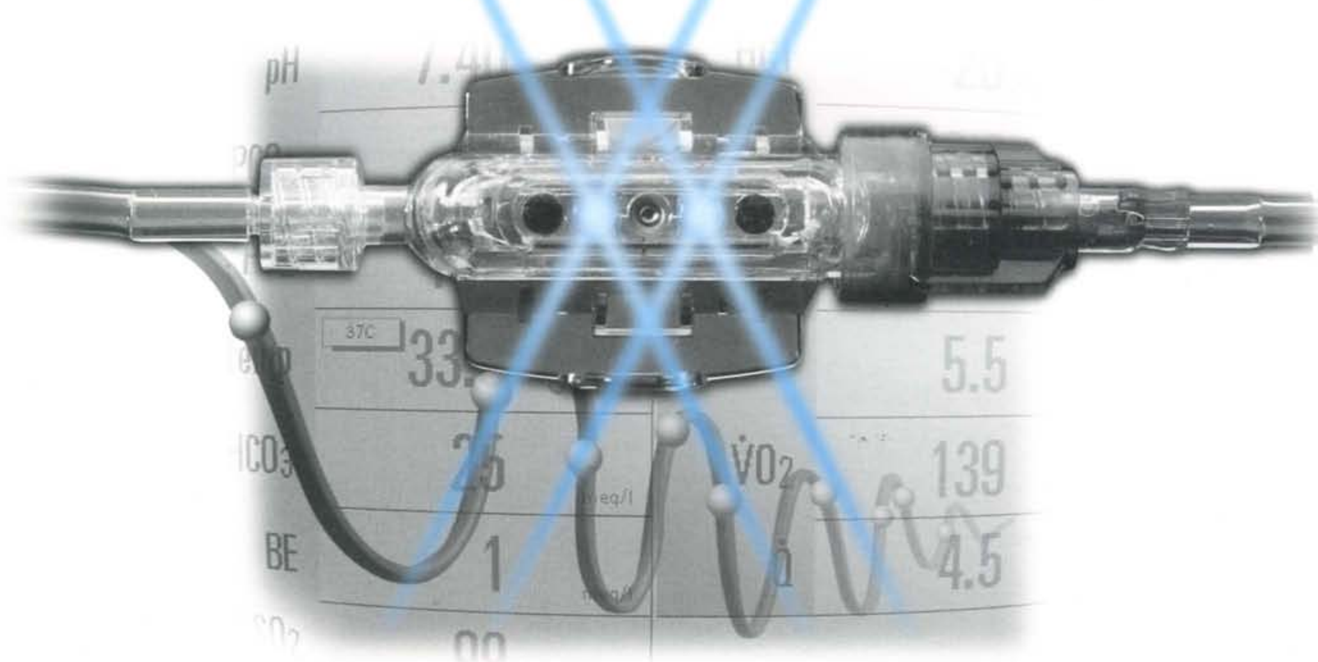
TERUMO®

Cardiovascular Systems

CAPIOX® CDI™ Sarns™

CDI™ Blood Parameter Monitoring System 500

Technical Compendium



CDI™ Blood Parameter Monitoring System 500

Introduction

The CDI™ Blood Parameter Monitoring System 500 was designed and developed to enable continuous monitoring of in-line blood parameters—pH, PCO_2, PO_2, potassium (K^+), oxygen saturation, hematocrit, hemoglobin, and temperature—during cardiopulmonary bypass (CPB). Using optical fluorometric 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 as accurate as those provided by traditional laboratory analyzers,[1] which use an electrochemical technology to measure blood parameters on samples taken at prescribed intervals or on demand. It also eliminates the need to consume or dispose of blood samples, as is required in laboratory analyzers.

