

# Products International | HemoSonics

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June 22, 2023



The Quantra System is the only whole blood hemostasis analyzer cleared by the FDA for use in **cardiac, trauma, liver transplantation, and major orthopedic surgeries** – making Quantra a truly comprehensive solution for **system-wide bleeding management**<sup>(1-3)</sup>.

- **Broadest indications** of any cartridge-based whole blood hemostasis analyzer<sup>(3)</sup>
- **Fastest** turnaround time<sup>(4-7)</sup>
- **Easy-to-read, actionable results** when time is critical<sup>(8,9)</sup>
- **Flexibility** to test in a variety of acute care settings<sup>(3,10)</sup>
- **Compact, easy** to use cartridge-based system<sup>(10)</sup>

Easily standardize across your health system to provide goal-directed therapy and help optimize blood product usage

## The Next Generation of Viscoelastic Hemostasis Testing

- Proprietary ultrasound technology directly measures changes in viscoelastic properties of a whole blood sample<sup>(3,7,11)</sup>

- Fully automated, sealed system<sup>(1-3)</sup>
- Flexible for any space; robust to vibration, fast start-up<sup>(3)</sup>
- Quick to learn - after a short, 30-minute training, new users were able to read and interpret the results of QPlus and QStat dials displayed with 95% proficiency<sup>(8,9)</sup>
- Simple three step workflow with **hands-on time of <1 minute**<sup>(3)</sup>
- Run samples directly from blue-top tubes; no wait time after draw, no pipetting<sup>(3)</sup>
- Strong correlation with applicable standard laboratory tests and VET systems<sup>(5-7,12-16)</sup>
- Easy to read, actionable results screens<sup>(8,9)</sup>
- Built-in electronic Quality Controls run every 8 hours; two levels of external biological Quality Controls<sup>(3,10)</sup>
- Integrates into existing IT infrastructure<sup>(17)</sup>
- Remote access to real-time and historical results with Quantra Desktop Remote Viewer (QDRV)<sup>(18)</sup>



## Expanded Menu of Cartridge Tests for Hemostasis Monitoring in Critical Care Settings





## Cardiovascular and Major Orthopedic Surgery

### QPlus Cartridge Time Parameters<sup>(1)</sup>:

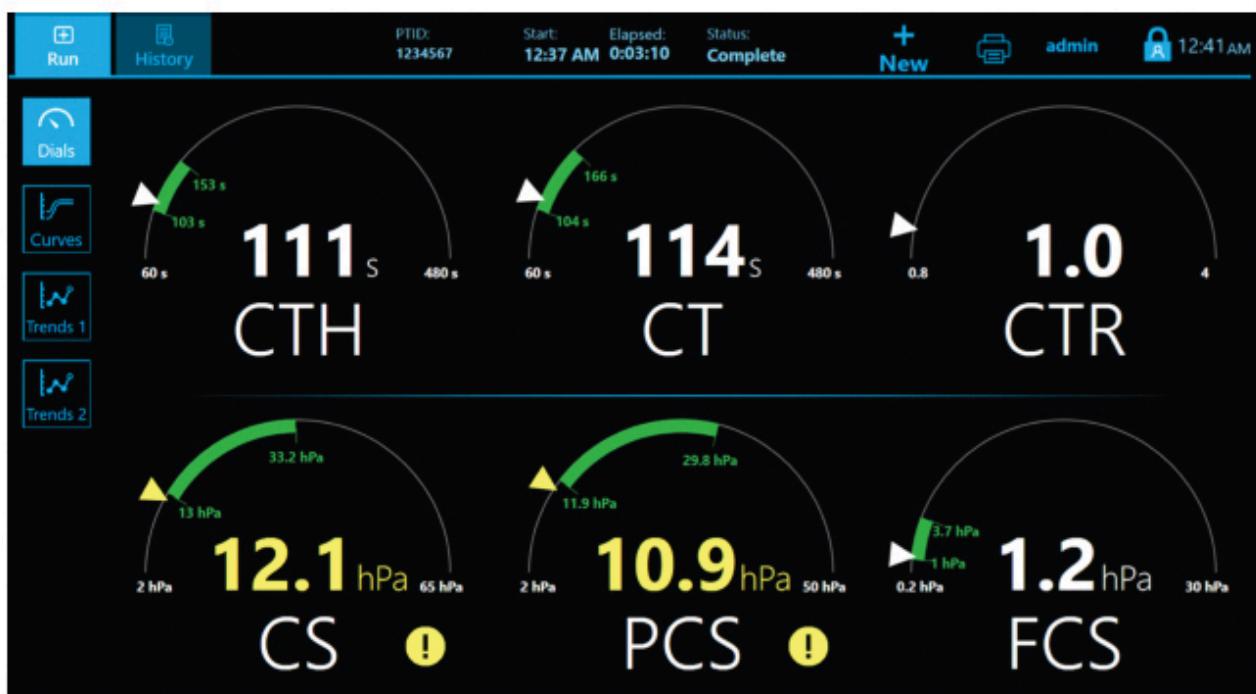
- **CT:** Clot time
- **CTH:** Clot Time with Heparinase
- **CTR:** Clot Time Ratio

