

REF 000GH100

GEM[®] Hemochron[®]100

Operator Manual • 000HZ6046EN.US • 01 • 03/2025
English



werfen



Accriva Diagnostics, Inc. - 6260 Sequence Drive, San Diego, CA 92121, USA
Tel: +1-858-263-2300 • www.werfen.com

EC REP

MDSS GmbH - Schiffgraben 41, 30175 Hannover, Germany



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Δ = Change Identifier: Change(s) to section since previous revision.

Δ Copyright

© 2022-2025. This document is the copyright of the manufacturer and must not be copied or reproduced in any form without prior consent. The manufacturer reserves the right to make technical improvements to this equipment and documentation without prior notice as part of a continuous program of product development.

Warranty

The manufacturer declares to the original purchaser that each GEM® Hemochron® 100 system manufactured and sold by the manufacturer or sold by an authorized distributor shall be free from defects in material and workmanship and, under normal and proper use conditions, warrants it for a period of 1 year from installation and no more than 13 months from the shipping date, except as otherwise provided in writing.

The manufacturer's obligation is limited to repairing, replacing, or modifying (at the manufacturer's undisputed judgment) at the manufacturer's factory, or elsewhere as designated by the manufacturer, the material whose defects have been verified, on condition that the purchaser has informed the manufacturer of any defects found within 10 days from receipt, or 10 days of discovery in case of defects which may not be identified in the normal inspection.

Damages caused by or connected to transport are excluded.

Transport to a manufacturer facility or authorized distributor will be at purchaser's charge and risk. Replacements, repairs, or alterations will in no case determine extension to the warranty period.

The warranty does not cover those parts which deteriorate or which are in any case considered consumables or those parts or "items" which by their nature are normally required to be replaced periodically consistent with normal maintenance. It is also understood that following the purchase and delivery of the instrument, the purchaser shall be deemed liable for any losses, damages, or complaints concerning persons or things incurred by the use or misuse of the instrument on behalf of the purchaser, its employees, co-operators, or others.

The manufacturer does not assume any obligation or warranty engagement concerning precision and/or accuracy of the measurements as well as for any damage to the instrument directly or indirectly resulting from the use of reagents and/or consumables different from those produced by the manufacturer specifically for its own instruments and for the same properly tested.

Warranty will not apply to those defective instruments or materials showing defects or damage arising from the following causes:

- 1** Insufficient or negligent care by the purchaser.
- 2** Insufficient or negligent maintenance by the purchaser in relation to the instructions contained in the manuals prepared by the manufacturer for this purpose; tampering or alterations of the instruments or in any case interventions or repairs made by any person not duly authorized by the manufacturer.
- 3** Misuse due to carelessness, negligence, or inexperience.
- 4** Employment of materials under heavier conditions than those for which they have been designed and manufactured and use of the same in combination with incompatible or dangerous products.
- 5** Non-observance of the regulations relevant to installation, power supply, and operation of the instruments.

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.

Bold Text:

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

Example:

- 1 Select  (Settings) > **Supervisor Settings** > **OID Entry Preference**.

Some words other than those that are used on user interface controls are also in **bold**. These words act as inline headings in bulleted lists.

Example:

- **Add a user note** – *Operators* can add a user note to the test result.

Italic Text:

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

Example:

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

Cross-references to other information are in *italic*:

Example:

See "*Patient Testing*" (page 48).

Paragraphs containing important information are in *italic*:

Example:

NOTE: *Supervisors have access to **User Settings** and **Supervisor Settings**.*

Δ Product Labeling, Symbols, and Icons

Before the instrument is operated, it is essential that all product labeling is read and understood. Product labeling includes any instructions, labels, and packaging accompanying the instrument, test cartridges, and LQC products.

Δ Serial Number (SN) Label

The serial number label on the bottom of the instrument contains important textual information and symbols (Figure 1). For a list of these symbols and their meanings, see “Symbols on Product Labeling”.

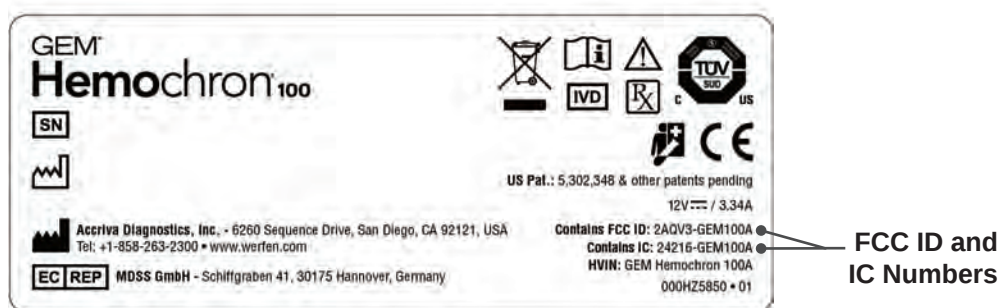


Figure 1: Example Instrument Serial Number Label

Symbols on Product Labeling

Symbol	Description	Symbol	Description
	Consult Instructions for Use		Fragile, Handle with Care
	Caution		This Way Up
	Do Not Reuse		Keep Dry
	Catalog Number		Direct Current (DC)
	Serial Number		Power Button (ON/OFF)
	Lot Number		Ethernet
	Quantity		Barcode Scanner
	Use-By Date		Electronic Equipment: Dispose of Properly
	Temperature Limit		Date of Manufacture
	Contains Sufficient for <n> Tests		Manufacturer
	Quality Control – Level 1 (Normal)		Authorized Representative in the European Community/European Union
	Quality Control – Level 2 (Abnormal)		In vitro Diagnostic Medical Device
	Biological Risks		Conformity to European Regulations
	Not Made with Natural Rubber Latex		Professional Use, Prescription Only
	Device for Near-Patient Testing		TÜV

Icons on the Display Screen

Home Screen Icons:

Icon	Description
	Patient Test – Select icon to test a patient sample. See “Patient Testing” (page 48).
	Quality Control – Select icon to run QC tests to ensure the system is operating properly. See “Quality Control (QC)” (page 54).
	Database – Select icon to view saved test results. See “Database” (page 67).
	Settings – Select icon to view or configure the Instrument Settings. See “Instrument Settings” (page 28). To configure more advanced settings on 1 or more instruments at the same time, see “Centralized Configuration Manager (CCM) Software” (page 79).

Basic Navigation Icons:

Icon	Description
	Back – Select icon to return to the previous screen.
	Home – Select icon to display the Home screen.

Battery Power Icons:

Icon	Description
	Battery is fully discharged.
	Battery is low.
	Battery is partially charged.
	Battery is fully charged and 100% is displayed.



NOTE: Flash symbol will appear on battery icon when power supply is connected.

Connectivity Icons:

Icon	Description
	Ethernet – The instrument is connected to the network through an Ethernet cable.
	Wi-Fi is Disconnected – The instrument was wirelessly connected to the network but is now disconnected.
	Wi-Fi Connection is Poor.
	Wi-Fi Connection is Fair.
	Wi-Fi Connection is Good.
	Wi-Fi Connection is Excellent.
	Network connection is active.
	Network connection is inactive, previous connection was successful.

Icon	Description
	Network connection is inactive, previous connection failed.
	Test Result Transmission In Process – Test results are being sent to the network.
	Test Result Transmission Sent – Test results were successfully sent to the network.
	Test Result Transmission Failed – Test results were <u>not</u> sent to the network.

Test-Related Icons:

Icon	Description
	Testing is allowed (EQC/LQC testing has passed): - For EQC – A patient or LQC test can be run. - For LQC – A patient test can be run.
	Testing is not allowed (EQC/LQC testing has failed): - For EQC – Before a patient or LQC test can be run, a successful EQC test must be run. - For LQC – Before a patient test can be run, a successful LQC test must be run.
	EQC/LQC Interval has expired.
	Warning Message – For a list of possible warning messages, see <i>Table 10</i> (page 74).
	Start Test – Select icon to start or run a test.
	Abort Test – Select icon to abort or cancel the test at any time.
	New Test – Select icon to start a new patient test.
	Result Details – Select icon to view detailed information about a test result.
	User Note – Select icon to enter a user note for a test result.
	Print – Select icon to print a test result.
	Information – Select icon to view details of the current test result.
	Insert Test Cartridge – The instrument prompts the <i>Operator</i> to insert a test cartridge.
	Remove Test Cartridge – The instrument prompts the <i>Operator</i> to remove the test cartridge.
	Warming Test Cartridge – The instrument is warming the test cartridge.
	Apply Sample to Test Cartridge – The instrument prompts the <i>Operator</i> to apply the sample to the test cartridge.
	Sample in Test Channel – The instrument is drawing the sample into the test channel.
	Checking Test Cartridge.

Symbols Used in this Manual

Particular attention should be given to paragraphs marked **CAUTION**, **WARNING**, **BIOHAZARD**, and **NOTE**. These paragraphs contain important information.

Symbol	Meaning
	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 serious personal injury, and/or damage to equipment.
	BIOHAZARD: This symbol alerts the user of potential biological risks associated with the medical device.
	NOTE: A note is supplementary information.
	Change Identifier: Change(s) to section since previous revision.

Definitions and Terms

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

Term	Definition
AC	Alternating Current
ACT	Activated Clotting Time
ACT-LR	Low Range Activated Clotting Time
CCM	Centralized Configuration Manager
CCM Accounts	Describes a user permission level for CCM software.
CCM Administrator	Can create, edit, and delete accounts for other <i>Admins</i> and <i>CCM Supervisors</i> .
CCM Supervisor	Can configure the list of instruments on the PC, and change settings of the instruments through the PC.
DB	Database
DC	Direct Current
DHCP	Dynamic Host Configuration Protocol
DNS	Domain Name Server
EQC	Electronic Quality Control
ESV	Electronic System Verification
Instrument Accounts	Describes a user permission level for instrument software.
Instrument Operator	Can operate the instrument and use the instrument menu to change basic settings.
Instrument Supervisor	Can operate the instrument and use the instrument menu to change basic and advanced settings.
LAN	Local Area Network
LIS	Laboratory Information System
Li-ion	Lithium-ion
LQC	Liquid Quality Control
MAC Address	Media Access Control Address
NTP	Network Time Protocol Server
OID	Operator Identification (Operator ID)
PC	Personal Computer
PID	Patient Identification (Patient ID)
POCT1-A	Point-Of-Care Connectivity (approved standard published by CLSI [Clinical and Laboratory Standard Institute]).
QC	Quality Control
SN	Serial Number (label on bottom of instrument)
TCP	Transmission Control Protocol
Test Cartridge/Test Cuvette	Instrument Consumables
Wi-Fi RSSI	Wi-Fi Signal Quality
WLAN	Wireless Local Area Network

Δ 1 Introduction

1.1 Intended Use

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

The GEM Hemochron 100 ACT+ (Activated Clotting Time Plus) test is a quantitative assay for monitoring anticoagulation with moderate to high unfractionated heparin (UFH) doses in fresh whole blood samples. This test is intended for monitoring UFH administered during cardiovascular surgery and cardiac ablation procedures. The GEM Hemochron 100 ACT+ test demonstrates linear correlation to the anticoagulation effects of UFH concentrations of 1.0 to 6.0 units/mL.

The GEM Hemochron 100 ACT-LR (Low Range Activated Clotting Time) test is a quantitative assay for monitoring anticoagulation with low to moderate unfractionated heparin (UFH) doses in fresh whole blood samples. This test is intended for monitoring UFH administered during extracorporeal life support and cardiology procedures. The GEM Hemochron 100 ACT-LR test demonstrates linear correlation to the anticoagulation effects of UFH concentrations up to 2.5 units/mL.

For *in vitro* diagnostic use. For professional use, Rx only.

1.2 User Proficiency

The GEM Hemochron 100 system should only be used by near-patient, laboratory, and healthcare professionals trained, experienced, and certified in the use of the GEM Hemochron 100 system in accordance with healthcare facility policies and procedures.

The manufacturer recommends that users undergo periodic proficiency testing through an accredited organization in accordance with their healthcare facility requirements.

1.3 Summary and Explanation

Events that lead to formation of a blood clot are simplified in coagulation theory into 2 interactive coagulation cascades that are referred to as the intrinsic and the extrinsic pathways.

The clotting factors involved in these pathways are numbered I through V and VII through XIII. The intrinsic pathway begins with the contact activation of factor XII and, through the interaction of several coagulation factors, results in the conversion of soluble fibrinogen to insoluble fibrin strands. The extrinsic pathway is initiated through the interaction of tissue factor with factor VII. Platelets, essential co-factors in this reaction, provide the platelet phospholipid surface on which coagulation reactions occur.

Activated Clotting Time (ACT+ and ACT-LR) tests are general coagulation screening tests that are used to measure the functionality of the blood coagulation cascade. The ACT test is the method of choice for monitoring heparin therapy during cardiac surgery and Percutaneous Coronary Intervention (PCI). Fresh whole blood is added to an activator (Celite®, silica/silicon dioxide activators, or kaolin), and then timed for the formation of a clot. The type of activator used will affect the degree of prolongation of the ACT to a given heparin dose.

The GEM Hemochron 100 ACT+ test uses a mixture of silica, kaolin, and phospholipids as an activator to create a rapid and highly sensitive alternative to existing ACT tests. This test demonstrates linearity at heparin concentrations ranging from 1.0–6.0 units of heparin per mL of blood, and it is not affected by high dose aprotinin therapy.

The GEM Hemochron 100 ACT-LR test uses a Celite activator. The test demonstrates linearity at heparin concentrations up to 2.5 units of heparin per mL of blood. The test is not intended for use with aprotinin therapy.

1.4 Principles of Operation

The GEM Hemochron 100 system measures whole blood activated clotting time using single-use disposable test cartridges. Each test cartridge contains all of the reagents necessary for a specified test. The *Operator* inserts a test cartridge into the instrument and then (optional) enters information about the sample either manually or by scanning the barcode using the barcode scanner. Once the test cartridge is warmed to $37^{\circ}\text{C} \pm 1.0^{\circ}\text{C}$ (96.8°F – 100.4°F), the instrument will prompt the *Operator* to add a blood sample into the sample well. The *Operator* initiates the test by pressing the  (Start Test) icon on the display screen. When the test begins, the instrument draws blood from the sample well into the test channel of the test cartridge, where the blood is mixed with the reagent. The remaining blood sample, not needed for testing, is automatically drawn out of the sample well and into an enclosed waste channel in the test 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 $37^{\circ}\text{C} \pm 1.0^{\circ}\text{C}$ (96.8°F – 100.4°F). A camera (optical system) monitors the motion of the sample and reagent 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.

Flow reduction below a predetermined value signals to the instrument that a fibrin 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 is displayed as Celite equivalent ACT value in seconds, not real-time seconds. Upon completion of the test, the whole blood clotting time is displayed and recorded by the instrument.

1.5 Description of the System

The GEM Hemochron 100 system consists of the instrument, Centralized Configuration Manager (CCM), a power supply, Liquid Quality Control (LQC) products, and the test cartridges for ACT+ and ACT-LR assays.

1.5.1 Instrument Components

Instrument components are shown in *Figure 2* and described in *Table 1*.



Figure 2: Instrument Components

Table 1: Instrument Components

No.	Component	Description
1	Barcode Scanner	Used for scanning barcodes to enter Operator ID (OID), Patient ID (PID), and LQC lot information. For a list of supported barcode formats, see <i>Table 17 (page 98)</i> in CCM . NOTE: This barcode scanner does not scan the barcode on the test cartridge. For more information about the barcode on the test cartridge, see "Barcode Label" in <i>Table 2 (page 16)</i> .
2	Power Button	Used to 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.
3	Power Supply Port	Connector port for the power supply cable when charging the battery.
4	Ethernet Port	Connector port for the Ethernet cable when connecting an instrument to a Local Area Network (LAN).
5	Color Touch Screen (Display Screen)	The interface that <i>Operators</i> use to operate the instrument.
6	Test Cartridge Insertion Chamber	The chamber into which a test cartridge is inserted.

1.5.2 Test Cartridges

GEM Hemochron 100 test cartridges are single-use disposable test devices with a sample well for application of samples.

NOTE: Test cartridges are not supplied with the system. They must be ordered separately. See “Materials Required, but Not Provided” (page 20).

During a patient or LQC test, the instrument prompts the *Operator* to insert a test cartridge into the instrument. After the instrument warms the test cartridge, it prompts the *Operator* to apply the sample into the **sample well** of the test cartridge. For a description of test cartridge components, see *Figure 3* and *Table 2*.

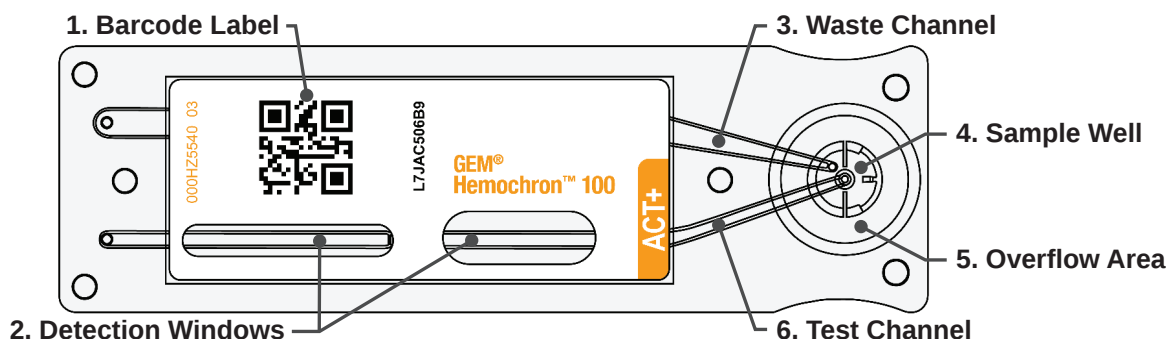


Figure 3: Test Cartridge Components

Table 2: Test Cartridge Components

No.	Component	Description
1	Barcode Label	The barcode label contains the test cartridge lot number, expiration date, and test type. When a test cartridge is inserted into the test cartridge insertion chamber, the instrument reads this information. Information on the label is also human-readable.
2	Detection Windows	An internal camera analyzes the sample through the detection windows.
3	Waste Channel	The instrument vacuum pump draws excess sample into the waste channel. This ensures that the sample volume is correct.
4	Sample Well	The location where the sample is applied.
5	Overflow Area	Excess sample flows into this area and then into the waste channel.
6	Test Channel	The instrument vacuum pump draws the sample into the test channel where it is mixed with reagent.

There are 2 types of test cartridges available. The type of test cartridge must match the type of test that will be performed:

- ACT+ (Catalog #: 000GACT+)
- ACT-LR (Catalog #: 000GACT-LR)

NOTE: Refer to the package insert accompanying the GEM Hemochron 100 test cartridges for storage, handling, and disposal instructions.

1.5.3 Centralized Configuration Manager (CCM) Software

The software titled *Centralized Configuration Manager for GEM Hemochron 100* is intended to be used with a PC (Microsoft Windows® operating system). Although the instrument menus can be used to configure some of the instrument settings, **CCM** can be used to configure more advanced settings and send those settings over the network to 1 or more instruments at the same time. For information, see “*Centralized Configuration Manager (CCM) Software*” (page 79).

NOTE: This software is not included in the instrument box. It must be ordered separately. See “Optional Materials” (page 20).

1.5.4 Liquid Quality Control (LQC) Product for an LQC Test

Specific LQC product is required when an LQC test is run. For information about the LQC product, see “*LQC Products*” (page 56).

NOTE: LQC product is not supplied with the system. It must be ordered separately. See “Materials Required, but Not Provided” (page 20).

1.6 Operational Warnings and Precautions

- For *in vitro* diagnostic use. For near-patient, laboratory, and healthcare professional use. Rx only.
- The system requires the use of personal protective equipment (gloves, gowns, safety glasses, etc.) where there could be contact with the skin when handling potentially infectious substances or surfaces, such as human samples or reagents.
- The GEM Hemochron 100 system should only be used by near-patient, laboratory, and healthcare professionals trained, experienced, and certified in the use of the GEM Hemochron 100 system in accordance with healthcare facility policies and procedures.
- While running a patient or LQC test, keep the instrument on a horizontal and stable surface.
- **DO NOT** operate the instrument in an environment that is not within the specified range. See “Operation” (page 18).
- **DO NOT** store or transport the instrument in an environment that is not within the specified range. See “Storage and Transport” (page 18) or box label.
- **DO NOT** drop the instrument. If the instrument was dropped during a test, **DO NOT** use the test results.
- **DO NOT** disassemble the instrument.
- When the power supply cable is disconnected from the instrument or from the wall, **DO NOT** grasp the electrical cable. Instead, grasp the connector.
- 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 relevant EMC standards, may compromise safety when using the instrument.
- The instrument is designed for use with GEM Hemochron 100 test cartridges only.
- Test cartridges and LQC products are for single-use only, **DO NOT** reuse.
- **DO NOT** use test cartridges or LQC products that are past their marked expiration date or have been improperly stored.
- Refer to the package insert accompanying the test cartridges or LQC products for storage and handling instructions.
- **DO NOT** force a test cartridge into the instrument. If resistance to insertion is encountered, gently remove the test cartridge and examine the Test Cartridge Insertion Chamber of the instrument. Remove any obstruction before attempting further use of the instrument (see “Routine Maintenance” (page 73)).
- If a sample is not applied within 5 minutes, the test will time out. If this occurs, dispose of the test cartridge and repeat the test using a new test cartridge.
- Patient blood samples, blood collection materials, used test cartridges, and LQC products are potentially infectious and must **IMMEDIATELY** be discarded into a container designed for sharp, medical biohazard waste and disposed per local and regional regulations. Use caution when handling and disposing of any sharp device. Strictly adhere to the institution's policies for the proper handling and disposal of biohazardous materials.
- The materials included as part of the GEM Hemochron 100 system are not made with natural rubber latex.
- Deleted test results cannot be recovered.
- Do not prepare the LQC product until the instrument displays  (Warming Test Cartridge). If the LQC product is prepared too early, premature clotting may adversely affect test result.
- If the EQC test feature is required (**Yes**), the instrument will be required to perform validation testing at regular intervals. The factory default setting for this feature is required (**Yes**) but can be changed using **CCM**. The manufacturer recommends that it be required (**Yes**). The decision to require (**Yes**) or not require (**No**) this feature shall be determined by and is the responsibility of the each institution.
- If the LQC test feature is required (**Yes**), the instrument will be required to run LQC tests at regular intervals. The factory default setting for this feature is not required (**No**) but can be changed using **CCM**. The manufacturer recommends that it be required (**Yes**). The decision to require (**Yes**) or not require (**No**) this feature shall be determined by and is the responsibility of the each institution.



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

1.7 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 test cartridge. For specific limitations, refer to the package insert for the individual assay.

As with all diagnostic tests, GEM Hemochron 100 test results should be evaluated in the context of a specific patient's condition and anticoagulant therapy. Any test 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.

Δ 1.8 Specifications

Specifications for the GEM Hemochron 100 instrument are listed below:

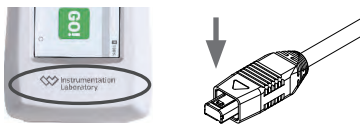
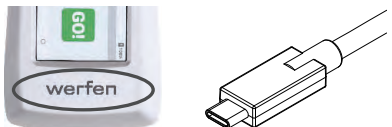
Dimensions and Weight:

Length:	18.8 cm (7.4 inches)
Width:	10.2 cm (4.0 inches)
Height:	5.1 cm (2.0 inches)
Weight:	0.68 kg (1.5 lbs.)

Operation:

Memory Capacity:	Instrument memory stores 10,000 test results (patient, LQC, and EQC tests)
Battery Life:	500 charges for a full new battery
Battery Type:	Lithium-ion
Battery Power:	7.2 VDC, 20.88 Wh
Operating Environment:	15°C–30°C (59°F–86°F), 20–85% RH (non-condensing), Elevation of 0–3,094 meters (10,151 feet)
Testing Environment:	Indoors, on a dry, clean, horizontal, and stable surface
Time to Test Results:	~4 minutes from sample introduction
Test Cartridge Incubation Temperature:	37°C ±1.0°C (96.8°F–100.4°F)
Test Cartridge Incubation Warm-Up Time:	30–90 seconds

Power Supply:

Description (Catalog #):	Power Supply (Cat. #: 000HZ5900X.US)	USB-C/USB-PD Power Supply (Cat. #: 000HZ5960X.D)
Input Power:	100–240 VAC, 50/60 Hz, 1–0.5 A	100–240 VAC, 50/60 Hz, 1–0.5 A
Output Power:	+12 VDC, 3.34 A, 40W MAX	12 VDC, 4.0 A, 60 W
Instrument Compatibility and Power Supply Connector Orientation:	 White arrow must face up.	 No orientation required.

NOTE: The company logo printed on the instrument's outer shell (circled in images above) indicates which power supply kit to order. Power supply kits are not interchangeable between these instruments.

Storage and Transport:

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

The GEM Hemochron 100 instrument is calibrated at the manufacturing facility to test and verify all functions. The instrument is also self-verifying, as all instrument functions are monitored and verified by the instrument software before each patient or LQC test is run. The instrument does not require additional calibration by the user.

Δ 2 Preparing the Instrument

Δ 2.1 Packaging and Other Materials

Materials Provided:

Ensure the package contains the following materials:

- **GEM Hemochron 100 Instrument** (Cat. #: 000GH100)
- **Power Supply**
 - 2 Cables, 110 VAC and 240 VAC (wall outlet to power converter)
 - Power Converter, AC to DC
- **Operator Manual (paper)**

Materials Required, but Not Provided:

To use the instrument, the following materials are required but not provided. To order them, contact your local representative for details.

Table 3: Materials Required, but Not Provided

Description		Catalog #
GEM Hemochron 100 Test Cartridges	• ACT+	000GACT+
	• ACT-LR	000GACT-LR
directCHECK™ Whole Blood Quality Controls (LQC product for LQC testing)	• ACT+ Level 1	DCGACT-1
	• ACT+ Level 2	DCGACT-2
	• ACT-LR Level 1	DCGLR-1
	• ACT-LR Level 2	DCGLR-2

Optional Materials:

Table 4: Optional Materials

Description	Catalog #
GEM Hemochron 100 Power Supply Kit	000HZ5900X.US
GEM Hemochron 100 USB-C/USB-PD Power Supply Kit	000HZ5960X.D
GEM Hemochron 100 Replacement Battery Kit	000HZ5639
Centralized Configuration Manager (CCM) Software for GEM Hemochron 100	000GCCM

NOTE: Refer to “Ordering Information” (page 116) for additional product information on all materials listed above.

Unpack and Inspect the Instrument:

NOTE: Do not discard the packaging material. It is recommended to keep the packaging in case the instrument must be shipped or otherwise transported.

- 1 Remove any protective packaging that may be present around the instrument.
- 2 Check the packaging to be sure the power supply, AC power cord, connecting cables, and other components have been removed. For the complete list of materials provided, see “Materials Provided” (page 20).
- 3 Remove the battery pull-tab from the bottom of the instrument (Figure 4).



Figure 4: Remove the Battery Pull-Tab

2 - Δ Preparing the Instrument

NOTE: If the battery power is at 0% after removing the battery pull-tab, remove and reinsert the battery. If the battery power is still at 0%, allow the instrument to charge for 12 hours.

NOTE: Inspect each component for signs of damage. If a component is damaged or missing, do **NOT** use the instrument. Contact your local representative immediately.

2.2 Instrument Power and Charging

2.2.1 Battery Information

The hand-held instrument is powered by a RoHS-compliant, rechargeable lithium-ion (Li-ion) battery. Battery life 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 an extended period of time, it is recommended to leave it disconnected from the power supply.

The instrument automatically checks to ensure enough battery power is available when the *Operator* powers on the instrument and when an *Operator* runs a test. For more information, see “*Electronic Quality Control (EQC) Testing*” (page 55).

The instrument records the percentage of battery power used based on the resource that is used. For more information, see “*View Battery Usage Information Based on System Resource*” (page 34).

To view the features that help save battery power, see “*Sleep Mode*” (page 23) and “*Automatic Shutdown*” (page 23).

2.2.2 Charging the Battery

NOTE: The power supply has been selected specifically for use with the instrument. Only use the power supply that is authorized by the manufacturer. Do not use any other power supply.

The battery must be charged under the following conditions:

- The instrument is being used for the first time. A charge of 12 hours is recommended.
- The instrument displays a low-battery message.

To Charge the Battery:

- 1 Connect the power supply cable to the power supply port on the side of the instrument (Figure 5).

NOTE: The battery pull-tab must be removed from the bottom of the instrument before charging (Figure 4 (page 20)).



Figure 5: Power Supply Port

- 2 Connect the power supply cable to a wall outlet. The power supply converts AC power to DC power. The instrument can be used while it is being charged.

NOTE: The battery charge indicator is displayed in the status bar at the top of the screen. For more information, see “*Battery Power Icons*” (page 10).

2.2.3 Power On the Instrument

To power on the instrument, press the power button (Figure 6).



Figure 6: Power Button

When the instrument is powered on, a beep is heard, several product logos are displayed, and an Electronic System Verification (ESV) test runs. See “Electronic Quality Control (EQC) Testing” (page 55). When the **Home** screen is displayed, the instrument can be operated. See “Home Screen Icons” (page 10).

2.2.4 Power Off the Instrument

To power off the instrument, do either of the following:

- Press and hold the power button until the confirmation dialog box is displayed. Confirm to power off the instrument.
- Press and hold the power button until the instrument is powered off.

NOTE: If the instrument is in sleep mode, wake the instrument by touching the screen or pressing the power button.

2.2.5 Sleep Mode

If the instrument is on and has not been used for a specified period of time, it will go into sleep mode to save battery power. While the instrument is in sleep mode, the screen is blank.

NOTE: The default period of time for sleep mode is set to 5 minutes. Supervisors can specify a different period of time. See “Set the Sleep Mode Interval” (page 32).

Operators and Supervisors can also manually put the instrument into sleep mode.

Put the Instrument into Sleep Mode:

To put the instrument into sleep mode, press the power button.

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.

2.2.6 Automatic Shutdown

Unlike sleep mode, if the instrument automatically shuts down, it must be fully restarted.

NOTE: The default period of time for automatic shutdown is set to **Never**. Supervisors can specify a different period of time for the instrument to shutdown. See “Set the Shutdown Interval” (page 32).

2.3 Display Screen

Use the touchscreen (display screen) to operate the instrument.

2.3.1 Selecting Items on the Screen

To select an item on the screen, tap it (touch it) (Figure 7).



Figure 7: Select Items on the Screen

2.3.2 Scrolling the Screen

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



Figure 8: Drag and/or Swipe to Scroll the Screen

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

2.3.3 Back and Home Icons

Back and **Home** icons are always displayed at the bottom of the screen (Figure 9).

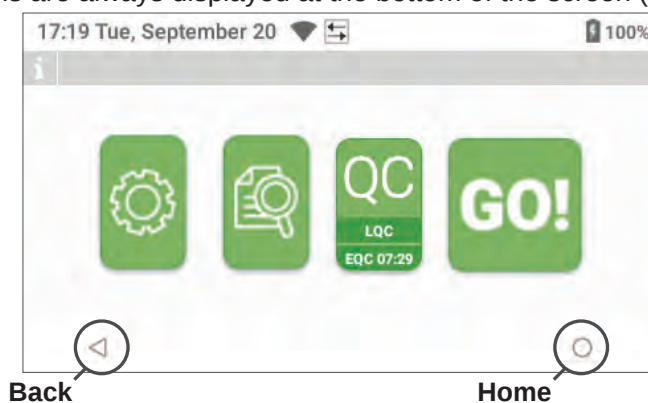


Figure 9: Back and Home Icons

2.4 Entering Information into the Instrument

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

2.4.1 Using the Virtual Keyboard

Use the virtual keyboard to manually enter text into a text field. 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 field (e.g., when the **Enter OID** dialog box is displayed [Figure 10], select **Enter OID**).

