GEM® Hemochron® 100

User Manual

CE IVD

Accriva Diagnostics
6260 Sequence Drive
San Diego, CA 92121

instrumentationlaboratory.com

This page intentionally left blank.

Table of Contents

Revision History

Release Date	Description
??? 2017	Original

Warranty

Copyright

Technical Support

This manual is published by Instrumentation Laboratory for use with the GEM® Hemochron™ 100.

For technical support, contact Instrumentation Laboratory:

Phone	United States: 800-579-2255 or 858-263-2502 International: 858-263-2502
Email	techsupport@instrumentationlaboratory.com

Questions or comments regarding the contents of this manual can be directed to the address at the front of this manual or to your Instrumentation Laboratory representative.

Preface

Text Conventions Used in this Manual

This manual uses the text conventions specified below.

Numbered Paragraphs for Procedures

1 Connect the power supply AC cable to an electrical service outlet.

2 Connect the power supply DC cable to the instrument.

Lettered Paragraphs for Processes

a) The Operator is prompted to insert a cartridge

b) A thermometer icon is displayed (the cartridge is being warmed)

c) A blood drop icon is displayed (the sample can be applied)

Bold Text

User interface controls, such as the names of menu items and field labels are in bold type. Example:

1 Select  > **Supervisor Settings** > **OID Password Required**.

Some words other than those that are used on user interface controls are also in bold type, but the font is larger. These words act as inline headings in bulleted lists. Example:

- **Add a user note** – Operators can add a user note to the test record before they remove the cartridge.

Italic Text

When a procedure specifies that the user needs to enter text into a field, that text is shown in italic text:

1 Enter *000* and select **Done**.

Cross-references to other information are in italic text:

See *Chapter 6: Patient Testing*.

Symbols Used in this Manual

The following symbols are used in this manual:

Symbol	Meaning
	Important information.
	Caution: A potential hazard that could cause minor personal injury or minor damage to the product or property.
	Warning: A potential hazard that could cause moderate to severe personal injury, moderate to severe damage to the product or other property, or death.
	Warning: Potential biological hazard.

Definitions and Terms

The following acronyms and abbreviations are used in this manual, on instrument screens:

Term	Definition
ACT	Activated Clotting Time
Ccn	The format for characters allowed in a barcode mask 'C' is for uppercase, 'c' is for lowercase and 'n' is for number mask. The Patient ID Barcode Entry mask can be 1 to 32 characters long.
CCM Supervisor	This describes a user permission level for Configuration Manager (CCM) software. Users with this level of permission can configure the list of instruments on the PC, and change settings of the instruments through the PC.
DB	Database
EQC	Electronic Quality Control

Instrument Supervisor	This describes a user permission level for the Hemochron device. Users with this level of permission change settings of the instruments through the instrument User Interface.
LQC	Liquid Quality Control
OID	Operator Identification
PC	Personal Computer
PID	Patient Identification
POCC	Point of Care Coordinator
QC	Quality Control

Chapter 1: Introduction to the System

Purpose of This Manual

This manual explains how to use the GEM® Hemochron™ 100.

Intended Use of the System

The GEM® Hemochron™ 100 is a battery-operated portable instrument that performs individual *in vitro* quantitative coagulation tests on fresh whole blood. These tests include Activated Clotting Time (ACT+ and ACT-LR). The system is for intended to be used with test cartridges available from Accriva Diagnostics. The system is intended for professional use only in point-of-care settings for patients aged 18 years and above. For *in vitro* diagnostic use. Rx only.

Principles of Operation

The GEM® Hemochron™ 100 system measures whole blood activated clotting times using single-use disposable cartridges. Each cartridge contains all of the reagents necessary for a specified test. The operator inserts a cartridge for the test into the instrument and then (if desired) enters information about the sample or scans the information from a barcode using the integral barcode scanner. The cartridge is warmed to 37°C (98.6°F) then an icon appears indicating to the operator that a blood sample can be added to the cartridge. The operator then places blood in the sample well of the cartridge and starts the assay. The instrument draws a precise volume of blood from the sample port into the micro-channel of the test cartridge where the blood is mixed with the reagents. The remainder of the blood sample, not needed for testing, is automatically drawn out of the sample well and into an enclosed waste channel in the cartridge.

The instrument mixes the sample and reagent by pumping the mixture back and forth at a predetermined rate within the test channel at a temperature maintained at 37°C (98.6°F). A camera (optical system) monitors the motion of the sample/reagent mix in the test channel. As the blood begins to clot, the flow of the blood sample within the test channel is impeded, reducing its rate of flow.

This reduction in flow velocity below a predetermined value signals to the instrument that a clot has formed. An internal timer measures the elapsed time between the start of the test and the clot formation. During the test, the elapsed time (in seconds) is displayed. Upon completion of the test the whole blood clotting time is displayed and recorded by the instrument.

Description of the System

The GEM® Hemochron™ 100 system consists of the instrument, a power supply, liquid quality control (LQC) material and the ACT+ and ACT-LR assays.

The Instrument

Instrument Overview

The instrument is a handheld device with a touch-sensitive screen that is used to execute commands and enter information. The screen also displays operating instructions, displays test results, and allows settings to be configured.

A test chamber in the instrument warms a cartridge to 37°C (98.6°F) and tests a whole blood sample after it is placed in the cartridge slot. When the test is completed, the results are displayed on the screen and stored in memory for viewing.

The instrument also has a barcode scanner for reading barcode information such as patient IDs and operator IDs.

Data management capabilities that are included with the instrument include:

- Storage of up to 100,000 test records (patient tests and QC tests) with associated information
- Designation of quality control (QC) levels, QC ranges, and QC lot numbers
- Date and time stamp for all test results
- Annotation to patient results
- Transfer of test results over a computer network (via Wi-Fi or Ethernet) to a remote PC
- Quality control and operator lockout capability

Instrument Components

Instrument components are shown in Figure 1 and described in Table 1.

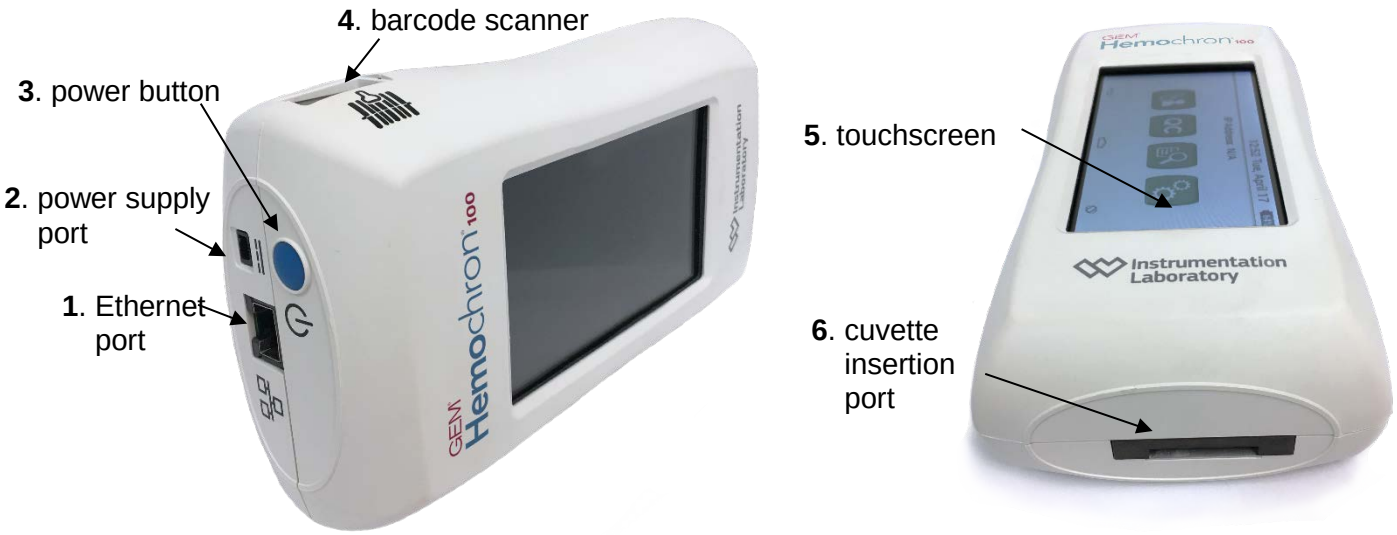


Figure 1 – Instrument Components

Table 1 – Instrument Components

Item Number	Component	Description
1	Ethernet port	Connect an Ethernet cable here so the instrument can be connected to a local area network (LAN).
2	power supply port	Connect the power supply cable here to charge the battery.
3	power button	Power the instrument on and off. This button is also used to put the instrument into sleep mode and wake the instrument from sleep mode.

Item Number	Component	Description
4	barcode scanner	Used for scanning barcodes to enter operator ID (OID), patient ID (PID), and information about liquid quality control (LQC) lots. Supported barcode formats:Aztec, Code 39, Code 128, Micro PDF417, QR. **NOTE** This scanner does not scan the barcode on the cartridge. The cartridge barcode is automatically scanned by an internal scanner when the cartridge is inserted into the cartridge insertion port.
5	touchscreen	The interface that Operators use to operate the instrument.
6	cartridge insertion port	The port into which a cartridge is inserted. The instrument warms the cartridge to the required temperature. The cartridge is secured during testing to measure the clotting time of a whole blood sample.

Cartridges

GEM® Hemochron™ 100 cartridges are single-use disposable test devices with wells for application of blood samples.

NOTE Cartridges are not supplied with the System. They must be ordered separately. See *Items Required, but Not Provided* in Chapter 2.

When a patient test or a liquid quality control (LQC) test is run, the instrument prompts the Operator to insert a cartridge into the port on the end of the instrument. After the instrument warms the cartridge, it prompts the Operator to apply a blood sample to it. For a description of cartridge components, see Figure 2 and Table 2.

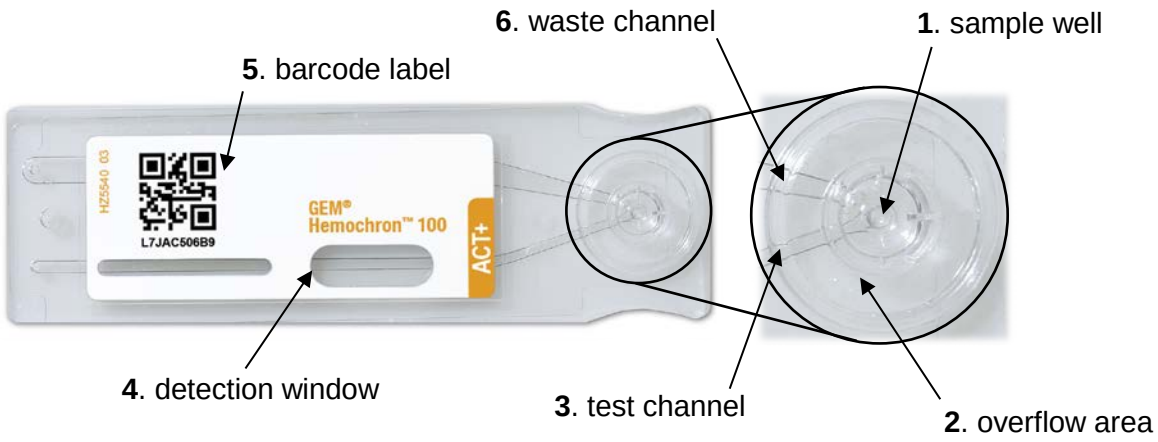


Figure 2 – Cuvette Components

Table 2 – Cartridge Components

Item Number	Component	Description
1	sample well	This is where the sample is applied.
2	overflow area	Excess sample flows into this area and then into the waste channel.
3	test channel	The instrument vacuum pump draws the sample into the test channel where it is mixed with reagent.
4	detection window	An internal camera analyzes the sample through the detection window.

Item Number	Component	Description
5	barcode label	The barcode label contains the cartridge lot number and expiration date. When a cartridge is inserted into the cartridge insertion port, an internal scanner reads this information. Information on the label is also human-readable. **NOTE** The internal scanner differs from the external scanner. The external scanner can be used to scan barcodes that contain other information, such as operator ID and patient ID.
6	waste channel	The instrument vacuum pump draws excess sample into the waste channel. This ensures that the sample volume is correct.

Two types of cartridges are available. The type of cartridge must match the type of test.

- ACT+
- ACT-LR

The cartridge packaging contains an insert with more information about cartridges, including storage and handling instructions. The cartridges for ACT+ and ACT-LR are compatible with the Hemochron Jr. Family System

Configuration Manager Software

The system includes software titled *Configuration Manager for GEM® Hemochron™ 100* for use on a PC (Microsoft Windows® operating system).

Although the instrument menus can be used to configure some of the instrument settings, Configuration Manager can be used to configure more advanced settings and to send those settings over the network to a single instrument or to more than one instrument at the same time.

For information, see *Chapter 4: Configuration Manager*.

Control Material for Running an LQC Test

Specific Control material is required when a liquid quality control (LQC) test is run. For information about control material, see *Control Material* on page 117 7.

NOTE Sample material is not supplied with the System. It must be ordered separately.

Product Labeling, Symbols, and Icons

Product labeling includes this manual and all associated documents, including the instructions that are packaged with cartridges and LQC sample material. Before the instrument is operated, it is essential that all product labeling is read and understood.

This section also contains information about:

- Symbols that appear on product labeling (see Table 3)
- Symbols that appear on the instrument (see Table 4)
- Icons that appear on the instrument display screen (see *Icons on the Display Screen* below)

Main Label on the Instrument

The main label on the bottom of the instrument contains important textual information and symbols. See Figure 3. For a list of these symbols and their meaning, see Table 3.

Figure 3 – Instrument Main Label

Symbols on Product Labeling

To interpret the meaning of symbols that are on product labeling, see Table 3.

Table 3 – Symbols on Product Labeling and Their Meaning

Symbol	Meaning
	Consult Instructions for Use
	Caution
	Catalog Number
	The lot information associated with cartridges and LQC sample material, including lot number and expiration date. For LQC material, it also includes the lot range.
	The instrument serial number. Record the serial number and store it in a secure place.
	Contents
	Use By
	Single Use – Do not reuse
	Temperature Limits
	Biological Risks
	Date of manufacture
	Manufacturer
	For *in vitro* diagnostic use
	Rx Only.
	Medical Equipment per Annex 1A, Item 8 Directive 2002/96/EC For Electronic Equipment Waste. For more information, contact Instrumentation Laboratory Technical Support.
	Fragile, handle with care
	Conformity to European Directives
	Authorized Representative in the European Community

Symbols on the Instrument Case

To interpret the meaning of symbols that are on the instrument case, see Table 4.

Table 4 – Symbols on the Instrument Case and Their Meaning

Symbol	Meaning
	Power button (On/Off)
	Direct Current - Power supply connector
	Ethernet port for a wired network connection
	External barcode scanner for scanning information such as operator ID and patient ID. *(**Writer's Note:** This image is a placeholder. Need the actual image.)*

Icons on the Display Screen

Main Icons on the Home Screen

Icon	Name	Meaning
	Patient Test	Test a patient sample. See *Chapter 6: Patient Testing*.
	Quality Control	Run tests to ensure the instrument is operating properly. See *Chapter 7: Quality Control*.
	Database	View saved test results. See *Chapter 8: Database*.
	Settings	Configure the instrument. See *Chapter 3: Instrument Settings*. To change more advanced settings on one or more instruments at the same time, see *Chapter 4: Configuration Manager*.

Basic Navigation Icons

Icon	Meaning
	Return to the previous screen
	Display the Home screen
	Rotate the screen display 180 degrees

Battery Power Icons

Icon	Meaning
	Battery is partially charged (the percentage of remaining power is shown); the power supply is not connected.
	Battery is fully discharged; the power supply is connected.
	Battery is partially charged; the power supply is connected.
	Battery is fully charged; the power supply is connected.

Test-Related Icons

Icon	Meaning
	Testing is allowed • **For EQC** – EQC testing has passed. An LQC test or patient test can be run. • **For LQC** – LQC testing has passed. A patient test can be run.
	Testing is not allowed • **For EQC** – EQC testing has failed. Before an LQC test or patient test can be run, an EQC test must be successfully run. • **For LQC** – LQC testing has failed. Before a patient test can be run, an LQC test must successfully be run.

	The QC interval timer has expired • **For EQC** – The EQC interval timer has expired. • **For LQC** – The LQC interval timer has expired.
	Abort the test
	The instrument is prompting the Operator to insert a cartridge
	The instrument is prompting the Operator to remove the cartridge
	The instrument is warming the cartridge
	The instrument is prompting the Operator to apply the sample to the cartridge
	The instrument is drawing the sample into the test channel and analyzing it
	Warning: The instrument aborted the test. For example, the sample volume was inadequate. For a list of possible warning messages, see Table 19.
	The instrument is processing
	Enter a user note after a test
	View details of the current test result

Connectivity Icons

Icon	Meaning
	Ethernet – The instrument is connected to the network through an Ethernet cable
	Wi-Fi is connected – The instrument is wirelessly connected to the network
	Wi-Fi is disconnected – The instrument was wirelessly connected to the network, but it is now disconnected

Operational Precautions and Warnings

- The system is for *in vitro* diagnostic use only.
- The system is for use only under the supervision of a physician.
- The system requires the use of personal protective equipment (e.g. gloves, gowns) where there could be contact with the skin when handling potentially infectious substances or surfaces (such as human samples or reagents).
- The instrument is designed for use with GEM® Hemochron™ 100 cartridges only.
- If a cartridge lot has expired, do not use the cartridge. Discard it.
- Store cartridges according to the instructions on the package insert that accompanies the cartridges.
- Store the instrument according to instructions on the box label.
- While running a patient test or LQC test, keep the instrument level.
- DO NOT operate the instrument in an environment that is not within the specified range:
  - Ambient temperature/humidity

    minimum: 15°C (59°F)

    maximum: 32°C (89.6°F)
  - Relative humidity, noncondensing: Less than 85%
  - Elevation

    minimum: 0

    maximum: approximately 3000 meters (10,000 feet)
- If the instrument was dropped during a test, DO NOT use the test results.
- DO NOT disassemble the instrument except in order to replace the battery by removing the cover from the battery compartment. The instrument does not contain any user-serviceable parts.
- When the power supply cable is disconnected from the instrument or from the wall, DO NOT grasp the electrical cable. Instead, grasp the connector.
- Patient blood samples, blood collection materials, and used cartridges are potentially infectious. Handle these items with care. Strictly adhere to all biohazard safety guidelines for handling and disposing of human blood.

- The use of accessory equipment not identified in this manual, or equipment that does not comply with either the equivalent safety requirements of this equipment or IEC 61010 or IEC 61326 standards, may compromise safety when using the instrument.

- **Warning:** Use of this instrument in a manner other than as specified in this manual may lead to injury.

Limitations

Test results are affected by poor technique during blood collection and delivery to the sample well. The accuracy of the test result is largely dependent upon the quality of the blood sample, which is dependent upon the technique used to collect the blood sample and to transfer the blood to the cartridge. For specific limitations, refer to the package insert for the individual assay.

As with all diagnostic tests, test results should be evaluated in the context of a specific patient's condition and anticoagulant therapy. Any results exhibiting inconsistency with the patient's clinical status should be repeated or supplemented with additional test data. Samples with a hematocrit less than 20% or greater than 55% are not recommended, due to an optical density outside the detection level of the instrument.

Specifications

Estimated Service Life

The estimated service life of the instrument is five years.

Dimensions and Weight

Length	18.8 cm (7.4 in)
Width	10.2 cm (4.0 in)
Height	5.1 cm (2.0 in)
Weight	0.68 kg (1.5 lb.)

Operation

Memory Capacity	Instrument memory holds up to 100,000 records of test results (patient tests, quality control tests, or a combination)
Battery Life	500 charges
Battery Type	lithium-ion
Battery Power	7.2 VDC, 20.88 Wh
Operating Time on Battery	110 minutes on fully charged battery
Operating Environment	15-32°C (59-89.6°F), < 85% RH (non-condensing)

Testing Environment	Indoors, on a dry, clean, horizontal and stable surface. Avoid nearby vibration equipment such as centrifuges.

Power Supply

Input Power	100-240 VAC, 50-60 Hz, 1.2 A
Output Power	+12 VDC, 3.4 A

Storage and transport

Storage Environment	-20°C to 55°C (-4°F to 131°F), < 85% RH, non-condensing

Calibration

The instrument is calibrated at the manufacturing facility to test and verify all functions. The instrument is also self-calibrating, as all instrument functions are monitored and verified by the instrument software before each LQC test or patient test is run. The instrument does not require additional calibration by the user.

Chapter 2: Prepare to Use the Instrument

Packaging, Contents, and Other Required Items

Package Contents

Ensure the package contains the following items:

- **Instrument**, GEM® Hemochron™ 100 System
- **Power supply**
  - cable, 110VAC (wall outlet to power converter)
  - power converter, AC to DC
- **USB drive or DVD**
  - software, Configuration Manager for GEM® Hemochron™ 100 System
  - PDF, User Manual, GEM® Hemochron™ 100 System
- **Manual (paper)**, Quick Reference Guide, GEM® Hemochron™ 100 System

Items Required, but Not Provided

To use the instrument, the following items are required but not provided. To order them, contact an Instrumentation Laboratory representative.

Description	Catalog Number	Quantity
Cartridges for GEM® Hemochron™ 100 • ACT+ cartridge • ACT-LR cartridge	 GACT+ GACT-LR	As needed
directCHECK® Quality Controls (sample material for Quality Control testing) • ACT+ - Normal (Level 1) - Abnormal (Level 2) • ACT-LR - Normal (Level 1) - Abnormal (Level 2)	 DCGACT-1 DCGACT-2 DCGLR-1 DCGLR-2	As needed

Optional Items

The following optional items are not provided. To order them, contact an Instrumentation Laboratory representative.

Description	Catalog Number	Cross Reference Part Number
	?	
Power supply, replacement • Power converter (AC to DC) • Cable, AC (to wall outlet)	 ? ?	HZ5195X HR1235
DVD or USB, *Report Maker GEM® Hemochron™ 100*	?	?

Unpack and Inspect the Instrument

NOTE Do not discard the packaging. Keep it in case the instrument must be shipped or otherwise transported.

1. Remove any protective packaging that may be present around the instrument.
2. Before removing the battery pull-tab from the bottom of the instrument, connect the power supply to the instrument. See Figure 4.

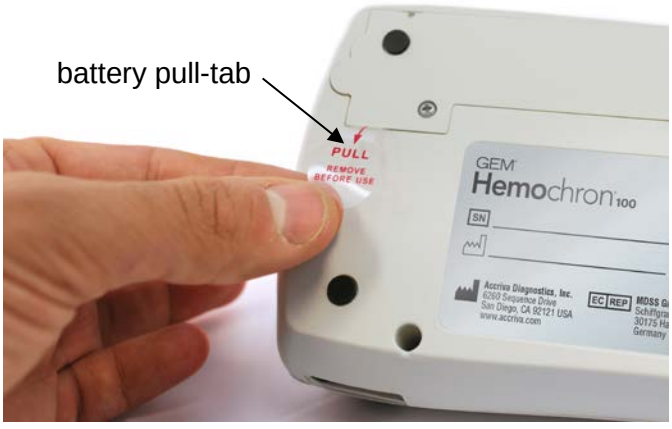


Figure 4 – Remove the battery pull-tab

3. Check the packaging to be sure the power supply, AC power cord, connecting cables, and other components have been removed. If a component is damaged, do not use the instrument. Contact a shipping representative immediately.

4 Check the package to ensure it contains all of the contents.

Instrument Power and Charging

Overview

Battery

The instrument is powered by a RoHS-compliant, lithium-ion (Li-ion) battery for mobile use. The battery is rechargeable.

When to Charge the Battery

Charge the battery under any of the following conditions:

- If the instrument is new
- If the instrument is used infrequently
- When the instrument displays a low-battery message

Before a test is run, the instrument automatically checks to ensure enough battery power is available. See *ESV Testing* on page 115 7.

Battery Usage Information Based on System Resource

The instrument records the percentage of battery power used based on the resource that used it. An example of a resource that uses battery power is the backlight system that illuminates the display screen. To view a list of resources and how they have used the battery power since it was last charged, see *View Battery Usage Information*.

Battery Life

Battery life cannot be estimated because it is greatly influenced by factors such as environmental temperature, depth of discharge before recharging, and usage pattern. Leaving the power supply connected to the instrument does not decrease battery life, but if the instrument is not used for weeks or months at a time, it is best to leave it disconnected from the power supply.

Disposing of the Battery

Dispose of the battery in accordance with local regulations for lithium-ion batteries.

Power Supply (Battery Charger)

To charge the battery, connect the power supply between an AC wall outlet and the instrument. See *Charge the Battery* on page 20. The power supply

converts AC power to DC power. The instrument can be used while the battery is being charged.

Important: The power supply has been selected specifically for use with the instrument. Use only the power supply that is authorized by Accriva Diagnostics. Do not use any other power supply.

Power Saving Features

The following features help save battery power:

- sleep mode (see *Sleep Mode* on page 22 2)
- automatic shutdown (see *Automatic Shutdown* on page 22)

Charge the Battery

Before using the instrument for the first time, charge the battery.

1. If a battery pull-tab is present on the bottom of the instrument, remove it. See Figure 4.
2. Connect the power supply cable to the instrument. See Figure 5.

Figure 5 -- Power supply port

NOTE The plug on the power supply cable can be inserted into the port on the instrument only one way.

3. Connect the power supply cable to a wall outlet.

The instrument can be used while it is being charged.

Power On the Instrument

To power on the instrument, press the power button. A beep is heard and the product logo is displayed within 5 seconds. See Figure 6.

Figure 6 – Power button

During power on, several product logos are displayed, and an electronic system verification (ESV) test runs. See *ESV Testing* on page 115 Chapter 7. When the Home screen is displayed, the instrument can be operated. See *Main Icons on the Home Screen*, Chapter 2.

Power Off the Instrument

To power off the instrument:

1. If the instrument is in sleep mode, touch the screen or press the power button to wake it.
2. Do either of the following:
   - Press and hold the power button until the confirmation dialog box is displayed. Confirm power off the instrument.
   - Press and hold the power button until the instrument is powered off.

Battery Charge Indicator

A battery charge indicator is always displayed at the top of the screen in the status bar.

Battery Indicator	Meaning
	Partially charged (percentage of remaining power is shown), power supply disconnected
	Fully discharged, power supply connected
	Partially charged, power supply connected
	Fully charged, power supply connected

Sleep Mode

If the instrument is on and has not been used for a specified period of time, it goes into sleep mode to save battery power.

NOTE Five minutes is the default period of time for sleep mode. Supervisors can specify a different length of time. See *Set the Sleep Mode Interval*, Chapter 3.

Supervisors and Operators can also manually put the instrument into sleep mode. While the instrument is in sleep mode, the screen is blank.

Put the Instrument into Sleep Mode

To put the instrument into sleep mode, press the power button. The screen goes blank.

Wake the Instrument from Sleep Mode

To wake the instrument from sleep mode, do either of the following:

- touch the screen
- press the power button

Automatic Shutdown

If the power supply is not connected to the instrument and if it is not used for one hour, it automatically shuts down. Unlike sleep mode, if the instrument automatically shuts down, it must be powered on (fully restarted).

One hour is the default length of time. Supervisors can specify a different length of time or specify that the instrument never shuts down. See *Set the Shutdown Interval* on page 38 3.

Main Icons on the Home Screen

Four main icons are on the Home screen:

Icon	Name	Meaning
	Patient Test	Test a patient sample. See *Chapter 6: Patient Testing*.
	Quality Control	Run tests to ensure the instrument is operating properly. See *Chapter 7: Quality Control*.
	Database	View saved test results. See *Chapter 8: Database*.
	Settings	Configure the instrument. See *Chapter 3: Instrument Settings*. To change more advanced settings on one or more instruments at the same time, see *Chapter 4: Configuration Manager*.