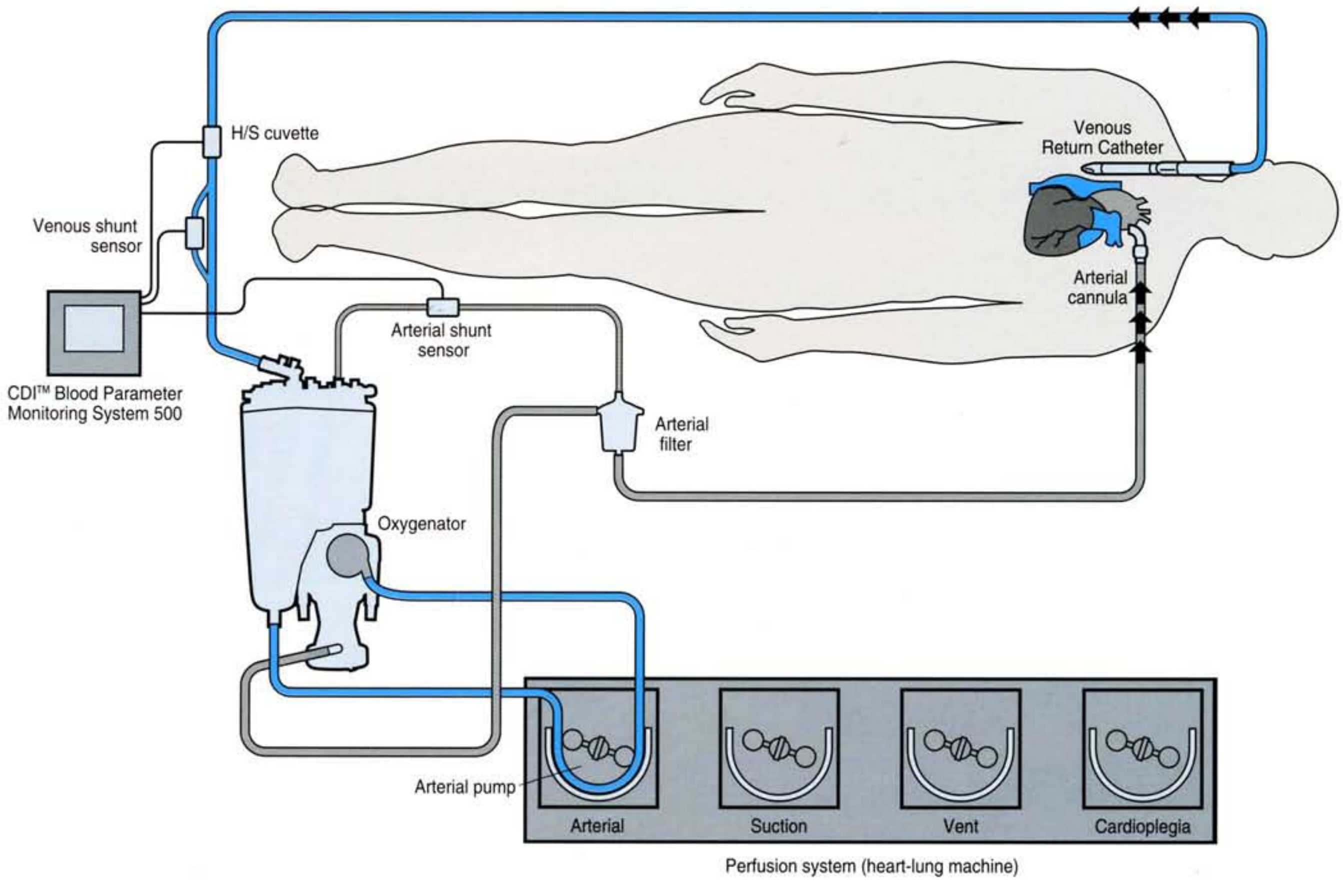


Figure 1 The CDI system 500 circuit.
The CDI system 500 is a continuous, in-line monitoring system based on optical fluorometric and reflectance technologies. Sensors are placed in the extracorporeal circuit allowing real-time response to changes in blood parameters.

