Quantra® Hemostasis Analyzer
User Manual

HemoSonics, LLC

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Important Information

Proprietary Rights: Quantra Hemostasis Analyzer, QPlus®, and QStat® are trademarks of HemoSonics, LLC.

The Quantra and its use may be covered by one or more U.S. and foreign issued patents or pending patent applications. Refer to www.hemosonics.com/patents/.

Disclaimer: This manual is intended to provide instructions on the proper use of the Quantra. It should be used in conjunction with appropriate training and support by HemoSonics personnel.

Use of the instrument in a manner different than that described in this manual may result in improper product function or injury. HemoSonics accepts no responsibility for liability from improper use of its products.

Use of the Quantra requires the operator to handle blood samples. It is the User's responsibility to fully understand and follow all appropriate regulations governing the handling of blood products and biological waste.

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REVISION HISTORY

Date of Revision	Revision Number	Description of Technical Changes
APR 2019	00	US Launch
SEP 2019	01	Added section for Optional Accessories
MAR 2020	02	Updated Technical Support Number, document number, reagent cartridge image, and MDS2 form.
JUN 2020	03	Added Quantra Desktop Remote Viewer to accessories (Remote Systems). Added instructions for saving data to USB and how to archive results. Updated Figures to display from v1.10.6 software. Updated troubleshooting and anomalies. For 510k submission.
NOV 2020	04	Additional disinfectants for use with the Quantra added. Updated quality control product information. Updated screen shots and added information regarding PPID. Enhanced curve screens.
DEC 2022	05	Addition of QStat Cartridge information and 2.1 software release. Minor updates to software: • Cleaning cartridge reminder • System event log export • POCT updates Updated manufacturing address
JUN 2023	06	Software 2.3 release. New QC screens and password requirements. Addition of proficiency testing. Revised hardware information based on current specifications.
OCT 2024	07	Software 2.7 Release. • LIS updates
APR-2025	08	Software 2.8 Release. • Added New Site-Specific Profile Section. • Updated Instrument Network Screen to Reflect MAC Address
SEP-2025	09	Software 2.9 Release • New obstetric patient profile and reference ranges • Updated Site-Specific Profile Section and running a test Section. • Updated Instrument Animations.

For Use with Software Version: 2.9 or later

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1. Text and Labeling Conventions

A. Glossary/Abbreviations

Alert – A system message informing the User of an event or condition. This does not require a User intervention.

Cartridge – Single use plastic component containing reagents in which coagulation testing is performed.

Cartridge ID – Unique identifier for each consumable cartridge lot.

Cartridge Time - Time from when the User presses START to when all tests are finished, and complete results are available.

CS - Clot stiffness. Output parameter – a measure of the stiffness of the clot

CSL – Clot Stability to Lysis – a measure of fibrinolysis

CT - Clot time. Output parameter – time at which the clot formation is first detected

CTH - Heparinase Clot Time. Output parameter. – Time at which the clot formation is first detected in the presence of excess heparinase.

CTR - Clot time ratio Output parameter – ratio of Clot Time to Heparinase Clot Time

FCS - Fibrinogen Contribution to Clot Stiffness. Output parameter

IQCP - Individualized Quality Control Plan

LIS - Laboratory Information System

Patient ID – Unique identifier for the patient

PCS - Platelet Contribution to Clot Stiffness. Output parameter

Personal protective equipment (PPE) - Equipment worn or used by workers to protect themselves from exposure to hazardous materials or conditions; provides a barrier between individuals and potentially hazardous elements.

POST - Power On Self-Test

Reference Range –A reference range for a diagnostic test refers to the set of values that is considered normal and serves as a baseline for healthcare providers to interpret a specific patient's test results by providing context for what constitutes a typical finding versus a potentially abnormal one. Reference ranges are typically established for reference populations that reflect the demographics of a general population but may also be established for specific populations defined by age or sex.

Reportable Range –A reportable range is the measurement range in which a diagnostic test can accurately and precisely measure and report results for patient samples.

QC – Quality control

Sample – Whole blood or control material supplied to the cartridge in an evacuated collection tube or vial.

Test – Analysis performed on a single sample aliquot in a single channel.

User ID – Unique identifier for an instrument operator.

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B. Symbols Used

Symbols are used in this manual and displayed on the Quantra Hemostasis Analyzer (Table 1).

Table 1. Symbols Used

Symbol	Found on	Relevance
	Instrument -Warning	Hazardous voltages inside instrument. Do not operate if instrument case is open or damaged.
	Instrument - Label	Current On
	Instrument - Label	Current Off
	Instrument - Label	Toggle Switch Current On/Off
	Instrument -Warning	Biological Risk
	Instrument -Label	Fuse Location
	Instrument -Label	Chassis Ground
	Instrument -Label	Read Manual or Instructions for Use
	Packaging -Label	Expiry Date
	Packaging -Label	Reference Number or Catalog Number
	Packaging -Label	Lot Number – A unique number assigned by the manufacturer to each lot of cartridges or quality control materials.
	Packaging -Label	Serial Number
	Packaging -Label	Manufacturer name and address
	Packaging -Label	Single use only
	Packaging -Label	Storage temperature limits.
	Software - Warning	Indicates when results for a given Quantra parameter are outside of the reference range.
	Software - Warning	Indicates when results for a given Quantra parameter are outside of the reportable range, there is a problem with the run, or results cannot be determined from this sample.
	Software - Warning	Indicates when the testing of a given Quantra parameter fails. A test error has occurred.
	WEEE Symbol	Indicates that the Quantra Analyzer must be disposed of following WEEE requirements.
	Packaging - Label	Caution US Federal Law restricts this device to sale by or on the order of a physician.

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2. Introduction and Intended Use

The Quantra Hemostasis Analyzer (Quantra, HS-002) is an automated *in vitro* diagnostic device intended to provide indications of the coagulation state of a patient's whole blood sample. The Quantra System uses SEER Sonorheometry to measure the kinetic changes as the sample clots in real time. The output consists of numerical values for clot time and clot stiffness-based coagulation parameters. The Quantra System is for use by professionals at the point of care or in a laboratory setting.

The Quantra System is indicated for use with all FDA-cleared Quantra cartridges.

The results of the Quantra System analysis should not be the sole basis for a patient diagnosis but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, further hemostasis tests.

A. Quantra Overview

The Quantra System (Figure 1) is an *in vitro* diagnostic device designed to assess a patient's coagulation status by measuring the changes in viscoelastic properties of a blood sample during clot formation in surgical and intensive care settings. The system consists of the Quantra Hemostasis Analyzer (instrument), QPlus cartridge and QStat cartridge (single-use disposable cartridge) and HemoSonics Quality Controls (external quality control materials).

Materials Provided

- Quantra Hemostasis Analyzer: REF HS-002

Related Materials

- QPlus Cartridge Kit of 10: REF KT-0004
- QStat Cartridge Kit of 10: REF KT-0020
- QPlus Control Level 1 Kit of 4: REF KT-0023
- QPlus Control Level 2 Kit of 4: REF KT-0025
- QStat Control Level 1 Kit of 4: REF KT-0027
- QStat Control Level 2 Kit of 4: REF KT-0032
- Quantra Cleaning Cartridge Kit of 10: REF KT-0012
- Quantra Printer: REF KT-0015
- Quantra Desktop Remote Viewer: REF KT-0039
- Blood collection supplies, minimum 2.7 mL, 3.2% sodium citrate tubes

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B. System Components

Quantra Instrument

The Quantra Hemostasis Analyzer (Quantra) is a fully integrated and automated diagnostic device that performs whole blood coagulation tests near the point of care. The base instrument and software component controls all aspects of the test sequence, including fluid handling, temperature control, and clot stiffness measurement. In addition, it controls the graphical user interface, result calculation, and result reporting. The instrument and software are a closed system, for use only with Quantra cartridges to perform specified tests.



Figure 1. Quantra Instrument

The instrument never comes in direct contact with either the patient samples or reagents; these are contained within the single-use cartridge.

Operation of the device is fully automated and requires minimal sample handling. After a cartridge is removed from its primary packaging, it is inserted into the instrument dock. A patient's whole blood sample, which is collected in a 3.2% sodium citrate blood collection tube (minimum volume 2.7 mL), is attached directly to the cartridge and the test is initiated using the touch screen interface. The fluidic system within the instrument draws the sample into the cartridge where it is warmed to 37°C, aliquoted, introduced and mixed with the lyophilized reagents, and analyzed. When the test is complete, the cartridge is released from the dock to be disposed in an appropriate biosafety sharps container.

Quantra Cartridge

Quantra cartridges, shown schematically in Figure 2 are a single-use plastic component in which coagulation testing is performed. The cartridge has lyophilized reagents in four wells that enable four independent reactions/tests to be run simultaneously without needing any reagent preparation or controlled pipetting. The cartridge has a sample port on one end to draw the blood sample into the cartridge without requiring any sample pipetting.

Sample testing involves placing a single cartridge into the Quantra Analyzer and attaching a citrated whole blood sample tube onto the cartridge's sample port. The blood is automatically pulled into the system through an inlet in the cartridge. The cartridge is the only component of the Quantra System that directly contacts blood.

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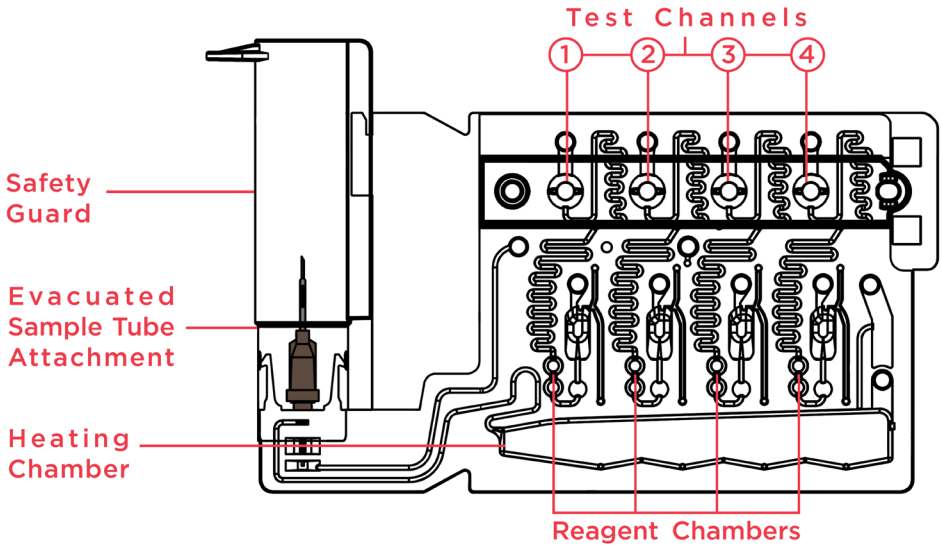

Figure 2. Disposable Cartridge Used with the Quantra Hemostasis Analyzer

HemoSonics External Quality Controls

The HemoSonics external quality controls are used to monitor performance of tests run on the Quantra Hemostasis Analyzer. Two levels are available for purchase to be used with their respective cartridges.

Quantra Cleaning Cartridge

The Quantra Cleaning Cartridge is an accessory for use with the Quantra Hemostasis Analyzer and is intended to be used for simple, periodic cleaning of the Quantra (Figure 3).

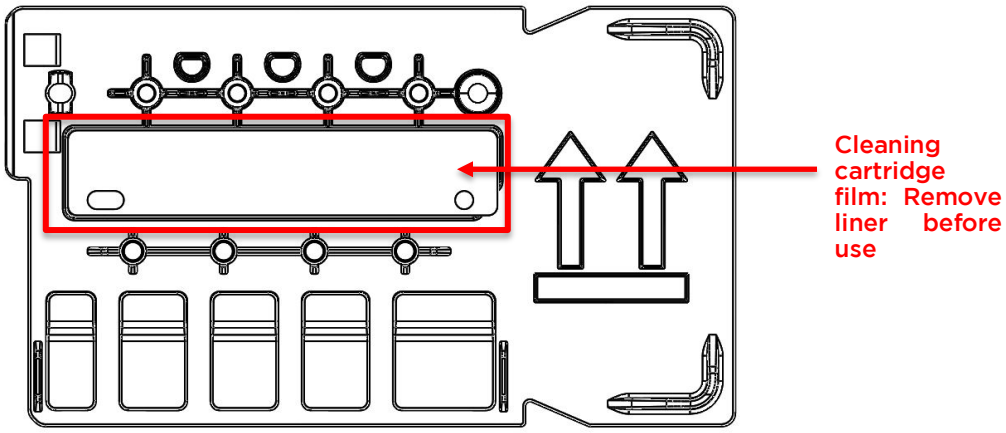

Figure 3. Quantra Cleaning Cartridge

C. Principle of Operation

The Quantra System is based on Sonic Estimation of Elasticity via Resonance (SEER) Sonorheometry, a proprietary technology that uses ultrasound to measure the changes in viscoelastic properties of whole blood during coagulation. SEER Sonorheometry applies a series of ultrasound pulses to a whole blood sample held in the cartridge and processes the returning echoes to measure the stiffness of the blood sample during the processes of coagulation.

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3. Reagent Cartridge Overview

A. Cartridge Description

Each Quantra Cartridge consists of four independent tests performed in parallel with different sets of reagents in four separate test channels. SEER Sonorheometry measures the evolution of shear modulus (i.e., clot stiffness) in all four channels as a function of time.

Refer to the specific Quantra Cartridge Instructions for Use (IFU), for the intended use, reagents used, performance and detailed instructions for storage and handling.

B. Parameters Reported by the QPlus Cartridge

Clot times and clot stiffness values from the four tests of the QPlus Cartridge are combined to form six parameters that depict the functional status of the patient's coagulation system. The parameters are summarized in Table 2.

Table 2. Parameters Reported by the QPlus Cartridge of the Quantra Hemostasis System

Parameter	Units	Description	Measurement
Clot Time (CT)	seconds	Clot time in citrated whole blood	Clot time measured in Channel #1 with activator of the intrinsic pathway (kaolin)
Heparinase Clot Time (CTH)	seconds	Clot time in citrated whole blood with heparin neutralization	Clot time measured in Channel #2 with activator of the intrinsic pathway (kaolin) and heparinase.
Clot Time Ratio (CTR)	no units	Assessment of residual heparin anticoagulation	Calculated as the ratio of clot time values of Channel #1 over Channel #2
Clot Stiffness (CS)	hecto Pascals (hPa)	Stiffness of the whole blood clot	Clot stiffness measured in Channel #3 with an activator of the extrinsic pathway (thromboplastin) and heparin inhibitor (polybrene)
Fibrinogen Contribution to Clot Stiffness (FCS)	hecto Pascals (hPa)	Contribution of functional fibrinogen to overall clot stiffness	Clot stiffness measured from Channel #4 with an activator of the extrinsic pathway (thromboplastin) and heparin inhibitor (polybrene) and platelet inhibitor (abciximab)
Platelet Contribution to Clot Stiffness (PCS)	hecto Pascals (hPa)	Contribution of platelet activity to overall clot stiffness	Calculated by subtracting clot stiffness value of Channel #4 from Channel #3

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C. Parameters Reported by the QStat Cartridge

Clot times and clot stiffness values from the four tests of the QStat Cartridge are combined to form five parameters that depict the functional status of the patient's coagulation and clot dissolution system. The parameters are summarized in Table 3.

Table 3. Parameters Reported by the QStat Cartridge of the Quantra Hemostasis System

Parameter	Units	Description	Measurement
Clot Time (CT)	seconds	Clot time in citrated whole blood	Clot time measured in Channel #1 with activator of the intrinsic pathway (kaolin)
Clot Stability to Lysis (CSL)	Percent %	Reduction of clot stiffness that is likely due to the influence of fibrinolysis	Calculated by normalizing the rate of stiffness reduction in channel #3 with the corresponding change in clot stiffness in channel #2.
Clot Stiffness (CS)	hecto Pascals (hPa)	Stiffness of the whole blood clot	Clot stiffness measured in Channel #3 with an activator of the extrinsic pathway (thromboplastin) and heparin inhibitor (polybrene)
Fibrinogen Contribution to Clot Stiffness (FCS)	hecto Pascals (hPa)	Contribution of functional fibrinogen to overall clot stiffness	Clot stiffness measured from Channel #4 with an activator of the extrinsic pathway (thromboplastin) and heparin inhibitor (polybrene) and platelet inhibitor (abciximab)
Platelet Contribution to Clot Stiffness (PCS)	hecto Pascals (hPa)	Contribution of platelet activity to overall clot stiffness	Calculated by subtracting clot stiffness value of channel #4 from channel #3

4. Set up and Configuration

The Quantra Hemostasis Analyzer will be initially set up and configured by HemoSonics personnel. The analyzer will be placed with a minimum of 2.25 inches (5.5 cm) of clearance on all sides of the device and 1 inch (2.5 cm) on top. Please maintain that minimum spacing. Do not block the fan on the upper left back of the instrument.

The external barcode scanner can be mounted on either the right or left side of the instrument. (The barcode scanner can be replaced by unplugging the USB cord from the rear of the Quantra; plug in the USB cord of the replacement unit.) To read a barcode, press the button to activate the laser beam.

WARNING: Do not place the instrument where direct sunlight or bright light might project into the cartridge shutter area during operation. This may result in an instrument failure or test error.

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5. Start-up and Shut Down

A. Start-Up

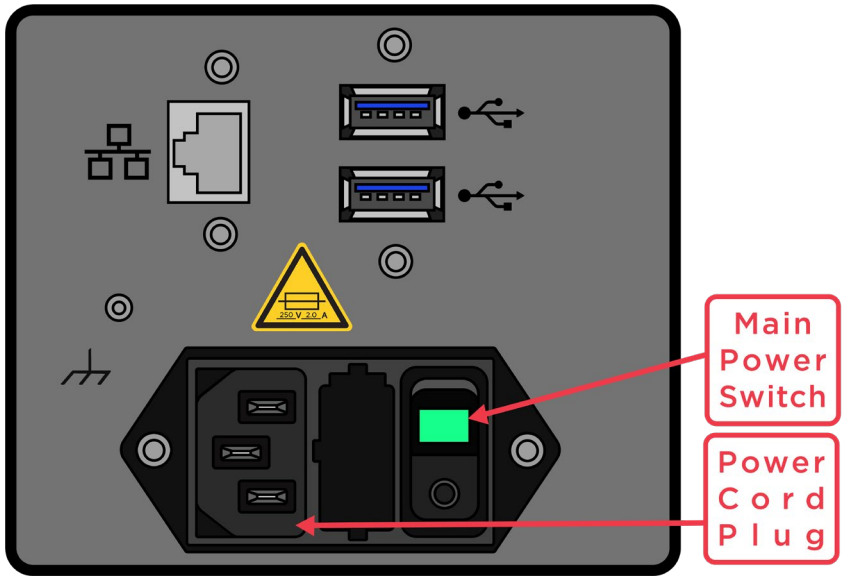

Figure 4. Main Power Switch

To start the instrument, follow these steps:

1. Plug the Main Power Cord into the instrument and an electrical outlet (Figure 4).
2. Turn on Main Power Switch located on back of instrument. An indicator on the switch lights when the power is on (Figure 4).
3. Level the Quantra Analyzer. The Quantra Analyzer must sit on a level surface to function properly. Moving the Quantra Analyzer might unlevel the instrument. It is equipped with a bubble leveling system located on the right side of the instrument. Use the bubble to ensure that the instrument is always level when used. **Note: check leveling each time the Quantra Analyzer is moved.**
4. To level the Quantra Analyzer:
    a. The instrument is level when the bubble is centered between the two lines on the bubble tube (Figure 5).

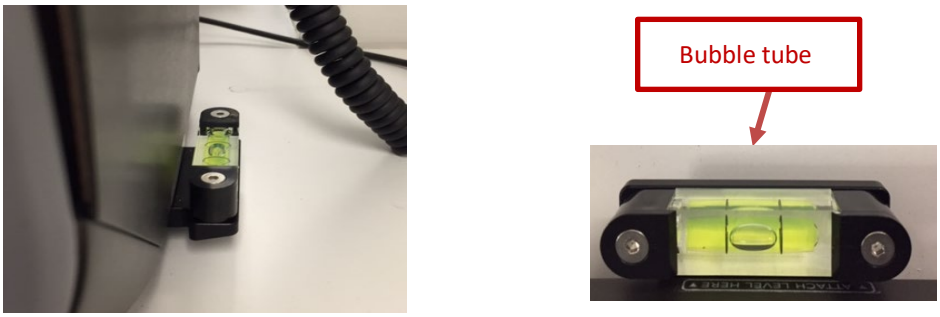

Figure 5. Quantra Analyzer Bubble Level.

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b. To center the bubble, rotate the two leveling screws located at the bottom front of the instrument. Rotate these screws the same amount in opposite directions at the same rate. This prevents the screws from becoming too tight or too loose.

5. Start the instrument by pressing the CPU Power Button located on the front of the instrument (Figure 6). The CPU Power Button will remain illuminated while the instrument is powered on. The system will indicate that it is initializing while it performs internal QC (Figure 7).



Figure 6. CPU Power Button



Figure 7. Quantra Initializing Screen

B. Shut Down

The Quantra Analyzer may remain on in between sample testing and during periods of inactivity. In the event of an Instrument Error and/or before moving the Quantra Analyzer, it should be shut down.

1. Press the CPU Power Button located on the front of the instrument.
2. When the CPU Power Button LED turns off, turn off the Main Power Switch located on the back of the instrument.
3. If relocating the instrument, remove the power cord from the outlet receptacle.

C. Quality Control

1. The Quantra System performs Internal Quality Control during powering on (initialization), after eight hours of inactivity, and while the test is running (see Internal QC).
2. There is also user performed External QC, which is described later in this manual (External Quality Control [QC]).

6. Components of the User Screen

To interface with the Quantra System, the user initiates actions by way the touch screen. Information provided during a test is displayed in the upper task bar (Figure 8), while in progress. The evolving numbers and final results are shown in the main body of the screen.



Figure 8. Upper Taskbar

A. Buttons

There are buttons on the upper taskbar and left sidebar for the user to navigate the Quantra System application.

1. Upper taskbar (Figure 8)
    a. **Run** – select to run a patient test or external Quality Control.
    b. **History** - select to retrieve tests whose results are stored on the instrument.
    c. **Admin** – select to configure the Quantra System. (Tab appears only after an administrator is configured.)
    d. **New** [Test].-.is displayed when a test is not being run
    e. **Cancel Button** – is displayed when a test is being run.
    f. **Print icon** – to print or download test results to USB drive.
    g. **New** – is displayed when a test has completed. Select to begin a new test.
    h. **Lock Screen** – Padlock icon – select to logout and block displaying results.
2. Left sidebar
    a. Dials – select to display the Dials View of results.
    b. Curves – select to display the Curves View of results.

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c. Trends 1 or Trends 2 – select to display numeric results of tests run during the past 48 hours for the patient test selected. Trends 1 displays Clot Stiffness parameters and Trends 2 displays clot time parameters.

B. Information Displayed on the Upper Taskbar (Figure 8)

a. PTID – Patient ID
b. Start – time in which the current test was started (hh:mm a.m. or p.m.).
c. Elapsed – time elapsed from when the blood first mixes with reagents (hh:mm).
d. Status –status of the current test run (In progress, Complete).
e. User –User ID (to the right of the lock icon).
f. Time – current time (hh:mm a.m. or p.m.).
g. Cartridge - cartridge usability time shown in the upper taskbar after a cartridge ID is entered (mm:ss). This timer signifies the period from the time the cartridge is removed from the moisture-proof pouch and the Cartridge ID is entered to the time when the "Start" button is clicked. If the test is not started before the usability period ends, the cartridge is ejected and is unusable. The user should remove the cartridge and dispose of it. The instrument will not allow the test to continue. The user must press the New button on the upper taskbar to begin a new test. **Note:** the user is responsible for disposing of the cartridge.

7. Running a Test

IMPORTANT: Please ensure that the Quantra Analyzer is turned on approximately 15 minutes before use to allow heaters to reach the proper operating temperature. The Quantra Analyzer will display "System Initializing" until the instrument has reached operating temperature and will accept a cartridge.

A. Cartridge preparation

Cartridges are sealed in moisture proof pouches. Refer to the Cartridge Instructions for Use, for the intended use, reagents used, performance and detailed instructions for storage and handling.

B. Log In

1. Scan or type in the User ID to initialize the instrument (Figure 9). If typing in the User ID or password (if required), press "Continue".

NOTE: Password are shown on the screen as "*". To show what is typed, select the eyeball icon to the right of the field to display.

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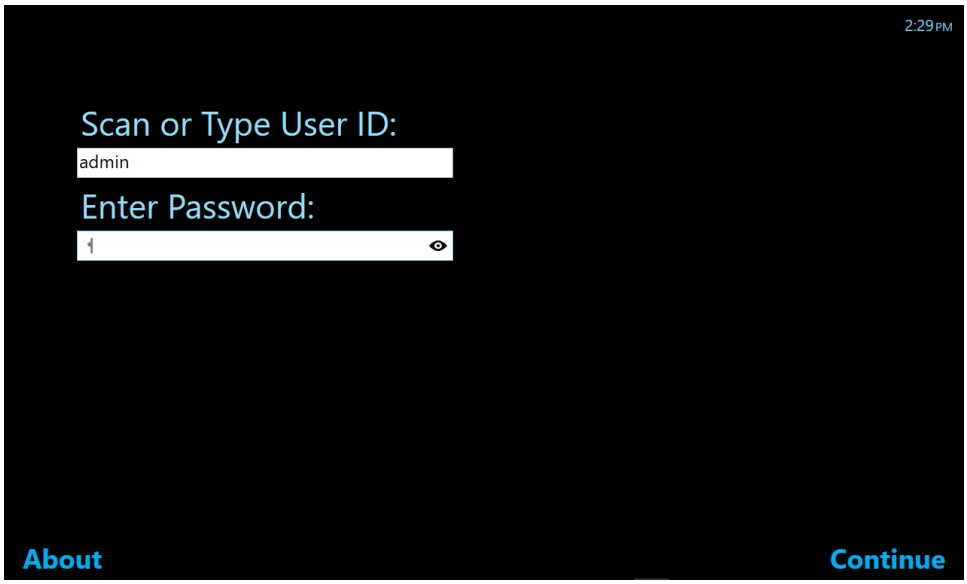

Figure 9. Enter User ID Screen

2. The device will display “Please Wait, System Initializing…” while the sample heating element is warming (Figure 10). The initial start-up of the instrument may take up to 15 minutes. There is negligible wait time when the system is already warm.