Touchscreen

Use the touchscreen (screen) to operate the instrument.

Selecting Items on the Screen

To select an item on the screen, tap it (touch it).

Figure 7 –Touch items on the screen

Scrolling the Screen

In some cases, the list of menu items is too long to fit on one screen. If a menu item is not visible, drag and swipe to scroll the screen.
See Figure 8.

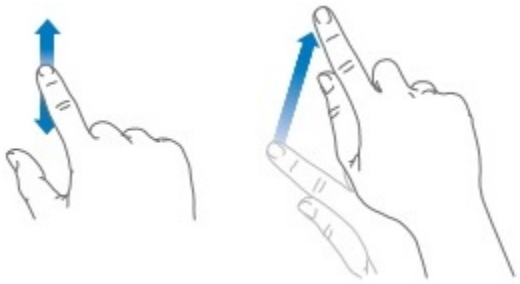


Figure 8 – Drag and swipe to scroll the screen

- To scroll slowly, **drag** the screen vertically
- To scroll quickly, **swipe** the screen vertically

Back, Home, and Rotate Screen icons

Back, Home, and Rotate Screen icons are always displayed at the bottom of the screen. See Figure 9.

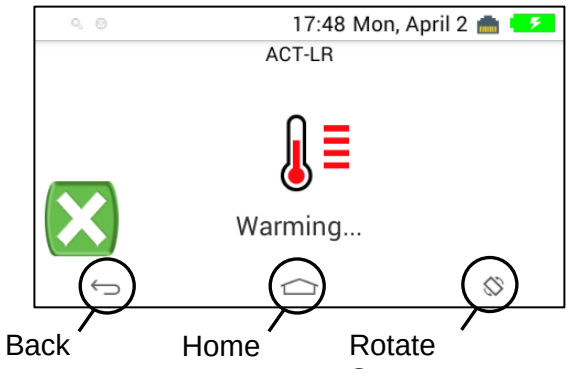


Figure 9 – Back, Home, and Rotate Screen icons

Rotating the screen 180 degrees allows Operators to operate the instrument with the cartridge slot positioned on either end of the instrument. This accommodates left-handed Operators and right-handed Operators.
See Figure 10.

Figure 10 – The Rotate Screen icon allows for instrument use with the cuvette slot on the left end or right end

Virtual Keyboard

To manually enter information into the instrument, use the virtual keyboard.
See *Using the Virtual Keyboard to Enter Information* on page 27 2.

Operator Roles and Permissions

There are two types of instrument operators that are distinguished by the complexity of the settings they are allowed to change:

- **Operators** can change basic settings
  - To see the settings that Operators can change, select > **User Settings**
  - For information about these settings and how to change them, see *Settings that Operators Can Change* on page 32
- **Supervisors** can change the same basic settings that Operators can change and can change advanced settings
  - To see the settings that Supervisors can change, select > **Supervisor Settings**
  - For information about these settings and how to change them, see *Settings that Supervisors Can Change* on Chapter 3.

Beep Volume

The instrument beeps under the following conditions:

- when an Operator powers on the instrument
- when an Operator selects an item on the screen
- at critical points during a test, such as when a test ends or an error message is displayed

To adjust the beep volume or turn off the beep:

1. Select > **User Settings**.
2. Move the volume slider horizontally to the desired level. To turn off the beep, move the slider to 0 (zero). When the beep is off, it will sound only when a few critical events occur, such as during testing.

Entering Information into the Instrument

Operators and Supervisors can enter information into the instrument using the virtual keyboard or by scanning a barcode.

Using the Virtual Keyboard to Enter Information

Use the virtual keyboard to manually enter text into text boxes. Examples of information that Operators can manually enter include operator ID (OID), patient ID (PID), passwords, and IP addresses.

- To display the virtual keyboard, touch a text box. For example, when the **Enter OID** dialog box is displayed, touch Enter OID. See Figure 11.

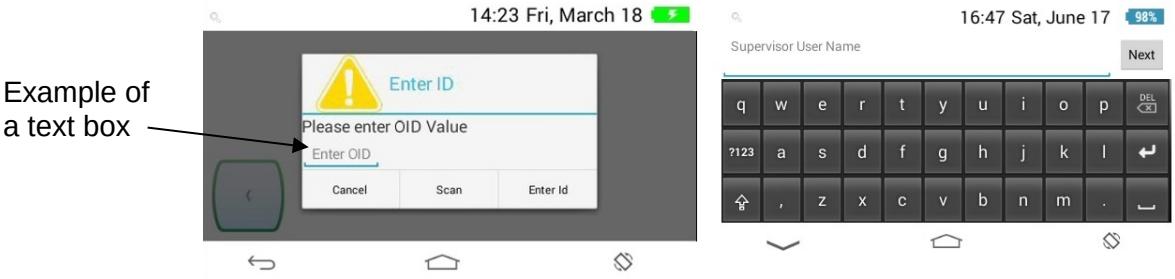


Figure 11 – To display the virtual keyboard, touch a text box

- To switch to the keyboard that contains numbers and symbols, select ?123. See Figure 12.

Figure 12 – The virtual keyboard that contains numbers and symbols

- To switch back to the keyboard that contains letters, select ABC.
- To enter upper case letters, select (Caps Lock).
- To enter a space, select the space bar.
- To backspace delete, select . This deletes the character to the left of the cursor.

- To move the cursor, touch the text in the text box to display the cursor and then move the cursor horizontally. See Figure 13.

Figure 13 – Cursor in a text box

Using the Barcode Scanner to Enter Information

Operators can use the barcode scanner to enter information into the instrument more quickly and accurately than by manually entering it. Operators can scan operator IDs (OIDs), patient IDs (PIDs), cartridge lot information, and LQC lot information.

If a Supervisor specifies that Operators are required to enter information, they can also specify that they are required to enter it using only the scanner.

NOTE The scanner does not read the barcode label on the cartridge. During testing, an internal scanner automatically reads the barcode label on the cartridge.

NOTE Do not point the scanner directly at anyone. The LED light from the scanner flashes brightly, which can be distracting.

When an Operator is required to enter information into the instrument (and if barcode scanning is allowed or required), a dialog box is displayed.

1. When the scanning dialog box is displayed, select **Scan** to activate the scanner light.
2. While the scanner light flashes, hold the instrument at a 90-degree angle to the barcode label. See Figure 14.

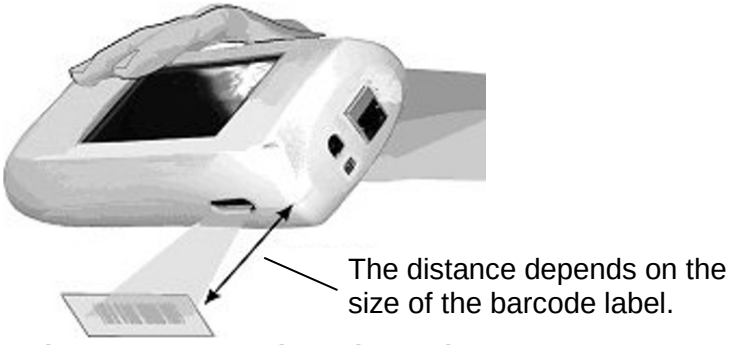


Figure 14 – Scanning a barcode

When the scanner reads the barcode, a beep sounds.

3. Verify that the information was entered into the dialog box.
4. Select **Done** to save the information or **Cancel** to exit without saving.

Login to the Factory Default Supervisor Account

Menu items under > **Supervisor Settings** are password-protected. A factory default Supervisor account is on the instrument:

- username: **supervisor** (with a lower case "**s**")
- password: **000**

NOTE A Supervisor should change the password for the factory default Supervisor account, record it, and then store it in a safe place. To change the password, use Configuration Manager. See *Chapter 4: Configuration Manager*.

To log in to the factory default Supervisor account:

1. Select > **Supervisor Settings**.
2. Select the **User Name** text box to display the virtual keyboard. See Figure 15.

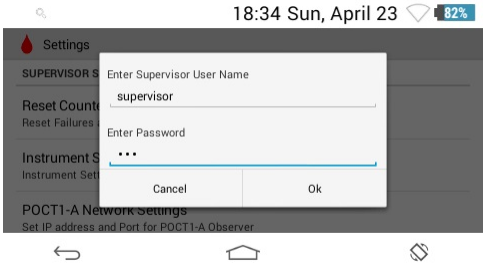


Figure 15 – Entering the factory default Supervisor password

For more information about the virtual keyboard, see *Virtual Keyboard* on page 25.

3. Enter *supervisor* (with a lower case "*s*") and select **Next**.
4. Select ?123 to display numbers and letters.
5. Enter *000* and select **Done**.
6. Select **Ok**.

Run a Demo Test

Operators can run a demo test that shows the sequence of steps in a patient test or LQC test. The demo test is not interactive. After the demo starts, simply watch it.

To run a demo test, select > **Demo**.

a) The demo prompts the Operator to insert a cartridge. (Do not insert a cartridge.) See Figure 16.

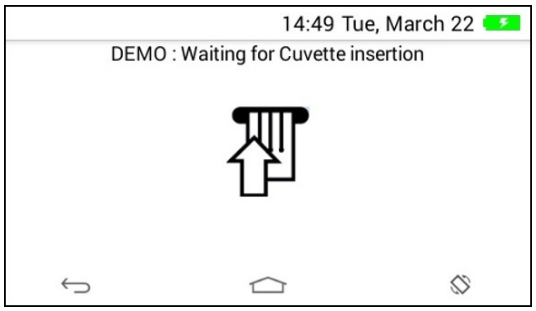


Figure 16 – Demo: Waiting for cuvette

b) The demo displays a thermometer icon that indicates that the cartridge is being warmed. See Figure 17.

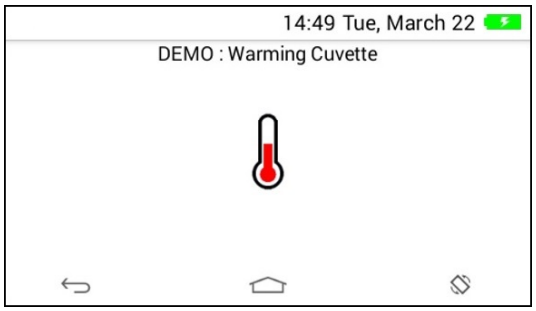


Figure 17 – Demo: Warming cuvette

c) The demo displays a blood drop icon that indicates the instrument is ready for the sample to be applied. See Figure 18.

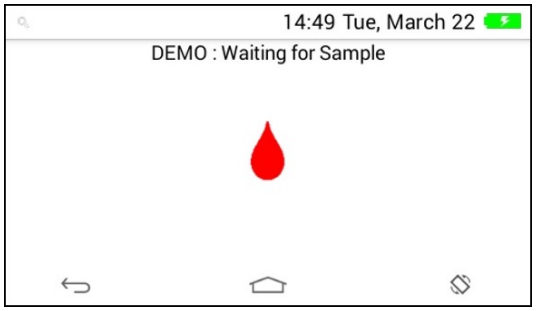


Figure 18 – Demo: Waiting for sample

d) The demo displays an animated icon that indicates the instrument is drawing the sample into the channels of the cartridge and is testing the sample. See Figure 19. At this point, the Operator would wait for the test results.

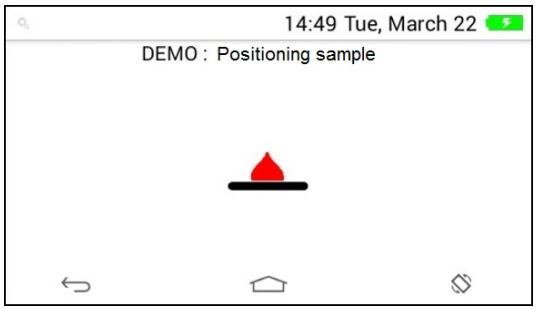


Figure 19 – Demo: Positioning sample

e) When clotting is detected, the test result is displayed as activated clotting time (ACT) in seconds. See Figure 20. At this point, the Operator could view more details about the test.

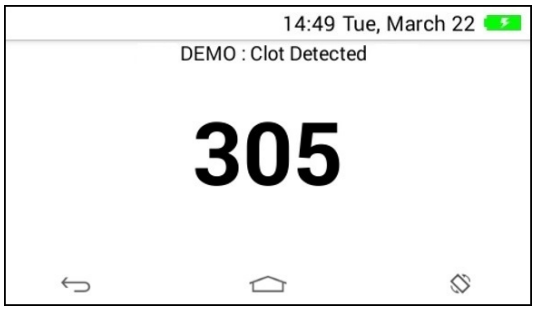


Figure 20 – Demo: Clot detected

This concludes the demo. For instructions on how to run a test, see the following:

- To run a patient test, see *Chapter 6: Patient Testing*
- To run a liquid quality control (LQC) test, see *Chapter 7: Quality Control*

Chapter 3: Instrument Settings

Operators and Supervisors can use the icon on the Home screen to do the following:

- **view read-only information** about the version of instrument hardware and software. Supervisors can also view information about battery usage (the amount of power that has been used by each resource).
- **change settings** to customize the instrument. Supervisors can make more advanced change than Operators can.

View Information about the Instrument

Choose the appropriate menu item to display read-only information about the instrument:

- **Operators:** Select > **User Settings** > **System Information**.
- **Supervisors:** Select > **Supervisor Settings** > **Instrument Settings** > **Instrument Information**. For information about battery usage, see *Battery Usage Information Based on System Resource* on page 19 2.

Settings that Operators Can Change

To see which settings Operators can change, select > **User Settings**. For more information about these settings, see *Table 5*.

Table 5 – Settings that Operators Can Change

Setting	Information
Display Brightness	Adjust the brightness of the display. See *Adjust the Display Brightness* on page 33 3.
Beep Volume	Adjust the beep volume. See *Adjust the Beep Volume* on page 33 3.
Font Size	Adjust the size of the display font. See *Adjust the Font Size* on page 33 3.
NOTE Supervisors also have access to these settings.	

Adjust the Display Brightness

1 Select > **User Settings**.

2 Drag the **Brightness** slider horizontally. See Figure 21.

Adjust the Beep Volume

3 Select > **User Settings**.

4 Drag the **Volume** slider horizontally. See Figure 21.

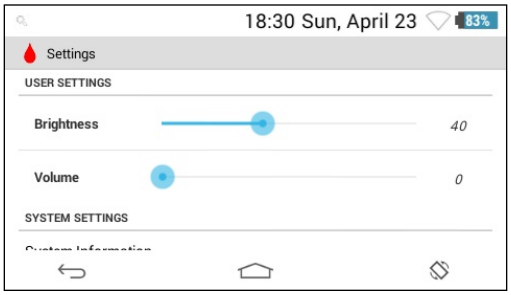


Figure 21 – Sliders for adjusting brightness and beep volume

Adjust the Font Size

1 Select > **User Settings** > **Font size**.

2 Select the preferred size (**Small, Normal**, **Large**, **Huge**). See Figure 22.

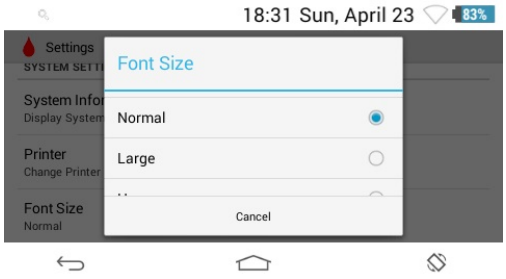


Figure 22 – Adjusting font size

Settings that Supervisors Can Change

NOTE Supervisors also have access to settings that Operators can change.

To see which settings Supervisors can change, select  > **Supervisor Settings**. For more information about these settings, see *Table 6*. Supervisors can also use Configuration Manager software to change many of these settings. Configuration Manager also allows Supervisors to make other more advanced changes. For more information, see *Chapter 4: Configuration Manager*.

Table 6 – Settings that Supervisors Can Change

Setting	More Information
Display Brightness	Adjust the brightness of the display. See *Adjust the Display Brightness* on Chapter 3.
Beep Volume	Adjust the beep volume. See *Adjust the Beep Volume* on page 33.
Font Size	Adjust the size of the display font. See *Adjust the Font Size* on page 33.
Display Language	English only
Date and Time	Set the date and time. See *Set the Date and Time* on page 36. Supervisors can choose whether to automatically get the date and time from the network. See *Enable the Date and Time to be Set Automatically* on page 38. **NOTE** To change the following settings, use Configuration Manager. See *Chapter 4: Configuration Manager*. • date format (MM/DD/YYYY, etc.) • time format (12-hour or 24-hour) • time zone
Sleep Mode Interval	Set the time that elapses before the instrument goes into sleep mode. See *Set the Sleep Mode Interval* on page 38.
Shutdown Interval	Set the time that elapses before the instrument automatically shuts down. See *Set the Shutdown Interval* on page 38.

Setting	More Information
OID Settings	For information about operator ID (OID) settings, see *Operator ID (OID) Settings* on page 40. • **Require entry/entry method/password** – Choose whether to require Operators to enter their OID, specify the method of entry (enter it manually or scan it), and choose whether to require them to enter a password. • **Allow OID reuse** – Allow Operators to reuse their OID (automatic reentry of an OID) and specify how long they can reuse it.
PID Settings	For information about patient ID (PID) settings, see *Patient ID (PID) Settings* on page 42. • **Require entry/entry method** – Choose whether to require Operators to enter a PID and specify the method of entry (enter it manually or scan it). • **Allow PID reuse** – Allow Operators to reuse a PID (automatic reentry of a PID) and specify how long they can reuse it.
Connectivity Settings	For more information, see *Connectivity Settings* on Chapter 3. • **Ethernet** – Connect the instrument to a network using an Ethernet cable. • **Wi-Fi** – Wirelessly connect the instrument to a network. • **POCT-1A** – Connect the instrument to a POCT-1A compliant network for use with middleware. • **CM Connection** – Set the IP address and port (for example, 50000) for connecting the instrument to the computer that Configuration Manager is installed on. Check with your institution's Network Administrator.
Auto Send	After a test, allow the instrument to automatically send the results to a network computer. See *Automatically Send Test Records to the Network (Auto Send)* on page 51.

Setting	More Information
Clear Test Records	Clear test records from the instrument database. See *Clear Test Records* on page 51.
Reset Counters	Reset the counters associated with quality control (QC). See *Reset Counters* on Chapter 3.
Test the Barcode Scanner	See *Test the Barcode Scanner* on page 52.

Factory Default Supervisor Account

When Supervisors select  > **Supervisor Settings**, they are required to log in to the instrument. A factory default Supervisor account is on the instrument. For more information about this account, see *Log In to the Factory Default Supervisor Account* on Chapter 2. Before anyone uses the instrument, a Supervisor should use Configuration Manager to change the password for this account.

Adjust the Font Size

1. Select  > **Supervisor Settings** > **Instrument Settings** > **Display** > **Font size**.
2. Select the font size (**Small, Normal**, **Large**, **Huge**).

   The font size is changed.

Set the Date and Time

The current date and time are always displayed in the status bar at the top of screen. For each test, the instrument records the date and time the test was run and displays it in the test record.

Supervisors can manually set the date and time or specify that the instrument automatically get the date and time from the network.

Manually Set the Date

1. Select  > **Supervisor Settings** > **Instrument Settings** > **Date and Time**.
2. If the box labeled **Automatic date & time** is checked, uncheck it.
3. Scroll the values for the month, day, and year.
4. Select **Done**.

To set the date format (MM-DD-YYYY, etc.), use Configuration Manager.

Manually Set the Time

1. Select > **Supervisor Settings** > **Instrument Settings** > **Date and Time**.
2. If the box labeled **Automatic date & time** is checked, uncheck it.
3. Scroll the values for the hour and minute.
4. Select **Done**.

Set the Format for the Date and Time

To set the date format (MM/DD/YYYY, etc.), use Configuration Manager.

To set the time format (12-hour time or 24-hour time), use Configuration Manager.

Set the Time Zone

To set the time zone, use Configuration Manager.

Enable the Date and Time to be Set Automatically

1. Select > **Supervisor Settings** > **Instrument Settings** > **Date and Time**.
2. Check the box labeled **Automatic date & time**.

   When the instrument is connected to the network, the date and time will automatically be synchronized with the date and time provided by the network.

   Supervisors can also use Configuration Manager to specify that the date and time be set automatically.

Adjust the Display Brightness

1. Select > **Supervisor Settings** > **Instrument Settings** > **Display** > **Brightness**.
2. Drag the **Brightness** slider horizontally.

Set the Sleep Mode Interval

When the instrument is on, if it is not used for a period time, it turns off the display. Supervisors can set the sleep mode interval. Select > **Supervisor Settings** > **Instrument Settings** > **Display** > **Sleep** and set the interval.

Set the Shutdown Interval

When the instrument is on, if it is not used for a period time and not connected to the power supply, it shuts down to save battery power.

Supervisors can set the shutdown interval. Select > **Supervisor Settings** > **Instrument Settings** > **Display** > **Shutdown** and select the interval.

To prevent the instrument from ever shutting down, select **Never** at the top of the list.

View Battery Usage Information

The instrument records the percentage of battery power used based on the resource that used it. An example of a resource that uses battery power is the backlight system that illuminates the display screen.

To view a list of resources that use battery power, choose  > **Supervisor Settings** > **Instrument Settings** > **Battery**.

Table 7 – Battery Usage Based on Resource

Resource	Information
<*time*> **on battery** (graph)	View the duration of time that the battery has been in use. To see details, select the graph.
Screen	View details about battery power used by the display. To save battery power, scroll down to Display and select it. The Display screen is displayed: • Select **Brightness** and decrease the display brightness. • Select **Sleep** and decrease the sleep mode interval time so the instrument goes to sleep sooner.
Wi-Fi	View details about battery power used by Wi-Fi. While Wi-Fi is on, the instrument periodically searches for a Wi-Fi signal. If Wi-Fi is not being used to connect the instrument to the network, turn off Wi-Fi to save battery power. As a convenience, while a Supervisor is viewing details about battery power used by Wi-Fi, they can scroll down to **Wi-Fi** and select it. This displays the screen where the Supervisor can turn off Wi-Fi. To turn off Wi-Fi, select  (this toggles the search to ).
Instrument idle	View details about battery power used while the instrument is idle
Android System	View details about battery power used by the Android system
Android OS	View details about battery power used by the Android operating system

Operator ID (OID) Settings

Supervisors can use the instrument menus to require Operators to enter their OID when they run tests. Supervisors can also require that only pre-registered OIDs are accepted. This requires that the OID first be registered (added to) Configuration Manager. Supervisors can also use Configuration Manager to require that Operators enter their password.

If an Operator enters their OID, it is recorded for the test result. If Operators are required to enter their OID, Supervisors can require them to scan it.

When Operators are required to scan their OID, the user is prompted to activate the scanner. For more information about using the scanner, see *Using the Barcode Scanner to Enter Information* on page 28

In addition to using the instrument menus to configure OID settings, Supervisors can also use Configuration Manager to configure these same settings and they can configure other more advanced OID settings.

Require Operators to Enter Their OID

Supervisors can require Operators to enter their OID when they run tests (patient tests and LQC tests).

1. Select  > **Supervisor Settings** > **OID Entry Preference**.

   A dialog box is displayed.

2. Select the appropriate option:

   - **Not Required** – Before Operators run a test, they are NOT required to enter their OID.
   - **Required (Scan or Manual Entry)** – Before Operators run a test, they are required to enter their OID. They can scan a compatible bar code or manually enter the OID.
   - **Scan Only** – Before Operators run a test, they are required to enter their OID by scanning a compatible bar code.

Specify the Method of Entry for an OID

When a Supervisor chooses whether or not to require Operators to enter their OID, they are also specifying the method the Operator is allowed to use to enter it. See *Require Operators to Enter Their OID* above.

Require Operators to Enter Their Password

If a Supervisor requires Operators to enter their OID, they can also require them to enter their password.

1 Select > **Supervisor Settings** > **OID Password Required**.

2 Select the appropriate option to enable or disable this feature:

- **OFF** = disabled
- **ON** = enabled (Operators must enter a password)

Reuse an OID (Automatic Entry of the Most Recent OID)

If a Supervisor requires Operators to enter their OID when they run a test, they can choose to have the instrument automatically enter the OID that was entered for the previous test. This is a convenience that keeps the Operator from having to manually reenter their OID when they run a series of tests. Instead, the Operator only needs to review the OID that was automatically entered and then accept it.

OID reuse can remain enabled for no less than 30 minutes and no more than 12 hours. The factory default duration is zero hours. This means OID reuse will not go into effect until the Supervisor specifies a duration other than 0 (zero). See *Specify How Long an OID can be Reused* on page 42.

NOTE If the instrument automatically shuts down or if an Operator manually shuts it down, the OID reuse duration is automatically reset to 0 (zero).

Allow OID Reuse During Patient Testing

1 Select > **Supervisor Settings** > **OID Reuse (During Patient Tests)**.

A dialog box is displayed.

2 Select the appropriate option to enable or disable OID reuse.

- **OFF** = disabled
- **ON** = enabled (the OID will automatically be entered into the dialog box)

NOTE OID reuse will not go into effect until the Supervisor specifies how long the feature is to remain enabled.

Allow OID Reuse During LQC Testing

1 Select > **Supervisor Settings** > **OID Reuse (During LQC Tests)**.

A dialog box is displayed.

2 Select the appropriate option to enable or disable OID reuse.

- **OFF** = disable
- **ON** = enabled (the OID will automatically be entered into the dialog box)

NOTE OID reuse will not go into effect until a Supervisor specifies how long the feature is to remain enabled.

Specify How Long an OID can be Reused

Before the OID reuse feature will go into effect, a Supervisor must specify how long Operators can reuse their OID.

1 Select > **Supervisor Settings** > **Operator ID Reuse Duration**.

2 Scroll the hours and minutes to select the duration. The minimum duration is 30 minutes; maximum duration is 12 hours.

NOTE After a period of instrument inactivity, the OID reuse duration is automatically reset to 0 (zero).

Patient ID (PID) Settings

Supervisors can require Operators to enter a PID when they run tests. If an Operator enters a PID, it is recorded for the test result. If Operators are required to enter a PID, Supervisors can require them to scan it. For more information about using the scanner, see *Using the Barcode Scanner to Enter Information* on page 28

Supervisors can use Configuration Manager to configure these same PID settings and they can use it to configure other more advanced PID settings.

Require Operators to Enter a PID

Supervisors can require Operators to enter a PID before they run a patient test.

1 Select > **Supervisor Settings** > **PID Entry Preference**.

A dialog box is displayed.

2 Select the appropriate option:

- **Not Required** – Before Operators run a patient test, they are NOT required to enter a PID/
- **Required (Barcode Scan or Manual Entry)** – Before Operators run a patient test, they are required to enter a PID. They can scan a compatible barcode or manually enter it.
- **Scan Only** – Before Operators run a patient test, they must enter a PID by scanning a compatible barcode.

Specify the Method of Entry for a PID

By choosing whether or not to require Operators to enter a PID, a Supervisor also specifies the method the Operator is allowed to use to enter the PID. See *Require Operators to Enter a PID* on page 42.

Reuse a PID (Automatic Entry of the Most Recent PID)

If a Supervisor requires an Operator to enter a PID when they run a patient test, they can choose to have the instrument automatically enter the PID that was entered for the previous test. This is a convenience that keeps the Operator from having to manually reenter the PID when they run a series of tests. Instead, the Operator only needs to review the PID that was automatically entered and then accept it.