### Initial results in ~5 minutes

- **CS:** Clot Stiffness
- **PCS:** Platelet contribution to Clot Stiffness
- **FCS:** Fibrinogen contribution to Clot Stiffness

### Complete results in ~12.5 minutes

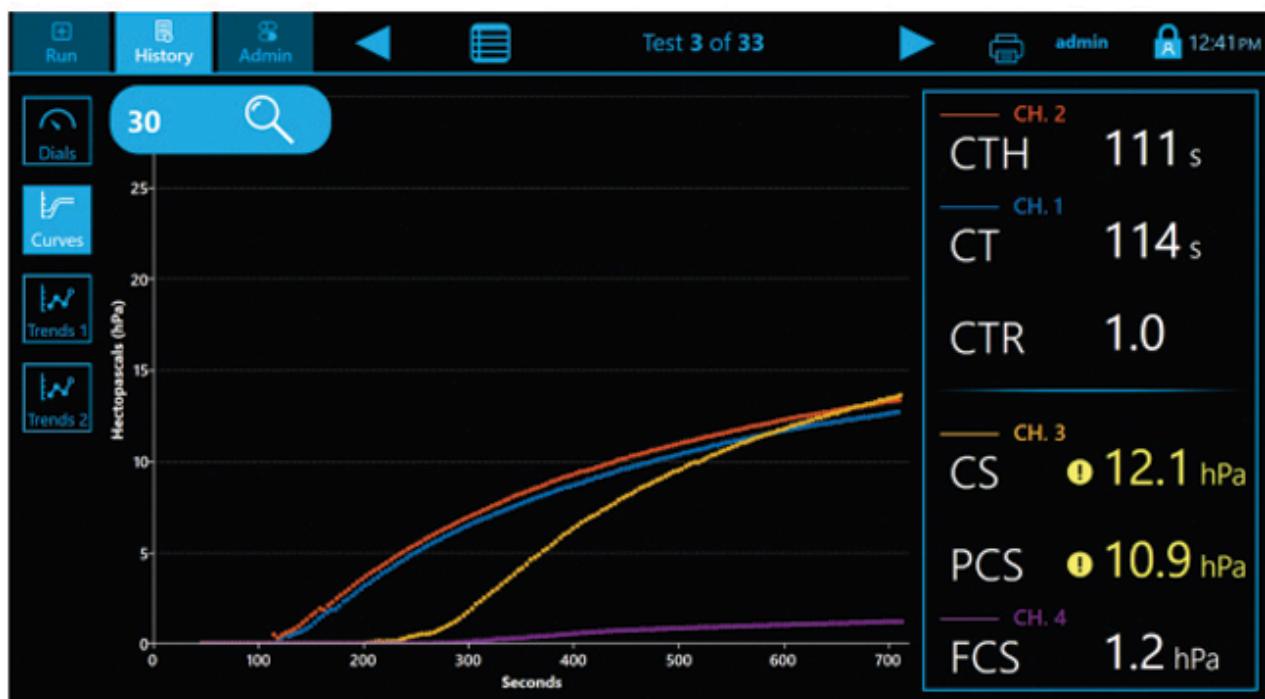
Dials



## Trends



## Curves



The Quantra System is currently the only VET system that directly outputs both Fibrinogen (FCS) and Platelet (PCS) Contributions to Clot Stiffness in one cartridge, helping clinicians better determine which blood products may be needed for individual patients.<sup>(1,19)</sup>

## Now Available!

**sthemE Qualiris** by Stago is a trusted External Quality Assessment (EQA) Proficiency Testing program designed to support hemostasis and thrombosis testing worldwide. For the Quantra System and QPlus Cartridge, Qualiris offers a proficiency testing program which runs in the Spring and Fall that is both comprehensive and easy-to-use. This program **enables laboratories to confidently perform external quality assessments** and review detailed comparisons among a diverse global peer group.



