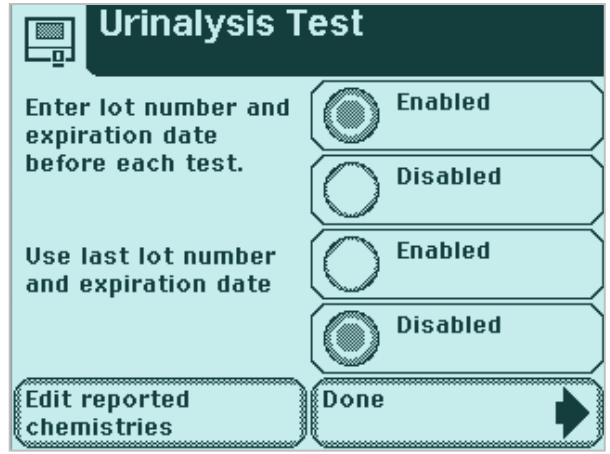


Path: Select Instrument Set Up > Instrument Settings > Connectivity > Wireless connection > Edit wireless settings

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.

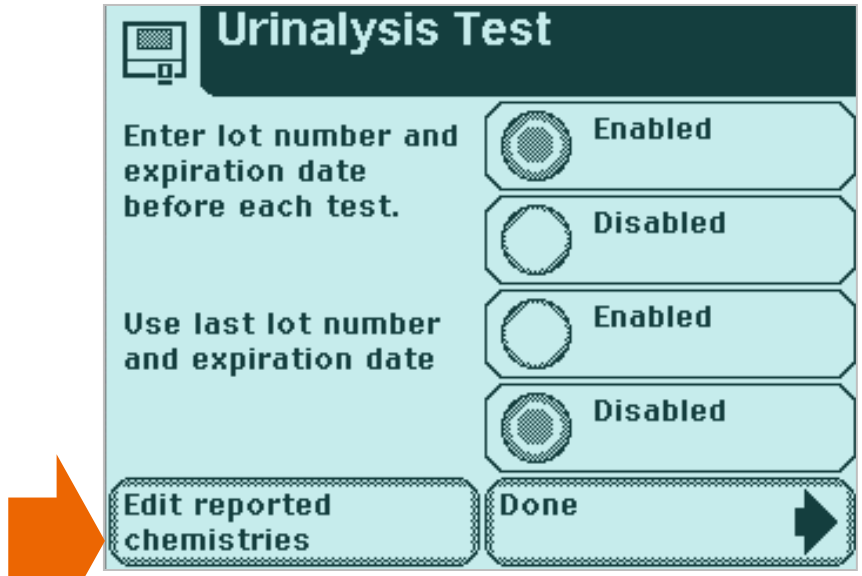


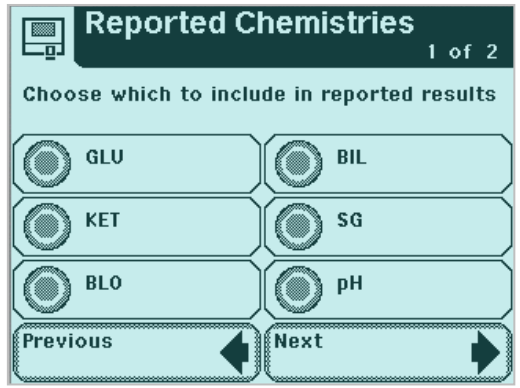


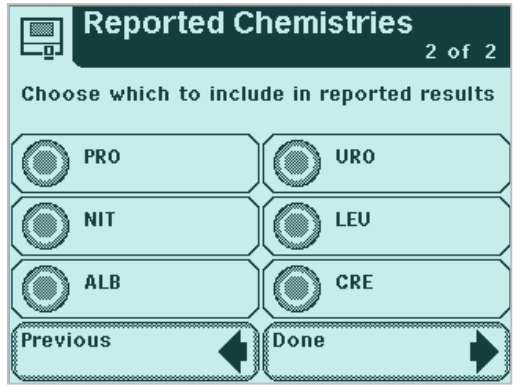
Path: Select Instrument Set Up > Instrument Settings > Urinalysis Test Settings