PID reuse can remain enabled for no less than 30 minutes and no more than 240 hours. The factory default duration is 0 (zero) hours. PID reuse will not go into effect until a Supervisor specifies a duration other than 0 (zero). See *Specify How Long a PID can be Reused* on page 44

NOTE If the instrument automatically shuts down or if an Operator manually shuts it down, the PID reuse duration is automatically reset to 0 (zero).

Allow Reuse of a PID

1 Select  > **Supervisor Settings** > **PID Reuse (During Patient Test)**.

A dialog box is displayed.

2 Select the appropriate option to enable or disable PID reuse.

- **OFF** = disabled
- **ON** = enabled (the PID will automatically be entered into the dialog box)

NOTE OID reuse will not go into effect until a Supervisor specifies how long the feature needs to remain enabled.

Specify How Long a PID can be Reused

If a Supervisor allows Operators to reuse a PID, the Supervisor must also specify the length of time the PID can be reused. The minimum is 30 minutes. The maximum is 240 hours.

1. Select > **Supervisor Settings** > **Patient ID Reuse Duration**.
2. Scroll the hours and minutes to select the duration.

NOTE After a period of instrument inactivity, the PID reuse duration is automatically reset to 0 (zero).

Connectivity Settings

Supervisors can configure the instrument to be connected to a computer network or other device. See *Table 8*.

Table 8 – Connectivity Options

Connection Type	Description
Ethernet (wired network)	Use an Ethernet cable to connect the instrument to a local area network (LAN)
Wi-Fi (wireless network)	Use Wi-Fi to connect the instrument to a wireless local area network (WLAN)
POCT-1A	Using Ethernet or Wi-Fi, Supervisors can connect the instrument to a POCT-1A-compliant network for use with middleware. See *Chapter 5: Configure a POCT-1A Network*.

Connecting the Instrument to a Network

Supervisors can connect the instrument to a computer network for the following reasons:

- to more easily configure instrument settings on one or more instrument using Configuration Manager
- send records of test results from the instrument to a network computer

Connection Indicators

- If the instrument is connected to the network, the IP address is displayed. Otherwise, **IP Address: N/A** is displayed. See Figure 23.

Figure 23 – An IP address on the Home screen indicates a network connection

- An icon in the status bar indicates the type of connection. See Figure 24.

Figure 24 – Network Connection Icons: Ethernet and Wi-Fi

- If a Supervisor changes the connection type (Ethernet to Wi-Fi or Wi-Fi to Ethernet), the IP address changes.

Connect to a Wired Network (Ethernet)

NOTE If a Supervisor establishes an Ethernet connection while the instrument is wirelessly connected to the network, the wireless connection will be terminated and the IP address of the Ethernet connection will be displayed on the Home screen. The instrument defaults to the Ethernet connection because it is faster than Wi-Fi.

The IP address for the network connection can be static or dynamic:

- **dynamic IP address (DHCP)** – The network assigns an IP address to the instrument
- **static IP address** – A Supervisor assigns an IP address to the instrument

1. If a static IP address is being used, get the following information from your institution's Network Administrator:
   - IP address
   - Subnet mask
   - Gateway
   - DNS 1
   - DNS 2
2. Connect an Ethernet cable between a network access point and the Ethernet port on the instrument.
3. Select  > **Supervisor Settings** > **Instrument Settings** > **Ethernet** > **Mode**.
4. Select the appropriate mode:
   - **Disabled** – Select this if the instrument does not need to be connected to the network.
   - **DHCP** – Dynamic Host Configuration Protocol. Each time the instrument is connected to the network, the network automatically sets the IP address, subnet mask, and gateway.
   - **Static** – Selecting this requires that the IP address, subnet mask, and gateway be manually entered.

NOTE A firewall might prevent the instrument from being connected to the network. See *Chapter 9: Service, Maintenance, and Troubleshooting*.

Connect to a Visible Wireless Network

NOTE If the instrument is currently connected to the network through the Ethernet, it is not possible to establish a wireless connection. The instrument defaults to the Ethernet connection because it is faster than Wi-Fi. To establish a Wi-Fi connection, first disconnect the Ethernet cable or use the instrument menus to disable the Ethernet connection.

1. The wireless network might be protected by a password. If it is, get the password for it from a Network Administrator.
2. Select  > **Supervisor Settings** > **Instrument Settings** > **Wi-Fi**.
3. Is the desired wireless network on the list of available networks?
   - **No** – Go to the next step.
   - **Yes** – Go to step 5.
4. Search for wireless networks as follows:

   Look at the top of the screen to see if Wi-Fi is on:

   - If  is displayed, Wi-Fi is off. To turn it on, select  or the empty rectangle next to it.
   - If  is displayed, Wi-Fi is on. To refresh the search, select **SEARCH**.
5. In the list of available wireless networks, select the one chosen for connection.

   A dialogue box for the wireless network is displayed. Signal strength and security protocol are also displayed.

   If the wireless network is protected by a password, scroll to the **Password** field, enter the password, and select **Done**.
6. (Optional) For advanced settings, check the box labeled **Show advanced options** and configure these settings.
7. Select **Connect**.

   If the network connection is established, the word **Connected** is displayed below the network name in the list of wireless networks.

NOTE A firewall might prevent the instrument from being connected to the network. See *Chapter 9: Service, Maintenance, and Troubleshooting*.

Connect to a Hidden Wireless Network

NOTE If the instrument is currently connected to the network through the Ethernet, it is not possible to establish a wireless connection. The instrument defaults to the Ethernet connection because it is a faster than Wi-Fi. To establish a Wi-Fi connection, first disconnect the Ethernet cable or use the instrument menus to disable the Ethernet connection.

Supervisors can “join” a closed wireless network. A closed wireless network is one that cannot be found when the instrument searches for available networks. To add a network to the list of available networks:

1. Select .

   The **Add network** dialog box is displayed.

2. Scroll down to the following fields and enter the information or select the appropriate setting from the drop-down list:
   - **Network SSID**
   - **Security** (select **None**, or **WPA/WPA2 PSK**), WEP is not recommended.
3. (Optional) For advanced settings, check the box labeled **Show advanced options** and configure these settings.
4. Select **Connect**.

   If the network connection is established, the word **Connected** is displayed in the list of wireless networks, below the network name.

NOTE A firewall might prevent the instrument from being connected to the network. See *Chapter 9: Service, Maintenance, and Troubleshooting*.

Disconnect from a Wireless Network

To disconnect from a wireless network:

1. Select the network to be disconnected from by tapping the network name.

   A dialog box for the wireless network is displayed.

2. Select **Forget**.

   The instrument is disconnected from the wireless network and the network is removed from the list of available networks.

Check the Quality of a Wireless Signal

To check the quality of a wireless signal, select > **Wi-Fi Signal Quality**.

NOTE Signal Quality is the Wi-Fi RSSI. It is also displayed while the details for a given wireless network are showed under > **Supervisor Settings** > **Instrument Settings** > **Wi-Fi**. The indicator is a relative indication See Figure 25

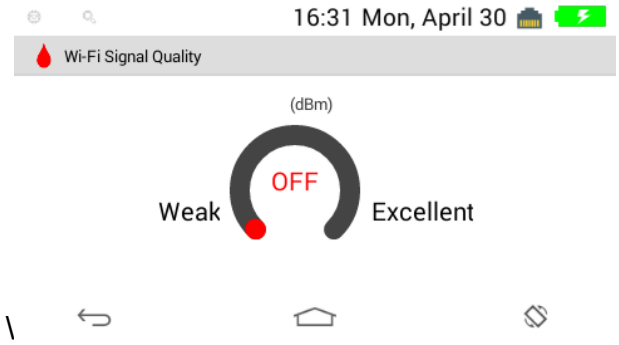


Figure 25 - Wi-Fi Signal Quality (Wi-Fi RSSI)

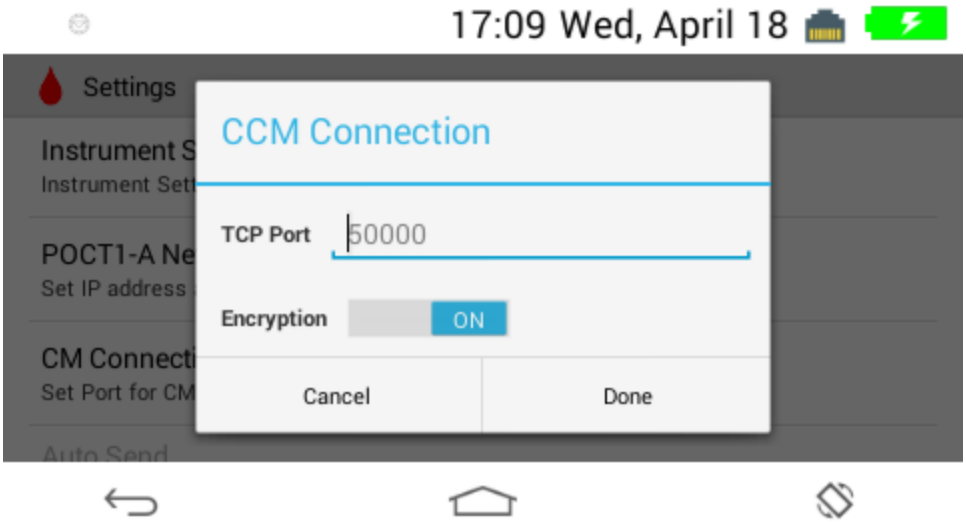
Configure a POCT-1A Network

Supervisors can configure a POCT-1A network for use with middleware. See *Chapter 5: Configure a POCT-1A Network*.

Set the Port Number and the encryption mode for Configuration Manager

Configuration Manager can send a POKE message to instruments to indicate that it is ready to communicate with them. The POKE message contains the remote poke port number.

1. Select > **Supervisor Settings** > **CM Connection Settings**.
2. In the dialog box, enter an unused port number such as *50000*. Check with a Network Administrator.
3. Select **Done**.
4. Select **Done** again.



NOTE In Configuration Manager, set the port number for the **Remote Poke Port** field so that it matches the port number that was entered above. For more information, see *Chapter 4: Configuration Manager*.

NOTE Verify that the encryption setting matches with the encryption setting on Configuration Manager.

For more information, see *Chapter 4: Configuration Manager.*

Automatically Send Test Records to the Network (Auto Send)

Supervisors can enable the Auto Send feature that automatically sends a test result to a computer on the network when an Operator removes a cartridge after a test.

NOTE If the instrument is not connected to the network, test results will not be sent. To connect the instrument to the network, see *Connecting the Instrument to a Network*.

When the instrument sends test results, the message **Sending Records** (and the percentage of completion) is displayed. After the results have been sent, the message **Send Records Complete** is displayed for a moment.

When viewing test results in the Database, Operators and Supervisors can manually send test records to a network computer using the **Send All** command. See *Chapter 8: Database*.

To configure Auto Send, select  > **Supervisor Settings** > **Auto Send**.

- **ON** = enabled (test results will automatically be sent to the network)
- **OFF** = disabled (test results will NOT be sent, but Operators can still manually send test results to the network using the **Send All** command)

Clear Test Records

A maximum of 100,000 test records can be stored in the instrument database. Supervisors can clear (delete) records to make room for new records.

Caution: Deleted records cannot be recovered.

If the database is full and an Operator runs a test, the oldest test record is overwritten. Periodically clear the database by doing the following:

1. (Optional) Back up the records that need to be deleted by doing either of the following:
   - send the records to a network computer. See *Chapter 8: Database*.
2. Clear the records.

In order to erase Database records (patient,EQC and LQC tests) two steps are required: First: Enable the option to erase Database in the Configuration Manager, *see Chapter 4: Configuration Manager, Table 12*. Second: follow the following indications

Clear All Test Records

1. Select > **Supervisor Settings** > **Clear All Test Records**.
2. Select **Delete All**.

   All records are deleted.

Clear Patient Test Records

1. Select > **Supervisor Settings** > **Clear All Patient Test Records**.
2. Select **Delete All**.

   All patient test records are deleted.

Reset Counters

Supervisors can reset the counters associated with quality control. For more information about counters, see *Chapter 4: Configuration Manager* and *Chapter 7: Quality Control*.

1. Select > **Supervisor Settings** > **Reset Counters**.
2. Check the box for each counter that needs to be reset.
3. Select **Reset**.

   The counters are reset.

Test the Barcode Scanner

Supervisors can test the barcode scanner.

1. Select > **Supervisor Settings** > **Barcode Scanner Test**.

   A dialog box for testing the barcode scanner is displayed.
2. Select **Scan** and then scan the barcode.

   The scanned information is displayed in the dialog box.
3. Compare the displayed information to the human-readable information on the barcode label.
   - If the information matches, the scanner is working.
   - If the information does not match, contact Instrumentation Laboratory Technical Support.
4. Select **Return** to return to the **Supervisor Settings** menu.

For more information about scanning barcodes, see *Using the Barcode Scanner to Enter Information* on page 28.

Chapter 4: Configuration Manager

Installing, Updating, and Uninstalling

Minimum System Requirements

Operating system	Microsoft Windows 7,8 or 10 with latest Service Pack installed
CPU	Intel Core i3 2.5 GHz
RAM	4 GB
Available disk space	100 MB

Install Configuration Manager

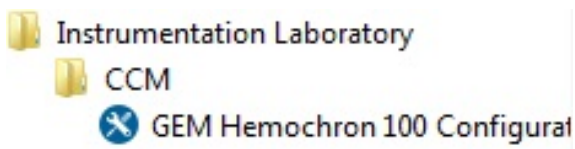
The installer file for Configuration Manager is on the DVD or USB drive from Accriva Diagnostics:

```
setup.exe
```

NOTE To install Configuration Manager, Windows Administrator privileges are required.

1. Copy the Configuration Manager Installation folder to the computer that Configuration Manager is being installed on.
2. Double-click the installer file setup.exe.

   The Setup Wizard is displayed.
3. Click **Run**.
4. Click **Next** several times until the installer starts.
5. When installation is complete, click **Close**.
6. Click the Windows Start button  . The Configuration Manager application shortcut is available in the Start menu under **Instrumentation Laboratory** > **CCM**:



NOTE Before using Configuration Manager, configure Windows Firewall. See *Configure Firewalls* on page 54.

Configure Firewalls

Before using Configuration Manager, configure all firewalls so they will not prevent the instrument from communicating over the network with the computer that Configuration Manager is running on. See Table 9.

Table 9 – Protocols and Ports for Configuring Firewalls

Protocol	Port
Outbound (from PC to instrument)	
TCP	50000
UDP	5353
IGMP	N/A
Inbound (from instrument to PC)	
TCP	50001
UDP	5353
FTP (data)	20
FTP (command)	21

NOTE Ports shown in Table 9 need to be enabled to allow CCM to run.

Update Configuration Manager

If a new version of Configuration Manager is released, install it over the existing version. Do not uninstall the previous version.

Account information for users of Configuration Manager (Admins and Supervisors) is retained on the system in an encrypted file. The new version of the application will recognize these accounts.

NOTE To update Configuration Manager, Windows Administrator privileges are required.

Uninstall Configuration Manager

To uninstall Configuration Manager:

1. Open Windows Control Panel.
2. Choose **Programs** (or **Programs and Features**) > **Uninstall a program**.
3. In the list of installed programs, select **CCM**.
4. Click **Uninstall**.

CAUTION When the application is uninstalled, some files remain on the system in one or more of the following folders:

C:\ProgramData\InstrumentationLaboratory\CCM\

C:\Users\All Users\InstrumentationLaboratory\CCM

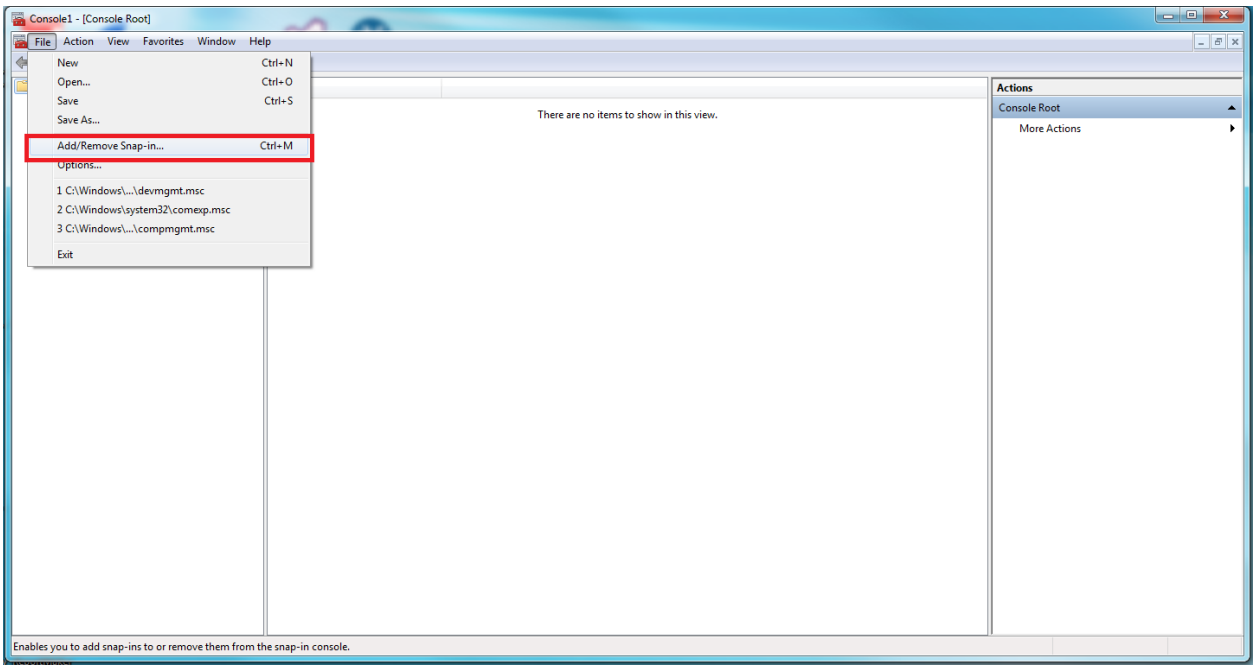
C:\Users\<username>\AppData\Local\Instrumentation_Laborator

The files in these folders contains configuration data and encrypted user account information for application users (Admins and Supervisors). If the application is going to be reinstalled and the user accounts might be needed in the future, do NOT delete this file from either folder. Otherwise, these folders can be deleted.

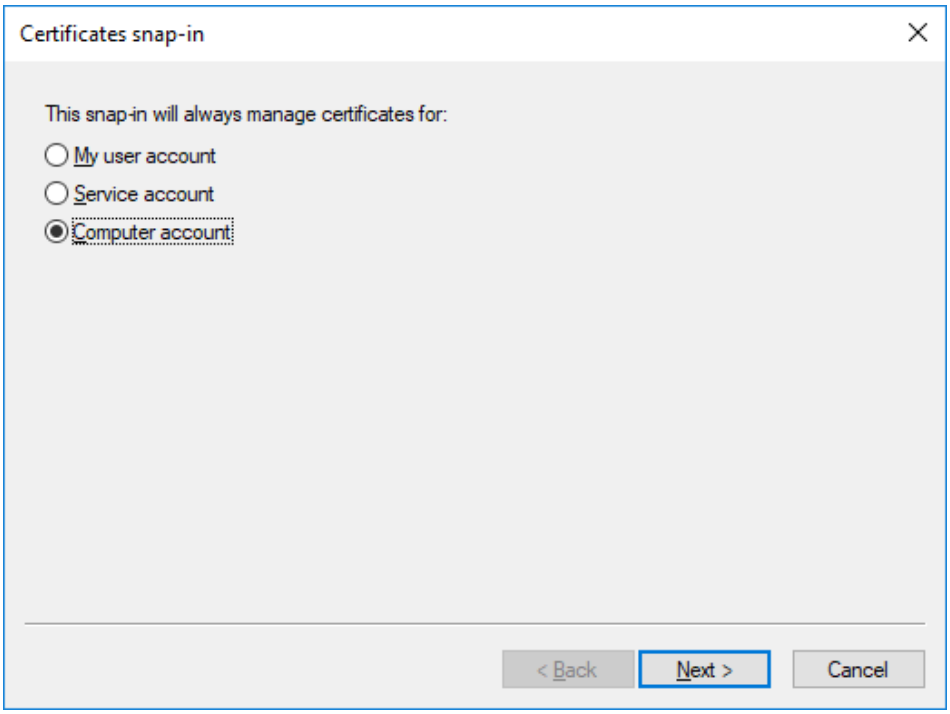
Install Encryption Certificate

To use encryption during POCT1A communication a trusted certificate must be installed on the PC.

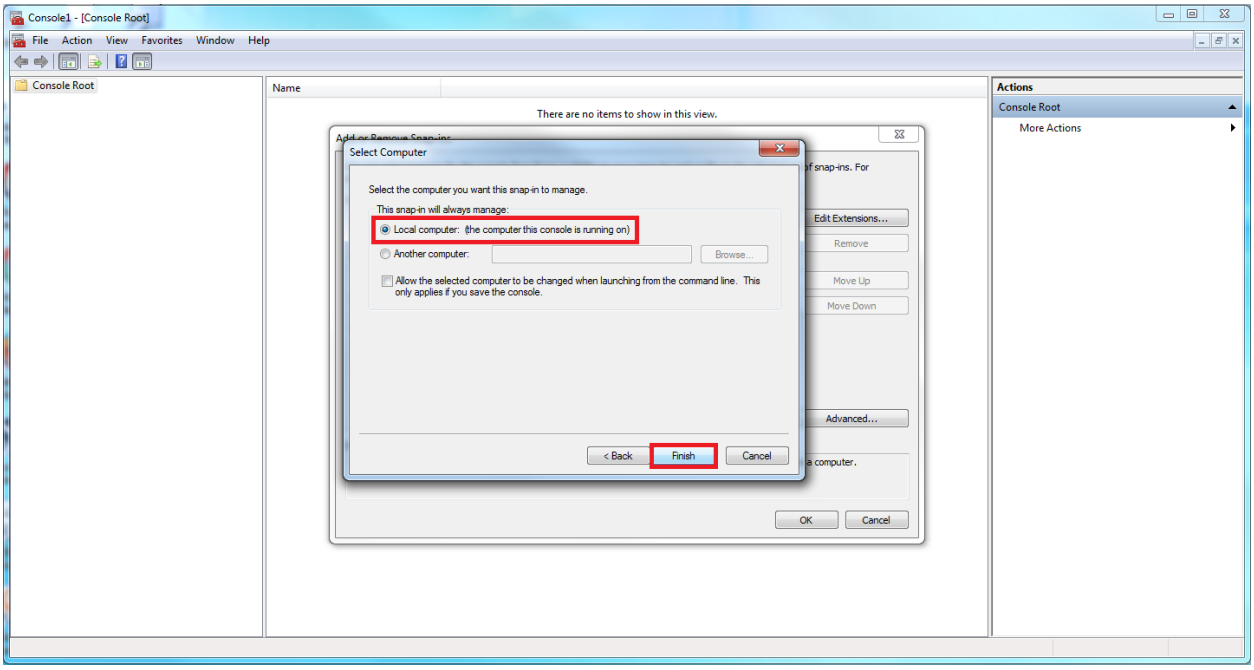
1. Log in as Administrator to the PC running Configuration manager.
2. Create directory for example c:\certificates and copy the certificate provided by Instrumentation laboratory/Accriva Diagnostics to it.
3. Run mmc.exe (this program is available on Windows Machine)
4. Select File, then Add/Remove Snap-in