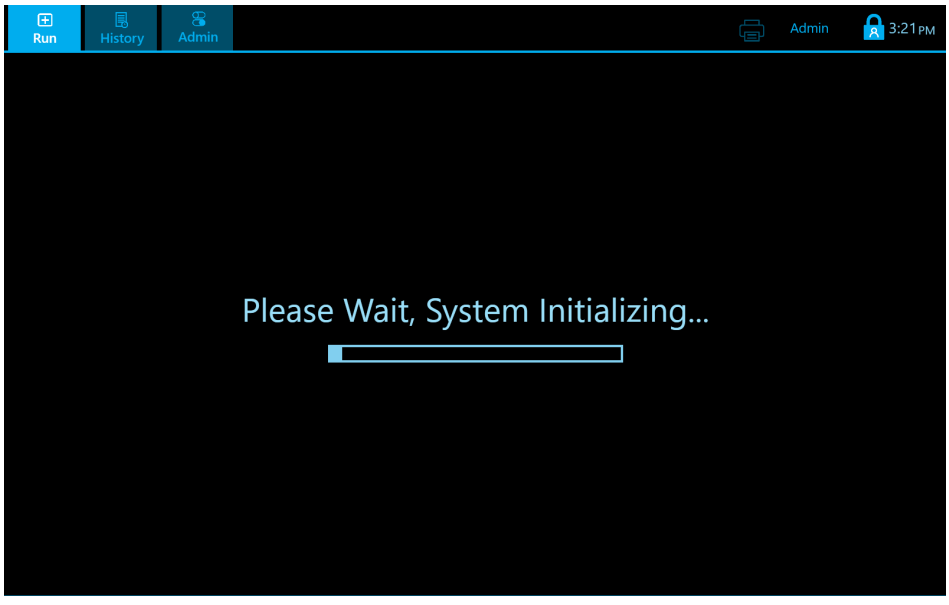

Figure 10. System Initializing Screen

C. Running a Test

NOTE: Do not begin the steps below until a blood sample or Quality Control material is ready to be loaded on the cartridge and analyzed.

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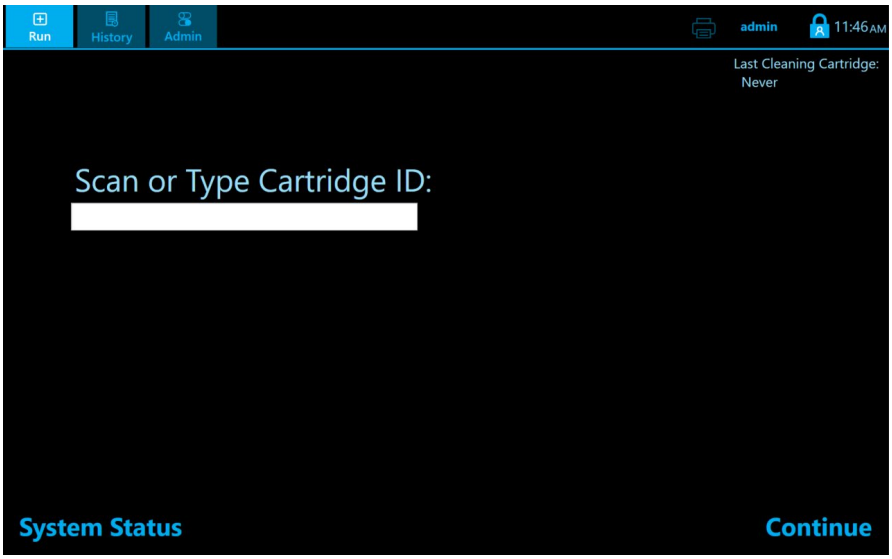

Figure 11. Enter Cartridge ID Screen

1. Scan or type in the Cartridge ID on the label affixed to the cartridge (Figure 11) If typed, transcribe the digits under the barcode on the cartridge label and press “Continue”.
2. Select and confirm a Profile from the list of enabled site-specific profiles on which the test will run. (Figure 12).

IMPORTANT: The Profile Selection screen (Figure 12) displays all enabled profiles for the selected cartridge type (QPlus or QStat). If more than one profile is enabled, you will be asked to select from the list. If only one profile is enabled, the system will not prompt you to choose a profile. In this case, the analyzer will automatically apply the range values from the enabled profile(Standard or Site Specific), skip the Profile Selection screen, and proceed directly to the screen shown in Figure 13.

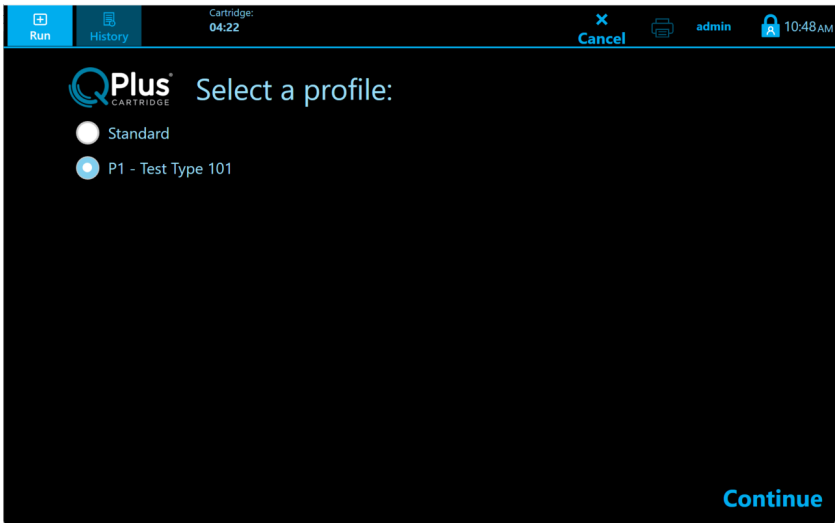

Figure 12 Select Profile Screen

3. Remove the cartridge from the airtight pouch immediately before use. Do not allow the cartridge to sit outside its airtight pouch for longer than 15 minutes.

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4. Visually inspect the cartridge before use. If the cartridge appears to be damaged in any way, do not use.

IMPORTANT : Open the cartridge pouch and use the cartridge immediately. Once the cartridge ID is scanned or typed, the instrument will begin a 15-minute safety timer. The test must be started within this 15-minute window or the instrument will automatically abort the test and require a new cartridge. If the cartridge is removed from its moisture-proof pouch or the pouch is opened for longer than 15 minutes, dispose of the cartridge.

5. When prompted, insert the cartridge into the instrument. Hold the cartridge on the end with the evacuated sample tube attachment. Insert the cartridge until resistance is felt, then gently push the cartridge until it clicks into place (Figure 13). The analyzer will position the cartridge slightly to the right and the shutter will close. The cartridge is now ready for the sample to be attached.

Note: Additionally, when a Site Specifc Profile is selected, the Profile name and cartridge type are displayed on the Insert Cartridge Screen, Confirmation Screen, footer of a test that is in progress, history screen footer, print preview, and printed reports.

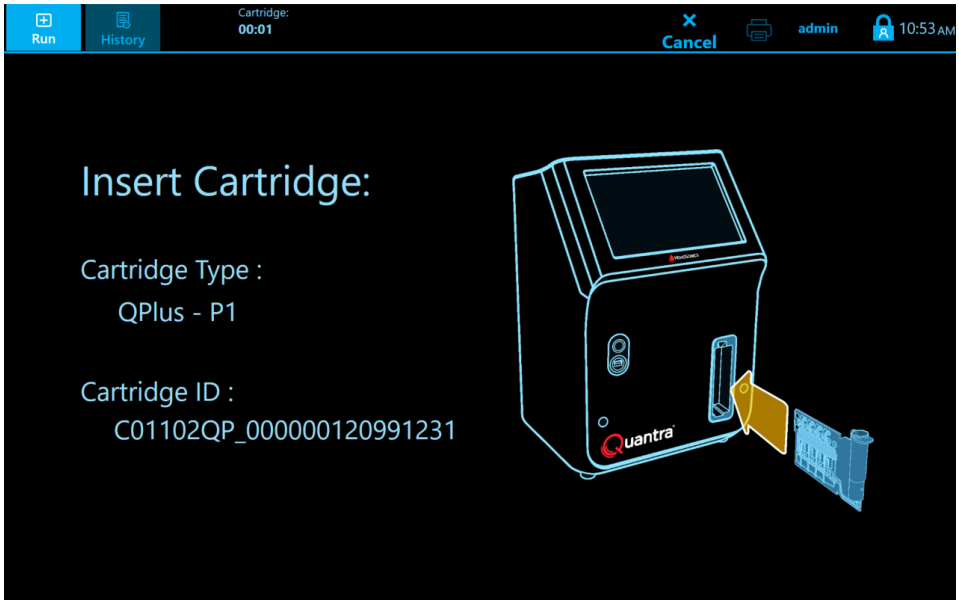

Figure 13. Insert Cartridge Screen

NOTE: There are three ways to run a test:

- Positive Patient ID (PPID) with POCT is enabled.
- Positive Patient ID (PPID) with LIS is enabled.
- Positive Patient ID (PPID) is not enabled.

Positive Patient ID (PPID) with POCT is enabled

1. The Scan or Type Patient ID screen displays. Scan or type in the Patient ID. If typed, follow by pressing “Continue” (Figure 14).

NOTE: If the patient barcode does not scan properly, an error message will appear. Continue by typing in the Patient ID on the touchscreen.

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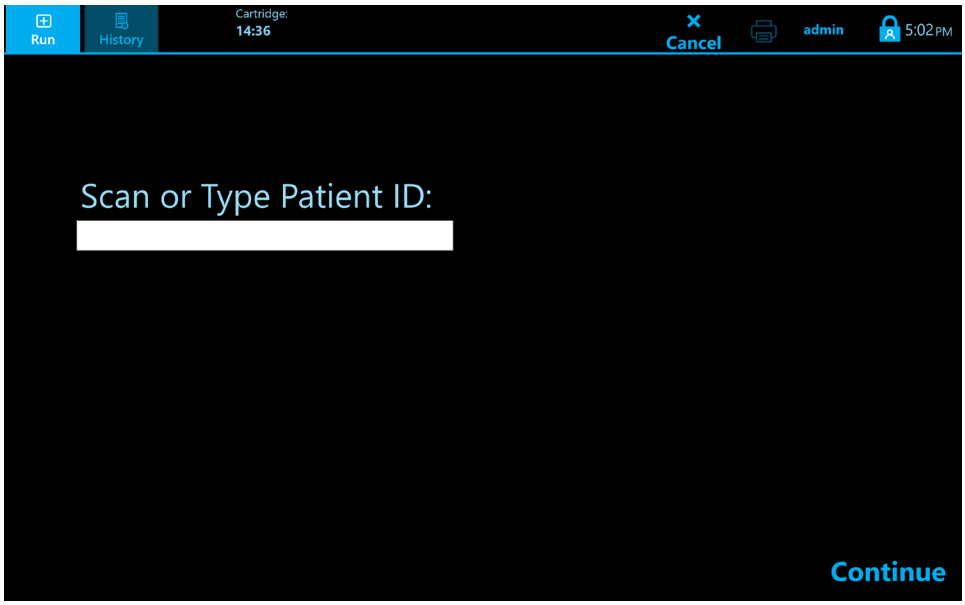

Figure 14. Enter Patient ID Screen

2. Confirm that the Cartridge Type and Patient ID are correct in the next screen.
    a. If Positive Patient ID (PPID) with POCT is enabled, the additional PPID is displayed in the lower half of the Confirm screen (Figure 15).
        i. If the PPID is incorrect, click the “Clear” button to clear the PPID info and continue without the PPID.
        ii. Otherwise, click the “Accept” button.
        iii. Either action displays the Edit Patient ID screen (Figure 16) with or without the PPID. If the information is correct, press “Confirm”. The Patient ID (PTID) will be displayed in the upper taskbar. If the information is incorrect, press “Edit”. This returns to the “Scan or Type Patient ID” window to input the correct information.

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Figure 15. Confirm Cartridge Type and Patient Name



Figure 16. Edit Patient ID Screen

Positive Patient ID (PPID) with LIS is enabled

1. There are three conditions of LIS:
    a. Pending order
    b. Not pending Order
    c. Order Not Found

Pending order

1. If Positive Patient ID (PPID) with LIS is enabled, The Scan or Type Container ID screen displays. Scan or type in the Container ID. If typed, follow by pressing “Continue” (Figure 17).

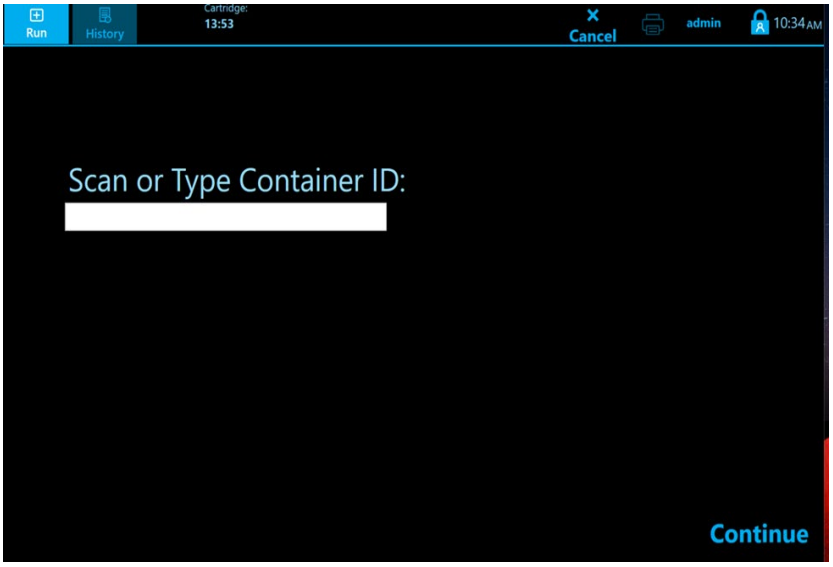

Figure 17. Enter Container ID Screen

2. Click “Accept” to confirm the Cartridge Type and Container ID (Figure 18).

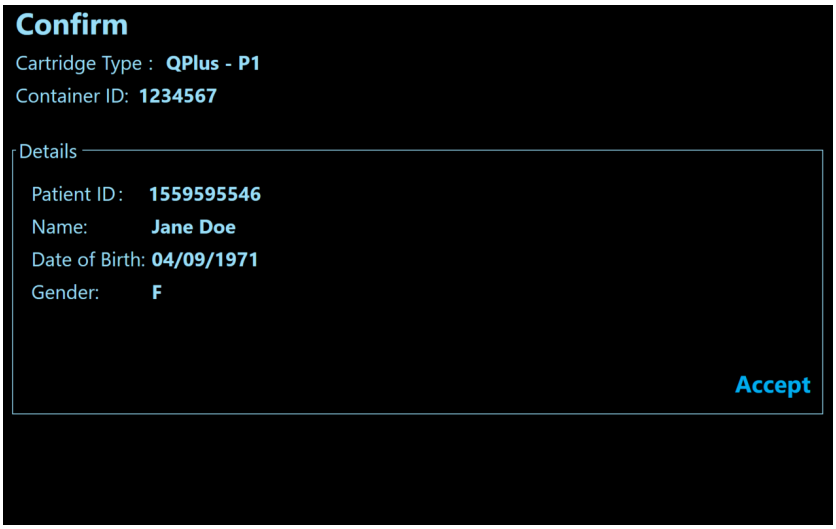

Figure 18. The Test Confirmation Screen

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3. The screen will display the Edit Container ID screen (Figure 19) If the information is correct, press “Confirm”. If the information is incorrect, press “Edit”. This returns the user to the “Scan or Type Container ID” window to input the correct information.



Figure 19. Edit the Test Confirmation Screen

Not Pending Order

1. If Positive Patient ID (PPID) with LIS is enabled and if the Scanned order does not match the ordered cartridge type, the following screen displays(Figure 20).

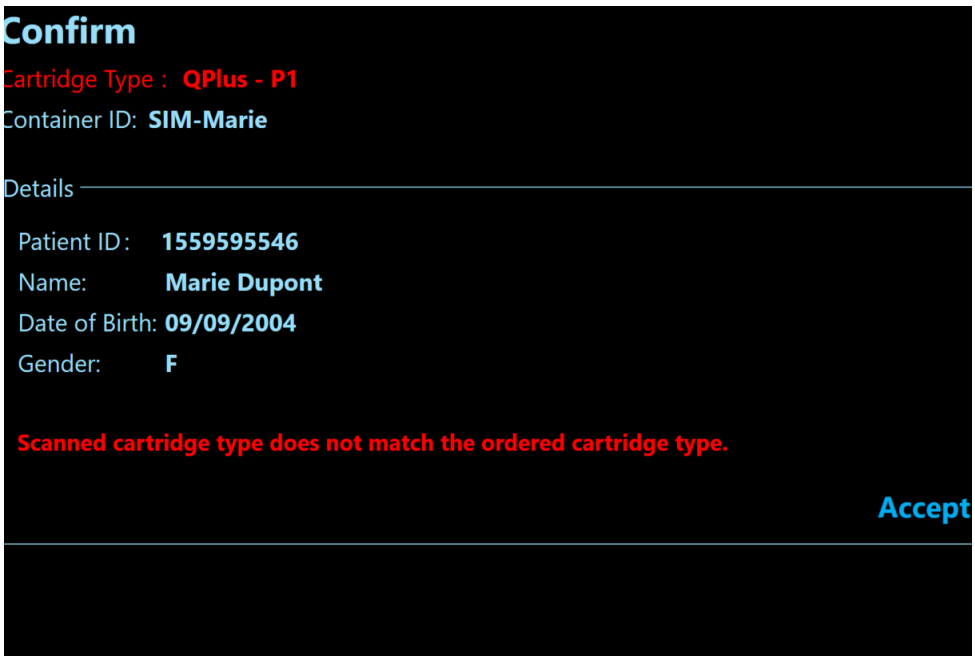

Figure 20. Order Not Pending Screen

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2. To Correct or Continue with this cartridge type, click Accept. The following screen display (Figure21)



Figure21. Incorrect Cartridge Type Screen

3. Press “Edit” to return to the “Scan or Type Container ID” window, or Press “Confirm” to Continue.

Order Not Found

4. If the scanned or typed Container ID doesn’t match the LIS system, the following screen displays. (Figure 22). Add the correct Patient ID and press “Accept”.

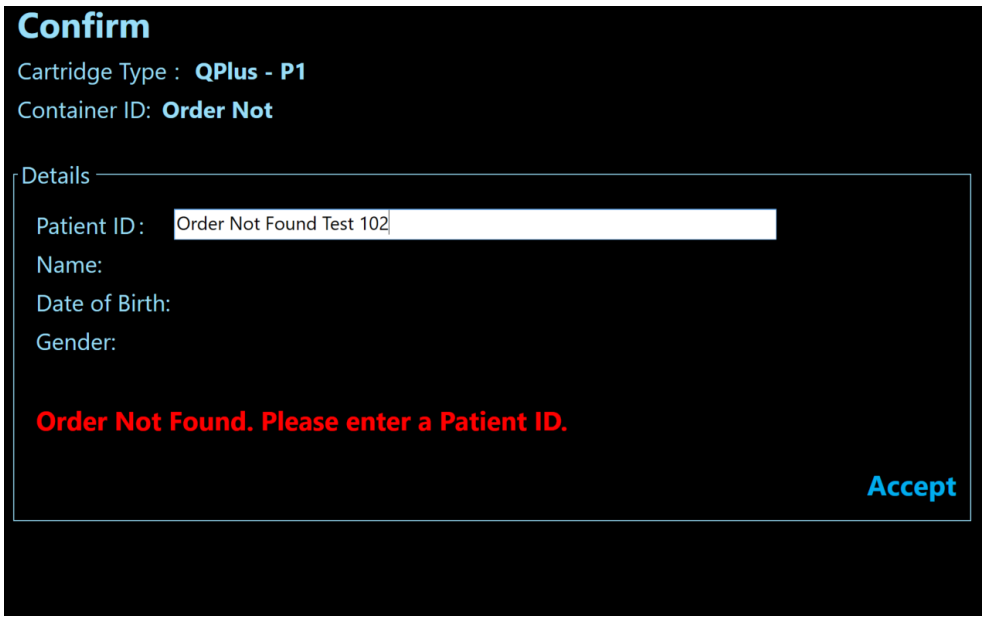

Figure 22. Order Not Found Screen

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Positive Patient ID (PPID) is not enabled

5. If Positive Patient ID (PPID) is not enabled, only the Cartridge Type and Patient ID is shown. If the information is correct, press “Confirm”. The Patient ID (PTID) will be displayed below the Cartridge Type (Figure 23). If the information is incorrect, press “Edit”. This returns the user to the “Scan or Type Patient ID” window to input the correct information.

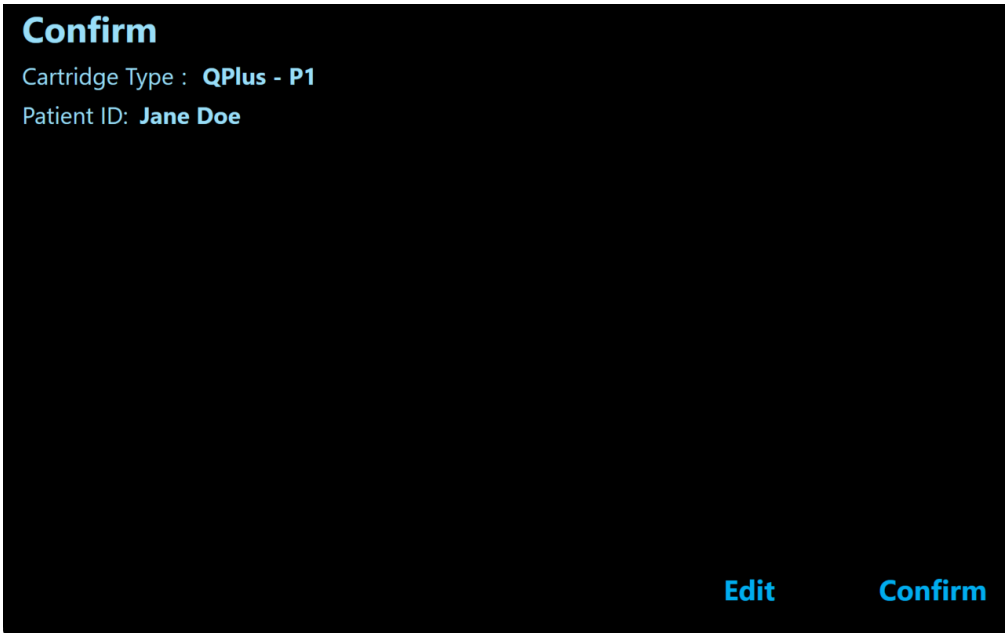

Figure 23. Test Confirmation Screen

6. Before loading a whole blood sample on the cartridge, make sure that the blood collection tube is filled to the minimum fill line. Gently invert the tube 5 or more times and when prompted, attach the tube containing the whole blood sample to the cartridge. Ensure the tube is pushed all the way down into the container safety guard to ensure the rubber cap is completely punctured. If the tube cap is removed and then replaced, the cap must be vented with a needle before running. Press “Start” to initiate the test. If running an external quality control, follow the preparation steps on the respective product Instructions for Use (such as QPlus Controls, QStat Controls, etc.) and follow the onscreen prompts for HemoSonics Quality Control (Figure 24):

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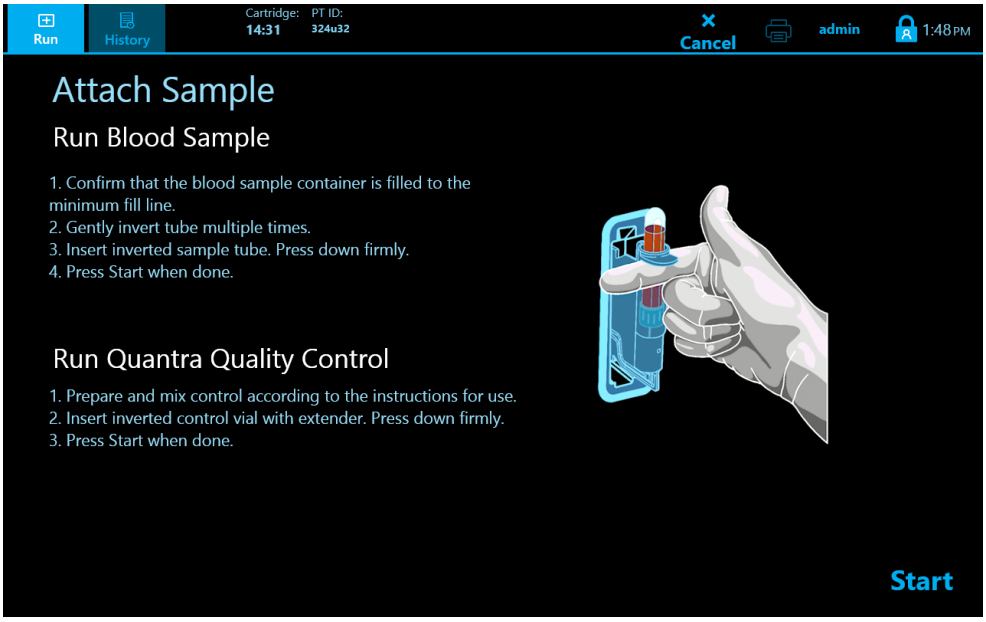

Figure 24. Attach Sample Instruction Screen

7. The screen will display the steps that occur before data acquisition. 1) Preparing Cartridge; 2) Mixing reagents and 3) Preparing Sample (Figure 25). The upper taskbar will show 1) the Patient ID (PTID), the test status ("In Progress"), the time the "Start" button was pressed ("Start hh:mm") and the Elapsed time (Elapsed: mm:ss), which is the time from when the blood mixes with the reagents until the test is completed.