Select Reported Chemistries

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



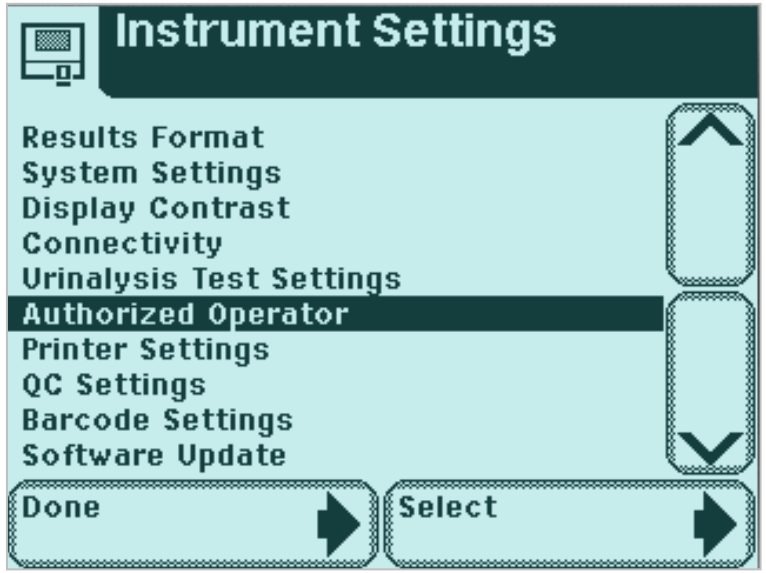




Path: Select Instrument Set Up > Instrument Settings > Urinalysis Test Settings

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

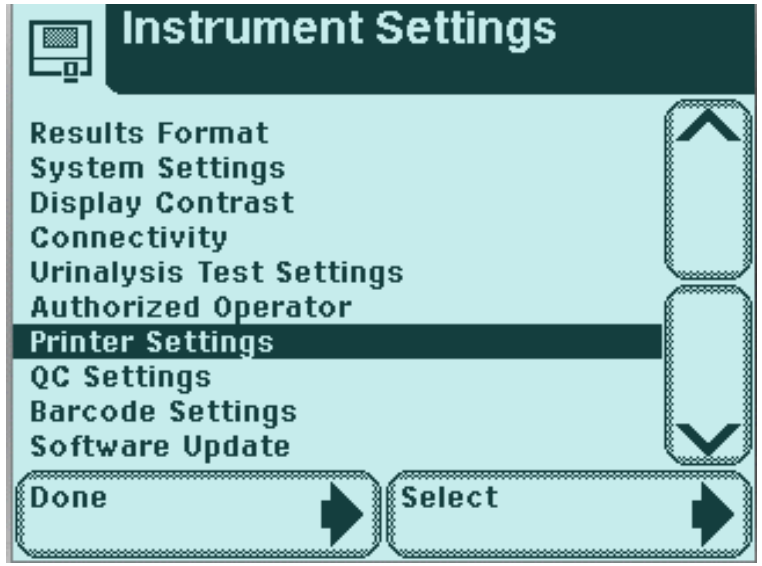
Set Up Authorized Operator Access

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

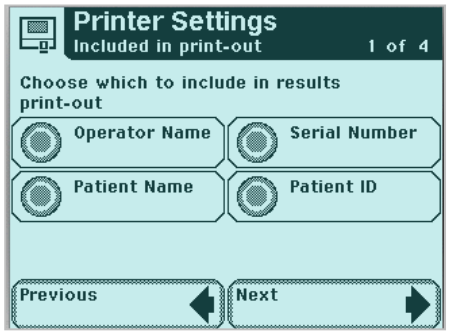
Path: Select Instrument Set Up > Instrument Settings > Authorized Operator