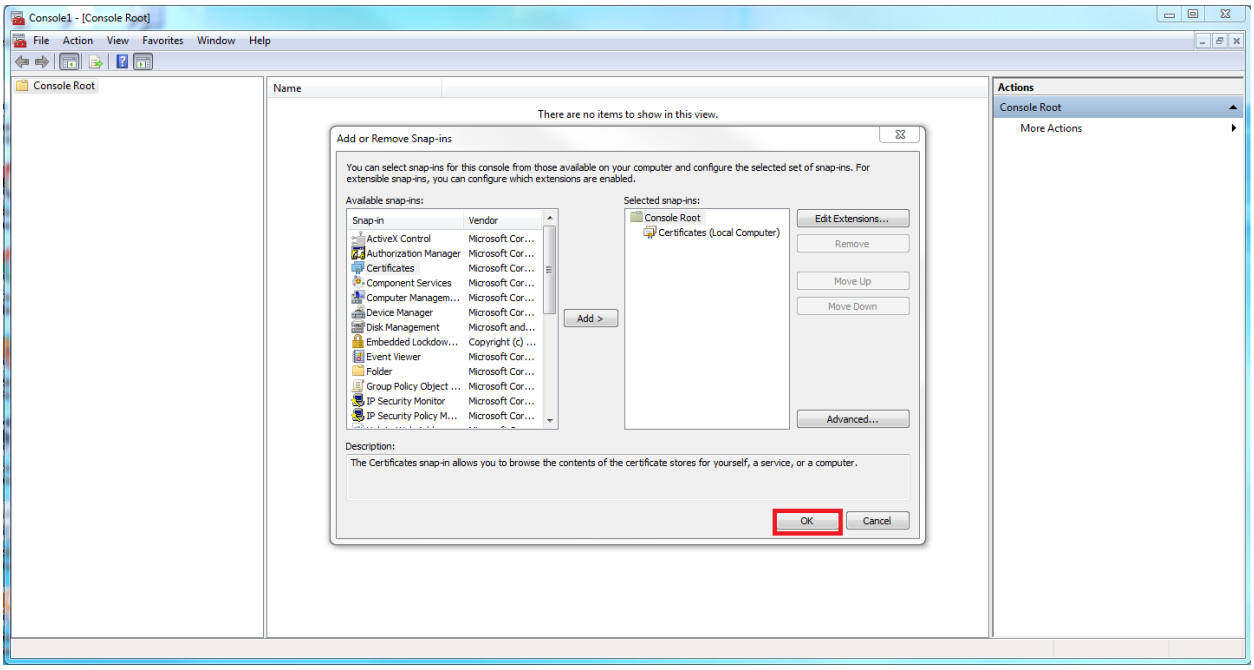
5. Select Computer Account



6. Select Local Computer and then Finish

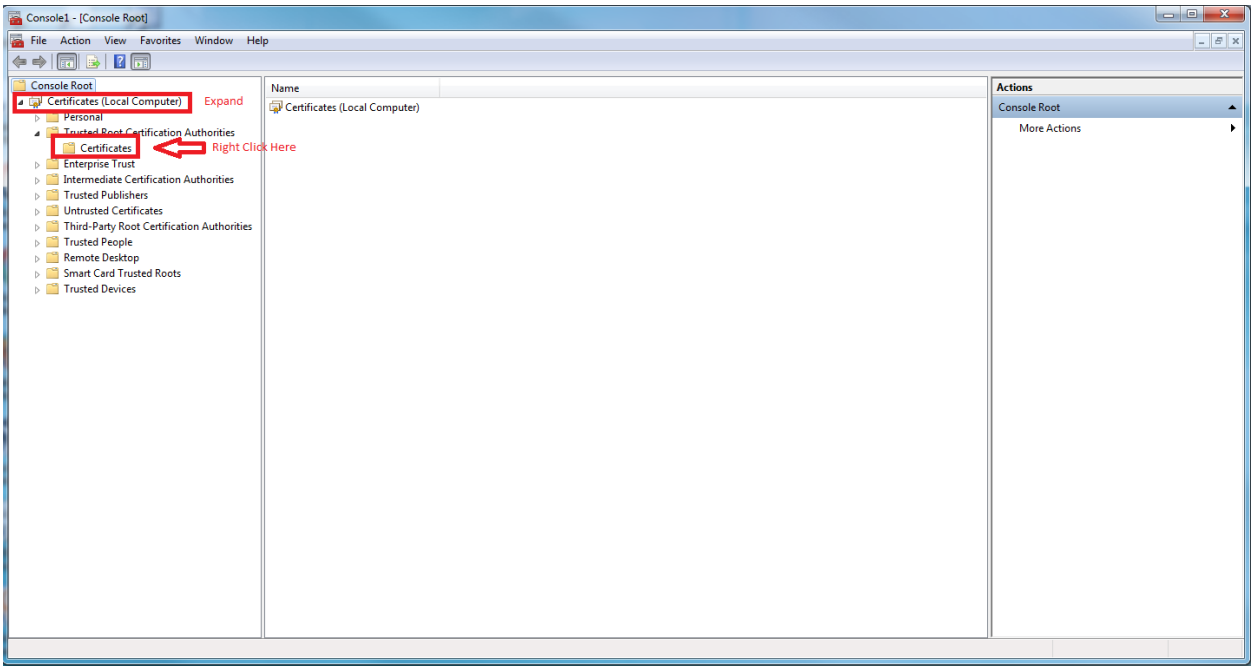


7. Select OK

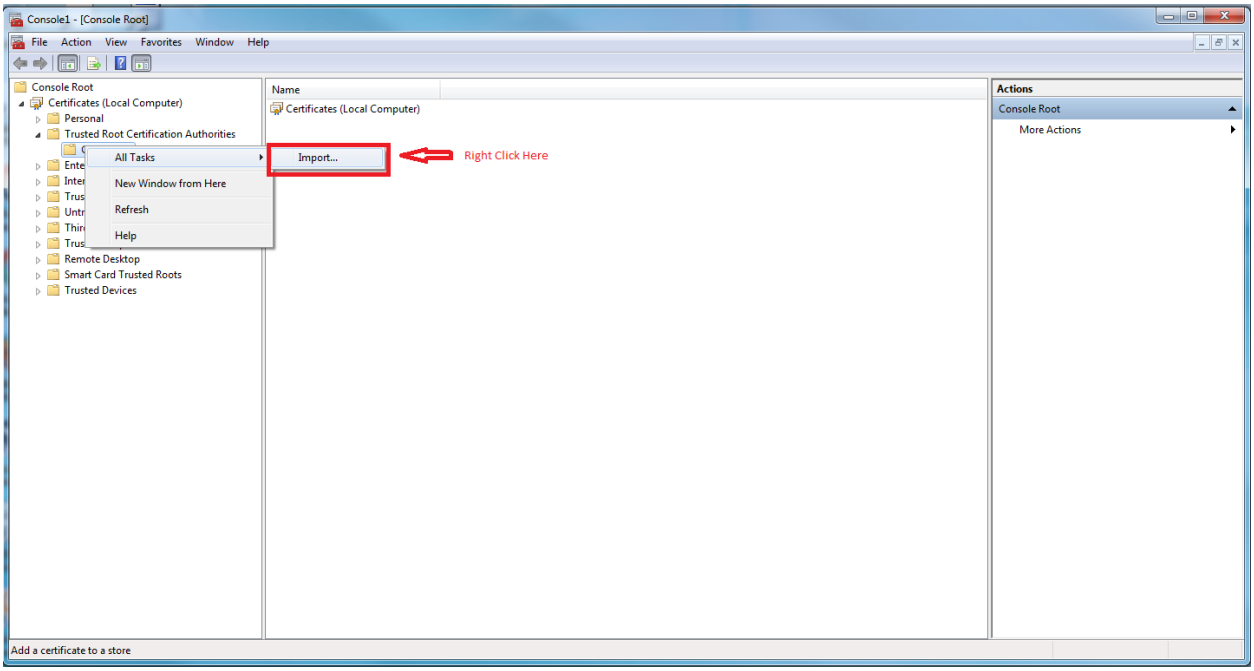


8. Expand Certificates

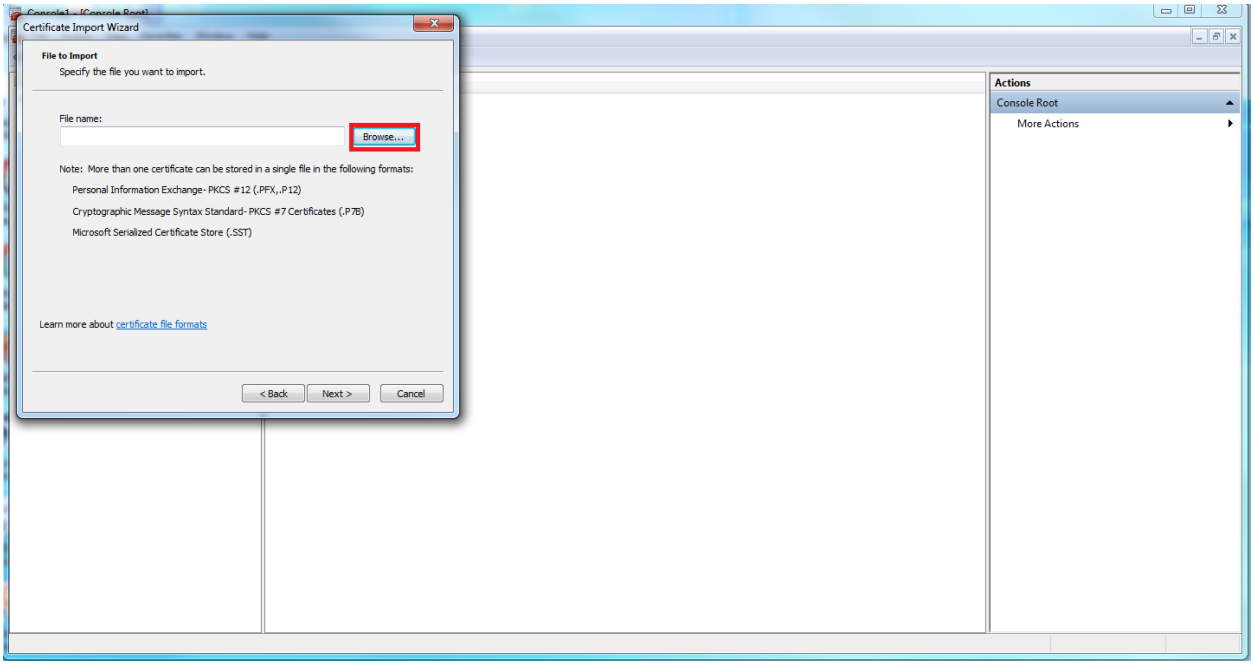
9. Expand Trusted Root Certification Authorities



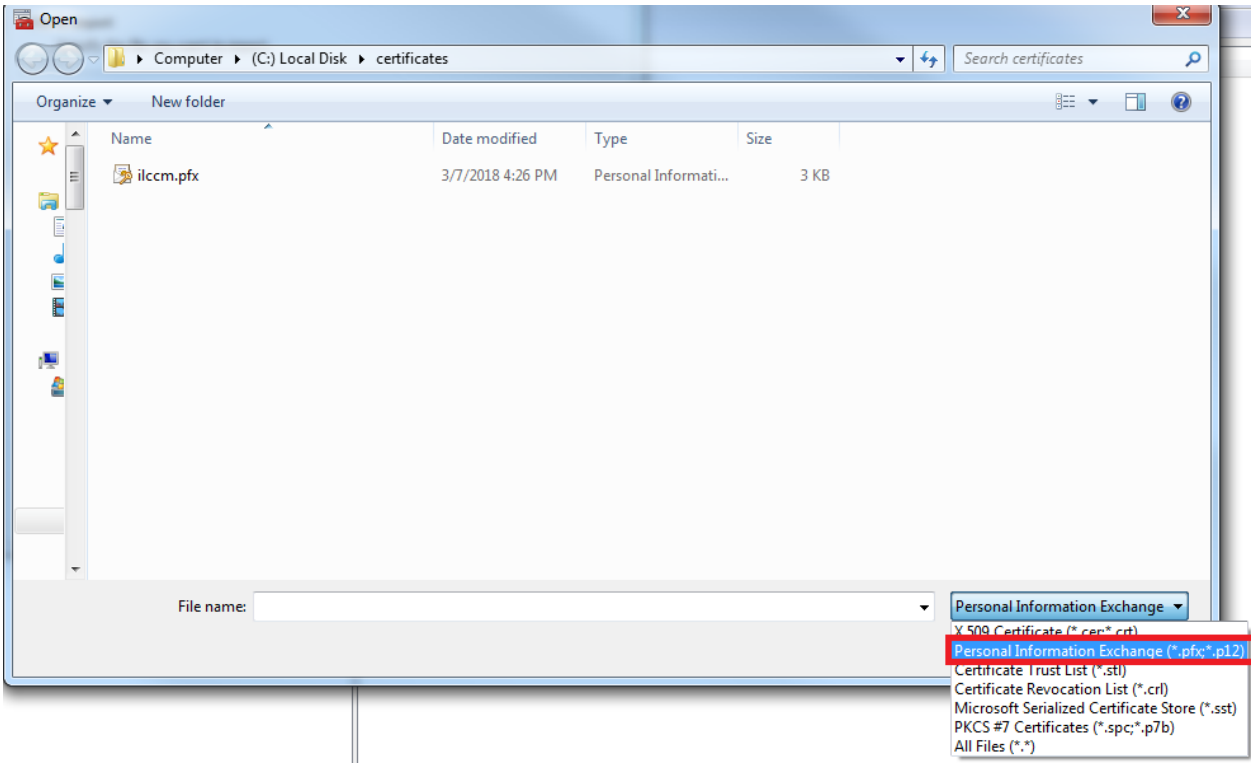
10. Right Click on . Trusted Root Certification Authorities-→Certificates
11. Right Click on Certificates -> All Tasks -> Import



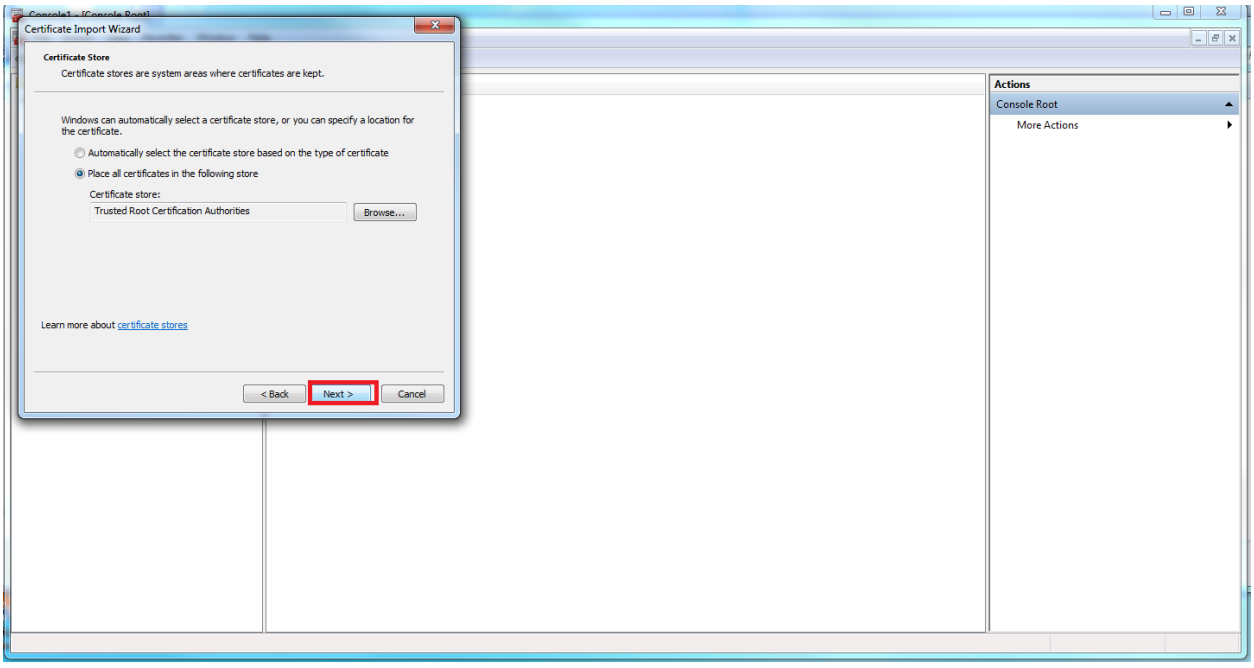
12. Click Next
13. Browse to the file location where you have saved the certificate provided by Instrumentation Laboratory/Accriva Diagnostics. For example if you have saved ilccm.pfx provided by Instrumentation Laboratory in C:\Certificates, then browse to C:\Certificates.Browse to c:\Certificates



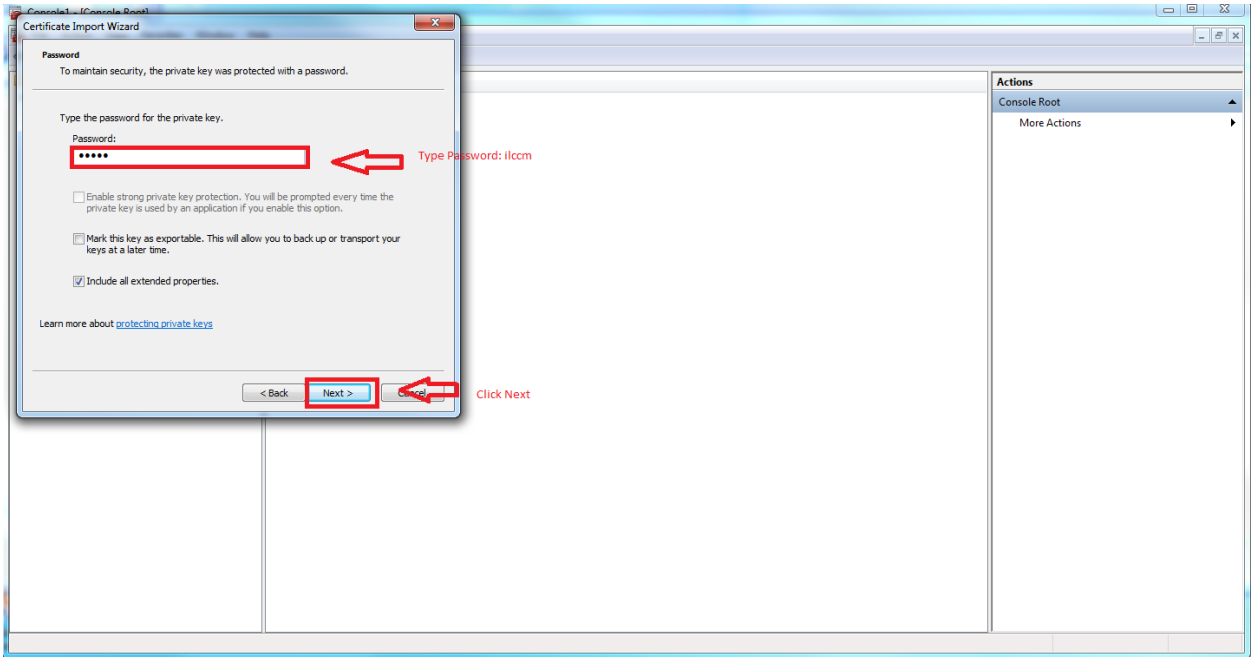
14. Select Personal Information Exchange (*.pfx;*.p12)



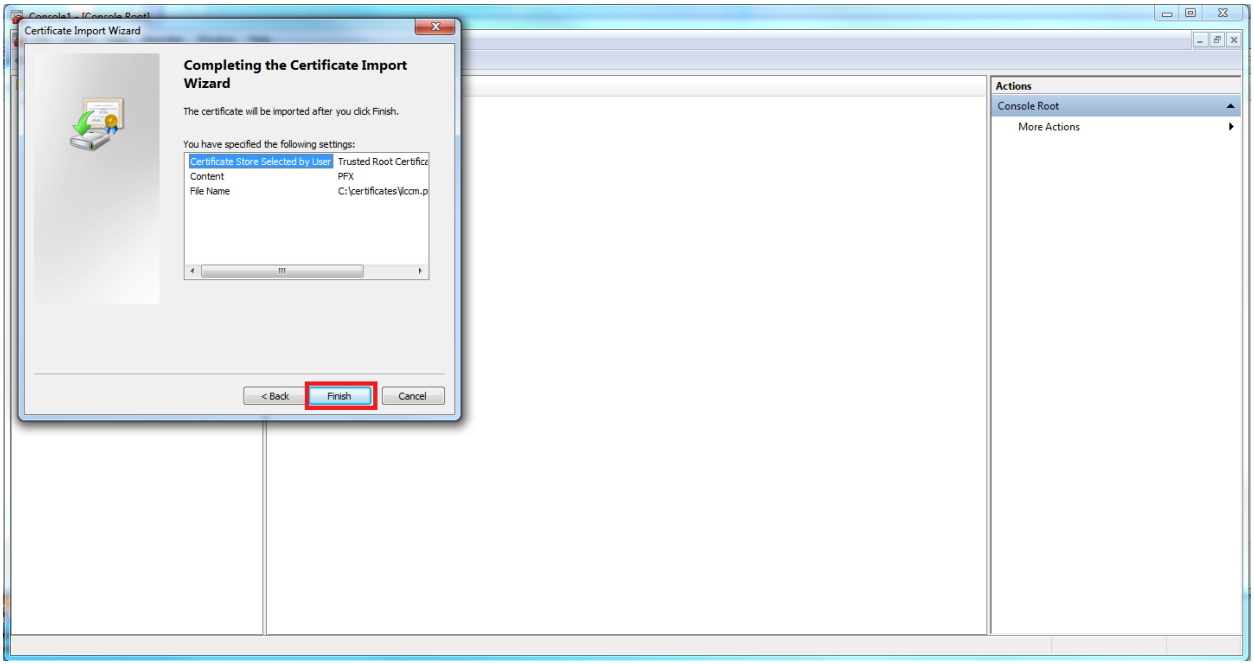
15. Select ilccm.pfx
16. Select Open
17. Select Next



18. Enter Password: ilccm



19. Click Next twice
20. Select Finish



Introduction

Purpose of Configuration Manager

Configuration Manager for GEM® Hemochron™ 100 (Configuration Manager) is PC-based software that Supervisors use to configure instruments.

Supervisors can use the instrument menus to change a limited number of configuration settings. Configuration Manager allows them to change advanced settings and send the settings over the network to more than one instrument at the same time.

Configuration Manager also allows Supervisors to:

- **Reuse configuration data** – After configuration data is created, Supervisors can export it to a file for reuse.
- **Generate a report** – Supervisors can generate a report that contains all of the configuration data associated with one or more instruments. Reports can be saved as a comma-separated value (.csv) file and opened it in a spreadsheet.
- **Update the instrument software** – Use Configuration Manager to install a new version of instrument software (firmware). The software on more than one instrument can be updated at the same time.

Main Parts of Configuration Manager

The Configuration Manager application consists of two main parts:

- Administrative Settings
- Configuration Settings

Users log into each part of the application separately. Before users can leave one part of the application and go to the other, they must log out of the part they are logged in to.

Administrative Settings

Configuration Manager Administrators (Admins) use this part of the application to create accounts for other Admins and Configuration Manager Supervisors. Only Admins can log in to this part of the application; Supervisors cannot log in to it.

Configuration Settings

This part of the application is where Supervisors configure instruments. Only Supervisors can log in to this part; Admins cannot log in to it.

System User Accounts

Four types of accounts are associated with the *GEM® Hemochron™ 100* System. Two accounts are for the Configuration Manager software application and two accounts are for instruments:

- Configuration Manager accounts
  - Administrator accounts
  - Supervisor accounts
- Instrument accounts
  - Instrument Supervisor accounts
  - Instrument Operator accounts

NOTE The account for a Configuration Manager Supervisor is distinct from the account for an instrument Supervisor.

Configuration Manager accounts

Configuration Manager Admin Accounts

Admins use the Administrative Settings part of the software to perform the following tasks:

- create, edit, and delete accounts for other Admins
- create, edit, and delete accounts for Configuration Manager Supervisors

A factory default Admin account exists in Configuration Manager:

username	*admin*
password	*000*

The first person who uses the software must log in using the factory default Admin account. When they do, they will be prompted to change the password. They should change it, record it, and store it in a safe place. That person can then create other Admin accounts.

Admin account information is stored in an encrypted file on the computer that Configuration Manager is installed on. When the software is upgraded, this file remains on the system so that these accounts do not need to be recreated. Therefore, the admin default password will not change unless the operator changes it.

Configuration Manager Supervisor Accounts

A factory default account for a Configuration Manager Supervisor does not exist in the software. An Admin must log in to the Administrative Settings part of the software and create a Configuration Manager Supervisor account. After they do, a Configuration Manager Supervisor can log in to the Configuration Settings part of the software.

Account information for Configuration Manager Supervisors is stored in an encrypted file on the computer that Configuration Manager is installed on. When the software is upgraded, this file remains on the system so that these accounts do not have to be recreated.

Instrument Accounts

In Configuration Manager, Supervisors create accounts for instrument Supervisors and instrument Operators and send those accounts to instruments as configuration data.

Instrument Supervisor Accounts

Configuration Manager Supervisors use the Configuration Settings part of the software to do the following:

- create accounts for instrument Supervisors and Operators and send those accounts to instruments
- configure instrument settings and send those settings to instruments

A factory default Supervisor account exists on the instrument:

username	**supervisor**
password	**000**

Use Configuration Manager to change the password for this account, record it, and store it in a safe place.

Supervisors can perform advanced functions on an instrument, such as configure the instrument and clear instrument lockout. This requires that they log in at the instrument.

Instrument Operator Accounts

Instrument Operators (“Operators”) perform the following tasks:

- operate instruments
- use the instrument menu to change basic settings (the changing of advanced settings is reserved for Supervisors)

NOTE A configuration manager supervisor or instrument supervisor can configure an instrument so Operators are not required to enter their operator ID (OID) or password to operate it. If an instrument is configured this way, anyone can operate it.

Overview of the User Interface

The Login Screen

When users start Configuration Manager, the Login screen is displayed. See Figure 26. Users can log in as an Admin or as a Supervisor.

- **Admin** – If a user logs in as an Admin, a screen for the Administrative Settings part of the application is displayed. See Figure 27. The first user who logs in to Configuration Manager must log in as an Admin using the factory default Admin account (*admin*/*000*). When they log in, they are prompted to change the password.
- **Supervisor** – If a user logs in as a Supervisor, a screen for the Configuration Settings part of the application is displayed. See Figure 28. Before a user can log in as a Supervisor, an Admin must create a Configuration Manager Supervisor account for them.

Figure 25 – The Configuration Manager log in screen

Administrative Settings

When a user logs in to Configuration Manager as an Admin, the **Administrative Settings** screen is displayed. See Figure 27.

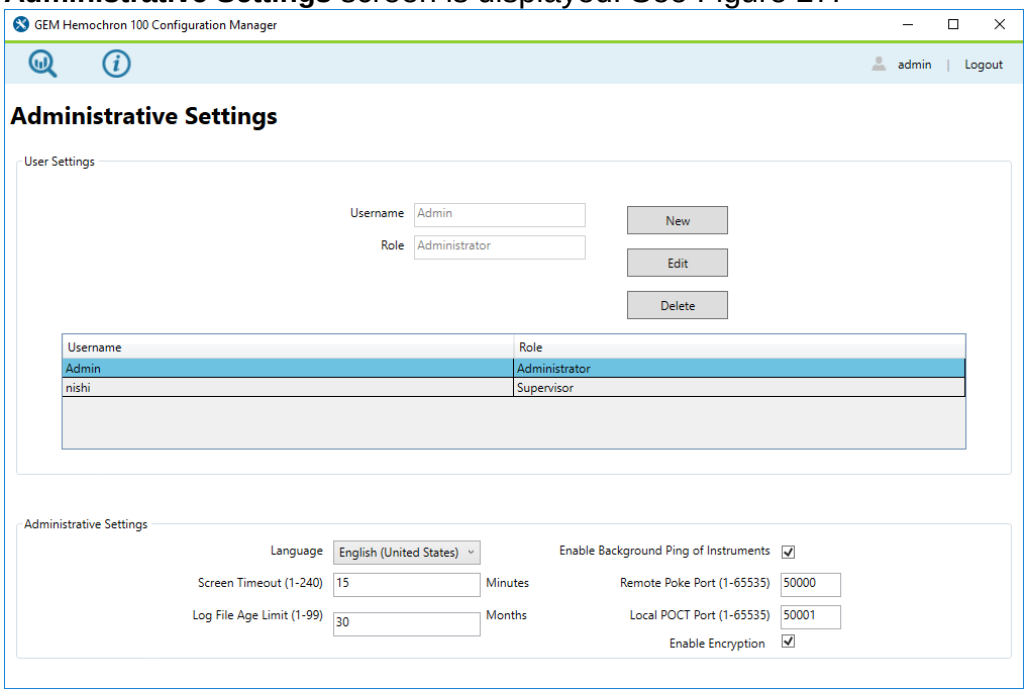
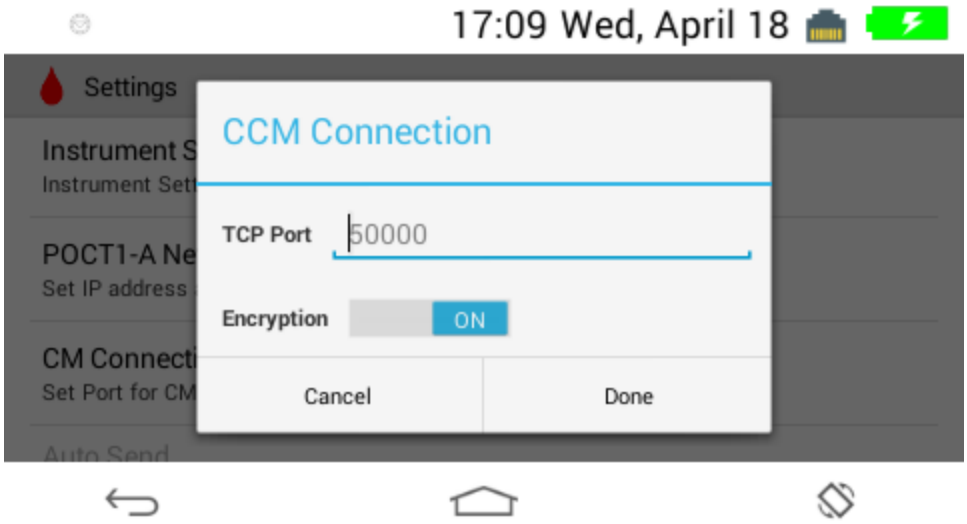


Figure 26 – Configuration Manager: The Administrative Settings screen

Admins use this part of the software to do the following:

- create accounts
  - create other Admin accounts
  - create Supervisor accounts
- set the display language for the Configuration Manager user interface (the language must match the display language of the instrument and the operating system).
- set screen timeout. This is the number of minutes of inactivity before the software locks the screen and requires the user to log in. During screen timeout, configuration data remains in session memory. It is not lost.
- Set the age limit of the audit log file. Every month a new log file will be created. This log file will be kept on the PC for the number of months specified in the log file age limit.
- Enable encryption of POCT01-A data in transit. By default, the encryption is enabled to allow secure communication. This setting needs to match the encryption setting for CCM on the device. See below



- Figure XX - configure settings that affect how Configuration Manager connects to the network and instruments

Configuration Settings

When a user logs in to Configuration Manager as a Supervisor, the Configuration Settings screen is displayed. See Figure 28.