CDI™ Blood Parameter Monitoring System 500
System Description

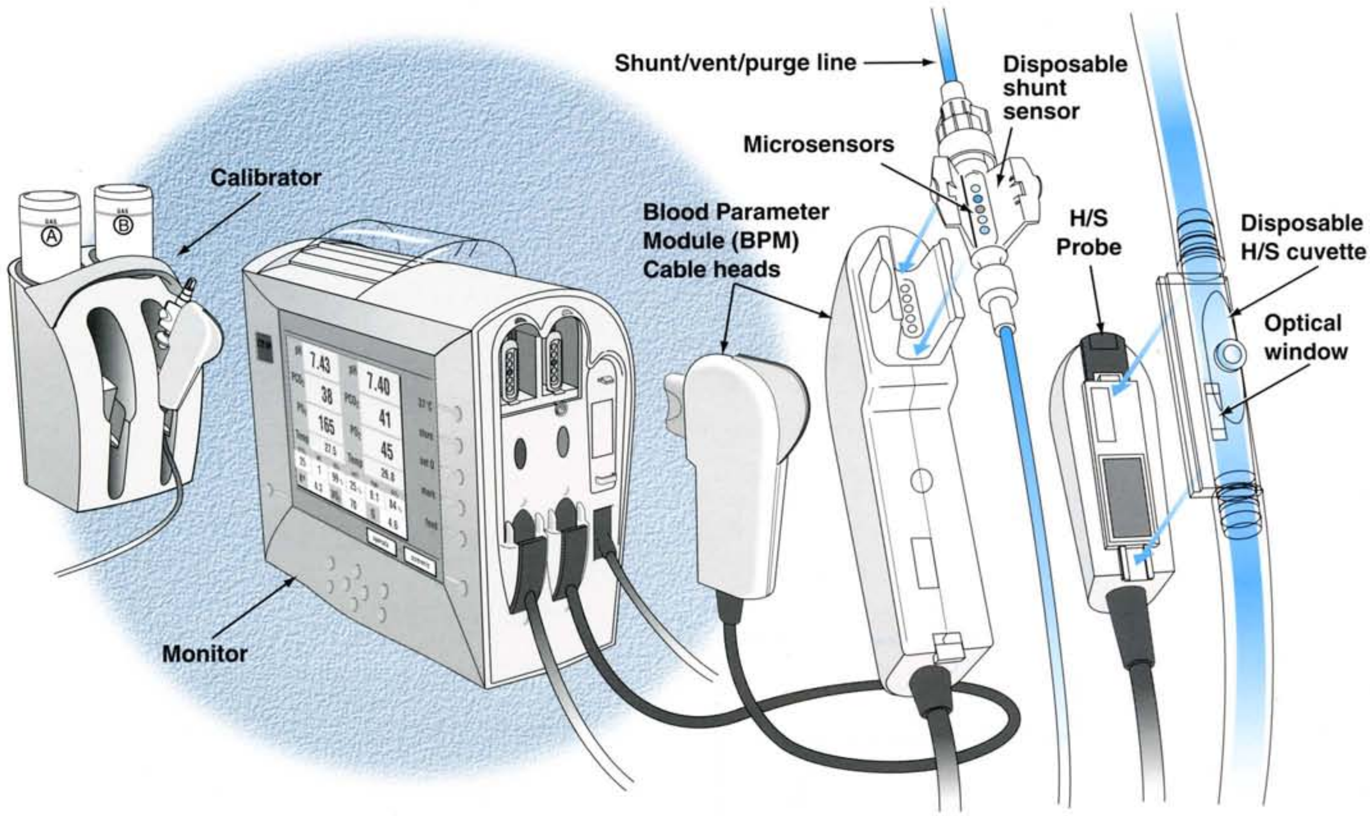


Figure 2 Components of the CDI system 500

System Overview

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

The disposable sensors and/or H/S cuvette are installed in the cable heads of the BPMs or the H/S probe, at a point in the circuit that will allow adequate exposure to blood (see Figure 2).

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, PCO_2, PO_2,

Table 1 Component Configurations of the CDI system 500

Parameter measured	Components	Technology utilized
Arterial pH, PO_2, PCO_2, K^+	Arterial BPM with shunt sensor	Optical fluorescence
Venous pH, PO_2, PCO_2, K^+	Venous BPM with shunt sensor	Optical fluorescence
Hct, Hgb, O_2 saturation	H/S probe with H/S cuvette	Optical reflectance

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. Because the BPMs and probe are modular, they can be added or changed in the field by a certified technician of Terumo Cardiovascular Systems.

Optical fluorescence with the CDI Shunt Sensor

The CDI system 500 uses optical fluorescence technology with the shunt sensor to measure pH, PCO_2, PO_2, and K^+ in blood.

The shunt sensor contains four microsensors — one each for pH, PCO_2, PO_2, and K+ — and a thermistor to measure temperature. The microsensors are in direct contact with the blood, enabling rapid response time. Earlier disposable sensor designs incorporated a membrane between the microsensors and the blood. Those designs required blood gases and hydrogen ions to diffuse through the membrane to contact the sensors, thereby creating a delay in the system's response time.

The CDI system 500 shunt sensor can be placed in any arterial or venous shunt, vent, or purge line with continuous flow (see Figure 1). A minimum blood flow of 35 ml/min is recommended for the shunt sensor.

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, PCO_2, PO_2 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, PCO_2, and PO_2 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.

Light emitting diodes (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.

