CDI® Blood Parameter Monitoring System 500

System Overview

The CDI System 500 consists of a monitor to process and display data, a user-selected combination of blood parameter modules (BPMs) and a hematocrit/oxygen saturation probe (H/S probe), disposable sterile sensors and H/S cuvette, and a calibrator.

The disposable sensors and H/S cuvette are installed in the corresponding cable heads at a point in the circuit which will allow adequate exposure to blood (see Figure 1).

Users select the combination of BPMs and H/S probe depending on the parameters to be monitored (see Table 1). BPMs, which measure arterial or venous pH, pCO₂, pO₂, and K⁺, use optical fluorescence technology in conjunction with the disposable CDI System 500 shunt sensor. The H/S probe, which measures hematocrit, hemoglobin and oxygen saturation, uses optical reflectance technology in conjunction with the disposable H/S cuvette.

![Figure 1: Components of the CDI System 500.](image)

<table>
<thead>
<tr>
<th>Parameters Measured</th>
<th>Components</th>
<th>Technology Utilized</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arterial, pH, pCO₂, pO₂, and K⁺</td>
<td>Arterial BPM with shunt sensor</td>
<td>Optical fluorescence</td>
</tr>
<tr>
<td>Venous, pH, pCO₂, pO₂, and K⁺</td>
<td>Venous BPM with shunt sensor</td>
<td>Optical fluorescence</td>
</tr>
<tr>
<td>Hct, Hgb, O₂ saturation</td>
<td>H/S probe with H/S cuvette</td>
<td>Optical reflectance</td>
</tr>
</tbody>
</table>

Table 1: Component configurations of the CDI System 500.
Optical Fluorescence with the CDI® Shunt Sensor

The CDI System 500 uses optical fluorescence technology with the shunt sensor to measure pH, pCO₂, pO₂, and K⁺ in blood. The shunt sensor contains four microsensors — one each for pH, pCO₂, pO₂, and K⁺ — and a thermistor to measure temperature. The microsensors are in direct contact with the blood, enabling rapid response time.

The CDI System 500 shunt sensor can be placed in any arterial or venous shunt or purge line with continuous flow (see Figure 2). A minimum blood flow requirement of 35 mL/min is necessary for proper measurement.

During normal operation of the CDI System 500, light emitting diodes (LEDs) in the cable heads direct light pulses toward the microsensors, which contain fluorescent dyes (see Figure 3). As these pulses strike the microsensors, fluorescent light is emitted. The intensity of the fluorescent light will vary depending on the pH, pCO₂, pO₂, and K⁺ in the blood. A photo detector in the cable head measures the intensity of the fluorescent light and converts it to numerical data which is displayed on the monitor screen.

The pH, pCO₂, and pO₂ measurements are taken every second. The K⁺ measurement is taken every six seconds.

Optical Reflectance with the CDI H/S Cuvette

The CDI System 500 uses optical reflectance technology with the H/S probe to measure total hemoglobin and percent oxyhemoglobin, which exhibit different absorbance and reflectance characteristics at different wavelengths.

The flow-through H/S cuvette is installed directly in the tubing circuit. A window in the cuvette allows optical measurement without blood contact (see Figure 1).

LEDs in the H/S probe direct light pulses of specific wavelength at the blood through the optical window in the H/S cuvette (see Figure 4). The absorbance characteristics of hemoglobin and oxyhemoglobin can be measured by the photodetector in the H/S probe. Hemoglobin and oxyhemoglobin measurements are taken every 18 milliseconds.

The output of the detector is converted to numerical data which is displayed on the monitor’s screen.

Cuvette Blood Flow Rates

The CDI System 500 should only be used where there is blood flow through the extracorporeal circuit. To perform accurately, the H/S cuvette requires blood flow rates shown in Table 3.

<table>
<thead>
<tr>
<th>H/S Cuvette Connector Size</th>
<th>Min Flow</th>
<th>Max Flow</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/2”</td>
<td>1.0 LPM</td>
<td>7.0 LPM</td>
</tr>
<tr>
<td>3/8”</td>
<td>0.5 LPM</td>
<td>4.0 LPM</td>
</tr>
<tr>
<td>1/4”</td>
<td>0.2 LPM</td>
<td>1.5 LPM</td>
</tr>
</tbody>
</table>

Table 3: Restoration of blood flow above the minimum through the H/S cuvette will restore performance of the system.
CDI® 500 Blood Parameter Monitoring System
Calibration of the Microsensors

pH, pCO₂, pO₂ Sensors

Sensors for pH, pCO₂, and pO₂ are calibrated using a two-point tonometered calibration system, similar to the system used to calibrate the electrodes in laboratory analyzers.