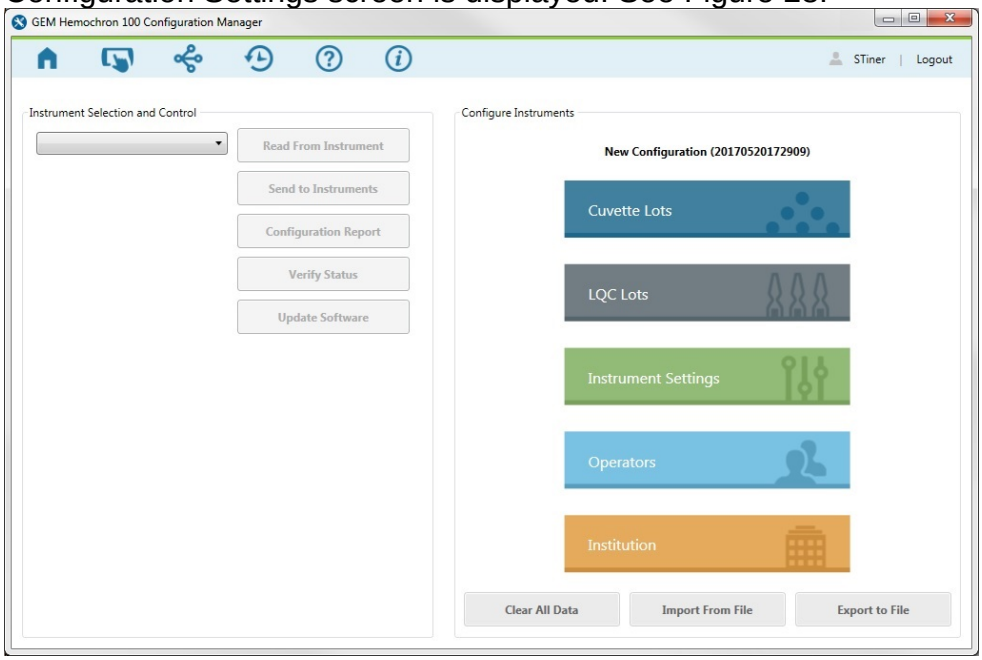


Figure 27 – Configuration Manager: The Configuration Settings screen

This is the main part of the application. Supervisors use it to do the following:

- add instrument groups (click in the upper left corner – this allows a Supervisor to add an instrument to a group so they can perform operations on a group of instruments at the same time)

- add instruments (click  in the upper left corner)
- view and export audit logs (click  in the upper left corner)
- view Help (click  in the upper left corner)
- view About (click  in the upper left corner)
- configure instruments
  - configure instruments (specify settings and send them to instruments)
  - read configuration data from instruments
  - export configuration data to a file for reuse
- generate a configuration data report for an instrument
- update instrument software (firmware)

Workflow for Using Configuration Manager

After Configuration Manager is installed, refer to the following workflow to use it (this is only an overview – detailed instructions appear later in this manual):

1 Prepare to use Configuration Manager for the first time.

- Start Configuration Manager.
- Log in to the factory default Admin account (*admin*/*000*). Change the password, record it, and store it in a safe place. The Administrative Settings part of the application is displayed.
- Create a Configuration Manager Supervisor account.
- Log out of the Administrative Settings part of the application.
- Log in as a Supervisor. The Configuration Settings part of the application is displayed.

2 Add instrument groups (click  in the upper left).

3 Add instruments (click  in the upper left).

4 Create configuration data.

- Cartridge Lots
- LQC Lots
- Instrument Settings (OID, PID, QC Lockout, etc.)
- Operators
  - add instrument Supervisors
  - add instrument Operators

- Institution (name, address, etc.)

5 Export configuration data to a file (save it for reuse).

6 Ensure each instrument that needs to be configured is connected to the CCM.

7 Send configuration data to instruments.

Log in to Configuration Manager for the First Time

The first user who logs in to Configuration Manager must log in using the factory default Admin account.

1 Start Configuration Manager.

The **Login** dialog box is displayed.

2 Enter the credentials for the factory default Admin account.

Username	*admin*
Password	*000*

3 Click **Login**.

A dialog box for changing the password is displayed. See Figure 29.

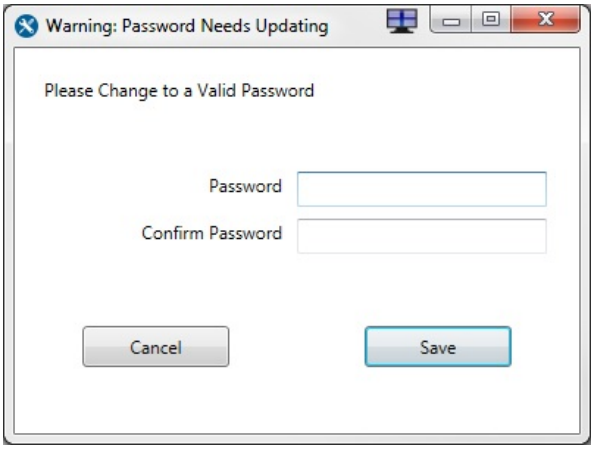


Figure 28 – Configuration Manager: Changing the password for the factory default Admin account

NOTE The password must contain at least seven characters. At least one character must be a special character (period, comma, &, @, *, $, etc.). For example: `@mypassword`

4 Enter the new password, enter it again to confirm it, and click **Save**. Record the new password and store it in a safe place.

The Administrative Settings screen is displayed.

Create Accounts for Configuration Manager Users

NOTE Use these procedures to create accounts for users of Configuration Manager. Accounts for instrument Supervisors and Operators are created during the instrument configuration process.

Create an Admin Account for Configuration Manager

NOTE It is not necessary to create additional Admin accounts. Admins can continue to use the factory default Admin account, but they must log in as an Admin using the password that was changed when the first person logged in to Configuration Manager.

1 Log in to Configuration Manager as an Admin.

The **Administrative Settings** screen is displayed. See Figure 30.

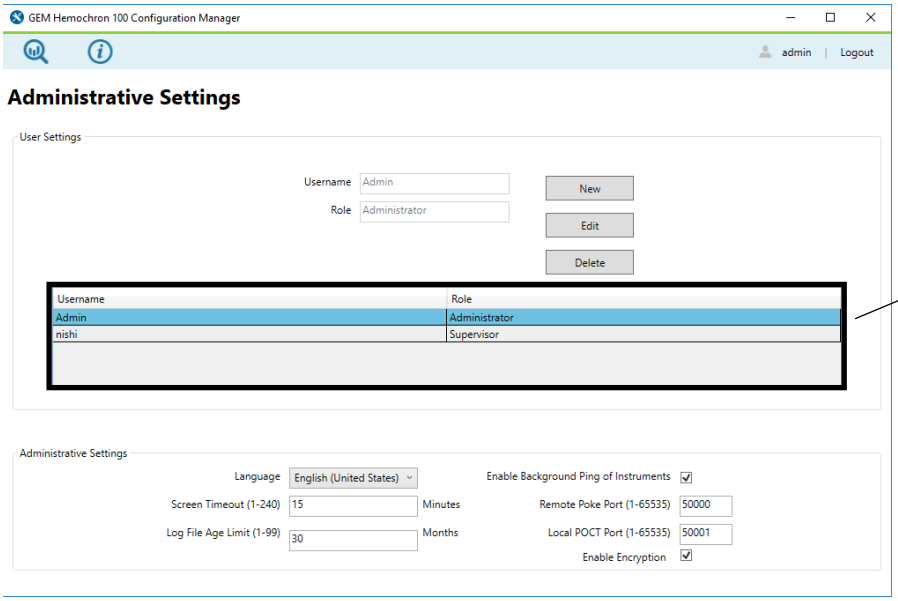


Figure 29 – Configuration Manager: List of user accounts

2 Click the **New** button.

The **Adding New Operator** dialog box is displayed.

3 Enter the username for the account.

4 In the **Role** drop-down list, select **Administrator**.

5 Enter the password.

NOTE The password must contain at least seven characters. At least one character must be a special character (period, comma, &, @, *, $, etc.). For example: `@mypassword`

6 Confirm entry of the password.

7 Click **OK**.

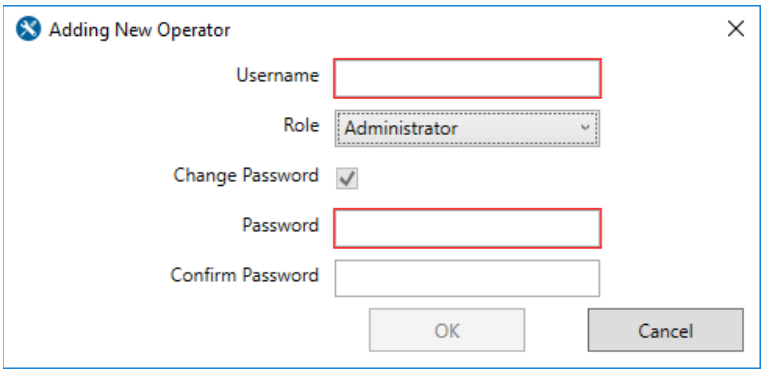
The **Administrative Settings** screen is displayed and the Admin account is added to the list of accounts. See Figure 30. To edit or delete an account, select it and click the appropriate button (**Edit** or **Delete**).

Create a Supervisor Account for Configuration Manager

A Supervisor account for Configuration Manager allows a Supervisor to use the application to configure instruments. This account is distinct from an instrument Supervisor account, which allows a Supervisor to perform advanced functions whey they operate an instrument.

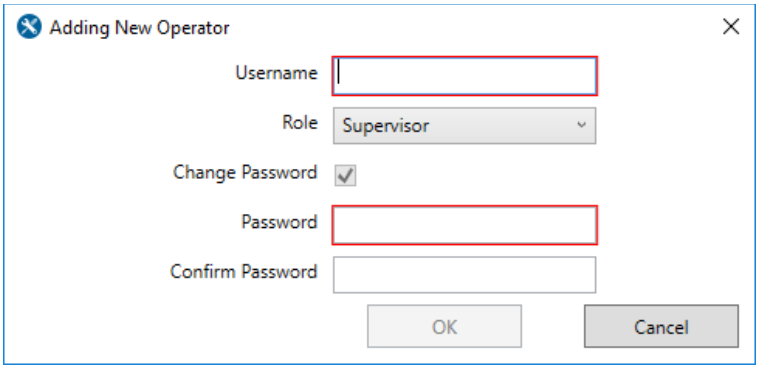
1 Log in to Configuration Manager as an Admin.

The **Administrative Settings** screen is displayed.



2 Click the **New** button.

The **Adding New Operator** dialog box is displayed.



3 Enter the username for the account.

4 Enter the password.

NOTE The password must contain at least seven characters. At least one character must be a special character (period, comma, &, @, *, $, etc.). For example: `@mypassword`

5 Confirm entry of the password.

6 In the **Role** drop-down list, select **Supervisor.**

7 **C**lick **OK**.

The **Administrative Settings** screen is displayed and the Supervisor account is added to the list of accounts. To edit or delete an account, select it and click the appropriate button (**Edit** or **Delete**).

Configure the Application

Several settings determine how the Configuration Manager application operates. These include miscellaneous settings (for example, display language) and network settings. To configure them, log in to Configuration Manager as an Admin.

Configure Miscellaneous Settings for the Application

Three miscellaneous settings affect how the application operates. When a user is logged in as an Admin, these settings are in the lower left corner of the screen. See Figure 31. For a description of them, see Table 10.

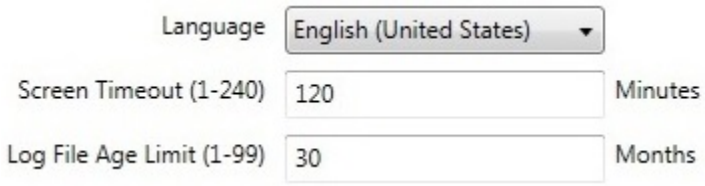


Figure 30 – Configuration Manager: Miscellaneous Administrative Settings

Table 10 – Configuration Manager: Miscellaneous Administrative Settings

Setting	Description
Display Language	Select a display language for the Configuration Manager user interface. When Configuration Manager is restarted, the change goes into effect. ⚠ **Important** Set the display language of the instrument and Configuration Manager so they are the same as the language of the operating system. For example, if the language of the operating system is French, set the display language of the instrument and Configuration Manager to French.
Screen Timeout (Lockout Interval)	The number of minutes of inactivity before the software locks the screen and requires an Operator to unlock it by entering their log in information. The maximum is 240 minutes (4 hours) The change goes into effect immediately.

Setting	Description
Log File Age Limit	The number of months that the log files will be maintained on PC. The maximum number is 99 months. The change goes into effect immediately. See *Log Files* on Chapter 4.

Configure Network Settings for the Application

Some network settings affect how the application operates. When a user is logged in as an Admin, these settings are in the lower right corner of the screen. See Figure 32. For a description of them, see Table 11. For assistance, check with a Network Administrator.

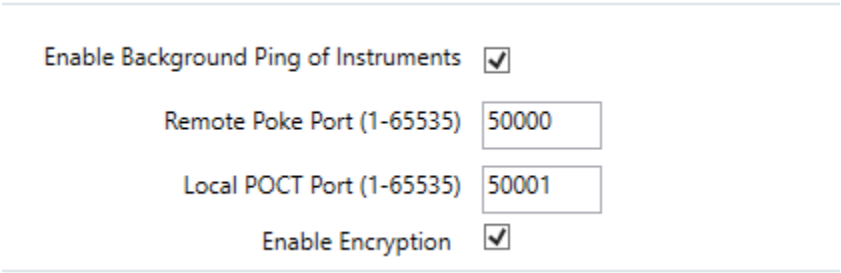


Figure 31 – Configuration Manager: Network Settings

Table 11 – Configuration Manager: Network Settings

Setting	Description
Enable Background Ping of Instruments	Allow Configuration Manager to ping instruments in the background to see if a connection can be established with the instruments.
Remote Poke Port (1-65535)	The port number for remote poking. The default value is 50000. Configuration Manager sends POKE messages to instruments to indicate that it wants to communicate with them. The POKE message contains the remote poke port number. This number must match the port number that was set at the instrument by selecting > **Supervisor Settings** > **CM Connection Settings**.

Local POCT Port (1-65535)	The port number for the local POCT1-A network. Enter a value of 50001.

Add Instruments and Instrument Groups

NOTE If an invalid value is entered into a text field, the box is outlined in red. The **OK** button remains disabled until a valid value is entered. To see a tooltip that shows the error message, hover your mouse over the field.

Before an instrument can be configured over the network, the instrument must be added to Configuration Manager so it will recognize it. Instrument groups allow users to perform operations on all of the instruments in a group.

Add an Instrument

When an instrument is added to Configuration Manager, it is "registered" so that it can communicate over the network with Configuration Manager.

1. Ensure the instrument that needs to be added is connected to the network.
2. Log in to Configuration Manager as a Supervisor.

   The Home screen that is used to configure instruments is displayed.
3. In the upper left corner, click  .

   The **Instrument Management** screen is displayed.
4. Click **New**.

   The **Adding New Instrument** dialog box is displayed.
5. In the **Nickname** field, enter a nickname for the instrument.
6. In the **IP Address / Hostname** field, enter either of the following:
   - the **IP address** displayed on the instrument Home screen
   - the **hostname**. Enter it in the form of *GEMH100-<serial number>*. For example, if the instrument serial number is *MC100022*, enter *GEMH100-MC100022*. The serial number is on the bottom of the instrument, on the main label.

   NOTE Alternatively, to read the serial number from an instrument into the **Serial Number** field, click the **Read from Device** button. If Configuration Manager cannot establish a connection with the instrument, see *Configure Firewalls* on page 54
7. (Optional – Add the instrument to a group) In the **Group** drop-down list, choose a group to add the instrument to.

NOTE If an instrument group does not exist, create one and then edit the instrument later to add the instrument to the group.

8. Click **OK**.

9 To return to the home screen, click  in the upper left corner.

Create a Group and Add an Instrument to It

An instrument group allows operations to be performed on all of the instruments in that group.

Important Plan carefully when choosing the names of instrument groups or adding instruments to instrument groups…

1 Log in to Configuration Manager as a Supervisor.

The Home screen that is used to configure instruments is displayed.

2 In the upper left corner, click  .

The **Instrument Group Management** screen is displayed.

3 Click **New**.

The **Adding New Group** dialog box is displayed.

4 In the **Group** field, enter a name for the group and click **OK**.

The instrument group is created and added to the list.

5 To add an instrument to a group, in the upper left corner, click  .

The **Instrument Management** screen is displayed.

6 In the list of instruments, select the instrument to add to the group.

7 Click **Edit**.

8 In the **Group** drop-down list, select the group and click **OK**.

9 To return to the home screen, click  in the upper left corner.

Configure Instruments

To configure instruments, a user must log in to Configuration Manager as a Supervisor, create configuration data, and send it to instruments.

Introduction

Before Instruments Can Be Configured

Before instruments can be configured, they must be added to Configuration Manager using the **Instruments** button in the upper left corner of the Home screen. Adding instruments to Configuration Manager allows it to recognize them through the network connection.

Workflow for Configuring Instruments

The workflow for configuring instruments is as follows (this is only an overview – detailed instructions appear later in this manual):

1. Create configuration data in a Configuration Manager session.
2. (Optional) Export the data to a configuration file (.cfg). This allows it to be saved it in case a user needs to import it later.
3. Ensure each instrument that is to be configured is connected to the network.
4. Send the configuration data to instruments.

NOTE Configuration files created on one computer cannot be used on another computer.

How Data is Stored in Memory during a Session

During a Configuration Manager session, configuration data that is created is temporarily stored in the computer's volatile memory (RAM). It is not saved to disk by default. To save it to disk, it must be exported using the **Export to File** button.

When a user logs out of Configuration Manager, if they have not sent the data to an instrument or exported it, an **Unsaved Changes** message is displayed. See Figure 33.

- **Discard Changes** – Discard the changes and log out.
- **Go Back** – Go back to the session so the data can be sent to an instrument or exported.

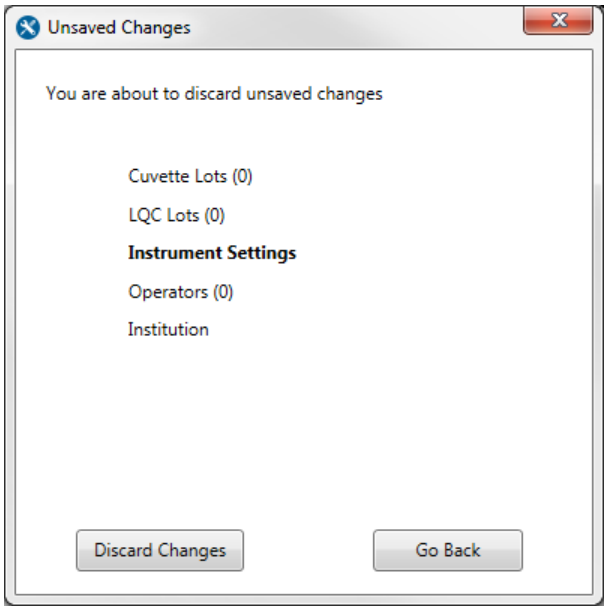


Figure 32 – Configuration Manager: The Unsaved Changes message

There are two ways to load data into a session:

- read it from an instrument. On the Home screen, in the upper left corner, select the **Read from Instrument** button.
- (if a configuration file exists) import it from a configuration file. On the Home screen, in the lower right corner, select the **Import From File** button.

All of the data in a session can be cleared. On the Home screen, in the lower right corner, click **Clear All Data**. This restores the data in the session to the factory default settings.

Create Configuration Data

To create configuration data, log in to Configuration Manager as a Supervisor. On the Home screen, click the appropriate button. See Figure 34.

Figure 33 – Configuration Manager:
Use these buttons to create configuration data

Configure Data for Cartridge Lots

1. Click the **Cartridge Lots** button.

   The **Cartridge Lots** dialog box is displayed. See Figure 35.

2. Click **New**.
3. In the drop-down list, choose the **Test Type** that matches the type of cartridge lot (**ACT+** or **ACT-LR**).
4. Enter the **Cartridge Lot Number**.
5. Enter the **Expiration Date**.
6. Click **OK**.

   The cartridge lot is added to the list of cartridge lots.

7. Click **OK** to save the changes.

To edit a cartridge lot or delete it, click the appropriate button (**Edit** or **Delete**).

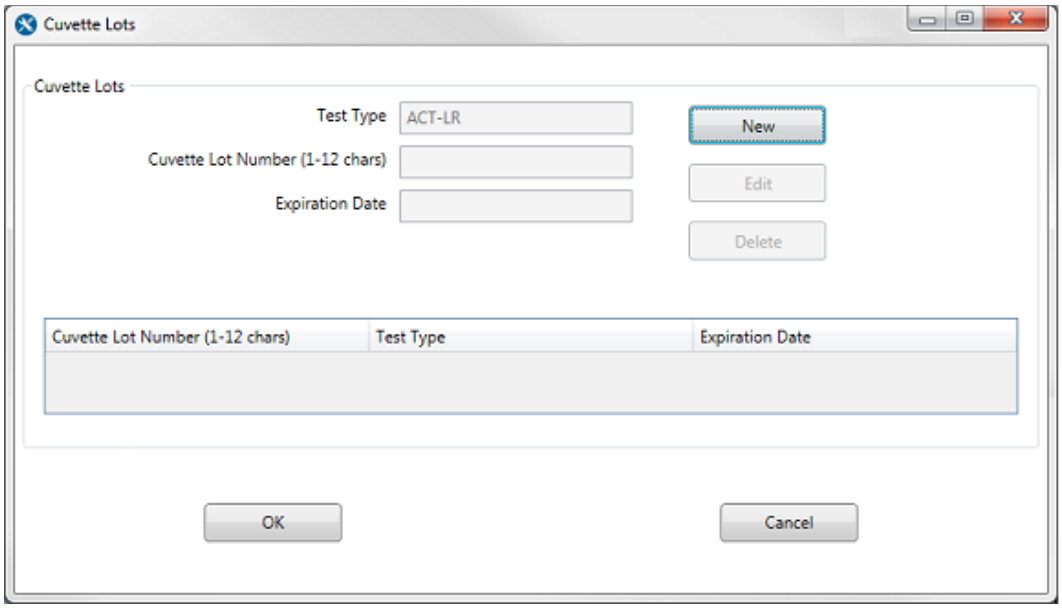


Figure 34 – Configuration Manager:
The Cartridge Lots dialog box

Configure Data for LQC Lots

1. Click the **LQC Lots** button.

   The **LQC Lots** dialog box is displayed. See Figure 36.

2. Click **New**.
3. In the **Test Type** drop-down list, choose the test type that matches the type of cartridge lot (**ACT+** or **ACT-LR**).
4. In the **LQC Level** drop-down list, choose the level that matches the LQC test:
   - **Level 1** (Normal)
   - **Level 2** (Abnormal)
5. Enter the **LQC Lot Number**.
6. Enter the **Ranges** (low and high)**.**
7. Enter the **Expiration Date**.
8. Click **OK**.

   The LQC lot is added to the list of LQC lots.

9. Click **OK** to save the changes.

To edit an LQC lot or delete it, click the appropriate button (**Edit** or **Delete**).

By editing an LQC lot, if you change the test type, range low and range high will be reset to zero. Please, make sure you enter appropriate values in this field before saving.

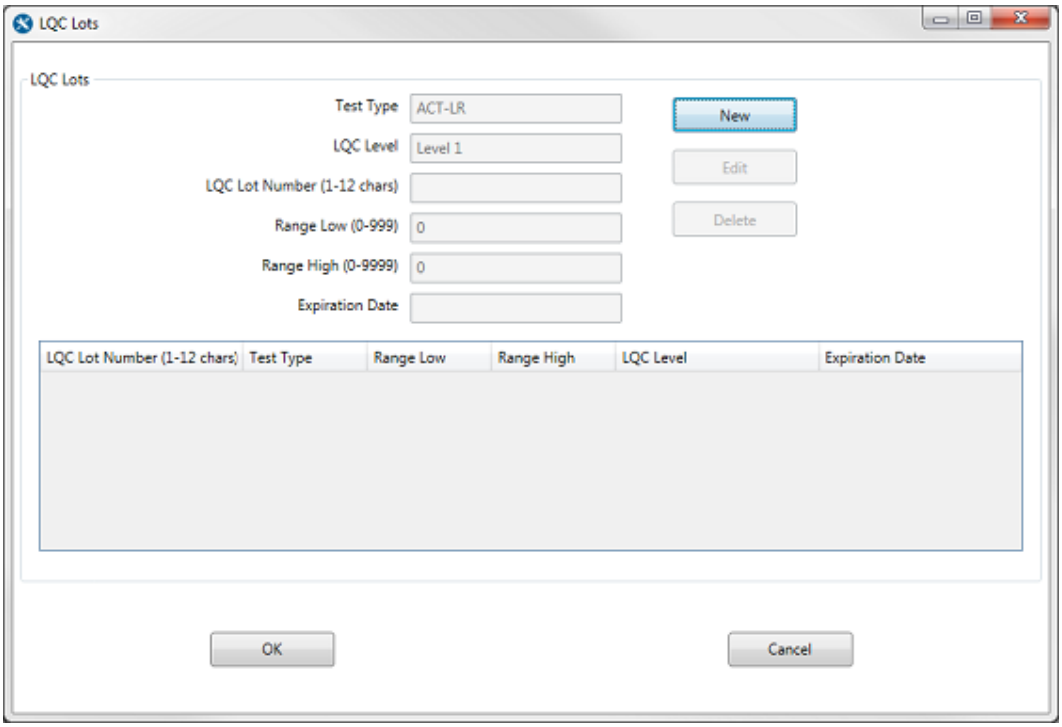


Figure 35 – Configuration Manager: The LQC Lots dialog box

Configure Data for Instruments (Instrument Settings)

1 Click the **Instrument Settings** button.

The **Instrument Settings** dialog box is displayed. See Figure 37.

2 At the top of the dialog box, click the appropriate tab: **General**, **LQC Settings**, **EQC Settings**, or **Version Info**.

3 Choose the settings:

- **General** – See Figure 37 and Table 12
- **LQC Settings** – See Figure 38 and Table 13 .
- **EQC Settings** – See Figure 39 and Table 14.
- **Version Info** – See Figure 40 and Table 15 .

NOTE If the value of a Yes/No drop-list is null (if it is not **Yes** or **No**), the existing setting on the instrument will remain the same when the data is sent to the instrument.