Vial Q 1 - Batch 3000002263 Exp. 2/27/2025

Overall participants		p (nb)	x* (Mean)	s* (SD)	CV	U (xpt)
Global	FCS	63	23.0	1.59	6.9	0.5
Peer group	QPLUS CARTRIDGE - QUANTRA ANALYSERS	63	23.0	1.59	6.9	0.5

Your result **22.6**

Legend : A B C

	D (Bias) %	Z score	Alarm
Global	FCS	-1.9	-0.28
Peer group	QPLUS CARTRIDGE - QUANTRA ANALYSERS	-1.9	-0.28

Overall participants

hPa

Recorded changes / Expiry date alert (Automatic update)

N/A

### Vial Q 1 Tested on 5/1/2024

		p (nb)	x* (Mean)	Your result	Alarm
CTH QPLUS CARTRIDGE - QUANTRA ANALYSERS	s	62	132.7	133.0	✓
CT QPLUS CARTRIDGE - QUANTRA ANALYSERS	s	63	131.0	132.0	✓
CS QPLUS CARTRIDGE - QUANTRA ANALYSERS	hPa	64	21.6	21.0	✓
FCS QPLUS CARTRIDGE - QUANTRA ANALYSERS	hPa	63	23.0	22.6	✓

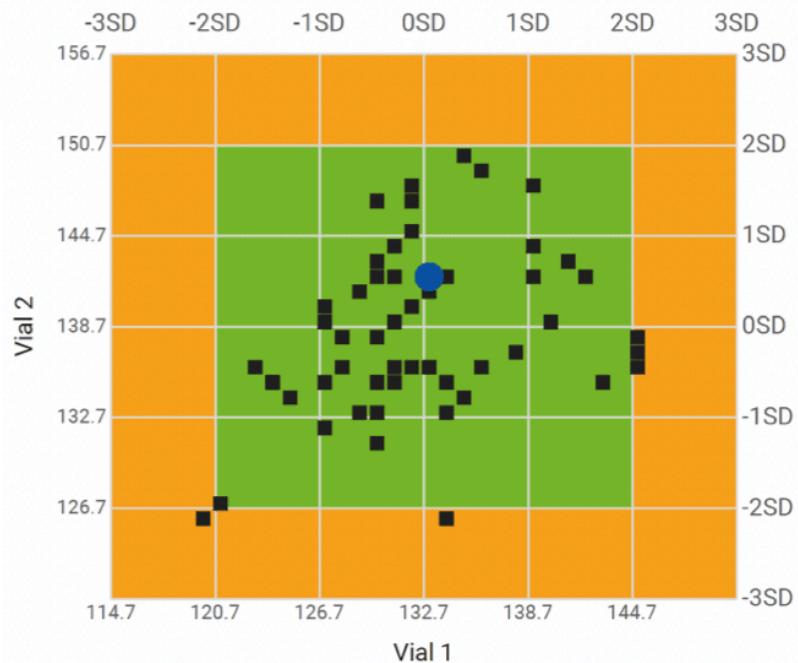
### Vial Q 2 Tested on 5/1/2024

		p (nb)	x* (Mean)	Your result	Alarm
CTH QPLUS CARTRIDGE - QUANTRA ANALYSERS	s	62	138.7	142.0	✓
CT QPLUS CARTRIDGE - QUANTRA ANALYSERS	s	64	213.3	213.0	✓
CS QPLUS CARTRIDGE - QUANTRA ANALYSERS	hPa	63	13.4	13.7	✓
FCS QPLUS CARTRIDGE - QUANTRA ANALYSERS	hPa	63	14.0	15.0	✓