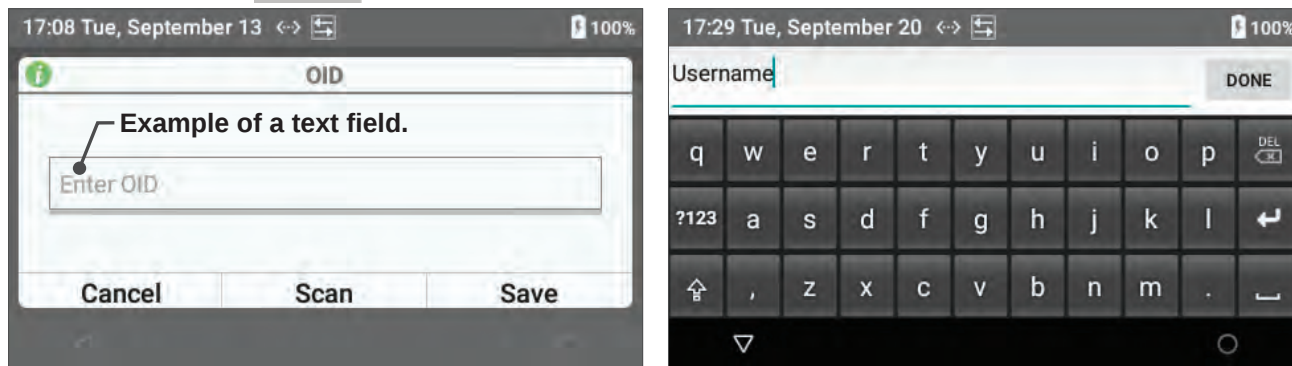


Figure 10: Display Virtual Keyboard

- To switch to the keyboard that contains numbers and symbols, select **?123** (Figure 11).

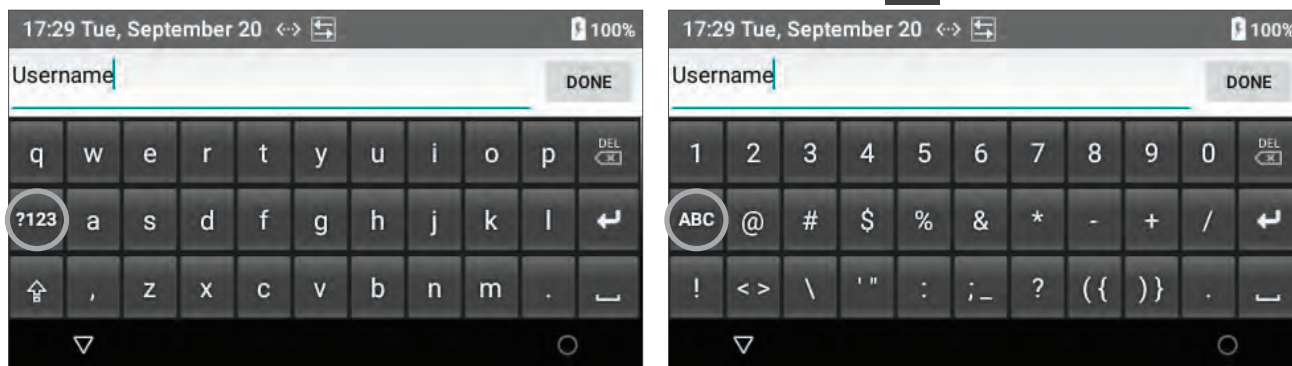


Figure 11: Virtual Keyboard with Numbers and Symbols

- To switch back to the keyboard that contains letters, select **ABC**.
- To enter upper case letters, select **⇧** (Caps Lock).
- To enter a space, select **␣** (Space Bar).
- To backspace delete, select **DEL** (Delete). This deletes the character to the left of the cursor.
- To move the cursor, touch the text in the text field to display the cursor and then move the cursor horizontally (Figure 12).



Figure 12: Cursor in a Text Field

2.4.2 Using the Barcode Scanner

Operators can use the barcode scanner to enter information into the instrument more quickly and accurately than by manual entry. **Operators can scan Operator IDs (OIDs), Patient IDs (PIDs), 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 barcode scanner.

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

NOTE: Do not point the barcode scanner directly at anyone. The LED light from the barcode 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 dialog box is displayed, select **Scan** to activate the barcode scanner light.
- 2 While the barcode scanner light flashes, hold the instrument at a 90° angle to the barcode label (Figure 13).



Figure 13: Scanning a Barcode

- 3 An audible beep will be heard when the barcode scanner reads the barcode.
- 4 Verify that the information was entered into the dialog box.
- 5 Select **Save** to save the information or **Cancel** to exit without saving.

3 - Δ Instrument Settings

Rotating the screen 180° allows *Operators* to use the instrument with the test cartridge insertion chamber positioned on either end of the instrument (*Figure 15*). This accommodates left-handed and right-handed *Operators*.



Figure 15: Rotating the Screen

3.2.2 Interval Timer

- 1 Select  (Settings) > **User Settings** > **Interval Timer**.
- 2 Use the toggle to select **Show** or **Hide**:
 - If **Show** (Show) and  (Toggle On) are displayed, the Interval Timer will be displayed during patient tests (*Figure 16*). To turn it off, set the toggle to **Off**  (Toggle Off).

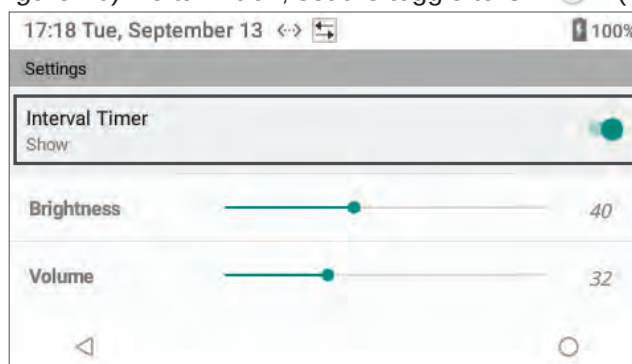


Figure 16: Interval Timer – Show

- If **Hide** (Hide) and  (Toggle Off) are displayed, the Interval Timer will not be displayed during patient tests (*Figure 17*). To turn it on, set the toggle to **On**  (Toggle On).

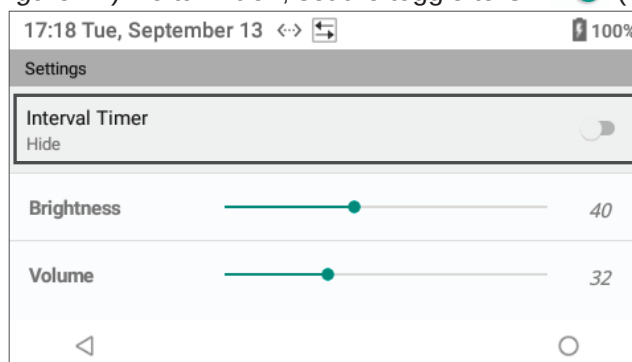


Figure 17: Interval Timer – Hide

NOTE: The factory default setting for Interval Timer is set to **Hide** (Hide).

(Optional) If the Interval Timer setting is set to **Show** (Show), the instrument can be configured to use the Test Interval Timer feature. See “Test Interval Timer Feature (Optional)” (page 52).

3.2.3 Adjust the Display Brightness

- 1 Select  (Settings) > **User Settings**.
- 2 Drag the **Brightness** slider horizontally to the desired level (*Figure 17* (page 27))

Δ 3 Instrument Settings

3.1 Instrument Accounts

There are 2 types of instrument *Operators* that are distinguished by the complexity of the settings they are allowed to change:

Instrument Operator:

Instrument *Operators* can operate the instrument and use the instrument menu to change basic settings. For more information, see “*User Settings (Basic Settings)*” (page 28).

Instrument Supervisor:

Instrument *Supervisors* use the instrument menu to change basic and advanced settings. For more information, see “*Supervisor Settings (Advanced Settings)*” (page 30).

3.2 User Settings (Basic Settings)

NOTE: Operators only have access to **User Settings**.

To view **User Settings**, select  (Settings) > **User Settings**. For more information about these settings, see Table 5.

Table 5: User Settings

Setting	Description
Rotate Screen	Tap to rotate the screen 180°. See “ <i>Rotate Screen</i> ” (page 28).
Interval Timer	Show or hide the Interval Timer during patient tests. See “ <i>Interval Timer</i> ” (page 27).
Brightness	Adjust the brightness of the display. See “ <i>Adjust the Display Brightness</i> ” (page 27).
Volume	Adjust the beep volume. See “ <i>Adjust the Beep Volume</i> ” (page 29).
System Information	View read-only information about the system. See “ <i>View System Information</i> ” (page 29).
Font Size	Adjust the size of the display font. See “ <i>Adjust the Font Size</i> ” (page 29).

3.2.1 Rotate Screen

- 1 Select  (Settings) > **User Settings** > **Rotate Screen**.
- 2 Tap **Rotate Screen** (Figure 14) and the screen will rotate 180°.

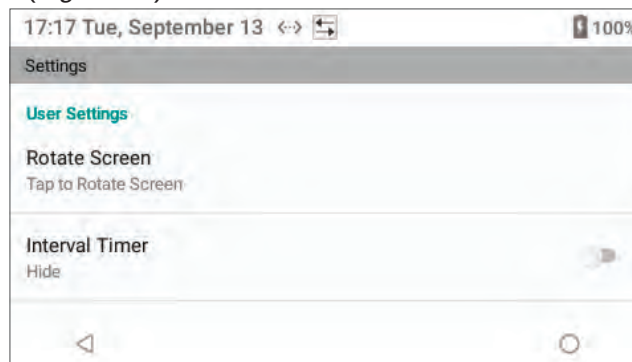


Figure 14: Rotate Screen

3.2.4 Adjust the Beep Volume

The instrument beeps under the following conditions:

- When the instrument is powered on.
- When an item on the screen is selected.
- 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  (Settings) > **User Settings**.
- 2 Drag the **Volume** slider horizontally to the desired level (*Figure 18*).

NOTE: To turn the beep off, move the slider to **0** (zero). When the beep is off, it will only beep at critical points during testing.

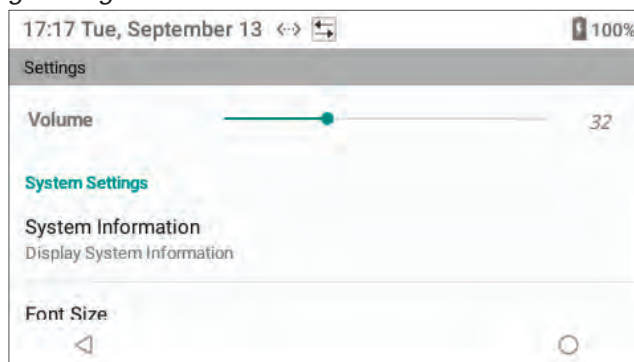


Figure 18: Adjusting Brightness and Beep Volume

3.2.5 View System Information

To view read-only information about the instrument hardware and software:

- Select  (Settings) > **User Settings** > **System Information**.

3.2.6 Adjust the Font Size

- 1 Select  (Settings) > **User Settings** > **Font Size**.
- 2 In the dialog box (*Figure 19*), select the preferred size (**Normal** or **Large**).

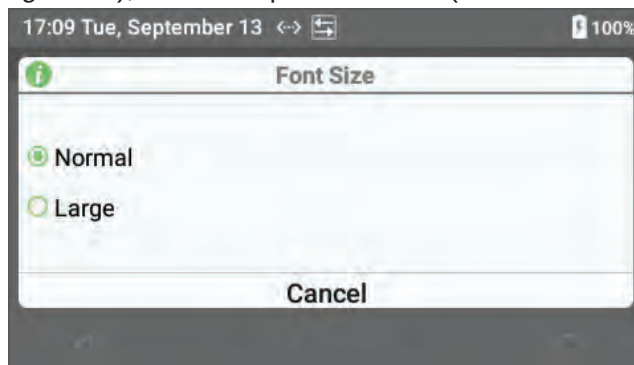


Figure 19: Adjusting Font Size

3.3 Supervisor Settings (Advanced Settings)

NOTE: Supervisors have access to **User Settings** and **Supervisor Settings**.

To view **Supervisor Settings**, select  (Settings) > **Supervisor Settings**. For more information about these settings, see *Table 6*. Supervisors can also use **CCM** software to change many of these settings and more advanced changes. For more information, see “*Centralized Configuration Manager (CCM) Software*” (page 79).

Factory Default Setting Supervisor Account:

NOTE: Menu items under  (Settings) > **Supervisor Settings** are password-protected.

Supervisors are required to log into the instrument. The factory default setting Supervisor account password should be changed, recorded, and stored in a safe place.

To change the password, use **CCM**. See “*GEM Hemochron 100 System User Accounts*” (page 79).

To Log into the Factory Default Setting Supervisor Account:

- 1 Select  (Settings) > **Supervisor Settings**.
- 2 A dialog box for entering the **Supervisor ID** and **Password** is displayed (*Figure 20*).

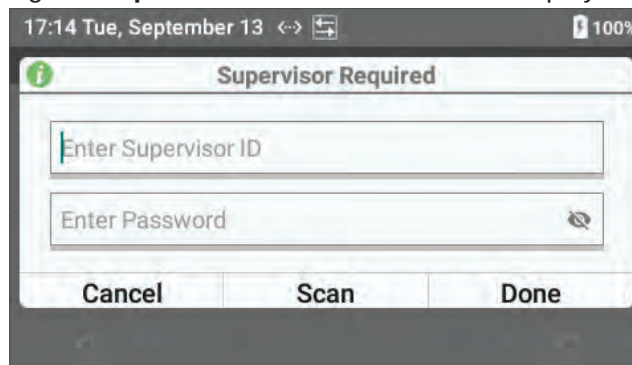


Figure 20: Enter Factory Default Setting Supervisor Password

- 3 To enter **Supervisor ID** and **Password**, do either of the following:
 - Select **Scan** and scan a compatible Supervisor ID barcode. If **OID Password Scan** is enabled in **CCM** (“*OID Password Scan*” (page 92)), select **Scan** to scan a compatible password barcode and then select **Done**.
 - Manually enter the **Supervisor ID** (touch the text field to display the virtual keyboard). Enter the **Supervisor ID**, select **Next**, enter the **Password**, and then select **Done**.

NOTE: For more information about the virtual keyboard, see “*Using the Virtual Keyboard*” (page 25).
- 4 Select **Done**.

To view **Supervisor Settings**, select  (Settings) > **Supervisor Settings**. For more information about these settings, see *Table 6*.

Table 6: Supervisor Settings

Setting	Description
Reset Counters	Reset the counters associated with the number of failed EQC/LQC tests and the number of patient tests after EQC/LQC lockout. See “ <i>Reset Counters</i> ” (page 32).
Instrument Name	Instrument Settings > Instrument Name. Set instrument name. See “ <i>Add Instrument Name</i> ” (page 32).
Sleep	Instrument Settings > Display > Sleep. Set the time that elapses before the instrument goes into sleep mode. See “ <i>Set the Sleep Mode Interval</i> ” (page 32).
Shutdown	Instrument Settings > Display > Shutdown. Set the time that elapses before the instrument automatically shuts down. See “ <i>Set the Shutdown Interval</i> ” (page 32).

Setting	Description
Date and Time	Instrument Settings > Date and Time. Set the date and time. See <i>“Set the Date and Time”</i> (page 33). Supervisors can choose whether to automatically get the date and time from the network. See <i>“Enable the Date and Time to be Set Automatically”</i> (page 33). NOTE: To change the following settings, use CCM . See <i>“Configure Instruments (Instrument Settings)”</i> (page 91): • Date Format (MM/DD/YYYY, DD/MM/YYYY, or YYYY/MM/DD) • Time Format (12 Hour or 24 Hour) • Time Zone
Battery	Instrument Settings > Battery. To view battery usage information, see <i>“View Battery Usage Information Based on System Resource”</i> (page 34).
Ethernet	Instrument Settings > Ethernet. Connect the instrument to a network using an Ethernet cable. For more information, see <i>“Connect to a Wired Network (Ethernet)”</i> (page 35).
Wi-Fi	Instrument Settings > Wi-Fi. Wirelessly connect the instrument to a network. For more information, see <i>“Connect to a Wireless Network (Wi-Fi)”</i> (page 36).
Security	Instrument Settings > Security. Use Wi-Fi Enterprise Certificates to securely connect the instrument to the Wi-Fi Network. See <i>“Update Wi-Fi Enterprise Certificate”</i> (page 106).
Language	Instrument Settings > Language. Select the instrument language. See <i>“Language”</i> (page 38).
Instrument Information	Instrument Settings > Instrument Information. To view read-only information about the system (IP Address, MAC Address, SW version, etc.), see <i>“View Instrument Information”</i> (page 38).
POCT1-A Network Settings	Connect the instrument to a POCT1-A compliant network for use with middleware. For more information, see <i>“POCT1-A Network Settings”</i> (page 38).
CM Connection Settings	Set the IP address and port (e.g., 50000) for connecting the instrument to the computer that CCM is installed on. Consult with the institution’s network administrator. For more information, see <i>“Set Port Number and Encryption Mode for CCM”</i> (page 39).
Auto Send	After a test, allow the instrument to automatically send the test results to a network. See <i>“Automatically Send Test Results to the Network (Auto Send)”</i> (page 40).
NTP Server Settings	Set the IP address of the NTP (Network Time Protocol) server. For more information, see <i>“NTP Server Settings”</i> (page 40).
OID Entry Preference	Specify the method of entry: Not Required , Required (Scan or Manual Entry) , or Scan Only . For information, see <i>“Require Operators to Enter Their OID and Specify the Method”</i> (page 40).
OID Reuse (During Patient Tests)	Allows instrument to reuse OID from previous patient test. For information, see <i>“Allow OID Reuse During Patient Testing”</i> (page 41).
OID Reuse (During LQC Test)	Allows instrument to reuse OID from previous LQC test. For information, see <i>“Allow OID Reuse During LQC Testing”</i> (page 41).
OID Reuse Duration	Period of time before OID reuse expires. For information, see <i>“Specify OID Reuse Duration”</i> (page 42).
PID Entry Preference	Specify the method of entry: Not Required , Required (Scan or Manual Entry) , or Scan Only . For information, see <i>“Require Operators to Enter a PID and Specify the Method”</i> (page 42).
PID Reuse (During Patient Test)	Allows instrument to reuse PID from previous patient test. For information, see <i>“Allow Reuse of a PID”</i> (page 43).
PID Reuse Duration	Period of time before PID reuse expires. For information, see <i>“Specify PID Reuse Duration”</i> (page 43).
Clear All Test Results	Erase all test results from the instrument. See <i>“Clear All Test Results”</i> (page 44).
Clear All Patient Test Results	Erase all patient test results from the instrument. See <i>“Clear All Patient Test Results”</i> (page 44).
Barcode Scanner Test	Check the barcode scanner. See <i>“Test the Barcode Scanner”</i> (page 44).

3.3.1 Reset Counters

Supervisors can reset (clear) the counters associated with the number of failed EQC/LQC tests and the number of patient tests after EQC/LQC lockout. For more information about counters, see “QC Lockout” (page 56) and “Configure Instruments (Instrument Settings)” (page 91).

- 1 Select  (Settings) > **Supervisor Settings** > **Reset Counters**.
- 2 Check the box for each counter that needs to be reset (Figure 21):
 - **Clear All EQC/LQC Failure Counters**
 - **Clear Number of Patient Tests After EQC/LQC Lockout**

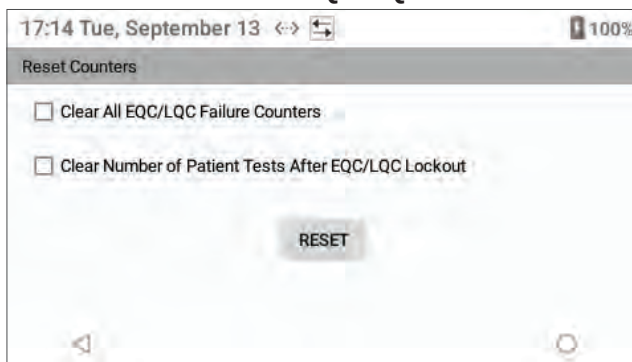


Figure 21: Reset Counters

- 3 Select **Reset** to reset (clear) the counters.

3.3.2 Add Instrument Name

- 1 Select  (Settings) > **Supervisor Settings** > **Instrument Settings** > **Instrument Name**.
- 2 Enter the **Instrument Name** and select **Save** (Figure 22).

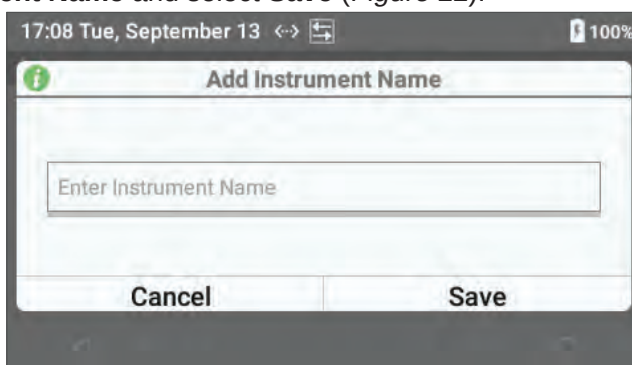


Figure 22: Add Instrument Name

3.3.3 Set the Sleep Mode Interval

If the instrument is on and has not been used for a specified period of time, it will go into sleep mode to save battery power. *Supervisors* can set the sleep mode interval.

- 1 Select  (Settings) > **Supervisor Settings** > **Instrument Settings** > **Display** > **Sleep**.
- 2 In the dialog box, select the desired interval.

3.3.4 Set the Shutdown Interval

If the instrument is on, has not been used for a specified period of time, and is not connected to the power supply, it will shut down to save battery power. *Supervisors* can set the shutdown interval.

- 1 Select  (Settings) > **Supervisor Settings** > **Instrument Settings** > **Display** > **Shutdown**.

-
- 2 In the dialog box (Figure 23), select the desired interval.

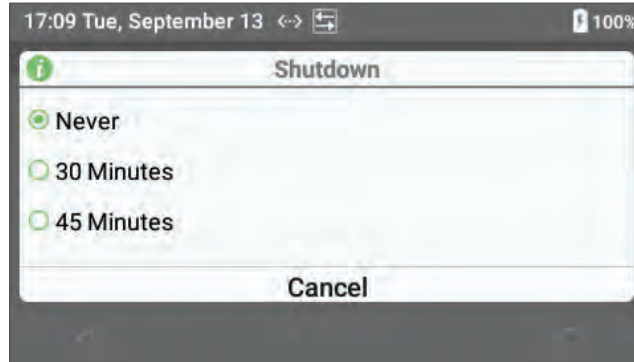


Figure 23: Shutdown Interval

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

3.3.5 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 result.

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

Enable the Date and Time to be Set Automatically:

- 1 Select  (Settings) > **Supervisor Settings** > **Instrument Settings** > **Date and Time**.
- 2 Set the toggle for **Automatic Date & Time** to **On**  (Toggle On).

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 **CCM** to specify that the date and time be set automatically. See “*Configure Instruments (Instrument Settings)*” (page 91).

Manually Set the Date:

- 1 Select  (Settings) > **Supervisor Settings** > **Instrument Settings** > **Date and Time**.
- 2 Set the toggle for **Automatic Date & Time** to **Off**  (Toggle Off).
- 3 Select **Set Date**.
- 4 In the dialog box (Figure 24), scroll the values for the month, day, and year.

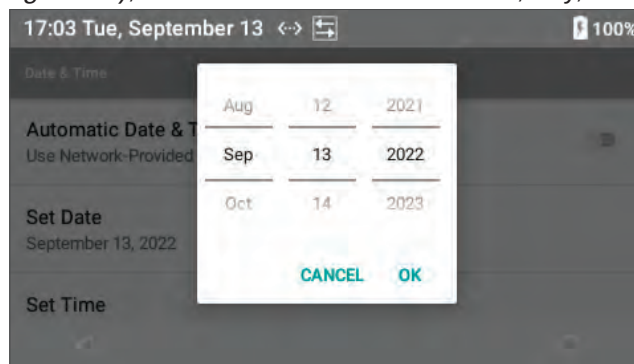
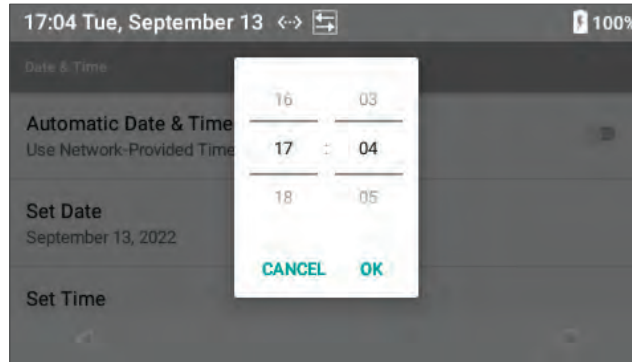


Figure 24: Set Date

-
-
-
-
- 5 Select **OK**.

Manually Set the Time:

- 1 Select  (Settings) > **Supervisor Settings** > **Instrument Settings** > **Date and Time**.
- 2 Set the toggle for **Automatic Date & Time** to **Off**  (Toggle Off).
- 3 Select **Set Time**.
- 4 In the dialog box (Figure 25), scroll the values for the hour and minute.

**Figure 25: Set Time**

- 5 Select **OK**.

Set the Format for the Date and Time:

- To set the date format (**MM/DD/YYYY**, **DD/MM/YYYY**, or **YYYY/MM/DD**), use **CCM**. See “Configure Instruments (Instrument Settings)” (page 91).
- To set the time format (**12 Hour** or **24 Hour**), use **CCM**.

Set the Time Zone:

- To set the time zone, use **CCM**.

3.3.6 View Battery Usage Information Based on System Resource

The instrument records the percentage of battery power used based on the resource that is used. 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, select  (Settings) > **Supervisor Settings** > **Instrument Settings** > **Battery**.

3.3.7 Connectivity Settings

Supervisors can configure the instrument to be connected to a network or other device. See Table 7.

Table 7: Connectivity Options

Connection Type	Description
Ethernet (Wired Network)	Use an Ethernet cable to connect the instrument to a Local Area Network (LAN). See “Connect to a Wired Network (Ethernet)” (page 35).
Wi-Fi (Wireless Network)	Use Wi-Fi to connect the instrument to a Wireless Local Area Network (WLAN) through 802.11 b/g/n connections at 2.4 & 5 GHz. See “Connect to a Wireless Network (Wi-Fi)” (page 36).
POCT1-A	Using Ethernet or Wi-Fi, <i>Supervisors</i> can connect the instrument to a POCT1-A-compliant network for use with middleware. See “POCT1-A Network Settings” (page 38).

Connecting the Instrument to a Network:

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

- To more easily configure instrument settings on 1 or more instruments using **CCM**.
- Send test results from the instrument to a network: GEMweb® Plus 500 from Werfen or other middlewares or Laboratory Information System (LIS).
 - GEMweb Plus 500 Custom Connectivity combines control of information, instruments, and *Operators* in 1 easy-to-use data management system.
 - Easier *Operator* management – Remote *Operator* configuration and instrument management.
 - Simplifies GEM Hemochron 100 instrument quality management.
 - Provides full traceability from a single interface, accessed from anywhere.
 - Open connectivity includes Werfen and non-Werfen instruments.

For more information about GEMweb Plus 500, contact your local representative.

Connection Indicators:

- If the instrument is connected to the network, the connection type (Ethernet or Wi-Fi) will be displayed in the status bar (Figure 26).

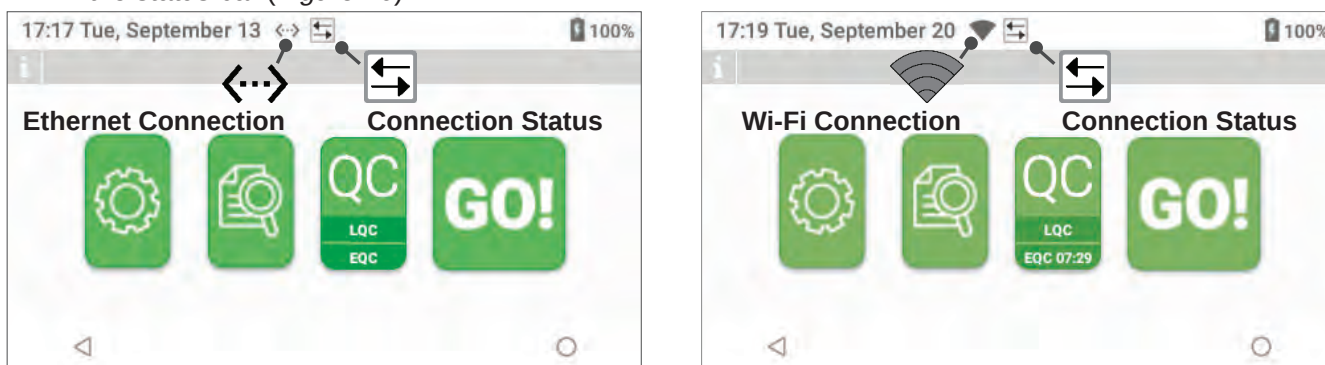


Figure 26: Network Connection Type and Status Icons

- 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 $\langle \dots \rangle$ (Ethernet) will be displayed in the status bar. The instrument defaults to the Ethernet connection because it is faster than Wi-Fi.

The IP address for the network connection can be **Dynamic** or **Static**:

- **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, contact the institution's network administrator for the following information:
 - **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  (Settings) > **Supervisor Settings** > **Instrument Settings** > **Ethernet** > **Mode**.

- 4 In the dialog box (Figure 27), 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**, **Gateway**, **DNS 1**, and **DNS 2**.
 - **Static** – Selecting this requires that the **IP Address**, **Subnet Mask**, and **Gateway** be manually entered.

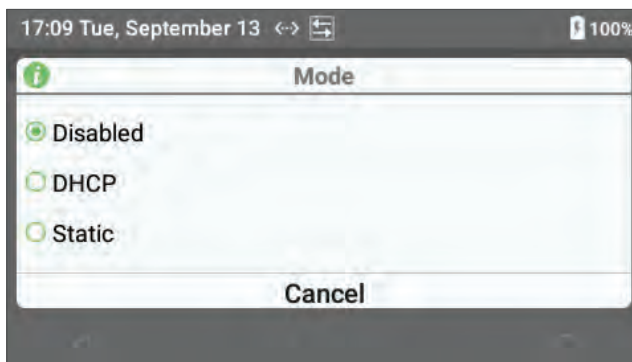


Figure 27: Ethernet Mode

NOTE: A firewall might prevent the instrument from being connected to the network. See “Install CCM Software and Configure Firewalls” (page 81).

Connect to a Wireless Network (Wi-Fi):

NOTE: If the institution uses Wi-Fi Enterprise Certificates, see “Update Wi-Fi Enterprise Certificate” (page 106) before connecting to a 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.

The wireless network might be protected by a password. If it is, contact the institution’s network administrator for the password.

- 1 Select  (Settings) > **Supervisor Settings** > **Instrument Settings** > **Wi-Fi**.
- 2 Select  from the right side of title bar.
- 3 Select **Wi-Fi Regulatory Domain**.
- 4 In the dialog box (Figure 28), select the appropriate option:
 - **US and Canada**
 - **Other Countries**

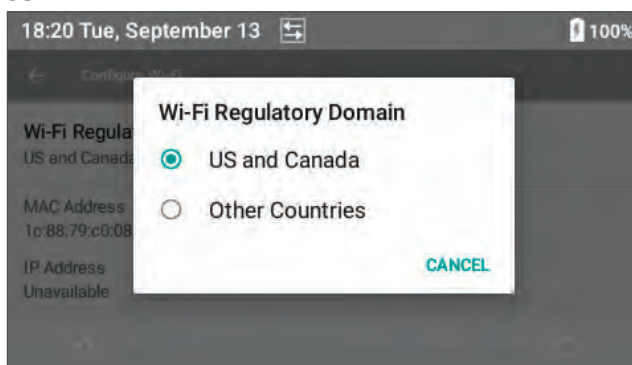


Figure 28: Wi-Fi Regulatory Domain

- 5 Select  (Settings) > **Supervisor Settings** > **Instrument Settings** > **Wi-Fi**.
Is the desired wireless network on the list of available networks?
 - **No** – Go to the next step.
 - **Yes** – Go to step 7 (page 37).

6 To search for wireless networks, ensure the Wi-Fi is **On**:

- If **Off** (Off) and  (Toggle Off) are displayed, Wi-Fi is **Off** (Figure 29). To turn it on, set the toggle to **On**  (Toggle On).