The calibration process uses the CDI Calibrator 540 and two canisters of calibration gases, Gas A and Gas B. The calibration gases contain precise, defined levels of pCO₂ and pO₂ gases (see Table 4). During calibration, the shunt sensors (attached to the BPM cable heads) are placed in the calibrator, allowing the calibration gases to flow through the buffer solution contained in each shunt sensor. This exposes the microsensors to the gases with known pCO₂ and pO₂ values. A predefined pH value for each calibration gas is determined by the interaction of the known pCO₂ level in the calibration gas with the buffer solution.

To perform the calibration, the system measures the fluorescent intensities emitted by a microsensor as it is exposed to Gas A and then Gas B. It then plots these two fluorescent measurements as a function of the predefined values of the calibration gases (see example for pO₂ in Figure 5). The system uses the two points to create a slope and a y-intercept for that parameter. During bypass, as the system measures the fluorescent intensity of the blood in the extracorporeal circuit, it uses the slope and intercept to extrapolate corresponding blood parameter values.

K⁺ Sensor

Calibration of the K⁺ microsensor also relies on a two-point slope and intercept calibration process. The slope is defined using the factory-measured value encoded in the calibration code entered from the sensor pouch during the initial calibration sequence (as described in the Operator’s Manual). The intercept point is obtained after the initiation of bypass using the K⁺ level in a patient blood sample; the sample is drawn; the CDI System 500 K⁺ reading is stored in the system; the sample is processed using the laboratory analyzer; the analyzer’s value is then entered into the CDI System 500 to recalibrate the stored reading.

H/S Probe

Each H/S probe is precalibrated at the factory for oxygen saturation, hematocrit, and hemoglobin values; and further calibration is not required before going on bypass. To meet system accuracy limits, perform an in vivo calibration as outlined in the Instructions For Use.

### Table 4: Calibrating gas values for the CDI System 500. Balance of gas mixture is nitrogen (N₂). Gases measured at 1 atm and 21°C.

<table>
<thead>
<tr>
<th></th>
<th>Gas A (Model CDI506)</th>
<th>Gas B (Model CDI507)</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH</td>
<td>7.234 pH units</td>
<td>7.611 pH units</td>
</tr>
<tr>
<td>pCO₂</td>
<td>7.5% ±0.1% (48.1 mm Hg)</td>
<td>2.8% ±0.1% (18.0 mm Hg)</td>
</tr>
<tr>
<td>pO₂</td>
<td>27.5% ±0.1% (176.4 mm Hg)</td>
<td>4.0% ±0.1% (25.7 mm Hg)</td>
</tr>
</tbody>
</table>

Figure 5: Example of a 2-point calibration for pO₂ sensor.
CDI® System 500 Measures or Calculates 11 Critical Blood Parameters

The CDI Blood Parameter Monitoring System 500 (CDI System 500) was designed and developed to enable continuous monitoring of in-line blood parameters — pH, pCO₂, pO₂, potassium (K⁺), oxygen saturation, hematocrit, hemoglobin, and temperature — during cardiopulmonary bypass (CPB). Using optical fluorescence and reflectance technologies and disposable sensors placed in the extracorporeal circuit, the CDI System 500 monitors and displays real-time changes in blood parameters.

The system provides continuous results and also eliminates the need to consume or dispose of blood samples, as is required in laboratory analyzers.

![Diagram of CDI System 500 setup](image)

**Figure 2:** The CDI System 500 shunt sensors and cuvette are placed in the extracorporeal circuit allowing real-time response to changes in blood parameters.

### System Accuracy Limits

The CDI System 500 has been subjected to rigorous bench tests to simulate the clinical use of the device and assessed for accuracy and precision over the system operating ranges of the measured parameters. Blood samples taken from the test circuit were analyzed in conventional analyzers, and these results were compared (on a sample-by-sample basis) to analyses provided by the CDI System 500.

Table 2 shows the mean difference between the two measurement techniques, and the standard deviation of the differences found.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Mean</th>
<th>Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH Sensor</td>
<td>-0.018</td>
<td>0.023</td>
</tr>
<tr>
<td>pCO₂ Sensor</td>
<td>-0.2</td>
<td>2.2</td>
</tr>
<tr>
<td>pO₂ Sensor – Arterial (&gt;80 mm Hg)</td>
<td>6.1</td>
<td>17.6</td>
</tr>
<tr>
<td>pO₂ Sensor – Venous (&lt;80 mm Hg)</td>
<td>1.3</td>
<td>2.3</td>
</tr>
<tr>
<td>Oxygen Saturation Value</td>
<td>-0.4</td>
<td>1.6</td>
</tr>
<tr>
<td>Temperature</td>
<td>-0.07</td>
<td>0.22</td>
</tr>
<tr>
<td>Total Hemoglobin Value</td>
<td>-0.09</td>
<td>0.38</td>
</tr>
<tr>
<td>Potassium Sensor</td>
<td>-0.06</td>
<td>0.19</td>
</tr>
<tr>
<td>Hematocrit Value</td>
<td>-0.4</td>
<td>1.2</td>
</tr>
</tbody>
</table>