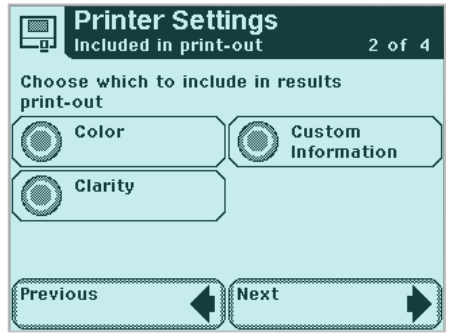
Select On-board Printer Settings

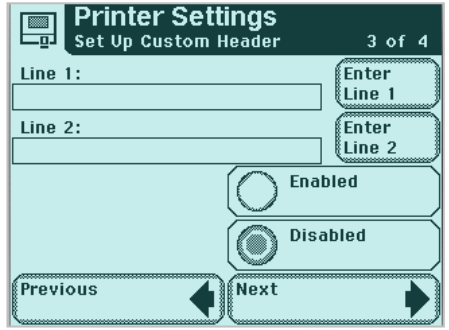
- Select information to include on print-out with each test result:
  - ✓ Operator name
  - ✓ Patient name
  - ✓ Patient ID
  - ✓ Serial number
  - ✓ Color
  - ✓ Clarity
  - ✓ Custom information
  - ✓ Customer headers



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

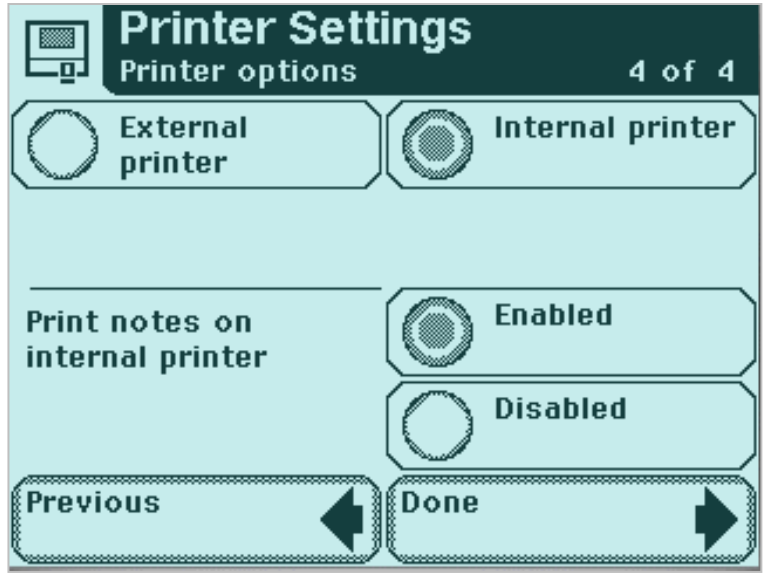






Define Printer Options

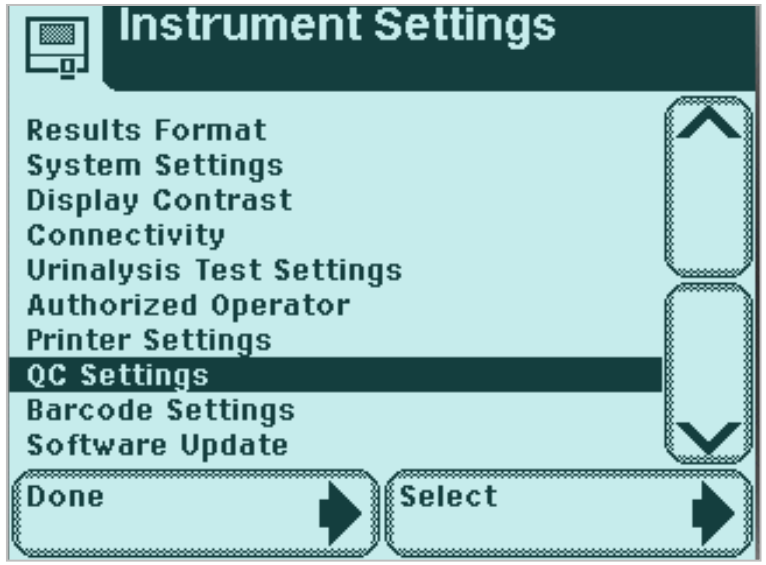
- Select printer type – internal or external.
- If customer notes to be printed with each result, select Enabled.