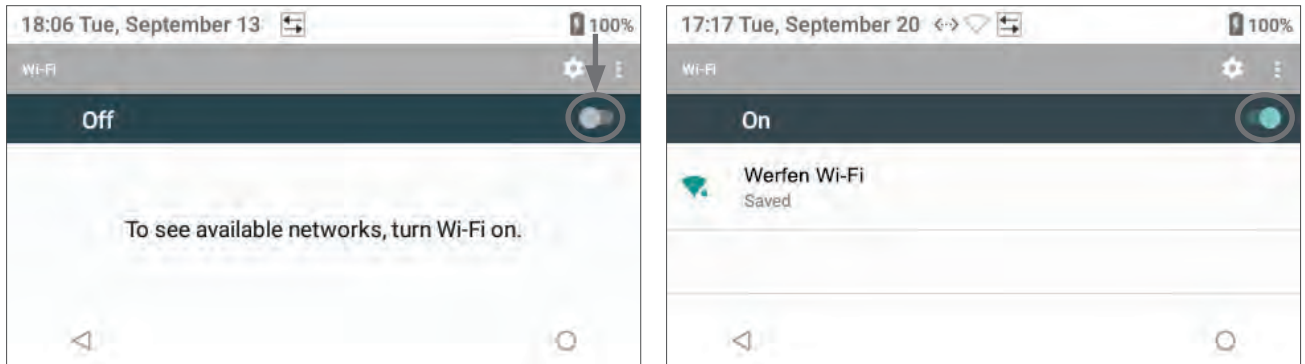


Figure 29: Turn On Wi-Fi

- If **On** (On) and  (Toggle On) are displayed, Wi-Fi is **On**.
- 7 In the list of available wireless networks, select the appropriate network for connection.
- To refresh the search, select  and then select **Refresh** (Refresh) from the right side of title bar (Figure 30).

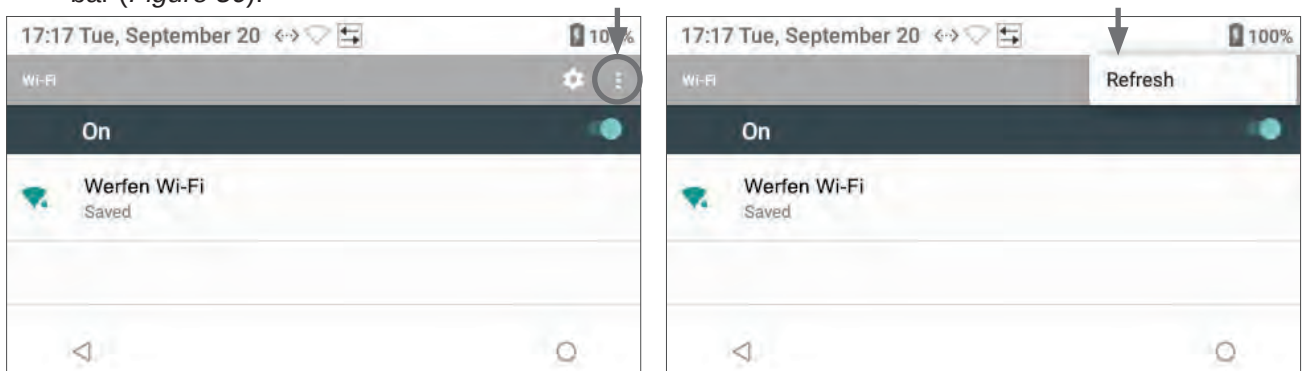


Figure 30: Refresh Search

- 8 A dialog box for the wireless network is displayed. Signal strength and security protocol are also displayed. Configure the following settings:
- **Security** – Select **None**, **WEP**, **WPA/WPA2 PSK**, or **802.1x EAP**.
NOTE: For 802.1x EAP (EAP Method), select PEAP, TLS, TTLS, or PWD.
 - **Phase 2 Authentication** – Select **None**, **PAP**, **MSCHAP**, **MSCHAPV2**, or **GTC**.
- 9 If the wireless network is protected by a password, scroll down to the **Password** text field, enter the password, and select **Save**.
- 10 (Optional) For advanced settings, scroll down to the **Advanced Options** drop-down list and configure the following settings:
- **Proxy** – Select **None**, **Manual**, or **Proxy Auto-Config**.
 - **IP Settings** – Select **DHCP** or **Static**.
NOTE: If Static is selected, add IP Address, Gateway, Network Prefix Length, DNS 1, and DNS 2.
- 11 Select **Save**.
- If the network connection is established, **Saved** is displayed below the network name in the list of wireless networks (Figure 30).

NOTE: A firewall might prevent the instrument from being connected to the network. See “Install CCM Software and Configure Firewalls” (page 81).

NOTE: Minimum Wi-Fi Signal Strength of -80 dBm with a SNR 10 dB (Signal must be 10 dB above the noise level).

NOTE: While Wi-Fi is connected, select **Advanced Options** > **IP Settings** and change the setting from **DHCP** to **Static** mode on each GEM Hemochron 100 instrument to maintain a fixed IP address.

NOTE: Network access must be restricted and isolated to the minimum required communication ports and protocols. This is a shared responsibility; the device should limit the exposed ports and the customer provided network shall be isolated/segmented from the business network. The segmentation should be provided by VLAN or by firewall, whichever is preferred. All unnecessary ports, protocols, and services should be blocked (e.g., ICMP).

Disconnect from a Wireless Network:

To disconnect from a wireless network:

- 1 Select  (Settings) > **Supervisor Settings** > **Instrument Settings** > **Wi-Fi**.
- 2 Select the network name and a dialog box for the wireless network is displayed.
- 3 Select **Forget** to disconnect the instrument from the wireless network.

Check the Quality of a Wireless Network Signal:

To check the quality of a wireless network signal:

- 1 Select  (Settings) > **Supervisor Settings** > **Instrument Settings** > **Wi-Fi**.
- 2 Select the network name and a dialog box containing the details of the wireless network is displayed.

NOTE: The indicator is a relative indication. See “Wi-Fi Signal Strength” (page 47).

Δ 3.3.8 Language

- 1 Select  (Settings) > **Supervisor Settings** > **Instrument Settings** > **Language**.
- 2 In the dialog box, select the preferred instrument language:
English, Spanish (Español), **French** (Français), **Italian** (Italiano), **German** (Deutsch), **Portuguese** (Português), **Swedish** (Svenska), **Norwegian** (Norsk), **Danish**, (Dansk), and **Finnish** (Suomi).

3.3.9 View Instrument Information

To view read-only information about the instrument hardware and software:

- Select  (Settings) > **Supervisor Settings** > **Instrument Settings** > **Instrument Information**.

3.3.10 POCT1-A Network Settings

Supervisors can configure a POCT1-A network for use with middleware. A POCT1-A network allows an instrument to communicate with other POCT1-A compliant devices.

- 1 Contact the institution's network administrator for the **IP Address** and **Port** that the instrument will use when it is connected to the POCT1-A network.
- 2 Select  (Settings) > **Supervisor Settings** > **POCT1-A Network Settings**.
- 3 In the dialog box (Figure 31), enter the **IP Address** and the **Port**.

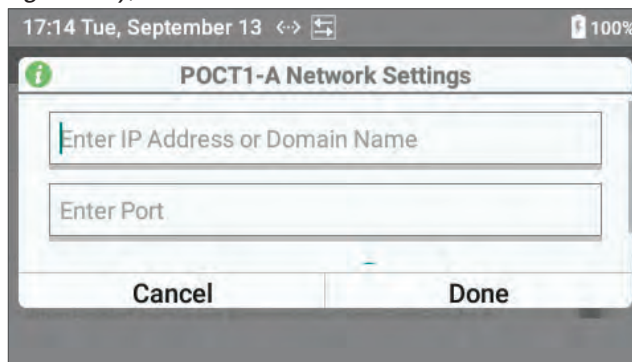


Figure 31: POCT1-A Network Settings

- 4 Scroll down (Figure 32) and use the toggle to select **On**  (Toggle On) or **Off**  (Toggle Off) for **Encryption**. The factory default setting for **Encryption** is set to **On**  (Toggle On).

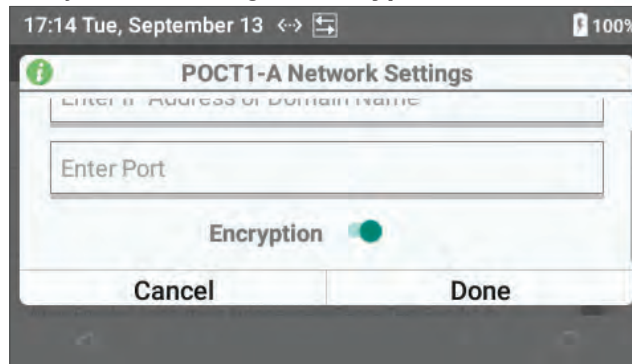


Figure 32: POCT1-A Network Settings – Encryption

- 5 Select **Done**.

3.3.11 Set Port Number and Encryption Mode for CCM

CCM 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  (Settings) > **Supervisor Settings** > **CM Connection Settings**.
- 2 In the dialog box (Figure 33), enter an unused **Port** number (e.g., 50000). For assistance, consult with the institution's network administrator.

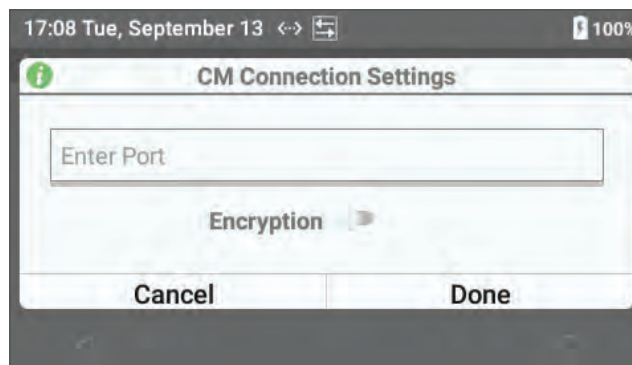


Figure 33: Configuring Port Number and Encryption Mode

NOTE: Verify that the **Encryption** settings match on the instrument and **CCM**.

NOTE: Verify that the **Port** setting on the instrument matches the **Remote Poke Port** setting on **CCM**. For the **Encryption** and **Remote Poke Port** settings on **CCM**, see “Configure Network Settings” (page 85).

- 3 Select **Done**.

NOTE: Supervisors can consult the **IP Address** and **MAC Address** in **Instrument Settings**. See “View Instrument Information” (page 38).

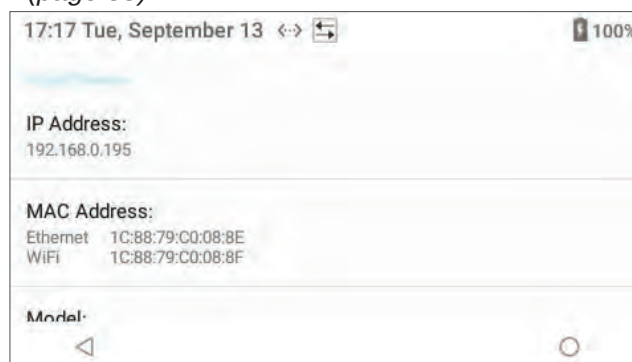


Figure 34: IP Address and MAC Address

3.3.12 Automatically Send Test Results to the Network (Auto Send)

Supervisors can enable the **Auto Send** feature that automatically sends a test result to a network when an *Operator* removes a test 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” (page 35).

When the instrument is sending test results to the network, the  (Test Result Transmission Sent) will be displayed indicating the transmission was successful. If  (Test Result Transmission Failed) is displayed, the transmission failed.

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

- **On**  (Toggle On) – Enabled (test results will automatically be sent to the network).
- **Off**  (Toggle Off) – Disabled (test results will **NOT** be sent but can still be manually sent to the network). This is the factory default setting.

NOTE: When viewing test results in the **Database**, *Operators* and *Supervisors* can manually send test results to the network using the **Send All** command. See “Database” (page 67).

3.3.13 NTP Server Settings

NOTE: To configure **NTP Server Settings**, set the toggle for **Automatic Date & Time** to **On**  (Toggle On). See “Enable the Date and Time to be Set Automatically” (page 33).

- 1 Select  (Settings) > **Supervisor Settings** > **NTP Server Settings**.
- 2 The default **NTP** server address (**2.android.pool.ntp.org**) is displayed (Figure 35). Select the text field and enter the new **NTP** server address.

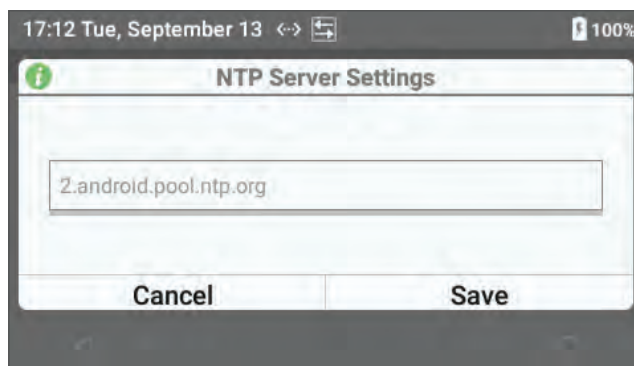


Figure 35: NTP Server Settings

- 3 Select **Save**.
- 4 To apply the **NTP Server Settings**, power the instrument off and back on.
- 5 Repeat process for all instruments.

3.3.14 Operator ID (OID) Settings

Supervisors can use the instrument menus to require *Operators* to enter an OID, registered OID, and password to run tests. A maximum of 10,000 OIDs can be either sent or stored on the instrument.

When *Operators* are required to scan their OID, the user is prompted to activate the barcode scanner. For more information about using the barcode scanner, see “Using the Barcode Scanner” (page 26).

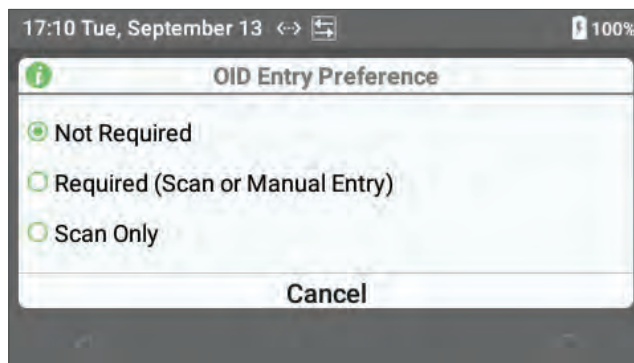
In addition to using the instrument menus to configure OID settings, *Supervisors* can also use **CCM** to configure these same settings and to configure other more advanced OID settings. See “Centralized Configuration Manager (CCM) Software” (page 79).

3.3.14.1 Require Operators to Enter Their OID and Specify the Method

Supervisors can require *Operators* to enter their OID when they run tests (patient and LQC tests). By choosing whether or not to require *Operators* to enter an OID, a *Supervisor* also specifies the method the *Operator* is allowed to use to enter the OID.

- 1 Select  (Settings) > **Supervisor Settings** > **OID Entry Preference**.

- 2 In the dialog box (Figure 36), 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 barcode or manually enter the OID.
 - **Scan Only** – Before *Operators* run a test, they are required to enter their OID by scanning a compatible barcode.

Figure 36: *OID Entry Preference*

3.3.14.2 *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 720 hours. The factory default setting duration is **0** (zero) hours. Meaning, OID reuse will not go into effect until the *Supervisor* specifies a duration other than **0** (zero). See “*Allow OID Reuse During Patient Testing*” (page 41).

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  (Settings) > **Supervisor Settings** > **OID Reuse (During Patient Tests)**.
- 2 Select the appropriate option to enable or disable OID reuse:
 - **Off**  (Toggle Off) – Disabled.
 - **On**  (Toggle On) – Enabled (the OID will automatically be entered into the dialog box).

Allow OID Reuse During LQC Testing:

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

3 - Instrument Settings

- 2 Select the appropriate option to enable or disable OID reuse:
 - **Off**  (Toggle Off) – Disabled.
 - **On**  (Toggle On) – Enabled (the OID will automatically be entered into the dialog box).

Specify OID Reuse Duration:

- 1 Select  (Settings) > **Supervisor Settings** > **OID Reuse Duration**.
- 2 In the dialog box (*Figure 37*), scroll the **Hours** and **Minutes** to select the duration. The minimum duration is 30 minutes; maximum duration is 720 hours.

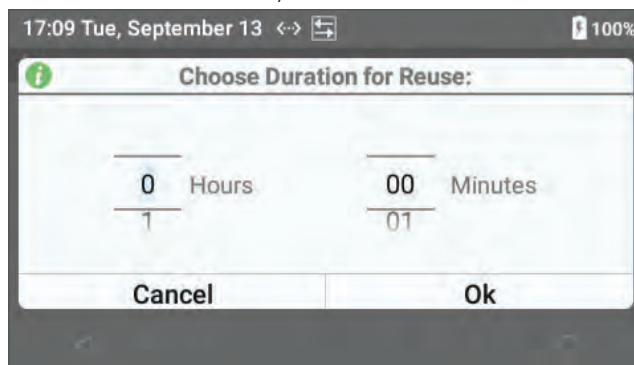


Figure 37: OID Reuse Duration

- 3 Select **OK**.

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

NOTE: OID reuse will not go into effect until the Supervisor specifies the period of time the feature is to remain enabled.

3.3.15 Patient ID (PID) Settings

Supervisors can use the instrument menus to require *Operators* enter PID to run tests.

When *Operators* are required to scan the PID, the user is prompted to activate the barcode scanner. For more information about using the barcode scanner, see “*Using the Barcode Scanner*” (page 26).

In addition to using the instrument menus to configure PID settings, *Supervisors* can also use **CCM** to configure these same settings and to configure other more advanced PID settings. See “*Centralized Configuration Manager (CCM) Software*” (page 79).

3.3.15.1 Require Operators to Enter a PID and Specify the Method

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

- 1 Select  (Settings) > **Supervisor Settings** > **PID Entry Preference**.

2 In the dialog box (Figure 38), select the appropriate option:

- **Not Required** – Before *Operators* run a patient test, they are **NOT** required to enter a PID.
- **Required (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 the PID.
- **Scan Only** – Before *Operators* run a patient test, they are required to enter a PID by scanning a compatible barcode.

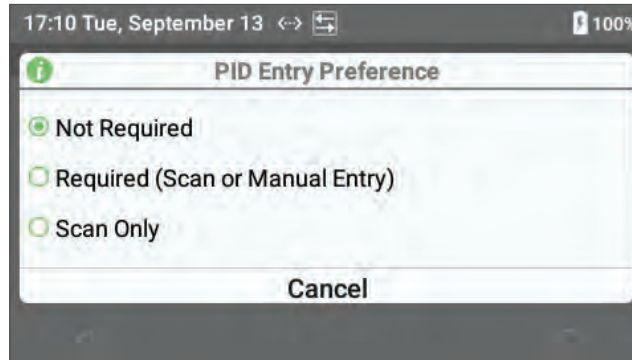


Figure 38: PID Entry Preference

3.3.15.2 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 1 hour and no more than 240 hours. The factory default setting duration is **0** (zero) hours. Meaning, PID reuse will not go into effect until a *Supervisor* specifies a duration other than **0** (zero). See “Specify PID Reuse Duration” (page 43).

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  (Settings) > **Supervisor Settings** > **PID Reuse (During Patient Test)**.
- 2 Select **On** to enable PID reuse:
 - **Off**  (Toggle Off) – Disabled.
 - **On**  (Toggle On) – Enabled (the PID will automatically be entered into the dialog box).

Specify PID Reuse Duration:

- 1 Select  (Settings) > **Supervisor Settings** > **PID Reuse Duration**.
- 2 In the dialog box (Figure 39), scroll the **Hours** and **Minutes** to select the duration. The minimum duration is 1 hour; maximum is 240 hours.

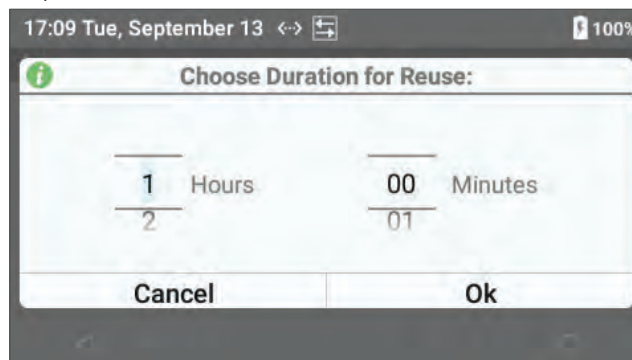


Figure 39: PID Reuse Duration

- 3 Select **OK**.

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

NOTE: PID reuse will not go into effect until a Supervisor specifies the period of time the feature needs to remain enabled.

3.3.16 Clear Test Results

A maximum of 10,000 test results (patient, LQC, and EQC tests) can be stored in the instrument database. Supervisors can clear (delete) test results.



CAUTION: Deleted test results cannot be recovered.

NOTE: To export **Test Records** see "Export Tests Records to a CVS File"

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

- (Optional) Back up the test results that need to be deleted by sending the test results to the network, see "Database" (page 67).
- Enable the setting to erase (delete) the **Database** in **CCM**, see Table 14 (page 91).
- Clear the test results.

To erase (delete) **Database** test results (patient, LQC and EQC tests), 2 steps are required:

- 1 Enable the setting to erase (delete) the **Database** in **CCM**, see Table 14 (page 91).
- 2 Follow instructions below on the instrument:

Clear All Test Results:

- 1 Select  (Settings) > **Supervisor Settings** > **Clear All Test Results**.
- 2 In the dialog box, select **Delete** to delete all test results.

Clear All Patient Test Results:

- 1 Select  (Settings) > **Supervisor Settings** > **Clear All Patient Test Results**.
- 2 In the dialog box, select **Delete** to delete all patient test results.

3.3.17 Test the Barcode Scanner

Supervisors can test the barcode scanner.

- 1 Select  (Settings) > **Supervisor Settings** > **Barcode Scanner Test**.
- 2 A dialog box for testing the barcode scanner is displayed (Figure 40).

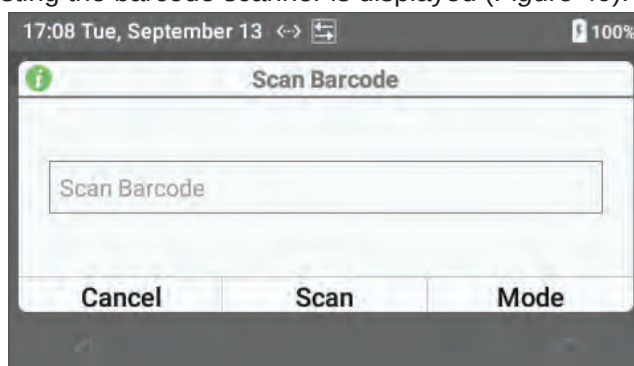


Figure 40: Barcode Scanner Test

- 3 Select **Mode**.

4 In the **Scan Mode** dialog box (Figure 41), select the appropriate option:

- **Default Scan**
- **OID Scan**
- **PID Scan**

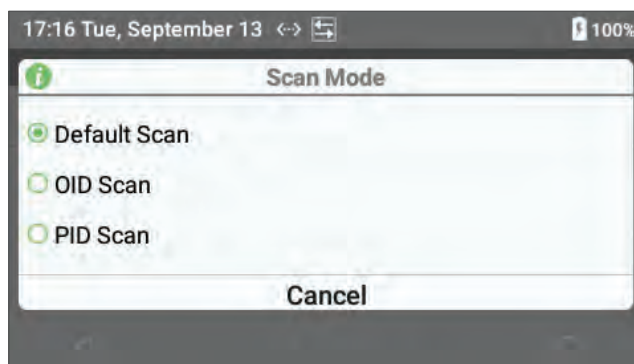


Figure 41: Scan Mode

5 Select **Scan** and then scan the barcode.

6 Compare the displayed information with the human-readable information on the barcode label:

- If the information matches, the barcode scanner is working and barcode parsing is **not** required.
- If the information does not match, barcode parsing is required. See “Barcode Settings Dialog Box” (page 98) in **CCM**.

7 Select **Cancel** to return to the **Supervisor Settings** menu.

For more information about using the barcode scanner, see “Using the Barcode Scanner” (page 26).

3.4 Run a Demo Test

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

To run a demo test, select  (Settings) > **Demo**.

1 The demo prompts the *Operator* to insert a test cartridge. **Do NOT insert a test cartridge** (Figure 42).

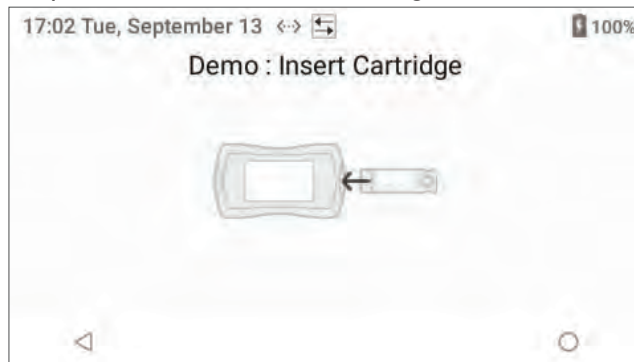


Figure 42: Demo – Insert Test Cartridge

- 2 The demo displays  (Warming Test Cartridge), indicating that the test cartridge is being warmed (Figure 43).



Figure 43: Demo – Warming Test Cartridge

- 3 The demo displays  (Apply Sample to Test Cartridge), indicating the instrument is ready for the sample to be applied (Figure 44).

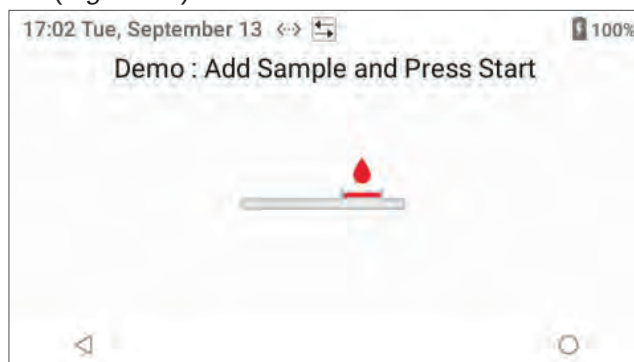


Figure 44: Demo – Add Sample and Press Start

- 4 The demo displays  (Sample in Test Channel), indicating the sample volume is adequate. The instrument draws the sample into the test channel of the test cartridge and proceeds with the analysis of the sample (Figure 45). At this point, the *Operator* would wait for the test results.



Figure 45: Demo – Positioning Sample

- 5 The demo displays the test result as Celite equivalent ACT value in seconds when clotting is detected (Figure 46). At this point, the *Operator* could view more details about the test.

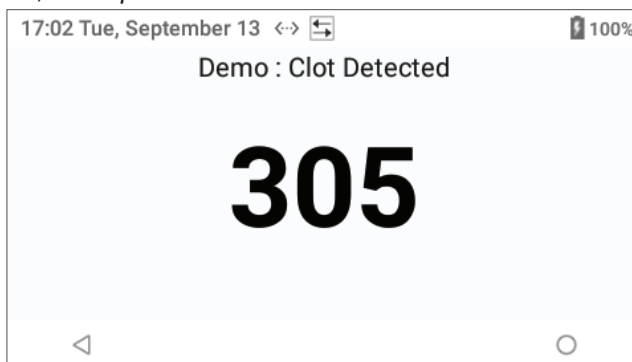


Figure 46: Demo – Clot Detected

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

- To run a patient test, see “Run a Patient Test” (page 49).
- To run an LQC test, see “Run an LQC Test” (page 63).

3.5 **Wi-Fi Signal Strength**

To see the details for the wireless network, see “Check the Quality of a Wireless Network Signal” (page 38). To check the strength of a wireless signal:

- Select  (Settings) > **Wi-Fi Signal Strength**.

NOTE: *Signal Strength is the Wi-Fi RSSI. The indicator is a relative indication (Figure 47).*

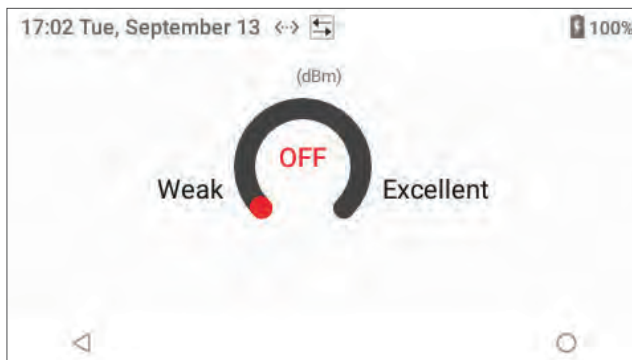


Figure 47: Wi-Fi Signal Strength (Wi-Fi RSSI)

Δ 4 Patient Testing

4.1 Considerations About Patient Testing



BIOHAZARD: Running a patient test requires the handling of human blood samples. Strictly adhere to the institution's policies for the proper handling and disposal of biohazardous materials.



BIOHAZARD: Test cartridges are for single-use only, do **NOT** reuse. Used test cartridges should be considered as potentially infectious. Strictly adhere to the institution's policies for the proper handling and disposal of biohazardous materials.

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” (page 56).

Test Cartridges:

Only use GEM Hemochron 100 test cartridges. Use the appropriate test cartridge for the type of test that will be performed. Test cartridges are for single-use only, do **NOT** reuse.

Patient Samples:

Operators must not prepare the patient sample until the instrument prompts them to apply the sample to the test cartridge. If the patient sample is prepared too early, premature clotting could cause erroneous test results. Refer to the appropriate GEM Hemochron 100 test cartridge package insert.

Test Results:

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

Test results that are within the analytical measurement range of the test are reported as Celite equivalent ACT value in seconds. The analytical measurement range for each test is a factory default setting and cannot be changed. Test results that are outside the analytical measurement range of the test are not reported and are logged as:

- **Out of Range Low** – The test result is lower than the analytical measurement range.
- **Out of Range High** – The test result is greater than the analytical measurement range.

If a test result is out of range, “Out of Range High” or “Out of Range Low” should not be interpreted as a test result and the test needs to be repeated. If the test result is still out of range, see “Troubleshooting” (page 73).

NOTE: Test results are stored in the instrument database. To view them, see “Database” (page 67).

4.2 Specimen Collection

Collect fresh whole blood samples for coagulation testing in accordance with institutional procedures and the Clinical and Laboratory Standards Institute (CLSI) guideline POCT14-A ensuring sufficient dead space volume of blood is removed prior to specimen collection, when applicable.

IMPORTANT: Collect blood specimens in a manner that prevents contamination with tissue thromboplastin, indwelling intravenous (IV) solutions, or alcohol cleansing solution. Discard samples that are not properly collected or contain visible clots or debris.

Use a 23-gauge or larger needle if a syringe is used for blood collection. If a sample is expelled through the same needle, do it slowly to prevent hemolysis.

Refer to the package insert accompanying the GEM Hemochron 100 test cartridges for specimen collection, storage, handling, and disposal instructions.

Δ 4.3 Run a Patient Test

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

NOTE: Keep the instrument on a horizontal and stable surface.

NOTE: If a test cartridge was left in the instrument from a previous test, remove and dispose in a biohazardous waste container in accordance with institutional guidelines.

(Optional) To use the Test Interval Timer for a patient test, see “Test Interval Timer Feature (Optional)” (page 52).

- 1 On the **Home** screen, select  (Patient Test) or insert a new test cartridge (in this case go to step 3).
NOTE: If the ESV test fails, run an EQC test. A successful EQC test is required to run a patient test. See “Run an EQC Test” (page 60). If the EQC test fails, contact Technical Support.
- 2 When  (Insert Test Cartridge) is displayed, insert the appropriate test cartridge (ACT+ or ACT-LR) for the type of test that needs to be performed.
NOTE: When inserting the test cartridge, fully insert into the Test Cartridge Insertion Chamber.
- 3 Wait while the instrument does the following:
 - Reads the test cartridge barcode, and
 - Displays  (Checking Test Cartridge).
- 4 Depending on instrument configuration:
 - If prompted to enter the OID, do either of the following:
 - Select **Scan** and scan a compatible OID barcode. If **OID Password Scan** is enabled in **CCM** (“OID Password Scan” (page 92)), select **Scan** to scan a compatible OID password barcode and then select **Done**.
 - Manually enter the OID (touch the text field to display virtual keyboard).
 - If the previous OID is already in the text field, select **Save** to reuse or select the text field and overwrite the OID. If required, enter the OID password before selecting **Save**.
 - If prompted to enter the PID, do either of the following:
 - Select **Scan** and scan a compatible PID barcode.
 - Manually enter the PID (touch the text field to display virtual keyboard).
 - If the previous PID is already in the text field, select **Save** to reuse and then **Yes** to confirm, or select the text field and overwrite the PID.
- 5 Wait while  (Warming Test Cartridge) is displayed, the instrument is warming the test cartridge.
- 6 When  (Apply Sample to Test Cartridge) is displayed, the test cartridge is ready to receive the sample.
- 7 A 5 minute countdown timer will be displayed that indicates to add the sample to the test cartridge.
NOTE: A sufficient quantity of blood must be added directly to the center sample well to fill it. Should a large drop of blood extend above the center of the sample well, gently push the excess blood into the overflow area.
 **CAUTION:** If a sample is not applied within 5 minutes, the test will time out. If this occurs, dispose of the test cartridge and repeat the test using a new test cartridge.
- 8 Select  (Start Test) to run the test.
NOTE: To abort the test, select  (Abort Test) at any time.
NOTE: By pressing  (Home) or  (Back), the test can be canceled.