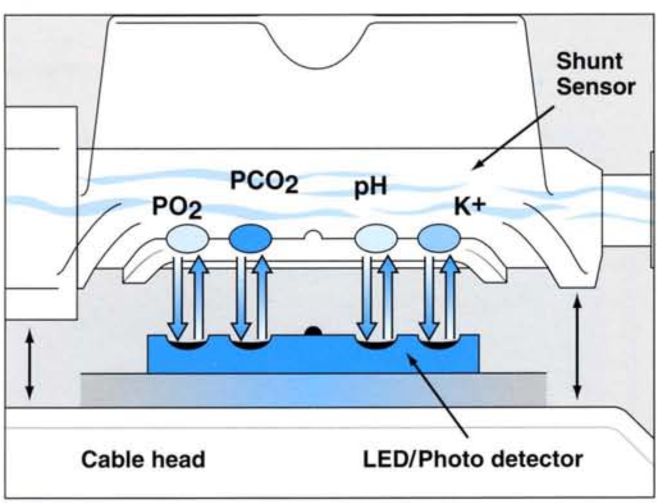


Figure 3 Optical fluorescence: CDI system 500 shunt sensor and BPM cable head

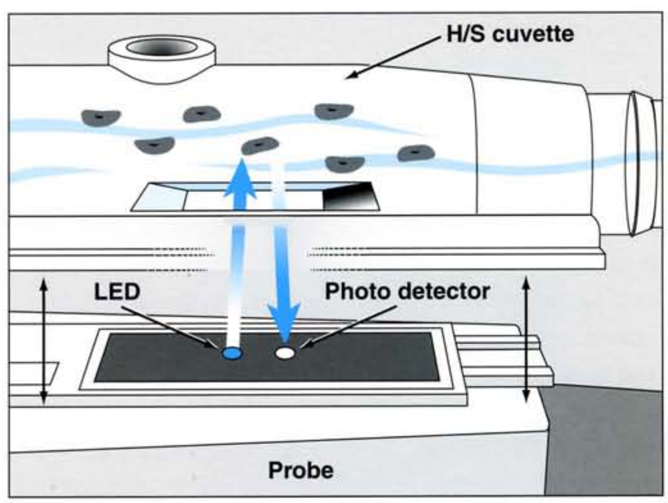


Figure 4 Optical reflectance: CDI H/S cuvette and probe

CDI™ Blood Parameter Monitoring System 500
Calibration of the Microsensors

pH, PCO_2, PO_2 Sensors

Sensors for pH, PCO_2 and PO_2 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 PCO_2 and PO_2 gases (see Table 2). 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 PCO_2 and PO_2 values. A predefined pH value for each calibration gas is determined by the interaction of the known PCO_2 level in the calibration gas with the buffer solution.

To perform the calibration, the system measures the flourescent intensities emitted by a microsensor as it is exposed to Gas A and then Gas B. It then plots these two flourescent measurements as a function of the predefined values of the calibration gases (see example for PO_2 in Figure 6). The system uses the two points to create a slope and a y-intercept for that parameter. During bypass, as the system measures the flourescent 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 Operators 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 a laboratory analyzer, the analyzer's value is then entered into the CDI system 500 to replace the stored reading.

H/S Probe

Each H/S probe is precalibrated at the factory for oxygen saturation, hematocrit, and hemoglobin values; no further calibration is required.

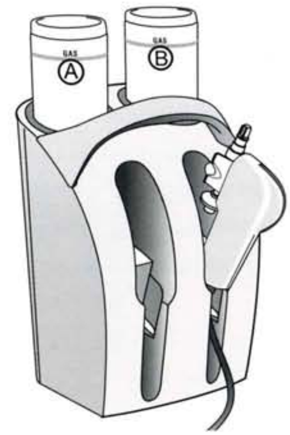


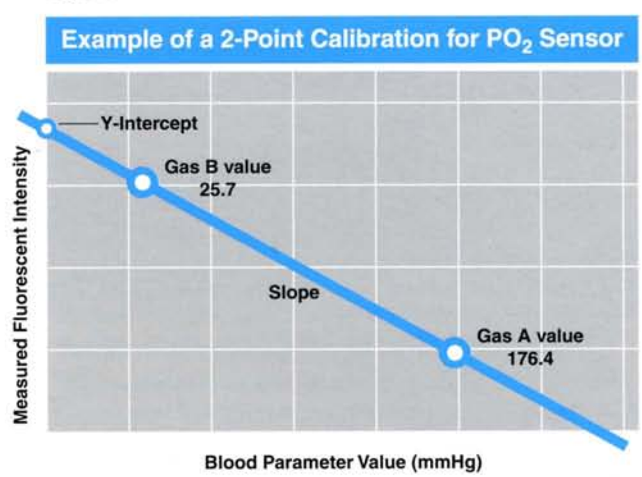
Figure 5
Calibration of the Shunt Sensor

Table 2 Calibrating gas values for the CDI system 500

	Gas A (Model CDI506)	Gas B (Model CDI507)
pH	7.234 pH units	7.611 pH units
PCO_2	7.5 ± 0.1% (48.1 mmHg)	2.8 ± 0.1% (18.0 mmHg)
PO_2	27.5 ± 0.1% (176.4 mmHg)	4.0 ± 0.1% (25.7 mmHg)

Balance of gas mixture is nitrogen (N_2).
Gases measured at 1 atm and 21° C.