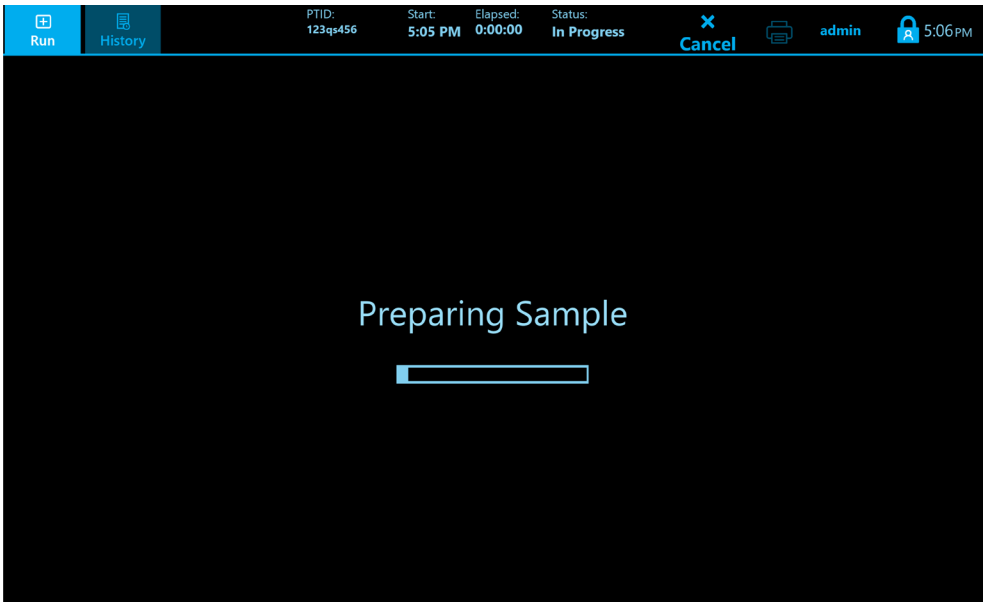

Figure 25. Sample Preparation Screen

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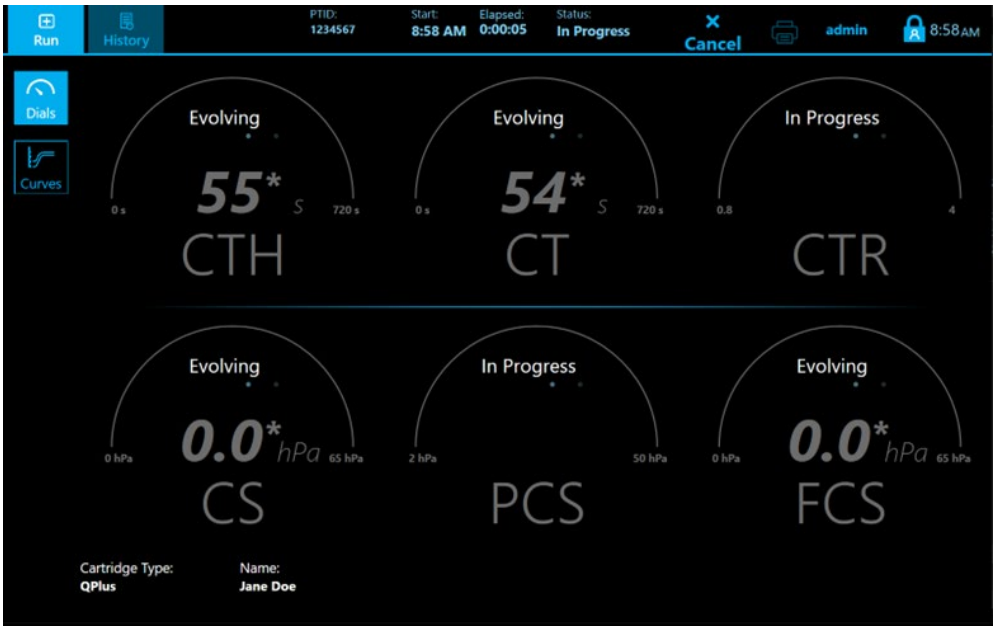
QPlus Cartridge Results View Description

1. Once sample analysis begins, the dial display format shows the dials for the parameters reported by the Quantra System specific to the cartridge being used. **NOTE:** The cartridge type is displayed on the lower left of the results screens. Figures 26-30 show the test parameters for the QPlus Cartridge:
   - CTH: Heparinase Clot Time
   - CT: Clot Time
   - CTR: Clot Time Ratio
   - CS: Clot Stiffness
   - PCS: Platelet Contribution to Clot Stiffness
   - FCS: Fibrinogen Contribution to Clot Stiffness

For the QStat Cartridge figures, see the section below with Figures 31-32.

2. While the test run starts and is proceeding, the dial display appears gray, and the dials are labeled "In Progress". When a number is displayed in the dial, the label changes from "In Progress" to "Evolving" for CTH, CT, CS, and FCS (Figure 26) until the results are displayed. The calculated results (CTR and PCS) are "In Progress" until the assay is completed. Dials shown are for the QPlus Cartridge.



Dials View: Results in progress

Figure 26. QPlus In Progress Screen

3. The dials are displayed in color when the results are available. The Reportable Range is indicated by the values displayed at each end of the dial's semi-circle. On the semi-circle dial, the Reference Range is shown in green except for CTR which has no Reference Range.

Figure 27 displays QPlus results that are within the Reference Range (white triangles on the green portion of the dials) for each parameter.

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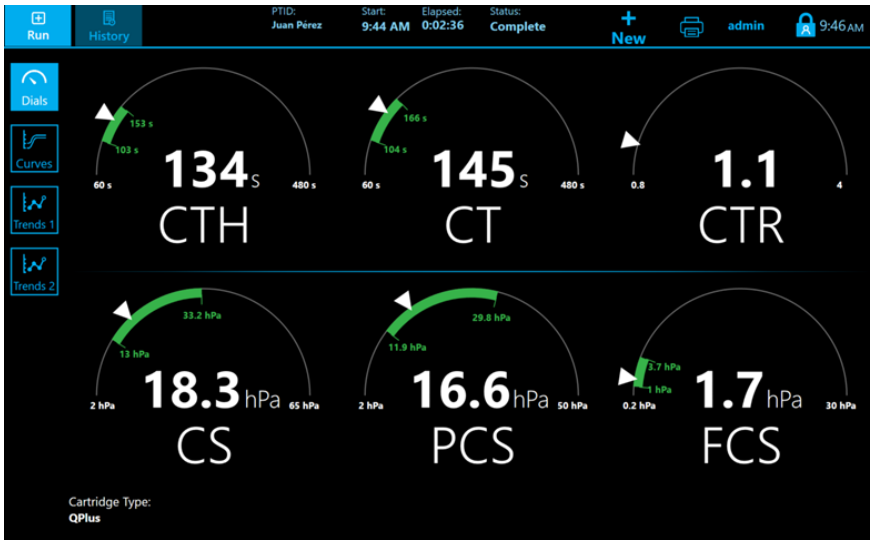

Figure 27. Dials Screen – QPlus Final Results

In Figure 28 an exclamation mark within a yellow circle signifies a result that is outside the Reference Range, but within the Reportable Range. A result that has an exclamation mark within an orange triangle signifies that the result is outside the Reportable Range, there is a problem with the run, or the result cannot be determined from the sample. An exclamation mark within a red octagon indicates that a test error occurred during the processing of the test on that cartridge's channel. Dials shown are for the QPlus cartridge.

In addition to numerical values, the Quantra outputs non-numerical values for output parameters. Certain non-numerical test results are expected from samples with specific characteristics, whereas other non-numerical test results may indicate an issue with a cartridge or the instrument. Table 4 provides a listing of the non-numerical test results that may be reported by the Quantra System.

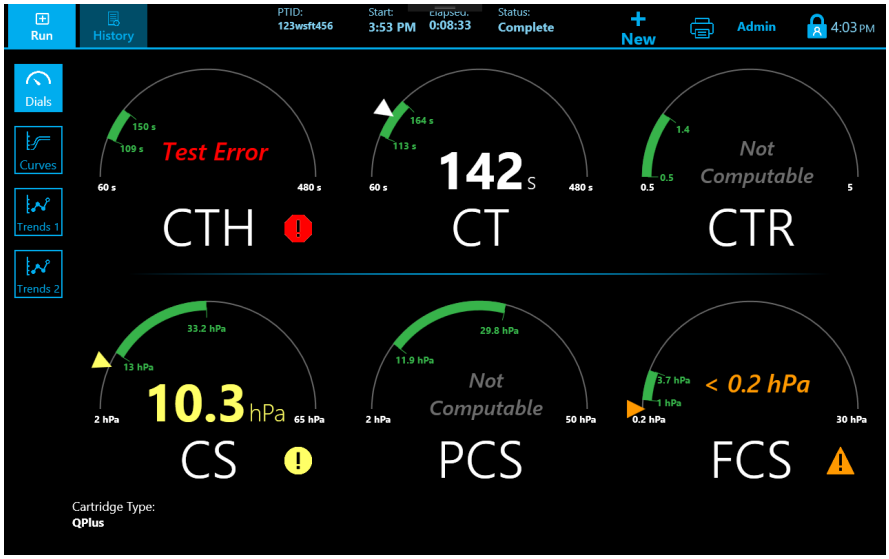

Figure 28. Dials Screen – QPlus Error Results

Table 4. Non-numerical Test Results Reported by the Quantra Analyzer System

Non-numerical Test Result	Description	Comment	Action Required	Colored Symbol
"Not Computable"	Displayed in the following situations: 1) For CTR and PCS, when data is missing for one or both components used to calculate the parameter. 2) When the clot initiation plus the time required to calculate clot stiffness (7 min) exceeds the maximum measurement period 3) For the QStat cartridge parameter CSL, when a clot does not form in either channel 2 or 3, or if after the maximum ultrasound sampling time no numeric result is computable.	In the case of 2), this behavior is observed with certain samples that form very weak clots or form clots very slowly. CS, FCS and PCS are not computed. Result is reflective of sample properties, not of an instrument/ cartridge issue. In the case of 3) if after the max sampling time the clot stiffness has not reached a peak, CSL cannot be computed.	None; Because result is due to sample properties and not the System, running a fresh sample on a new cartridge will give same result	None
"Test Stopped"	Displayed when the user cancels the test run and the test is not completed for the CSL parameter.	For software version 1.7.xx and onward, applies only to the QStat cartridge.	None.	None
"No Clot Detected"	Displayed when a cartridge ran successfully to completion, but a clot did not form in one of the channels within the assay measurement period.	Result is expected for CT for samples taken during cardiac bypass. Result is reflective of low coagulation function	None; Result is reflective of low coagulation function	
">Maximum reportable #"	Displayed when a cartridge ran successfully to completion and a clot was detected but result is above the reportable range for a given parameter.	>max reportable for CT and CTH reflects low coagulation function. >max reportable for CS, FCS, PCS reflects high coagulation function	Use result; Result is reflective of low or high coagulation function (see comments)	
"<Minimum reportable #"	Displayed when a cartridge ran successfully to completion and a clot was detected but a result is below the reportable range for a given parameter.	<min reportable for CT and CTH reflects high coagulation function. <min reportable for CS, FCS, PCS reflects low coagulation function	Use result; Result is reflective of low or high coagulation function (see comments)	
"Test Error"	Displayed under the following conditions: 1) Cartridge or instrument error 2) Software identified an error in the relationship between parameters (e.g., FCS>CS). 3) Software quality checks identified an abnormal shear modulus curve and clot parameters could not be determined. 4) Clot formed before data acquisition began	These are potential instrument or cartridge failures	Repeat run with fresh sample on new cartridge	

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4. Test results are also viewable as a coagulation curve showing the development of a clot over time via the Curves View (Figure 29). Using the buttons on the left sidebar, a User can toggle between the Dials View and the Curves View as the test progresses or after the test is completed. For the Curves View, final results are displayed in the right sidebar once they are available (Figure 30). The user has the option of changing the y-axis scale on the curve screens. The default upper limit is 65 hPa. Clicking on the 65 in the circle on the y-axis will change the upper limit of the y-axis to 30 hPa. Curves shown are for the QPlus Cartridge.

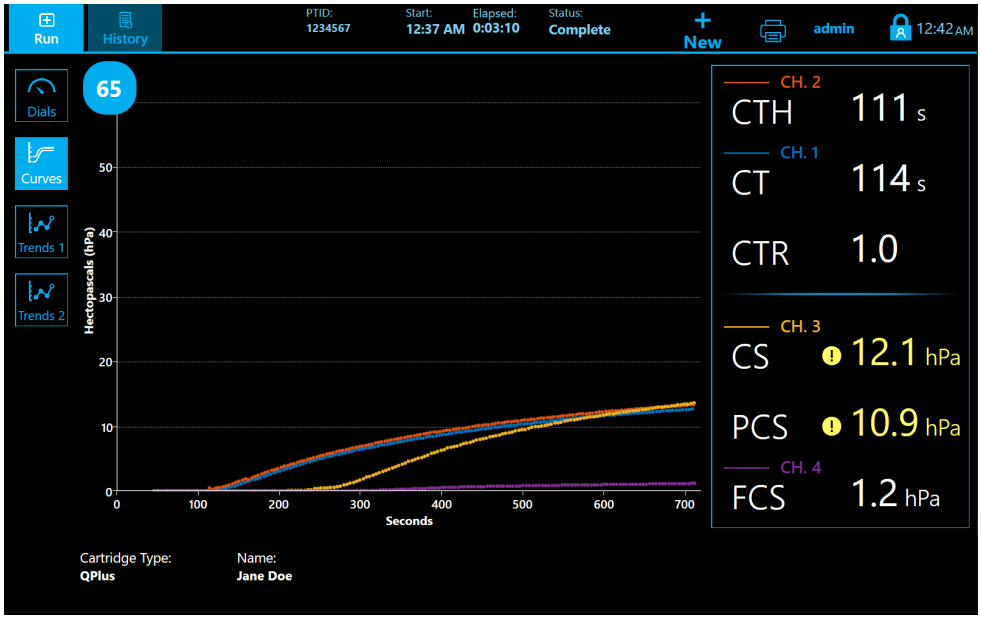

Figure 29. Curves View – QPlus Final Results

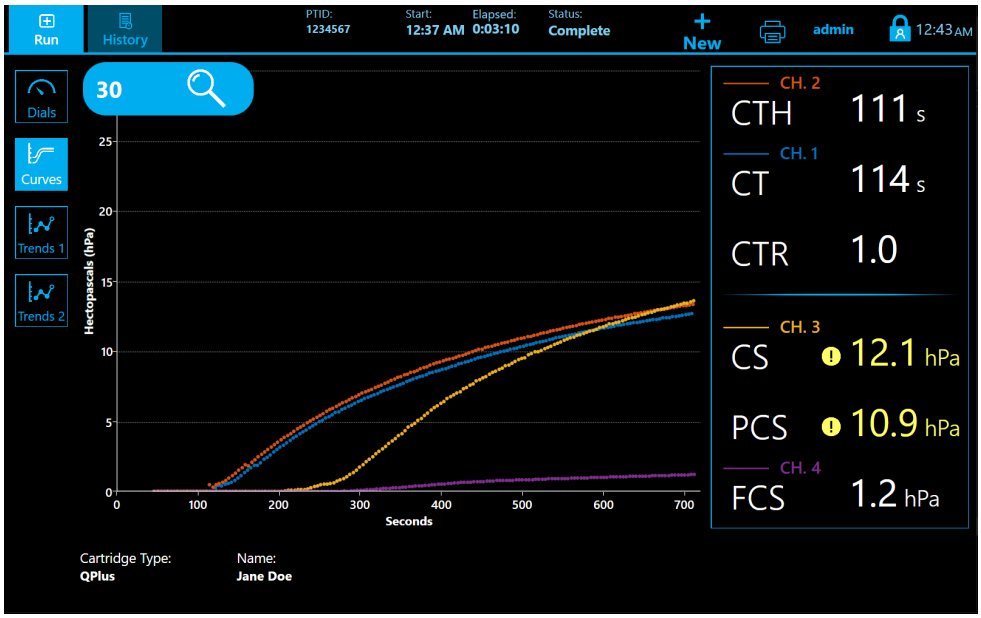

Figure 30. Curves View – QPlus Final Results Zoomed In

5. Once the test is completed:

a. The cartridge is partially ejected, and a message is displayed to remove the cartridge. Click “OK” to dismiss the message.
b. To remove the cartridge, slide it out and place the used cartridge in a biohazard sharps container.
c. Press “New” to run another sample.

6. Also, when the test completes, the “Trends1” and “Trends2” buttons are displayed on the left sidebar. The Trends Screens display the results of the current test and up to five tests performed using this patient ID (PTID) over the previous 48 hours (the tests must be performed on the same Quantra Analyzer).

a. Trends 1 – displays the clot stiffness parameters (CS, PCS, FCS)
b. Trends 2 – displays the clot time parameters (CTH, CT)

Trends are described in detail in the section Trends History Screen.

QStat Cartridge Results View Description

Figure 31 displays QStat Cartridge results below. The results for CSL, CS, PCS, and FCS are within their respective reference ranges and depicted with white triangles on the green portion of the dials (Reference Range). The QStat Cartridge differs from QPlus in that there are no CTH or CTR values, but it reports CSL (Clot Stability to Lysis).

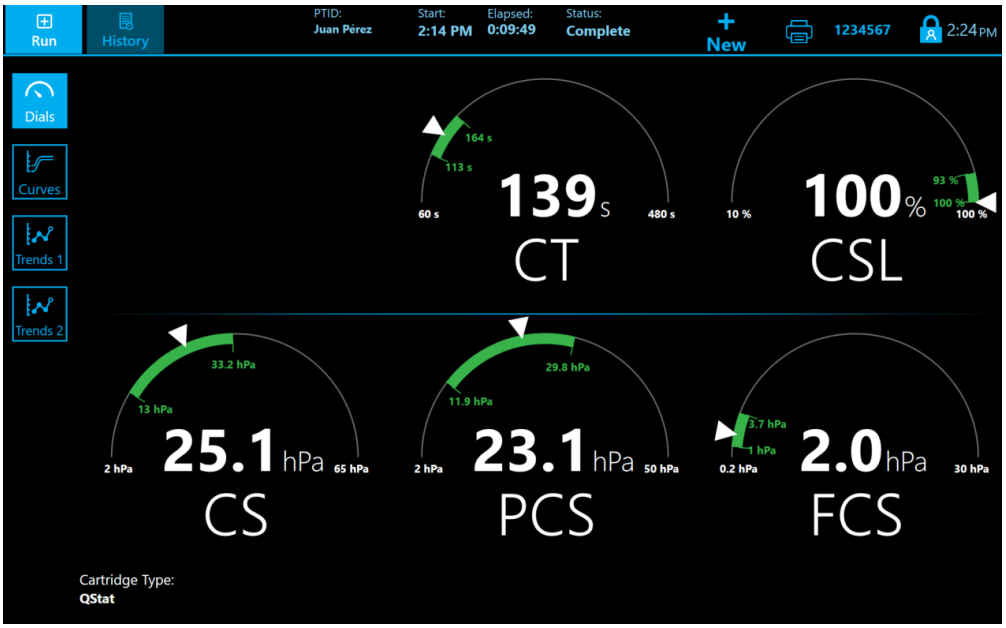

Figure 31 Dials View - QStat Final Results

As with the QPlus Cartridge, test results can be viewed as a coagulation curve via the Curves View (Figure 32). Using the buttons on the left sidebar, a User can toggle between the Dials View and the Curves View as the test progresses or after the test is completed. For the Curves View, final results are displayed in the right sidebar once they are available. The channel numbers (CH #) associates the parameters with the curve(s) displayed. Curves shown are for the QStat Cartridge.

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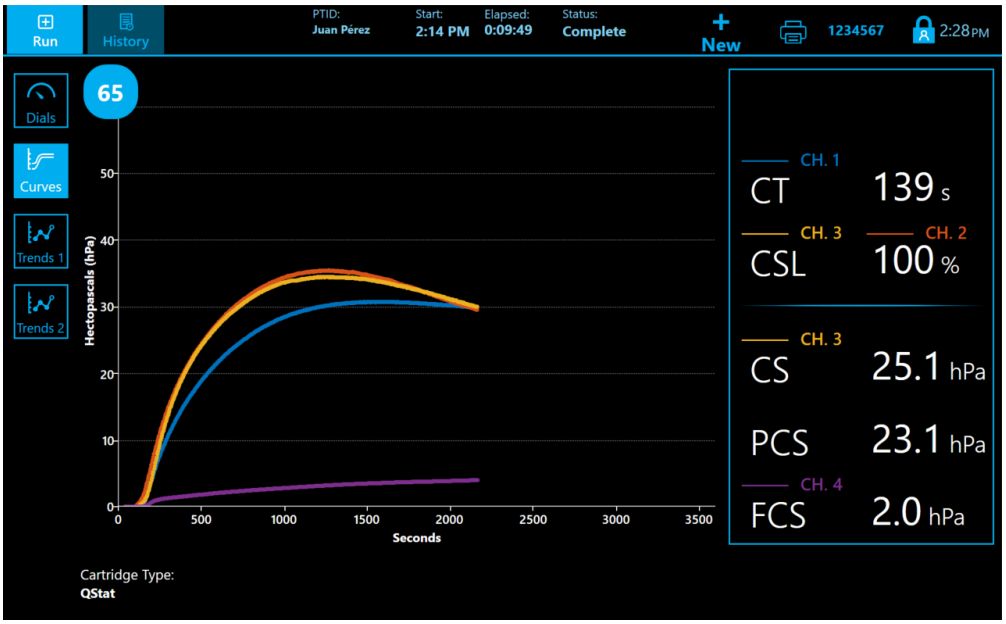

Figure 32. Curves View - QStat Final Result

Trends are described in detail in the section Trends History Screen.

D. Understanding the Dials Display

The Quantra System Dials Display conveys the numerical and non-numerical results in the center of each individual dial at the end of the test:

1. The Reportable Range for a given parameter is indicated in white numbers on the right and left of the dial.
2. The normal Reference Range for a given parameter is displayed as a bold green line on the dial.
3. Colored symbols located on the right side of a dial indicate either test results that do not fall within the Reference, Reportable Range or a test error.

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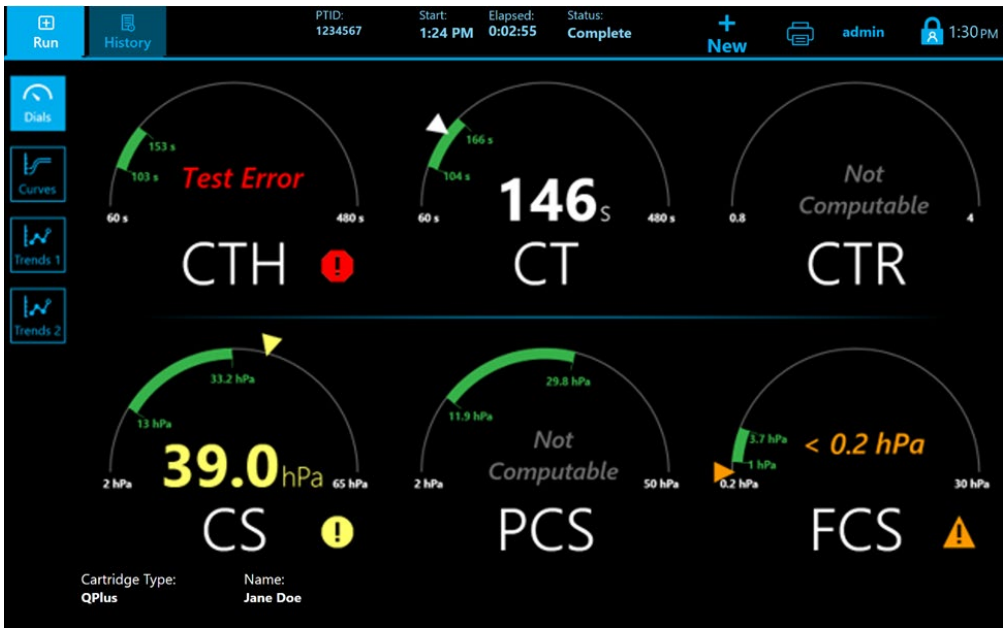

Figure 33. Dials Screen - Final Results

The following represents potential scenarios displayed on the Dials Display of the Quantra System along with suggested interpretations:

- If the result displayed for CT and/or CTH is above the upper end of the Reference Range (prolonged clot times), it may suggest a possible hypocoagulable condition.
- If the result displayed for CT and/or CTH is below the lower end of the Reference Range (shortened clot times), it may suggest a possible hypercoagulable condition.
- If a result displayed for CS, PCS or FCS is above the upper end of the Reference Range (high clot stiffness), it may suggest a possible hypercoagulable condition.
- If a result displayed for CS, PCS or FCS is below the lower end of the Reference Range (low clot stiffness), it may suggest a possible hypocoagulable condition.
- If the result displayed for CTR is greater than 1.4, it may suggest the presence of residual heparin in the sample.
- If the result displayed for CTR is less than 1.4, it may suggest that residual heparin is not present in the sample.

Identifying the influence of heparin in a sample

- In the case that CT is prolonged (above the upper end of the Reference Range) but CTH is within the Reference Range resulting in a CTR that is greater than 1.4, suggests the possible influence of heparin in sample (example shown in Figure 34).

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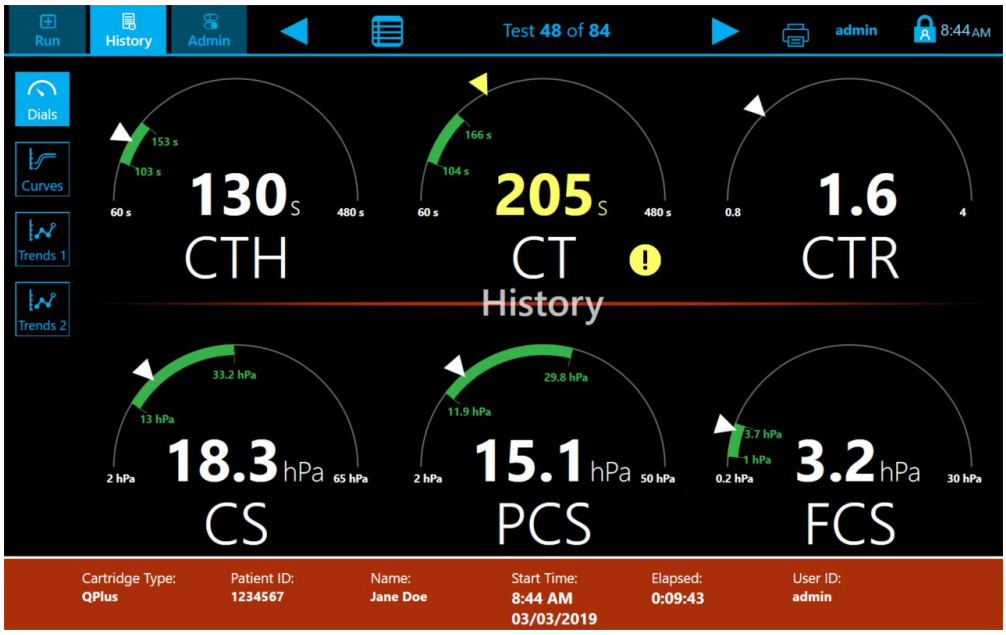

Figure 34. Case #1

- In the case that both CTH and CT are similarly prolonged (above the upper end of the Reference Range) but CTR is less than 1.4, suggests a possible hypocoagulable condition not due to the influence of heparin (example shown in Figure35).

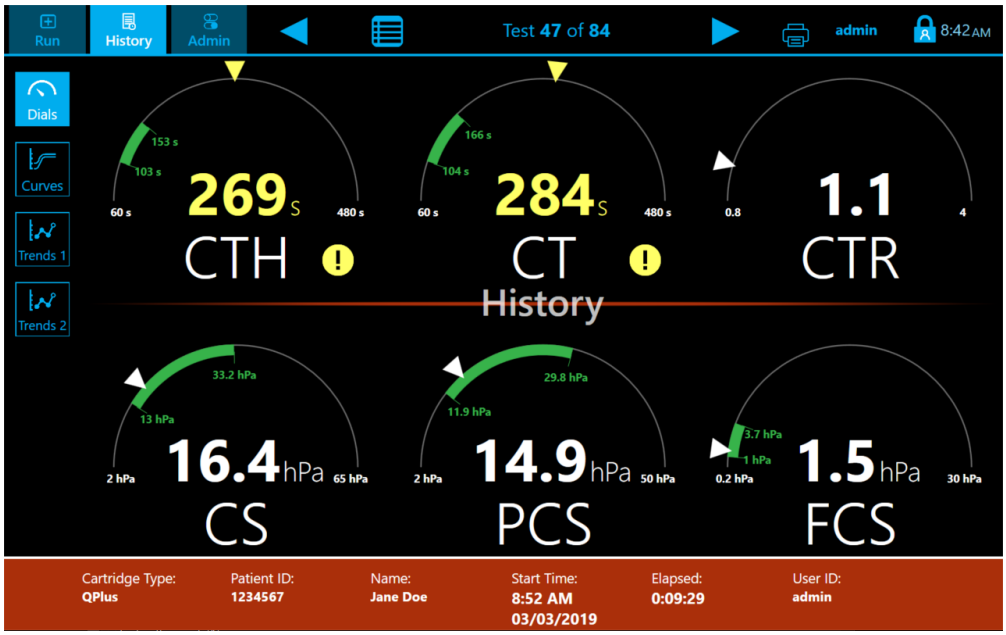

Figure 35. Case #2

- In the case of a sample taken from a patient undergoing cardiopulmonary bypass surgery. Due to heparin anticoagulation during bypass, a clot will not be detected in the channel in

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the cartridge that measures CT during the assay measurement period. This leads to a result of “No Clot Detected” for CT. A Clot Time was measurable in the presence of a heparin inhibitor therefore, a numerical value was reported for CTH. Because the calculation of CTR requires numerical values for both CT and CTH, CTR is “Not Computable” for this sample (Figure 36).