**Table 2:** Mean measurement technique and standard deviation differences found.
## Product Specifications

### Displayed Parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>System Operating Ranges</th>
<th>System Display Ranges</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH</td>
<td>6.8 to 7.8 pH units</td>
<td>6.5 to 8.5 units</td>
</tr>
<tr>
<td>pCO₂</td>
<td>10 to 80 mm Hg (1.3 to 10.7 kPa)</td>
<td>10 to 200 mm Hg (1.3 to 26.7 kPa)</td>
</tr>
<tr>
<td>pO₂</td>
<td>20 to 500 mm Hg (2.7 to 66.7 kPa)</td>
<td>10 to 700 mm Hg (1.3 to 93.3 kPa)</td>
</tr>
<tr>
<td>K</td>
<td>3.0 to 8.0 mmol/L</td>
<td>1.0 to 9.9 mmol/L</td>
</tr>
<tr>
<td>Temperature (T)</td>
<td>15° to 40° C</td>
<td>1° to 45° C</td>
</tr>
<tr>
<td>Oxygen saturation (SO₂)</td>
<td>60 to 100%</td>
<td>35 to 100%</td>
</tr>
<tr>
<td>Hematocrit (Hct)</td>
<td>17 to 38%</td>
<td>12 to 45%</td>
</tr>
<tr>
<td>Total hemoglobin (Hgb)</td>
<td>5.6 to 12.6 g/dL</td>
<td>4.0 to 15.0 g/dL</td>
</tr>
<tr>
<td>Oxygen consumption (VO₂)</td>
<td>10 to 400 mL/min</td>
<td>10 to 400 mL/min</td>
</tr>
<tr>
<td>Base Excess (BE)</td>
<td>-25 to 25 mEq/L</td>
<td>-25 to 25 mEq/L</td>
</tr>
<tr>
<td>Bicarbonate (HCO₃⁻)</td>
<td>0 to 50 mEq/L</td>
<td>0 to 50 mEq/L</td>
</tr>
<tr>
<td>Blood flow (Q)</td>
<td>0 to 9.9 L/min</td>
<td>6.5 to 8.5 units</td>
</tr>
</tbody>
</table>

### Serial Data Output

The CDI® System 500 has a serial data output port, which allows use with an external serial printer, computer, or data acquisition system. When the CDI System 500 is attached to an external device, users can send patient data (blood parameter values over the course of an operation) from the CDI System to this device.

A second serial interface port, called the pump interface, allows the CDI System 500 to receive flow (Q) data from selected pumps. These are the Terumo® Advanced Perfusion System 1, Sarns™ Modular Perfusion System 8000 and 9000, Sarns™ Centrifugal Pump, Sorin S3, Sorin SC, Medtronic BioMedicus 550 Centrifugal Pump, and the Maquet HL20. When using the pump interface port with the Terumo® Advanced Perfusion System 1, data can also be sent from the CDI System 500, to display blood parameter values on the Central Control Monitor.

### Output Type

- "ASCII Output," "Sarns 9000" or "Packet Mode" (if Sarns 9000 is selected, all other values on the screen become unchangeable).

### Data Bits

- “8 data/1 stop” or “7 data/2 stop”

### Parity

- “none,” “even,” or “odd”

### Baud Rate

1200, 2400, 4800, 9600, 19200, or 38400

### Output Interval

0, 0.1, 0.5 minutes, or 1-10 minutes (“0” means the CDI System 500 will send data on demand only).

### Monitor Power Requirements

- 100-240 VAC, 50/60 Hz
- 12 volt backup battery
- Data Output Port: RS-232 serial interface
- Pumping Systems Input Port: RS-232/RS-485 serial interface

### Model CDI510H Shunt Sensor

- Sterile, heparin-treated
- Priming volume 1.2 mL

### System Display Update

- Every six seconds

### System Measurement Cycle Time

- pH, pCO₂, pO₂ = one measurement per second
- K⁺ = one measurement per six seconds
- SO₂, Hct, Hgb = one measurement per eighteen milliseconds

### H/S Cuvette

- Sterile
- Priming volume for # 6914 (1/4” x 1/4”) = 4 mL
- Priming volume for # 6913 (3/8” x 3/8”) = 9 mL
- Priming volume for # 6912 (1/2” x 1/2”) = 16 mL

### Product Specification

<table>
<thead>
<tr>
<th>Specification</th>
<th>Size (H x W x D)</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monitor</td>
<td>11” x 12.5” x 6”</td>
<td>16.1 lb.</td>
</tr>
<tr>
<td>Calibrator</td>
<td>12.5” x 8” x 8”</td>
<td>8.4 lb.</td>
</tr>
</tbody>
</table>

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