Figure 6



In-Vitro Time Response of the Shunt Sensor

Accurate time response measurements for the CDI system 500 in-line shunt sensors are obtained in a controlled laboratory environment using "step change" methodology. This methodology creates as instantaneous a change in the level of a blood parameter as possible, a "step change." A baseline level of each parameter, pH, PCO_2, PO_2 and K^+, is established in the circuit. A change in the concentration of the parameter is introduced. The time it takes for the sensor to detect 90% of the change is then recorded.

The graphs below represent results from a typical series of step change tests. For example, in the time response test for the pH sensor, the pH level in the circuit is established at 7.62 pH units. The pH level of the circuit is then changed from 7.62 to 7.31 pH units. In 30 seconds, the system recorded 7.34 pH units, which represents 90% equilibrium.

The time for the CDI system 500 to display 90% of the step change for pH, PCO_2, PO_2 and K^+ ranged from 24 seconds (for PO_2) to 42 seconds (for K^+) at a blood temperature of 37°C. Time response results for each analyte are found in Figures 7-10.

Figure 7

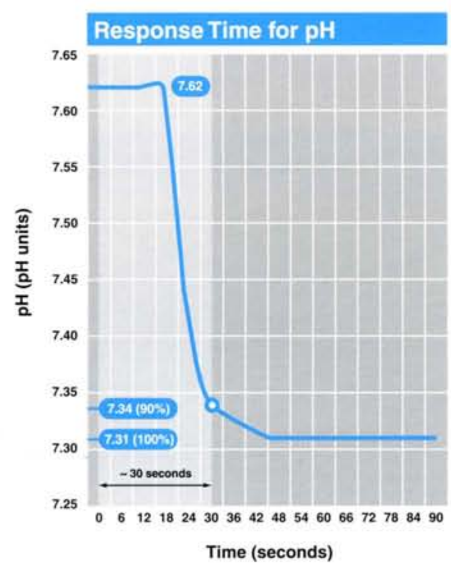


Figure 8

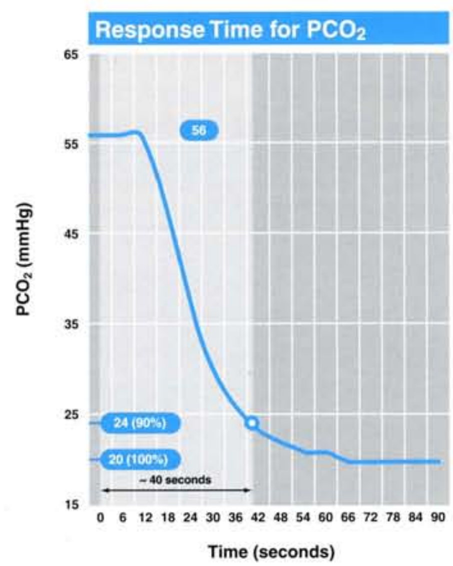


Figure 9

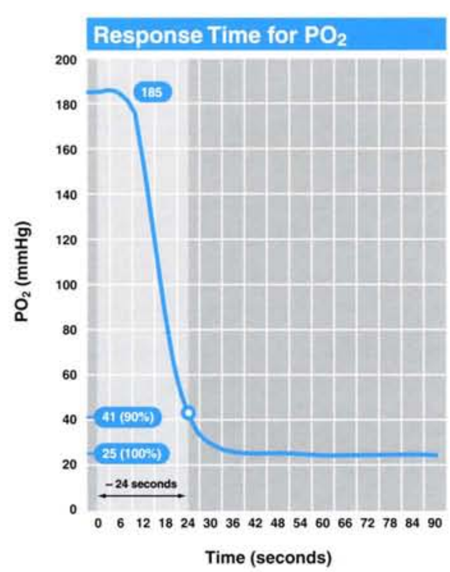
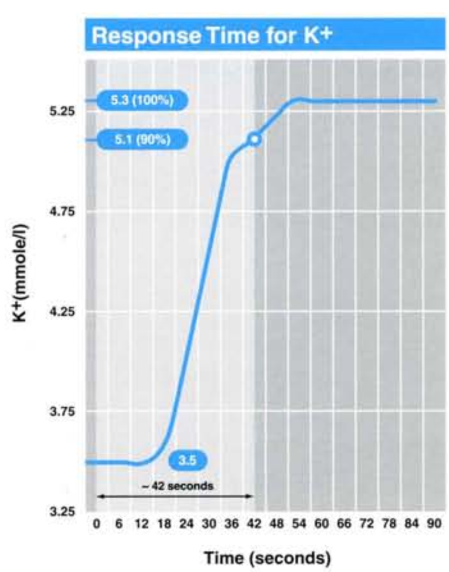