9 Wait while the instrument does the following:

- Displays  (Sample in Test Channel), 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 test cartridge.
- Draws the sample from the sample well into the test channel of the test cartridge and proceeds with the analysis of the sample.
- Measures ACT (a counter displays the number of seconds).
- Displays the test result. Test results are displayed as Celite equivalent ACT value in seconds, not real-time seconds. If the test result is out of range, repeat the test. If the test result is still out of range, see "Troubleshooting" (page 73).

10 The test result is displayed (Figure 48).

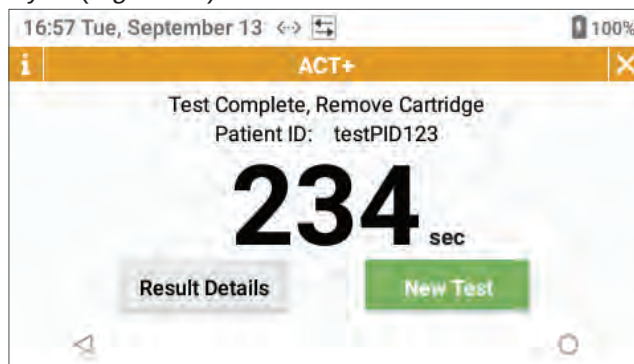


Figure 48: Patient Test Result

11 Remove the test cartridge and dispose in a biohazardous waste container in accordance with institutional guidelines.



BIOHAZARD: Test cartridges are for single-use only, do **NOT** reuse. Used test cartridges should be considered as potentially infectious. Strictly adhere to the institution's policies for the proper handling and disposal of biohazardous materials.

NOTE: The test result will remain on the screen until a new test is performed or the user selects **X** (Figure 48).

NOTE: If **Auto Send** is enabled, the instrument will automatically send the test result to the network and  (Test Result Transmission Sent) will be displayed indicating the transmission was successful (Figure 49). If **Auto Send** is not enabled, the user will need to manually send each test result. This action will transmit the current result together with other pending, unsent results.



Figure 49: Test Result Transmission Sent

12 From the patient test result screen (Figure 48), the user can do any of the following:

- **Start a new test** – Select **New Test** (New Test) to start a new patient test. The instrument will indicate to remove the test cartridge  (Remove Test Cartridge).
- **Add a user note** – Select **Result Details** (Result Details) and then select  (User Note). Enter the note (30 characters maximum) and select **Save**.
- **View details of the test result** – Select **Result Details** (Result Details) and detailed information about the test result is displayed (Figure 50).

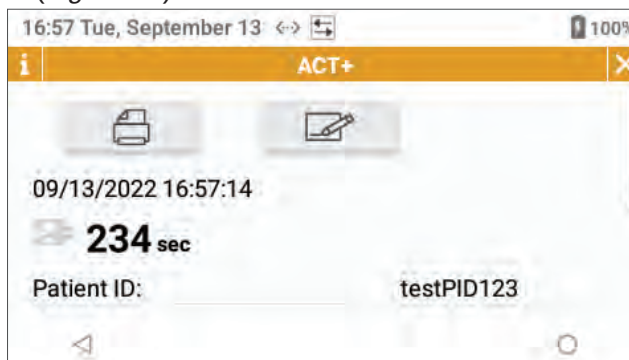


Figure 50: Patient Test Result Details

NOTE: The test result date refers to the test start date and time, not the time the test result was sent or completed.

- **Print the test result** – Select **Result Details** (Result Details) and then select  (Print). Select the desired printer from the drop-down list and then select  (Print) to print the test result (Figure 51). To configure the network printer, see “Printer Configuration” (page 68).

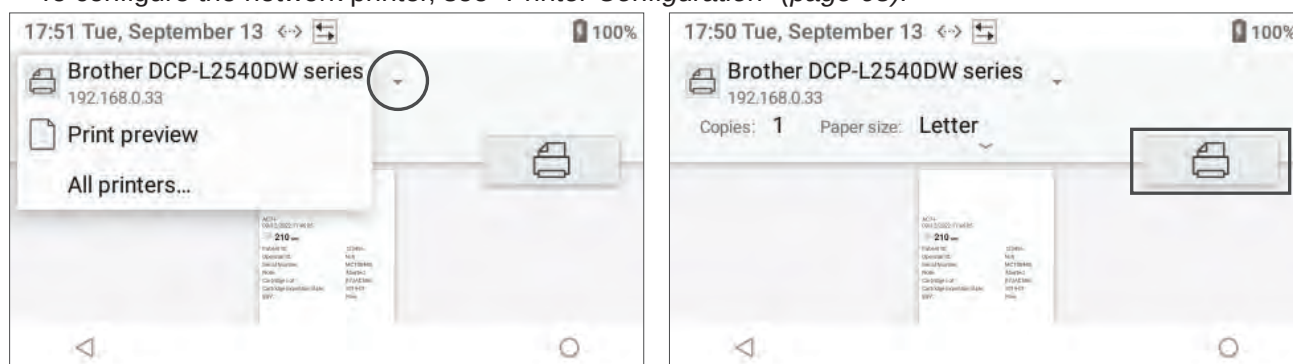


Figure 51: Print Patient Test Result

NOTE: Patient test results are stored in the instrument database. To view them, see “Database” (page 67).

4.4 Patient Test Results Data

As a complementary feature, during an active singular procedure, the GEM Hemochron 100 instrument can display up to 10 sequential patient test results on the left side of the display screen. To access these test results, select **i** (Information) (Figure 52). To close this feature, select **i** (Information).



Figure 52: Patient Test Results Data

This feature can be helpful for patient management (e.g., during cardiopulmonary bypass or atrial ablation procedures) by showing in a list the baseline and the sequential ACT tests to that particular patient (up to 10 test results).

The test results displayed will only be available for the current PID and automatically cleared when a new PID is recorded.

NOTE: If PID is not required, the test pane will display **No Patient ID**, and the last 10 test results will not be associated to any PID (Figure 53).

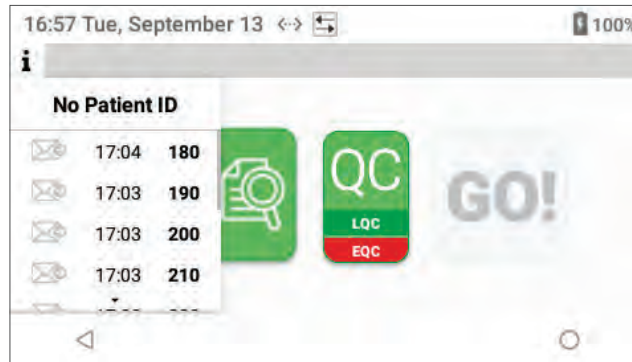


Figure 53: No Patient ID

4.5 Test Interval Timer Feature (Optional)

This is an optional feature used to notify the *Operator* that a specified period of time has elapsed since the last patient test. Once the Test Interval Timer has expired, the *Operator* receives a notification (Figure 54). This notification can be accompanied by 1 audible beep and/or an audible beep that is repeated every minute until the *Operator* acknowledges the notification by selecting **Ok**.

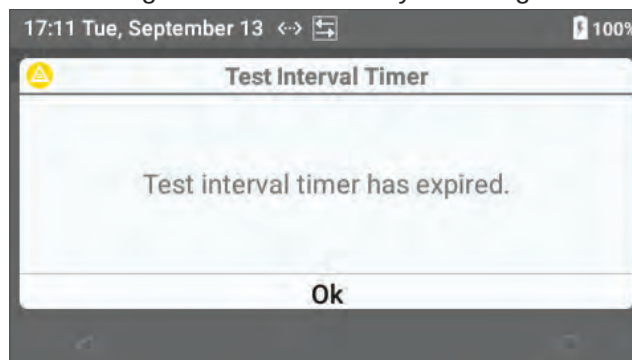


Figure 54: Test Interval Timer Expired

To Enable the Test Interval Timer Feature:

NOTE: The Interval Timer setting must be set to **Show** (Show) to use the Test Interval Timer feature. To configure Interval Timer setting, see “Interval Timer” (page 27).

- 1 On the **Home** screen, select **i** (Information), then change the status from  (Disabled) to  (Enabled). See Figure 55.

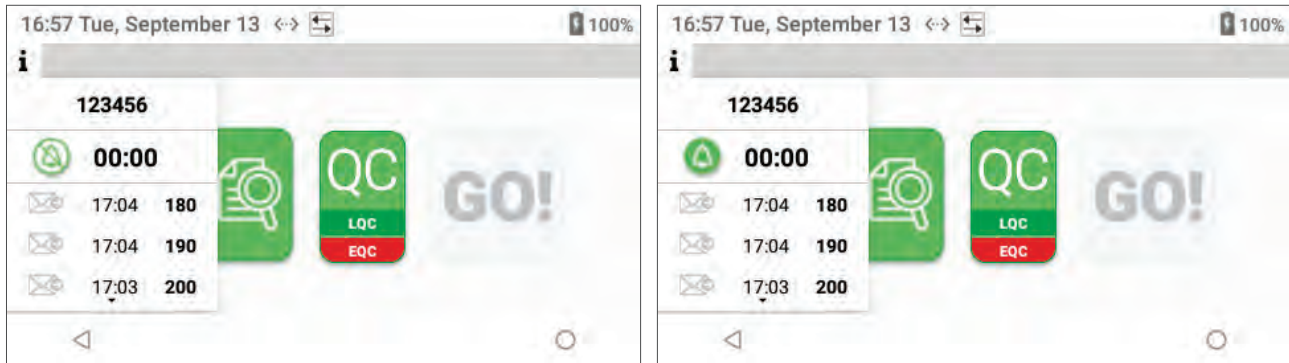


Figure 55: Test Interval Timer Feature – Disabled to Enabled

- 2 In the dialog box (Figure 56), scroll the **Minutes** for **Notification Time** to select the duration or manually enter the value (touch the text field to display virtual keyboard).

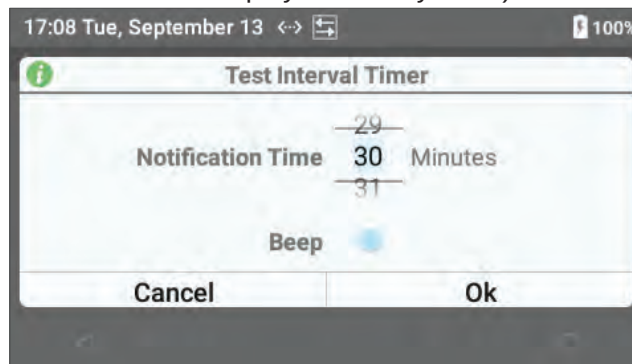


Figure 56: Test Interval Timer – Notification Time

- 3 (Optional) Scroll down (Figure 57) and use the toggle to select **On** or **Off** for the following options:
 - **Beep:**
 - **On**  (Toggle On) – Enabled (the notification is accompanied by 1 audible beep).
 - **Off**  (Toggle Off) – Disabled (the notification is **NOT** accompanied by an audible beep).
 - **Repeat:**
 - **On**  (Toggle On) – Enabled (the audible beep will be repeated every minute until the notification is acknowledged by the *Operator*).
 - **Off**  (Toggle Off) – Disabled (the audible beep is **NOT** repeated).

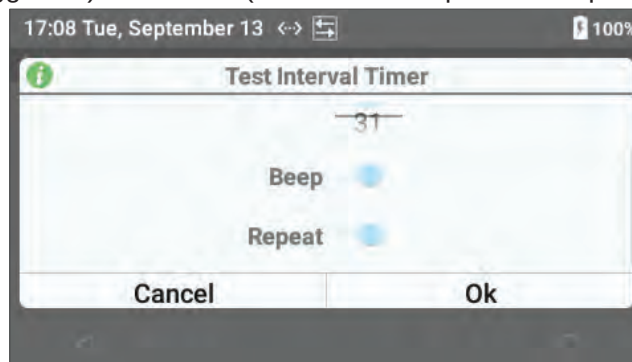


Figure 57: Test Interval Timer – Beep and Repeat Options

- 4 Select **Ok**.

$\Delta 5$ Quality Control (QC)

Global and/or local regulatory agencies recommend that medical and laboratory instrumentation be enrolled in a quality assurance program adequate in maintaining accurate and reliable system performance.

The GEM Hemochron 100 performs QC checks automatically during system operation to ensure vital functional and analytical components are operational.

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

- Testing system performance using internal Electronic Quality Control (EQC).
- Testing cartridges in accordance with the package insert for each assay using 2 levels of external Liquid Quality Control (LQC) products.

NOTE: *The instrument is calibrated at the manufacturing facility to test and verify all functions. The instrument is also self-verifying, 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 2 types of QC testing:

- **EQC testing** – During EQC testing, the instrument runs an internal test. This test does not check the liquid assay function, so a test cartridge and LQC product are not used. For more information, see “*Electronic Quality Control (EQC) Testing*” (page 55).
- **LQC testing** – This test checks the liquid assay function of the instrument using LQC product and a test cartridge.
 - For information about test cartridges, see “*Test Cartridges*” (page 16).
 - For information about LQC products, see “*LQC Products*” (page 56).
 - For information about LQC testing in general, see “*Liquid Quality Control (LQC) Testing*” (page 56).

QC of the GEM Hemochron 100 Instrument:

The GEM Hemochron 100 instrument should have 2 levels of QC performed every 8 hours of operation. This requirement can be accomplished by conducting internal EQC or external LQC testing.

QC of the GEM Hemochron 100 Test Cartridges:

Performance of **each lot** of GEM Hemochron 100 test cartridges should be validated with 2 levels (Level 1 [Normal] and Level 2 [Abnormal]) of LQC using directCHECK Whole Blood Quality Controls:

- When a **new shipment** is received, AND
- **Once per 30 calendar days thereafter.**

Following successful performance validation, the test cartridges will not require any further LQC unless a shift in clinical results is suspected; however, each institution should follow its own quality assurance policy to determine LQC testing frequency.

The manufacturer’s acceptable performance ranges for the test cartridges are included with each box of LQC product.

5.1 Electronic Quality Control (EQC) Testing



CAUTION: If the EQC test feature is required (**Yes**), the instrument will be required to perform validation testing at regular intervals. The factory default setting for this feature is required (**Yes**) but can be changed using **CCM**. The manufacturer recommends that it be required (**Yes**). The decision to require (**Yes**) or not require (**No**) this feature shall be determined by and is the responsibility of the each institution.

When manually or automatically started, EQC testing will initiate 3 phases (ESV, EQC Level 1, and EQC Level 2) of instrument validation. The first phase, Electronic System Verification (ESV), begins the testing sequence. Once ESV is complete and passes specific component checks, further comprehensive validation tests immediately follow with EQC Level 1 and then EQC Level 2. Once all validation tests successfully pass, the display will indicate **EQC Pass**, including the subtests evaluated. This information is also stored in the instrument database.

If the EQC testing is aborted by the user, the test result will be displayed as **Aborted**. To view details of the test result, select **Result Details** (Result Details). **Pass** or **Aborted** will be displayed next to each phase indicating when the test was aborted.

If ESV fails during the course of EQC testing, neither EQC Level 1 or EQC Level 2 testing will begin. Similarly, if ESV passes but EQC Level 1 fails, EQC Level 2 will not start. The display will indicate **EQC Fail** if ESV, EQC Level 1, or EQC Level 2 testing does not meet **ALL** validation criteria. See “Troubleshooting” (page 73) for assistance or contact Technical Support.

In addition to the EQC, an ESV test is automatically performed under the following conditions:

- After powering on the instrument.
- During EQC test.
- Before patient and LQC test (for patient test, the ESV is not shown on the display screen).

Table 8: ESV and EQC Tests

	ESV	EQC Level 1	EQC Level 2
Instrument Component	• Internal Voltages • Analytic Firmware CRC • Assay Definition File CRC • Calibration and Factory CRC • Battery Health • Real-Time Clock • Processor Communication • Heater ESV • Pump ESV	• Camera • Illumination • Heater Level 1 • Pump Level 1	• Heater Level 2 • Pump Level 2
Test Run Time	3 seconds	120 seconds	Configured for 300 seconds, total time = 180 Configured for 500 seconds, total time = 380
Total elapsed time to perform an EQC test is approximately 5 or 8.5 minutes (configuration dependent)			

5.2 Liquid Quality Control (LQC) Testing

An LQC test checks the assay function of the instrument. During this test, the instrument prompts the *Operator* to insert a test cartridge into the instrument and apply the LQC product.



CAUTION: If the LQC test feature is required (**Yes**), the instrument will be required to run LQC tests at regular intervals. The factory default setting for this feature is not required (**No**) but can be changed using **CCM**. The manufacturer recommends that it be required (**Yes**). The decision to require (**Yes**) or not require (**No**) this feature shall be determined by and is the responsibility of the each institution.



BIOHAZARD: Test cartridges are for single-use only, do **NOT** reuse. All used test cartridges and LQC products should be considered as potentially infectious. Strictly adhere to the institution's policies for the proper handling and disposal of biohazardous materials.

LQC Products:

directCHECK Whole Blood Quality Controls are the recommended LQC products for the GEM Hemochron 100 instrument. The LQC product and test cartridge must match the type of LQC test that needs to be run. See *Table 3 (page 20)*.

Acceptable performance ranges for the LQC product are included in the package insert of the LQC product. For assistance, contact your local representative.

LQC Test Results:

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

5.3 QC Lockout

The QC lockout feature prevents *Operators* from running a patient test if the instrument does not meet the performance range. There are 2 types of lockout:

- **Patient Test Lockout** – This feature prevents *Operators* from running patient tests. This occurs when a QC test fails or when an interval expires.
- **QC Test Lockout** – This feature prevents *Operators* from running additional QC tests after the maximum allowed number of failures have been exceeded.

5.3.1 Patient Test Lockout

Patient test lockout occurs under the following conditions:

- **Failed QC Test** – If a QC test fails (EQC or LQC).
- **Expired QC Interval** – If the instrument is configured so that a QC test must be run at specified intervals and the QC Interval expires.

Failed QC Test:

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

Expired QC Interval:

A *Supervisor* can use **CCM** to set a timer on the instrument that will run for a specified period of time. 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*” (page 58).

The *Supervisor* specifies a separate interval for EQC and LQC testing:

- **EQC Interval** – The factory default setting interval is set to 8 hours.
- **LQC Interval** – The LQC lockout feature is disabled by default (the factory setting), so LQC testing will never be required. To set an LQC Interval, the *Supervisor* must first enable LQC lockout.

The *Supervisor* can allow *Operators* to run as many as 240 patient tests after the QC Interval expires (after lockout would have occurred), effectively temporarily overriding interval lockout. After the QC Interval 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 *Supervisor* must log into **CCM** as a *Supervisor*. See “*Configure Instruments (Instrument Settings)*” (page 91).

5.3.2 QC Test Lockout

The instrument counts the number of failed QC tests. A *Supervisor* can allow *Operators* to run as many as 9 additional failed QC tests after the first QC test fails. The *Supervisor* specifies the number of additional tests separately for EQC and LQC tests:

- **Additional failed EQC tests allowed** – By default (when the instrument is in factory default setting), after an EQC test fails, *Operators* can run 1 more EQC test. If the EQC test fails, lockout will occur.
- **Additional failed LQC tests allowed** – By default (when the instrument is in factory default setting), 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 *Supervisor* 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 *Supervisor* must either log into the instrument and run a successful 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 *Supervisor* must log into **CCM**. See “*Configure Instruments (Instrument Settings)*” (page 91).

5.3.3 Clearing a Lockout

To clear a lockout, a *Supervisor* must intervene as follows:

- **Failed QC Test** – To clear a lockout based on a failed QC test, any *Operator* must run a successful QC test (both Level 1 and Level 2 are required). In an emergency, the *Supervisor* can use the instrument menus or **CCM** to clear the lockout.
- **Expired QC Interval** – To clear a lockout based on an expired QC Interval, any *Operator* must run the QC test. If the test passes, the lockout is cleared and the QC Interval is reset.

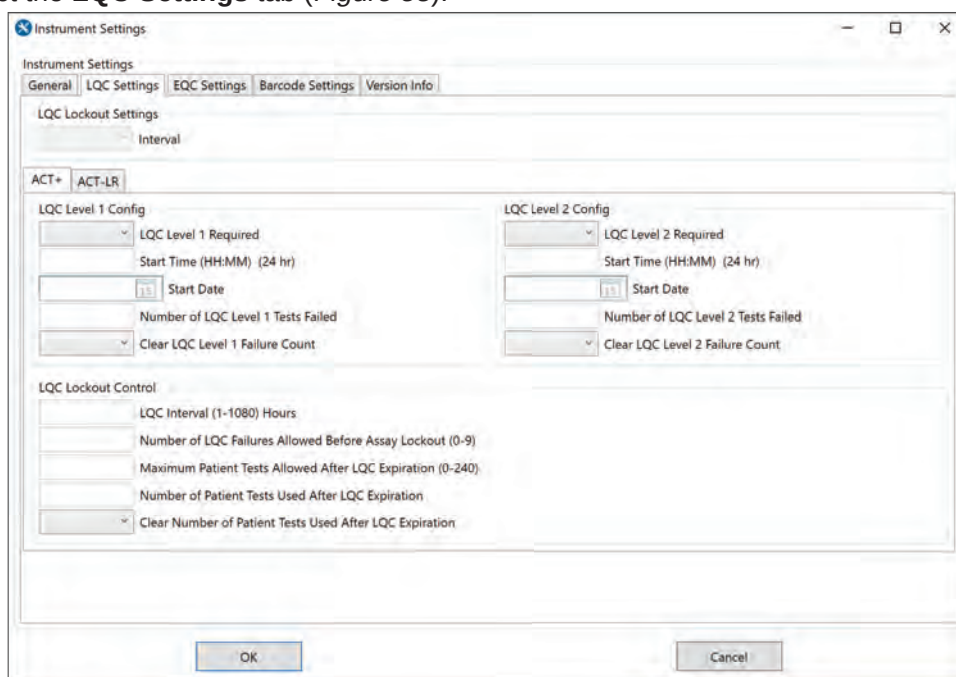
To Clear a Lockout Using the Instrument Menus:

- 1 Select  (Settings) > **Supervisor Settings** > **Reset Counters**.
- 2 Check the box for each counter that needs to be reset.
- 3 Select **Reset**. For more information, see “Reset Counters” (page 32).

To Clear a Lockout Using CCM:

To Clear an LQC Lockout:

- 1 Select the **LQC Settings** tab (Figure 58).



The screenshot shows the 'Instrument Settings' dialog box with the 'LQC Settings' tab selected. The dialog is divided into several sections:

- LQC Lockout Settings**: Includes an 'Interval' dropdown.
- ACT+ / ACT-LR**: Two sub-tabs for configuring LQC levels.
- LQC Level 1 Config**: Includes 'LQC Level 1 Required' (dropdown), 'Start Time (HH:MM) (24 hr)' (dropdown), 'Start Date' (calendar icon), 'Number of LQC Level 1 Tests Failed' (dropdown), and 'Clear LQC Level 1 Failure Count' (dropdown).
- LQC Level 2 Config**: Includes 'LQC Level 2 Required' (dropdown), 'Start Time (HH:MM) (24 hr)' (dropdown), 'Start Date' (calendar icon), 'Number of LQC Level 2 Tests Failed' (dropdown), and 'Clear LQC Level 2 Failure Count' (dropdown).
- LQC Lockout Control**: Includes 'LQC Interval (1-1080) Hours' (dropdown), 'Number of LQC Failures Allowed Before Assay Lockout (0-9)' (dropdown), 'Maximum Patient Tests Allowed After LQC Expiration (0-240)' (dropdown), 'Number of Patient Tests Used After LQC Expiration' (dropdown), and 'Clear Number of Patient Tests Used After LQC Expiration' (dropdown).

At the bottom of the dialog are 'OK' and 'Cancel' buttons.

Figure 58: Clear an LQC Lockout in CCM

NOTE: The **LQC Settings** tab contains 2 sub-tabs: 1 for each type of test (**ACT+** and **ACT-LR**). Be sure to change the settings on each tab.

- 2 Select **Yes** in the **Clear LQC Level 1 Failure Count** drop-down list.
- 3 Select **Yes** in the **Clear LQC Level 2 Failure Count** drop-down list.
- 4 Select **Yes** in the **Clear Number of Patient Tests Used After LQC Expiration** drop-down list.
- 5 Select **OK**.

To Clear an EQC Lockout:

- 1 Select the **EQC Settings** tab (*Figure 59*).

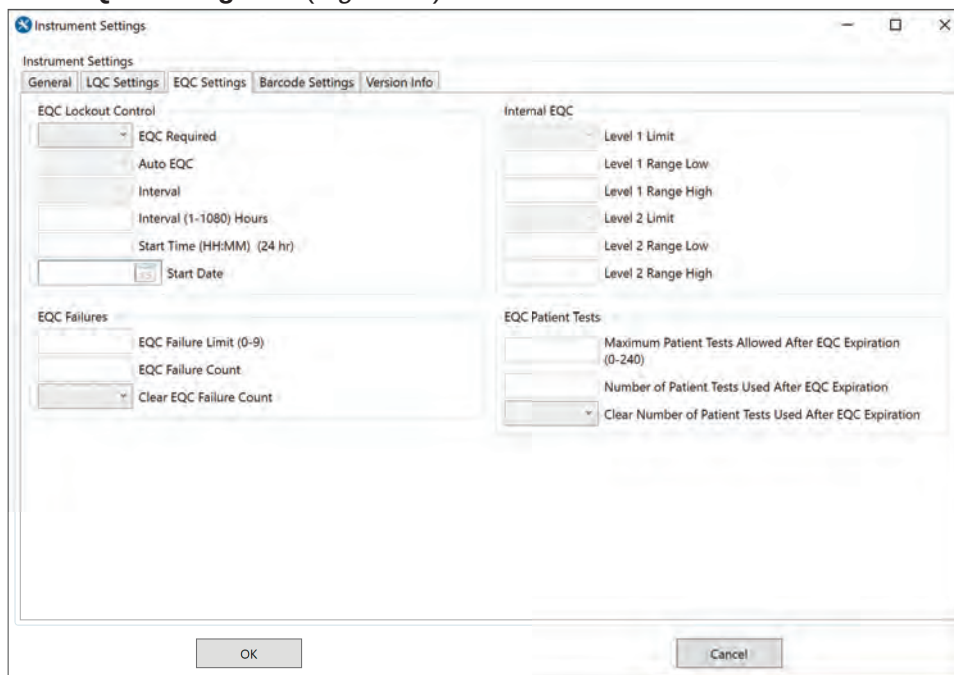


Figure 59: Clear an EQC Lockout in CCM

- 2 Select **Yes** in the **Clear EQC Failure Count** drop-down list.
- 3 Select **Yes** in the **Clear Number of Patient Tests Used After EQC Expiration** drop-down list.
- 4 Select **OK**.

Δ5.4 Run an EQC Test

Before Running an EQC Test:

NOTE: If a test cartridge was left in the instrument from a previous test, remove and dispose in a biohazardous waste container.

Run an EQC Test:

- 1 On the **Home** screen, select  (Quality Control).
- 2 Select the **EQC** tab (Figure 60).

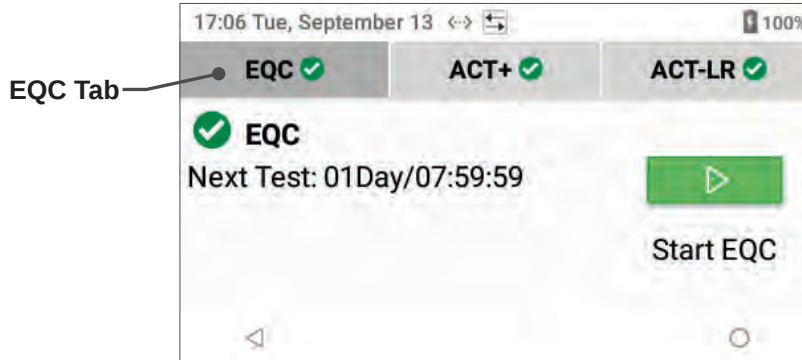


Figure 60: Select EQC Tab

- 3 Select  (Start Test).
 - The EQC test starts. Information about test progress is displayed (Figure 62).
 - If the EQC tab displays  (EQC Interval Expired) or , the EQC Interval has expired or the previous EQC test failed (Figure 61).

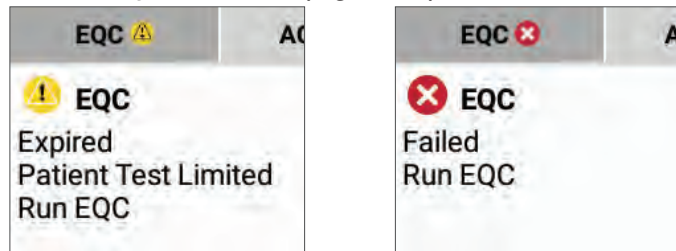


Figure 61: LQC and Patient Testing is Not Allowed

NOTE: The QC status is also displayed on the QC icon located on the **Home** screen.  (QC Expired) for Expired and  (QC Failed) for Failed.

NOTE: To abort the test, select  (Abort Test) at any time (Figure 62).

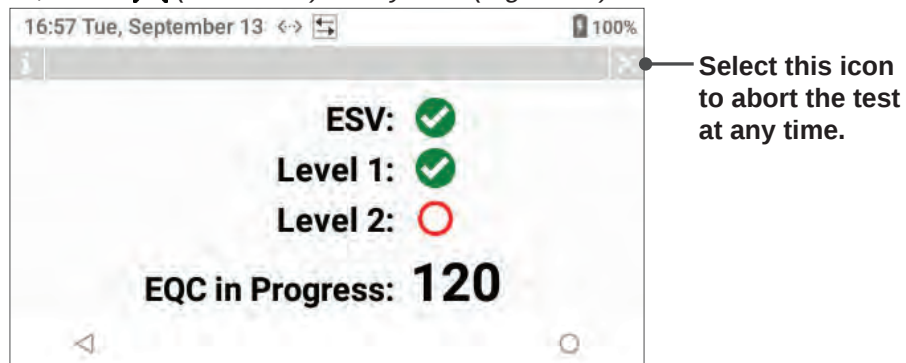


Figure 62: EQC Test in Progress

NOTE: By pressing  (Home) or  (Back), the test can be canceled.

5 - Δ Quality Control (QC)

- 4 Wait until the EQC test result is displayed.
- **Pass** – If the test passes (Figure 63), go to the next step.

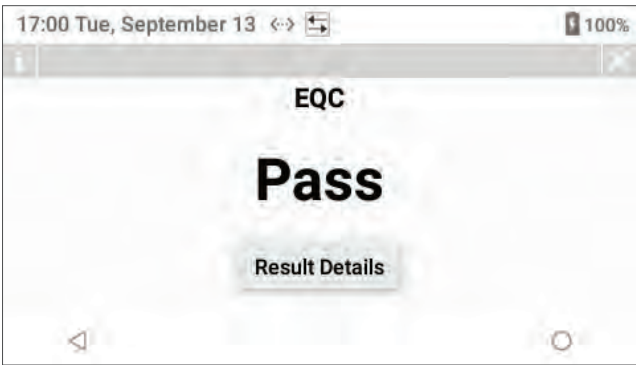


Figure 63: EQC Test Result – Pass

- **Fail** – If the test fails (Figure 64), run the EQC test again. If the test fails again, see “Troubleshooting” (page 73). If the test continues to fail, contact Technical Support.