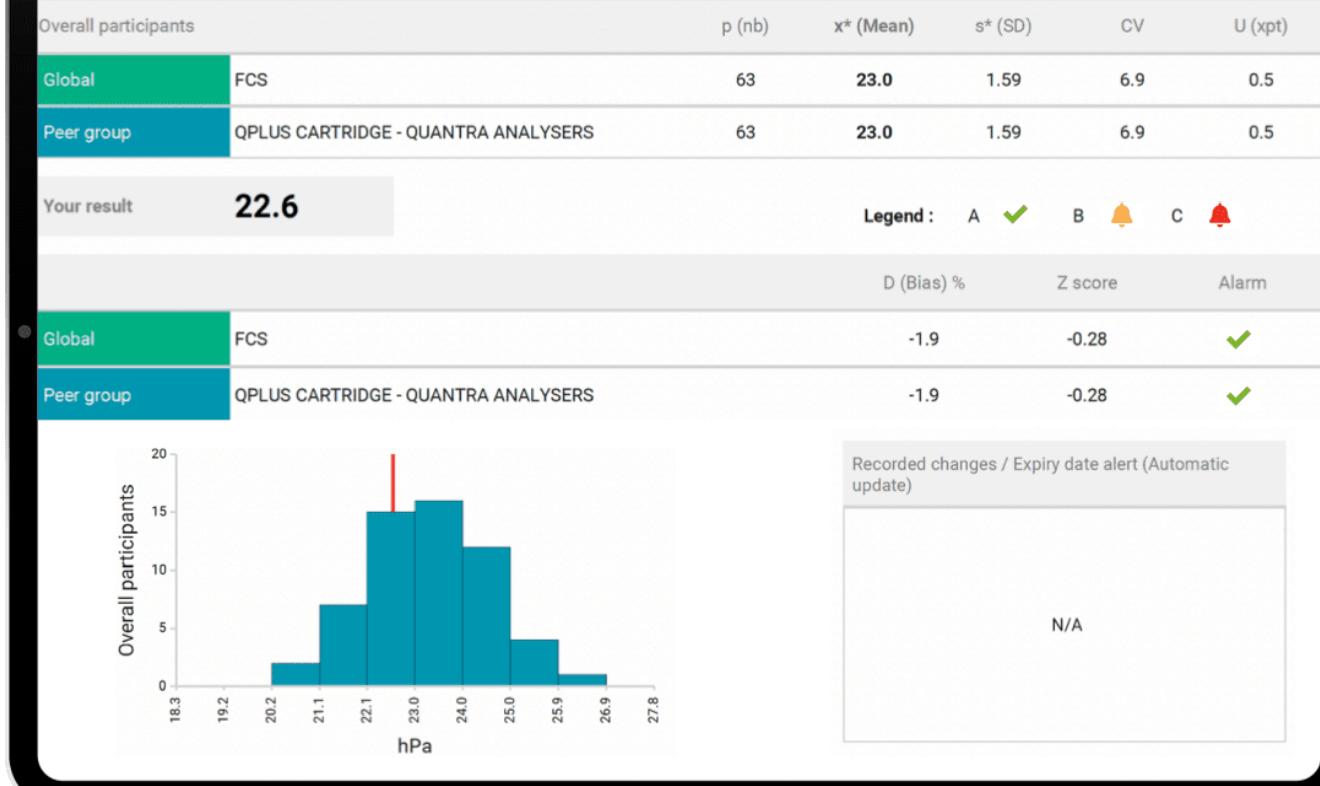
## "YOUDEN PLOT" graphs

CTH --- s

- QPLUS CARTRIDGE - QUANTRA ANALYSERS
- My Result



Vial Q 1 - Batch 3000002263 Exp. 2/27/2025



### Colored indicators and in-depth charts to quickly identify assay performance

Synthesis per level annual report<sup>1</sup>

### Vial Q 1 Tested on 5/1/2024

		p (nb)	x* (Mean)	Your result	Alarm
CTH QPLUS CARTRIDGE - QUANTRA ANALYSERS	s	62	132.7	133.0	✓
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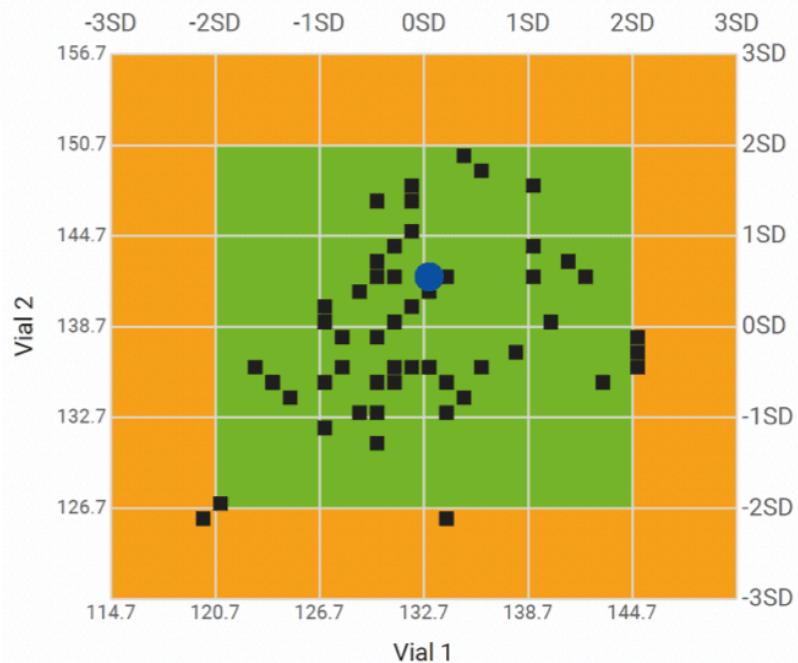
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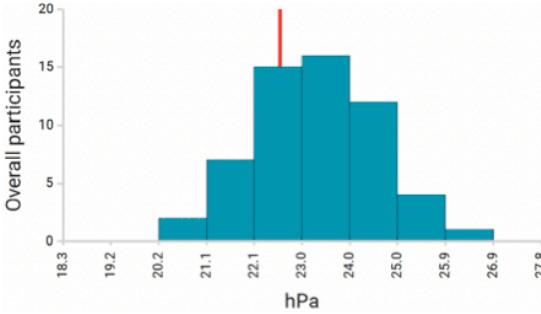
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Your result		<b>22.6</b>	Legend : A  B  C 			
			D (Bias) %	Z score	Alarm	
Global	FCS		-1.9	-0.28		
Peer group	QPLUS CARTRIDGE - QUANTRA ANALYSERS		-1.9	-0.28		
		Recorded changes / Expiry date alert (Automatic update) N/A				