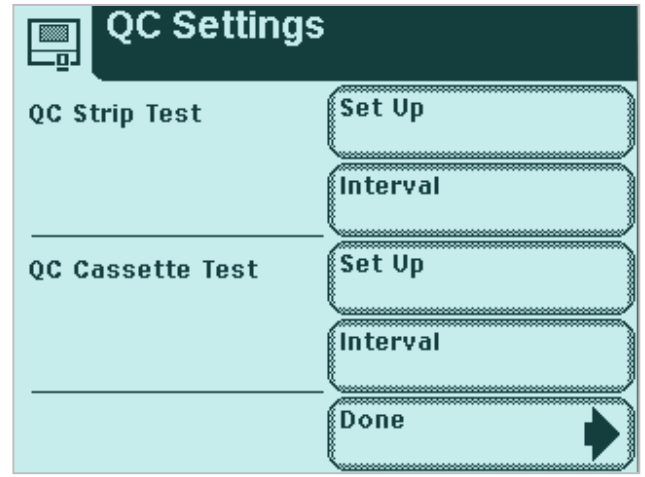


Path: Select Instrument Set Up > Instrument Settings > Printer Settings

Customize – Quality Control (QC) Set Up

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

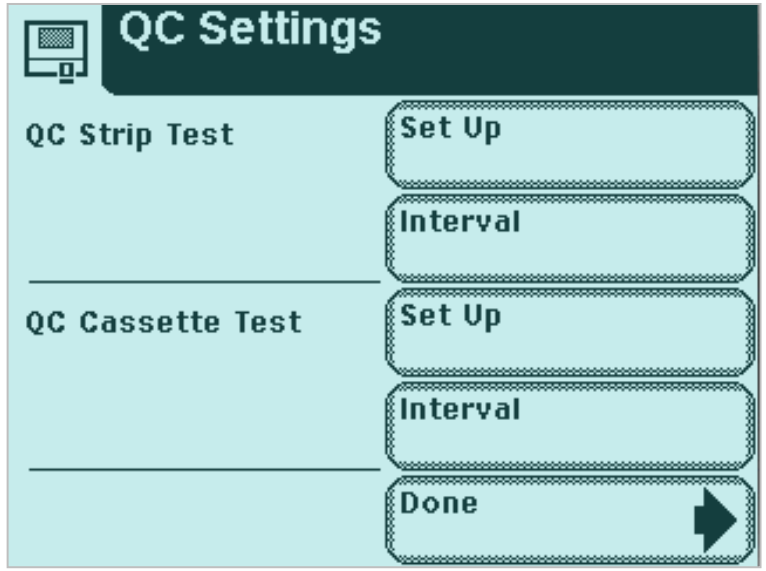


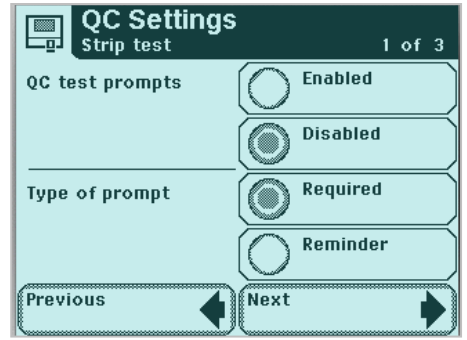


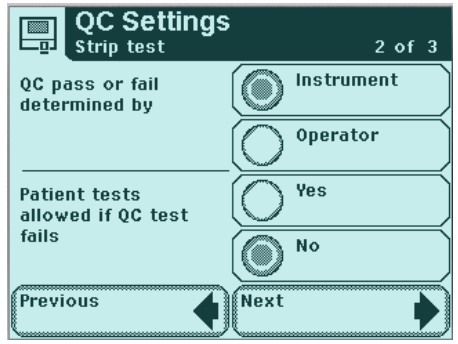
Path: Select Instrument Set Up > Instrument Settings > QC Settings