Figure 10



Clinical evaluation of the CDI™ Blood Parameter Monitoring System 500 Comparison with Laboratory Analyzers

During clinical evaluations with the CDI system 500, investigators in four institutions concluded that values for arterial pH, PCO_2, PO_2 and K^+ obtained by the system are as accurate as those obtained by traditional laboratory analyzers.[2]

The two-month evaluation involved four locations:

St. Mary's Hospital, Mayo Clinic, MN
Medical University of South Carolina, SC
University of Nebraska Medical Center, NE
University of Iowa Hospital and Clinics, IA

A minimum of three samples was drawn from the bypass circuit on each of the 75 cardiopulmonary bypass surgery patients. As a blood sample was drawn, the blood parameter values displayed by the CDI system 500 were recorded. These recorded values were compared with the laboratory analyzer values. Data from all four sites were analyzed together, yielding over 200 data points.

Results

Table 3 (right) shows the mean differences and standard deviations between the values measured by the CDI system 500 and the laboratory analyzers. The results of the study are shown in the bubble plots (far right).

The clinically acceptable range for the accuracy of the values are shown as blue lines in each bubble plot. For pH, PCO_2, and K^+, the range is based on the criteria from the US Clinical Laboratory Improvement Amendments of 1988 (CLIA '88), a commonly recognized method to monitor the proficiency of laboratory analyzers in accordance with US Federal regulations.

As indicated in Table 4, the CLIA target value could not be used for PO_2 values because it represents a variable range (± 3 standard deviations) as opposed to a fixed interval (e.g., ± 5 mmHg). The investigators therefore used ± 10% of the reference, or laboratory analyzer, value to evaluate the performance of the PO_2 sensor.

In each parameter measured, pH, PCO_2, PO_2 and K^+, most data points fell within the limits of the target values. All investigators concluded that the CDI system 500 provides values that meet the accuracy standards for laboratory analyzers.

Table 3

	pH (units)	PCO_2 (mmHg)	PO_2 (mmHg)	K^+ (mmole/l)
Mean Difference (Bias)	0.00	-0.3	7.5	0.12
Standard Deviation	0.02	3.3	13.8	0.31
Number of Data Points	263	263	262	190

Table 4

Blood Gas Parameters	CLIA '88 Mean Target Values	CDI System 500 Bias
pH	± .04 pH units	0.00 pH units
PCO_2	± 5 mmHg	-0.3 mmHg
PO_2	± 3 standard deviations	NA
K^+	± 0.5 mmole/l	0.12 mmole/l