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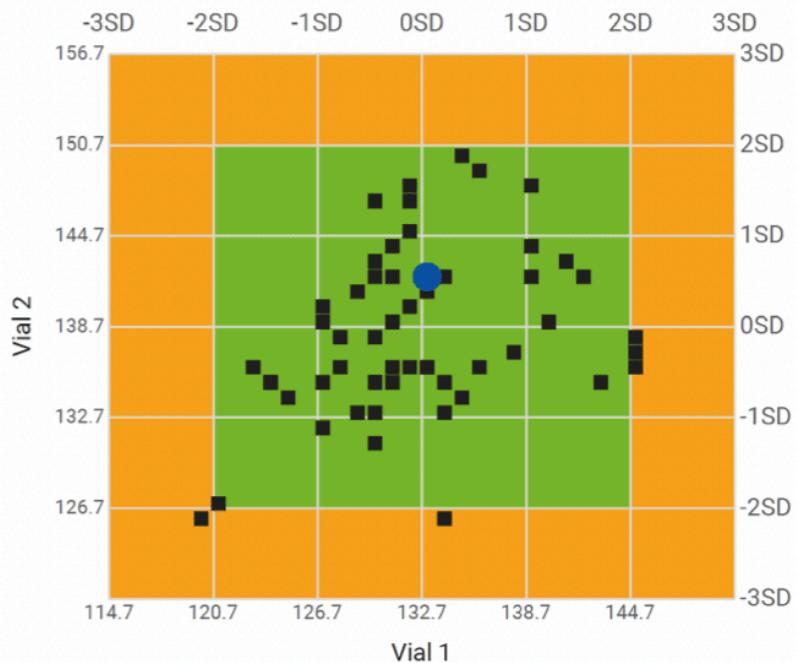
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## "YOUTEN PLOT" graphs

CTH---S

- QPLUS CARTRIDGE - QUANTRA
- ANALYSERS
- My Result



[Explore Qualiris](#)

<sup>1</sup>Not concerned by accreditation



## Trauma and Liver Transplantation

QStat Cartridge time to results<sup>(2)</sup>:

CT: Clot Time

Initial results in ~ 5 minutes

- **CS:** Clot Stiffness
- **FCS:** Fibrinogen contribution to Clot Stiffness
- **PCS:** Platelet contribution to Clot Stiffness