Customize – QC Strip Set Up

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







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

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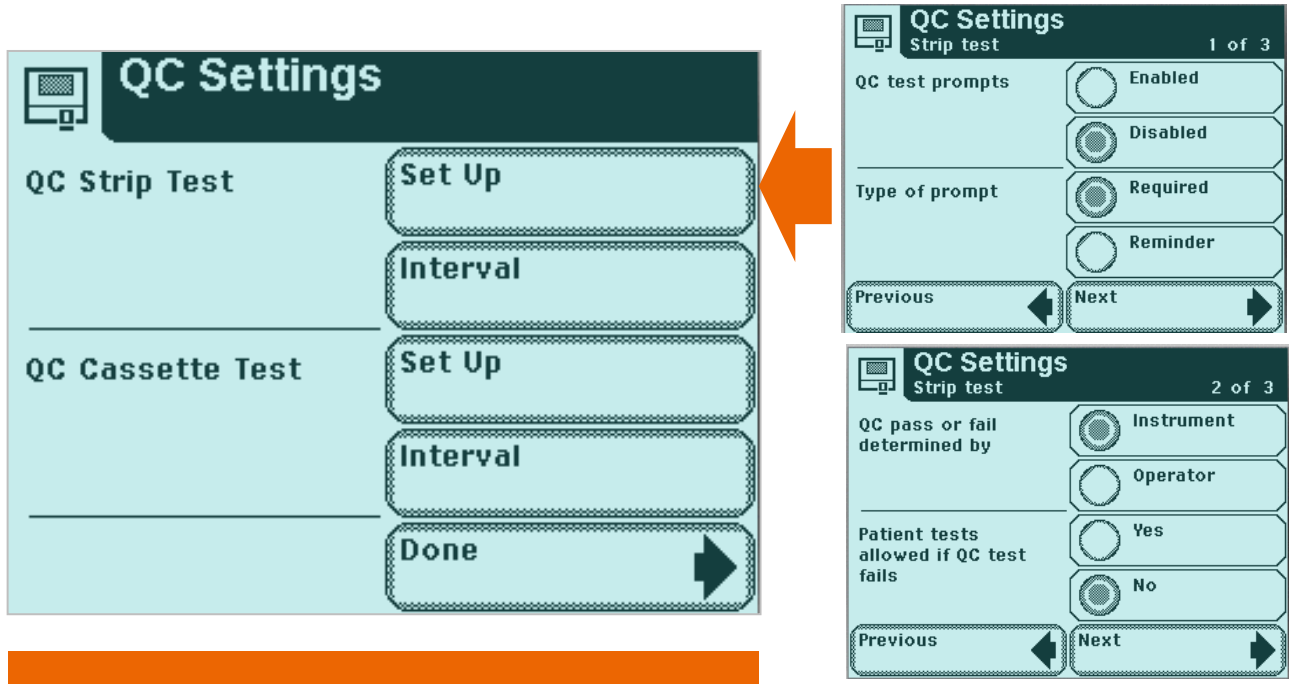
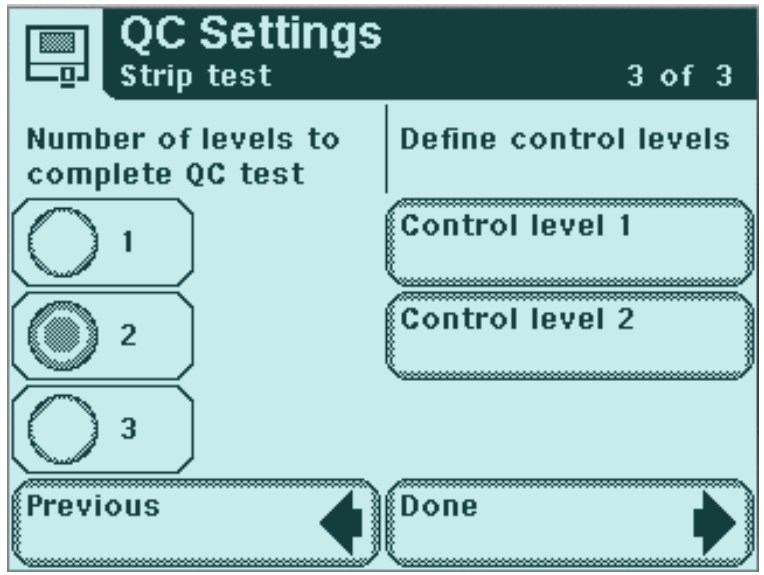