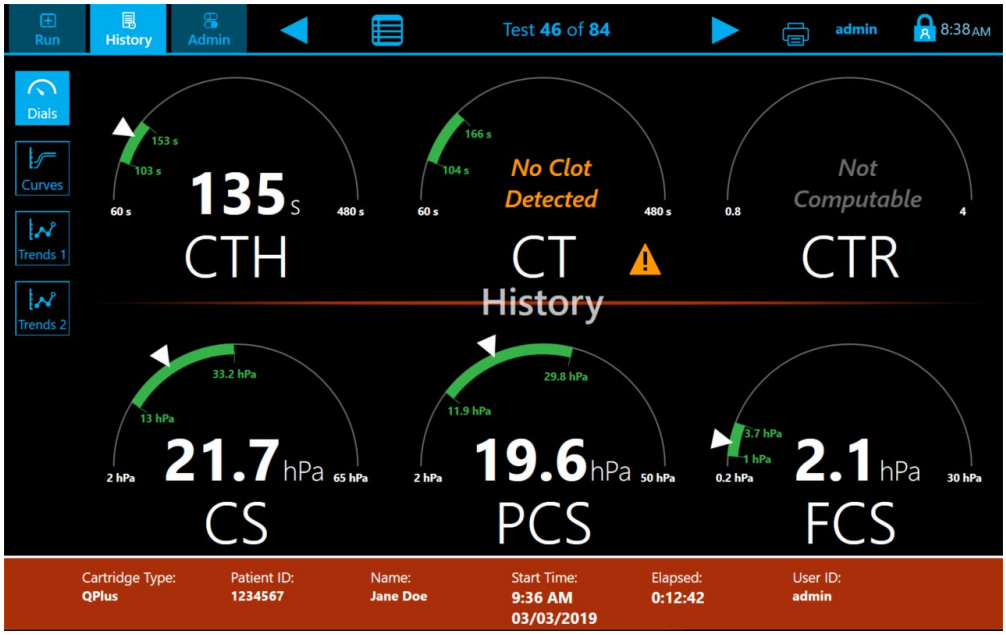

Figure 36. Case #3

E. Ending a Test Early

1. Press “Cancel” to stop a run that is in process.
2. The system will ask for confirmation to cancel the test (Figure 37). Select “Yes” to end the test.

NOTE: For each of the tests that are completed, the results are displayed on the dial. For any tests that are not completed, “Not Computable” is displayed on the dial. One exception is for the CSL parameter on the QStat Cartridge. If the QStat Cartridge is stopped prematurely, “Test Stopped” will be displayed on the dial for CSL.

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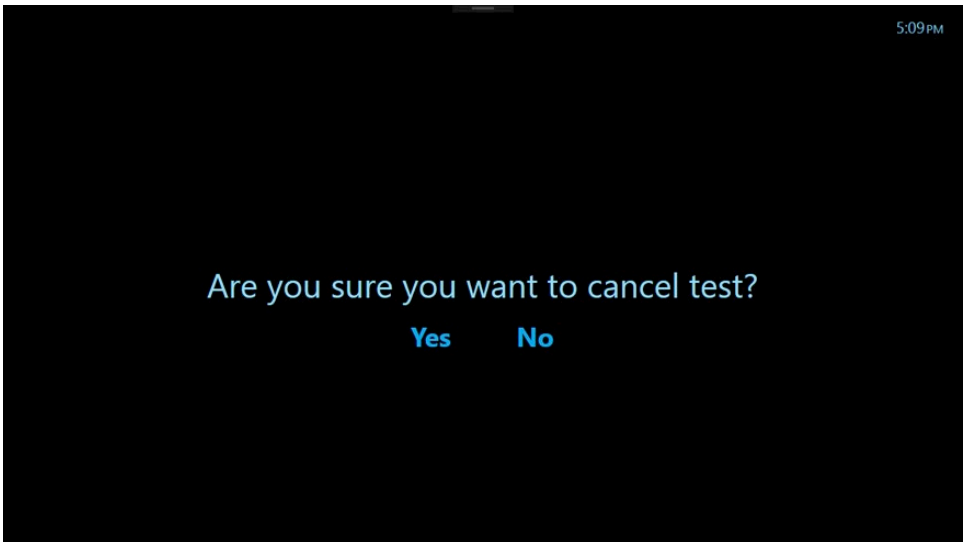

Figure 37. Cancel Test Verification Screen

F. Locking the Screen

During a sample run, the screen can be locked to prevent the screen results from being viewed until an authorized User logs in.

1. Press the lock icon on the top right of the upper taskbar.
2. The Scan or Type User ID screen is displayed. To unlock the screen, enter or scan any authorized user ID.

G. About Screen

Press the “About” button on the User ID entry screen to obtain information about the current software version loaded on the Quantra System (Figure 38).

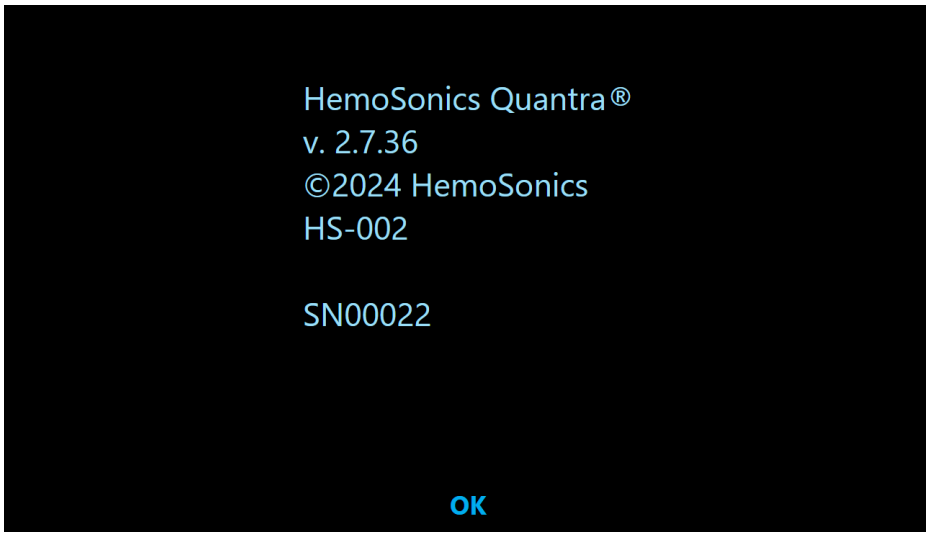

Figure 38. Quantra ‘About’ Screen.

8. History

Selecting the History button on the upper taskbar allows the user to review past test results run and stored on the Quantra Analyzer. The Past Tests screen is displayed below(Figure 39).

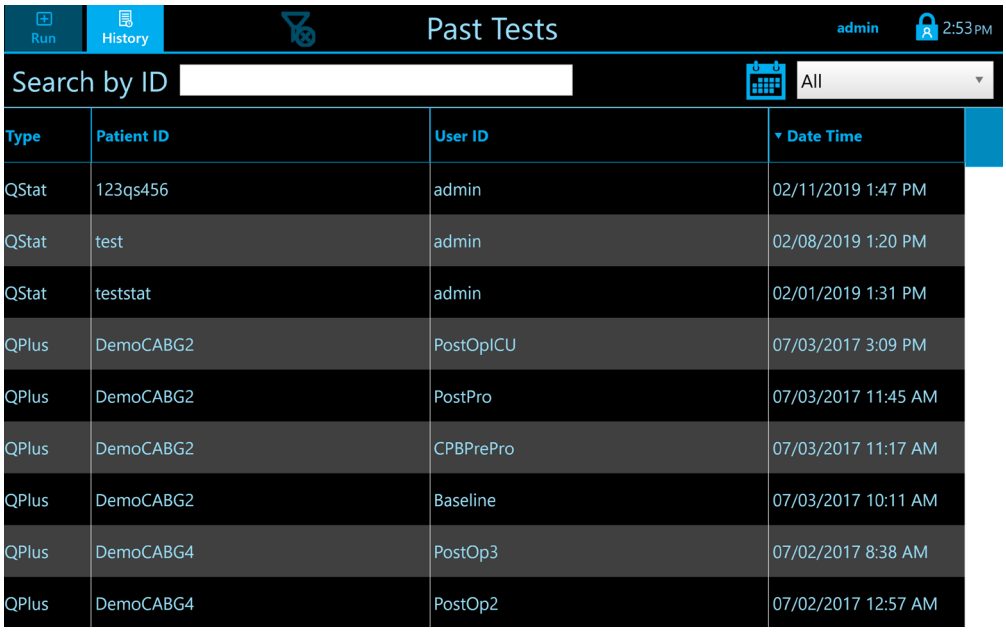

Figure 39. 'Past Tests' Display Screen.

A. Sorting records

Search for results in the following ways:

- Sort by Cartridge Type- Click on the Type header to sort the column by cartridge type. Tap the triangle on the column header to order the list in descending or ascending alphabetical order.
- By Patient or User ID - To search for records with a particular Patient ID or User ID, enter the ID in the "Search by ID" field to list all records with the entered ID.
- By Time Period - Click the calendar icon and select one of the following: Select All, Previous 1 day, Previous 3 days, Previous 7 days, Previous 30 days, or Previous 60 days.
- By column – Tap the header to sort the contents of the column. The type of sorting is None, Ascending (triangle icon pointing up), and Descending (triangle icon pointing down). In Figure 39, the Date Time shows descending order.
- Advanced sorting technique: Multiple sorting methods can be combined. For instance, one can search for a specific user or patient followed by sorting by date in ascending or descending order to find a particular test.
- The Funnel icon in the upper taskbar clears the search criteria and reverts to the full history list.

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B. Displaying Results

- Select the test from the history list to be displayed. The results are shown in the current view mode. To display in a different mode, select a mode button in the left sidebar (Dials, Curves, Trends 1, Trends 2; Figure 36). When displayed under the History mode, the bottom task bar has a background colored red. The dials will also delineate the clot time versus clot stability dials with a red divider line and labeled “History”.
- Results displayed in the History section have a different upper taskbar. The number of tests in the Past Tests screen after searching will be shown and noted in the upper taskbar (Figure , e.g., Test 1 of 2). By selecting the left and right triangles, you can scroll through the separate test results available.

The bottom taskbar displays information specific to the test (Cartridge Type, Profile name, Patient ID, Date, Start Time, Elapsed time, User ID).

Dials History Screen

Select the Dials button to view the results in Dials View. Figure 40 displays the selected test from the Past Tests screen. Use the left and right triangles to scroll through the tests associated with this patient ID.

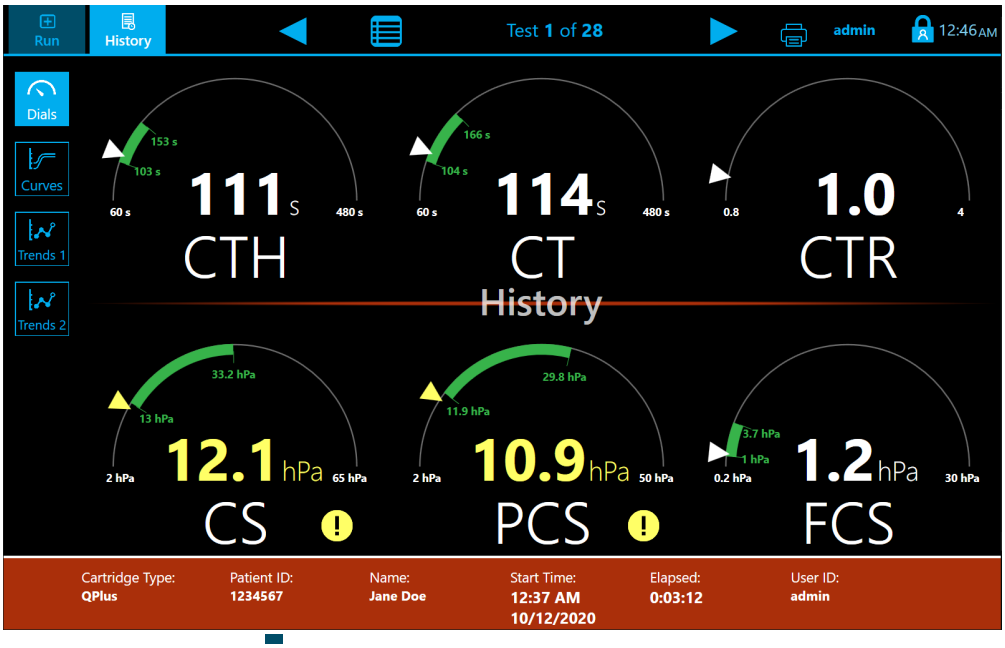

Figure 40. History Display - Dials View – QPlus

Curves History Screen

Selecting the Curves button on the left sidebar of the History Display screen displays the Curves View (Figure 41).

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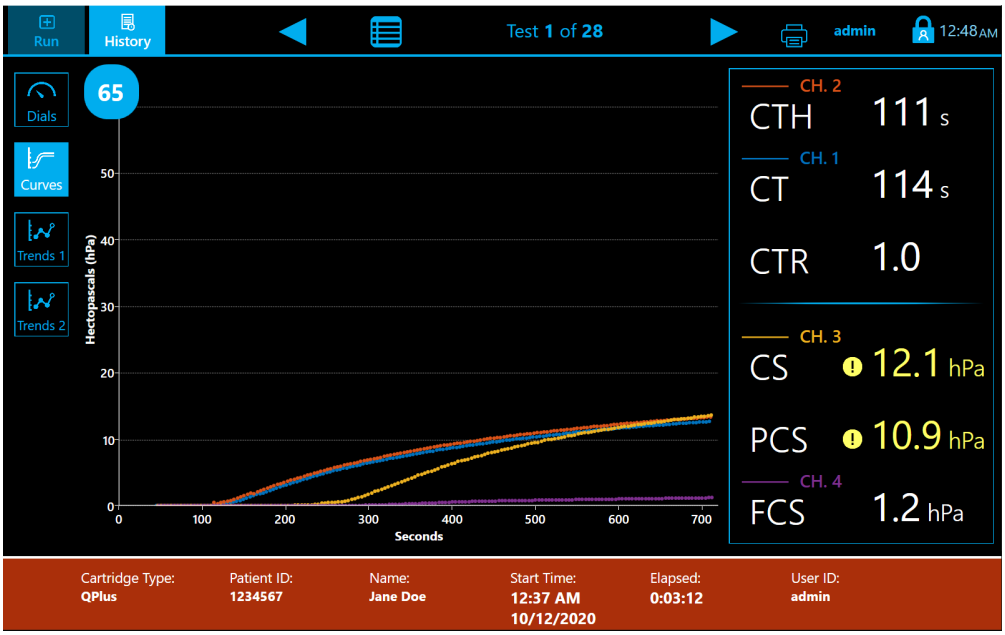

Figure 41. History Display - Curves View – QPlus

Trends History Screen

Selecting the Trends 1 or Trends 2 button on the left sidebar of the History Display screen displays the respective Trends View screen.

The Trends Screens display the current test results and up to six tests with this patient ID over the last 48 hours (the tests must be performed on the same Quantra Analyzer). The selected test is indicated with the date and time in the footer. The timeline, including the selected test and any available previous tests are indicated on the x-axis; the selected test is shown on the far right. The selected test can be thought of as hour zero. The following examples demonstrate trends for tests on a QPlus Cartridge.

1. Trends 1 – displays the Clot Stiffness parameters (CS, PCS, FCS).
2. Trends 2 – displays the Clot Time parameters (CTH, CT).

In the example shown in Figure 42, the six testing time points for CS, PCS, and FCS are shown and distributed across the x-axis. Most of the tests displayed are clustered around the most recent time point (~1:04 PM). A much earlier time point is shown to the left, which was performed approximately 25 hours before the most recent test. The corresponding CT and CTH trends data points are shown in Figure 43. The user can select the Zoom + or – buttons to examine the points more closely or distantly. To zoom in on the cluster of points, in Figure 43 selecting the + button removes the oldest time point from the display, which results in the data points displayed in Figure 44. This effectively zooms in on the cluster of points (the remaining five) and spreads the time points along a narrower range of times, compared with Figure 43. Selecting the + button once more would then show the most recent four time points. Selecting the – button returns the next older point to the display.

NOTE: If a point is near the top or bottom of the vertical scale, itmight be cut in half, but the value is still displayed.

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Figure42. Trends 1 Screen – QPlus



Figure 43. Trends 2 Screen - QPlus

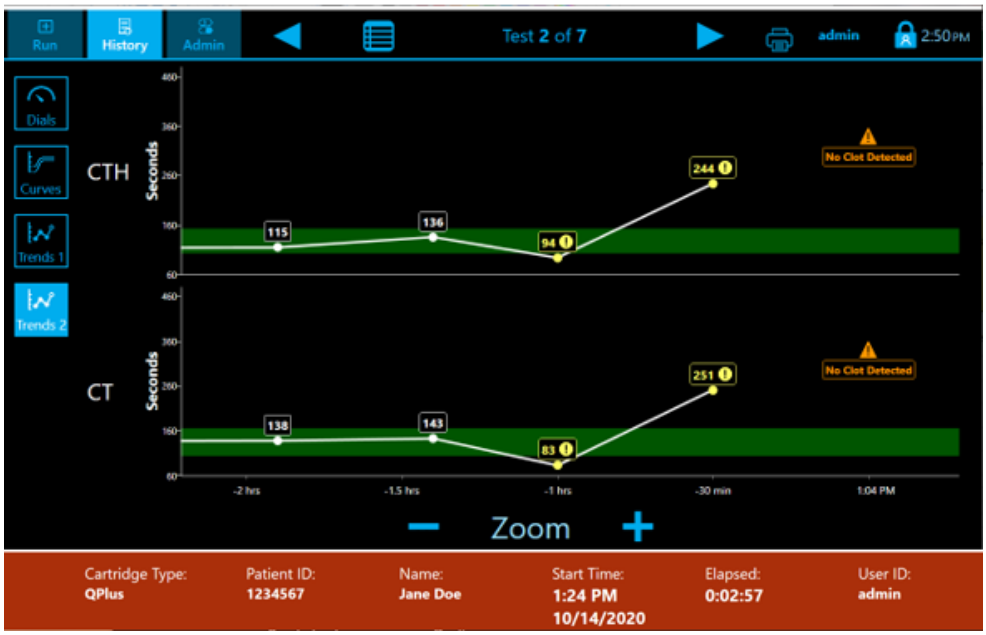

Figure 44. Trends 2 Zoomed In – QPlus

9. Printing

When the accessory Quantra System printer is attached, a printout of the selected test can be created.
NOTE: Only a HemoSonics-supported printer is configured to print results from the Quantra System.

1. Insert the printer's USB plug into the USB port behind the instrument (Figure 4).
2. Press the print icon on the upper taskbar, and a preview printout is displayed (Figure 45) with:
    a. Header containing patient and test information. If PPID is enabled, the patient's name could be included.
    b. The result with the Reference and Reportable Ranges for the parameters on the cartridge being used.
3. Choose "x" on the bottom left of the print preview to close the preview window.
4. Click the print icon on the lower right of the print preview.
5. The bottom section of the print preview provides the printer's status:
    a. Ready – printer is functional. Press the print icon on the bottom right of the print preview window to print the report.
    b. Communication Error – Printer not connected or printer malfunction.
    c. Door Open – printer door is not closed.
    d. High Temperature Error – temperature above operational specification – let cool.
    e. Unknown Error.
    f. Battery Charging – battery voltage too low for printing.
    g. Connecting – Quantra System is connecting with the printer.
    h. Printing – Quantra Systemis sending data to the printer.
    i. Out of Paper – printer out of paper. **NOTE:** The last two meters of the print roll is marked with fuchsia to indicate the end of the roll.

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- Lift the rear compartment to open print tape roll compartment.
- Insert a new roll between the two tension holders with the paper exiting the roll coming up towards the back of the printer. Close the lid. **NOTE:** The printer paper is thermal. Please store at temperatures no higher than the Quantra System operating range (list range).

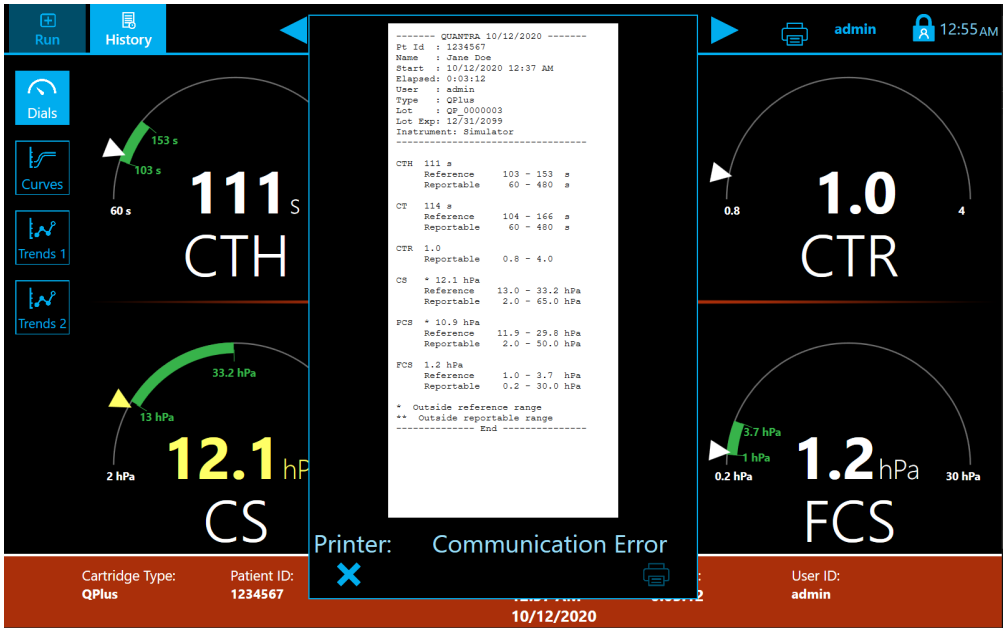

Figure 45 Print Preview Screen (QPlus)

6. LED Indications
    - None – battery charging no error (or unplugged).
    - Blinking Red/Orange – Printer offline, exception, or fault.
    - Solid Green – Ready to print.

NOTE: Any Patient ID or User ID that is longer than the allowed space on the printer tape will be truncated.

10. Saving Dials, Curves, and Trends Display Screens to USB Drive

Users can save a copy of the Dials, Curves and Trends display screens either at the end of a test run or when looking at the test history. The steps are the same from either location, but the output will have the history screen format.

1. With the test selected in history or at the end of a test run, click on the printer icon to display a drop-down list of a printer or USB drive icon (Figure 46).
2. Insert a USB drive and click “Check for USB drive”.
3. When a USB drive is detected, the status displays “Ready” and a check mark icon appears on the lower left (Figure 47).

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a. Replacing Patient ID – to prevent transfer of Protected Health Information (PHI) and Personal Data (PD), select the Replace Patient ID check box. In the text field enter the alternate Personal Data identifier (Figure 47).
b. To save the file, select the check mark icon (Figure 47). The file is saved in a folder labeled "HemoSonicsData". The file created is a compressed (zipped) file. Its name begins with Quantra Images and ends with the patient ID, either original or the replaced name.

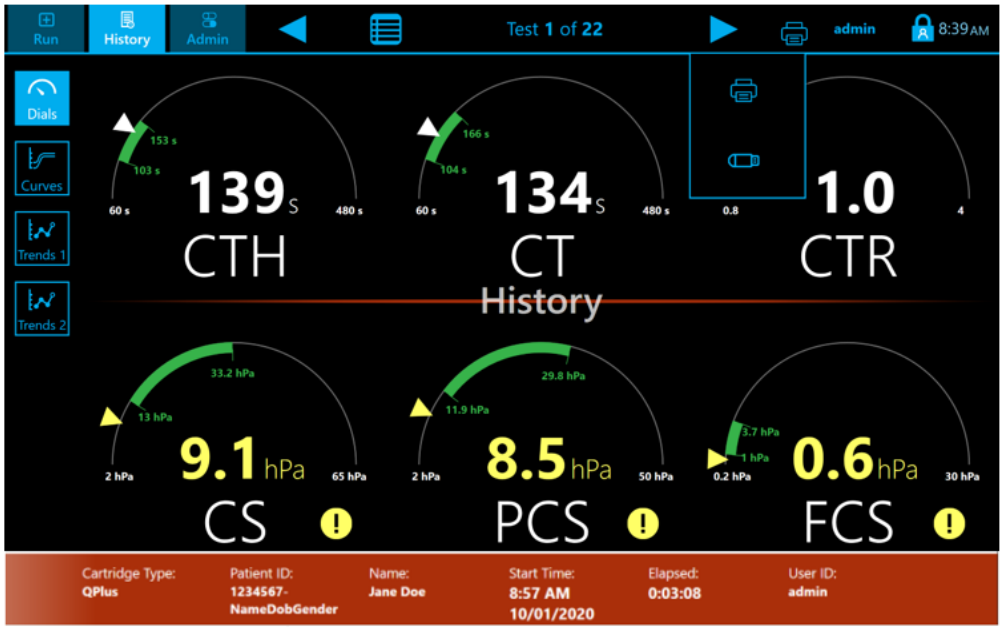

Figure 46. USB Icon to Save Test Results Graphs

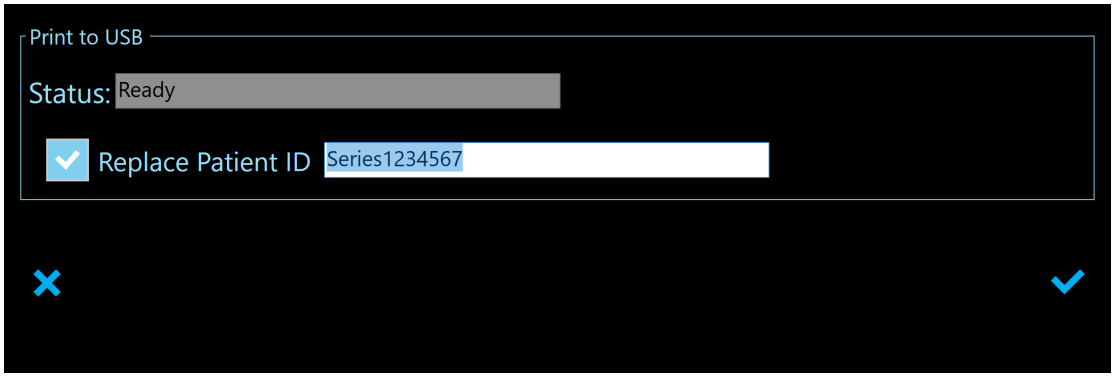

Figure 47. Print to USB Screen

11. Quality Control (QC)

The Quantra System has a comprehensive Quality Assurance Program that is based on a combination of labeling, automated quality internal control checks and the utilization of external biological control materials to support the development of a local Individual Quality Control Plan (IQCP).