Example: The value of this Yes/No drop-list is null

4 Click **OK** to save the changes and return to the Home screen.

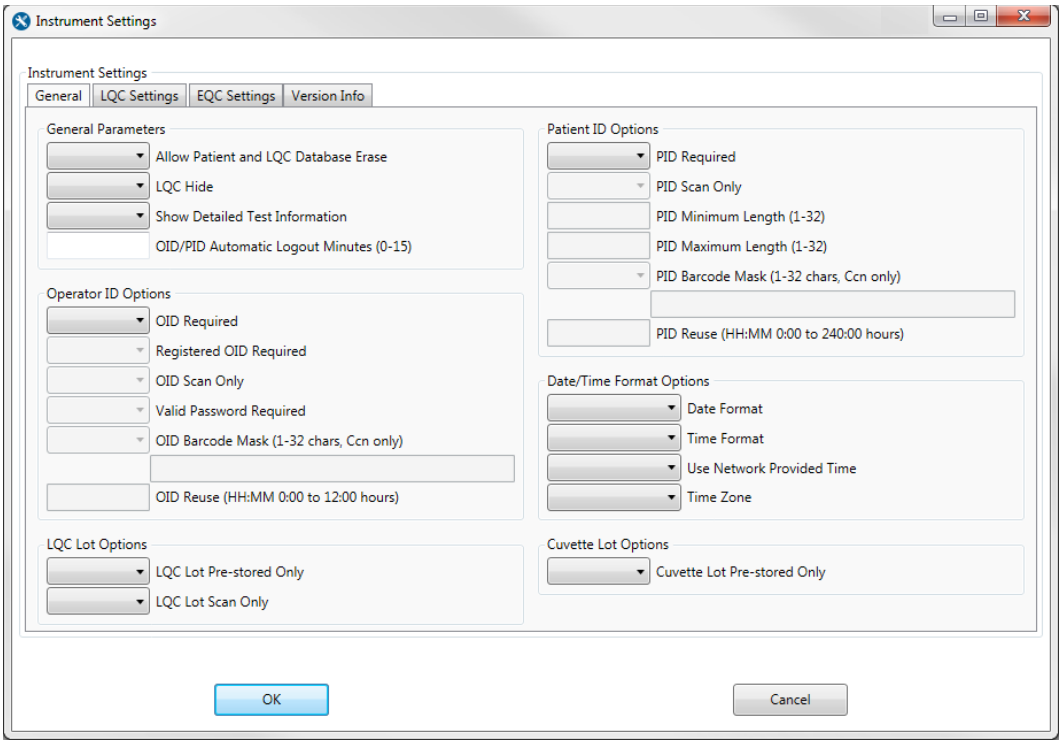


Figure 36 – Configuration Manager: The Instrument Settings dialog box

Table 12 – Configuration Manager: Instrument Settings > General

Setting	Description
General Parameters	
Allow Patient and LQC Database Erase	Choose whether to allow Supervisors to erase (delete) test results (patient tests and LQC tests) from the database using the instrument menus. • **Yes** – Allow the database to be erased. • **No** – Do not allow the database to be erased. On the instrument, see > **Supervisor Settings** > **Clear All Test Records**.
LQC Hide	Choose whether to display **Pass** or **Fail** instead of numerical results after an LQC test. • **Yes** – Display **Pass** or **Fail**. • **No** – Display numerical results.
Show Detailed Test Information	Choose whether to allow Operators to see the number of patient tests allowed for each subtype after the LQC interval expires. • **Yes** – Operators can see the number of patient tests allowed. • **No** – Operators cannot see the number of patient tests allowed. The number is not shown.
OID/PID Automatic Logout Minutes (0-15)	The number of minutes before Operators are automatically logged out.
Operator ID Options	
OID Required	Choose whether to require Operators to enter their OID before they run an LQC test or patient test. • **Yes** – Operators must enter their OID. • **No** – Operators are not required to enter their OID.
Registered OID Required	Before Operators run a test, choose whether to require them to enter a registered OID (an OID associated with an Instrument Operator account created in Configuration Manager). • **Yes** – Operators must enter a registered OID. • **No** – Operators can enter an unregistered OID.
OID Scan Only	Choose whether to require Operators to scan their OID. • **Yes** – Operators must scan their OID. • **No** – Operators can scan their OID or manually enter it.

Setting	Description
Valid Password Required	Choose whether to require that Operators enter a valid password before they run a test. • **Yes** – Operators must enter a password. • **No** – Operator are not required to enter a password.
OID Barcode Mask (1-32 chars, Ccn only)	When Operators enter an OID by scanning it or manually entering it, choose whether to invoke a mask that requires that the OID be in a specified format. • **Yes** – OIDs must not exceed 32 characters and must be in a specified format. They must contain only "Ccn" characters: uppercase letters (example, "C"), lower case letters (example, "c"), and numerals (example, "1"). To specify the format, enter the appropriate characters in the text box below and to the right of the Yes/No drop-down list. For example, if a mask of *ncC* is entered into the text box, it will be possible to enter an OID of **1vB** or **5gU**. Or if a mask of *CCnccc* is entered, an OID of **AJ2bcb** or **DD3aax** can be entered. • **No** – OIDs must not exceed 32 characters, but can be in any format and can contain any character.
OID Reuse (HH:MM 0:00 to 12:00 hours)	The duration of time that an OID can be reused. To prevent an OID from being reused at all, enter *0:00*. If the instrument automatically shuts down or if an Operator manually shuts it down, the reuse duration is automatically reset to *0:00*.
LQC Lot Options	
LQC Lot Pre-stored Only	Choose whether to require that Operators use only LQC material that has been registered in (added to) Configuration Manager. • **Yes** – Operators must use only registered LQC material. • **No** – Operators can use unregister LQC material.
LQC Lot Scan Only	When an Operator enters LQC lot information, choose whether to require that they enter it by scanning only. • **Yes** – Operators must scan LQC lot information. They cannot manually enter it. • **No** – Operators can manually enter LQC lot information or scan it.

Setting	Description
Patient ID Options	
PID Required	Before Operators run a patient test, choose whether to require them to enter a PID. • **Yes** – Operators must enter a PID. • **No** – Operators are not required to enter a PID.
PID Scan Only	When Operators enter PIDs, choose whether to require that they enter them by scanning only. • **Yes** – Operators must scan PIDs. They cannot manually enter them. • **No** – Operators can manually enter PIDs or scan them.
PID Minimum Length (1-32)	The minimum number of characters allowed for a PID.
PID Maximum Length (1-32)	The maximum number of characters allowed for a PID.
PID Barcode Mask (1-32 chars, Ccn only)	When Operators enter a PID by scanning it or manually entering it, choose whether to invoke a mask that requires that the PID be in a specified format. • **Yes** – PIDs must not exceed 32 characters and must be in a specified format. They must contain only "Ccn" characters: uppercase letters (example, "C"), lower case letters (example, "c"), and numerals (example, "1"). To specify the format, enter the appropriate characters in the text box below and to the right of the Yes/No drop-down list. For example, if a mask of *ncC* is entered into the text box, it will be possible to enter a PID of **1vB** or **5gU**. Or if a mask of *CCnccc* is entered, a PID of **AJ2bcb** or **DD3aax** can be entered. • **No** – PIDs must not exceed 32 characters, but can be in any format and can contain any character.
PID Reuse (HH:MM 0:00 to 240:00 hours)	The duration of time that a PID can be reused. To prevent a PID from being reused at all, enter *0:00*.

Setting	Description
Data/Time Format Options	
Date Format	Specify the format of how the date will be displayed.
Time Format	Specify the format of how the time will be displayed.
Use Network Provided Time	Choose whether to synchronize the time-of-day clock with the time provided by the network. • **Yes** – Synchronize the clock with the network. • **No** – Do not synchronize the clock (the clock must manually be set).
Time Zone	The time zone in which the instrument is operated.
Cartridge Lot Options	
Cartridge Lot Pre-stored Only	Choose whether to require that Operators use only cartridges that have been registered using (added to) Configuration Manager. • **Yes** – Operators must use only registered cartridges. • **No** – Operators can use unregistered cartridges.

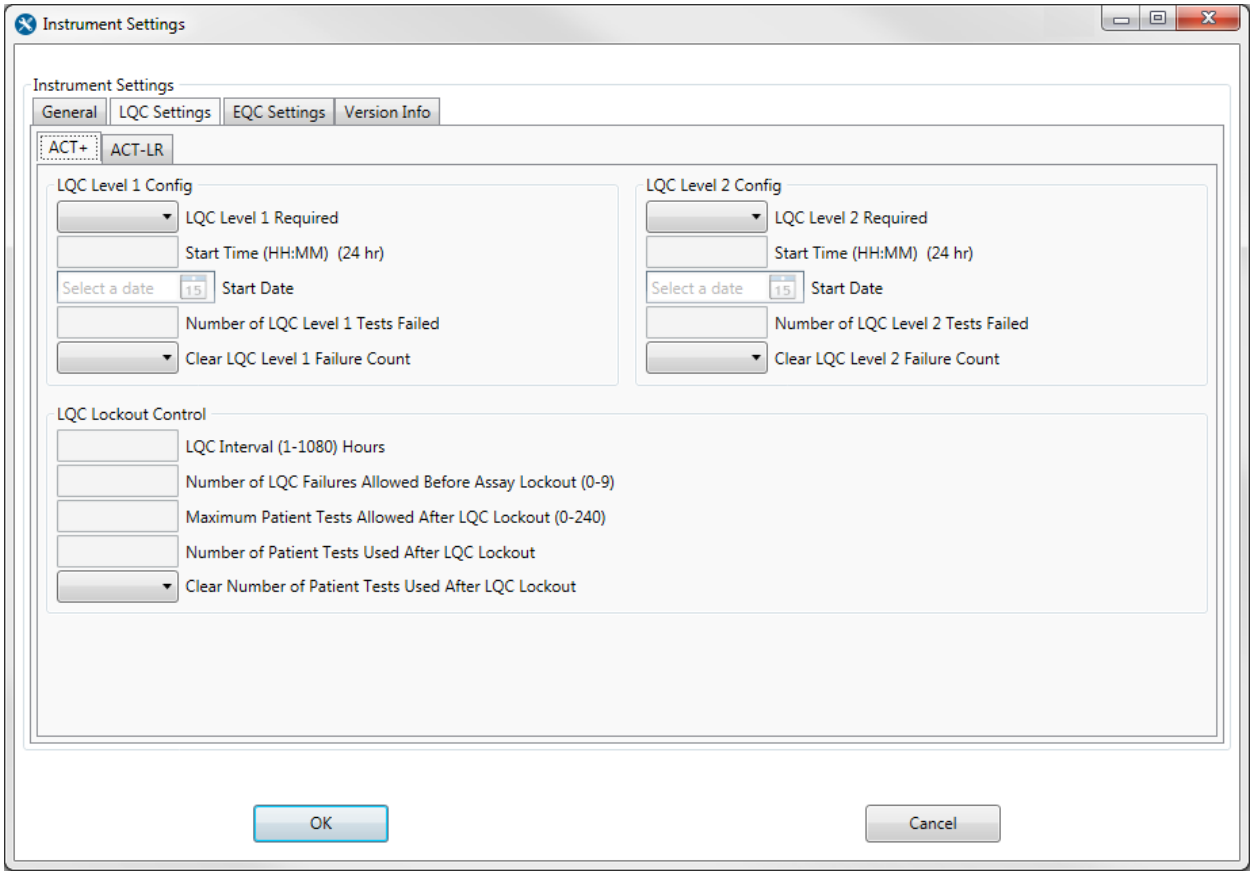


Figure 37 – Configuration Manager:
The LQC Settings dialog box

Table 13 – Configuration Manager: Instrument Settings > LQC Settings

NOTE The **LQC Settings** tab contains two sub-tabs: one for each type of test (**ACT+** and **ACT-LR**). Be sure to change the settings on each tab.

Setting	Description
LQC Level (1/2) Config	
LQC Level (1/2) Required	Choose whether to enable the QC lockout feature associated with LQC tests. See *QC Lockout* on page 119 • **Yes** – Enable the lockout feature. • **No** – Disable the lockout feature. If this feature is enabled, Supervisors can do the following: • prevent Operators from running any more LQC tests after a specified number of LQC test failures • prevent Operators from running any more patient tests after the LQC interval timer expires **CAUTION** If the LQC test feature is enabled, the instrument will require that LQC tests be run at regular intervals. This feature is disabled at the factory, but it can be enabled using Configuration Manager. The manufacturer recommends that it be enabled. The decision to enable or disable this feature shall be determined by and is the responsibility of the Lab Director. When lockout occurs, before an Operator can run a test, a Supervisor must clear the lockout. See *Clearing a Lockout* on page 121
Start Time (HH:MM) (24 hr)	The time of day that the LQC interval timer starts running. For information about the LQC interval timer, see the description of the field labeled **LQC Interval (1-1080) Hours**. The current time is automatically entered by default. Enter the value in 24-hour time format. For example, for 7:00 PM, enter *19:00*.
Start Date	The date the LQC interval timer starts running.

Setting	Description
Number of LQC Level (1/2) Tests Failed	A counter that displays the number of failed LQC tests that Operators have run. This value is read-only. After the first LQC test fails, the counter is incremented each time an additional LQC test fails. For more information, see the description of the field labeled **Number of LQC Failures Allowed Before Assay Lockout (0-9)**.
Clear LQC Level (1/2) Failure Count	Choose whether to clear the counter that displays the number of failed LQC tests. • **No** – Do not clear the counter. • **Yes** – Clear the counter. When Yes is selected, the counter labeled **Number of LQC Level (1/2) Tests Failed** will be cleared (reset) when configuration data is sent to the instrument .
LQC Lockout Control	
LQC Interval (1-1080) Hours	How long the LQC interval timer runs. When the timer expires, patient test lockout occurs, preventing Operators from running patient tests. See *QC Lockout* on Chapter 7. A Supervisor can configure the instrument so that after the timer expires, Operators are allowed to run as many as 240 additional patient tests. See the description for the field labeled **Maximum Patient Tests Allowed After LQC Lockout (0-240)**. When the additional patient tests have been run, the next time an Operator tries to run a patient test, lockout occurs. (This effectively postpones lockout.) A Supervisor must clear a lockout. See *Clearing a Lockout* on page 121.

Setting	Description
Number of LQC Failures Allowed Before Assay Lockout (0-9)	The number of additional failed LQC tests that Operators are allowed to run before QC lockout. See *QC Lockout* on page 119. By default, if an LQC test fails, Operators can run one more LQC test. If that test fails, Operators are locked out. A Supervisor can configure the instrument so that Operators are allowed to run as many as nine additional LQC tests after the first test fails. This postpones lockout. To prevent Operators from running any additional failed LQC tests, enter *0*. The first time an LQC test fails, lockout will occur. If additional LQC test failures are allowed, each time an additional LQC test fails the value in the field labeled **Number of LQC Level (1/2) Tests Failed** is incremented. A Supervisor can clear (reset) this value by checking the box labeled **Clear LQC Level (1/2) Failure Count**. When configuration data is sent to the instrument, the counter will be cleared.
Maximum Patient Tests Allowed After LQC Lockout (0-240)	The number of additional patient tests that Operators are allowed to run after the LQC interval timer expires. Supervisors can allow Operators to run as many as 240 additional patient tests after the timer expires. When the maximum number of patient tests has been run, if an Operator tries to run another patient test, QC lockout occurs. See *QC Lockout* on page 119. To prevent Operators from running any additional patient tests, enter *0*. As soon as the timer expires, lockout will occur. When an additional patient test has been performed, the value in the field labeled **Number of Patient Tests Used After LQC Lockout** is incremented. Supervisors can clear this value by selecting Yes for **Clear Number of Patient Tests Used After LQC Lockout**.
Number of Patient Tests Used After LQC Lockout	The number of patient tests that Operators have run after the LQC interval timer expired. This value is read-only. After the LQC expiration, this counter is incremented each time a patient test is run. For more information, see the description for the field labeled **Maximum Patient Tests Allowed After LQC Lockout (0-240)**.

Setting	Description
Clear Number of Patient Tests Used After LQC Lockout	Choose whether to clear the counter that displays the number of patient tests Operators have run after LQC expiration. • **No** – Do not clear the counter • **Yes** – Clear the counter When Yes is selected, the counter labeled **Number of Patient Tests Used After LQC Lockout** will be cleared (reset) when configuration data is sent to the instrument.

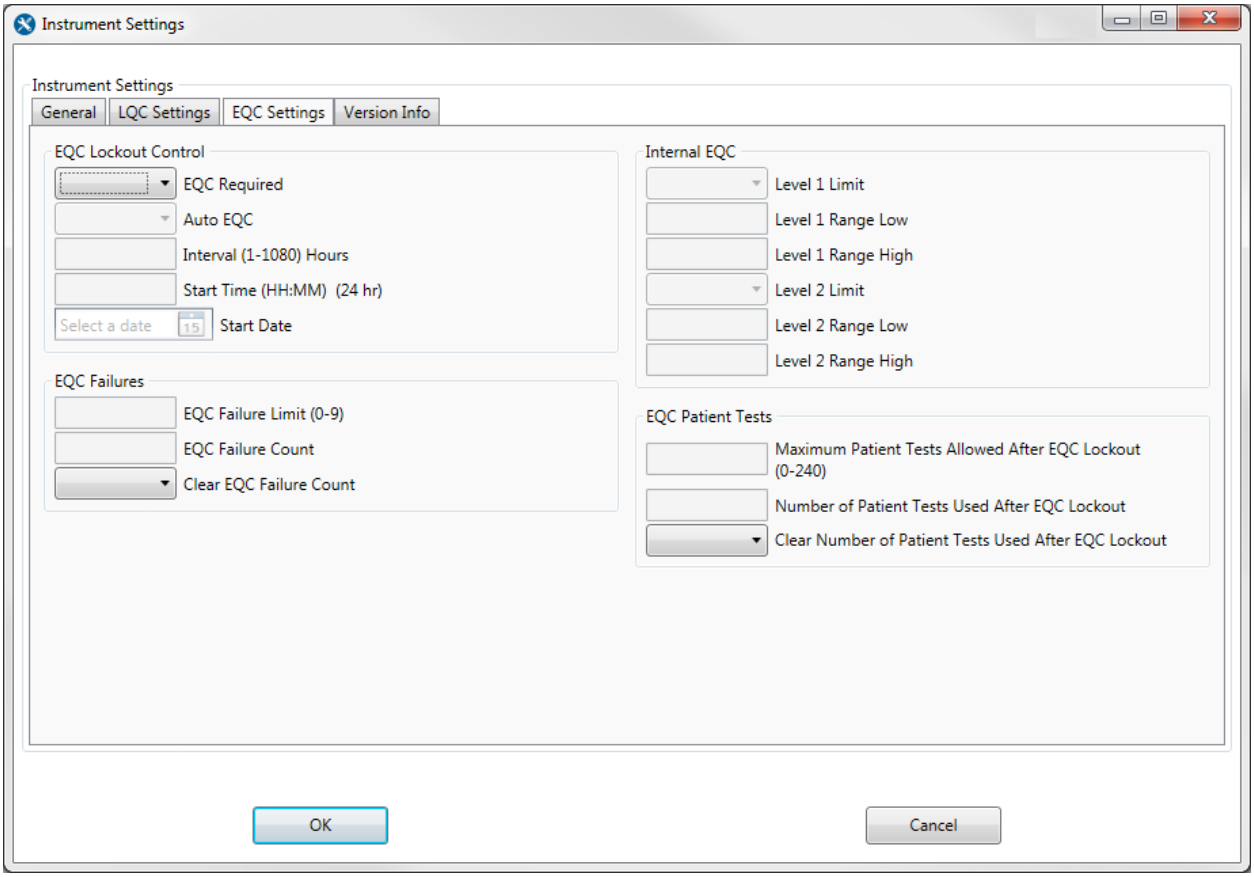


Figure 38 – Configuration Manager: The EQC Settings dialog box

Table 14 – Configuration Manager: Instrument Settings > EQC Settings

Setting	Description
EQC Lockout Control	
EQC Required	Choose whether to enable the QC lockout feature associated with EQC tests. See *QC Lockout* on page 119 • **Yes** – Enable the lockout feature. • **No** – Disable the lockout feature. **CAUTION** If the EQC test feature is enabled, the instrument will require that EQC tests be run at regular intervals. This feature is enabled at the factory. Although it is possible to disable it, the manufacturer recommends that it remain enabled. The decision to enable or disable this feature shall be determined by and is the responsibility of the Lab Director. If this feature is enabled, Supervisors can do the following: • prevent Operators from running any more EQC tests after a specified number of EQC test failures • prevent Operators from running any more patient tests after the EQC interval timer expires When lockout occurs, before an Operator can run a test, a Supervisor must clear the lockout. See *Clearing a Lockout* on page 121.
Auto EQC	Choose whether to automatically run the EQC test at the specified interval. • **Yes** – Automatically run the EQC test at the specified interval. Note when the interval timer expires, the EQC test will automatically start, and the result will automatically be stored in the database. EQC will automatically start even if power is not connected. • **No** – Do not automatically run the EQC test at the specified interval. **Important** If Auto EQC is enabled, ensure cartridges are routinely removed from the instrument after a test. If a cartridge is in the slot when the EQC test starts, a warning message will be displayed and the test will not run.

Setting	Description
Interval (1-1080) Hours	How long the EQC interval timer runs. When the timer expires, patient test lockout occurs, preventing Operators from running patient tests. See *QC Lockout* on page 119. A Supervisor can configure the instrument so that after the timer expires, Operators are allowed to run as many as 240 additional patient tests. This postpones lockout. See the description for the field labeled **Maximum Patient Tests Allowed After EQC Lockout (0-240)**. When the additional patient tests have been run, the next time an Operator tries to run a patient test, lockout occurs. A Supervisor must clear the lockout. See *Clearing a Lockout* on page 119.
Start Time (HH:MM) (24 hr)	The time of day that the EQC interval timer starts running. For information about the EQC interval timer, see the description of the field labeled **Interval (1-1080) Hours**. The current time is automatically entered by default. Enter the value in 24-hour time format. For example, for 7:00 PM, enter *19:00*.
Start Date	The date that the EQC interval timer starts running.
EQC Failures	
EQC Failure Limit (0-9)	The number of additional failed EQC tests that Operators are allowed to run before QC lockout. See *QC Lockout* on page 119. By default, if an EQC test fails, Operators can run one more EQC test. If that test fails, Operators are locked out. A Supervisor can configure the instrument so that Operators are allowed to run as many as nine additional EQC tests after the first test fails. This postpones lockout. To prevent Operators from running any additional failed EQC tests, enter *0*. The first time an EQC test fails, lockout will occur. If additional EQC test failures are allowed, the value in the field labeled **EQC Failure Count** is incremented each time an additional EQC test fails.

Setting	Description
EQC Failure Count	A counter that displays the number of additional failed EQC tests that Operators have run. This value is read-only. After the first EQC test fails, the counter is incremented each time an additional EQC test fails. A Supervisor can clear this value by selecting Yes for field **Clear EQC Failure Count**. The counter will be cleared (reset) when configuration data is sent to the instrument. The counter will also be cleared when user runs an EQC test and it passes. For more information, see the description for the field labeled **EQC Failure Limit (0-9)**.
Clear EQC Failure Count	Choose whether to clear (reset) the counter that displays the number of failed EQC tests Operators have run. • **No** – Do not clear the counter. • **Yes** – Clear the counter. With "Yes" option, when configuration data is sent to the instrument, the counter labeled **EQC Failure Count** will be cleared.
Internal EQC	
Level 1 Limit	Select nothing (null) or 120.
Level 1 Range Low	The expected low range for Level 1. This value is read-only.
Level 1 Range High	The expected high range for Level 1.
Level 2 Limit	Select nothing (null), 300 seconds, or 500 seconds.
Level 2 Range Low	The expected low range for Level 2. This value is read-only.
Level 2 Range High	The expected high range for Level 2. This value is read-only.

Setting	Description
EQC Patient Tests	
Maximum Patient Tests Allowed After EQC Lockout (0-240)	The number of additional patient tests that Operators are allowed to run after the EQC interval timer expires. Supervisors can allow Operators to run as many as 240 additional patient tests after the timer expires. When the maximum number of patient tests has been run, if an Operator tries to run another patient test, lockout occurs. See *QC Lockout* on page 119. To prevent Operators from running any additional patient tests, enter *0*. As soon as the timer expires, lockout will occur. When an additional patient test has been run, the value in the field labeled **Number of Patient Tests Used After EQC Lockout** is incremented. Supervisors can clear this value by selecting "Yes" for field labeled **Clear Number of Patient Tests Used After EQC Lockout**. But it is recommended to actually run passing EQC test to clear the value in field labeled **Number of Patient Tests Used After EQC Lockout.**
Number of Patient Tests Used After EQC Lockout	A counter that displays the number of additional patient tests that Operators have run. This value is read-only. After the EQC interval timer expires, this counter is incremented each time an Operator runs an additional patient test. For more information, see the description for the field labeled **Maximum Patient Tests Allowed After EQC Lockout (0-240)**.
Clear Number of Patient Tests Used After EQC Lockout	Choose whether to clear (reset) the counter that displays the number of patient tests Operators have run after EQC Lockout. • **No** – Do not clear the counter. • **Yes** – Clear the counter. When "Yes" option is selected and configuration data is sent to the instrument, the counter labeled **Number of Patient Tests Used After EQC Lockout** will be cleared.

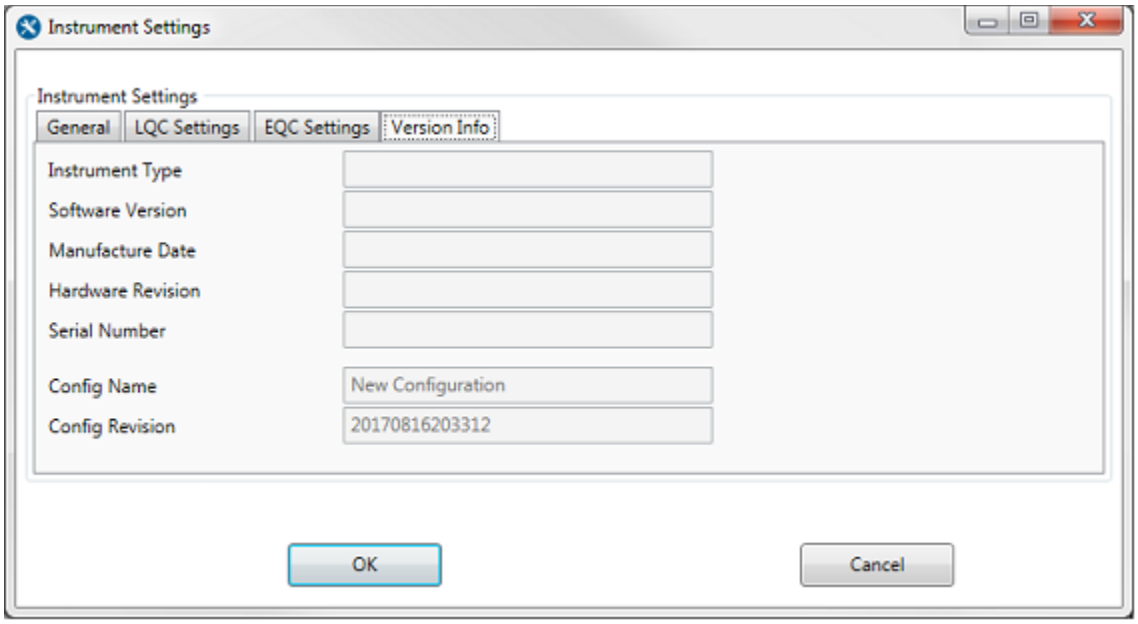


Figure 39 – Configuration Manager: The Version Info dialog box

Table 15 – Configuration Manager: Instrument Settings > Version Info

Note The **Version Info** tab contains read-only information. This information is displayed only after data is read from the instrument connected to Configuration Manager.

Setting	Description
Instrument Type	The type of instrument
Software Version	The version of software (firmware) on the instrument
Manufacture Date	The date the instrument was manufactured
Hardware Revision	The revision number (version) of the instrument hardware
Serial Number	The instrument serial number
Config Name	The name of the configuration file (.cfg) that was imported into the current session
Config Revision	The revision number of the configuration file (.cfg). It contains the date and time stamp: <*YYYYMMDDHHMMSS*>.

Configure Data for Instrument Operators and Supervisors

1. Click the **Operators** button.

   The **Operators** dialog box is displayed. See Figure 41.

2. Click **New**.

   The **Adding New Operator** dialog box is displayed.

3. Choose the settings. For a description of each setting, see Table 16.
4. Click **OK**.

   The Operator (or Supervisor) is added to the list of Operators.

5. Click **OK** again to save the changes and return to the Home screen.

To edit or delete an Operator, click the appropriate button (**Edit** or **Delete**).