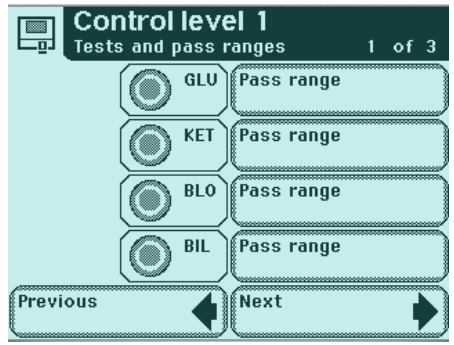
Path: Select Instrument Set Up > Instrument Settings > QC Settings

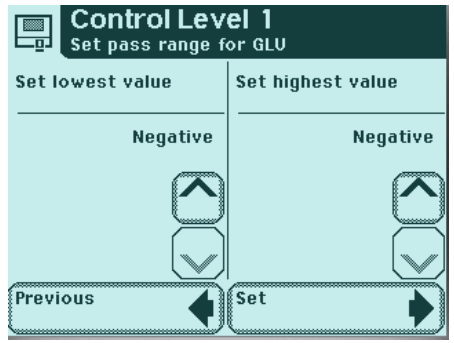
Define the QC Testing Protocol

- 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



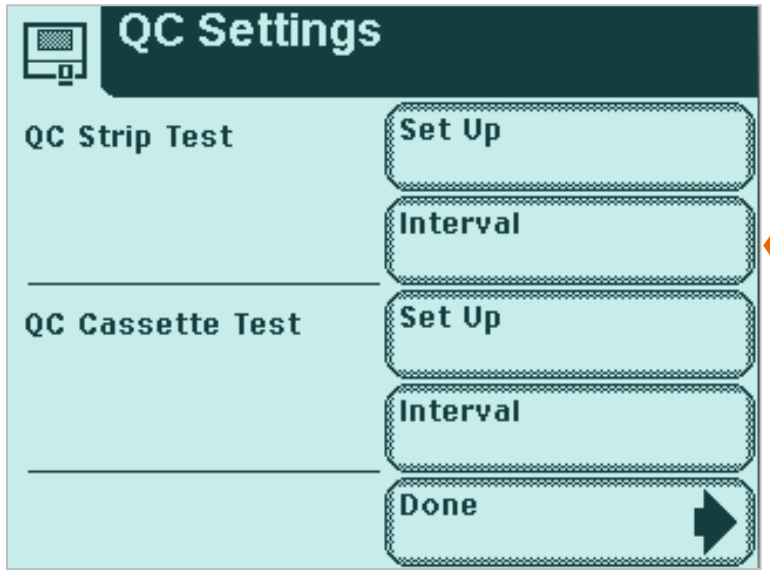
Path: Select Instrument Set Up > Instrument Settings > QC Settings