A. Internal QC

The Quantra System performs automated internal QC checks to verify that key instrument and consumables meet acceptable criteria. Checks are performed at power up, during each test run, and eight (8) hours after the last test was run. Clicking on System Status in the Scan or Type Cartridge ID screen (Figure 11) displays the most recent internal QC result (Figure 48) broken down into five main areas (System, Heating, Ultrasound, Fluidics, Docking). If any problems are detected, they are reported in the event log and displayed on the screen during the initial phases when preparing to run a test (see next section).

These internal checks are performed frequently and decrease the odds of a run error occurring that is caused by instrument or cartridge malfunction. To print the report, use the USB Quantra Printer and select the Print Icon on the Print Preview Screen . Select the cross icon to exit the dialog box. (Figure 48). If configured and connected, these internal QC resuts will be automatically transferred via the POCT/LIS (See Administrator Configuration Section).

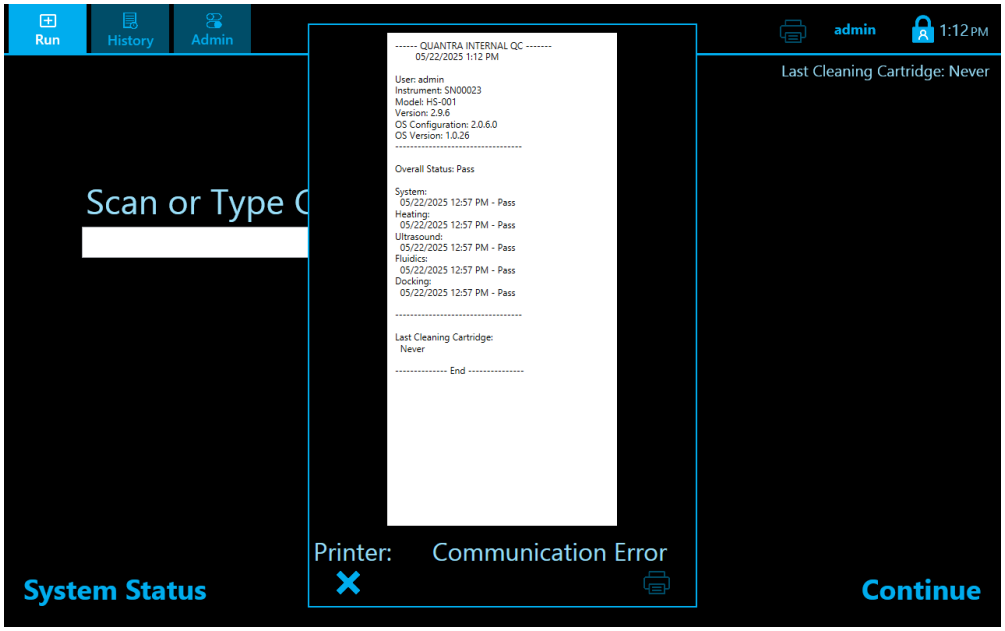

Figure 48. Internal QC Report

Contact HemoSonics LLC at +1 (800) 280-5589 (USA) or support@hemosonics.com, if any assistance is needed.

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B. External Quality Control (QC)

NOTE: Be careful to use the appropriate reagent cartridge with the appropriate external quality control materials (e.g. QPlus Cartridge only with QPlus Controls and QStat Cartridge only with QStat Controls). Do not mix and match cartridges and QC products as you may get incorrect results or the QC run may fail (Figure 49).

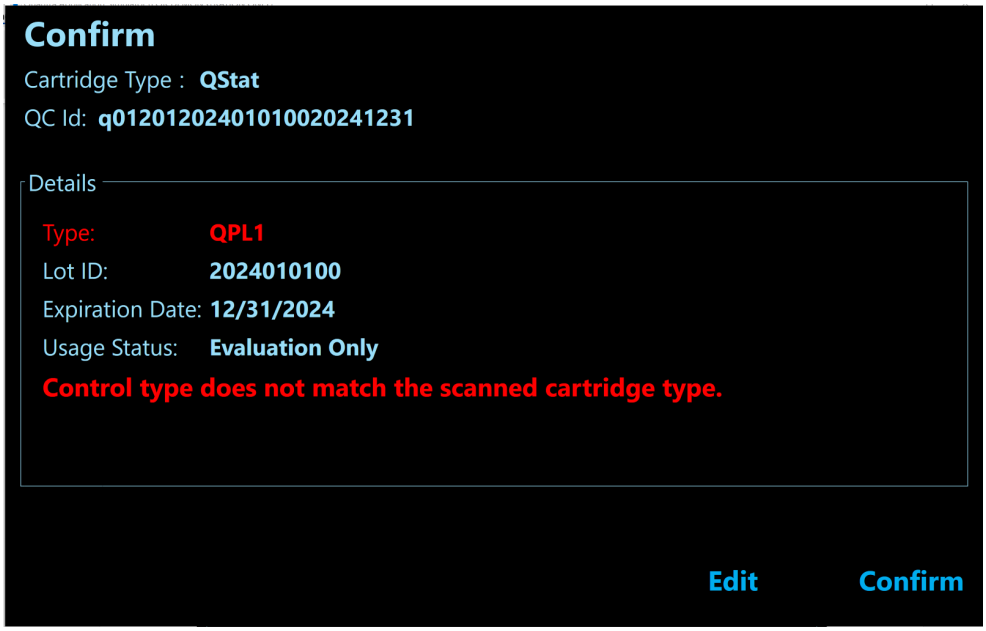

Figure 49. Incorrect QC Type Screen

Refer to the HemoSonics quality control Material Instructions for Use for the intended use, reagents used, performance, and detailed instructions for storage and handling. Each container of the HemoSonics external quality control vial is sufficient for 1 test.

Quality Controls are recommended for use when changing cartridge lots, changing control lots, or after significant changes are made to the Quantra Analyzer (e.g., software update). Additional external quality control checks may be utilized based on the laboratory's quality control policies. The frequency of QC testing should be in accordance with local and/or federal regulations or with accreditation requirements.

See the Administrator Tab, Lots section (E) to scan or enter a quality control material lot number and input the target ranges found on the lot specific Value Assignment card included with the control material packaging box.

In the Administrator Tab, section Cartridge (D), the administrator can set a required frequency interval for running external QC.

To perform external QC, follow the steps used to run a test (Section 0). HemoSonics QC materials must reach room temperature before use. For details, see the storage and handling section of the appropriate QC Instructions for Use. The results of the external QC output are compared with the target range values assigned to the control material being assayed.

1. In place of scanning the patient ID, scan the barcode on the vial of HemoSonics Quality Control material to be tested. NOTE: In the subsequent screen, confirm that the appropriate vial was

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scanned or entered. Verify that Cartridge Type and QC Type match on the confirmation screen before pressing “Confirm.” The Cartridge Type is displayed in blue and Type (the QC name) is shown in yellow to help highlight the product names.

2. In place of the blood sample container, insert the prepared control material (refer to Quality Control Instructions for Use) with the vial extender oriented to assist with pushing the control material onto the needle in the cartridge (see the instructions on Figure 24).

3. To print results, use the Quantra Printer connected to the USB port and select the Print Icon . Select the cross icon to exit the dialog box. If configured and connected, these external QC results will be automatically transferred via the POC/LIS (See Administrator Configuration Section for configuration).

Note: For best performance, reboot the instrument at least once a month. The instrument will pass/fail external QC and allow the user to proceed with testing or lock out testing until QC is passed. This is configurable by the administrator. If the QC run fails, HemoSonics recommends rerunning the control material. If the repeated run fails, contact HemoSonics LLC at (+1) (800) 280-5589 (USA) or support@hemosonics.com.

External QC for the QPlus Cartridge

HemoSonics recommends running QC Level 1 and Level 2 with the QPlus Cartridge when changing cartridge lots, changing control lots, or after significant changes are made to the Quantra Analyzer (e.g., software update). These QC materials are manufactured to produce values within specific minimum and maximum values for the QPlus output parameters CTH, CT, CTR, CS, and FCS. The QC materials do not include platelets therefore, values for the PCS parameter are typically at or below the reportable range (≤ 2 hPa). However, specific limits for PCS will be provided from the lot-specific value assignment range limits of the CS and FCS parameters.

If desired, the performance of the PCS parameter can be tested using whole blood drawn from a healthy donor according to the following procedure.

1. Identify a donor who has no known coagulation defects and is not taking any medications known to affect coagulation status.
2. Collect whole blood from the donor by venipuncture into two 2.7 mL evacuated tubes containing 3.2% sodium citrate per standard phlebotomy practices.
3. Run one whole blood sample on the QPlus Cartridge as a patient sample (not as a QC sample). The test result for PCS from the “normal” sample should fall within the established reference range for PCS.
4. For PCS, QC values below 2.0 hPa will not trigger an Out-of-Reportable-Range warning symbol (orange triangle), as PCS control values are expected to fall at or below the reportable range.
5. To create an “abnormal” sample, spike the second whole blood sample with the platelet inhibitor Abciximab (ReoPro®; Eli Lilly, VL7140, supplied as 10 mg/5 mL). Add 30.0 uL of the Abciximab solution to the second collection tube to achieve a final concentration of 20 ug/mL. Recap the tube and gently mix. Vent the tube by inserting a needle into the rubber septa to release positive pressure from the tube.

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6. Run sample on the QPlus Cartridge as a patient sample (not as a QC sample). For the sample treated with Abciximab, the PCS value should fall below the site's established reference range for PCS and may be below the PCS reportable range.

If additional confirmation of the performance of the QPlus Cartridge and the QC materials is desired, performance can be tested using whole blood drawn from one or more healthy donors according to the following procedure.

a. Identify a healthy donor(s) that has(have) no known coagulation defects and is not taking any medications known to affect coagulation status.
b. Collect whole blood from the donor(s) by venipuncture into two 2.7 mL evacuated tubes containing 3.2% sodium citrate per standard phlebotomy practices.
c. Run the whole blood sample on the QPlus Cartridge as a patient sample (not as a QC sample). The test results for each QPlus parameter from the "normal" sample should fall within the established reference ranges for each QPlus parameter.

12. Errors

The system will notify the user of any internal quality control failures at the point they are detected. Additional details of the failure are included on the screen (Figure 50) on startup and from the event log (Administrator Configuration Section B). If a restart of the System does not clear the error, contact HemoSonics LLC at (+1) (800) 280-5589 or support@hemosonics.com.

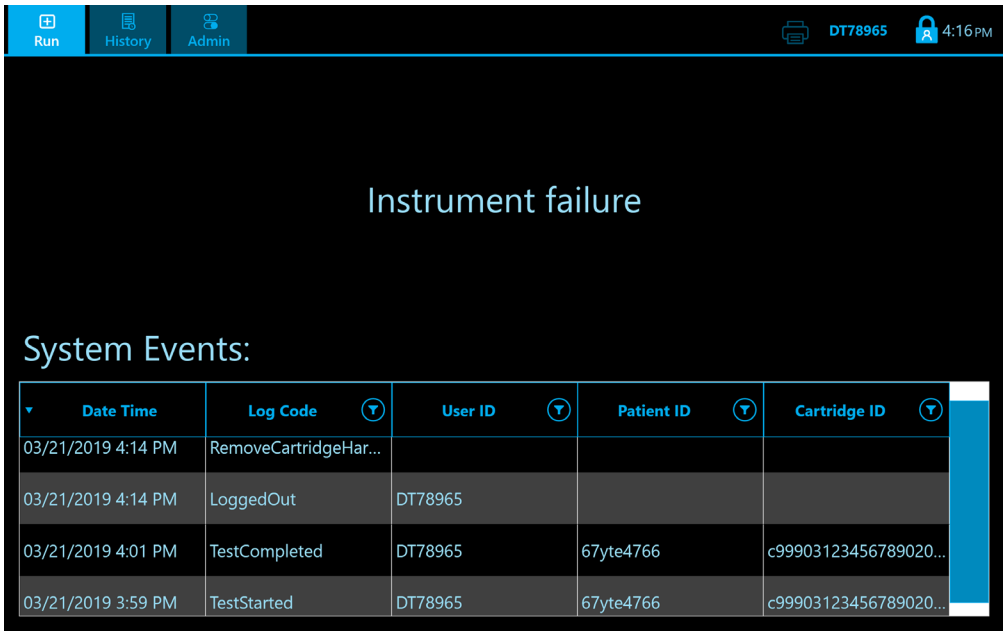

Figure 50. Event Log Screen

Sorting Error Records

- By DateTime – select the DateTime column header to sort in ascending or descending order. In Figure 50, the sort is in descending order.
- By column (Log Code, User ID, Patient ID, or Cartridge ID) – Tap on the funnel icon . A list of the different entries in that column will appear. Either select all or the particular items

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wanted to display. For example, selecting Test Completed in the Log Code Column will filter all completed tests.

- Advanced sorting technique: One can search for a specific user or patient, followed by sorting by date in ascending or descending order to find a particular test.

13. Administrator Configuration

To configure the instrument settings or view Event logs, click the “Admin” button (displayed when an administrator is logged in). Settings and Events can be configured/viewed by pressing the screen title at the center of the top bar that corresponds to the following list of categories or by using the left and right arrow tabs to scroll through the list.

- QC History
- Events
- Users
- Cartridge
- Lots
- Instrument
- Remote Systems
- Software Update

A. External QC History

Selecting the QC History category displays the External QC material assayed on the Quantra Analyzer(Figure 51). The administrator can sort or filter results by each column. If configured and connected, these external QC results will be automatically transferred to the POCT/LIS (See Remote Systems).

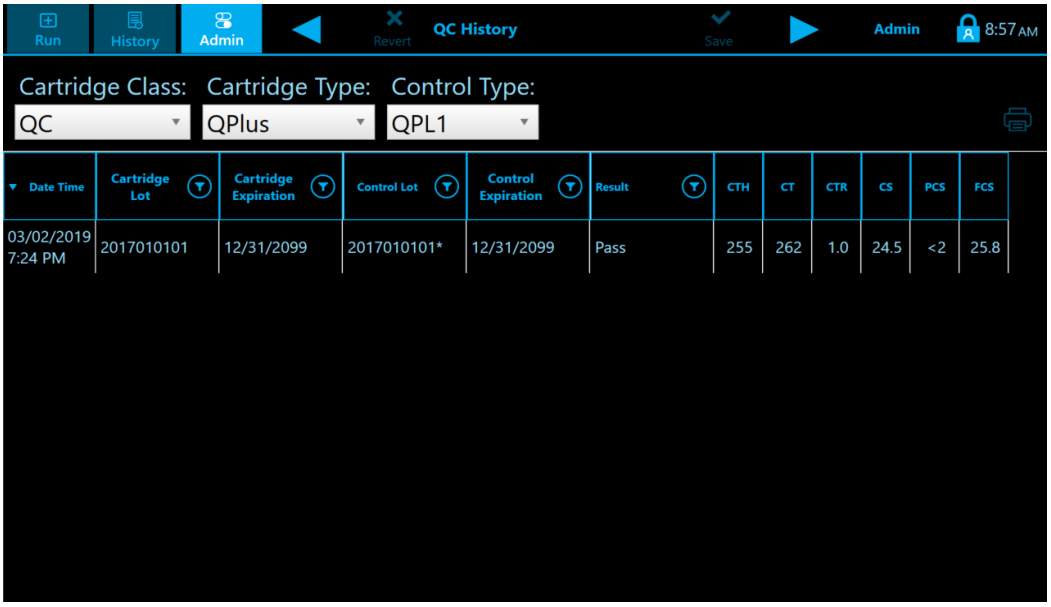

Figure 51. External QC History Screen

Sorting Results

- Choosing Cartridge Class (QC, Maintenance, Proficiency), Cartridge Type (QPlus, QStat), and Control Type (QPL1, QPL2) by selecting each from its own drop-down field.
- Note: For additional information on Proficiency Testing (KT-0048), please contact HemoSonics customer support.

Sorting Records

- **By DateTime** – select the Date Time column header to sort in ascending or descending order.
- **Filtered by column value** (Cartridge Lot, Cartridge Expiration, Control Lot, Control Expiration, Result) – tap on the funnel icon . A list of the different entries in that column will appear. Either select all or the particular items wanted to display. For example, the Results column would have either Pass, Fail, or select all. Selecting Fail will display all the results that failed for control material.

B. Event Logs

To view the event log, choose the Events category in the administrator section (drop-down list or use arrow tabs on the upper taskbar). Logged events are listed (Figure 52).

Sort events by choosing a date or filtering by selecting items in the other columns (Log Code, User ID, Patient ID, Cartridge ID). The Event Log is enhanced to include new event categories for Profile Deleted, Profile Added, and Profile Modified. These events will include the cartridge type, profile name, and profile Id. For detailed information on an event, click the arrow on the leftmost column of the selected event.

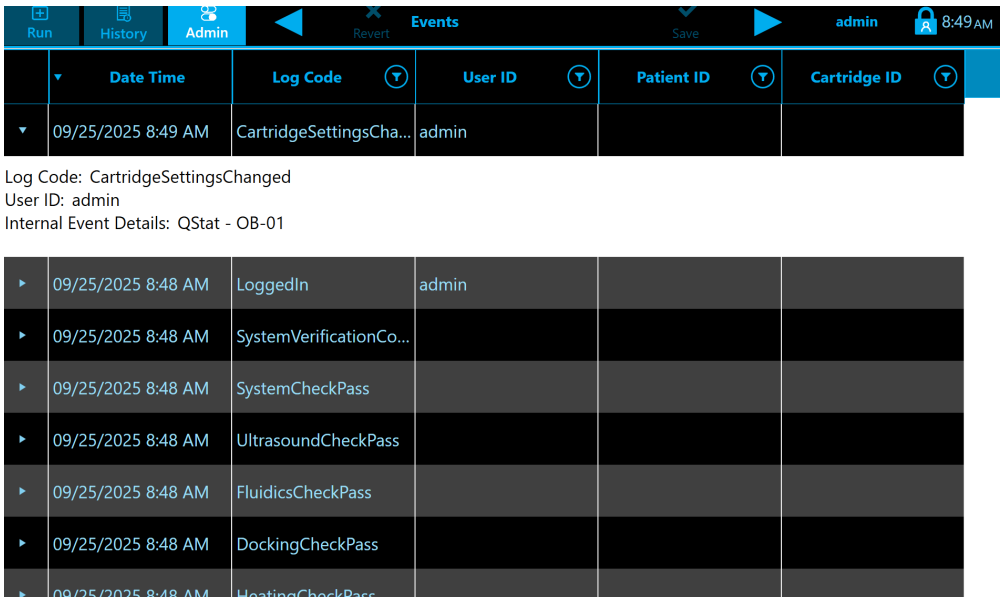

Figure 52. Events Capture Screen

C. Users

NOTE: After the first user is entered as an administrator, only administrators can enter and edit users.

1. To add a user, select the "+" icon (Figure 53).

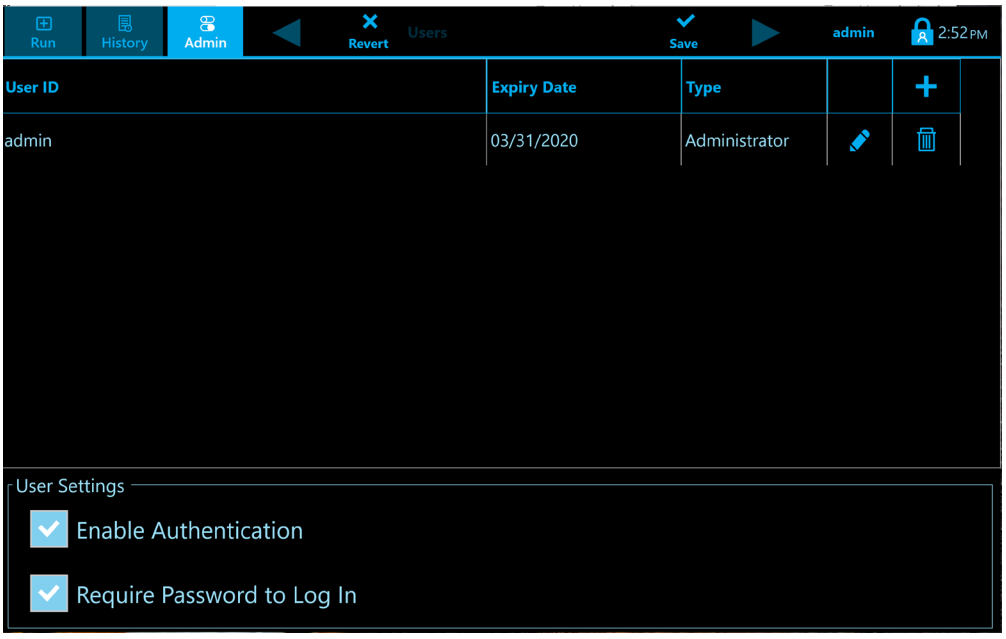

Figure 53. User Configuration Screen

2. Enter the:
   a. User ID
   b. Expiry date for the user on the system
   c. Choose whether the user is
      i. Normal
      ii. Administrator
3. Click the checkmark symbol to load the user information to the system and "Save" to save. Click the cross mark to cancel the entry.
4. Select the pencil icon to edit entries and the trash can icon to delete entries.
5. Select the Trash Can icon to delete the user entry.
6. When a newly entered administrator logs in for the first time, they will be asked to enter and confirm a password.

User Settings

- Enable Authentication – checks if the user is entered as an approved user.
- Require Password to Log In – Users must enter their password when logging in..

NOTE: Passwords may contain both alphanumeric and special characters.

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D. Cartridge

The Cartridge category is used to define Site-Specific Profiles and QC Lockout rules for the different cartridge types. For each Cartridge type the Reportable and Reference Ranges can be adjusted by the administrator (Figure 54).

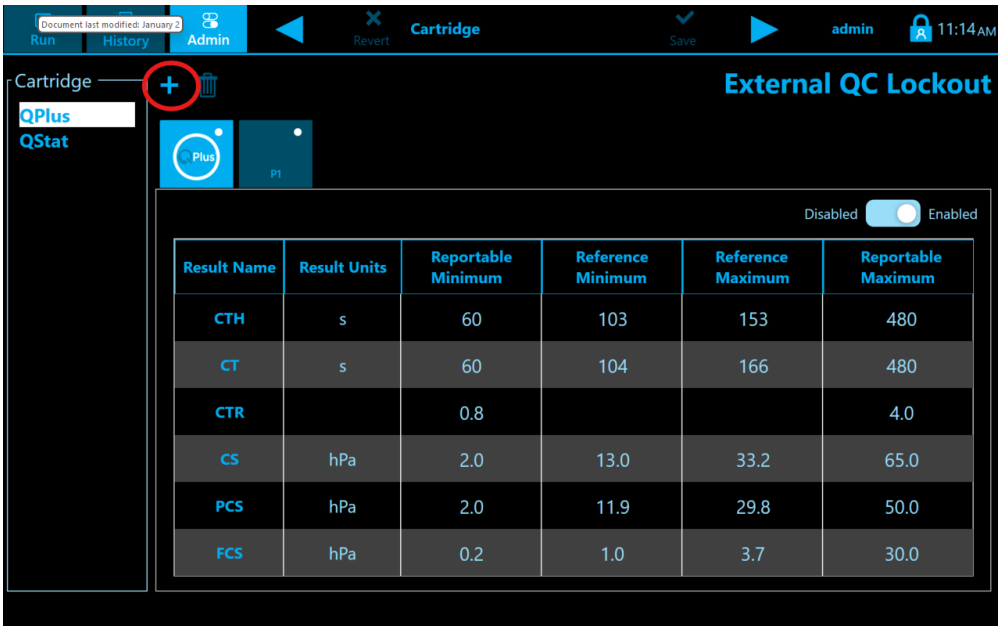

Figure 54 Cartridge Configuration Screen

IMPORTANT. HemoSonics provides established range values for all cartridge types. These ranges cannot be removed or changed, but the user can copy or disable them.

Site Specific Profile

Users can create Site-Specific profiles to customize Reference and Reportable Ranges for a given cartridge type. For the Reportable Range, the Range can only be made narrower, not widened beyond the default values. Only the Admin may narrow the Reportable Ranges. Invalid input will not be saved and is indicated by a red border around the text box.

Note:

1. **Reportable and Reference Ranges –The Reportable and Reference Ranges are set by the manufacturer prior to installation, but alternate Reference Range values can be provided by adding Site-Specific Profiles.**
2. **The QPlus CTR value can be customized under the Site-Specific Profile. When disabled, it will display as N/A (Figure 55). To view or edit the ranges, click the field to display the values. To disable the ranges again, Click N/A on the keyboard (Figure 56).**
3. **For the QStat Cartridge, both the QStat Standard and QStat OB profiles are enabled by default.**

- To add a Site-Specific Profile for the Standard configuration, select the Standard profile and then click the “+” Icon on Cartridge Confirmation Screen (Figure 54). The following screen will be displayed (Figure 55)

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Figure 55 QPlus Custom CTR Screen

- To add a Site-Specific Profile for the OB configuration, select the QStat Cartridge , Select OB profile and then click the “+” Icon on Cartridge Confirmation Screen (Figure 54) to create a new OB Site Specific range.

  Disclaimer: Sites may develop and apply their own reference range profiles for use with the Quantra Hemostasis System. HemoSonics does not validate nor assume responsibility for any site-specific modifications.

  Figure 54 shows an example of a newly added profile.

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Figure 56 Site Specific Profile Screen

- Enter Profile Name (no longer than 5 characters), Description (no longer than 30 characters) as well as the Custom Site-Specific Range.
- click on “Save” to save it. (Figure 56)
- Users can add up to 9 Site-Specific Profiles for the QPlus Cartridge and 8 Site-Specific profiles for the QStat Cartridge.

Note: Users cannot Create two profiles with the same name.

Note: When enabling a reference range profile (site specific or Hemosonics defined Standard), if the enabled slider does not update accordingly when selected, pressing the Save button will allow user to see the update has been Implemented.

- Site-Specific profiles will appear in the order that they are created. The first profile will always be the standard QPlus or QStat, and the remaining profiles after that will be site specific.

  To Delete a Profile, Select the Profile from the list of Profiles (Figure 56) and click on. 

  The following Screen will be Displayed (Figure 57).