Figure 11

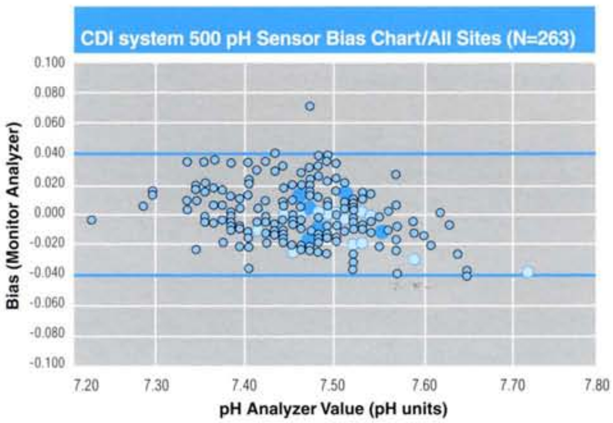


Figure 12

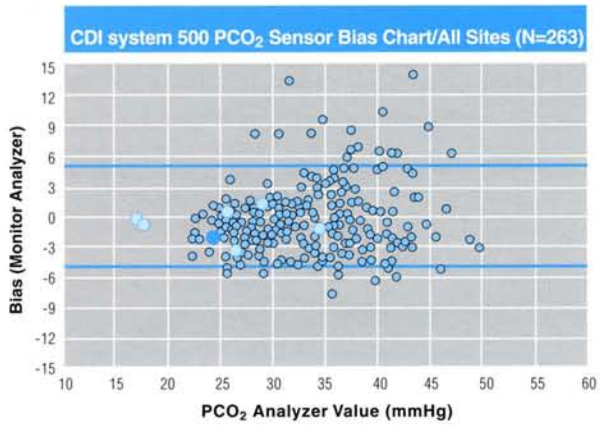


Figure 13

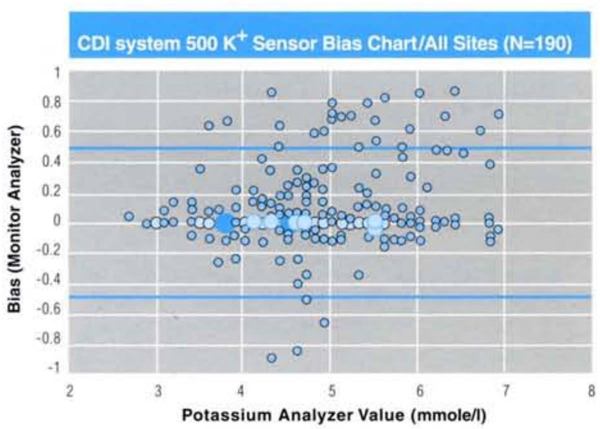
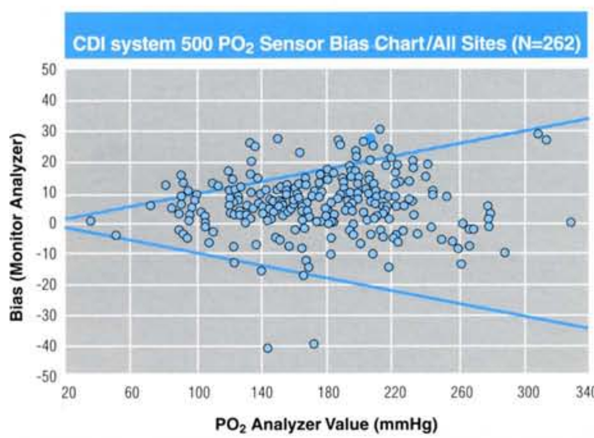


Figure 14



In Figures 11-14, the y-axis represents the bias, or difference, between the value obtained by the CDI system 500 and the value obtained by the lab analyzer. The x-axis represents the lab analyzer value for the same data points. For pH, PCO_2 and K^+, upper and lower limits of CLIA mean target values are represented by the pair of parallel lines across the data field. For PO_2, the range of target values is defined by 10% of the laboratory analyzer value; as PO_2 increases, the acceptable variance from the laboratory analyzer value increases.

CDI™ Blood Parameter Monitoring System 500 Time Course Plots: Continuous in-line monitoring versus intermittent measuring with laboratory analyzers

The CDI system 500 provides a continuous measurement of blood gas values across time (see Figures 15-18), compared with the discrete and intermittent measurements of laboratory blood gas analyzers. The unbroken line on each graph displays the continuous output of the CDI system 500 for each parameter for the duration of an entire bypass procedure.

The dots represent the intermittent measurements taken at different time intervals by the analyzer. Fluctuations in the patient's levels of each parameter are more readily apparent when measured continuously by in-line monitoring than when measured intermittently.