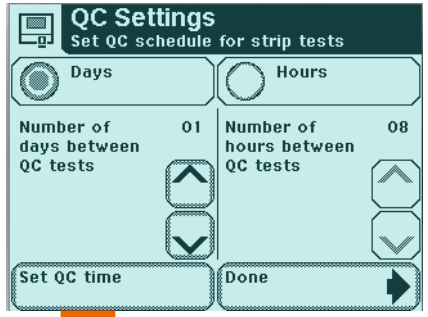


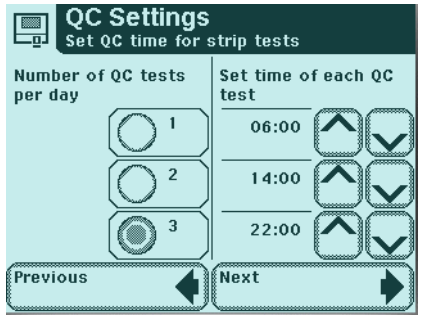


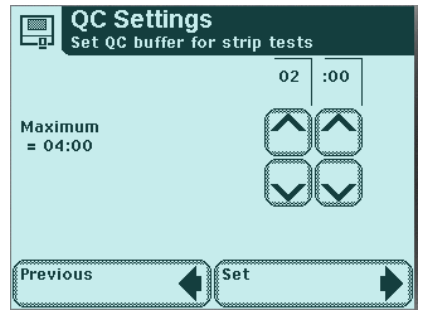
Customize – QC Testing Interval

- 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







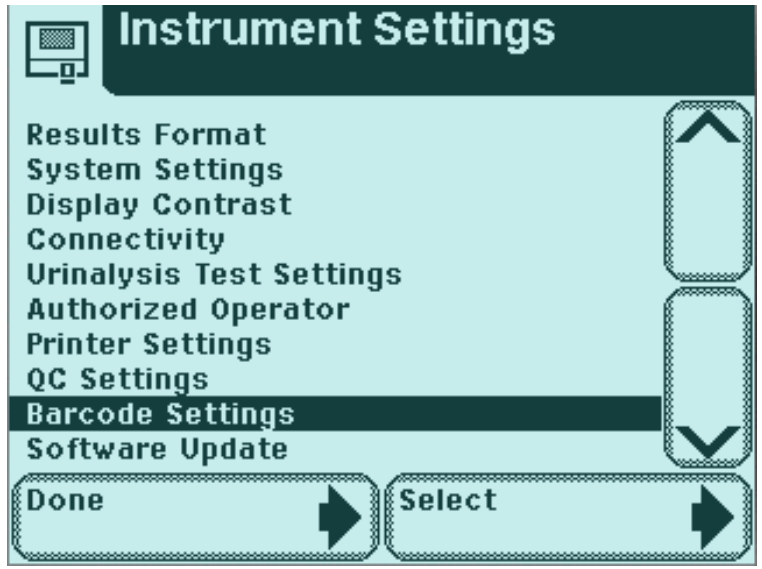


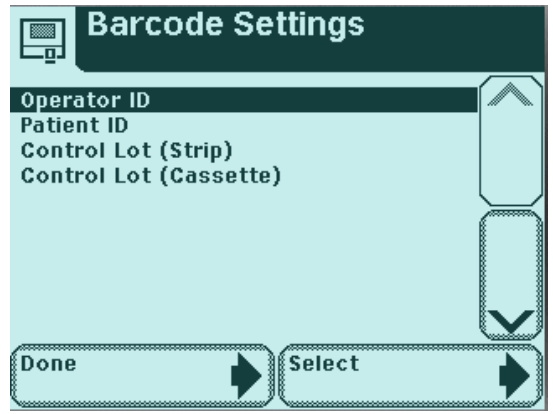
Path: Select Instrument Set Up > Instrument Settings > QC Settings

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)