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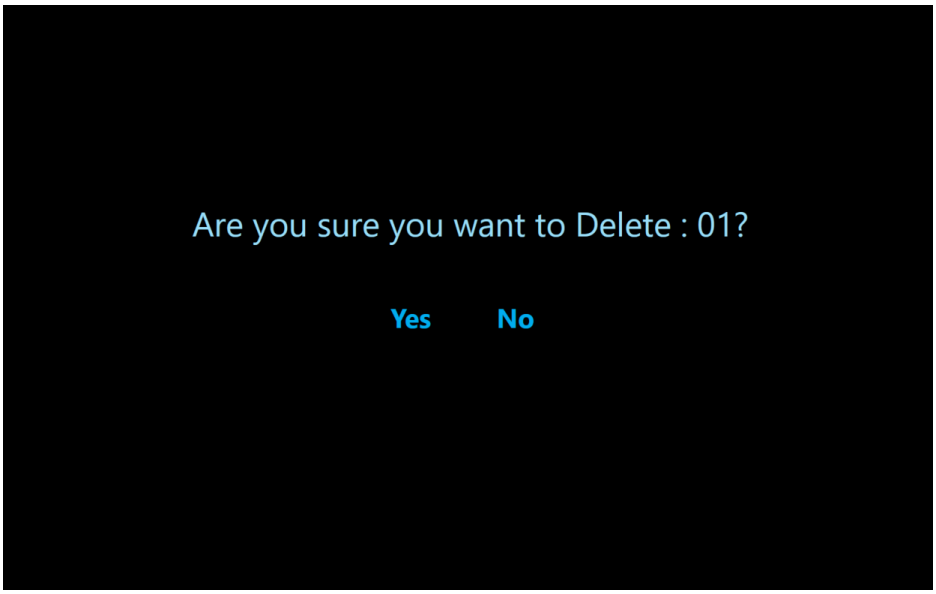

Figure 57 Delete Custom Profile Screen.

- Click on "Yes" to proceed.

External QC Lockout

To Update External QC Lockout settings, click on External QC Lockout button on the Cartridge Confirmation Screen (Figure 54), The following Screen will be displayed (Figure 58).

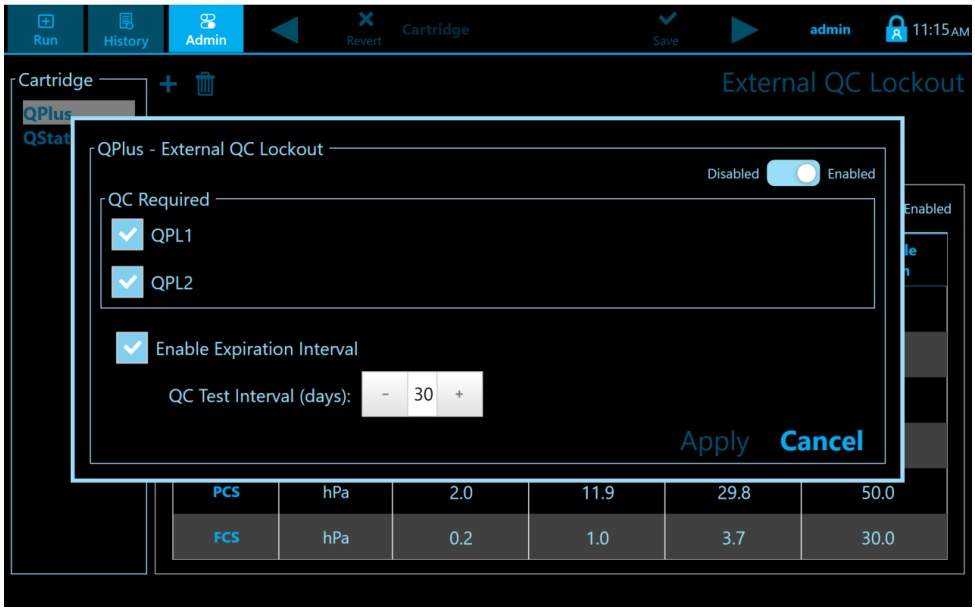

Figure 58. External QC Lockout Screen

4. The user can set the number of days between 1 to 60 for a required external QC (Figure 58).

   Note: External QC Lockout – the administrator can configure the Quantra System to lockout users if a successful external QC is not performed within a set interval.

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When QC lockout and expiration interval are activated, the scan cartridge screen also displays the current status of the external QC runs (Passes, Failed, Expired, or the time left, if seven days or fewer, until the expiration of the test interval). See Figure 59.

i. Enable Lockout – if the control material run does not pass based on the target ranges set for that material, then the Quantra System is locked and won't perform tests until the external QC run has passed.

ii. Enable Expiration Interval – if enabled, the administrator enters the number of days before external QC must be performed.

1. Check Enable Lockout to activate Enable Expiration Interval.
2. Check Expiration Interval to activate QC Test Interval (days).
3. Enter the number of days before external QC certification status expires (default 30 days).

QC Required – the administrator selects which levels of control materials must be run for external QC (Level 1, Level 2, or both).

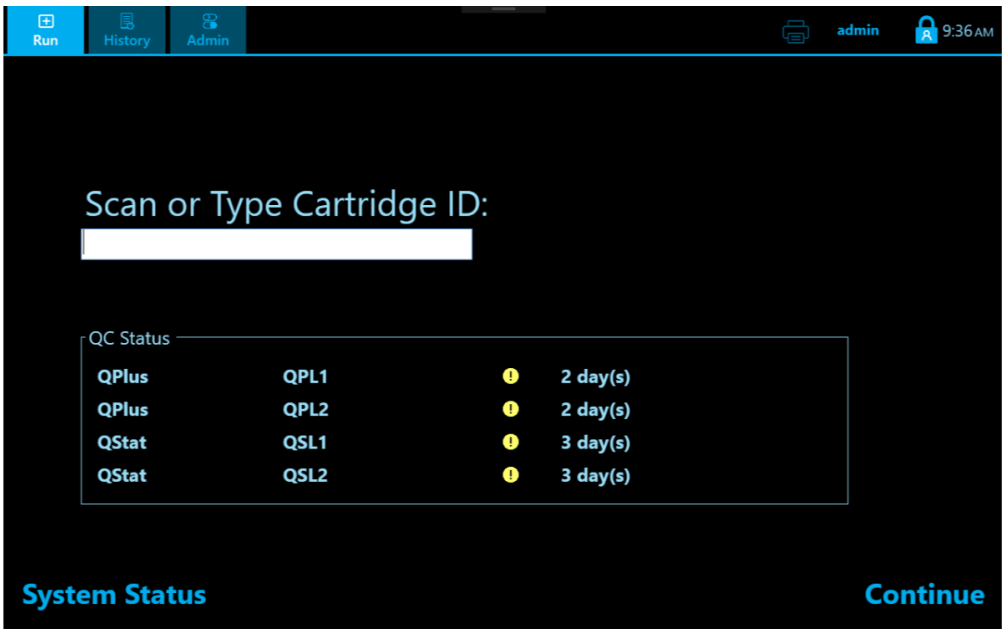

Figure 59. QC Status Screen

E. Lots

Choose the Lots category in the administrator section to view or enter cartridge or control material lot numbers to be evaluated or approved for use on the Quantra System. The evaluation mode allows the cartridge or control material to be used on the Quantra System, but not for patient sample runs (cartridge) or for passing external QC (control material). For each lot of external controls, specific target ranges are entered. Cartridge Reference and Reportable Ranges can be configured via the Cartridge category. **For the Reportable Range, the range can only be made narrower, not wider.**

1. The lot screen lists the type of cartridge or control material, the lot number, the expiration date, the barcode, and the usage status (Figure60).

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a. Pencil icon – select for editing
b. Trash Can icon – select to delete entry

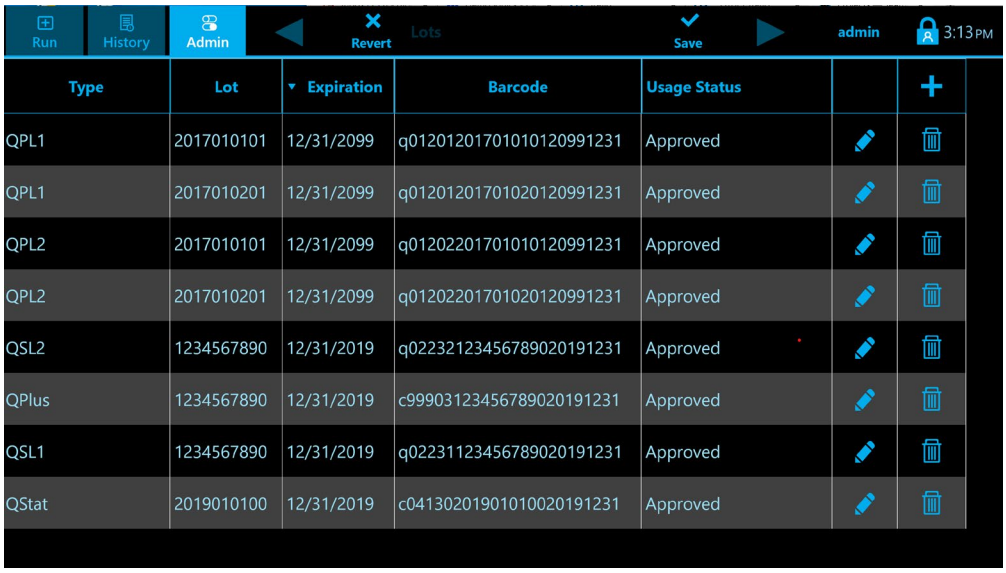

Figure60. Lot Listing Screen

2. To enter a control material lot, select the "+" icon.
3. A dialog box appears with instructions to enter a barcode. Scan the control barcode from the diluent vial, Scan 1 on the value assignment card, or type in the barcode. When a properly formatted barcode is recognized, the display (Figure 51(example shows control material)) is expanded to show:
    a. Barcode
    b. Usage Status: (choose)
        i. Approved
        ii. Evaluation Only [default selection]
        iii. Reject
    c. Type [name of cartridge or control material]
    d. Lot
    e. Expiration
    f. Table listing for each assay parameter:
        i. Minimum and Maximum Reportable Range
        ii. Minimum and Maximum Target Range [external control material] (Figure 51)
4. Entering Value Assignments for External Quality Controls
    a. Scan Method to Input Target Value Assignments
        i. Press the "Scan Ranges" button
        ii. Use the barcode scanner as instructed to scan the value assignment barcode (Scan 2) found at the bottom of the lot-specific Value Assignment Card. The values will be populated in the target minimum and maximum fields; or
    b. Enter Values Manually

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i. Use the keypad to enter the target value assignments from the lot-specific control material product Instructions for Use insert into the corresponding field of the target range.

NOTE: The initial Value Assignment Cards for the Quantra System Quality Controls only had one barcode. As an improvement to the process, starting with the lyophilized QPlus Controls, the Value Assignment Card will include 2 barcodes. Please contact Technical Support if you have any questions.

c. For the Level 1 and Level 2 Quality Controls: Scan the Control Lot number from the Value Assignment Card (Labeled as “Scan 1st” on Value Assignment Card) (Figure 61).

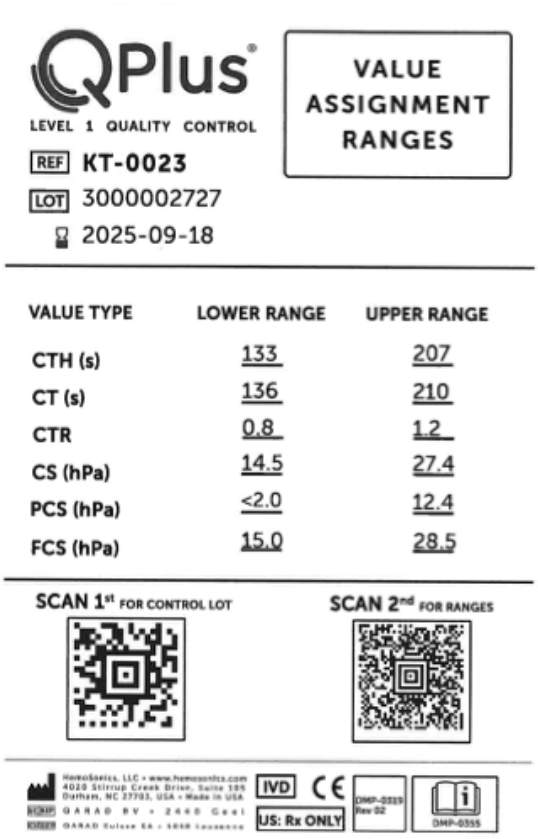

Figure 61 Value Assignment Card Example

d. Scan Method to Input Target Value Assignments

i. Press the “Scan Ranges” button

ii. Use the barcode scanner to scan the value assignment barcode found on the lot-specific Value Assignment Card (Labeled as “Scan 2nd” on Value Assignment Card). See Figure 60 - The values will be populated in the target minimum and maximum fields; or

e. Enter Values Manually

i. Use the keypad to enter the target value assignments from the lot-specific control material product IFU to the corresponding field of the target range.

5. Saving entry

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a. Select the cross mark to cancel the entry of information.
b. Select the check mark to retain the entered information

    i. The Lots screen appears in the upper taskbar, select

        1. Save to save the information entered
        2. Revert to cancel entry.



Figure 62. Lot Specific Value Assignment Entry Screen

F. Instrument

Choose the Instrument tab in the administrator section to format and set date and time, and login settings (Figure 63).

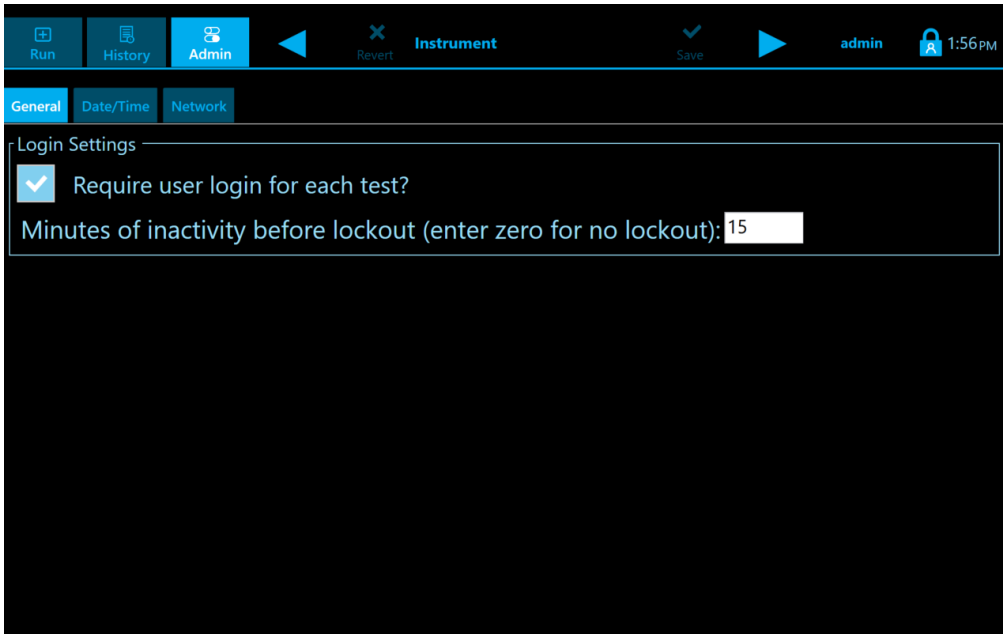

Figure 63. Instrument Configuration

1. The administrator can also set whether operator login is required for each test by selecting the checkbox under Login Settings. If this is selected, the Analyzer requires the user to login for each new test.
2. The administrator can enter the number of minutes of operator inactivity before automatic logout occurs.
3. Date and time can be selected for (Figure 64):
    - Time Zone
    - Date
    - Time
    - Click “Apply” to set values.
    - 12 (AM/PM) or 24-hour clock

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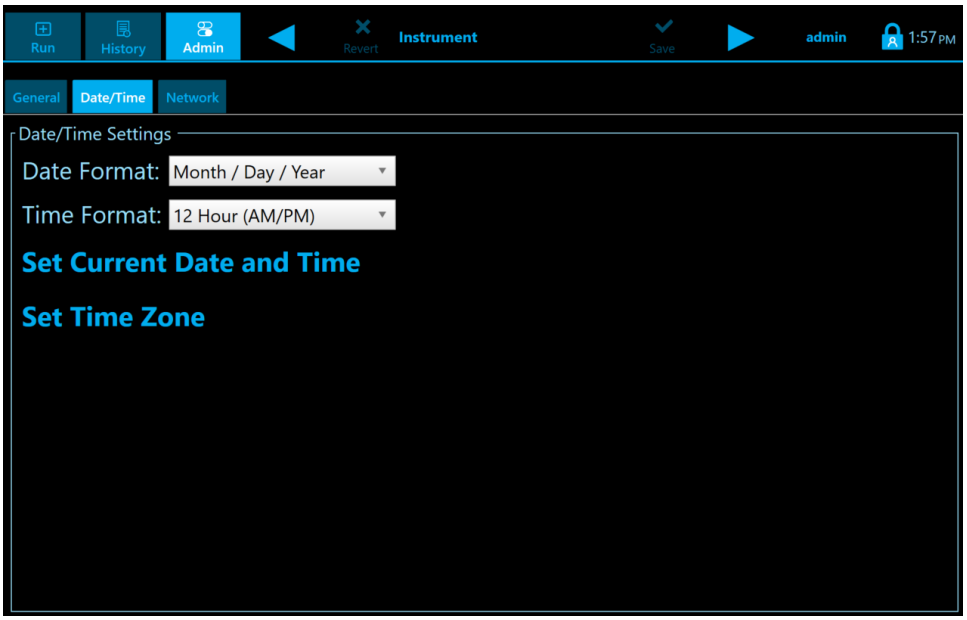
- 

Figure 64. Date/Time Configuration

4. Network Information – displays the connected network address and the MAC Address (Figure 65).

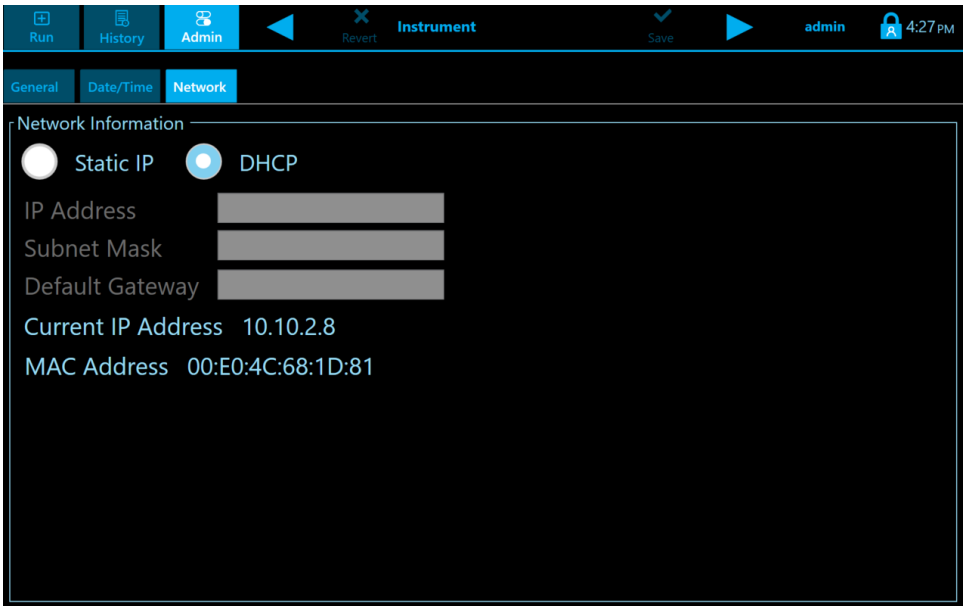
1. 

Figure 65 Network Configuration

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G. Remote Systems

Use the Remote Systems configuration tab to configure the following:

1. Data Manager (Figure 66)
    a. Use the Data Manager Type drop-down list to choose a connectivity standard: None, **POCT** (Point-of Care, POCT01-A2), or **LIS** (Laboratory Information System, LIS2-A2) for a network connection.
    b. After selecting a data manager, a dialog appears for the user to enter:
        i. IP Address
        ii. Port
    c. On the taskbar select “Save” to save the setting or “Revert” to not save change.
    d. Activating Positive Patient Identification
        i. Select POCT or LIS as the Data Manager Type
        ii. Select “Enable Positive Patient Identification” (Figure 67 and Figure 68)

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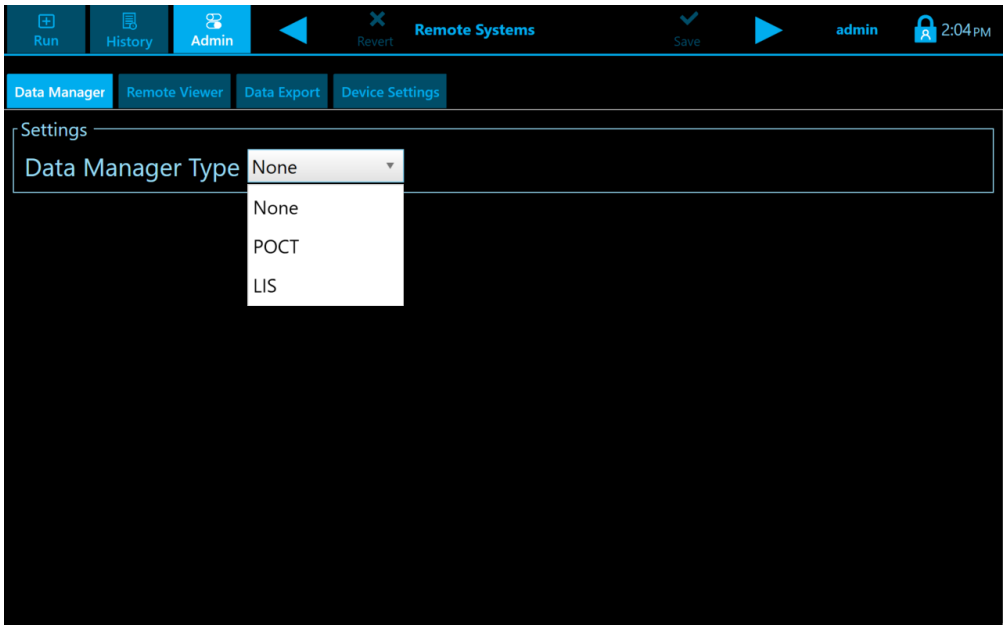

Figure 66. Data Manager Selection Screen

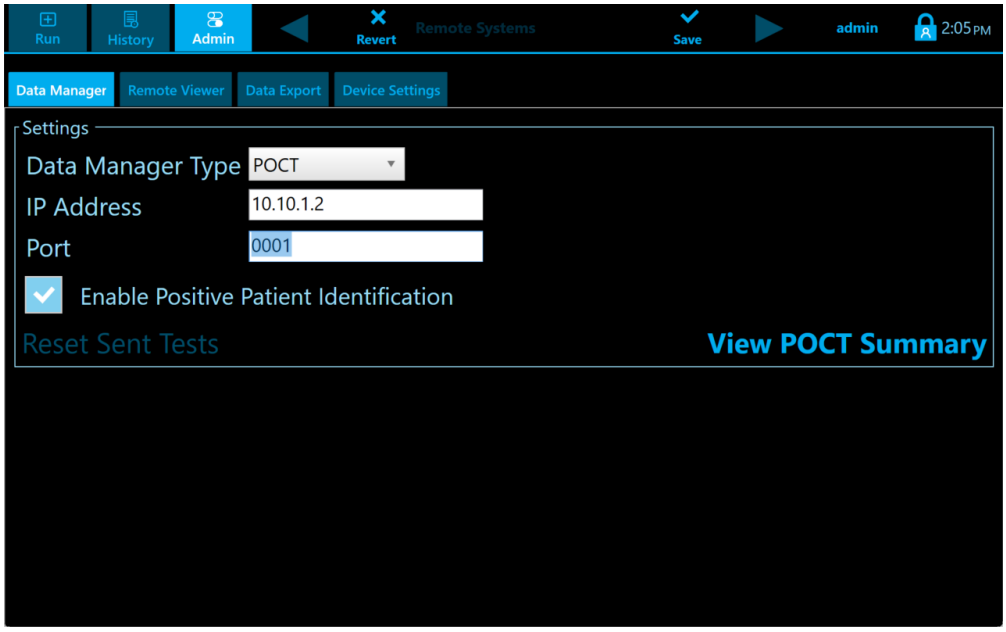

Figure 67. Enable Positive Patient Identification

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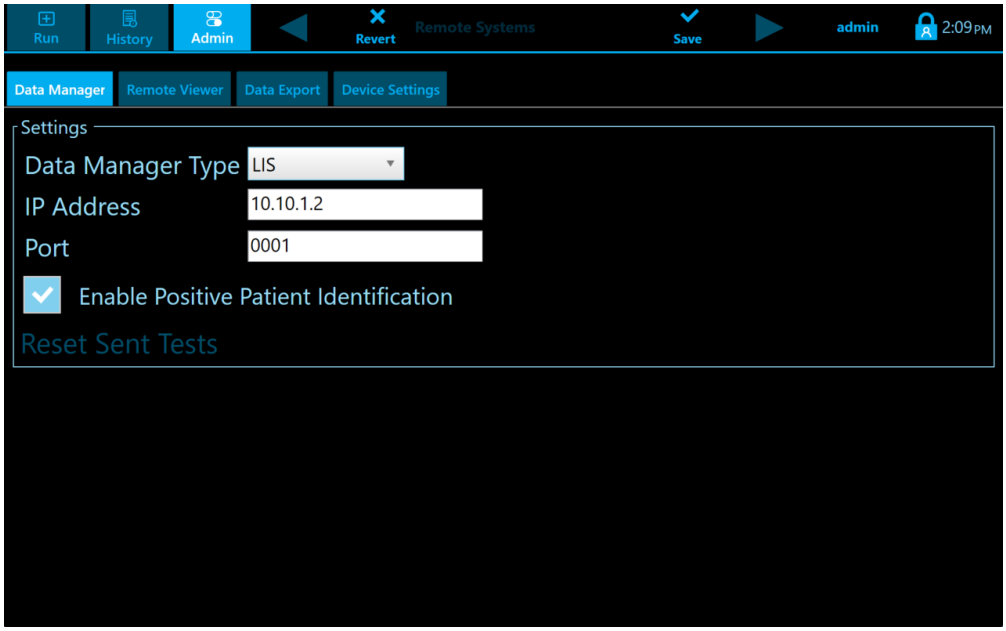

Figure 68. Enable Positive Patient Identification

2. Desktop Remote Viewer

The Quantra Desktop Remote Viewer is a separate component that allows users to connect to a Quantra System to remotely view tests in progress as well as historical results and trends. Instructions for use are in DMP-0476 (Quantra Desktop Remote Viewer). The administrator can configure the Quantra System to be part of the Remote Viewer network.

NOTE: Recommend no more than five Desktop Remote Viewers connected simultaneously to a single Quantra Analyzer.

Choose the Remote Viewer tab to enable the remote viewer (Figure 69)

a. Select the checkbox “Enable Remote Viewer”. IP address is displayed (if available).
b. On the taskbar, select “Save” to save the setting or “Revert” to not save changes.