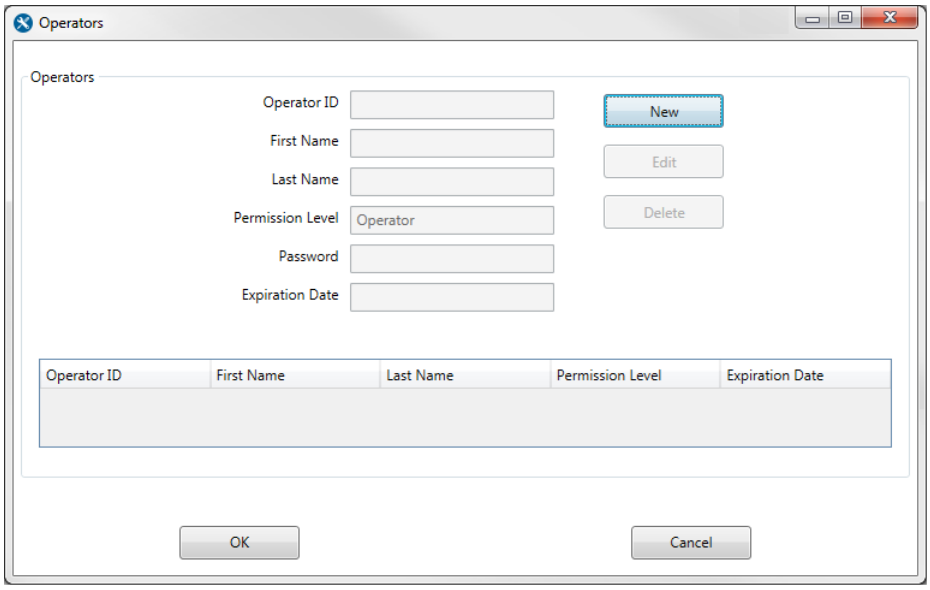


Figure 40 – Configuration Manager: The Operators dialog box

Table 16 – Configuration Manager: Operator settings

Setting	Description
Operator ID	The operator's ID **NOTE** Enter letters and numbers only; spaces and other special characters are not allowed.
First Name	The operator's first name
Last Name	The operator's last name
Permission Level	The type of operator (**Operator** or **Supervisor**)
Password	The password for the operator account
Expiration Date	The date that the operator account will expire. If a date is not entered, the operator account will never expire.

Configure Institution Data

1 Click the **Institution** button.

The **Institution** dialog box is displayed. See Figure 42.

2 Add data about your institution.

3 Click **OK** to save the changes.

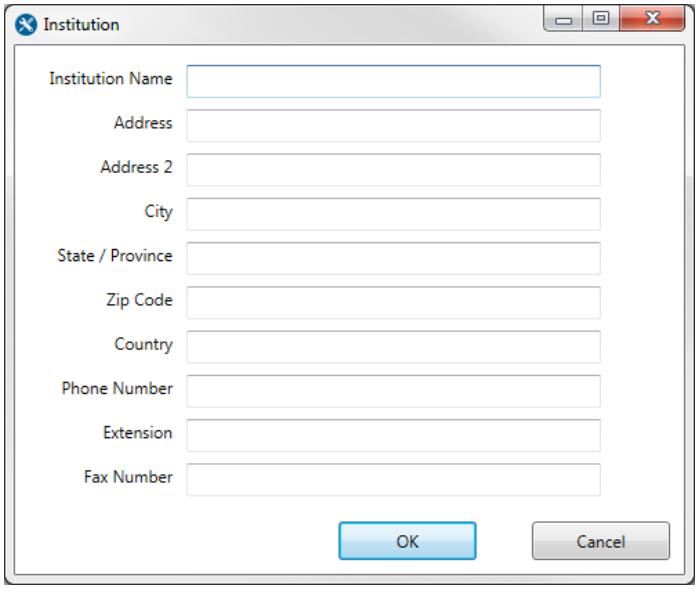


Figure 41 – Configuration Manager: The Institution dialog box

Send Configuration Data to Instruments

After configuration data is created, send it to one or more instruments.

1 Ensure each of the instruments that configuration data is to be sent to is connected to the network.

NOTE If an IP address is displayed on the instrument screen, the instrument is connected to the network.

2 Under **Instrument Selection and Control**, in the drop-down list, select the instrument or group of instruments that configuration data is to be sent to.

3 The icon to the right of each instrument name indicates whether a network connection is established between the instrument and Configuration Manager. Is a connection established?

	**Yes**, a network connection is established. Go to the next step.
	No, a network connection is not established. See *Configure Firewalls on* Chapter 4*.*

4 Click **Send to Instruments**.

The **Send to Instruments** dialog box is displayed with a checkbox next to each type of configuration data. See Figure 43. If the text of a data item is **bold**, that type of data was changed in the session.

5 Check the data items that are to be sent to the instruments.

Important For LQC Lots and Cartridge Lots: If there is any lot data in the form (if any lot data was changed in the session), the box is automatically checked. If there is no lot data in the form, the box is not automatically checked. In this case, to leave lot data on the instrument as is (no change), leave the box unchecked. To delete all lot data from the instrument, check the box. This will send an empty list to the instrument, effectively deleting all the existing lot data.

6 Click **OK**.

The configuration data is sent to each instrument.

For specific information about the LQC Lots and Cuvette Lots checkboxes, read the **Important** note above.

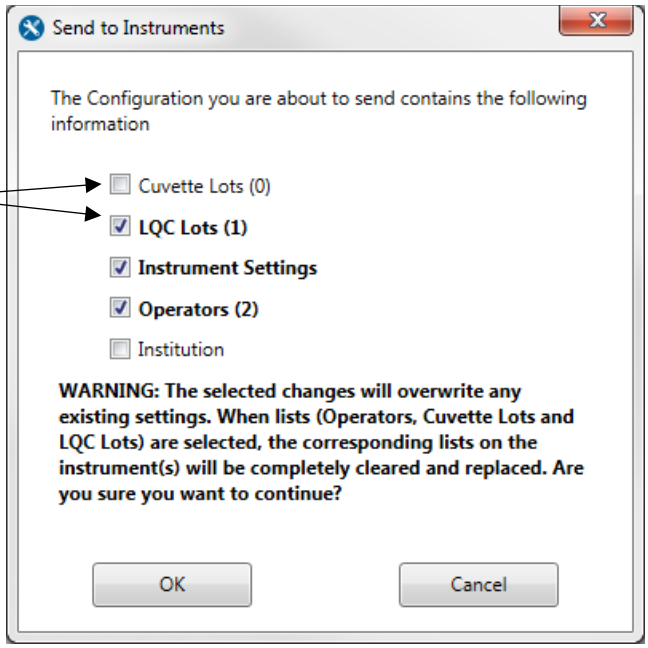


Figure 42 – The Send to Instruments dialog box

Export Configuration Data

During a Configuration Manager session, configuration data that is created exists in the computer's volatile memory (RAM). This data can be exported to a configuration file.

1. On the Home screen, in the lower right corner, click **Export to File**.

   The **Export to File** dialog box is displayed with a checkbox next to each type of configuration data. If the text of a data item is **bold**, that type of data was changed in the session.

2. Check the data items that need to be exported.
3. Click **OK**.
4. Choose a location to save the file to, edit the filename, and click **Save**.

   Configuration data is saved in the configuration file (.cfg). If this file is imported, the data in it will be loaded into the Configuration Manager session.

Import Configuration Data

Configuration data can be imported from a configuration file (.cfg) into a Configuration Manager session and can be edited before it is sent to instruments.

To import data: On the Home screen, in the lower right corner, click **Import From File**.

Generate a Configuration Report

A report that contains all of the configuration data on an instrument can be generated. After the report is generated, it can be saved in a comma-separated value (.csv) file and opened in a spreadsheet.

1. Log in to Configuration Manager as a Supervisor.
2. Ensure the instrument that for which the report needs to be created is connected to the network.

NOTE If an IP address is displayed on the instrument screen, the instrument is connected to the network.

3. Under **Instrument Selection and Control**, in the drop-down list, select the instrument or group for which the report needs to be created.
4. The icon to the right of the instrument name indicates whether a network connection is established between the instrument and Configuration Manager. Is a connection established?

	**Yes**, a network connection is established. Go to the next step.
	No, a network connection is not established. See *Configure Firewalls* on page 54

5. Click **Configuration Report**.

   The configuration report is displayed. If necessary, maximize the window or drag a corner of it to resize it.

6. To save the configuration report to a .csv file, click **Export**. The file can be opened in a spreadsheet.

Log Files

When Supervisors use Configuration Manager, system activity is recorded in log files. Accriva Diagnostics recommends that customers review log files every 30 days as part of a Quality Assurance plan.

Audit Log File

To view the audit log file (`ccm-audit.log`), log in as a Supervisor and click the **Audit Log** button. To export the audit log to a text (.txt) file, click **Export Log**. Time-stamped versions of this file are located in the following folder:

C:\ProgramData\InstrumentationLaboratory\CCM

NOTE The encrypted hidden log files created on one computer cannot be decrypted using LogDecrypter program on another computer.

Debug Log File

The debug log file (`ccm-debug.log`) records POCT1-A messages that are sent between the instrument and Configuration Manager. Instrumentation Laboratory Technical Support can use the information in the event that a problem with the instrument occurs. Time-stamped versions of this file are located in the following folder:

C:\ProgramData\InstrumentationLaboratory\CCM

Update the Instrument Software

Use Configuration Manager to update the instrument software (firmware).

1. Get the build package that contains the latest instrument software from Accriva Diagnostics:

   `GEM100<build number>.zip`

2. Log in to Configuration Manager as a Supervisor.
3. Ensure the instrument that needs to be updated is connected to the network.

   NOTE If an IP address is displayed on the instrument screen, the instrument is connected to the network.

4. Under **Instrument Selection and Control**, in the drop-down list, select the instrument that needs to be updated.
5. The icon to the right of the instrument name indicates whether a network connection is established between the instrument and Configuration Manager. Is a connection established?

	**Yes**, a network connection is established. Go to the next step.
	No, a network connection is not established. See *Configure Firewalls* on page 54

6. Click **Update Software**.
7. Select the instrument software build package:

   `GEM100<build number>.zip`

8. Click **Open**.

   The updating process begins. During the process, the instrument is automatically shut down and restarted twice, so allow time for the process to run.

Chapter 5: Configure a POCT1-A Network

A POCT-1A network allows an instrument to communicate with other POCT-1A compliant devices.

1. Contact a Network Administrator to get the IP address and TCP port that the instrument will use when it is connected to the POCT-1A network.
2. Select > **Supervisor Settings** > **POCT1-A Network Settings**.

   A dialog box that allows the IP address and TCP port to be entered is displayed. See Figure 44.
3. Enter the **IP Address**.
4. Enter the **TCP Port**.

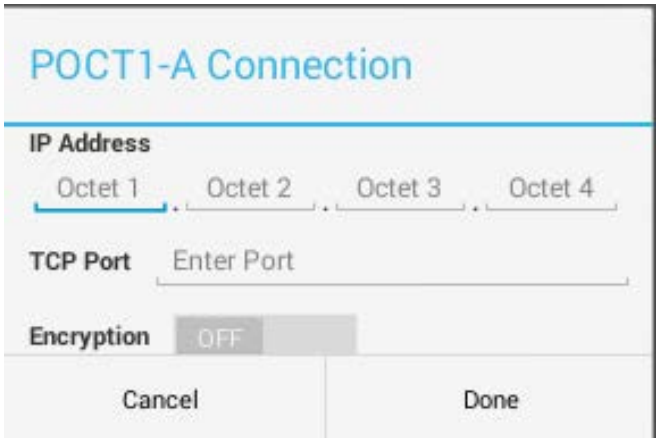


Figure 43 – Configuring a POCT-1A network

For supporting encryption of POCT1-A data in transit, a trusted certificate must be installed on the device that runs POCT1-A network server. For more information, *see chapter 4: Configuration Manager (Install Encryption Certificate).*

Chapter 6: Patient Testing

About Patient Testing

BIOHAZARD Running a patient test requires that human blood samples be handled. Strictly adhere to all biohazard safety guidelines for handling and disposing of human blood.

BIOHAZARD Cartridges are for single use only. Used cartridges may create potential biohazard outcomes.

QC Lockout

If patient test lockout is in effect, Operators are prevented from running patient tests until the lockout is cleared. For more information, see *QC Lockout* on Chapter 7.

Cartridges

Use only *GEM® Hemochron™ 100* cartridges. Use the appropriate type of cartridge (either ACT+ or ACT-LR) for the type of test that will be run. Cartridges are for single use only. Do not reuse them.

Patient Samples

Operators must not prepare the patient sample until the instrument prompts them to apply the sample to the cartridge. If an Operator prepares the sample too early, it will begin to clot. A patient sample must not contain any added anticoagulant during or after blood draw (do not use collection tubes that contain anticoagulant).

Test Results

At the end of the test, when the results are displayed, an Operator can add a user note to the test record and view details of the test result.

Results that are within the analytical range of the test are reported in units of Celite seconds. The analytical range for each test is set at the factory and cannot be changed. Results that are outside the analytical range of the test are not reported and are logged as an error.

- **Out of Range Low** – the result is less than the analytical range
- **Out of Range High** – the result is greater than the analytical range

If a result is out of range, immediately run the test again. If the result is still out of range, see *Chapter 9: Service, Maintenance, and Troubleshooting*.

Results of previous patient tests are stored in the instrument database. To view them, see *Chapter 8: Database*.

Run a Patient Test

BIOHAZARD Running a patient test requires the handling of human blood samples. Strictly adhere to all biohazard safety guidelines for handling and disposing of human blood.

NOTE Operators must not prepare the patient sample until the instrument prompts them to apply it to the cartridge. If an Operator prepares the sample too early, it will begin to clot.

1 If a cartridge is in the instrument, remove it and dispose of it.

2 On the Home screen, select .

If an ESV test runs and is displayed, go to the next step.

- If the ESV test passes, go to the next step. If it fails, run an EQC test. If the EQC test fails again, contact Instrumentation Laboratory Technical Support.
- If a warning message is displayed, patient test lockout is in effect. See Figure 45. Have a Supervisor clear the lockout and then repeat the test. See *QC Lockout* on page 119.

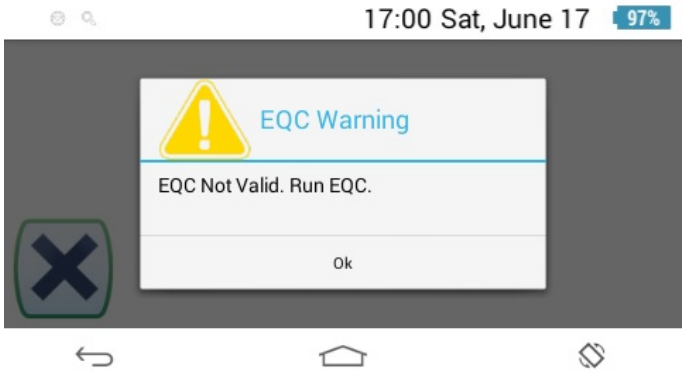


Figure 44 – Example of a warning message. Patient test lockout is in effect.

3 When is displayed, insert a cartridge. Use the appropriate cartridge (either ACT+ or ACT-LR) for the type of test that needs to be run.

NOTE To cancel the test at any time, select .

The instrument checks the cartridge and reads the barcode label . The instrument reads only the first eight characters of the cartridge lot

number on the barcode. It does not read additional characters, such as **-P1**.

4 When prompted to enter the OID, manually enter it, scan it, or accept the previously entered OID. If necessary, confirm the entry. If necessary, enter the Operator password.

5 If prompted to enter the PID, manually enter it, scan it, or accept the previously entered PID.

6 Wait while the instrument warms the cartridge  .

7 When  is displayed, apply the sample to the cartridge.

- A five-minute countdown timer is displayed. Within five minutes, add the sample to the cartridge and start the test. After five minutes, the test times out. If it does, dispose of the cartridge and run the test again using a new cartridge.
- Keep the instrument level. Ideally, set it on a level surface.
- Fill the sample well from the bottom up by letting the drop fall directly into the center of the well, rather than let the sample flow down from the outer edge.
- Add enough sample so that the lower wall of the center well is completely filled. Usually one large drop or two small drops is enough.
- If the meniscus (convex crescent) of the sample extends above the wall, the well is overfilled. If this happens, push the excess sample into the overflow area.
- Do not generate air bubbles in the sample well.

8 Select to run the test.

9 Wait while the instrument does the following:

a) displays  , indicating that the sample volume is adequate. If a message that indicates there is a problem with the sample is displayed, repeat the test using a new cartridge.

b) moves the sample from the sample well into the test channel of the cartridge and checks the integrity of the reagent

c) measures ACT (a counter shows the number of seconds)

d) displays the test result. Results are displayed as ACT Celite-equivalent value (CEV) in seconds, not real-time seconds. If the result is out of range, repeat the test. If the result is still out of range, see *Chapter 9: Service, Maintenance, and Troubleshooting*.

NOTE After  is displayed, Operators can remove the cartridge at any time, but before they do, they should read all of the next step including the notes below it.

10 Operators can **add a user note** to the test record or **view details** of the test result.

NOTES

- **Add a user note** – A user note can be added to the test record before the cartridge is removed. To add a user note,  select the User Note icon, enter the note (30 characters maximum), select **Done**, and then go to the next step.
- **View details** – (If the cartridge has not been removed)

  To view details of the test result, select the Information icon.  Detailed information about the test result is displayed. Go to the next step.

BIOHAZARD Cartridges are for single use only. Do not reuse them. Used cartridges contain biohazardous waste. Strictly adhere to all biohazard safety guidelines for handling and disposing of human blood.

11 Remove the cartridge and dispose of it in a biohazardous waste container.

NOTE Results of previous patient tests are stored in the instrument database. To view them, see *Chapter 8: Database*.

Chapter 7: Quality Control

Introduction to Quality Control (QC)

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and other regulatory agencies recommend that medical and laboratory instrumentation be enrolled in a quality assurance program adequate in maintaining accurate and reliable performance of the equipment. Complete records of such quality control must be kept.

Routine quality control testing should be part of a comprehensive quality assurance program. Quality control testing of the instrument consists of the following operations:

- Testing system performance and verifying system temperature using internal electronic system verification (ESV).
- Testing cartridges in accordance with the package insert for each assay using two levels of liquid controls.

NOTE The instrument is calibrated at the manufacturing facility to test and verify all functions. The instrument is also self-calibrating, as all instrument functions are continuously monitored and verified by the instrument software when a test is run. The instrument does not require additional calibration by the user.

There are two types of QC testing:

- **Electronic QC (EQC) testing** – During EQC testing, the instrument runs an internal test. This test does not check the liquid assay function, so a cartridge and sample material are not used. For more information, see *Electronic Quality Control (EQC) Testing* on page 115
- **Liquid QC (LQC) testing** – This test checks the liquid assay function of the instrument using sample material and a cartridge.
  - For information about cartridges, see *Cartridges* on Chapter 1.
  - For information about sample material, see *Control Material* on Chapter 7.
  - For information about LQC testing in general, see *Liquid Quality Control (LQC) Testing* on page 117

Electronic Quality Control (EQC) Testing

CAUTION If the EQC test feature is enabled, the instrument will require that EQC tests be run at regular intervals. This feature is enabled at the factory. Although it is possible to disable it, the manufacturer recommends that it remain enabled. The decision to enable or disable this feature shall be determined by and is the responsibility for each institution.

Levels of EQC Testing

There are three levels of EQC testing. The test at each level checks different functions of the instrument:

- Electronic system verification (ESV)
- Level 1 testing
- Level 2 testing

ESV Testing

An ESV test is commonly known as a power-on self-test (POST test). It checks to ensure enough battery power remains to run an LQC test and a patient test and checks the following functions of the instrument:

- Electronic functions (internal voltage, memory, connectivity)
- Electromechanical functions (heater, vacuum pump)
- The optical function that analyzes a sample during an LQC test and a patient test

An ESV test automatically runs under the following conditions:

- When an Operator powers on the instrument
- When an Operator runs a QC test
  - When an Operator runs an EQC test. See *Run an EQC Test* on Chapter 7*.*
  - When an Operator runs an LQC test. See *Run an LQC Test on* Chapter 7*.*
  - When an Operator runs a patient test. See *Chapter 6: Patient Testing*.

Level 1 and Level 2 Testing

An EQC testing is done at 2 levels, the difference between them is the duration of the test. Both Level 1 and 2 executes the same tests as ESV, but has additional tests more focused on critical instrument functions such as timing, optical, electrical, and mechanical functions. As a result, EQC testing is more complex and take longer.

EQC Test Results

The result of an EQC test is either **Passed** or **Failed**. When an EQC test is complete, Operators can view details of the result. Details include a list of specific subtests that were run and the state (Passed or Failed) of each subtest.

Liquid Quality Control (LQC) Testing

A LQC test checks the assay function of the instrument. During this test, the instrument prompts the Operator to insert a cartridge into the instrument and apply sample material to it.

CAUTION If the LQC feature is enabled, the instrument will require that LQC tests be run at regular intervals**.** This feature is disabled at the factory, but it can be enabled using Configuration Manager. The decision to enable or disable it shall be determined by and is the responsibility of the institution.

BIOHAZARD Cartridges are for single use only. Used cartridges may create potential biohazard outcomes. **All used test cartridges and directCHECK vials should be considered as potentially infectious, handled with care and disposed of in accordance with standard medical waste disposal policy.**

Control Material

For Control Material, use directCHECK® Quality Controls. The Control material and cartridge must match the type of LQC test that needs to be run. See *Table 17*.

Table 17 – LQC Testing: Test Types, Sample Material, and Cartridges

Test Type	Sample Material Catalog Number	Cartridge Catalog Number
ACT+		
• Normal (Level 1)	DCJACT-N	GACT+
• Abnormal (Level 2)	DCJACT-A	GACT+
ACT-LR		
• Normal (Level 1)	DCJLR-N	GACT-LR
• Abnormal (Level 2)	DCJLR-A	GACT-LR

Acceptable performance ranges for sample material are included in the package insert. For assistance, contact an Instrumentation Laboratory representative.

LQC Test Results

The result of an LQC test is either **Passed** or **Failed**. If the ACT value is in the expected performance range, the test passes. If the ACT value is not in the expected performance range, the test fails. When an LQC test is complete, Operators can view details of the result.

QC Lockout

The QC lockout feature prevents Operators from running a patient test if the instrument does not meet the performance range. There are two kinds of lockout:

- **Patient test lockout** – lockout that prevents Operators from running patient tests. This occurs when a QC test fails or when an interval timer expires
- **QC test lockout** – lockout that prevents Operators from running additional QC tests after the first QC test fails

Lockout that Prevents Operators from Running Patient Tests

Patient test lockout occurs under the following conditions:

- If a QC test fails (EQC or LQC)
- If the instrument is configured so that a QC test must be run at specified intervals and the interval timer expires

Lockout Based on a Failed QC Test

If a QC test fails, run the test again. If it continues to fail, contact Instrumentation Laboratory Technical Support.

Lockout Based on An Expired Interval Timer

A Point-of-Care Coordinator (POCC) or Supervisor can use Configuration Manager to set a timer on the instrument that will run for a specified period. When the timer expires, patient test lockout occurs. This is called interval lockout. When interval lockout occurs, Operators are not allowed to run a patient test until a Supervisor clears the lockout. See *Clearing a Lockout* on page 121

The POCC specifies a separate interval for EQC testing and LQC testing.

- **EQC interval** – The factory default interval is eight hours.
- **LQC interval** – The LQC lockout feature is disabled by default (the factory setting), so LQC testing based on interval time will never be required. To set an LQC interval time, the POCC must first enable LQC lockout.

The POCC can allow Operators to run as many as 240 patient tests after the interval timer expires (after lockout *would have* occurred), effectively temporarily overriding interval lockout. After the interval timer expires, the instrument begins to count the number of patient tests that have been run. When the allowed number of patient tests have been run, lockout occurs. At this point, the lockout must be cleared before Operators can continue to run patient tests.

To specify QC testing intervals, the POCC must log in to Configuration Manager as a Supervisor. See *Chapter 4: Configuration Manager*.

Lockout that Prevents Operators from Running QC Tests

The instrument counts the number of failed QC tests. A POCC can allow Operators to run as many as nine additional failed QC tests after the first QC test fails. The POCC specifies the number of additional tests separately for EQC tests and LQC tests.

- **Additional failed EQC tests allowed** – By default (when the instrument is in factory condition), after an EQC test fails, Operators can run two more failed EQC tests. If they run another EQC test and it fails, lockout occurs.
- **Additional failed LQC tests allowed** – By default (when the instrument is in factory condition), LQC lockout is disabled. If an LQC test fails, Operators are allowed to run an unlimited number of additional failed LQC tests. To restrict the number of additional failed LQC tests that Operators are allowed to run, the POCC must first enable LQC lockout.

When the allowed number of additional failed QC tests have been run, QC lockout occurs (Operators are not allowed to run QC tests). At this point, a POCC or Supervisor must either log in to the instrument and run a passing test or clear a setting that will restore the instrument to its normal state. When the lockout is cleared, Operators can continue to run QC tests.

To specify the number of additional failed QC tests that Operators can run after the first QC test fails, the POCC must log in to Configuration Manager as a Supervisor. See *Chapter 4: Configuration Manager*.

Clearing a Lockout

To clear a lockout, a Supervisor or POCC must intervene as follows:

- **Failed QC test** – To clear a lockout based on a failed QC test, a Supervisor can run a passing QC test. In an emergency, the Supervisor can use the instrument menus or Configuration Manager to clear the lockout.
  - To clear a lockout using the instrument menus, see *Reset Counters* on page 52 Chapter 3.
  - To clear a lockout using Configuration Manager, see *Table 13* and *Table 14* on Chapter 4*.* These tables contain a description of fields named **Clear EQC Failure Count** and **Clear LQC Level (1/2) Failure Count**. These fields are used for resetting a counter that clears the lockout.
- **Expired interval timer** – To clear a lockout based on an expired interval timer, a Supervisor must log in to the instrument to allow the Operator to run the QC test. If the test passes, the lockout is cleared and the interval timer is reset.

Run an EQC Test

BIOHAZARD Operating the instrument requires the handling of human blood samples. Strictly adhere to all biohazard safety guidelines for handling and disposing of human blood.

1. If a cartridge is in the instrument, remove it and dispose of it.
2. On the Home screen, select QC.
3. Select the **EQC** tab. See Figure 46.
4. Select ▶.

   The EQC test starts. Information about test progress is displayed. Operators can abort the test at any time. See Figure 46.

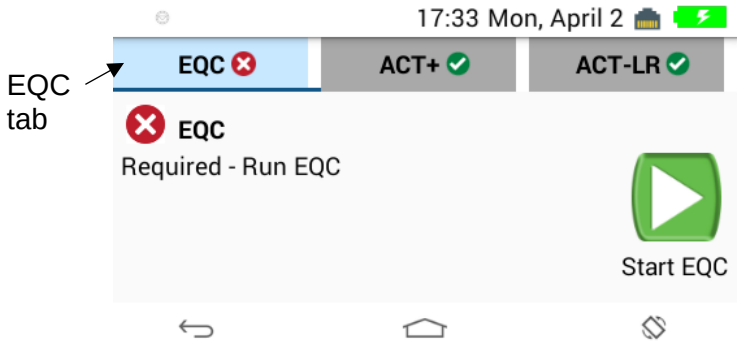


Figure 45 – Quality Control screen. The EQC tab is selected.

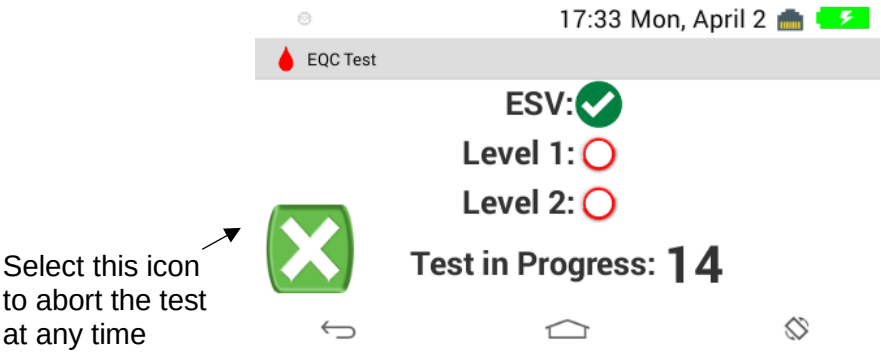


Figure 46 – An EQC test in progress. Operators can abort the test at any time.