Results in ~ 12.5 minutes

**CSL:** Clot Stability to Lysis

Lysis results in 25 – 60 minutes

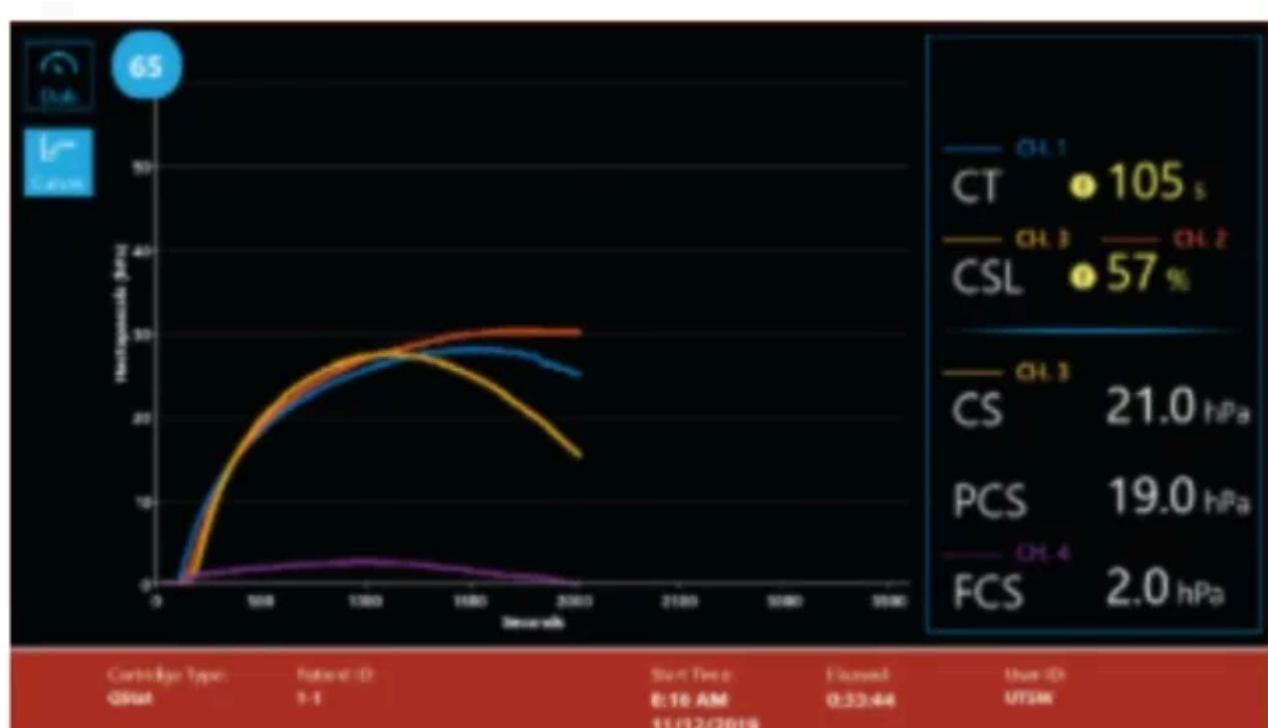
Dials



Trends



Curves



Multiple display screens present a comprehensive review of results for easy interpretation.<sup>(3)</sup>



## Technical Specifications

### Quantra QPlus and QStat Output Parameters

Parameter	Unit	Reportable Ranges	Healthy Reference Range
<b>Clot Time (CT)</b>	seconds (sec)	60-480	113-164
<b>Clot time with Heparinase (CTH)</b> - QPlus Cartridge only	seconds (sec)	60-480	103-153
<b>Clot Time Ratio (CTR)</b> - QPlus Cartridge only	no units (ratio)	0.8 to 4	Calculated parameter. CTR values > 1.4 indicate the prolongation of intrinsic CT, likely due to the influence of heparin.
<b>Clot Stiffness (CS)</b>	hectoPascals (hPa)	2-65	13.0-33.2
<b>Fibrinogen Contribution to Clot Stiffness (FCS)</b>	hectoPascals (hPa)	0.2-30	1.0-3.7
<b>Platelet Contribution to Clot Stiffness (PCS)</b>	hectoPascals (hPa)	2-50	11.9-29.8
<b>Clot Stability to Lysis (CSL)</b> - QStat cartridge only	Percent	10-100	93-100

A reference range study was conducted for the QPlus cartridge by collecting whole blood samples from 129 healthy donors across three sites. The data were evaluated as recommended in EP28-A3c "Defining, Establishing and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline – Third Edition" CLSI, October 2010. The reference range for the Clot Stability to Lysis (CSL) parameter was similarly determined in a study of 43 healthy adult donors conducted at two sites in the US with the QStat Cartridge. The reference ranges determined from these studies are expressed as the central 95% confidence interval of the mean. It is recommended that each hospital/laboratory confirm these ranges or establish its own expected values for the populations it serves.

#### Principle

Sonic Estimation of Elasticity via Resonance (SEER) Sonorheometry is an ultrasound-based technology that measures the shear modulus of whole blood during coagulation and clot lysis.

#### Configuration

Cartridge based closed system; closed tube sampling.