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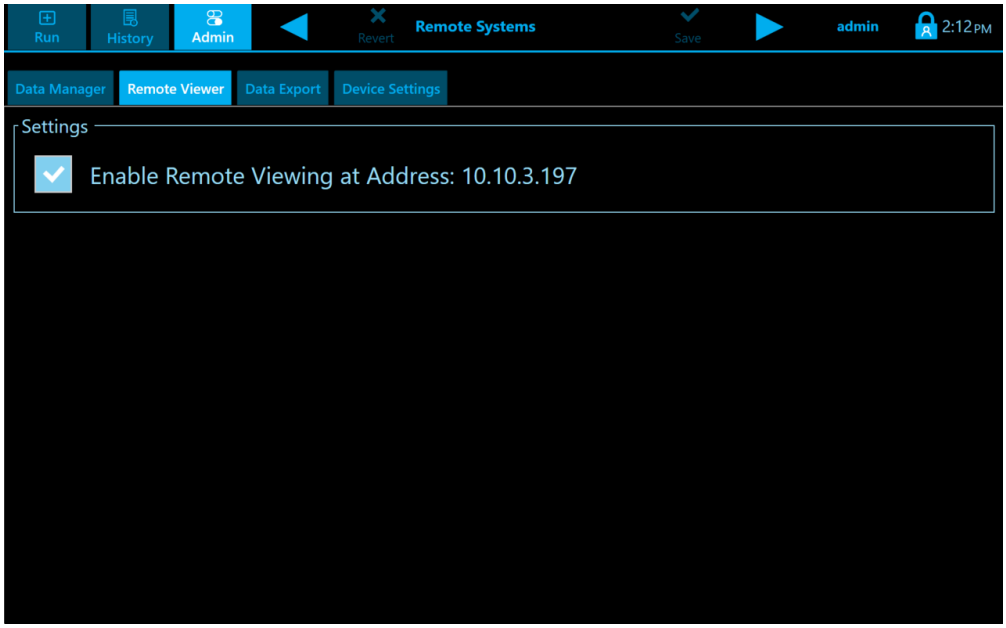

Figure 69. Enable Remote Viewer Screen

NOTE: If unable to connect to the Quantra System, please verify that the Enable Remote Viewer checkbox is enabled and that the IP address for the instrument selected is correct.

3. Data Export

Choose this tab to export the External QC History or the Event Log files to a USB memory stick (Figure 70). Select items to be exported by clicking the appropriate check box. Follow the instructions displayed in the Status field.

a. Insert USB Drive into the front USB port.
b. Click the “Check for USB Drive button”.
c. When status indicates “Ready to Export”, click the “Export” button.
d. A dialog box displays the list of exported files and indicates if the Save is complete. Select “Done” to exit the screen (Figure 71).

Data for the External QC History are exported as comma-delimited (.csv) files listing:

- Instrument
- Version
- Cartridge Type
- Control Type
- Cartridge Lot
- Cartridge Lot Expiration
- Control Lot
- Control Expiration

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- User ID
- Date Time
- Result (P/F)
- CTH (s) [for QPlus]
- CT (s) [for QPlus, QStat]
- CS (hPa) [for QPlus, QStat]
- FCS (hPa) [for QPlus, QStat]
- CTR
- PCS (hPa)

Data for the Event Log are exported as comma-delimited (.csv) files listing:

- Event log code
- User ID
- Date Time
- Patient ID
- Cartridge ID

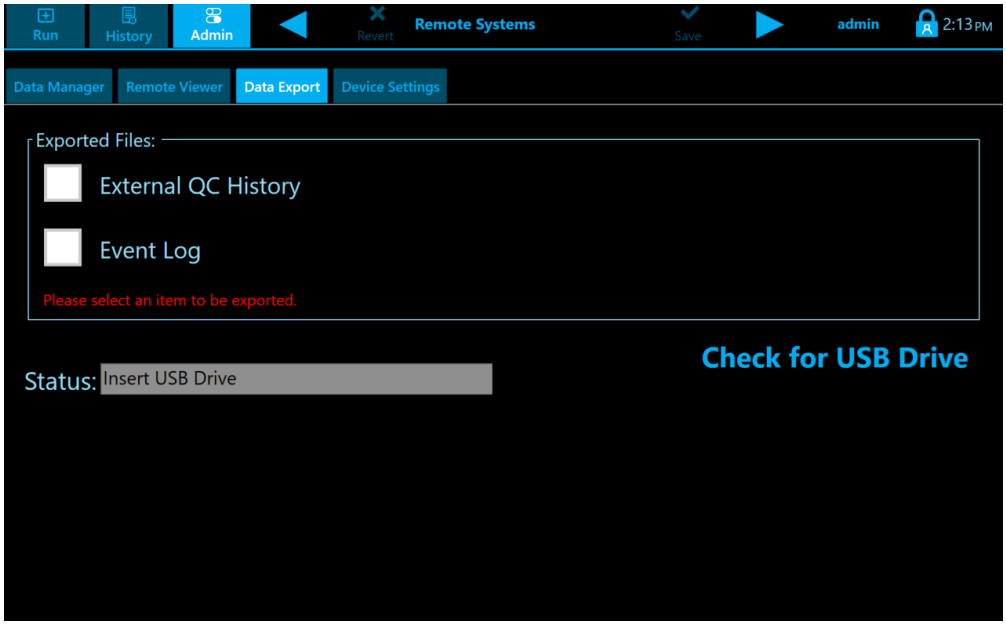

Figure 70. Data Export Screen

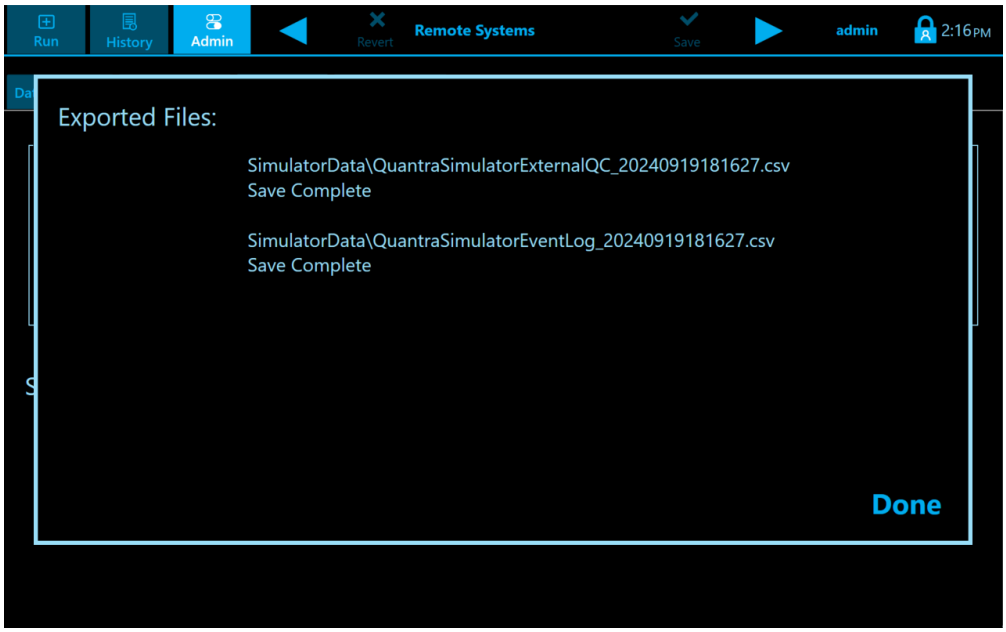

Figure 71. Exported Files Screen

4. Device Settings- Use this function to save the administrator-implemented configuration settings, except for language settings, to a USB memory stick. The configuration settings can be used to restore the settings on a Quantra System or configure other Quantra Analyzers to the same settings. Choose this tab to archive data on the Quantra System (Figure 72).

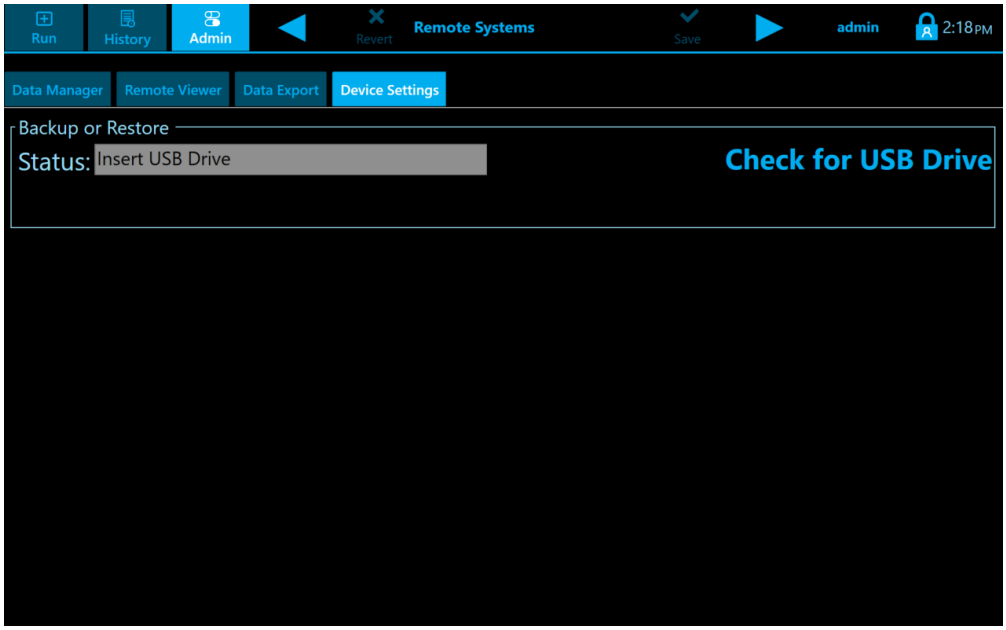

Figure 72. Device Settings Dialog Screen

5. To backup a configuration file
   a. Insert a USB memory drive.

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b. Click the “Check for USB Drive” button. If a USB drive is detected, the screen changes with a status of “Ready” (Figure 73).

i. To backup configuration settings to a file

1. Click the “Backup to USB Drive” button
2. In the subsequent screen, enter a password for this file and reenter the password to verify (Figure 74).
3. Click on the “OK” button. A screen appears with the title of the backup file (Figure 75). Press “Done” when finished.

ii. To restore configuration settings from a file

1. Click the “Restore from USB Drive” button
2. In the subsequent screen, select the file to restore (Figure 76).
3. Click “OK”.
4. Enter the password and click “OK”.
5. The subsequent screen asks, “Overwrite all device settings from the backup file?”. Click “OK” to proceed. (Figure 77)

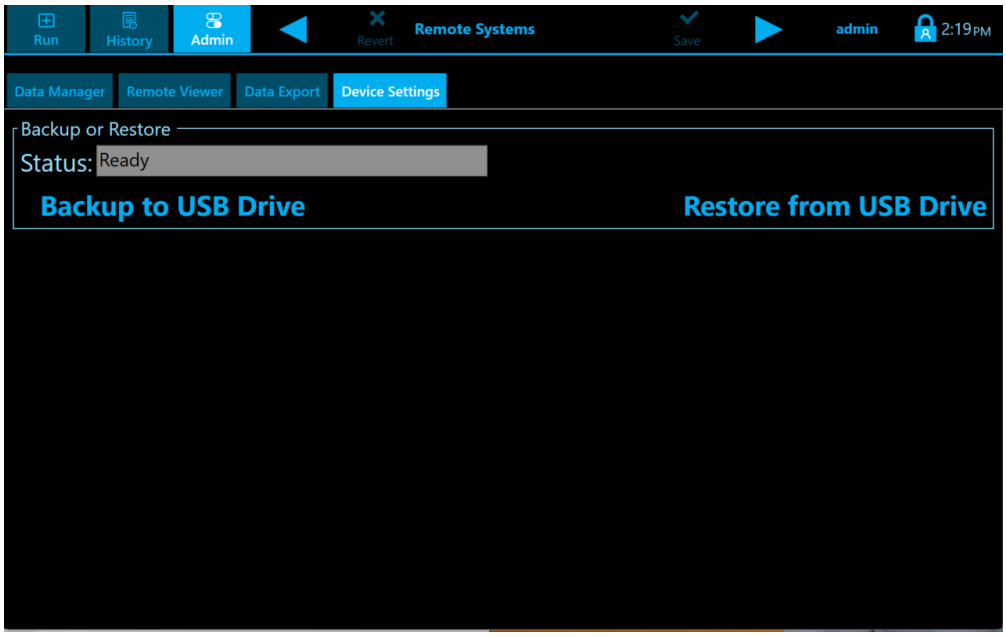

Figure 73 USB Drive: Backup or Restore Screen

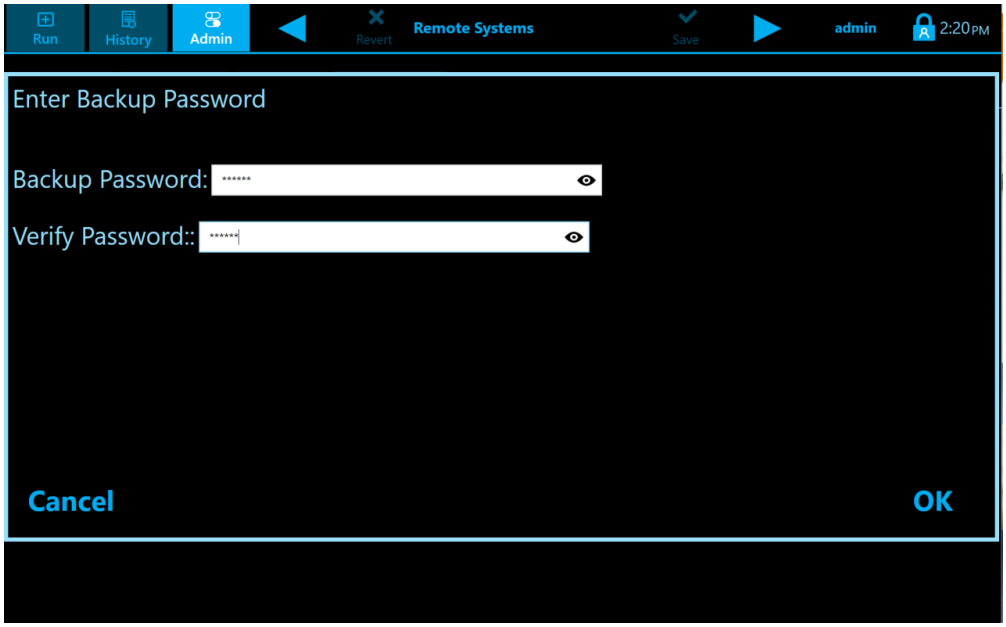

Figure 74. Enter Password for Backup File Screen

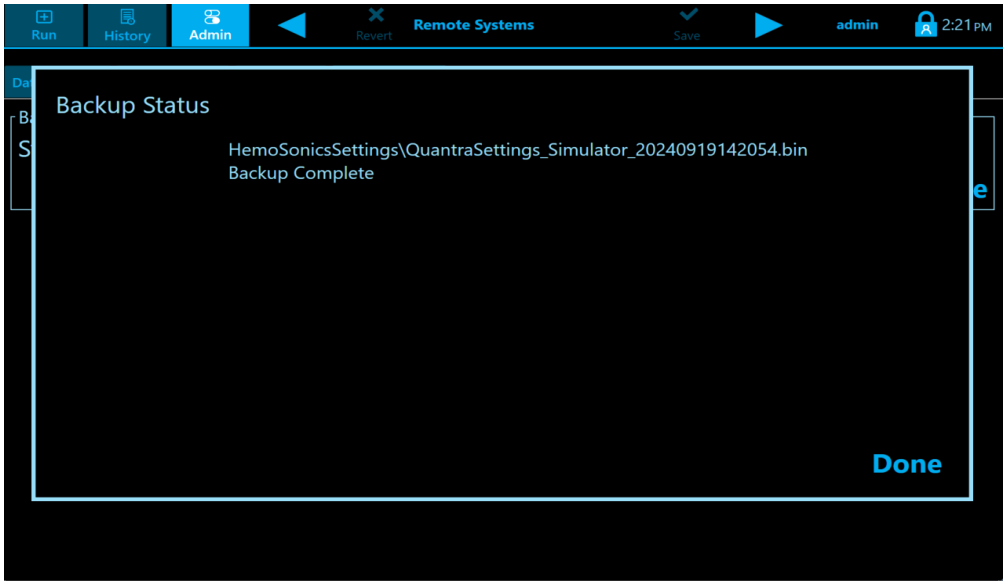

Figure 75. Backup Status Screen with Filename

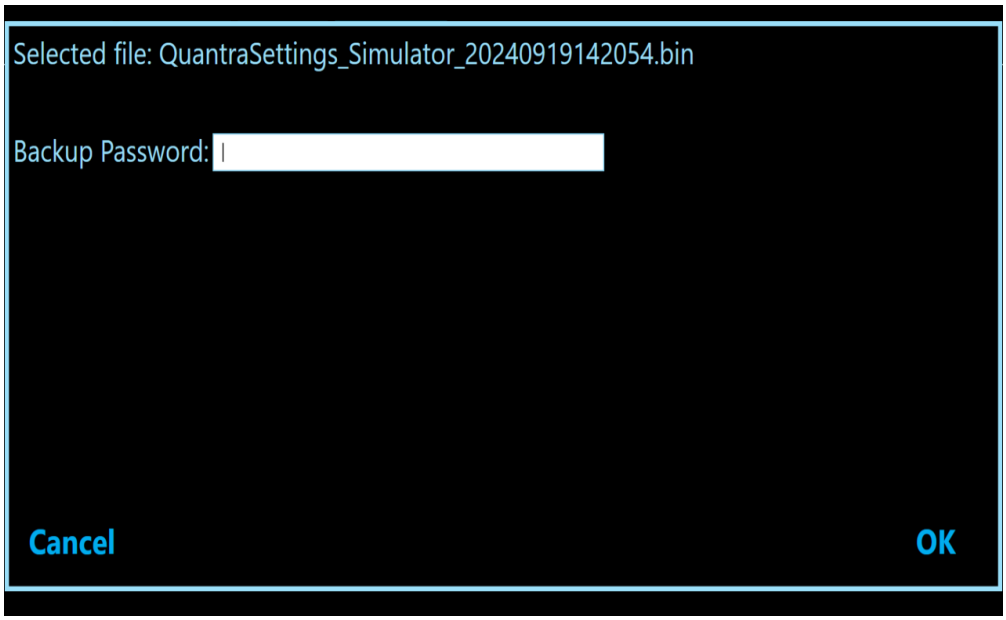

Figure 76. Enter Password for Backup File Screen

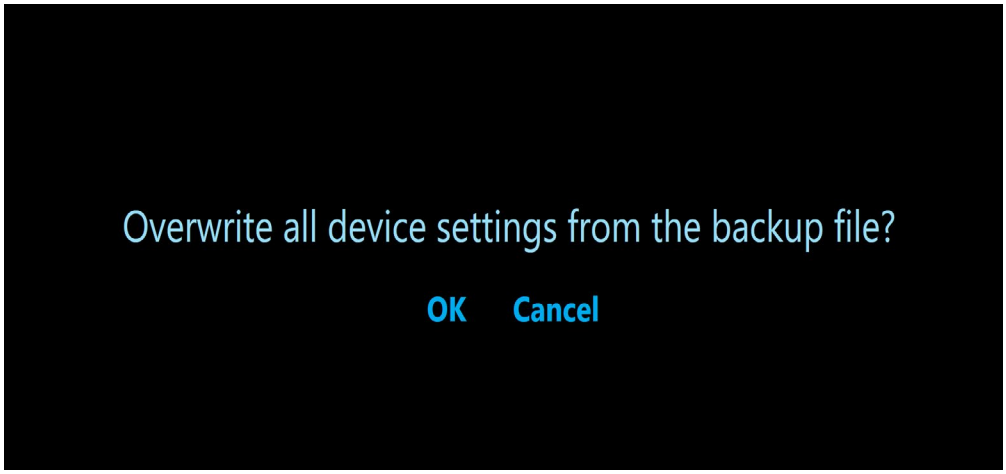

Figure 77. Overwrite Device Settings Confirmation Screen

H. Software Update

The Administrator can update the Quantra System software with the software loaded onto a USB drive. The screen displays the current software version installed (Figure 78). Follow the instructions on the update status screen to update.

1. After inserting the USB drive, click “Select Installer” to choose the software version to install on the displayed screen.
2. Select the version to install (text will be highlighted).
3. Click “OK” to install or “Cancel” to exit the screen.

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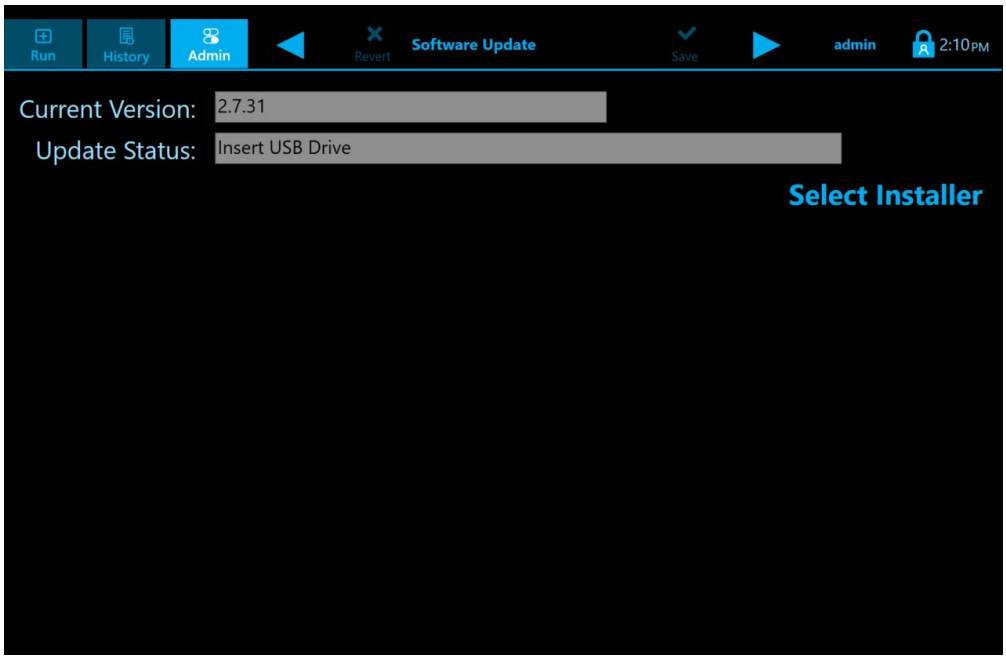

Figure 78. Software Update

14. Cybersecurity

HemoSonics assessed its cybersecurity needs by examining the Quantra System processes, identifying critical information, determining threats, analyzing vulnerabilities, and assessing risks. The following countermeasures were applied:

- Users confirm attempts to remote internet connections
- There is no internet connection to the circuit board that runs the Quantra System assay components
- Users' interaction with the Quantra System operating system is prevented by disallowing input of selected system commands
- System commands associated with sensitive information are audited
- Operating system firewall implements the specified rule list
- The Quantra System will only accept the following USB devices
  - Removable hard drives
  - HID compliant input devices
  - USB hubs
  - Printers
- The Quantra System employs write filters between the system disk partition and disk hardware to intercept attempts to write to the hard drive and then writes to a virtual drive
- Changes made to the system disk partition do not persist after system restart
- The Quantra System hard drive and its test records are encrypted

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- Exported test data are encrypted
- Users are authenticated against a list of approved user IDs
- Lockout occurs after an inactivity period, which requires user login to continue instrument interaction

The Quantra System uses Static and Dynamic Host Configuration Protocol (DHCP) to provide an Internet Protocol address (IP) and related configuration information (subnet mask, default gateway).

- Software updates and security patches are installed by way of encrypted files downloaded to a USB drive (Software Update).
- The users can neither install non-HemoSonics Quantra System software onto the Quantra Analyzer nor alter the operating system.

HemoSonics suggests the following IT security checklist to be performed by the organization's network security expert before integrating the Quantra System into their network.

1. Determine the maximum frequency interval to install routine Quantra System software updates (e.g., quarterly, yearly, as available), and the frequency to install critical software updates.
2. Assess whether an emergency access procedure is necessary. If needed, establish, validate, implement, and document the procedure.
3. Evaluate network exposure of the deployed device and configure appropriate network security for data communication. Examples are:
    a. Build barriers (e.g., firewalls) between the Quantra System, the organization's network, and the Internet.
    b. Segment the network into multiple networks and limit communication among the networks, for example, virtual LANs and demilitarized zones.
    c. Prevent the use of externally addressable IP addresses to limit exposure to the Internet.
4. Provide an environment that minimizes security threats against the networked device, along with protecting other systems that are connected to the device.

Additionally, and as a guide, HemoSonics has completed the Manufacturer Disclosure Statement for Medical Device Security (MDS^2) and included it as an appendix (Section 22). This information can assist the purchaser's information technology team assess any vulnerabilities and risks associated with the health information stored on the Quantra System when coupled to their network.

15. Maintenance

A. Overview

The Quantra System does not require frequent maintenance by the user. However, it is recommended to perform light cleaning and simple maintenance on a routine basis to maintain its reliability. The recommended cleaning schedule should be used as a general guideline. Consider adjusting the schedule based on the room's environmental condition.

The following materials are needed for maintenance of the Quantra System:

1. Quantra Cleaning Cartridge (HemoSonics REF KT-0012)

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2. The following external solutions may be used to wipe down the external surfaces of the Quantra System.
    - Bacillol AFTissues (Formulation: Propanol and Ethanol)
    - Bacillol 30Tissues (Formulation: Propanol and Ethanol)
    - Dismozon plus (Formulation: Hydrogen peroxide)
    - PDI Super Sani-Cloth - EPA REG # 9480-4 (Formulation: Quaternary ammonium and Isopropanol (IPA))
    - PDI Sani-Cloth AF3 - EPA REG # 9480-9 (Formulation: Alcohol free Quaternary ammonium)
    - Metrex CaviWipes – EPA REG # 46781-8 (Formulation: Quaternary ammonium and Isopropanol)
    - Cleaning/disinfecting solution; 10% sodium hypochlorite, Cavicide™, or 70% isopropanol.

NOTE: Other disinfectants using Quaternary Ammonium with and without alcohol, and hydrogen peroxide-based disinfectants that meet applicable country regulations/registrations may also be used. The specific disinfecting products must conform to applicable local, regional, or country regulatory requirements.

B. Regular Maintenance

As needed, based on use or the local environment, wipe down the system covers, touchscreen, and shutter with cleaning solution using a soft cloth. **NOTE:** when wiping the touchscreen, spray the cleaning solution on the cloth before applying it to the screen. Do not allow liquid to flow into the edges of the screen. It is recommended that the touchscreen be wiped dry after disinfecting to clean any leftover residue left by the disinfecting agents.

Inspect the instrument for damage to covers, touchscreen, barcode scanner, and shutter. Contact HemoSonics at (+1) (800) 280-5589 (USA) or support@hemosonics.com, if any issues are detected.

C. Weekly Maintenance

1. Use the Quantra Cleaning Cartridge (KT-0012), which has a barcode that is unique to the cleaning procedure.
2. Follow the on-screen prompts.
3. Remove the protective film covering the cleaning tape and insert the cartridge into the Quantra Analyzer.
4. Remove the cleaning cartridge when the cleaning routine is finished. “Cleaning Completed” will be displayed on screen.
5. Discard the cleaning cartridge into the biohazard container.
6. Record each run with the cleaning cartridge in the Maintenance Log Form (optional).