Figure 15

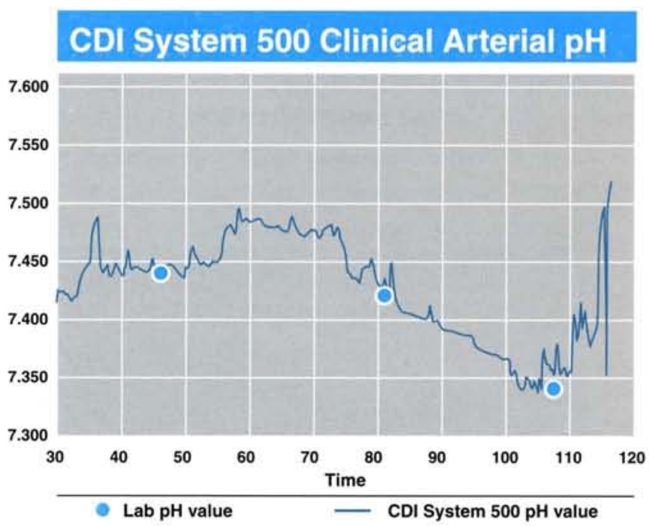


Figure 16

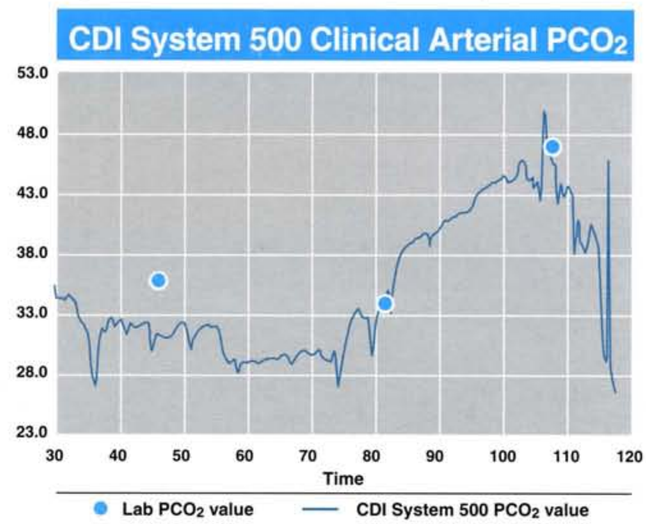


Figure 17

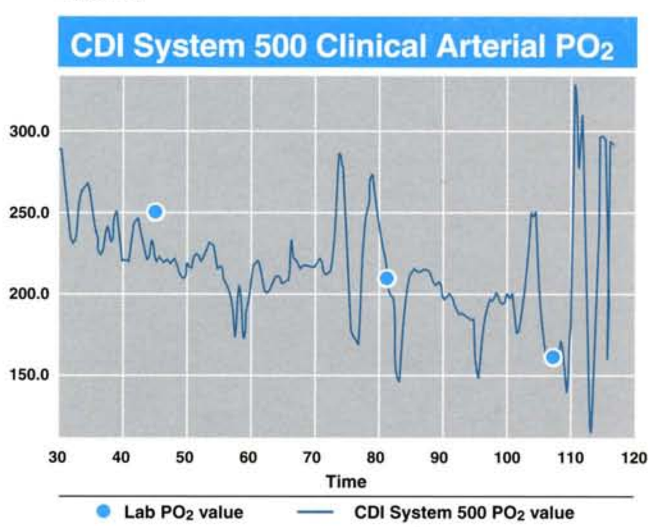
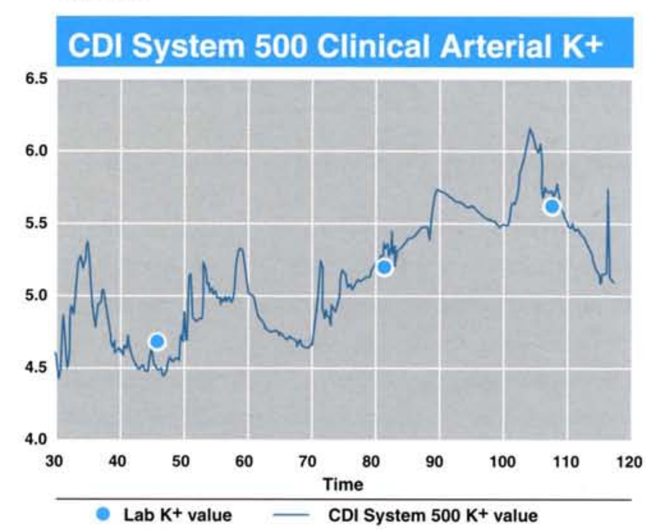


Figure 18



Product Specifications

Displayed Parameters	Normal Operating Ranges	Resolution
pH	6.8 to 8.0	0.01
PCO_2	10 to 80 mmHg (1 to 11 kPa)	1 mmHg (0.1 kPa)
PO_2	10 to 500 mmHg (1 to 67 kPa)	1 mmHg (0.1 kPa)
K^+	1.0 to 8.0 mmole/l	0.1 mmole/l
Temperature	10° to 45° Celsius	1° Celsius
Oxygen saturation (SO_2)	60% to 100%	1%
Hematocrit (Hct)	15% to 45%	1%
Total hemoglobin (Hgb)	5 to 15 g/dl	0.1 g/dl
Oxygen consumption (VO_2)	10 to 400 ml/min	1 ml/min
BE	-25 to 25 mEq/l	1 mEq/l
HCO_3	0 to 50 mEq/l	1 mEq/l
Blood flow	0 to 7.0 l/min	0.1 l/min

Physical Specifications	Size	Weight
Monitor	HxWxD 11" x 12.5" x 6"	Weight 16.1 lb.
Calibrator	HxWxD 12.5" x 8" x 8"	Weight 8.4 lb.

Monitor power requirements and specifications
100-240 VAC, 50/60 Hz
12 volt lead acid backup battery
Data Output Port: RS-232 Serial Interface
Pumping Systems Input Port: RS-232/RS-485 Serial Interface

CDI Shunt Sensor
Sterile, heparin-treated
Priming volume 1.2 ml

CDI H/S Cuvette
Sterile, heparin- or nonheparin-treated
Priming volume 1/4" = 4ml
Priming volume 3/8" = 9ml
Priming volume 1/2" = 16ml

System measurement cycle time
pH, PCO_2, PO_2 = one measurement per second
K^+ = one measurement per six seconds
SO_2, Hct, Hgb = one measurement per eighteen milliseconds

System display update
Every six seconds

1 & 2 Southworth R, Sutton R, Mize S, et al., "Clinical Evaluation of a New In-Line Continuous Blood Gas Monitor". *J Extra-Corp Technol. 1998: 30(4) pages 166-170.*

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