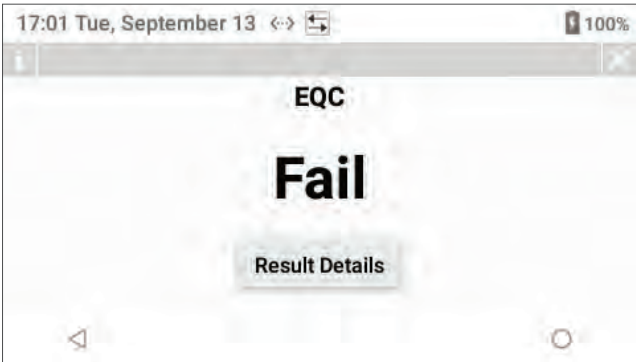


Figure 64: EQC Test Result – Fail

- 5 From the EQC test result screen, the user can do any of the following:
- **View details of the test result** – Select **Result Details** (Result Details) and detailed information about the test result is displayed. Select **ESV Result**, **EQC Level 1 Result**, or **EQC Level 2 Result** (Figure 65) to display the individual components that were tested during the EQC test.

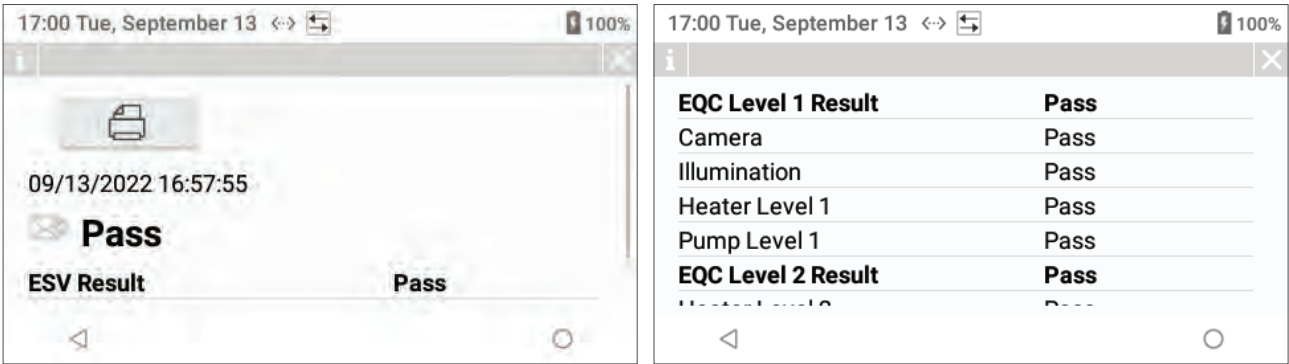


Figure 65: View Test Result Details

NOTE: The test result date refers to the test start date and time, not the time the test result was sent or completed.

- **Print the test result** – Select **Result Details** (Result Details) and then select  (Print). Select the desired printer from the drop-down list and then select  (Print) to print the test result (Figure 66). To configure the network printer, see “Printer Configuration” (page 68).

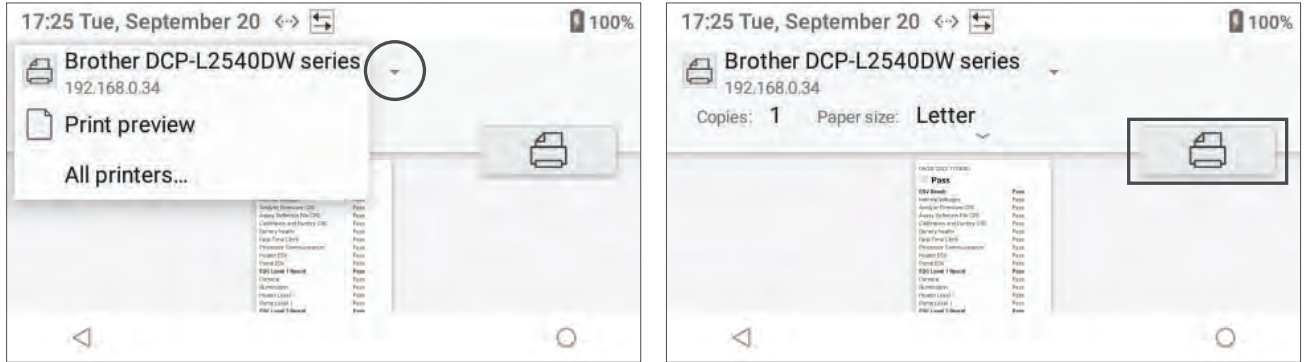


Figure 66: Print EQC Test Result

- **End the test** – Select . The **Home** screen is displayed.

NOTE: EQC test results are stored in the instrument database. To view them, see “Database” (page 67).

NOTE: If **Auto Send** is enabled, the instrument will automatically send the test result to the network and  (Test Result Transmission Sent) will be displayed indicating the transmission was successful (Figure 67). If **Auto Send** is not enabled, the user will need to manually send each test result. This action will transmit the current result together with other pending, unsent results.



Figure 67: Test Result Transmission Sent

Δ5.5 Run an LQC Test



BIOHAZARD: Running an LQC test requires the handling of biohazardous material. Strictly adhere to the institution's policies for the proper handling and disposal of biohazardous materials.

Before Running an LQC Test:

Have directCHECK Whole Blood Quality Controls ready for use as the LQC product during this test.

NOTE: Ensure the label on the LQC packaging is not damaged. If the label is damaged, it might be unreadable; use another package.

NOTE: Keep the instrument on a horizontal and stable surface.

NOTE: If a test cartridge was left in the instrument from a previous test, remove and dispose in a biohazardous waste container in accordance with institutional guidelines.

Run an LQC Test:

- 1 On the **Home** screen, select  (Quality Control).
- 2 Select the appropriate tab (**ACT+** or **ACT-LR**) for the type of LQC test that needs to be run (Figure 68).

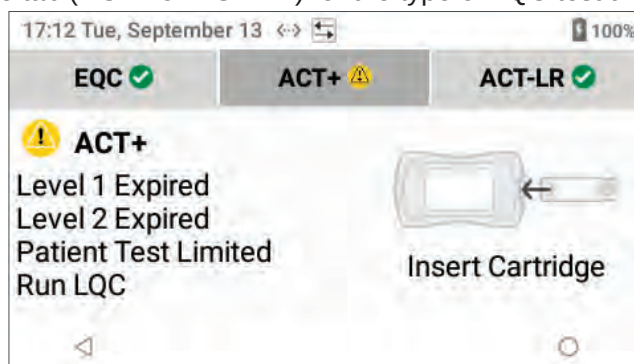


Figure 68: LQC Testing is Allowed

- 3 When  (Insert Test Cartridge) is displayed, insert the appropriate test cartridge (ACT+ or ACT-LR) for the type of LQC test that needs to be performed.
NOTE: When inserting the test cartridge, fully insert it into the Test Cartridge Insertion Chamber.
- 4 A dialog box for entering LQC lot information is displayed (Figure 69).

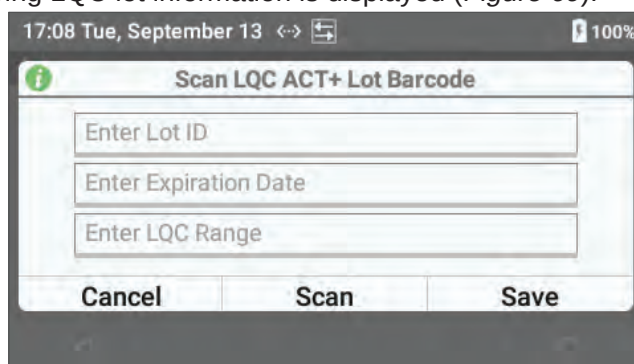


Figure 69: Enter LQC Lot Information

- 5 To enter the LQC lot information, do either of the following:
 - Select **Scan** and scan the compatible barcode on the Acceptable Performance Range label provided on the package insert of the LQC product.
 - Manually enter the Acceptable Performance Range label information (touch the text field to display virtual keyboard).
- 6 Compare the LQC lot information in the dialog box with the human-readable LQC lot information on Acceptable Performance Range label to verify it was entered correctly.
- 7 Select **Save**.

NOTE: If an error about incorrect LQC lot information is displayed, ensure that this LQC lot information exists in **CCM**. See “Configure LQC Lots Data” (page 90).

- 8 If prompted to enter the OID, do either of the following:
- Select **Scan** and scan a compatible OID barcode. If **OID Password Scan** is enabled in **CCM** (“OID Password Scan” (page 92)), select **Scan** to scan a compatible OID password barcode and then select **Done**.
 - Manually enter the OID (touch the text field to display virtual keyboard).
 - If the previous OID is already in the text field, select **Save** to reuse or select the text field and overwrite the OID. If required, enter the OID password before selecting **Save**.

- 9 Wait while the instrument does the following:
- Runs an ESV test,
 - Reads the test cartridge barcode,
 - Displays  (Checking Test Cartridge), and
 - Displays  (Warming Test Cartridge).

NOTE: To abort the test, select  (Abort Test) at any time.

NOTE: By pressing  (Home) or  (Back), the test can be canceled.

NOTE: If the ESV test fails, run an EQC test. If the EQC test fails, contact Technical Support.

- 10 Wait while  (Warming Test Cartridge) is displayed, the instrument is warming the test cartridge. While the test cartridge is being warmed, prepare the LQC product for use by following the instructions provided in the package insert.



CAUTION: Do not prepare the LQC product until the instrument displays  (Warming Test Cartridge). If the LQC product is prepared too early, premature clotting may adversely affect test result.

- 11 When  (Apply Sample to Test Cartridge) is displayed, the test cartridge is ready to receive the sample.
- 12 A 5 minute countdown timer will be displayed that indicates to add the sample to the test cartridge.
- NOTE:** A sufficient quantity of the sample must be added directly to the center sample well to fill it. Should a large drop of the sample extend above the center of the sample well, gently push the excess sample into the overflow area.



CAUTION: If a sample is not applied within 5 minutes, the test will time out. If this occurs, dispose of the test cartridge and repeat the test using a new test cartridge.

- 13 Select  (Start Test) to run the test.
- NOTE:** To abort the test, select  (Abort Test) at any time.
- NOTE:** By pressing  (Home) or  (Back), the test can be canceled.

- 14 Wait while the instrument does the following:
- Displays  (Sample in Test Channel), 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 test cartridge and a new LQC sample.
 - Draws the sample from the sample well into the test channel of the test cartridge and proceeds with the analysis of the sample.
 - Measures ACT (a counter displays the number of seconds).
 - Displays the test result. Test results are displayed as Celite equivalent ACT value in seconds, not real-time seconds. If the test result is out of range, repeat the test. If the test result is still out of range, see “Troubleshooting” (page 73).

15 The test result is displayed (Figure 70).

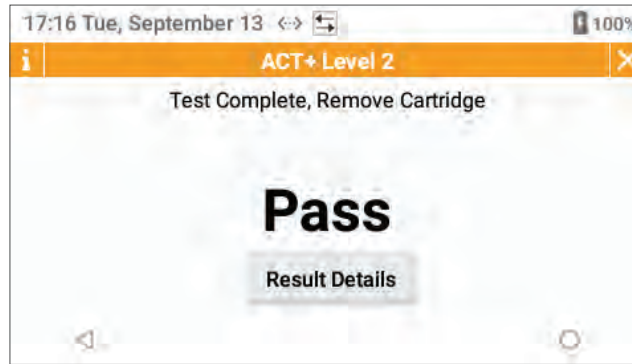


Figure 70: LQC Test Result

- **Pass** – If the test passes, go to the next step.
- **Fail** – If the test fails, review the package insert for LQC product. Run the test again with a new test cartridge. If the test fails again, contact Technical Support.

16 **Remove the test cartridge** and dispose in a biohazardous waste container in accordance with institutional guidelines.



BIOHAZARD: Test cartridges are for single-use only, do **NOT** reuse. All used test cartridges and LQC products should be considered as potentially infectious. Strictly adhere to the institution's policies for the proper handling and disposal of biohazardous materials.

NOTE: The LQC test result will remain on the screen until a new test is performed or the user selects **X** (Figure 70).

NOTE: If **Auto Send** is enabled, the instrument will automatically send the test result to the network and  (Test Result Transmission Sent) will be displayed indicating the transmission was successful (Figure 71). If **Auto Send** is not enabled, the user will need to manually send each test result. This action will transmit the current result together with other pending, unsent results. .



Figure 71: Test Result Transmission Sent

17 From the LQC test result screen (Figure 70), the user can do any of the following:

- **Add a user note** – Select **Result Details** (Result Details) and then select  (User Note). Enter the note (30 characters maximum) and select **Save** (Figure 72).

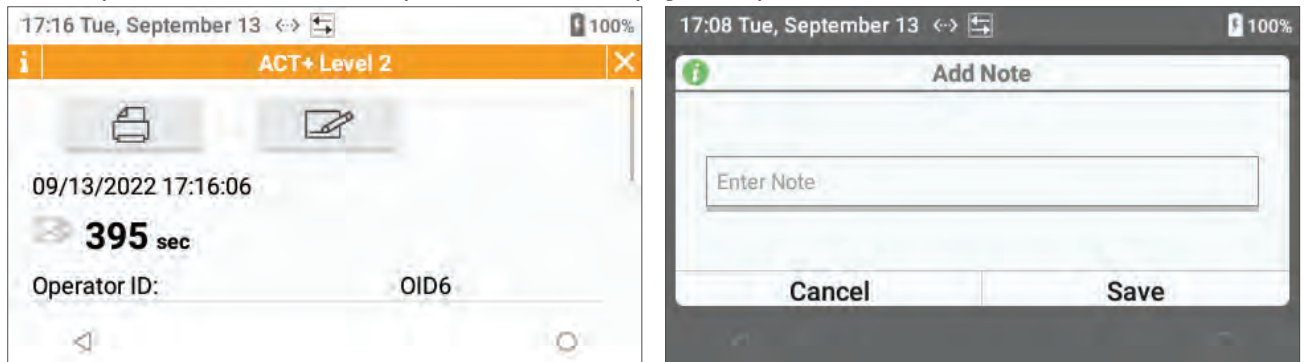


Figure 72: Add User Note

NOTE: The test result date refers to the test start date and time, not the time the test result was sent or completed.

- **View details of the test result** – Select **Result Details** (Result Details) and detailed information about the test result is displayed (Figure 73). **NOTE:** The test result date refers to the test start date and time, not the time the test result was sent or completed.

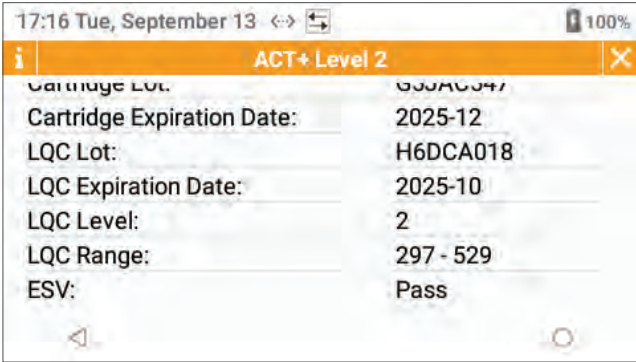


Figure 73: LQC Result Details

- **Print the test result** – Select **Result Details** (Result Details) and then select **Print** (Print). Select the desired printer from the drop-down list and then select **Print** (Print) to print the test result (Figure 74). To configure the network printer, see “Printer Configuration” (page 68)



Figure 74: Print LQC Test Result

NOTE: LQC test results are stored in the instrument database. To view them, see “Database” (page 67).

Δ6 Database

Δ6.1 Introduction

A maximum of 10,000 test results (patient, LQC, and EQC tests) can be stored in the instrument database. Test results can be viewed, cleared (deleted), and/or sent to the network (e.g., GEMweb Plus 500).

When viewing test results, the following options are available:

- **For Patient Test Results:**

- **DATE** **Date**
- **PID** **PID** (Patient ID)
- **OID** **OID** (Operator ID)
- **STATUS** **Status** (Transmission Status) – (**All**, **Sent**, **Unsent**, and **Fail**)

- **For LQC Test Results:**

- **DATE** **Date**
- **OID** **OID** (Operator ID)
- **RESULT** **Result** – (**All**, **Pass**, **Fail**, and **Abort**)
- **STATUS** **Status** (Transmission Status) – (**All**, **Sent**, **Unsent**, and **Fail**)

- **For EQC Test Results:**

- **DATE** **Date**
- **RESULT** **Result** – (**All**, **Pass**, **Fail**, and **Abort**)
- **STATUS** **Status** (Transmission Status) – (**All**, **Sent**, **Unsent**, and **Fail**)

See below for additional information about each of the available selections:

- **Date** – To filter by date, select **DATE** (Date), select the **Date Range**, and then select **Ok**. The selection criteria will be displayed on the screen. To exit, select **X** or select other tab. This search is available for **Patient**, **LQC**, and **EQC** test results.

NOTE: The test result date refers to the test start date and time, not the time the test result was sent or completed.

- **PID or OID** – To filter by a specific PID or OID, select **PID** (PID) or **OID** (OID), select **Scan** to scan a compatible PID/OID barcode or manually enter the PID/OID (touch the text field to display virtual keyboard), and select **Find**. The selection criteria will be displayed on the screen (Figure 75). To exit, select **X** or select other tab. This search is available for **Patient** (both PID and OID) and **LQC** (only OID) test results.

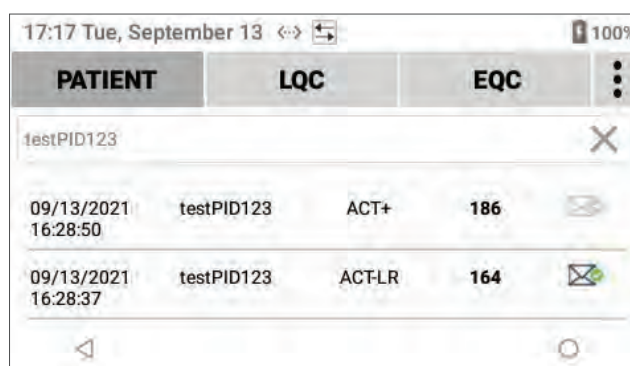


Figure 75: Filter by PID or OID

- **Result** – To filter by test result, select **RESULT** (Result), then select **All**, **Pass**, **Fail**, or **Abort**. The selection criteria will be displayed on the screen. To exit, select **X** or select other tab. This search is available for **LQC** and **EQC** test results.
- **Status** – To filter by transmission status, select **STATUS** (Status), then select **All**, **Sent**, **Unsent**, or **Fail**. The selection criteria will be displayed on the screen. To exit, select **X** or select other tab. This search is available for **Patient**, **LQC**, and **EQC** test results.

NOTE: To view the test result details of a specific test in the **Database**, select the test result and test result details will be displayed (Figure 76).

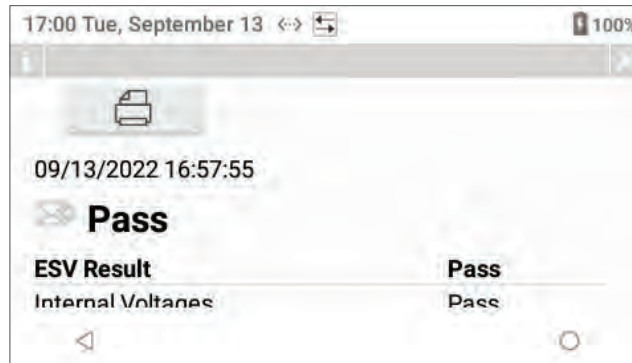


Figure 76: View Test Result Details

6.2 View/Send Test Results

- 1 Select  (Database). A list of test results is displayed.
- 2 Select the appropriate tab (**Patient**, **LQC**, or **EQC**) for the type of test that needs to be viewed or sent.
- 3 In the upper right corner, select  to open the **Database** menu (Figure 77).

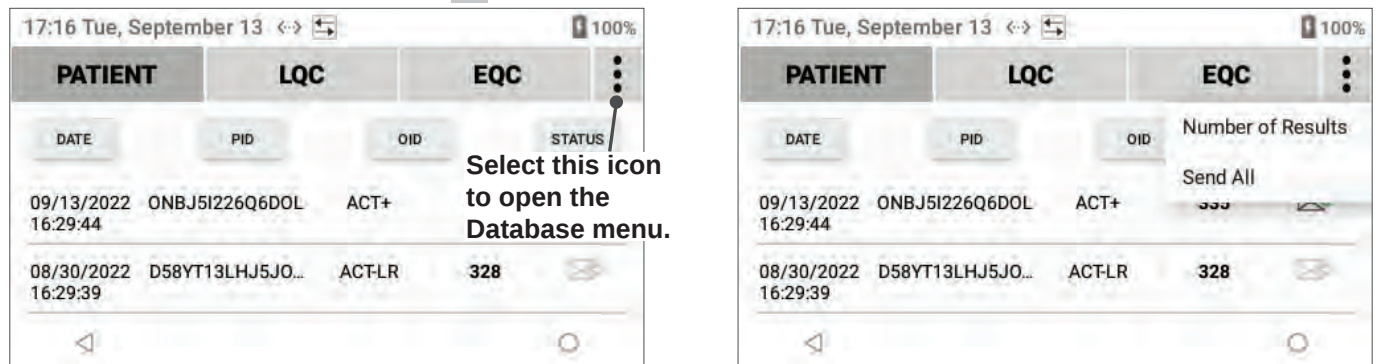


Figure 77: Database Menu

- 4 Select the appropriate option (Table 9):

Table 9: Options on the Database Menu

Option	Description
Number of Results	Display the total number of test results in the database.
Send All	Send all test results to the network.

6.3 Printer Configuration

NOTE: The instrument and the printer need to be connected to the same network.

Add a Network Printer:

- 1 Select  (Database), select the desired test result (**Patient**, **LQC**, or **EQC**), and then select  (Print). The **Print preview** screen is displayed (Figure 78).

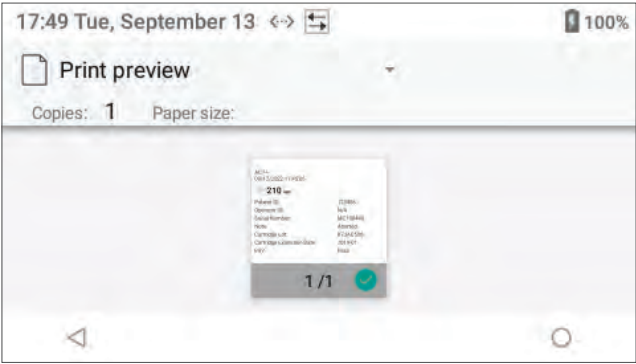


Figure 78: Print Preview

- 2 Select the drop-down list (▾) to display the available printers on the network (Figure 79).

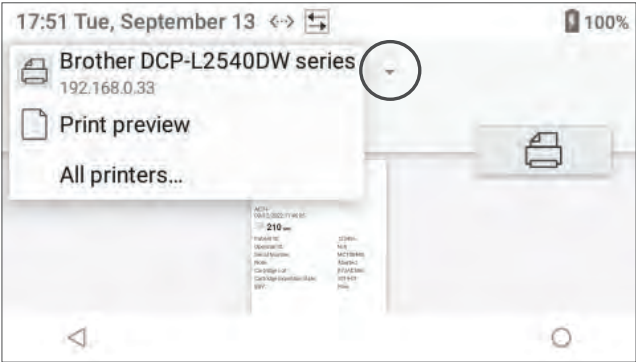


Figure 79: Available Printers

NOTE: If it is the first-time printing from this instrument, select **All printers...** from the drop-down list to display all available printers on the network (Figure 80).

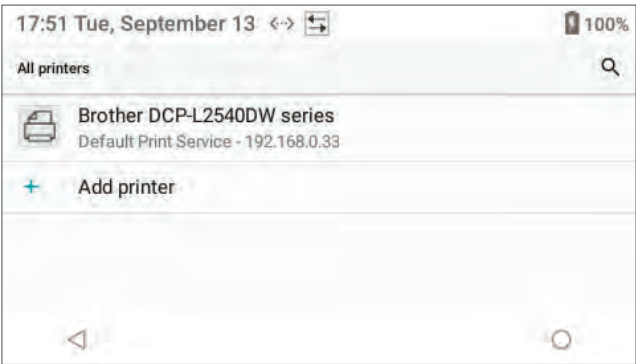


Figure 80: All Available Printers

- 3 Is the desired printer on the list of available network printers?
- **No** – Go to the next step.
 - **Yes** – Go to step 7 (page 71).

4 Select **Add printer**, **Add printer by IP address**, and then select **Default Print Service** (Figure 81).

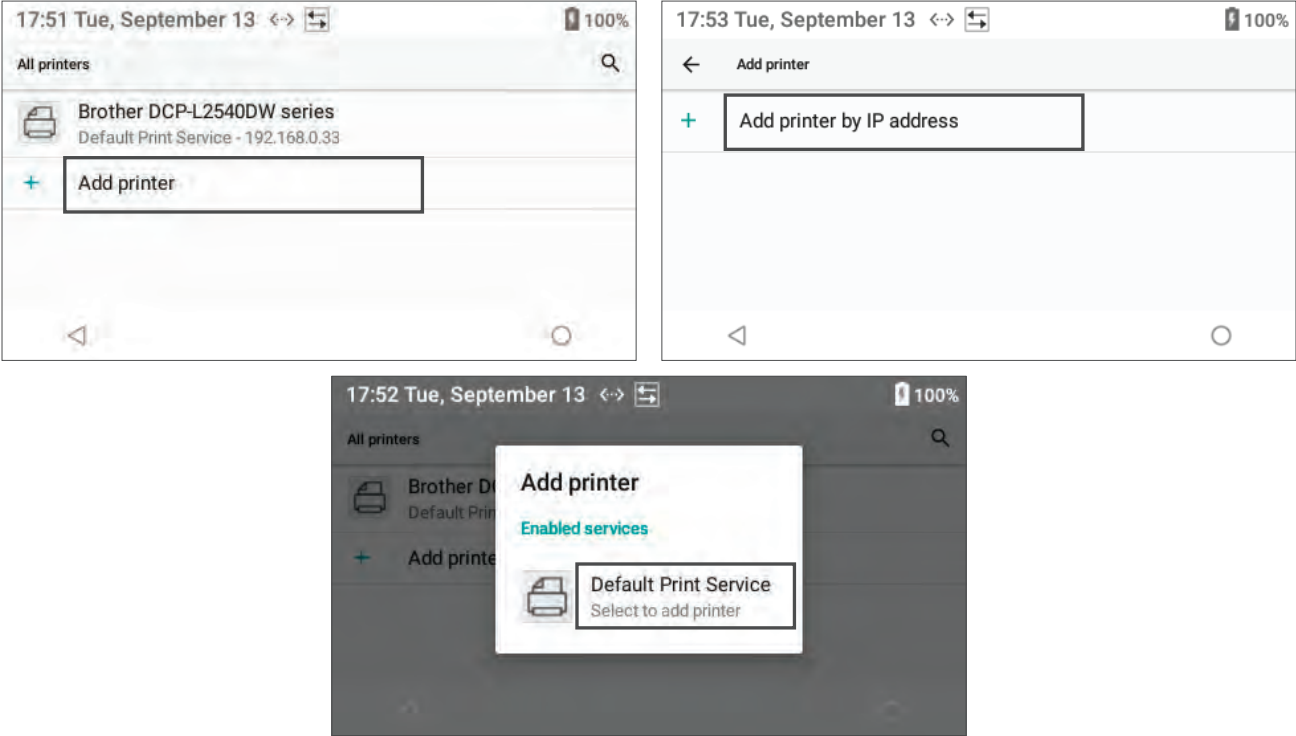


Figure 81: Adding a Printer

5 In the **Add printer by IP address** dialog box (Figure 82), enter the **IP Address** or **Hostname**, and then select **Add**.

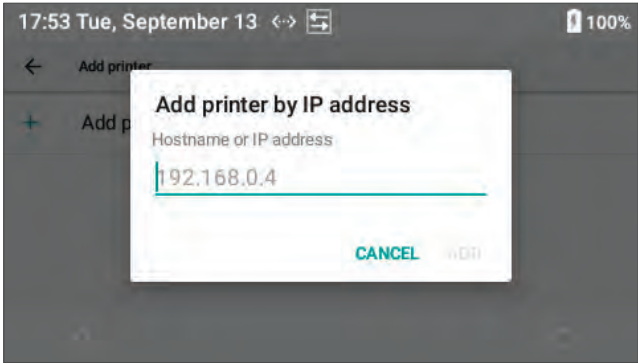


Figure 82: Enter the IP Address or Hostname

6 The new printer will appear under the **Saved printers** list (Figure 83).



Figure 83: Saved Printers

- 7 Select the desired printer and then select  (Print) (Figure 84) to print the test result.



Figure 84: Print the Test Result

Change Printer Settings:

- 1 Select the desired printer and then click on the blank area next to **Paper size** to display printing layout (Figure 85).

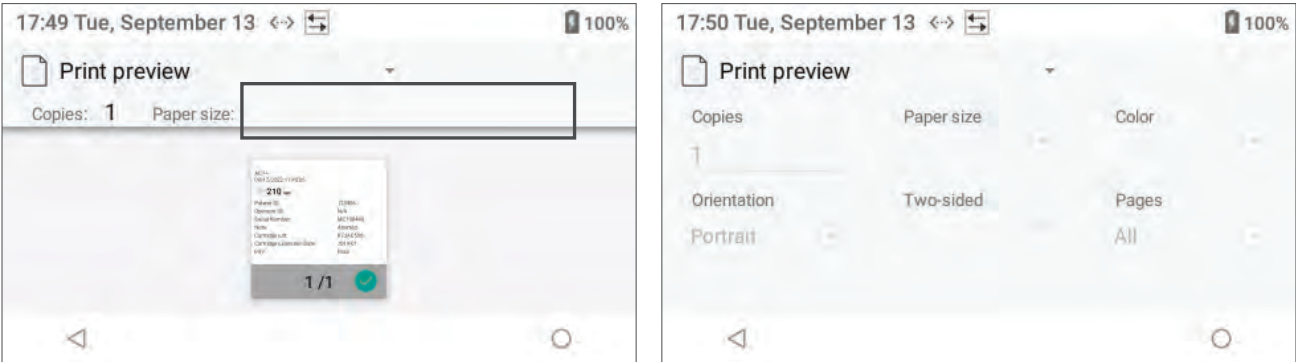


Figure 85: Change Printer Settings

- 2 Update as needed.

Remove or Select a Network Printer:

- To remove an existing printer, select and hold the desired printer and then select **Forget printer** (Figure 86).

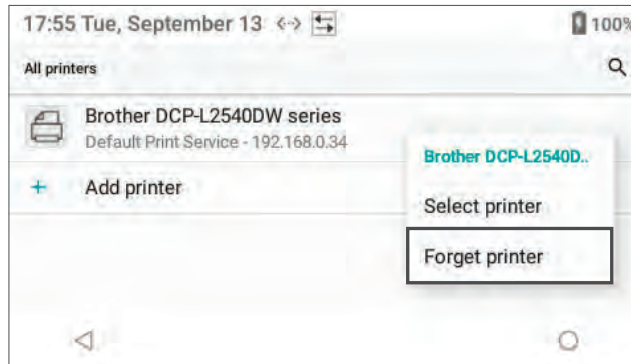


Figure 86: Remove Printer

- Default printer configuration:** The last printer used by the instrument will automatically become the default printer. The default printer will be the first printer displayed in the list of available printers. To select an existing printer, select and hold the desired printer and then select **Select printer** (Figure 87).

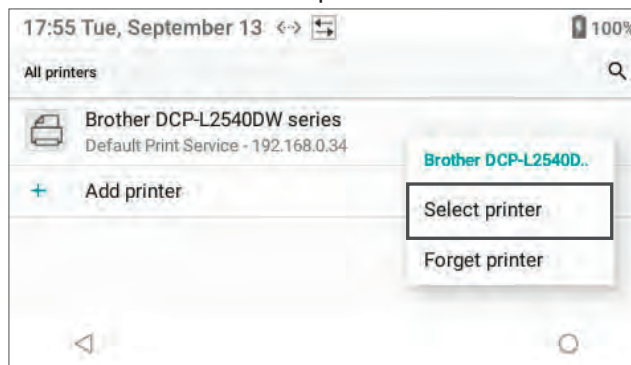


Figure 87: Select Printer

7 Service, Maintenance, and Troubleshooting

7.1 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 handling and/or cleaning the instrument, put on personal protective equipment (gloves, gowns, safety glasses, etc.).