## Sample Volume

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**3.2% citrated venous whole blood** 3 mL

**Undiluted venous whole blood** 2.7 mL

## Physical Characteristics and Footprint

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**Dimensions** 36 cm (w) x 49 cm (h) x 30 cm (d)

**Weight** 16.5 kg

**Clearance** Top 2.5 cm, Sides 5.5 cm, Rear 5.5 cmHeat

**Output** 75 Watts

## Display

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**Color touch screen** 22 cm x 14 cm

## Connectivity

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**Data Input and Output** 3 USB in the rear, 1 USB in front 1- RJ45 in the rear

**Integrated Outputs** CLSI LIS02-A2, CLSI POCT01-A2

**Middleware Drivers** AegisPOC® and AQUIRE POC®, Siemens POCCelerator®

**LIS / HIS / Other Middleware** Developed as needed

## Electrical Specifications

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**Voltage** 100-240 VAC

**Current** 1.3 A

**Power** Input Maximum 250 Watts/Output 75 Watts

**Frequency** 50/60 Hz

**Power Connection Standard** 3-prong grounded; \*hospital-grade cord\*

## Parts and Accessories

System Component	Ref. #
Quantra Hemostasis Analyzer	HS-001
QPlus Cartridge, Kit of 10	KT-0010
Qstat Cartridge, Kit of 10	KT-0022
QPlus Control Level 1, Kit of 4 (Lyophilized 2-8 C)	KT-0024
QPlus Control Level 2, Kit of 4 (Lyophilized 2-8 C)	KT-0026
QStat Control Level 1, Kit of 4 (Lyophilized 2-8 C)	KT-0028
QStat Control Level 2, Kit of 4 (Lyophilized 2-8 C)	KT-0038
Cleaning Cartridge, Kit of 10	KT-0012
Quantra Printer	KT-0015
Quantra Desktop Remote Viewer, Software	KT-0016
Qualiris Proficiency Testing Kit for QPlus	KT-0048

## Introducing our new fibrinogen POC solution



qLabs® FIB

Fibrinogen Monitoring System

Fibrinogen plays a critical role in the haemostatic process and has been identified as the first factor to reach critically low levels during active bleeding such as trauma and PPH.

Stago is proud to introduce the new qLabs FIB, a point-of-care device that measures fibrinogen levels within 1 to 10 minutes. This enables rapid, goal-directed therapy, with early administration of fibrinogen supplementation in the management of critical bleeds.

### Features and Specs

<b>Quantification of functional fibrinogen</b>	Clot-based fibrinogen measurement correlated to Clause fibrinogen method
<b>Sample Type</b>	Venous whole blood in standard coagulation citrated tube (blue cap, 3.2% (0.109 M) sodium citrate)
<b>Sample Volume</b>	15 $\mu$ L
<b>Precision</b>	CV $\leq$ 7.0%
<b>Hematocrit Range</b>	20% to 60%
<b>Shelf Life at Room Temperature</b>	24 months

### Features and Specs

Designation	Ref.#	Packaging
<b>qLabs® FIB meter</b>	Q-3 Plus	Unit
<b>eStation II docking station</b>	MBI92	Unit
<b>qLabs® FIB Test strips</b>	QS-18 Pro	24 strips/box
<b>qLabs® FIB Controls level 1</b>	QS-18-CLN	4 x 1 mL
<b>qLabs® FIB Controls level 2</b>	QS-18-CLP	4 x 1 mL

**Indications:** The Quantra Hemostasis System is comprised of the Quantra Hemostasis Analyzer, QPlus Cartridge, QStat Cartridge, Quantra Quality Controls (Level 1 and Level 2), Quantra Cleaning Cartridge, and Quantra Desktop Remote Viewer (QDRV) Software.

The QPlus Cartridge is indicated for the evaluation of blood coagulation in perioperative patients age 18 years and older to assess possible hypocoagulable and hypercoagulable conditions in cardiovascular or major orthopedic surgeries before, during, and following the procedure.

The QStat Cartridge is indicated for the evaluation of blood coagulation and clot lysis in patients age 18 years and older to assess possible hypocoagulable and hypercoagulable conditions in trauma and liver transplantation procedures

Results obtained with the Quantra System should not be the sole basis for patient diagnosis.

Rx Only.

