

## Quantra™ Hemostasis Analyzer – Product Specifications

DMA-238004-0002

### Intended Use

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

The Quantra is indicated for use with any cleared Quantra cartridge.

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

- |  |                         |
|--|-------------------------|
| • Voltage  | Frequency               |
| • 100 – 120 V  | 50/60 Hz                |
| • 200 – 240 V  | 50/60 Hz                |
| • Current  | 1.3 A                   |
| • Power  | Input Maximum 250 Watts |
| • Power Connection Standard  | 3-prong grounded        |
| • Fuse   | 2.0A, 250 VAC           |
| • Note: 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. |                         |

### B. Environment 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) |

### D. Data Input and Output

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


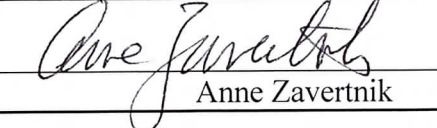

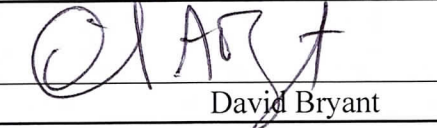
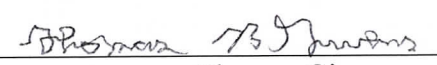
**Quantra™ Hemostasis Analyzer – Product Specifications**  
**DMP-238004-0240**

**1. REVISION HISTORY**

| Revision Number | Description of Change | Originator   | Department  |
|-----------------|-----------------------|--------------|-------------|
| 00              | Original Release      | Dexter Louie | Engineering |

**2. APPROVAL**

*Signature denotes the approver has read, understands, and agrees with the content of this document.*

| Title   | Signature  | Date        |
|---|--|-------------|
| R & D, Engineering<br>(Owner)                                   | <br>Dexter Louie     | 10 Oct 2017 |
| Regulatory Affairs &<br>Quality Systems<br>(Reviewer, approver) | <br>Anne Zavertrnik | 12 OCT 2017 |
| Clinical Affairs<br>(Reviewer, approver)                        | <br>Debbie Winegar | 09 Oct 2017 |
| Operations<br>(Reviewer, approver)                              | <br>David Bryant   | 13 OCT 2017 |
| Engineering<br>(Reviewer, approver)                             | <br>Thomas Givens  | 19 Oct 2017 |