- Inspect the exterior of the instrument and clean it under the following conditions:
 - Regularly according to the institution's schedule.
 - Before sending the instrument to the manufacturer for service.
 - Before transporting the instrument to another department in the institution or to another institution.
- **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.
- Besides normal cleaning, routine maintenance is not required.
- Safely handling a spill depends upon the material that was spilled. If unsure how to safely handle a spill, consult the institution's standard operating procedures.
- 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.

7.2 Instrument Repair

In the unlikely event that the GEM Hemochron 100 system requires repair; the instrument may have to be sent to your authorized service center.

Contact Technical Support to determine if the instrument 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 the instrument.

If the instrument needs to be returned or needs to be shipped, the instrument has to be decontaminated. See "Routine Maintenance" (page 73).

7.3 Troubleshooting

7.3.1 Cannot Connect to Instruments

If **CCM** 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 Wireless Network (Wi-Fi)" (page 36).

If **CCM** still cannot communicate with an instrument, a firewall might be blocking the connection. See "Install CCM Software and Configure Firewalls" (page 81).

7.3.2 Error Messages

If a failure occurs when operating the instrument, an error message is displayed (*Figure 88*).

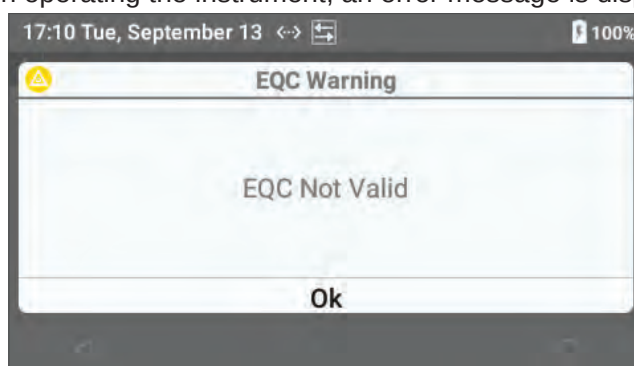


Figure 88: Error Message

For a list of error messages, their causes, and the corrective action to take, see *Table 10*.

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

If a particular error message is displayed repeatedly, write down the error message and contact Technical Support. Have the instrument serial number and test cartridge lot number ready when contacting Technical Support.

Table 10: Troubleshooting Messages

	Error Message	Cause	Corrective Action
Errors During Patient or QC Test	Cartridge Barcode Not Read. Repeat Test.	The barcode on the test cartridge was not recognized.	Remove the test cartridge and insert a new one. If error persists, contact Technical Support.
	Cartridge Lot Expired.	The test cartridge that is being used has reached its expiration date.	Remove the test cartridge and repeat the test using materials that are within their expiration date.
	Cartridge Warming Error. Repeat Test.	The test cartridge has not been equilibrated and is too cold.	Equilibrate the test cartridges to room temperature before using them.
	EQC Communication Error. Run EQC.	Instrument internal error.	Power the instrument off and back on, then run a manual EQC. If error persists, contact Technical Support.
	EQC Testing Locked	EQC has reached the maximum number of attempts for failure.	A <i>Supervisor</i> must log into the instrument and run a successful EQC to clear (reset) the counter.
	ESV Failed.	ESV (Electronic System Verification) has failed and patient tests are not allowed.	Run a successful EQC to run a patient test.
	Incorrect LQC for Cartridge.	LQC test type does not match test cartridge test type.	Remove the test cartridge and repeat the test with a new test cartridge and the appropriate LQC test type.
	Invalid Entry. Retry.	The system has detected an invalid entry.	Repeat the entry using correct data.
	Invalid PID – Must Not Contain Spaces	The PID cannot contain spaces.	Enter or scan the proper PID.
	Invalid PID Character Length	The PID length is not valid.	Enter the proper PID length.
	Lot Expired	The test cartridge and/or LQC lot that is being used has reached its expiration date.	Remove the test cartridge and repeat the test using materials that are within their expiration date.
	Maximum Patient Test Limit Reached.	EQC or LQC has expired and patient tests are not allowed. For more information on QC expiration, select the QC icon located on the Home screen and then select the tab that contains a  (Testing Failed).	Run a successful EQC or LQC.
	Maximum Test Failures Reached.	EQC or LQC has reached the maximum number of attempts for failure and patient tests are not allowed.	A <i>Supervisor</i> must log into the instrument and run a successful EQC or LQC to clear (reset) the counter.

Errors During Patient or QC Test (Continued)	Error Message	Cause	Corrective Action
	No Patient Test Allowed.	EQC, LQC, or ESV has failed.	For EQC – Run a successful EQC. For LQC – Run a successful LQC. For ESV – Run a successful EQC.
	Out of Range High.	The test result is outside clinical range. When the sample does not clot or clots in greater time than the allowable range of the assay.	Repeat the test with a new test cartridge. It is important to note that these warnings are system messages, not clinical values, and should not be used for patient-management decisions.
	Out of Range Low.	The test result is outside clinical range. When the sample clots in a time less than the allowable range for the assay. This message could indicate, but not limited to, sample has clotted prematurely, did not mix correctly in the test cartridge or bubbles may be present.	Repeat the test with a new test cartridge. It is important to note that these warnings are system message, not clinical values, and should not be used for patient-management decisions.
	Patient Tests Remaining	EQC or LQC has expired but patient tests are allowed.	Run a successful EQC or LQC.
	Sample Applied Too Early. Repeat Test.	Sample has been added before  (Apply Sample to Test Cartridge) is displayed.	Repeat the test with a new test cartridge. If error persists, contact Technical Support.
	Sample Not Found. Repeat Test.	The user has pressed  (Start Test) before adding the sample into the test cartridge.	Repeat the test with a new test cartridge and apply the sample when the message appears.
	Sample Too Large. Repeat Test.	Excess sample has been detected.	Repeat the test with a new test cartridge by adding 1–2 drops of the sample, and if needed push the excess sample into the overflow area.
	Sample Too Small. Repeat Test.	Insufficient sample has been detected.	Repeat the test with a new test cartridge by adding 1–2 drops of the sample.
	Supervisor required.	Maximum test failures has been reached.	A <i>Supervisor</i> must log into the instrument and run a successful EQC or LQC.
	Test Aborted or Interrupted	EQC, LQC, or patient test has been canceled for any of the following reasons: - Pressing either  (Home),  (Back), or  (Abort Test) during test, - Removing the test cartridge for LQC or patient test, or - Introducing a test cartridge during EQC testing.	Repeat the test with a new test cartridge for LQC or patient test.
	Test Channel Not Detected. Repeat Test.	Test channel in the test cartridge was not detected.	Repeat the test with a new test cartridge. If error persists, contact Technical Support.
	Test Interval Timer has expired.	The test interval timer has elapsed. The counter will be counting up until a new patient test has performed.	There is no action needed, the counter will stop when a new patient test is performed.
	Test Timed Out. Repeat Test.	The sample was not applied or  (Start Test) was not pressed within 5 minutes, therefore the test has timed out.	Remove the test cartridge and repeat the test with a new test cartridge within the expected time.
	Unrecognized Cartridge Lot	The test cartridge lot was not recognized.	Verify that the test cartridge lot used is valid. Remove the test cartridge and insert a new one. If error persists, contact Technical Support.

	Error Message	Cause	Corrective Action
Instrument	Battery Low. Connect Power Outlet.	Low battery.	Connect power outlet to run a test.
	Heater Error.	The ambient temperature is outside limits (too high).	Check the ambient temperature, if it is within range, run EQC. If EQC passes the instrument can be used. If error persists, contact Technical Support.
	Instrument Error. Repeat Test.	Instrument error.	Retry testing. If error persists, contact Technical Support.
	Instrument Not Ready	Instrument error.	Retry testing. If error persists, contact Technical Support.
	Internal Communication Failure. Restart Instrument.	Instrument error.	Retry testing. If error persists, contact Technical Support.
	Internal Error. Restart Instrument.	Instrument error.	Retry testing. If error persists, contact Technical Support.
	Pump Error.	Instrument error.	Run a manual EQC test. If the error is not cleared, power the instrument off and back on. If error persists, contact Technical Support.
	Software Error.	Internal instrument error.	Power the instrument off and back on, then run a manual EQC. If error persists, contact Technical Support.
	System Clock Error. Set Date and Time.	Date and time are not correct.	A <i>Supervisor</i> must log into the instrument to update the date and time settings in order to use the instrument (Supervisor Settings > Instrument Settings > Date and Time).
	Temperature Too High. Instrument Cooling. Please Wait Before Repeating Test.	Temperature error.	Wait > 25 minutes for the instrument to cool down. Repeat the test at room temperature conditions.
	The battery is getting low __% remaining	Low battery.	Connect power outlet to run a test.
Connectivity	Thermistor Error.	Heater internal error.	Power the instrument off and back on, then run a manual EQC. If error persists, contact Technical Support.
	Error: Received Message With Unexpected Instrument Version (E135)	The software versions of CCM and instrument do not match.	Install the correct software versions for CCM and instrument. If error persists, contact Technical Support.
	Network Fault. Check Network Settings.	The instrument cannot send the test result to LIS.	Check both instrument network settings and LIS settings. If error persists, contact Technical Support.
	POCT1-A Error Database Access. Contact Technical Support.	Database error.	Power the instrument off and back on. If error persists, contact Technical Support.

	Error Message	Cause	Corrective Action
Set Up the Network	Couldn't Configure Static Ethernet Settings	Ethernet error configuration.	Check Wi-Fi/Ethernet settings on both instrument and institution's network. If error persists, contact Technical Support.
	DHCP Failed	DHCP failed.	Check Wi-Fi/Ethernet settings on both instrument and institution's network. If error persists, contact Technical Support.
	Invalid Gateway Address Entered	Invalid entry.	Check Wi-Fi/Ethernet settings on instrument. If error persists, contact Technical Support.
	Invalid IP Address Entered	Invalid entry.	Check Wi-Fi/Ethernet settings on instrument. If error persists, contact Technical Support.
	Invalid Subnet Mask Entered	Invalid entry.	Check Wi-Fi/Ethernet settings on instrument. If error persists, contact Technical Support.
	Network Error: No Route via Specified Gateway	Network Error: No Route via Specified Gateway.	Check Wi-Fi/Ethernet settings on both instrument and institution's network. If error persists, contact Technical Support.
Centralized Configuration Manager	Busy	The selected instrument is in busy state (e.g., running a test) and cannot send or receive configuration file.	Wait until the instrument is ready ().
	Cannot update software. Make sure the charger is connected and the battery level is at least 20%.	The charger is not connected and/or the battery is < 20%.	Wait until the instrument has reached > 20% battery and connect to the power outlet before upgrading the software.
	Could Not Connect (E100)	The application could not communicate with the instrument.	Check network connectivity and retry when the instrument is ready ( .
	Could Not Contact Instrument (E110)	The application could not communicate with the instrument.	Ensure Remote Poke Port setting on CCM matches the Port setting on the instrument.
	Error: Instrument Not Responding	The instrument is not ready to receive the configuration file or software upgrade.	Make sure that the instrument is powered on, connected to the network, and retry. If error persists, contact Technical Support.
	Instrument Hostname Not Found in DNS-SD List (E129)	The application could not find the IP address of the instrument.	Check network connectivity on the instrument and ensure network firewall has Port 5353 open.
	Invalid Entry	An invalid value was entered into the text field(s).	Enter valid values and/or characters.
	Invalid username or password.	The login information is not valid.	Enter a valid username and/or password.
	Read/Write Operation Timed Out (E105)	The application has timed out waiting for the operation to complete.	Ensure Encryption settings match on the instrument and CCM .
	The Operators List must contain at least one Supervisor	CCM requires at least 1 <i>Operator</i> with <i>Supervisor</i> role.	Create a <i>Supervisor</i> account then create the <i>Operator</i> account.
	There was an error while reading the file.	The file content is invalid or corrupted.	Import a different configuration file.

7.3.3 Changes in Performance Characteristics

In the event of a change in performance characteristics, refer to “*Troubleshooting*” (page 73).

If troubleshooting does not resolve the issue, contact Technical Support (page 116), which will provide subsequent steps to enable a more thorough investigation.

If during the use of this device or as a result of its use, a serious incident has occurred or a product performance issue has been observed, please report it to the manufacturer and/or its authorized representative or, your local affiliate, and to your national authority.

7.4 Disposing of Products

7.4.1 Disposing and/or Replacing a Battery

NOTE: The battery is comprised of 2 lithium-ion cells.

Instructions:

- 1 Remove the 2 screws on the back of the instrument with a Philips screw driver size 1.
- 2 Remove the battery door.
- 3 Pull the battery pack out.
- 4 Place the new battery pack in the battery compartment.
- 5 Secure the battery door in its location by tightening the 2 screws using the Philips screw driver size 1.



CAUTION: Do not overtighten the 2 screws.

- 6 Connect the power supply cable to the power supply port, power the instrument on, and verify that the instrument is charging. See “Battery Power Icons” (page 10). If the instrument is not charging, contact Technical Support.
- 7 Dispose of the battery in accordance with local regulations for lithium-ion batteries or contact your local distributor to collect for disposal.

7.4.2 Disposing of an Instrument

Treat the instrument as biohazard and decontaminate prior to disposal. Treat the instrument as electronic waste per local regulations or contact your local distributor for information regarding the disposal of any end-of-life instruments.

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

7.4.3 Disposal of Other Materials

Patient blood samples, blood collection materials, used test cartridges, and LQC products are potentially infectious and must **IMMEDIATELY** be discarded into a container designed for sharp, medical biohazard waste and disposed per local and regional regulations. Use caution when handling and disposing of any sharp device. Strictly adhere to the institution's policies for the proper handling and disposal of biohazardous materials.

Δ 8 Centralized Configuration Manager (CCM) Software

8.1 CCM Introduction

Centralized Configuration Manager is a PC-based software that is used to configure the GEM Hemochron 100 instruments.

Although the instrument menus can be used to configure some of the instrument settings, **CCM** can be used **to configure more advanced settings and send the settings over the network to 1 or more instruments at the same time.**

CCM also allows *Supervisors* to do the following:

- **Generate a configuration data report** – Use **CCM** to generate a report containing all of the configuration data associated with 1 or more instruments. Reports can be saved as a comma-separated value file (.csv) and opened in a spreadsheet.
- **Reuse configuration data** – After configuration data is created, use **CCM** to export to a file for reuse.
- **Update the instrument software** – Use **CCM** to install a new version of instrument software (firmware). When updating the software on the instruments, multiple instruments can be updated at the same time.

The **CCM** software application consists of 2 modules:

- **Administrative Settings** – To create and manage *Admins* and *CCM Supervisor* accounts.
- **Configuration Settings** – To configure instruments.

NOTE: Users log into each module separately. Users must log out of 1 module before logging into the other module.

8.1.1 GEM Hemochron 100 System User Accounts

There are 4 types of accounts associated with the GEM Hemochron 100 system. 2 accounts are for the **CCM** software application and 2 accounts are for instrument(s):

CCM Accounts:

- *CCM Administrator*
- *CCM Supervisor*

Instrument Accounts:

- *Instrument Operator*
- *Instrument Supervisor*

NOTE: The Supervisor can use the instrument settings menu to configure that specific instrument or use **CCM** to configure more advanced instrument settings and send those settings over the network to 1 or more instruments at the same time.

CCM Administrator (Admin):

Admins use the **Administrative Settings** module (Figure 89 (page 82)) to do the following:

- Create, edit, and delete accounts for other *Admins*.
- Create, edit, and delete accounts for *CCM Supervisors*.

A factory default setting *Admin* account exists in **CCM**:

Username	<i>admin</i>
Password	<i>000</i>

The first user to log into the software must log in using the factory default setting *Admin* account (*admin/000*). Once logged in, the user will be forced to change the password. The new password should be recorded and stored in a safe place. The new *Admin* is able to create other *Admin* and *CCM Supervisor* accounts.

Admin account information is stored in an encrypted file on the same computer that installed the **CCM** software. 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 it is changed by the *Admin*.

CCM Supervisor:

CCM Supervisors use the **Configuration Settings** module (Figure 96 (page 86)) to do the following:

- Create accounts for instrument *Operators* and *Supervisors* and send those accounts to instruments as configuration data.
- Configure more advanced instrument settings and send those settings to instruments as configuration data.
- Change the password for *Supervisor*.

A factory default setting account for a *CCM Supervisor* does not exist in the software. An *Admin* must log into the **Administrative Settings** module and create a *CCM Supervisor* account. Once created, a *CCM Supervisor* can log into the **Configuration Settings** module.

CCM Supervisor account information is stored in an encrypted file on the same computer that installed the **CCM** software. When the software is upgraded, this file remains on the system so that these accounts do not have to be recreated.

8.1.2 Overview for Using CCM Software**Prepare to Use CCM Software for the First Time:**

- 1 Install **CCM** onto computer.
- 2 Start **CCM**.
- 3 Log into the factory default setting *Admin* account (*admin/000*). Change the password, record, and store in a safe place. The **Administrative Settings** module is displayed.
- 4 Create a *CCM Supervisor* account.
- 5 Log out of the **Administrative Settings** module.

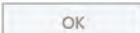
Configure CCM Software Settings:

- 1 Log in as an *Admin*. The **Administrative Settings** module is displayed.
- 2 Configure **Miscellaneous Settings**.
- 3 Configure **Network Settings**.
- 4 Log out of the **Administrative Settings** module.

Use CCM Software:

- 1 Log in as a *Supervisor*. The **Configuration Settings** module is displayed.
- 2 Add instruments (click  [Add Instrument] in the upper left corner).
- 3 Add instrument groups (click  [Add Instrument Group] in the upper left corner).
- 4 Create configuration data:
 - **Cartridge Lots**
 - **LQC Lots**
 - **Instrument Settings** (OID, PID, QC Lockout, etc.)
 - **Operators** – Add instrument *Supervisors* and/or add instrument *Operators*.
 - **Institution** (Name, Address, etc.)
- 5 Export configuration data to a file (save for reuse).
- 6 Ensure each instrument that needs to be configured is connected to the network.
- 7 Send configuration data to instruments.

NOTE: Configuration files created on a computer cannot be used on another computer.

NOTE: If a mandatory text field is blank or an invalid value is entered into a text field, the text field is outlined in red (). The  (OK) button remains disabled until a valid value is entered. To see a tooltip that displays the error message, place the cursor over the text field.

NOTE: To import the configuration settings from an instrument, see “Import Configuration Data” (page 104).

Δ 8.2 Installing, Updating, and Uninstalling CCM Software

Minimum System Requirements:

Operating System	Microsoft Windows 10 or 11 with latest Service Pack installed. For more information, see “Connectivity Settings” (page 34).
CPU	Intel Core i3 2.5 GHz
RAM	4 GB
Available Disk Space	100 MB

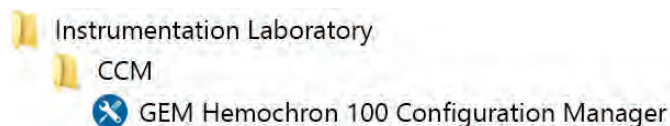
8.2.1 Install CCM Software and Configure Firewalls

The installer file for **CCM** is on the CD or USB drive from the manufacturer:

setup.exe

NOTE: To install **CCM**, Windows Administrator privileges are required.

- 1 Copy the **Centralized Configuration Manager** installation folder to computer.
- 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 **GEM Hemochron 100 Configuration Manager** application shortcut is available in the Start menu under **Instrumentation Laboratory > CCM**:



- 7 **Configure Firewalls** – Before using **CCM**, configure all firewalls so they will not prevent the instrument from communicating over the network with the computer using the **CCM** software (Table 11).

Table 11: Protocols and Ports for Configuring Firewalls

Protocol	Port
Outbound (from PC to instrument)	
TCP	50000
UDP	5353
ICMP	N/A
Inbound (from instrument to PC)	
TCP	50001
UDP	5353
SFTP	21726

NOTE: Ports shown in Table 13 (page 85) need to be enabled to allow **CCM** to run.

NOTE: UDP Port 5353 is needed to connect the device using mDNS (multicast DNS) name. If this port cannot be enabled, please connect using IP address of the instrument.

8.2.2 Update CCM Software

If a new version of **CCM** is released, install over the existing version. Do not uninstall the previous version. Account information for users of **CCM** (*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 **CCM**, Windows Administrator privileges are required.

8.2.3 Uninstall CCM Software

To uninstall **CCM**:

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



CAUTION: When the application is uninstalled, some files remain on the system in 1 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.

8.3 Administrative Settings

When a user logs into **CCM** as an *Admin*, the **Administrative Settings** module (Figure 89) is displayed.

Figure 89: CCM – Administrative Settings Module

CCM Administrators (*Admins*) use the **Administrative Settings** module to do the following:

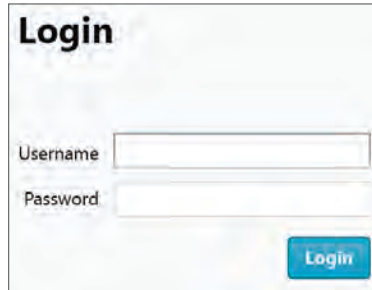
- **Manage CCM Accounts** – Create, edit, and delete other *Admin* accounts and/or *Supervisor* accounts.
- **Language** – Set the display language for the **CCM** user interface.
- **Screen Timeout (1–240)** – Set screen timeout. This is the number of minutes of inactivity before the software locks the screen and requires the user to log in. During screen timeout, configuration data remains in session memory. It is not lost.
- **Log File Age Limit (1–99)** – 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 POCT1-A Data in Transit** – By default, the encryption is enabled to allow secure communication. This setting (on **CCM**) must match the **Encryption** setting on the instrument. For the **Encryption** setting on the instrument, see “Set Port Number and Encryption Mode for CCM” (page 39).

NOTE: Only CCM Admins are allowed to access this module; CCM Supervisors cannot.

8.3.1 Logging into CCM for the First Time

The first user to log into **CCM** must log in using the factory default setting *Admin* account (*admin/000*).

- 1 Start **CCM**. The **Login** dialog box (Figure 90) is displayed.



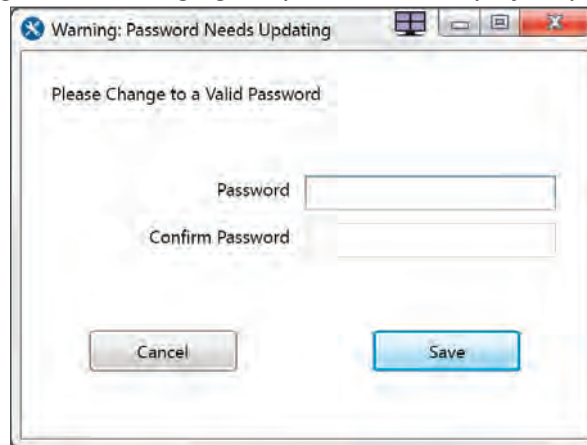
The image shows a 'Login' dialog box. It has a title bar with the word 'Login'. Inside, there are two text input fields: 'Username' and 'Password'. Below the 'Password' field is a blue button labeled 'Login'.

Figure 90: CCM – Login Screen

- 2 Enter the credentials for the factory default setting *Admin* account.

Username	admin
Password	000

- 3 Click **Login**. A dialog box for changing the password is displayed (Figure 91).



The image shows a 'Warning: Password Needs Updating' dialog box. It has a title bar with a warning icon and the text 'Warning: Password Needs Updating'. Inside, there is a message 'Please Change to a Valid Password'. Below this are two text input fields: 'Password' and 'Confirm Password'. At the bottom are two buttons: 'Cancel' and 'Save'.

Figure 91: CCM – Changing Factory Default Setting Admin Account Password

- 4 Enter the new password, confirm entry of the password, and click **Save**. Record the new password and store in a safe place.

NOTE: The password must contain at least 7 characters. At least 1 character must be a special character (period, comma, &, @, *, \$, etc.) (e.g., @mypassword).

- 5 The **Administrative Settings** module (Figure 89 (page 82)) is displayed.

8.3.2 Create CCM User Accounts

Use the following procedure to create accounts for **CCM** users (*Admins* and *Supervisors*).

NOTE: Accounts for instrument Operators and Supervisors are created during the instrument configuration process. See “Create Instrument Operators and Supervisors” (page 101).

NOTE: It is not necessary to create additional Admin accounts. Admins can continue to use the factory default setting Admin account, but they must log in as an Admin using the new password that was created when the first person logged into **CCM**. For more information, see “Logging into CCM for the First Time” (page 83).

To Create a CCM User (Admin or Supervisor) Account:

- 1 Log into **CCM** as an **Admin**. The **Administrative Settings** module is displayed.
- 2 Select the **New** button. The **Adding New Operator** dialog box (Figure 92) is displayed.

Figure 92: CCM – Adding New Operator

- 3 Enter the **Username** for the account.
- 4 In the **Role** drop-down list, select **Administrator** or **Supervisor**.
- 5 Enter the password, confirm entry of the password, and click **OK**.

NOTE: The password must contain at least 7 characters. At least 1 character must be a special character (period, comma, &, @, *, \$, etc.) (e.g., @mypassword).

- 6 The **Administrative Settings** module is displayed and the *Admin* or *Supervisor* account is added to the list of user accounts (Figure 93).

NOTE: To edit or delete an account, select the account from the list (Figure 93) and the appropriate button (**Edit** or **Delete**).

Figure 93: CCM – List of User Accounts

8.3.3 Configure CCM Software Settings

Several settings determine how the **CCM** application operates. These include miscellaneous settings and network settings.

8.3.3.1 Configure Miscellaneous Settings

To view the miscellaneous settings that affect how the **CCM** application operates, see *Table 12*. When a user is logged into **CCM** as an *Admin*, these settings are in the lower left corner of the **Administrative Settings** module (*Figure 94*).

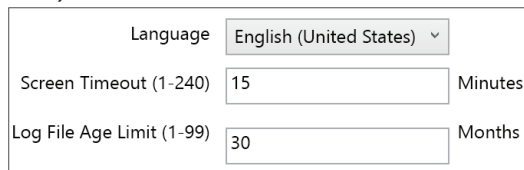


Figure 94: CCM – Miscellaneous Administrative Settings

Table 12: CCM – Miscellaneous Administrative Settings

Setting	Description
Display Language	Only English is available.
Screen Timeout (1–240)	The number of Minutes of inactivity before the software locks the screen and requires an <i>Operator</i> to unlock it by entering their login information. The maximum is 240 minutes (4 hours). The change goes into effect immediately.
Log File Age Limit (1–99)	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 “ <i>Log Files</i> ” (page 105).

8.3.3.2 Configure Network Settings

To view the network settings that affect how the **CCM** application operates, see *Table 13*. When a user is logged into **CCM** as an *Admin*, these settings are in the lower right corner of the **Administrative Settings** module (*Figure 95*). For assistance, consult with the institution's network administrator.

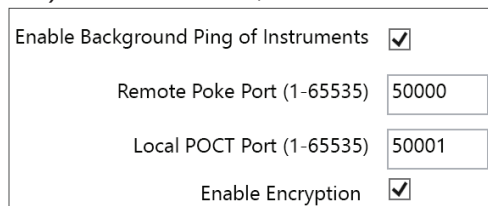


Figure 95: CCM – Network Settings

Table 13: CCM – Network Settings

Setting	Description
Enable Background Ping of Instruments	Allow CCM 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. CCM 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 on the instrument by selecting  (Settings) > Supervisor Settings > CM Connection Settings .
Local POCT Port (1–65535)	The port number for the local POCT1-A network. The default value is 50001.
NOTE: Verify that the Encryption settings match on the instrument and CCM . NOTE: Verify that the Remote Poke Port setting on CCM matches the Port setting on the instrument. For the Encryption and Port settings on the instrument, see “Set Port Number and Encryption Mode for CCM” (page 39).	

Δ 8.4 Configuration Settings

When a user logs into **CCM** as a *Supervisor*, the **Configuration Settings** module (Figure 96) is displayed.

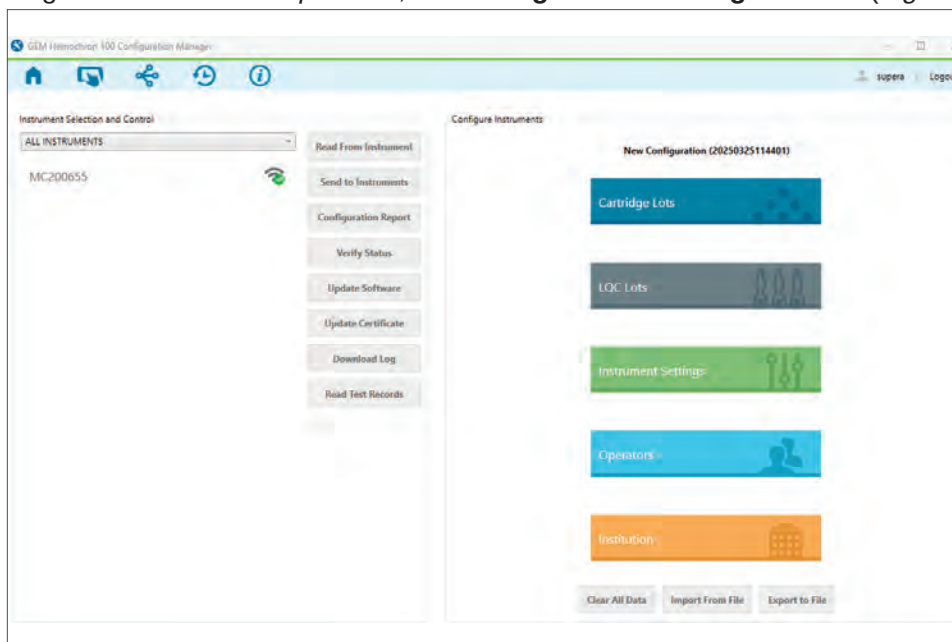


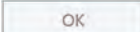
Figure 96: CCM – Configuration Settings Module

This is the main module of the **CCM** application. *CCM Supervisors (Supervisors)* use the **Configuration Settings** module to do the following:

- Add instruments (click  [Add Instrument] in the upper left corner). Adding instruments allows **CCM** to recognize them through the network connection.
- Create an instrument group (click  [Add Instrument Group] in the upper left corner). This allows a *Supervisor* to add an existing instrument to a group so they can perform operations on a group of instruments at the same time.
- View and export audit logs (click  [Export Audit Log] in the upper left corner).
- View about (click  [About] 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 (save for reuse).
- Generate a configuration data report for an instrument or import from an existing file.
- Update instrument software (firmware).
- Read test records (Patient, EQC, and LQC) from one or multiple instruments and save them to a CSV file.

NOTE: Only *CCM Supervisors* are allowed to access this module; *CCM Admins* cannot.

8.4.1 Add Instruments and Instrument Groups

NOTE: If a mandatory text field is blank or an invalid value is entered into a text field, the text field is outlined in red (). The  (OK) button remains disabled until a valid value is entered. To see a tooltip that displays the error message, place the cursor over the text field.

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

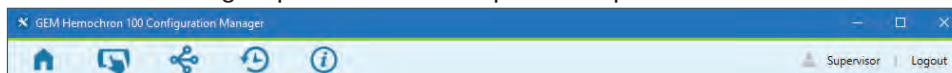


Figure 97: CCM – Configuration Settings Title Bar

8.4.1.1 Add an Instrument

When an instrument is added to **CCM**, it is “registered” so that it can communicate over the network with **CCM**.

- 1 Ensure that the instrument is connected to the network.

NOTE: If  (Ethernet) or  (Wi-Fi) is displayed in the status bar of the instrument screen, the instrument is connected to the network.

- 2 Log into **CCM** as a *Supervisor*. The **Home** screen that is used to configure instruments (**Configuration Settings**) is displayed.
- 3 In the upper left corner, select  (Add Instrument). The **Instrument Management** screen is displayed.
- 4 Select **New**. The **Adding New Instrument** dialog box is displayed.
- 5 In the **Nickname** text field, enter a nickname for the instrument.
- 6 In the **IP Address / Hostname** text field, enter either of the following:
 - The **IP Address** displayed on the instrument.
 - The **Hostname** in the format: *GEMH100-<serial number>*.
(e.g., if the instrument serial number is *MC100022*, enter *GEMH100-MC100022*. The serial number is on the label located on the bottom of the instrument.)