D. As Needed Maintenance

1. Wipe down external surfaces with disinfecting solution if the exterior of the instrument is contaminated.
2. If the internal surfaces of the Quantra Analyzer become contaminated, Contact HemoSonics at (+1) (800) 280-5589 (USA) or support@hemosonics.com.

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16. Safety Overview

Safe use of the Quantra System and successful operations are partly an outcome of proper use of the Quantra Analyzer, cartridges, external controls, and proper handling of blood samples.

A. Intended use

The Quantra Hemostasis System is for *in vitro* diagnostic use. The Quantra System is for use by professionals at the point of care or in a laboratory setting. See Intended Use/Indications for Use section for full description.

B. Technical assistance

Contact HemoSonics at (+1) (800) 280-5589 (USA) or support@hemosonics.com, if any assistance is needed.

C. Environmental Conditions

Section 17(B) describes the specific environmental conditions for storing and operating the Quantra System. If the Analyzer has been stored at a temperature outside the temperature range, allow it to equilibrate to room temperature before use.

D. Biological hazard

WARNING: Assume that all specimens, control materials, waste fluids, leaks, and spills contain potentially infectious biological material.

The unused and/or disinfected Quantra Hemostasis Analyzer is not a biohazard risk. The unit does analyze human blood samples, therefore care is recommended to handle all specimens and spills in accordance with Universal Precautions, including the use of Personal Protective Equipment (PPE), as prescribed in accordance with your standard operating procedures. Precautions are also recommended when cleaning/disinfecting the analyzer if leaks or spills occur.

Although there might not be visible spills, follow the regular maintenance in section 15(B).

E. Chemical hazard

WARNING: Storage and handling of Quantra Cartridges and HemoSonics Quality Controls shall adhere to all handling instructions on the manufacturer's package insert, including the use of Personal Protective Equipment (PPE) for all cleaning agents.

Skin or eye contact with cleaning agents may be hazardous.

F. Electrical hazard

WARNING: Only qualified service personnel are authorized to remove equipment covers or perform internal instrument adjustments.

Always adhere to basic safety precautions for electrical equipment. The operator should never remove the covers from the analyzer. Dangerous high voltages exist inside the analyzer that can harm or kill. Only HemoSonics-trained technicians are responsible for maintenance that requires removal of the covers.

Use the power cord supplied by HemoSonics and ensure connection to a grounded power source.

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G. Pinch, crush, and puncture hazards

WARNING: Keep hands away from moving parts.

Pinch and crush hazards exist in the cartridge loading area. Keep hands away from the loading area when the shutter is not closed or when clamping the cartridge.

H. Laser exposure

WARNING: Laser radiation. Do not stare into beam.

The barcode reader is a Class 2 laser.

I. Hazards from sharp objects and sharp edges

WARNING: Use extreme care when handling syringes and when near sharp edges on the instrument.

Failure to use caution near sharp objects could result in an injury. Always dispose of used cartridges in an approved sharps container of appropriate size.

J. Transporting the Analyzer

Before transporting the analyzer, ensure that the instrument has been turned off. Follow the steps in section 5(B). To set-up at another location, follow the steps in section 5(A).

NOTE: performing external QC (see previous section) after initial set-up, moving the instrument, or after servicing ensures that the Quantra System performs as specified against control material.

K. Electromagnetic Compatibility

IEC60601-1-2:2014 Class A Group 1: The Quantra System uses a medical-grade, low-voltage power supply and does not use RF transmission systems during operation. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

Use Environment – Hospitals including operating rooms, operating room hallway, healthcare laboratories, except near the RF shielded room of an ME system for magnetic resonance imaging (MRI), where the intensity of EM disturbances is high.

Consequence of high Electromagnetic Interference - If the intensity of electromagnetic interference is high, there could be a loss or degradation of signal causing internal quality control errors. If this occurs, restart the Quantra System.

HF Surgical Equipment Compatibility - The Quantra Analyzer has been tested to be compatible for operation in the vicinity of HF Surgical Equipment and can be used during HF surgery for patient sample evaluation.

Warnings related to electromagnetic compatibility:

WARNING: Use of the Quantra System adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they operate normally.

WARNING: Do not install the Quantra System in RF shielded room of an ME system for MRI. The Quantra System contains ferromagnetic components. Moving it into a strong magnetic field generated by an ME system for MRI could result in injury or death.

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WARNING: Use of accessories, transducers and cables other than those specified or provided by HemoSonics could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Table 5. Cables Associated with the Quantra System

Connected To	Location on Instrument	Length
Bar Code Reader	Back Panel	52 or 60 inches
NEMA 5-15P Hospital Grade	Back Panel	6 feet
Ethernet CAT-6 Port	Back Panel	6 feet
USB Flash Drive	Front Panel	3 inches
DS457 – Bar Code Reader	Back Panel	9 feet

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Quantra System, including cables specified by HemoSonics. Otherwise, the Quantra Systems performance could be degraded.

Electrostatic Discharge Considerations

With the buildup of electrostatic charge, a potential conductive contact or sparking might result in an Electrostatic Discharge (ESD) event to the Quantra System.

In the laboratory, artificial-induced high-voltage ESD can cause the screen of the Quantra System to flicker. In all test cases, the Analyzer returned to normal operation after the flickering event. If the screen flickers, the operator should wait for the screen to resume normal function before continuing with the test operation.

Implement the following precautions to reduce the risk for ESD events to medical instrumentation:

- Maintain constant RH% in your operating environment within industry recommended limits.
- Since synthetic garments are more prone to charge build-up, consider wearing garments that use natural fibers.
- Avoid operating medical instrumentation in rooms with carpet or flooring materials known to produce static charge

NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required), this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or reorienting the equipment.

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17. Instrument Specifications

A. Electrical Specifications

- Voltage — 100-240 V ~
- Current — 1.3 A
- Power — Input Maximum 250 Watts
- Frequency — 50/60 Hz
- Power Connection Standard — 3-prong grounded
- Fuse — 2.0 A; 250 VAC; Fuse location is between the power cord input and main power switch. To replace the two fuses, detach the AC power cord, compress the two tabs and pull out.
- Power Consumable — 102W peak operating/40W standby
- Voltage Dropout — Withstands a 70% voltage dip for at least 500 milliseconds.

B. Environmental Requirements

- Heat output — 75 Watts
- Operating Temperature — 15° to 32° C
- Relative Humidity — 20 to 85%
- Altitude — Sea level to 1800 m
- Location — Flat level surface. Indoor use only. Remove from sources of direct heat, moisture, and sunlight.

C. Physical Characteristics

- Size (W x D x H) — 12 in. x 14 in. x 19.25 in. (30 cm X 36 cm X 49 cm)
- Weight — 36 lbs. (16.5 kg)
- Clearance — Top 1 in. (2.5 cm), Sides 2.25 in. (5.5 cm), Rear 2.25 in. (5.5 cm)
- Noise Level — The maximum volume level is **approximately 55 decibels**

D. Data Input and Output

- 2-USB in the rear, 1-USB in front
- 1- RJ45 in the rear

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18. Accessories

- Power cord and Barcode Scanner Kit: REF KT-0037
- Quantra Cleaning Cartridge: REF KT-0012
- Quantra Printer: REF KT-0015
- QPlus Cartridge Kit of 10: REF KT-0004
- QStat Cartridge Kit of 10: REF KT-0020
- QPlus Control Level 1 Kit of 4: REF KT-0023
- QPlus Control Level 2 Kit of 4: REF KT-0025
- QStat Control Level 1 Kit of 4: REF KT-0027
- QStat Control Level 2 Kit of 4: REF KT-0032
- Quantra Desktop Remote Viewer: REF KT-0039

For information and to order Quantra System accessories, contact HemoSonics LLC Contact HemoSonics, LLC (+1) (800) 280-5589 (USA).

19. Non-System Related Accessories

A. Uninterruptible Power Supply (UPS): REF KT-0043

An Uninterruptible Power Supply (UPS) is available for purchase for use with the Quantra Analyzer. When used properly, it provides up to 30 minutes of use in the event there is a main power source outage or when disconnected from the main power source.

NOTE: Before running a test on the Quantra System, ensure there is sufficient charge in the UPS; otherwise, the UPS may not provide power up to 30 minutes in the event of a power outage. The UPS passively charges while plugged into wall power. It takes about 8 hours of charging to reach its peak capacity. The user display (4) on Figure 78 shows UPS information, current load, estimated runtime, battery information. To maintain optimal battery charge, leave the UPS plugged into an AC outlet at all times.

To Install UPS System for Use with the Quantra System:

1. Level the instrument.
2. Remove UPS product from packaging and verify no visible damage occurred to the UPS unit during shipping.
3. Set aside the USB and Serial Cable supplied with the UPS. These are supplied by the UPS manufacturer; however, they will not be needed for use with the Quantra System.
4. Place the UPS in a desired location next to the Quantra System. Only connect one UPS to one Quantra Analyzer.
5. Connect the main power cord from the back of the Quantra Analyzer into the UPS (8 on Figure 78. UPS Schematic). Ensure no other equipment is connected to the UPS other than the one Quantra Analyzer.

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6. Connect the AC inlet cable (12 on Figure 78. UPS Schematic) of the UPS into the 120V wall power.
7. Turn on the UPS by depressing the main power button (1 on Figure 79) located on the front of the unit.
8. The Quantra System may now be used as normal.

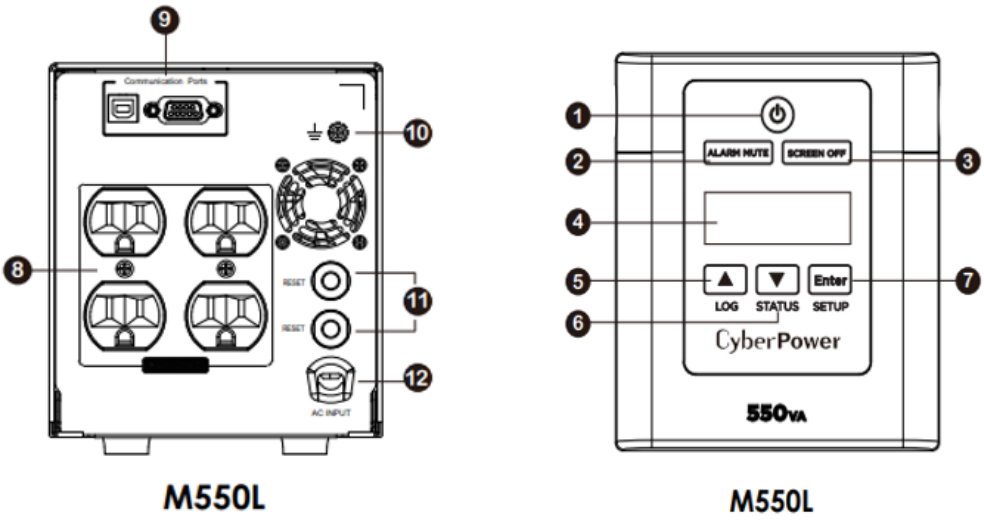

Figure 79. UPS Schematic (left is back panel; right is the front panel)

Contact HemoSonics, LLC (+1) 800-280-5589 (USA), for information and ordering Quantra System accessories.

20. Troubleshooting

A. General

If I forgot my User ID, how can I run a test?

- An administrator would reassign a User ID or uncheck the “Enable Authentication” option
- Administrator logs in with their User ID
- Select the “Admin” tab
- Locate the User ID, reset or remind user
- Or disable “Enable Authentication”. This allows all User ID's to run tests.

What if the shutter door is left open for a prolonged time?

- Run a cleaning cartridge to remove any debris the fan may have pulled in.

Should I hear the instrument running? Is it supposed to be this loud?

- Certain phases of the Quantra operation are louder than others. Usually, when there is mechanical movement (shutter movement, cartridge insertion and docking) and when the ultrasound is on, there may be increased fan speed and noise.

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A black window appears on the screen

- An error has occurred. Follow procedures in the Restart section (see below).

The touch screen doesn't respond and appears frozen.

- If a test is running, attempt to disconnect and reconnect the barcode scanner cable from the instrument to resolve the issue.
- If unsuccessful, wait for the test to finish and the cartridge to eject.
- To restart the instrument, press the front CPU Power Button and wait until the power button LED turns Off. Then, repress the CPU Power Button to turn on the instrument.

On rare occasions, the screen is fuzzy.

- Follow procedures to Restart.

When switching from non-administrator to an administrator user, the ADMIN button is not enabled

- Wait until system initialization finishes before switching to a different user type.

A warning message appears on the screen that the RAM is full

- Follow procedures in the Restart section (see below) to reset the RAM.

Must the barcode scanner be used in the manner configured at setup?

- The external barcode scanner can be mounted on either the right or left side of the instrument. (The scanner can be replaced or moved by unplugging the USB cord from the rear of the Quantra System and plugging in the USB cord of the replacement or repositioned unit.) To read a barcode, press the button to activate the laser scanning beam.

What happens if a Patient ID is viewed as a Control Material number?

- Click the box that indicates using the entry as a Patient ID.

Network connections are unreliable, or there are system verification failures when connecting.

- Try using a different DHCP address not in the 10.11.11.0/24 subnet range.

Can I switch to an earlier version of Quantra software after updating to a newer version?

- Versions of Quantra software prior to 1.10.29 are not compatible to run QPlus Control products (e.g. QPL1 and QPL2). If a user wishes to downgrade to an earlier software version, the instrument must be returned to the appropriate factory defaults.

Why does the clock time on the Analyzer not retain its setting?

- This could indicate a battery failure that powers the CMOS chip on the computer board. Call technical support (HemoSonics LLC at (+1) 800-280-5589 (USA)) or contact support@hemosonics.com

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B. Start Up

What happens if the instrument takes too long to start up?

- The instrument should complete initialization in under 20 minutes. If initialization does not finish within this time, press the button on the front of the instrument to cycle the power (Restart).

What items should be noted for cartridge inspection before running?

- Ensure the foil pouch containing the cartridge is still airtight. Look for an intact seal on both ends and any holes in the outer packaging. Do not use a cartridge if the foil pouch is not intact.
- Ensure the pressure-sensitive adhesive (PSA) covers the reagent wells of all 4 channels. The PSA should be completely flat without creases or bubbles.
- Make sure there are reagent beads (LyoSpheres) in the wells. There should be 2 beads in channels 1, 2, and 4, but channel 3 only has 1 bead.

What should be done if the needle guard is loose?

- Do not use the cartridge if the needle guard is loose. If the sample is attached while the guard becomes loose, complete the test, take a photo of the cartridge, record the lot number, and discard the cartridge. Send the collected information to HemoSonics.

During POST, the system stops and indicates that another operation is running.

- If this occurs, press the button on the front of the instrument to cycle the power (Restart).

During login, switching from a non-administrator to an administrator does not cause a switch?

- If this occurs, restart the Quantra System and wait until the initialization completes before switching from a non-admin to an admin user.

During the power-up of a “cold” Quantra System, there is an Instrument Failure?

- If this occurs, press the button on the front of the instrument to cycle the power (Restart). When cold, the temperature reading difference on paired thermistors might read greater than specified.

C. Run

If I entered an incorrect patient ID, can it be corrected?

- Corrections can be made when asked to confirm entered patient ID and cartridge ID information. Once the patient ID is confirmed, it cannot be edited.

What do I do if I’m locked out during a test run?

- To unlock, enter or scan your user ID.
- The instrument can be configured to lock out users after an inactivity interval. The administrator can adjust this interval.
- The administrator logs into the Quantra System
- Select the “Admin” tab

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- Select “Instrument”, adjust the minutes of inactivity, or enter "0" for no lockout.

What happens if the Analyzer does not eject the cartridge after finishing the run?

- Follow the instructions to perform a restart. When the device has completed its system reboot, the cartridge will eject.
- The device will also give a system error. To clear this error, restart the machine. After the system initialization, the device will be ready to run.

What does an air leak look like?

- An air leak can be caused by a defective cartridge when 1) the bonding between components is not airtight, 2) the tape covering the beads has gaps, or 3) the sample tube is not fully seated against the needle/seal assembly (user error). An air leak causes the test to end early. Depending on the leak’s location, varying amounts of blood will be drawn into the cartridge Heating Chamber (see Figure 2).
- The system will report an Instrument Error during Preparing Sample.

What do Instrument Failure and Test errors look like? What do I do if I get one?

- Cartridge fill errors may lead to an “Instrument Failure” or “Test Error” message that necessitates a Restart. Check that the bubble in the bubble level is within the lines and that the instrument is not tilted. The following may be observed when the cartridge is removed:
- Very little blood enters the cartridge.
- Bubbles may be present in the Test Chambers (see Figure 2).
- One Test Chamber does not fill, but the rest of the Test Chambers fill correctly. In this instance, the test runs normally for all channels except the one that did not fill. The data from the other channels with completed runs can be used.

When the device started running, the sample blood is pulled into the inlet vent path instead of into Reservoir 1. What do I do?

- This can occur if samples were not properly pressurized. If the cap from the sample tube has been removed, then recapped, a positive pressure might occur. Equalize pressure by inserting a hypodermic needle into the tube cap to vent the pressure. This does not cause the machine to error but renders the cartridge unusable. Vent the sample and rerun with a new cartridge.

What happens if the Quantra System loses power or is shutdown during a run?

- If power is lost during a run, the run will not be recorded. The user may log this for their institution’s record. The cartridge might not be ejected depending on when the power is lost. When power is restored to the machine, follow the procedures to restart to eject the cartridge and perform a system check.

What happens if blood leaks from the cartridge?

- Blood leaks from the cartridge are extremely rare. If blood leaks from the sample tube, it will be localized within the sample tube guide due to the presence of a washer.
- Blood can leak from the cartridge if a filter in the cartridge is missing. In this instance, blood may contaminate the manifold area of the Quantra System. This will cause a system failure

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with a system shutdown. Contact HemoSonics at (+1) (800) 280-5589 (USA) or support@hemosonics.com if this occurs.

How can I see a message if the displayed screen keyboard blocks the message?

- If this occurs, close the keyboard.

An error occurs when inserting a cartridge into the Quantra System.

- This is an infrequent occurrence. If it happens, restart the Quantra System. If the problem persists, call technical support (HemoSonics LLC at (+1) 800-280-5589 (USA)) or support@hemosonics.com .

When running the Quantra Desktop Remote Viewer the viewer closes and displays the sign on screen.

- This is an infrequent occurrence. If it happens, simply log onto the desktop remote viewer.
- The Quantra System crashes when inserting a USB memory stick. Restart the Quantra System.

D. Restart

1. Press the CPU Power Button in front of the Quantra System once to shut down the Analyzer.
2. After the Analyzer powers off (the CPU Power Button LED will turn off), press the CPU Power Button again to restart the Analyzer.
3. If a test was running when the screen freezes, use the History button on the upper Taskbar to retrieve the results of that test run.
4. Under certain circumstances, (e.g., when ejecting a cartridge on a restart) a second restart may be needed to reset the Analyzer and run internal QC (system verification).

21. Disposal of Analyzer

If you purchased HemoSonics branded electrical or electronic products and intend to discard these products at the end of their useful life, please do not dispose of them in the municipal waste. HemoSonics has labeled its branded electronic products with the Waste Electronic and Electrical Equipment (WEEE) Symbol (Figure 80) to alert customers that products bearing this label should **not** be disposed of in a landfill or with municipal or household waste. Instead, contact HemoSonics for disposal instructions or collection arrangements.



Figure 80. WEEE Symbol

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22. Appendices

A. The Manufacturer Disclosure Statement for Medical Device Security (MDS2) per ANSI/NEMA HN 1-2019

The Manufacturer Disclosure Statement for Medical Device Security (MDS^2) to assist information technology team in assessing any vulnerabilities and risks associated with the health information stored on the Quantra System when coupled to their network. To obtain a copy of the full document, please contact HemoSonics, LLC.

B. General Quantra System Software Troubleshooting

The following is a summary of known software anomalies and their mitigations.

Description	Mitigation
After establishing a Remote Desktop Connection, when canceling the remote data connection, a System Null Reference Exception error might occur. A Quantra System Recovery screen is displayed.	In the Quantra System Recovery screen, choose "Restart" to restart the Quantra Analyzer.
Using the POCT interface an error occurred. When transferring a near maximum number of stored records over the POCT interface, an error can occur.	Retry transfer. Usually transfer over POCT is a record at a time. Transferring a large number of files at a single time should be rare.
If the front power button is pressed quickly after the main switch in the rear is toggled on, a start-up error can occur.	After turning on the main switch in the rear, wait 5 seconds before pressing the button on the front panel.
It is theoretically possible that when setting the date and time close to midnight, that the timing lag when setting up the remote data service can occur after midnight has been reached. This could result in the instrument being set a day behind.	When setting the date and time on a remote instrument, avoid setting it when the time nears midnight.
If a user turns off the main switch before the LED on the front power button is off, the event log becomes corrupt and is replaced with an empty event log. The data loss is not recoverable.	After turning off the power switch in the front, wait until the LED is off before toggling the switch off in the rear.
When exporting QC History, the instrument stops working and displays a recovery application.	In the Quantra System Recovery screen, choose "Restart" to restart the Quantra Analyzer.
When in the QC History screen, none of the results columns can be sorted ascending or descending.	The sorting mechanism looks for input text (words). It does not sort by numerical value.
The dials screen for a test does not display dials.	This occurs when a query for tests is in progress as a new test is started. The results analysis service becomes unresponsive. Restarting the

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Description	Mitigation
	Quantra System restores the function. The results of the test run are available in History.
User not automatically logged out of QDRV on computer	User to consult IT department to configure their Windows computer to log out automatically.
Target range end values might overlap on the dials display if the target range is narrow.	In the configuration of the control material's target range lot, check the values to ascertain that the range is correct and is narrow.
The operator and patient lists on the Quantra System might temporarily become unsynchronized with the POCT when the connection to the POCT is disconnected and then reconnected.	Wait for the synchronization to be reestablished with POCT.
When entering the target range for control materials, if entering a single value for a parameter, both input boxes are bordered in red. In rare instances only one of the two input boxes is bordered in red.	This software anomaly is being investigated.
The cartridge open pouch viability expiration message is not displayed when in the patient confirmation screen.	User to edit and/or confirm patient information to move on to the next screen as quickly as possible.
After scanning a cartridge, the Quantra System software stops functioning.	User to restart the Quantra System following the instructions in the Troubleshooting section.
Service Tab Test Connection Logic is Not correct	To be resolved in a future release
QSTAT/OB Admin Cartridge Profile Disabled Glitch	Included workaround in user manual.

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C. Maintenance Log

Quantra System Maintenance

Month: _____ Year:_____

Day of Month

Regular Maintenance:	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Clean Outer Surface																
Clean Touchscreen																
Clean Shutter																
Check Barcode scanner																

Regular Maintenance:	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Clean Outer Surface															
Clean Touchscreen															
Clean Shutter															
Check Barcode scanner															

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Weekly Maintenance:	Wk 1	Wk 2	Wk 3	Wk 4
Run cleaning cartridge				

Monthly Maintenance:

Reboot Quantra Analyzer	**Date:**	**Performed By:**

Reviewed By: _____ Date: _____

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D. External QC Log

QPlus Cartridge QC Log

External QC	Quantra System S/N _____	QPlus Cartridge	Level 1 or 2 (circle)	Lot # _____	Expiration:_____
Range:	CT:_____s	CTH:_____s	CS:_____hPa	FCS:_____hPa	

Date	Op Init	CT Result	Pass (Y/N)	CTH Result	Pass (Y/N)	CS Result	Pass (Y/N)	FCS Result	Pass (Y/N)	Overall P/F and comment:

Reviewed by: _____

Comments:

_____

_____

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QStat Cartridge QC Log

External QC	Quantra System S/N _____	QStat Cartridge	Level 1 or 2 (circle)	Lot # _____	Expiration:_____
Range:	CT:_____s	CSL:_____%	CS:_____hPa	FCS:_____hPa	

Date	Op Init	CT Result	Pass (Y/N)	CSL Result	Pass (Y/N)	CS Result	Pass (Y/N)	FCS Result	Pass (Y/N)	Overall P/F and comment:

Reviewed by: _____

Comments:

_____

_____

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E. Patient Download CSV Contents

Common Columns:

Name	Description	example
Instrument	Serial number of the instrument	SN00014
Version	Software version number (about screen)	1.10.5
Cartridge Type	QPlus or QStat	QPlus
Cartridge Lot	10-digit Cartridge Lot code	2017010101
Cartridge Expiration	expiration date for the cartridge lot (formatted per Quantra date format setting)	01/01/2088
User ID	User ID who ran the test	Johnny Tester
Date Time	Local (per Quantra) date time for the start of test	04/30/2018 8:00 PM
Date Time (UTC)	UTC date time for the start of the test	04/30/2018 3:00 PM
Patient ID	Patient ID for the test (other Patient data will not be included)	PT0000TEST
Test Duration (sec)	Elapsed duration of the test in seconds	907

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QPlus Columns:

Name	Description	example
QPlus CTH	Result formatted as text print	* 82 s
QPlus CTH Reference	range as: [min - max] s	[103 - 153] s
QPlus CTH Reportable	range as: [min - max] s	[60 - 480] s
QPlus CT	Result formatted as text print	** < 60 s
QPlus CT Reference	range as: [min - max] s	[104 - 166] s
QPlus CT Reportable	range as: [min - max] s	[60 - 480] s
QPlus CTR	Result formatted as text print	Not Computable
QPlus CTR Reference	range as: [min - max]	[]
QPlus CTR Reportable	range as: [min - max]	[0.8 - 4.0]
QPlus CS	Result formatted as text print	23.1 hPa
QPlus CS Reference	range as: [min - max] hPa	[13.0 - 33.2] hPa

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QPlus CS Reportable	range as: [min - max] hPa	[2.0 - 65.0] hPa
QPlus PCS	Result formatted as text print	20.8 hPa
QPlus PCS Reference	range as: [min - max] hPa	[11.9 - 29.8] hPa
QPlus PCS Reportable	range as: [min - max] hPa	[2.0 - 50.0 hPa]
QPlus FCS	Result formatted as text print	2.4 hPa
QPlus FCS Reference	range as: [min - max] hPa	[1.0 - 3.7] hPa
QPlus FCS Reportable	range as: [min - max] hPa	[0.2 - 30.0] hPa

Note: All columns that include the SVC prefix are for diagnostic use by HemoSonics technical support.

User can ignore these columns or remove them from the CSV file.

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23. Product Instructions for Use Appendices

- DMP-0210 Quantra Cleaning Cartridge IFU
- DMP-0241 QPlus Cartridge Kit IFU
- DMP-0274 QStat Cartridge Kit IFU
- DMP-0355 QPlus Control Level 1 Kit IFU
- DMP-0356 QPlus Control Level 2 Kit IFU
- DMP-0405 QStat Control Level 1 Kit IFU
- DMP-0406 QStat Control Level 2 Kit IFU
- DMP-0476 Quantra Desktop Remote Viewer IFU
- DMP-0239 Quantra Printer IFU

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