5 Wait until the result of the EQC test is displayed.

- **Passed** – If the test passes, go to the next step. See Figure 48.

Figure 47 – EQC test result: Passed

- **Failed** – If the test fails, run the test again. See Figure 49. If the test continues to fail, see *Chapter 9: Service, Maintenance, and Troubleshooting*. If the test fail again, contact Instrumentation Laboratory Technical Support.

Figure 48 – EQC test result: Failed

6 Choose the appropriate option:

- **End the test** – Press  . The Home screen is displayed. Details of the test result can still be viewed using the Database feature. See *Chapter 8: Database*.
- **View** details of the test result – Select  . Details of the test result are displayed. See Figure 50.

NOTE The results of previous EQC tests are stored in the instrument database. To view them, see *Chapter 8: Database*.

Run an LQC Test

BIOHAZARD Running an LQC test requires the handling of biohazardous material. Strictly adhere to all biohazard safety guidelines for handling and disposing of biohazardous material.

1 Have directCHECK® Quality Controls ready for use as sample material during this test.

NOTE Operators must not prepare the sample material until the instrument prompts them to apply it to the cartridge. If the sample material is prepared too early, premature clotting will cause erroneous results.

2 Ensure the label on the sample material packaging is not damaged. If the label is damaged, it might be unreadable; use another package.

3 If a cartridge is in the instrument, remove it and dispose of it.

4 On the Home screen, select QC.

The Quality Control screen is displayed.

5 Choose the appropriate option, depending on the status of EQC.

- **LQC testing is allowed** – If ✓ is displayed for EQC, LQC testing is allowed. See Figure 51. Go to the next step.

Figure 49 – The Quality Control screen. LQC testing is allowed because the previous EQC test passed.

- **LQC testing is not allowed** – If ⚠ or ✗ is displayed for EQC, LQC testing is not allowed. EQC is in this state either because the EQC interval time expired or because the previous EQC test failed. See Figure 52.

Figure 50 – The Quality Control screen. LQC testing is not allowed, either because the EQC interval timer expired or because the previous EQC test failed.

Run an EQC test by selecting QC. For more information, see *Run an EQC Test* on page 122 If the test passes, go to the next step. If the test fails, contact Instrumentation Laboratory Technical Support.

6 Select the appropriate tab (**ACT+** or **ACT-LR**) for the type of LQC test that needs to be run.

7 Select QC to start the test.

An ESV test automatically runs.

NOTE To cancel the test at any time, select ✗.

8 If prompted to enter the OID, do one of the following:

- Manually enter it
- scan it
- Accept the previously entered OID (if the instrument was configured this way)

The dialog box for entering LQC lot information is displayed. See Figure 53.

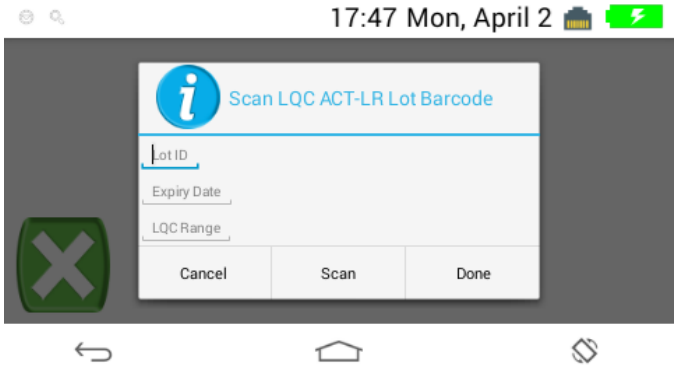


Figure 51 – Dialog box for entering LQC lot information

9 Enter LQC lot information.

NOTES

- To manually enter information into a field, touch the text in the field. The virtual keyboard is displayed.
- If information from the previous test is already in the fields, reuse it or overwrite it with new information.
  - **Reuse** – To reuse the information, select **Done**. If prompted to enter the OID or password, enter it and select **Ok**.
- **Do not reuse** – To overwrite the information, select the **Lot ID** field and edit the value in it. Do the same for the **Expiry Date** field and the **LQC Range** field. For the Expiration Date manually enter only the year and month to be recorded as it always expires at the end of the month. If information must be scanned, select **Scan** and scan the barcode label.

10 Verify that the LQC lot information was entered correctly. To do this, compare the information in the dialog box with the human-readable information on performance range label.

11 Select **Done**.

12 Is an error about incorrect LQC lot information displayed?

- **No** – Go to the next step.
- **Yes** – Ensure that the information that was entered exists in Configuration Manager and then go to the next step. See *Chapter 4: Configuration Manager*.

13 When  is displayed, insert a cartridge, but do not obtain the control material until instructed to do so later in this procedure.

NOTES

- A five-minute countdown timer is displayed. Within five minutes, add the sample to the cartridge and start the test. After five minutes, the test times out. If it does, dispose of the cartridge and run the test again using a new cartridge.
- Insert the appropriate cartridge (ACT+ or ACT-LR) for the type of LQC test that needs to be run.
- When inserting the cartridge, fully insert it into the slot.

CAUTION Do not obtain the blood sample until the instrument displays the warming  icon. If the sample is obtained too early, premature clotting may adversely affect result.

14 Wait while the instrument does the following:

- runs an ESV test
- reads the cartridge barcode
- displays  (the instrument is preparing for the test)
- displays  (the instrument is warming the cartridge)

NOTES

- If the ESV test fails, run an EQC test. If the EQC test fails, contact Instrumentation Laboratory Technical Support.
- The instrument reads only the first eight characters of the cartridge lot number on the barcode. Additional characters, such as **-P1**, are not read.

15 While the cartridge is being warmed, prepare the control material for use by following the instructions provided on the package insert.

NOTE In the next step, when the sample is applied to the cartridge, keep the instrument level. Ideally, set it on a level surface.

16 When  is displayed, apply the sample to the cartridge.

- Fill the sample well from the bottom up by using the extended ridge on the sample well as described in the package insert.
- Add enough sample so that the lower wall of the center well is completely filled. Usually one large drop or two small drops is enough.
- If the meniscus (convex crescent) of the sample extends above the wall, the well is overfilled. If this happens, push the excess sample into the overflow area.
- Do not generate air bubbles in the sample well.

17 Select  to run the test.

18 Wait while the instrument does the following:

a) Displays  , indicating that the sample volume is adequate. If a message that indicates there is a problem with the sample is displayed, repeat the test using a new cartridge.

b) Moves the sample from the sample well into the test channel of the cartridge and checks the integrity of the reagent

c) Measures ACT (a counter shows the number of seconds)

d) Displays the test result. See Figure 54.

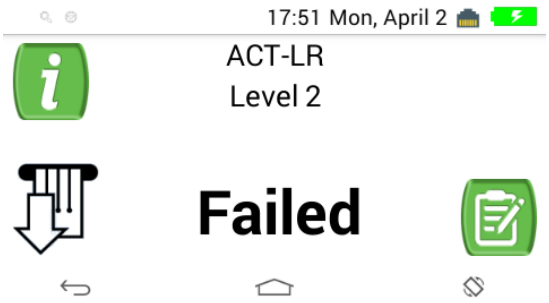


Figure 52 – LQC test: Two possible results

19 What is the result?

- **Passed** – Go to the next step.
- **Failed** – Review the instructions that came with the sample material. Run the test again with a new cartridge. If the test fails again, contact Instrumentation Laboratory Technical Support.
- **An error message is displayed** – For an example, see Figure 55. Review the instructions that came with the sample material. Run the test again with a new cartridge. If the test fails again, see *Chapter 9:*

Service, Maintenance, and Troubleshooting. If the test continues to fail, contact Instrumentation Laboratory Technical Support.

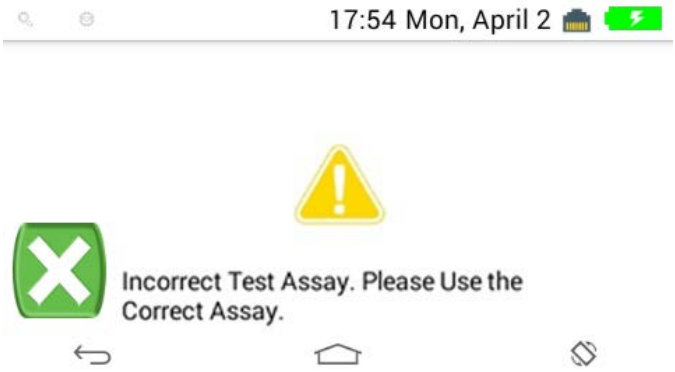


Figure 53 – LQC Test: Example of an Error Message

NOTE After  is displayed, Operators can remove the cartridge at any time, but before they do, they should read all of the next step including the notes below it.

20 Operators can **add a user note** to the test record and **view details** of the test result.

NOTES

- **Add a user note** – A user note can be added to the test record before the cartridge is removed. To add a user note, select the  User Note icon, enter the note (30 characters maximum), select **Done**, and then go to the next step.
- **View details** – (If the cartridge has not been removed)

  To view details of the test result, select the Information icon. 
  Detailed information about the LQC test result is displayed. Results are displayed as ACT Celite-equivalent
  value (CEV) in seconds, not real-time seconds. Go to the next step.
- If the cartridge has been removed, details of the test result can still be viewed by using the Database feature. See *Chapter 8: Database*.

BIOHAZARD Cartridges are for single use only. Do not reuse them. Used cartridges contain biohazardous waste. Dispose of them in a biohazardous waste container in accordance with local regulations.

21 Remove the cartridge and dispose of it in a biohazardous waste container.

NOTE The results of previous LQC tests are stored in the instrument database. To view them, see *Chapter 8: Database*.

Chapter 8: Database

Introduction

Test results (patient tests, EQC tests, and LQC tests) are saved in the instrument database. As many as 100,000 test results can be saved. Results can be viewed, cleared (deleted), and sent to a computer on the network.

When viewing results, the following viewing options are available:

- Show the total number of records
- Show all records
- Show records sorted by
  - Patient
  - Operator
  - Date
  - Cartridge lot number
  - LQC lot number

View, Send Records

1 Select  .

A list of test results is displayed.

2 In the upper right corner, select to open the Database menu. See Figure 56.

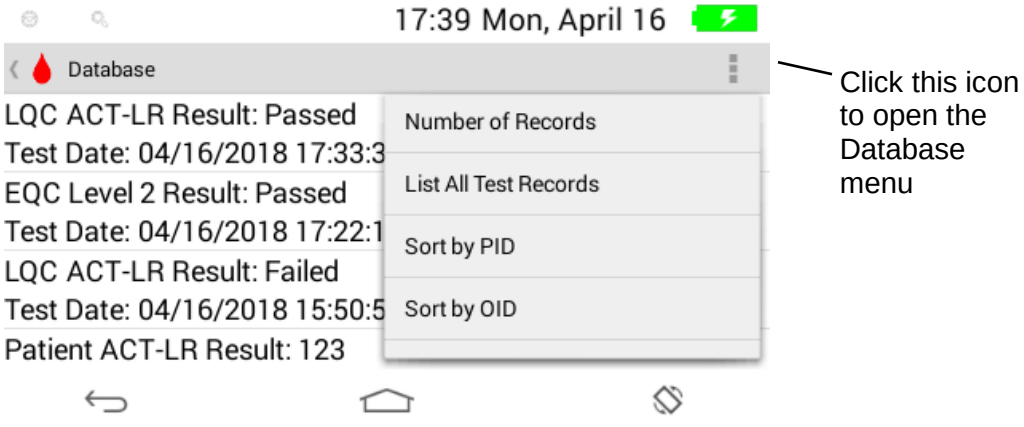


Figure 54 – The Database menu

3 Select the appropriate option. See Table 18.

Table 18 – Options on the Database menu

Option	Description
Number of Records	Show the total number of records in the database
List All Test Records	List all of the records in the database
Sort by PID	Sort the records by PID
Sort by OID	Sort the records by OID
Sort by Date	Sort the records by date
Sort by Cartridge Lot	Sort the records by cartridge lot
Sort by LQC Lot	Sort the records by LQC lot
Send All	Send all records to the network

Chapter 9: Service, Maintenance, and Troubleshooting

Routine Maintenance

BIOHAZARD When cleaning the instrument, strictly adhere to all biohazard safety guidelines for handling and disposing of human blood.

Observe the following for routine maintenance:

NOTE Before cleaning the instrument, put on personal protective equipment (gloves, eye protection and a laboratory coat or jacket) before handling the instrument.

- Do NOT clean the instrument with solvents or strong cleaning solutions. They might damage the plastic components of the instrument.
- To remove residual dried blood or other foreign matter from the exterior of the instrument, use PDI Super Sani-Cloth® Germicidal Disposable Wipes or equivalent wipes. Allow the surface to remain moistened for 2 minutes.
- Inspect the exterior of the instrument and clean it under the following conditions:
  - regularly according to your institution's schedule
  - before sending the instrument to Accriva Diagnostics for service
  - before transporting the instrument to another department in your institution or to another institution
- Use PDI Super Sani-Cloth® Germicidal Disposable Wipes or equivalent disinfectant to clean and disinfect affected areas that are contaminated with blood.
- Besides normal cleaning, routine maintenance is not required.
- Safely handling a spill depends upon the material that was spilled. If unsure about how to safely handle a spill, consult the standard operating procedures for your institution.
- When handling samples, use universal safety precautions.
- To avoid spreading contamination to laboratory personnel or equipment, spills should be immediately disinfected with an appropriate disinfectant solution.

Analyzer repair

In the unlikely event that the GEM® Hemochron™ 100 requires repair, the analyzer may have to be sent to your authorized Service Center.

Contact to your IL technical support department in order to determine if the unit requires repair.

NOTE:

Use the original packaging to ship the GEM® Hemochron™ 100 **or contact your local service center for shipping packaging. This will prevent damage from occurring to your instrument.**

If your units needs to be returned, or needs to be shipped, the analyzer has to be decontaminated.

Troubleshooting

Cannot Connect to Instruments

If Configuration Manager cannot communicate with instruments over the network:

- For a **wired** (Ethernet) connection: Ensure an Ethernet cable is connected to the instrument.
- For a **wireless** (Wi-Fi) connection: Ensure a Wi-Fi connection been established between the instrument and the network. See *Connect to a Visible Wireless Network* or *Connect to a Hidden Wireless Network* on page 48

If Configuration Manager still cannot communicate with an instrument, a firewall might be blocking the connection. See *Configure Firewalls* on page 54 4.

Error Messages

If a failure occurs when operating the instrument, an error message is displayed. See Figure 58.

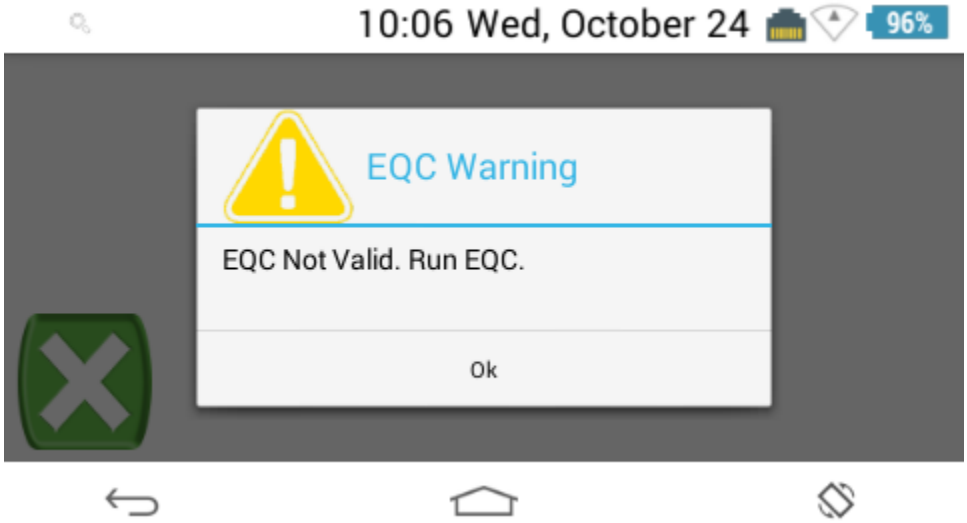


Figure 58- Error message

For a list of error messages, their causes, and the corrective action to take, see Table 19.

For instructions on resolving errors related to cartridges, refer to the cartridge package insert.

If a particular error message is displayed repeatedly, write down the error message and contact Instrumentation Laboratory Technical Support. Have

the instrument serial number and cartridge lot number ready when contacting Instrumentation Laboratory.

Table 19 – Error Messages

Common Error Message	Cause and Corrective Action
Sample Too Large. Repeat Test.	The sample size is too large to obtain a result. Repeat the test using a new cartridge with the instrument on a level surface.
Sample Too Small. Repeat Test.	The sample size is too small to obtain a result. Repeat the test using a new cartridge.
Premature Sample Error. Repeat Test.	The sample was not seen or was added too early. Repeat the test using a new cartridge.
Sample Not Found	The test has been started before the sample was applied onto the cartridge. Repeat the test using a new cartridge.
Out of Range High	The sample does not clot or clots in greater time than the allowable range of the assay.
Out of Range Low	The sample clots in a time less than the allowable range for the assay.
Aborted Test	The cartridge was removed during testing. Repeat the test using a new cartridge.
Time Out	Five minutes elapsed between inserting cartridge and adding the sample. Repeat the test using a new cartridge.
Barcode Fault	The cartridge barcode cannot be read. Re-insert the cartridge or replace it.
Expired Lot	The cartridge lot is expired. Repeat the test using non expired cartridge.
Used Cuvette Detected	The instrument detects a used cartridge. Repeat the test using a new cartridge.
EQC Test Failed	Any one of the individual tests performed during EQC fails
Channel Not Found/Camera Failure	The instrument fails to find the image of sample channel or place the photo sites within the camera image. Repeat the test using a new cartridge.
Invalid Entry	The OID, PID, LQC lot number, or supervisor password that was entered is incorrect. Check and re-enter the information.
Invalid Date and Time	The date and time at power on is earlier than during the previous use. Check the date and time setting.

Common Error Message	Cause and Corrective Action
Low Battery	The battery charge level is less than 20% (+/- 2%). Or less than the expected amount to run three tests. Charge the battery
Critically Low Battery	A Critically Low Battery message shall be displayed when the battery charge level is 10% (+/-).Charge the battery
BATTERY DEAD. CHARGE BATTERY.	The battery capacity is not adequate to run a test. Charge the battery.
BATTERY FAULT. CALL TECHNICAL SUPPORT.	The battery temperature is out of range. Contact Instrumentation Laboratory Technical Support.
Temperature Timeout	The cartridge does not reach the desired temperature. Repeat the test using a new cartridge.
Unsupported Assay	The test cartridge is not supported by the system. Repeat the test using a new cartridge.
CLOCK FAULT. CALL TECHNICAL SUPPORT.	A real time clock fault has occurred. Contact Instrumentation Laboratory Technical Support.
DATABASE FAULT. CALL TECHNICAL SUPPORT.	A database access fault occurred. Contact Instrumentation Laboratory Technical Support.
DETECTOR FAULT. CALL TECHNICAL SUPPORT.	The photo detector intensity is too high or too low. Contact Instrumentation Laboratory Technical Support.
EXTERNAL DC HIGH. UNPLUG. CALL TECHNICAL SUPPORT.	The external DC voltage is too high. Unplug the AC/DC Power Module. Contact Instrumentation Laboratory Technical Support.
FACTORY TESTS FAULT. CALL TECHNICAL SUPPORT.	Instrument self testing was not completed. Contact Instrumentation Laboratory Technical Support.
INTERNAL POWER FAULT. CALL TECHNICAL SUPPORT.	A power supply failure occurred. Contact Instrumentation Laboratory Technical Support.
Low Battery	The battery charge level is less than 20% (+/- 2%). Or less than the expected amount to run three tests. Charge the battery
Critically Low Battery	A Critically Low Battery message shall be displayed when the battery charge level is 10% (+/-).Charge the battery
LOW PRESSURE	The pressure is too low. Repeat the test using a new cartridge.
Network Fault	Communication with the external computer was unsuccessful. Check the communication cables and settings.

Common Error Message	Cause and Corrective Action
POCT Fault	The Instrument cannot retrieve a record from the database to send.
NO BATTERY. CONNECT BATTERY.	The battery is not connected properly. Check the battery connection.
PHOTO FAULT	A light level was detected when LEDs were off. Contact Instrumentation Laboratory Technical Support.
POCT FAULT. TRY AGAIN.	Communication of the test result(s) was unsuccessful. Retry sending the result(s).
PRESSURE FAULT	A pressure transducer error occurred. Contact Instrumentation Laboratory Technical Support.
PUMP FAULT. CALL TECHNICAL SUPPORT.	The pump home sensor could not be detected. Contact Instrumentation Laboratory Technical Support.
SOFTWARE FAULT. CALL TECHNICAL SUPPORT.	A software error occurred. Contact Instrumentation Laboratory Technical Support.
TEMPERATURE FAULT. CALL TECHNICAL SUPPORT.	The temperature sensor is out of range. Contact Instrumentation Laboratory Technical Support.

Disposing of Products

Disposing of a Battery

Dispose of the battery in accordance with local regulations for lithium-ion batteries.

Disposing of an Instrument

Treat the instrument as biohazard and decontaminate it.

If the battery is in the instrument, adhere to local regulations for the disposal of lithium-ion batteries.

Treat the instrument as electronic waste per local regulations.

Regulatory Compliance

The *GEM® Hemochron™ 100* instrument complies with the following safety standard requirements and directives:

CAN/CSA C22.2 No. 61010-1:2012
CAN/CSA C22.2 No. 61010-2-101:2009
CAN/CSA C22.2 No. 61010-2-010:2009

UL 61010-1:2008

IEC/EN 61010-1:2010
IEC/EN 61010-2-081
IEC/EN 61010-2-010:2003

EN 55011:2009 A1:2010, Group 1 Class A
EN 61326-1:2006, Class A limit
EN 61326-1:2006, Table 2 Limits

This instrument has been designed and tested to CISPR 11 Class A. In a domestic environment it might cause radio interference. It might be necessary to mitigate the interference.

It is the responsibility of Accriva Diagnostics to provide electromagnetic compatibility information to the customer or users. It is the user's responsibility to insure that a compatible electromagnetic environment for the instrument can be maintained so the device will perform as intended.

Do not use this instrument in close proximity to sources of strong electromagnetic radiation (that is, unshielded intentional RF sources), as these may interfere with proper operation.

Protection Against Ingress of Liquids: Ordinary (no protection as defined by IEC 60529)

Product Cleaning and Disinfection: Only according to recommendations of the manufacturer's accompanying documentation. Use PDI Super Sani to clean and disinfect the instrument

Mode of Operation Of Equipment: Continuous

Degree of Safety of Application in the Presence of Flammable Anesthetic Mixture With Air, Oxygen or Nitrous Oxide: **Not Suitable**

NOTE As defined in the above standards, the classification of **Not Suitable** is not intended to indicate that the instrument is not suitable for

use in an Operating Room (OR) environment. Rather, it is intended to indicate that the instrument is not suitable for use in the direct presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide.

All relevant documentation is kept on file at Accriva Diagnostics.

The GEM® Hemochron™ 100 complies with applicable regulations:

- **FCC Interference Statement (Part 15.105 (b))**

This equipment has been tested and found to comply with the limits for a Class B 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 equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

Reorient or relocate the receiving antenna.

Increase the separation between the equipment and receiver.

Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

Consult the dealer or an experienced radio/TV technician for help.

- **FCC Part 15 Clause 15.21**

"Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment"

- **FCC Part 15.19(a)** [interference compliance statement], unless the following statement is already provided on the device label:-

"This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation."

- **ISED RSS-Gen Notice**

“This device complies with Industry Canada’s licence-exempt RSSs. Operation is subject to the following two conditions:

(1) This device may not cause interference; and

(2) This device must accept any interference, including interference that may cause undesired operation of the device.”

5150-5250MHz band is restricted to indoor operations only.

“Le présent appareil est conforme aux CNR d’Industrie Canada applicables aux appareils radio exempts de licence. L’exploitation est autorisée aux deux conditions suivantes :

1) l’appareil ne doit pas produire de brouillage;

2) l’appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d’en compromettre le fonctionnement.”

La band 5150-5250MHz ont restreints à une utilisation à l’intérieur seulement.

Legal Notices and Licenses

Instrumentation Laboratory, the Instrumentation Laboratory logo, and *GEM® Hemochron™ 100* are trademarks of Instrumentation Laboratory, registered in the U.S. and other countries. *GEM® Hemochron™ 100* is a trademark of Instrumentation Laboratory.

For Instrumentation Laboratory and third party software license agreements presented at activation or included with the product and presented with any software updates, see the following URL:

www.instrumentationlaboratory.com/

Acknowledgments:

Portions of this Instrumentation Laboratory Software may utilize the following copyrighted material, the use of which is hereby acknowledged.

APACHE SOFTWARE FUNDATION (ASF) LICENSE

Licensed to the Apache Software Foundation (ASF) under one or more contributor license agreements. See the NOTICE file distributed with this work for additional information regarding copyright ownership. The ASF licenses this file to you under the Apache License, Version 2.0 (the "License"); you may not use this file except in compliance with the License. You may obtain a copy of the License at http://www.apache.org/licenses/LICENSE-2.0.

Unless required by applicable law or agreed to in writing, software distributed under the License is distributed on an "AS IS" BASIS, WITHOUT WARRANTIES OR CONDITIONS OF ANY KIND, either express or implied. See the License for the specific language governing permissions and limitations under the License.

GNU GENERAL PUBLIC LICENSE

Version 2, June 1991

Copyright © 1989, 1991 Free Software Foundation, Inc.

59 Temple Place - Suite 330, Boston, MA 02111-1307, USA

Everyone is permitted to copy and distribute verbatim copies of this license document, but changing it is not allowed.

Preamble

The licenses for most software are designed to take away your freedom to share and change it. By contrast, the GNU General Public License is intended to guarantee your freedom to share and change free software--to make sure the software is free for all its users. This General Public License applies to most of the Free Software Foundation's software and to any other program whose authors commit to using it. (Some other Free Software Foundation software is covered by the GNU Library General Public License instead.) You can apply it to your programs, too.

When we speak of free software, we are referring to freedom, not price. Our General Public Licenses are designed to make sure that you have the freedom to distribute copies of free software (and charge for this service if you wish), that you receive source code or can get it if you want it, that you can change the software or use pieces of it in new free programs; and that you know you can do these things.

To protect your rights, we need to make restrictions that forbid anyone to deny you these rights or to ask you to surrender the rights. These restrictions translate to certain responsibilities for you if you distribute copies of the software, or if you modify it.

For example, if you distribute copies of such a program, whether gratis or for a fee, you must give the recipients all the rights that you have. You must make sure that they, too, receive or can get the source code. And you must show them these terms so they know their rights.

We protect your rights with two steps: (1) copyright the software, and (2) offer you this license which gives you legal permission to copy, distribute and/or modify the software.

Also, for each author's protection and ours, we want to make certain that everyone understands that there is no warranty for this free software. If the software is modified by someone else and passed on, we want its recipients to know that what they have is not the original, so that any problems introduced by others will not reflect on the original authors' reputations.

Finally, any free program is threatened constantly by software patents. We wish to avoid the danger that redistributors of a free program will individually obtain patent licenses, in effect making the program proprietary. To prevent this, we have made it clear that any patent must be licensed for everyone's free use or not licensed at all.