NOTE: Alternatively, to read the serial number from an instrument into the **Serial Number** text field, click the **Read From Instrument** button. If **CCM** cannot establish a connection with the instrument, see “Install CCM Software and Configure Firewalls” (page 81).

- 7 (Optional – Add the instrument to a group) In the **Group** drop-down list, select a group to add the instrument to.

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

- 8 Click **OK**.

To return to the **Home** screen, click  (Home) in the upper left corner.

8.4.1.2 Create an Instrument Group (Optional)

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

NOTE: Plan carefully when choosing the names of instrument groups or adding instruments to instrument groups.

- 1 Log into **CCM** as a *Supervisor*. The **Home** screen that is used to configure instruments (**Configuration Settings**) is displayed.
- 2 In the upper left corner, click  (Add Instrument Group). The **Instrument Group Management** screen is displayed.
- 3 Click **New**. The **Adding New Group** dialog box is displayed.
- 4 In the **Group** text 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  (Add Instrument). 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**.

To return to the **Home** screen, click  (Home) in the upper left corner.

8.4.2 Configure Instruments

To configure instruments, a user must log into **CCM** as a *Supervisor*, create configuration data, and send to the instruments over the network.

NOTE: Before an instrument can be configured over the network, the instrument must be added to **CCM**. For more information, see “Add an Instrument” (page 87).

Overview for Configuring Instruments:

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

NOTE: Configuration files created on a computer cannot be used on another computer.

Saving Configuration Changes:

During a **CCM** session, configuration data that is created is temporarily stored in the computer’s volatile memory (RAM). It is not saved by default.

CCM can be used to do the following:

- **Export to File** – To save all of the data as a configuration file, see “Export Configuration Data” (page 104).
- **Clear All Data** – All of the data in a session can be cleared.
On the **Home** screen, in the lower right corner, click the **Clear All Data** button. This restores the data in the session to the factory default settings.

When a user logs out of **CCM**, if they have not sent the data to an instrument or exported it, an **Unsaved Changes** dialog box (Figure 98) is displayed.

- **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.

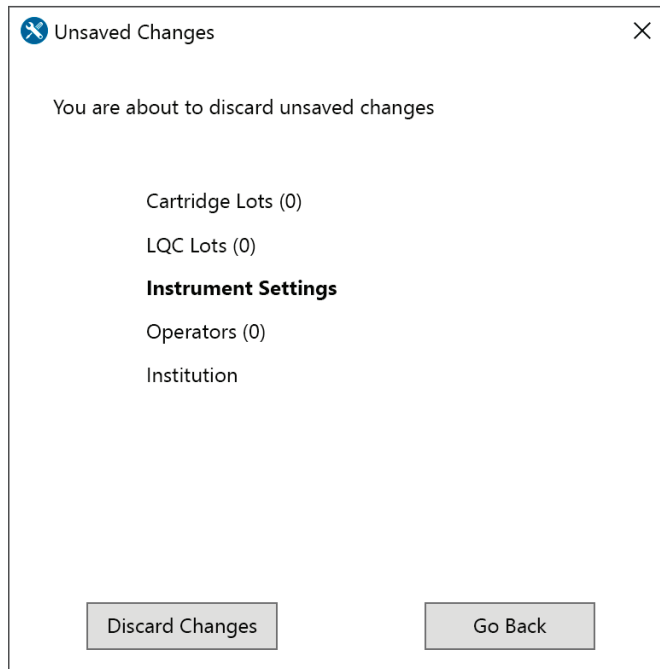


Figure 98: CCM – Unsaved Changes Message

8.4.2.1 Create Configuration Data

To create configuration data, log into **CCM** as a **Supervisor**. On the **Home** screen, select the appropriate button (*Figure 99*):

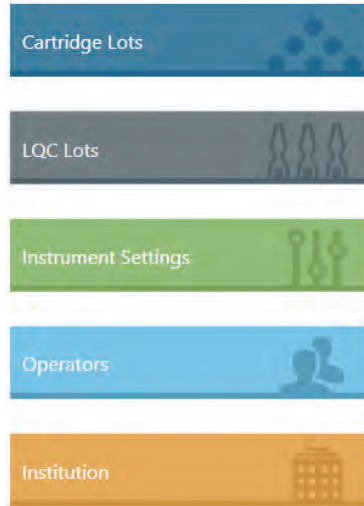


Figure 99: CCM – Create Configuration Data

8.4.2.1.1 Configure Cartridge Lots Data

- 1 Click the **Cartridge Lots** button.
The **Cartridge Lots** dialog box (*Figure 100*) is displayed.

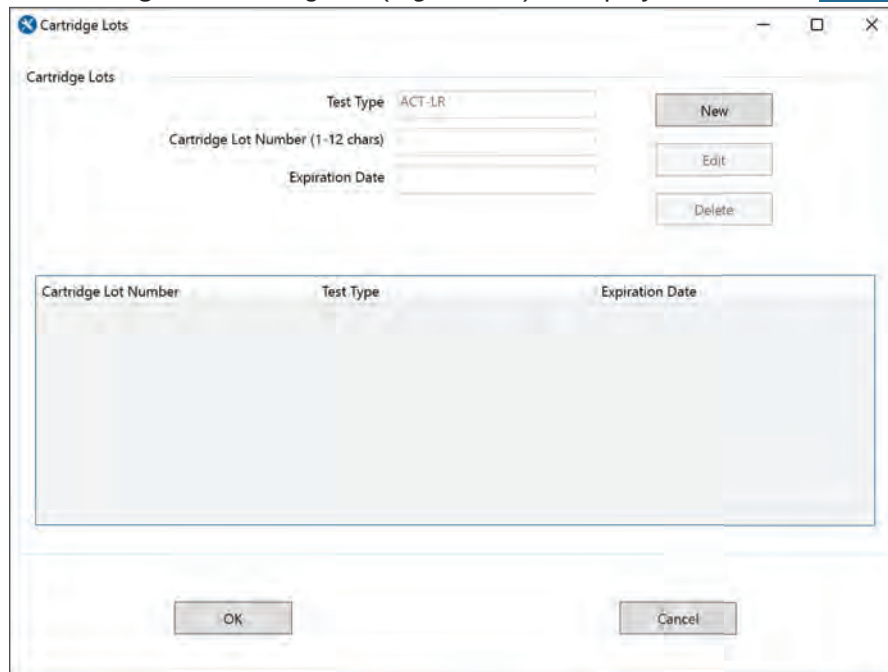


Figure 100: CCM – Cartridge Lots Dialog Box

- 2 Click **New**. The **Adding New Cartridge Lot** dialog box (*Figure 101*) is displayed.

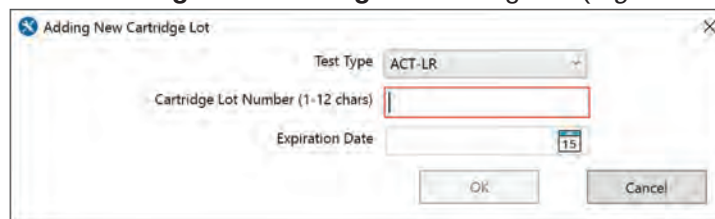


Figure 101: CCM – Adding New Cartridge Lot

- 3 Enter the following test cartridge lot information:
 - In the **Test Type** drop-down list, select the appropriate test type for the test cartridge lot (**ACT+** or **ACT-LR**).
 - Enter the **Cartridge Lot Number**.
 - Enter the **Expiration Date**.
 - Click **OK**. The test cartridge lot is added to the list of **Cartridge Lots**.
- 4 Click **OK** to save the changes (*Figure 100 (page 89)*).

NOTE: To edit or delete a test cartridge lot, select the test cartridge lot from the list (*Figure 100 (page 89)*) and the appropriate button (**Edit** or **Delete**).

8.4.2.1.2 Configure LQC Lots Data

- 1 Click the **LQC Lots** button.
The **LQC Lots** dialog box (*Figure 102*) is displayed.

Figure 102: CCM – LQC Lots Dialog Box

- 2 Click **New**.
- 3 Enter the following LQC lot information:
 - In the **Test Type** drop-down list, select the appropriate test type for the LQC lot (**ACT+** or **ACT-LR**).
 - In the **LQC Level** drop-down list, select the appropriate level for the LQC lot (**Level 1** [Normal] or **Level 2** [Abnormal]).
 - Enter the **LQC Lot Number**.
 - Enter the **Ranges (Low and High)**.
 - Enter the **Expiration Date**.
 - Click **OK** and the LQC lot is added to the list of **LQC Lots**.
- 4 Click **OK** to save the changes.

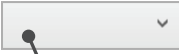
NOTE: To edit or delete an LQC lot, select the LQC lot from the list (*Figure 102*) and the appropriate button (**Edit** or **Delete**).

NOTE: When editing an LQC lot, if the test type is changed, the **Range Low** and **Range High** values will be reset to **0** (zero). Please ensure the appropriate values are entered in this text field before saving.

8.4.2.1.3 Configure Instruments (Instrument Settings)

- 1 Click the **Instrument Settings** button.
The **Instrument Settings** dialog box (Figure 103) is displayed.
- 2 At the top of the dialog box, select the appropriate tab (**General**, **LQC Settings**, **EQC Settings**, **Barcode Settings**, or **Version Info**).
- 3 Select the settings:
 - **General** – See Figure 103 and Table 14 (page 91).
 - **LQC Settings** – See Figure 104 and Table 15 (page 93).
 - **EQC Settings** – See Figure 105 and Table 16 (page 95).
 - **Barcode Settings** – See Figure 106 and Table 17 (page 98).
 - **Version Info** – See Figure 108 and Table 18 (page 100).

NOTE: If the value of a **Yes/No** drop-down list is blank (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-down list is blank.

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

General Settings Dialog Box:

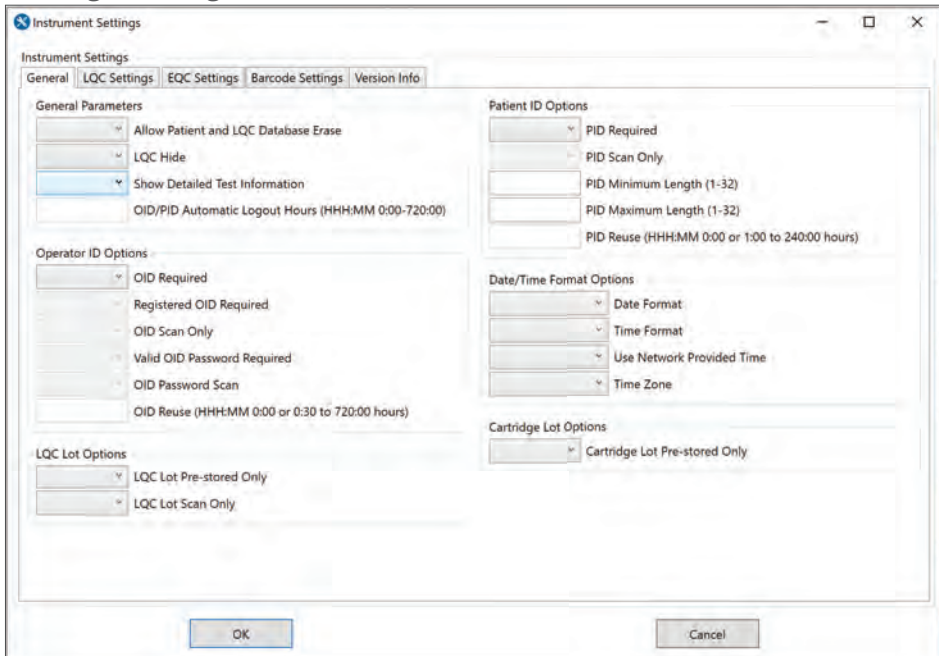


Figure 103: CCM – General Settings Dialog Box

Table 14: CCM – Instrument Settings > General

	Setting	Description
General Parameters	Allow Patient and LQC Database Erase	Choose whether to allow <i>Supervisors</i> to erase (delete) test results (patient 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.
	LQC Hide	Choose whether to display Pass or Fail instead of numeric test results after an LQC test: • Yes – Displays a Pass or Fail test result. • No – Displays a numeric test result.
	Show Detailed Test Information	Choose whether to allow <i>Operators</i> to see the number of patient tests allowed after the LQC Interval expires: • Yes – <i>Operators</i> can see the number of patient tests allowed. • No – <i>Operators</i> cannot see the number of patient tests allowed. The number is not shown.
	OID/PID Automatic Logout Hours (HHH:MM 0:00–720:00)	The number of hours (0:00–720:00) before <i>Operators</i> are automatically logged out.

	Setting	Description
Operator ID Options	OID Required	Choose whether to require <i>Operators</i> to enter their OID before they run a patient or LQC test: • Yes – <i>Operators</i> must enter their OID. • No – <i>Operators</i> cannot enter their OID.
	Registered OID Required	Choose whether to require <i>Operators</i> to enter an OID associated with the instrument <i>Operator</i> account created in CCM : • Yes – <i>Operators</i> must enter a registered OID. • No – <i>Operators</i> can enter any OID.
	OID Scan Only	Choose whether to require <i>Operators</i> to scan their OID: • Yes – <i>Operators</i> must scan their OID. • No – <i>Operators</i> can scan or manually enter their OID.
	Valid OID Password Required	Choose whether to require that <i>Operators</i> enter a valid password before they run a test: • Yes – <i>Operators</i> must enter a password. • No – <i>Operators</i> are not required to enter a password.
	OID Password Scan	Choose whether to require that <i>Operators</i> enter/scan a valid password before they run a test: • Yes – <i>Operators</i> must scan or manually enter a password. • No – <i>Operators</i> must manually enter a password.
	OID Reuse (HHH:MM 0:00 or 0:30 to 720:00 hours)	The period of time that an OID can be reused. To prevent an OID from being reused, enter <i>0:00</i> to disable this option.
LQC Lot Options	LQC Lot Pre-stored Only	Choose whether to require that <i>Operators</i> only use LQC lots that have been registered in (added to) CCM : • Yes – <i>Operators</i> must only use registered LQC lots. • No – <i>Operators</i> can use any LQC lot.
	LQC Lot Scan Only	Choose whether to require <i>Operators</i> to use the barcode scanner when entering the LQC lot information: • Yes – <i>Operators</i> must scan LQC lot information. • No – <i>Operators</i> can scan or manually enter LQC lot information.
Patient ID Options	PID Required	Choose whether to require <i>Operators</i> to enter a PID before they run a patient test: • Yes – <i>Operators</i> must enter a PID. • No – <i>Operators</i> are not required to enter a PID.
	PID Scan Only	Choose whether to require <i>Operators</i> to use the barcode scanner when entering PIDs: • Yes – <i>Operators</i> must scan PIDs. • No – <i>Operators</i> can scan or manually enter PIDs.
	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 Reuse (HHH:MM 0:00 or 1:00 to 240:00 hours)	The period of time that a PID can be reused. To prevent a PID from being reused, enter <i>0:00</i> to disable this option.
Date/Time Format Options	Date Format	Specify the format of how the date will be displayed (e.g., MM/DD/YYYY , DD/MM/YYYY , or YYYY/MM/DD).
	Time Format	Specify the format of how the time will be displayed (e.g., 12 Hour or 24 Hour).
	Use Network Provided Time	Choose whether to automatically synchronize with the date and time provided by the network: • Yes – Synchronize the date and time with the network. • No – Do not synchronize the date and time (must be set manually).
	Time Zone	The time zone in which the instrument is operated.
Cartridge Lot Options	Cartridge Lot Pre-stored Only	Choose whether to require that <i>Operators</i> only use test cartridge lots that have been registered in (added to) CCM : • Yes – <i>Operators</i> must only use registered test cartridge lots. • No – <i>Operators</i> can use any test cartridge lot.

LQC Settings Dialog Box:
Figure 104: CCM – LQC Settings Dialog Box

NOTE: The **LQC Settings** tab contains 2 sub-tabs: 1 for each type of test (**ACT+** and **ACT-LR**). Be sure to change the settings on each tab.

Table 15: CCM – Instrument Settings > LQC Settings

	Setting	Description
LQC Lockout Settings	Interval	If LQC is required: Fixed Time Schedule – The LQC is required to run at a specified time. Factory default value is fixed (e.g., <i>Configured time: 9 am, interval 24 hr. User start LQC at 8 am, next LQC will be required to run at 9 am [same day]</i>). Rolling – The LQC test will be run at a specified interval. The start time will be based on the start time of the last successful LQC test (e.g., <i>Configured time: 9 am, interval 24 hr. User start LQC at 8 am, next LQC will be required to run at 8 am</i>).
	LQC Level (1/2) Required	Choose whether to require (Yes) or not require (No) the QC lockout feature associated with LQC tests: Yes – LQC Level 1 and/or Level 2 is required. No – LQC Level 1 and/or Level 2 is <u>not</u> required. CAUTION: If the LQC test feature is required (Yes), the instrument will be required to run LQC tests at regular intervals. The factory default setting for this feature is not required (No) but can be changed using CCM. The manufacturer recommends that it be required (Yes). The decision to require (Yes) or not require (No) this feature shall be determined by and is the responsibility of the each institution. When QC lockout occurs, a <i>Supervisor</i> must clear the lockout before an <i>Operator</i> can run a test.
LQC Level (1/2) Config	Start Time (HH:MM) (24 hr)	The time of day that the LQC Interval starts running. The current time from the PC is automatically populated by default. Enter the value in 24 hour time format (e.g., for 7:00 pm, enter 19:00).
	Start Date	The date the LQC Interval starts running.
	Number of LQC Level (1/2) Tests Failed	A counter that displays the number of additional failed LQC tests that <i>Operators</i> 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 for the field labeled “Number of LQC Failures Allowed Before Assay Lockout (0–9)”.

	Setting	Description
LQC Level (1/2) Config (Cont.)	Clear LQC Level (1/2) Failure Count	Choose whether to clear (reset) the counter that displays the number of failed LQC tests that <i>Operators</i> have run: • 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 Interval (1–1080) Hours	Specify the period of time until the LQC Interval expires. When the LQC Interval expires, patient test lockout occurs, preventing <i>Operators</i> from running patient tests. A <i>Supervisor</i> can configure the instrument so that after the LQC Interval expires, <i>Operators</i> 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 LQC Expiration (0–240)”. When the additional patient tests have been run, the next time an <i>Operator</i> tries to run a patient test, lockout occurs. A <i>Supervisor</i> must clear the lockout.
LQC Lockout Control	Number of LQC Failures Allowed Before Assay Lockout (0–9)	The number of additional failed LQC tests that <i>Operators</i> are allowed to run before QC lockout. By default, if an LQC test fails, <i>Operators</i> can run 1 more LQC test. If the LQC test fails, lockout will occur. A <i>Supervisor</i> can configure the instrument so that <i>Operators</i> are allowed to run as many as 9 additional failed LQC tests after the first test fails. This postpones lockout. To prevent <i>Operators</i> from running any additional failed LQC tests, enter 0 (zero). The first time an LQC test fails, lockout will occur. If additional LQC test failures are allowed, the value in the field labeled “Number of LQC Level (1/2) Tests Failed” is incremented each time an additional LQC test fails. A <i>Supervisor</i> can clear (reset) this value by checking the box labeled “Clear LQC Level (1/2) Failure Count”. NOTE: Both levels need to be cleared. The counter will be cleared (reset) when configuration data is sent to the instrument.
	Maximum Patient Tests Allowed After LQC Expiration (0–240)	The number of additional patient tests that <i>Operators</i> are allowed to run after the LQC Interval expires. <i>Supervisors</i> can allow <i>Operators</i> to run as many as 240 additional patient tests after the LQC Interval expires. When the maximum number of patient tests has been reached, if an <i>Operator</i> tries to run another patient test, QC lockout occurs. To prevent <i>Operators</i> from running any additional patient tests, enter 0 (zero). As soon as the LQC Interval expires, QC lockout will occur. When an additional patient test has been run, the value in the field labeled “Number of Patient Tests Used After LQC Expiration” is incremented. <i>Supervisors</i> can clear this value by selecting Yes in the field labeled “Clear Number of Patient Tests Used After LQC Expiration”. NOTE: It is recommended to run a successful LQC test to clear the value in the field labeled “Number of Patient Tests Used After LQC Expiration”.
	Number of Patient Tests Used After LQC Expiration	A counter that displays the number of additional patient tests that <i>Operators</i> have run after the LQC Interval expired. This value is read-only. After the LQC interval expires, this counter is incremented each time an <i>Operator</i> runs an additional patient test. For more information, see the description for the field labeled “Maximum Patient Tests Allowed After LQC Expiration (0–240)”.
	Clear Number of Patient Tests Used After LQC Expiration	Choose whether to clear (reset) the counter that displays the number of patient tests that <i>Operators</i> have run after the LQC Interval expired: • No – Do not clear the counter. • Yes – Clear the counter. When Yes is selected, the counter labeled “Number of Patient Tests Used After LQC Expiration” will be cleared (reset) when configuration data is sent to the instrument. NOTE: It is recommended to run a successful LQC test to clear the value in the field labeled “Number of Patient Tests Used After LQC Expiration”.

EQC Settings Dialog Box:
Figure 105: CCM – EQC Settings Dialog Box**Table 16: CCM – Instrument Settings > EQC Settings**

	Setting	Description
EQC Lockout Control	EQC Required	Choose whether to require (Yes) or not require (No) the QC lockout feature associated with EQC tests. See “QC Lockout” (page 56). Yes – EQC is required. No – EQC is <u>not</u> required. CAUTION: If the EQC test feature is required (Yes), the instrument will be required to perform validation testing at regular intervals. The factory default setting for this feature is required (Yes) but can be changed using CCM. The manufacturer recommends that it be required (Yes). The decision to require (Yes) or not require (No) this feature shall be determined by and is the responsibility of the each institution. When QC lockout occurs, a <i>Supervisor</i> must clear the lockout before an <i>Operator</i> can run a test.
	Auto EQC	Choose whether to automatically run the EQC test at the specified interval: No – Do not automatically run the EQC test at the specified interval. Yes – Automatically run the EQC test at the specified interval. NOTE: When the EQC Interval expires, the EQC test will automatically start, and the test result will automatically be stored in the database. EQC will automatically start even if power is not connected. NOTE: If Auto EQC is enabled, ensure test cartridges are routinely removed from the instrument after a test. If a test cartridge is in the test cartridge insertion chamber when the EQC test starts, a warning message will be displayed and the test will <u>not</u> run.
	Interval	If EQC is required (default): Fixed Time Schedule – The EQC is required to run at a specified time (e.g., <i>Configured time: 9 am, interval 8 hr. User start EQC at 8 am, next EQC will be required to run at 9 am [same day]</i>). Rolling – The EQC test will be run at a specified interval. Factory default value is rolling. The start time will be based on the start time of the last successful EQC test (e.g., <i>Configured time: 9 am, interval 8 hr. User start EQC at 8 am, next EQC will be required to run at 4 pm</i>).

	Setting	Description
EQC Lockout Control (Continued)	Interval (1–1080) Hours	Specify the period of time until the EQC Interval expires. When the EQC Interval expires, patient test lockout occurs, preventing <i>Operators</i> from running patient tests. A <i>Supervisor</i> can configure the instrument so that after the EQC Interval expires, <i>Operators</i> 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 Expiration (0–240) ”. When the additional patient tests have been run, the next time an <i>Operator</i> tries to run a patient test, lockout occurs. A <i>Supervisor</i> must clear the lockout.
	Start Time (HH:MM) (24 hr)	The time of day that the EQC Interval starts running. For information about the EQC Interval, see the description for the field labeled “ Interval (1–1080) Hours ”. The instrument time is automatically populated by default. Enter the value in 24 hour time format (e.g., for 7:00 pm, enter 19:00).
	Start Date	The date that the EQC Interval starts running.
EQC Failures	EQC Failure Limit (0–9)	The number of additional failed EQC tests that <i>Operators</i> are allowed to run before QC lockout. By default, if an EQC test fails, <i>Operators</i> can run 1 more EQC test. If the EQC test fails, lockout will occur. A <i>Supervisor</i> can configure the instrument so that <i>Operators</i> are allowed to run as many as 9 additional failed EQC tests after the first test fails. This postpones lockout. To prevent <i>Operators</i> from running any additional failed EQC tests, enter 0 (zero). 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.
	EQC Failure Count	A counter that displays the number of additional failed EQC tests that <i>Operators</i> have run. This value is read-only. After the first EQC test fails, the counter is incremented each time an additional EQC test fails. The counter will be cleared (reset) when the <i>Operator</i> runs a successful EQC test. A <i>Supervisor</i> can clear this value by selecting Yes in the field labeled “ Clear EQC Failure Count ”. The counter will be cleared (reset) when configuration data is sent to the instrument. 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 that <i>Operators</i> have run: • No – Do not clear the counter. • Yes – Clear the counter. When Yes is selected, the counter labeled “ EQC Failure Count ” will be cleared (reset) when configuration data is sent to the instrument.
Internal EQC	NOTE: When EQC is required (Yes is selected in the field labeled “ EQC Required ”), it can be configured using the following default features (optional):	
	Level 1 Limit	Select 120 seconds.
	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. This value is read-only.
	Level 2 Limit	Select 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 Expiration (0–240)	The number of additional patient tests that <i>Operators</i> are allowed to run after the EQC Interval expires. <i>Supervisors</i> can allow <i>Operators</i> to run as many as 240 additional patient tests after the EQC Interval expires. When the maximum number of patient tests has been reached, if an <i>Operator</i> tries to run another patient test, QC lockout occurs. To prevent <i>Operators</i> from running any additional patient tests, enter 0 (zero). As soon as the EQC Interval expires, QC lockout will occur. When an additional patient test has been run, the value in the field labeled “Number of Patient Tests Used After EQC Expiration” is incremented. <i>Supervisors</i> can clear this value by selecting Yes in the field labeled “Clear Number of Patient Tests Used After EQC Expiration”. NOTE: It is recommended to run a successful EQC test to clear the value in the field labeled “Number of Patient Tests Used After EQC Expiration”.
	Number of Patient Tests Used After EQC Expiration	A counter that displays the number of additional patient tests that <i>Operators</i> have run after the EQC Interval expired. This value is read-only. After the EQC Interval expires, this counter is incremented each time an <i>Operator</i> runs an additional patient test. For more information, see the description for the field labeled “Maximum Patient Tests Allowed After EQC Expiration (0–240)”.
	Clear Number of Patient Tests Used After EQC Expiration	Choose whether to clear (reset) the counter that displays the number of patient tests that <i>Operators</i> have run after the EQC Interval expired: • No – Do not clear the counter. • Yes – Clear the counter. When Yes is selected, the counter labeled “Number of Patient Tests Used After EQC Expiration” will be cleared (reset) when configuration data is sent to the instrument. NOTE: It is recommended to run a successful EQC test to clear the value in the field labeled “Number of Patient Tests Used After EQC Expiration”.

Barcode Settings Dialog Box:

The screenshot shows the 'Barcode Settings' dialog box within the 'Instrument Settings' application. The 'Barcode Settings' tab is selected, displaying various configuration fields. The 'Identifier' is set to 'Patient ID'. 'Barcode Type' is set to 'All'. 'Group Delimiter Character' and 'Group Position' are empty. 'Prefix' and 'Suffix' are empty. 'Start or Range Position' and 'Remove Character' are empty. 'Check Digit' is checked. There are 'New', 'Edit', and 'Delete' buttons on the right. At the bottom are 'OK' and 'Cancel' buttons.

Figure 106: CCM – Barcode Settings Dialog Box

- 1 On the instrument, select  (Settings) > **Supervisor Settings** > **Barcode Scanner Test**.
- 2 When the dialog box is displayed, select **Scan** and then scan the Operator ID and Patient ID barcodes to verify if barcode parsing is required.
- 3 In the **Barcode Settings** dialog box (Figure 106) on **CCM**, click **New**. The **Adding New Barcode Settings** dialog box is displayed.
- 4 Configure barcode parsing as needed. For a description of each setting, see *Table 17*.

Table 17: CCM – Instrument Settings > Barcode Settings

Setting	Description
Identifier	Select Patient ID or Operator ID .
Barcode Type	Select the appropriate barcode type from the drop-down list of supported barcodes. By default, All is selected. Supported barcodes: Aztec, Codabar, Code 11, Code 128, Code 39, Code 93, DataMatrix, EAN-13, EAN-8, GS1 DataBar, GS1 DataBar Expanded, GS1 DataBar Limited, GS1-128, Interleaved 2 of 5, Matrix 2 of 5, MaxiCode, MicroPDF417, MSI, PDF417, QR code, Telepen, UPC-A, UPC-E, UPC-E1.
Group Delimiter Character	To separate barcode strings into groups, select the delimiter character from the drop-down list OR manually enter the delimiter character(s) into the text field.
Group Position	Enter a number to identify the group position that will be displayed from the barcode string.
Prefix	To remove a prefix from the barcode string.
Suffix	To remove a suffix from the barcode string.
Start or Range Position	To identify the starting position or range a characters that will be displayed from the barcode string.
Remove Character	To remove a specific character or group of characters (exact order) from the barcode string.
Check Digit	To enable or disable the validation of the check digit. By default, the check digit validation is enabled for the following barcode types: Codabar, Code 11, Code 39, Interleaved 2 of 5. Therefore, if the barcode string does <u>not</u> contain a check digit, the check digit validation should be disabled.

- 5 Click **OK**. The information is added to the **Barcode Settings** dialog box (Figure 106).
- 6 Click **OK** again to save the changes and return to the **Home** screen.
- 7 Send the configuration data to the instrument. For more information, see “Send Configuration Data to Instruments” (page 103).

- 8 Initiate a patient test to confirm that the Operator ID and/or Patient ID displayed on the instrument screen contain the appropriate barcode parsing.

NOTE: To edit or delete a barcode setting, select the **Identifier** from the list (Figure 106) and the appropriate button (**Edit** or **Delete**).

Example of Barcode Parsing:

- 1 On the instrument, select  (Settings) > **Supervisor Settings** > **Barcode Scanner Test**.
- 2 When the dialog box is displayed, select **Scan** and then scan the Patient ID barcode label.
- 3 Information provided by **Barcode Scanner Test**:
 - Barcode String: **WX-123456|YY**
 - Barcode Type: **Code 39**

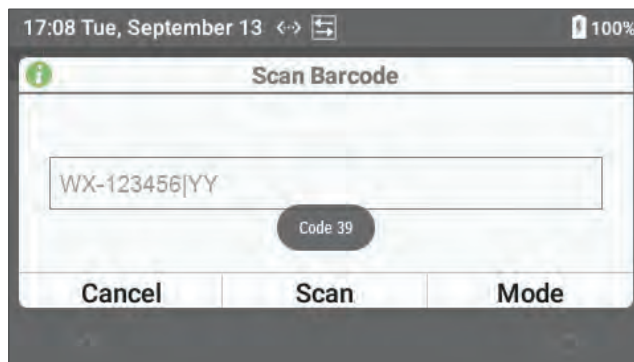


Figure 107: Example Barcode Scanner Test

- 4 The barcode string (**WX-123456|YY**) displayed in the dialog box (Figure 107) does not match the human-readable information (**123456**) on the barcode label.
- 5 In the **Barcode Settings** dialog box (Figure 106 (page 98)) on **CCM**, select **New**. The **Adding New Barcode Settings** dialog box is displayed.
- 6 Enter the following information:
 - Select **Patient ID** in the **Identifier** drop-down list.
 - Select **Code 39** in the **Barcode Type** drop-down list.
 - Manually enter **-|** into the **Group Delimiter Character** text field to separate **WX-123456|YY** into 3 groups:

1	2	3
WX	123456	YY
 - Enter **2** into the **Group Position** text field to identify **123456** as the Patient ID.
 - Disable the **Check Digit** validation.
- 7 Click **OK**. The information is added to the **Barcode Settings** dialog box (Figure 106 (page 98)).
- 8 Click **OK** again to save the changes and return to the **Home** screen.
- 9 Send the configuration data to the instrument. For more information, see “Send Configuration Data to Instruments” (page 103).
- 10 Initiate a patient test to confirm that the Patient ID displayed on the instrument screen contains the appropriate barcode parsing.