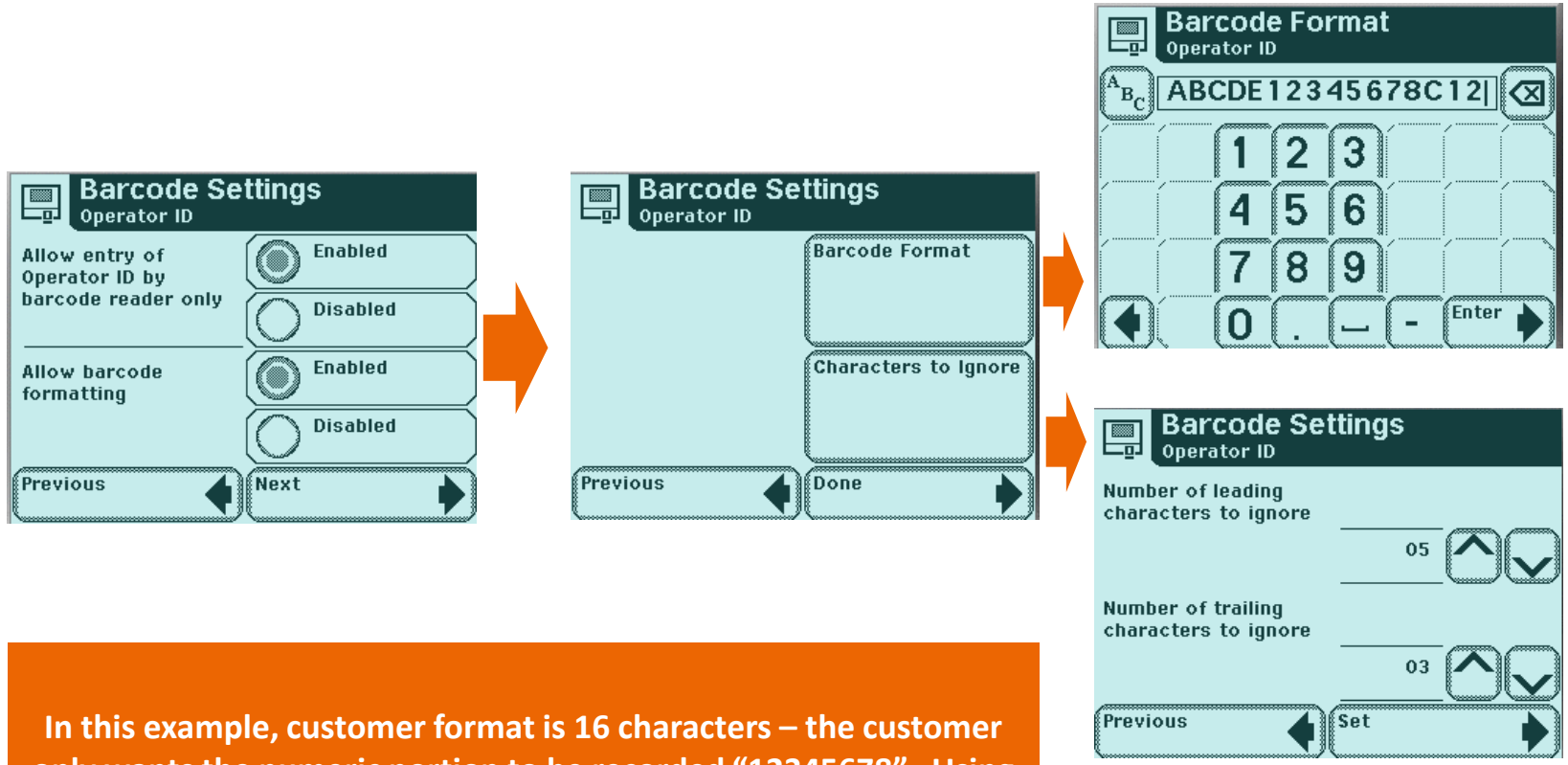




Path: Select Instrument Set Up > Instrument Settings > Barcode Settings

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



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!