**References:** **1.** QPlus Cartridge Instructions for Use (IFU). HemoSonics, LLC. **2.** QStat Cartridge Instructions for Use (IFU). HemoSonics, LLC. **3.** Quantra® Hemostasis Analyzer User Manual. 2020. HemoSonics, LLC. **4.** Baulig W, Akbas S, Schütt PK, et al. Comparison of the resonance sonorheometry based Quantra® system with rotational thromboelastometry ROTEM® sigma in cardiac surgery – a prospective observational study. *BMC Anesthesiol.* 2021;21(1):260. **5.** Idowu O, Ifeanyi-Pillette I, Owusu-Agyemang P, et al. The quantra hemostasis analyzer compared to thromboelastography (TEG) in the surgical oncologic population: a prospective observational trial. *J Surg Oncol.* 2021;124(5):894-905. **6.** Michelson EA, Cripps MW, Ray B, Winegar DA, Viola F. Initial clinical experience with the Quantra QStat System in adult trauma patients. *Trauma Surg Acute Care Open.* 2020;5(1):e000581. **7.** Groves DS, Welsby IJ, Naik BI, et al. Multicenter evaluation of the Quantra QPlus System in adult patients undergoing major surgical procedures. *Anesth Analg.* 2020;130(4):899-909. **8.** Winegar DA, Viola F. Is the Quantra QPlus system easy to interpret? American Association of Clinical Chemistry (AACC) Annual Scientific Meeting, Virtual Congress, December 13-17, 2020. **9.** Winegar DA, Gillespie C, Sanchez-Illan M. Improving the interpretation of viscoelastic test results in the critical care setting. American Association of Clinical Chemistry (AACC) Annual Scientific Meeting, July 24-28, 2022. **10.** Leadbetter NH, Givens TB, Viola F. Unique approach to quality assurance in viscoelastic testing. *J Appl Lab Med.* 2020;5(6):1228-1241. **11.** Ferrante EA, Blasier KR, Givens TB, Lloyd CA, Fischer TJ, Viola F. A novel device for the evaluation of hemostatic function in critical care settings. *Anesth Analg.* 2016;123(6):1372-1379. **12.** DeAnda A, Levy G, Kinsky M, et al. Comparison of the Quantra QPlus System with thromboelastography in cardiac surgery. *J Cardiothorac Vasc Anesth.* 2021;35(4):1030-1036. **13.** Naik BI, Durieux ME, Knisely A, et al. SEER sonorheometry versus rotational thromboelastometry in large volume blood loss spine surgery. *Anesth Analg.* 2016;123(6):1380-1389. **14.** Huffmyer JL, Fernandez LG, Haghidian C, Terkawi AS, Groves DS. Comparison of SEER sonorheometry with rotational thromboelastometry and laboratory parameters in cardiac surgery. *Anesth Analg.* 2016;123(6):1390-1399. **15.** Reynolds PS, Middleton P, McCarthy H, Spiess BD. A comparison of a new ultrasound-based whole blood viscoelastic test (SEER sonorheometry) versus thromboelastography in cardiac surgery. *Anesth Analg.* 2016;123(6):1400-1407. **16.** Baryshnikova E, Di Dedda U, Ranucci M. A comparative study of SEER sonorheometry versus standard coagulation tests, rotational thromboelastometry, and multiple electrode aggregometry in cardiac surgery. *J Cardiothorac Vasc Anesth.* 2019;33(6):1590-1598. **17.** Quantra System IT and Networking Guide. HemoSonics, LLC. **18.** Quantra Desktop Remote Viewer Instructions for Use (IFU). HemoSonics, LLC. **19.** Ranucci M, Baryshnikova E. Sensitivity of viscoelastic tests to platelet function. *J Clin Med.* 2020; 9(1):189.

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# HEMOSONICS

## Quantra® Printer – Product Specifications

DMP-238004-0295

### Intended Use

The Quantra Printer is used to print results from the Quantra Analyzer. The Quantra Analyzer output consists of numerical values for clot time and clot stiffness based coagulation parameters.

The results of the Quantra 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. Electrical Specifications

- Input Voltage USB 5 V
- Input Power Two-cell, 7.4 V DC, 2200 mAh Li-ion rechargeable battery

## B. Physical Characteristics

- Size (W x D x H) 4.0" W x 1.75" H x 4.0" D (100 mm X 45 mm X 100 cm)
- Weight 0.7 lbs. (0.3 kg)

### C. Output

- Printing Method Direct Thermal
- Print resolution Up to 400 dots per 25 mm

## D. Sensors and Protection

- Sensors Door Open, Paper Out, Printhead Temperature
- Printhead Protection Pulse Width, Voltage, Temperature Monitoring, and Wear Equalizer

## E. Product Specification

- Paper Type Roll (80mm wide)
- Paper Capacity 40 ft (12m)
- Environmental RoHS Compliant and REACH Compliant