Version Info Dialog Box:

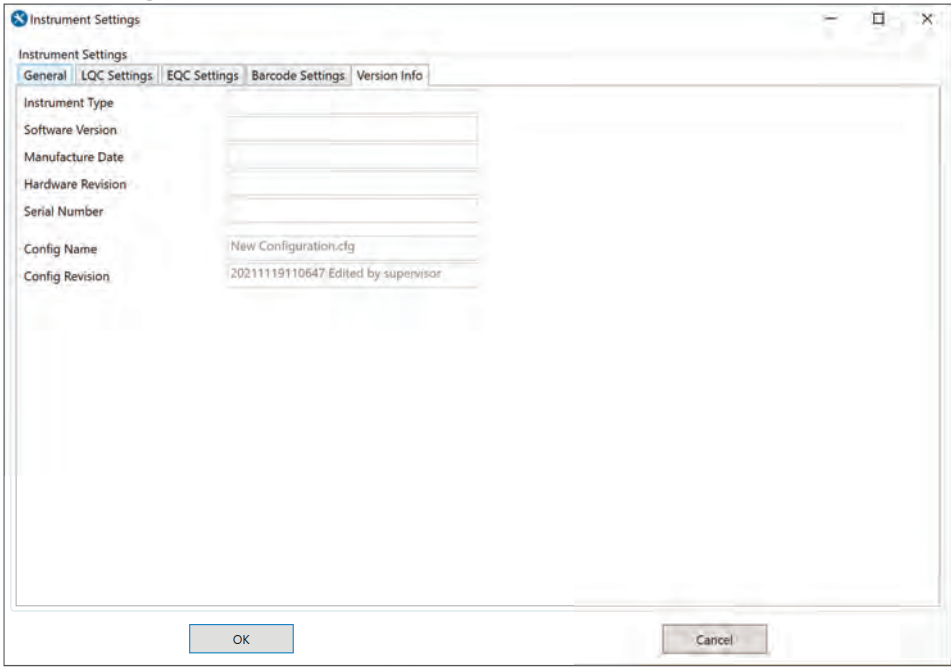


Figure 108: CCM – Version Info Dialog Box

NOTE: The **Version Info** tab contains read-only information. This information is displayed only after data is read from the instrument connected to **CCM**.

Table 18: CCM – Instrument Settings > Version Info

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

8.4.2.1.4 Create Instrument Operators and Supervisors

- 1 Click the **Operators** button.
The **Operators** dialog box (Figure 109) is displayed.

Figure 109: CCM – Operators Dialog Box

- 2 Click **New**. The **Adding New Operator** dialog box is displayed.
- 3 Enter the *Operator* settings. For a description of each setting, see Table 19.

Table 19: CCM – Operators Settings

Setting	Description
Operator ID	The <i>Operator</i> 's ID. NOTE: The <i>Operator ID</i> length must be 1–32 characters.
First Name	The first name of the <i>Operator</i> . NOTE: The first name length must be 1–28 characters.
Last Name	The last name of the <i>Operator</i> . NOTE: The last name length must be 1–28 characters.
Permission Level	The type of <i>Operator</i> account (Operator or Supervisor).
Password	The password for the <i>Operator</i> account. NOTE: The password length must be 7–32 characters. At least 1 character must be a special character (period, comma, &, @, *, \$, etc.).
Expiration Date	The date that the <i>Operator</i> account will expire. If a date is not entered, the <i>Operator</i> account will never expire.

- 4 Click **OK**. The *Operator* (or *Supervisor*) account is added to the list of *Operators*.
- 5 Click **OK** again to save the changes and return to the **Home** screen.

NOTE: To edit or delete an *Operator*, select the *Operator* account from the list (Figure 109) and the appropriate button (**Edit** or **Delete**).

NOTE: If using an *Operator* list from other middleware (e.g., GEMweb Plus 500), the limitation on *Operator ID* (character length and/or password) will be determined by the middleware software.

8.4.2.1.5 **Configure Institution Data**

- 1 Click the **Institution** button.
The **Institution** dialog box (*Figure 110*) is displayed.

A standard Windows-style dialog box titled "Institution". It contains several text input fields stacked vertically, each with a label to its left: "Institution Name", "Address", "Address 2", "City", "State / Province", "Zip Code", "Country", "Phone Number", "Extension", and "Fax Number". At the bottom right of the dialog box are two buttons: "OK" and "Cancel".

Figure 110: CCM – Institution Dialog Box

- 2 Add data about the institution.
- 3 Click **OK** to save the changes.

8.4.2.2 Send Configuration Data to Instruments

After configuration data is created, **CCM** can be used to send to 1 or more instruments.

- 1 Ensure each instrument that needs to receive the configuration data is connected to the network.
NOTE: If  (Ethernet) or  (Wi-Fi) is displayed in the status bar of the instrument screen, the instrument is connected to the network.
- 2 Under **Instrument Selection and Control** (Figure 96 (page 86)), in the drop-down list, select the instrument or group of instruments that need to receive the configuration data.
- 3 The icon to the right of each instrument name indicates whether a network connection is established between the instrument and **CCM**.

	Network connection is established. Go to the next step.
	Network connection is not established. See “Install CCM Software and Configure Firewalls” (page 81).

- 4 Click the **Send to Instruments** button.
- 5 The **Send to Instruments** dialog box (Figure 111) is displayed with a check box next to each type of configuration data. If any of the items are in **bold**, the configuration data was changed in the session.

For specific information about the LQC Lots and Cartridge Lots check boxes, read the important note in step 6.

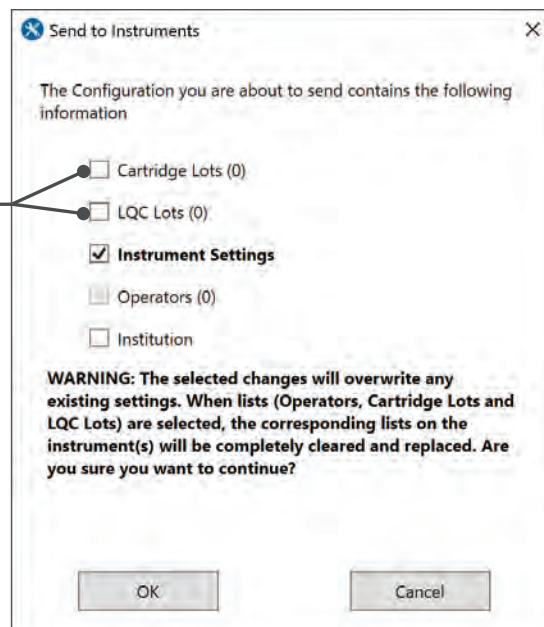


Figure 111: CCM – Send to Instruments Dialog Box

- 6 Check the configured data before sending to the instruments.
NOTE: For **LQC Lots** and **Cartridge Lots**:
 - If there is any lot data in the configuration session (if any lot data was changed in the session), the box is automatically checked.
 - If there is no lot data in the configuration session, 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.
- 7 Click **OK** to send the configuration data to each instrument.
NOTE: If the configuration data is sent to the instrument while the instrument is displaying test results (patient, LQC, and EQC tests), the instrument will display the **New Configuration** dialog box with a 2 minute countdown timer. Select the appropriate option:
 - **Postpone** – The configuration data will be applied when the instrument is not performing a test or displaying test results.
 - **Apply** – The configuration data will be applied immediately.

If **Postpone** or **Apply** are not selected within 2 minutes, the configuration data will be applied when the countdown timer expires.

8.4.2.3 Export Configuration Data

During a **CCM** 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 this data, it must be exported to a configuration file.

- 1 On the **Home** screen (*Figure 96 (page 86)*), in the lower right corner, click the **Export to File** button.
- 2 The **Export to File** dialog box (*Figure 112*) is displayed with a check box next to each type of configuration data. If any of the items are in **bold**, the configuration data was changed in the session.

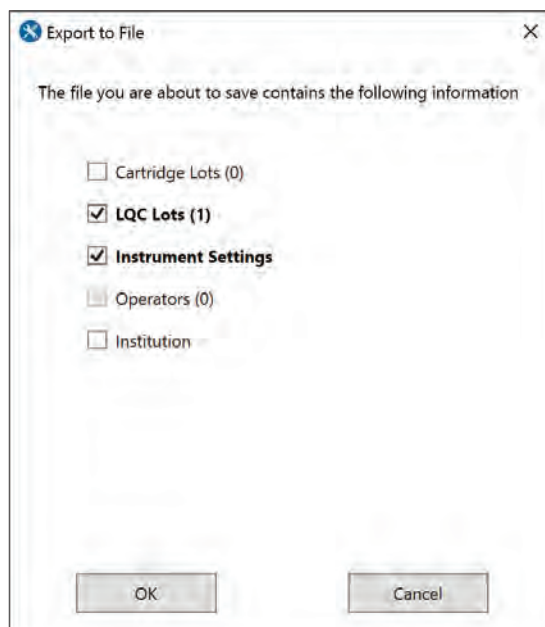


Figure 112: CCM – Export to File Dialog Box

- 3 Check the box for the data items that need to be exported.
- 4 Click **OK**.
- 5 Select a location to save the file, 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 **CCM** session.

8.4.2.4 Import Configuration Data

Configuration data can be imported from a configuration file (.cfg) or the instrument into a **CCM** session and can be edited before it is sent to instruments.

There are 2 ways to import data into a **CCM** session (*Figure 96 (page 86)*):

- **Read from Instrument** – On the **Home** screen, in the upper left corner, select the **Read From Instrument** button.
- **Import from Configuration File** (only if configuration file exists) – On the **Home** screen, in the lower right corner, select the **Import From File** button.

NOTE: To import the configuration settings from an existing instrument, first read from the instrument, edit the configuration data, and then send to the instruments or to a group of instruments.

8.4.3 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 file (.csv) and opened in a spreadsheet.

- 1 Log into **CCM** as a *Supervisor*.
- 2 Ensure each instrument is connected to the network.
NOTE: If <··> (Ethernet) or  (Wi-Fi) is displayed in the status bar of the instrument screen, the instrument is connected to the network.
- 3 Under **Instrument Selection and Control** (Figure 96 (page 86)), in the drop-down list, select the instrument or group of instruments 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 **CCM**.

	Network connection is established. Go to the next step.
	Network connection is not established. See “Install CCM Software and Configure Firewalls” (page 81).

- 5 Click the **Configuration Report** button. The configuration report is displayed. If necessary, maximize the window or drag a corner to resize.
NOTE: To save the configuration report to a comma-separated value file (.csv), click **Export**. The file can be opened in a spreadsheet.

8.4.4 Log Files

When *Supervisors* use **CCM**, system activity is recorded in log files.

8.4.4.1 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 file (.txt), click the **Export Log** button. Time-stamped versions of this file are located in the following folder:

C:\ProgramData\InstrumentationLaboratory\CCM

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

8.4.4.2 Debug Log File

The debug log file (ccm-debug.log) records POCT1-A messages that are sent between the instrument and **CCM**. 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

8.4.5 Update Instrument Software

Use **CCM** to update the instrument software (firmware).

- 1 Get the build package that contains the latest instrument software from the manufacturer:
GEMH100.zip
- 2 Log into **CCM** as a *Supervisor*.
- 3 Ensure the instrument that needs to be updated is connected to the network and the **power supply cable**.

NOTE: If  (Ethernet) or  (Wi-Fi) is displayed in the status bar of the instrument screen, the instrument is connected to the network.

- 4 Under **Instrument Selection and Control** (Figure 96 (page 86)), 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 **CCM**.

	Network connection is established. Go to the next step.
	Network connection is not established. See “Install CCM Software and Configure Firewalls” (page 81).

- 6 Click the **Update Software** button.
- 7 Select the instrument software build package:
GEMH100.zip
- 8 Click **Open** and then select **OK** in the dialog box to confirm the download.
- 9 The updating process begins. During the process, the instrument is automatically shut down and restarted twice, so allow time for the process to run.

8.4.6 Update Wi-Fi Enterprise Certificate

Use CCM to Update Wi-Fi Enterprise Certificate:

- 1 Log into **CCM** as a *Supervisor*.
- 2 Ensure each instrument that needs to be updated is connected to the network.
NOTE: If  (Ethernet) or  (Wi-Fi) is displayed in the status bar of the instrument screen, the instrument is connected to the network.
- 3 Under **Instrument Selection and Control** (Figure 96 (page 86)), in the drop-down list, select the instrument, group of instruments, or all instruments that need to be updated with the Wi-Fi Enterprise Certificate.
- 4 The icon to the right of the instrument name indicates whether a network connection is established between the instrument and **CCM**.

	Network connection is established. Go to the next step.
	Network connection is not established. See “Install CCM Software and Configure Firewalls” (page 81).

- 5 Click the **Update Certificate** button.
- 6 Select the Wi-Fi Enterprise Certificate file, click **Open**, and then select **OK** in the **Update Certificate** dialog box (Figure 113) to upload the certificate onto the instrument.

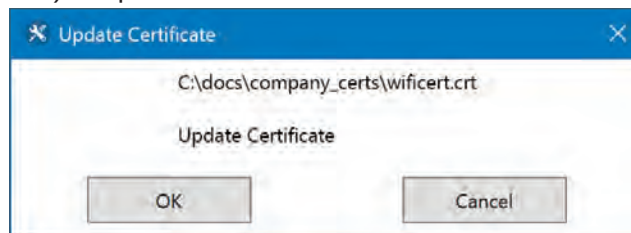


Figure 113: CCM – Update Certificate

- 7 Upon completion, select **OK** in the **Update Certificate Results** dialog box (Figure 114) to confirm the download.

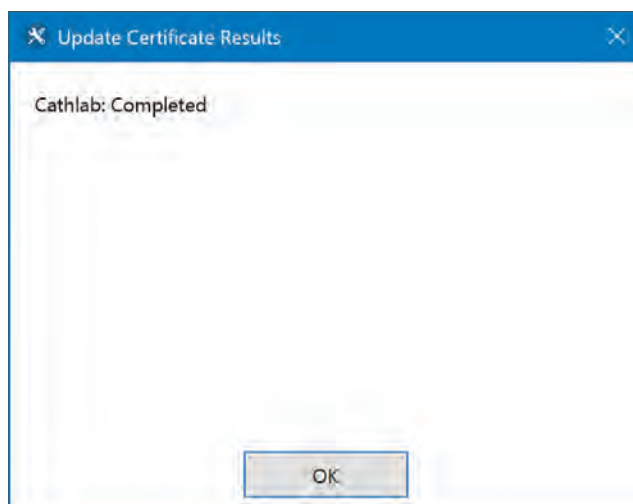


Figure 114: CCM – Update Certificate Results

- 8 The instrument will display a message indicating that the Wi-Fi Certificate download was successful (Figure 115). Select **Ok**.



Figure 115: Download Successful

Use Each Instrument to Download the Certificate:

- 1 On each instrument, select  (Settings) > **Supervisor Settings** > **Instrument Settings** > **Security** > **Install Certificate**.
- 2 The instrument will display a message indicating that the Wi-Fi Certificate download was successful. Select **Ok**.

NOTE: To view and/or modify stored credentials, select **User Credentials**.

NOTE: To remove all certificates, select **Clear Credentials**.

NOTE: To configure Wi-Fi, see “Connect to a Wireless Network (Wi-Fi)” (page 36).

8.4.7 Download Instrument Log Files

Use CCM to Download Log Files:

- 1 Log into **CCM** as a *Supervisor*.
- 2 Ensure each instrument that needs to be updated is connected to the network.
NOTE: If  (Ethernet) or  (Wi-Fi) is displayed in the status bar of the instrument screen, the instrument is connected to the network.
- 3 Under **Instrument Selection and Control** (Figure 96 (page 86)), in the drop-down list, select the instrument, group of instruments, or all instruments to download log files.
- 4 The icon to the right of the instrument name indicates whether a network connection is established between the instrument and **CCM**.

	Network connection is established. Go to the next step.
	Network connection is not established. See “Install CCM Software and Configure Firewalls” (page 81).

- 5 Click the **Download Log** button.
- 6 Select the location to save the logs.
- 7 Select **OK** in the **Download Log Results** dialog box (Figure 116).
NOTE: If requested, send to Technical Support. Technical Support can use the information in the event that a problem with the instrument occurs.

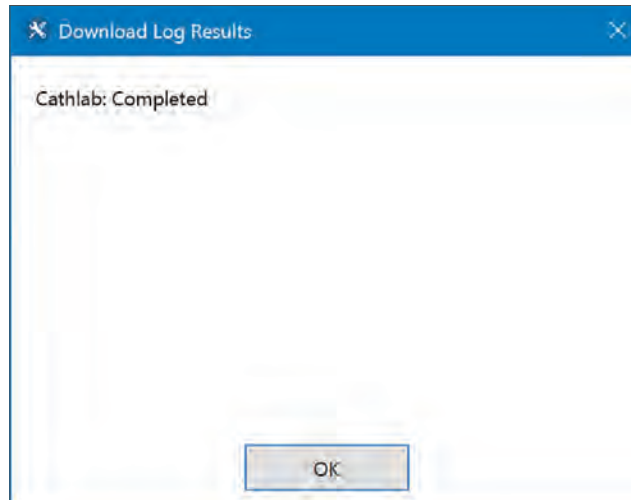


Figure 116: CCM – Download Log Results

Δ 8.4.8 Export Tests Records to a CSV File

A report that contains all tests records data (Patient, EQC, and LQC) from one or multiple instruments 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 into **CCM** as a *Supervisor*.
- 2 Ensure each instrument is connected to the network.
NOTE: If  (Ethernet) or  (Wi-Fi) is displayed in the status bar of the instrument screen, the instrument is connected to the network.
- 3 Under **Instrument Selection and Control** (Figure 96 (page 86)), in the drop-down list, select the instrument or group of instruments 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 **CCM**.

	Network connection is established. Go to the next step.
	Network connection is not established. See “Install CCM Software and Configure Firewalls” (page 81).

- 5 Click the **Read Test Records** button.

6 Save the **Test Records** file to your preferred location.

7 Unzip the downloaded file and extract its contents.

For each individual instrument, the extracted folder will contain three CSV files:

- Patient Test records
- EQC records
- LQC records

Examples of CSV Test Records are shown below:

Patient Test:

	Date 1	Date 2	Test	Value	Note	ESV	Operator ID	Patient ID	Cartridge Lot	Cartridge Exp. Date	Serial Number
Patient Test	1/21/2025	11:09	ACT+	107	Example: User Note	Pass	OID123	PID123	D1JAC502	2027-01	MC100512
	1/21/2025	11:05	ACT+	420		Pass	OID124	PID126	D1JAC502	2027-01	MC100520
	1/21/2025	11:13	ACT+	0	Aborted	Pass	OID125	PID124	D1JAC502	2027-01	MC100512
	1/21/2025	11:15	ACT+	0	Out of Range Low	Pass	OID123	PID125	D1JAC502	2027-01	MC100512

NOTE: The Patient Test CSV file will include a 'Note' column that may display either a user-entered note or an instrument-generated error (e.g., Aborted, Out of Range). If a test is aborted or encounters an instrument error, the Value column will display 0 for that entry.

EQC:

	Date 1	Date 2	EQC Result	ESV Result	EQC Level 1 Result	EQC Level 2 Result	Internal Voltages	Analytical Firmware CRC	Assay Definition File CRC	Calibration and Factory CRC ID	Battery Health
EQC	2/18/2025	11:21	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
	RealTime Clock	Processor Communication	Heater ESV	Pump ESV	Camera	Illumination	Heater Level 1	Heater Level 2	Pump Level 1	Pump Level 2	
EQC (Cont.)	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	

LQC:

	Date 1	Date 2	Test	LQC Level	Value	Result	Note	LQC Range	ESV	Operator ID	Cartridge Lot	Cartridge Expiration Date	LQC Lot	LQC Expiration Date	Serial Number
LQC	2/13/2025	8:32	ACT+	2	344	Pass		297-529	Pass	OID3	G5JAC547	2026-12	K4DCA027	2026-05	MC1000512

Δ 9 Regulatory Compliance

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

NOTE: Refer to the instrument's SN label for applicable FCC ID or IC number (Figure 1 (page 9)).

FCC ID and IC Numbers	
FCC ID 2AQV3-GEM100 / IC 24216-GEM100	FCC ID 2AQV3-GEM100A / IC 24216-GEM100A
CAN/CSA-C22.2 No. 61010-1:2012 + U1:2015-07 + U2:2016-04 CAN/CSA-C22.2 No. 61010-2-010:2015 CAN/CSA-C22.2 No. 61010-2-101:2015	CAN/CSA-C22.2 No. 61010-1:2012/R:2018-10 CAN/CSA-C22.2 No. 61010-2-010:2019 CAN/CSA-C22.2 No. 61010-2-101:2019
EN 61010-1:2010 EN 61010-2-010:2014 EN 61010-2-101:2017	EN 61010-1:2010/A1:2019 EN IEC 61010-2-010:2020 EN IEC 61010-2-101:2022
UL 61010-1:2012 + R:2015-07 + R:2016-04 UL 61010-2-010:2015	UL 61010-1:2012/R:2019-07 UL 61010-2-010:2019 UL 61010-2-101:2019
IEC 61010-1:2012 IEC 61010-2-101:2015 IEC 61010-2-010:2014 Supplemented by UL 61010-2-101:2015 IEC 60601-1-2:2014	IEC 61010-1:2010/AMD1:2016 IEC 61010-2-010:2019 IEC 61010-2-101:2018

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]**

"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 license-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."

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

This equipment has been tested and found to comply with the respective limits in each table below, pursuant to Part 15 of the Federal Communications Commission (FCC) Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in its intended use environment.

This instrument has not been evaluated for safety and compatibility in the magnetic resonance (MR) environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the instrument in the MR environment is unknown.

This instrument has not been tested for use in the MR environment.

NOTE: This instrument is not intended for use during the operation of an MR system for an MR procedure. That is, this instrument should not be inside of the bore of the MR system, exposing this instrument to the time-varying and Radio Frequency (RF) fields activated during an MR procedure.

Wireless Characteristics and Compliance:

This instrument complies with the requirements of FCC Part 15 Subpart B, Innovation, Science and Economic Development Canada (ISED) ICES-003, and EN 61326-1:2013 as shown below:

	FCC ID 2AQV3-GEM100 / IC 24216-GEM100	FCC ID 2AQV3-GEM100A / IC 24216-GEM100A
FCC ID:	2AQV3-GEM100	2AQV3-GEM100A
IC Certificate:	24216-GEM100	24216-GEM100A
HVIN	N/A	GEM Hemochron 100A
Product Name:	GEM Hemochron 100	GEM Hemochron 100
Model(s):	GEM100	GEM100
Equipment Type:	Wireless Handheld Hemochron	Wireless Blood Hemostasis System
Classification:	Portable Transmitter Handheld Only	Portable Transmitter Next to Extremity
TX Frequency Range:	2412–2462 MHz; 5180–5320 MHz; 5500–5700 MHz; 5745–5825 MHz	2412–2462 MHz; 5150–5350 MHz; 5500–5700 MHz; 5745–5825 MHz; 2402–2480 MHz
Frequency Tolerance:	±2.5 ppm	±2.5 ppm
Maximum RF Output:	2450 MHz (b) – 15.50 dB, 2450 MHz (g) – 19.00 dB, 2450 MHz (n) – 21.50 dB, 5250 MHz (a) – 16.00 dB, 5250 MHz (n) – 16.00 dB, 5600 MHz (a) – 17.50 dB, 5600 MHz (n) – 17.50 dB, 5800 MHz (a) – 17.00 dB, 5800 MHz (n) – 17.00 dB Conducted	2450 MHz (b) – 20.0 dBm, 2450 MHz (g) – 20.0 dBm, 2450 MHz (n20) – 20.0 dBm, 5 GHz (a) – 20.0 dBm, 5 GHz (n/ac20) – 20.0 dBm, 5 GHz (n/ac40) – 18.0 dBm, 5 GHz (ac80) – 16.0 dBm, 2450 MHz (BT) – 11.0 dBm Conducted
Signal Modulation:	DSSS, OFDM	GMSK, DSSS, OFDM
Antenna Type:	Internal; PIFA Antenna	Internal Antenna
FCC Rule Parts:	Part 2, 15C, 15E	Part 2, 15C, 15E
KDB Test Methodology:	KDB 447498 D01 v06, KDB 248227 v02r02, KDB 616217 D04 v01r02	KDB 447498 D01 v06, KDB 248227 D01 v02r02
Industry Canada:	RSS-102 Issue 5, Safety Code 6	RSS-102 Issue 5, Safety Code 6
Maximum SAR Value:	1.02 W/kg Reported 10 Gram Average	2.60 W/kg Reported
Maximum Simultaneous SAR:	1.45 W/kg Reported 10 Gram Average	0.09 Separation Ratio
Separation Distance:	0 mm	0 mm

List of Wireless Technologies Utilized:

FCC ID 2AQV3-GEM100 / IC 24216-GEM100						
Band	Technology	3GPP Nominal Power dBm	Setpoint Nominal Power dBm	Tolerance dBm	Lower Tolerance dBm	Upper Tolerance dBm
WLAN – 2.4 GHz	802.11b	N/A	13.5	±2	11.5	15.5
WLAN – 2.4 GHz	802.11g	N/A	17.0	±2	15.0	19.0
WLAN – 2.4 GHz	802.11n	N/A	19.5	±2	17.5	21.5
WLAN – 5 GHz Band I, IIA	802.11a (36–56)	N/A	13.0	±2	11.0	15.0
WLAN – 5 GHz Band IIA	802.11a (60–64)	N/A	14.0	±2	12.0	16.0
WLAN – 5 GHz Band I, IIA	802.11n (36–56)	N/A	13.0	±2	11.0	15.0
WLAN – 5 GHz Band IIA	802.11n (60–64)	N/A	14.0	±2	12.0	16.0
WLAN – 5 GHz Band IIC	802.11a	N/A	15.5	±2	13.5	17.5
WLAN – 5 GHz Band IIC	802.11n	N/A	15.5	±2	13.5	17.5
WLAN – 5 GHz Band III	802.11a	N/A	15.0	±2	13.0	17.0
WLAN – 5 GHz Band III	802.11n	N/A	15.0	±2	13.0	17.0
FCC ID 2AQV3-GEM100A / IC 24216-GEM100A						
WLAN – 2.4 GHz	802.11bgn20	N/A	N/A	N/A	N/A	20.0
WLAN – 5 GHz	802.11an20ac20	N/A	N/A	N/A	N/A	20.0
WLAN – 5 GHz	802.11n/ac40	N/A	N/A	N/A	N/A	18.0
WLAN – 5 GHz	802.11ac80	N/A	N/A	N/A	N/A	16.0

Wireless Quality of Service (QoS):

This instrument uses wireless technology for the transmission of data to external devices. No reliance on wireless communication is necessary for specimen analysis and/or calculation of analytical test results. Inadequate QoS will result in a communications error flagged to the *Operator* through the instrument user interface. For an indicator of the network quality, see “*Connectivity Icons*” (page 10).

Cybersecurity:

Refer to the *GEM Hemochron 100 Cybersecurity and Privacy Guide* (P/N: 000HZ7043).

Addressing Wireless Connectivity Problems / Coexistence:

This instrument is able to provide essential performance (assay analysis) without the use of a network connection. In the event of a perceived or actual communications failure, relocate the instrument closer to the desired wireless access point and/or identify and eliminate any wireless interference. The instrument has been tested to, and met the requirements of medical coexistence ANSI C63.27.

Test Limits per EMC Standards:

Complies with IEC 60601-1-2:2014 or IEC 60601-1-2:2020 and EN 61326-1/CISPR 11 Class B, and meets the limits listed below:

Emissions Product Standards			
Standard	Test Description	Test Level / Limits	
		FCC ID 2AQV3-GEM100 / IC 24216-GEM100	FCC ID 2AQV3-GEM100A / IC 24216-GEM100A
CISPR 11	Radiated Emission	Class B	Class B
CISPR 11	Conducted Emission	Class B	Class B
IEC 61000-3-2	Harmonics	Class A	AC Mains EN 61000-3-2
IEC 61000-3-3	Flicker	Pst ≤ 1.0 Plt ≤ 0.65 dc ≤ 3.3% dmax ≤ 4.0%	AC Mains EN 61000-3-3

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Complies with IEC 61236-1-2 and meets the limits of IEC 60601-1-2 as shown below:

Immunity Standards (Professional Healthcare Facility Environment)		
Standard	Test Description	Test Level / Limits
		FCC ID 2AQV3-GEM100 / IC 24216-GEM100 and FCC ID 2AQV3-GEM100A / IC 24216-GEM100A
IEC 61000-4-2	Electrostatic Discharge	±8 kV Contact Discharge ±2, 4, 8, and 15 kV Air Discharge
IEC 61000-4-3	Radio Frequency Electromagnetic Field Amplitude Modulated	80 MHz to 2.7 GHz 3 V/m 80% AM 1 kHz
IEC 61000-4-3	Proximity Field from Wireless Transmitters	385 MHz: 27 V/m @ 18 Hz Pulse Modulation 450 MHz: 28 V/m @ FM Modulation 710 MHz, 745 MHz, 780 MHz: 9 V/m @ 217 Hz Pulse Modulation 810 MHz, 870 MHz, 930 MHz: 28 V/m @ 18 Hz Pulse Modulation 1720 MHz, 1845 MHz, 1970 MHz: 28 V/m @ 217 Hz Pulse Modulation 2450 MHz: 28 V/m @ 217 Hz Pulse Modulation 5240 MHz, 5500 MHz, 5785 MHz: 9 V/m @ 217 Hz Pulse Modulation
IEC 61000-4-4	Electrical Fast Transients	±2.0 kV AC/DC Mains ±1.0 kV Signal and Control Lines (100 kHz repetition frequency)
IEC 61000-4-5	Surge	±0.5 and 1 kV (Line to Line (DM)) ±0.5, 1, and 2 kV (Line to Line (CM)) SIP/SOPS ±2.0 kV (Line to Ground)
IEC 61000-4-6	Radio Frequency Common Mode	0.150 MHz to 80 MHz 3 Vrms (6 Vrms in ISM radio bands between 0.15 MHz to 80 MHz) 80% AM 1 kHz (Applies to both enclosure and SIP/SOPS)
IEC 61000-4-8	Power Frequency Magnetic Field	30 A/m (50 Hz or 60 Hz field)
IEC 61000-4-11	Voltage Dips and Interruptions	0% of Vnom 0.5 cycles at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°
		0% of Vnom 1 cycle at 0°
		70% of Vnom 25/30 cycles at 0°
		0% of Vnom 250/300 cycles

RFID / Interference:

Description	FCC ID 2AQV3-GEM100 / IC 24216-GEM100	FCC ID 2AQV3-GEM100A / IC 24216-GEM100A
Compliance Standard	AIM 7351731 Rev 2.00:2017-02-03	IEC 61000-4-39
Specification	Compliant	Radiated fields in close proximity (RFID)
Test Level/Limits	Compliant	Frequency 134.2 kHz, 13.56 MHz Level (A/m) 65, 7.5 Modulation CW Pulse - 2.1 kHz, Pulse - 50KHZ

European Union Directive 2012/19/EU on Waste Electrical and Electrical Equipment (WEEE):

Werfen is committed to meeting or exceeding the conditions of the WEEE Directive and being a good environmental partner.

In compliance with the WEEE Directive, beginning with product shipped after August 13, 2005, all instruments are labeled with the following symbol:



Disposing of this product correctly helps prevent potential negative consequences for the environment and for human health. Recycling conserves natural resources.

Δ Regulatory Compliance

Penalties may be applicable for incorrect disposal of this waste in accordance with national (European) legislation.

Please contact your local distributor for information regarding the disposal of any end-of-life instruments.

Summary of Safety and Performance:

The Summary of Safety and Performance will be accessible in the European database on medical devices (Eudamed) at <https://ec.europa.eu/tools/eudamed>. Currently, it is available on the manufacturer's website.

RoHS Compliance:

The manufacturer certifies that the GEM Hemochron 100 instrument is in compliance with the Directive 2011/65/EU of the European Parliament and of the Council of June 8, 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS 3).

Electrical Safety:

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. Bleach is not recommended.
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 the manufacturer.

Δ 10 Legal Notices and Licenses

Acknowledgments:

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OpenCV

Version 4.0.1 December 22, 2018

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Operator Manual • 000HZ6046EN.US • 01 • 03/2025
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Accriva Diagnostics, Inc. - 6260 Sequence Drive, San Diego, CA 92121, USA
Tel: +1-858-263-2300 • www.werfen.com



MDSS GmbH - Schiffgraben 41, 30175 Hannover, Germany

