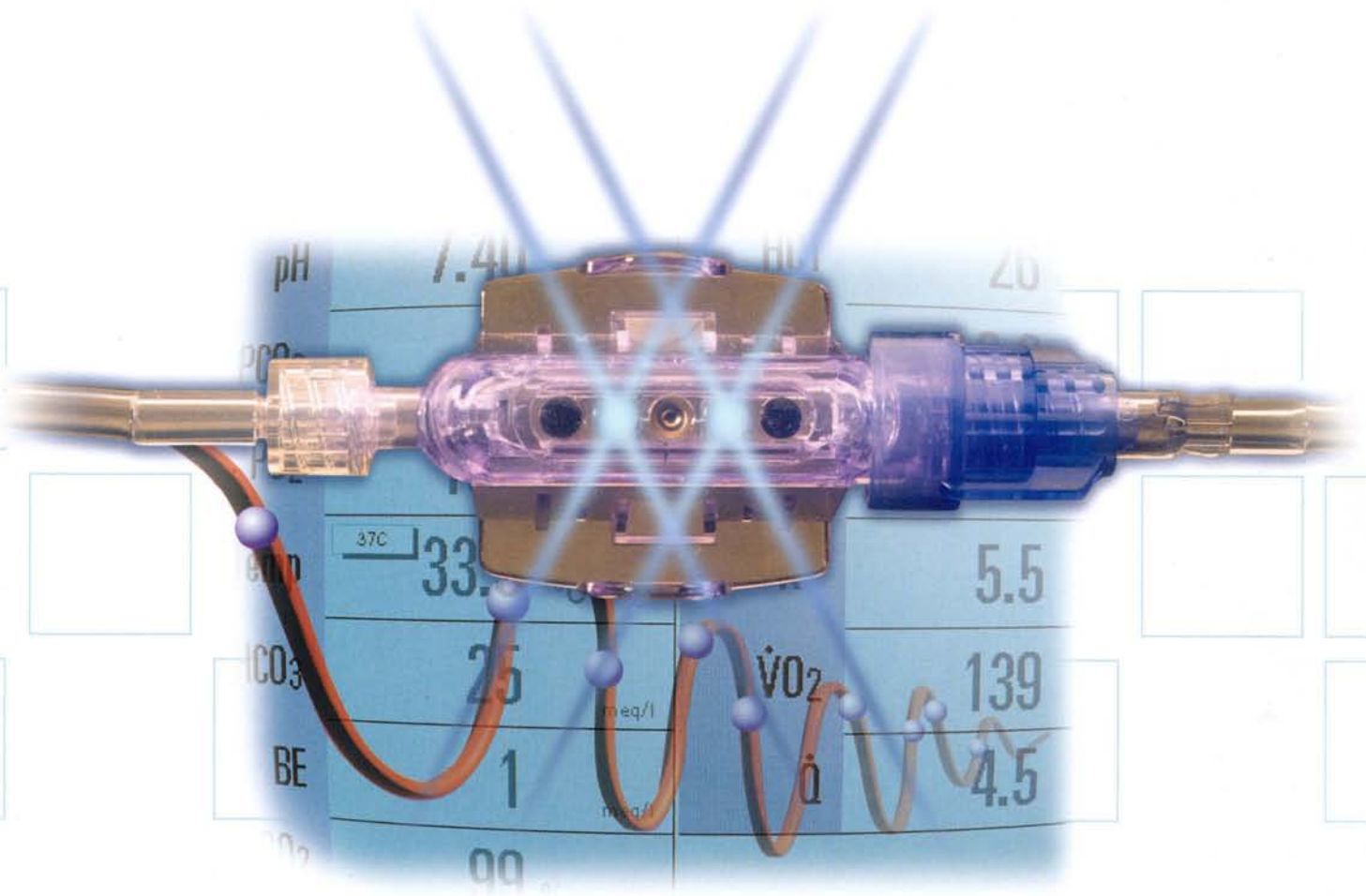


CDI™ 500 Blood Parameter Monitoring System

Breakthrough technology for faster, more precise, clinical decision making during cardiac surgery.



The CDI™ 500 Blood Parameter Monitoring System provides continuous information on blood parameters for faster, more precise, clinical decision making during cardiac surgery.

What is the CDI 500 system?

Based on optical fluorescence and reflectance technologies, the CDI 500 system continuously measures or calculates 11 critical blood parameter values during cardiopulmonary bypass. Access to continuous information is a key advantage in optimum patient management because it enables clinicians to react without delay to changes in blood parameter values. The CDI 500 system's combination of accuracy and speed facilitates sound clinical decision making.

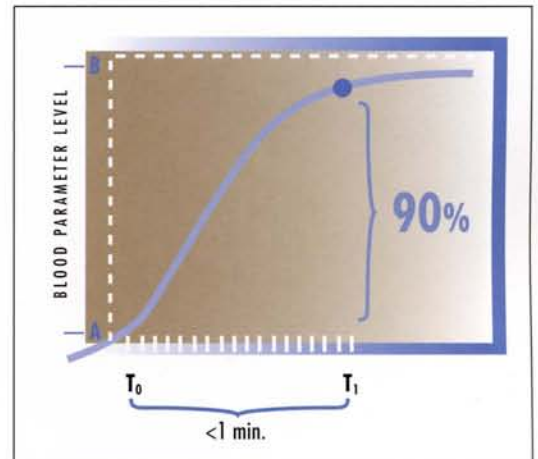
The CDI 500 system measures or calculates pH, pCO₂, pO₂, K⁺, temp, SO₂, hematocrit, hemoglobin, base excess, bicarbonate and oxygen consumption. With its quick response time and lab quality accuracy, the CDI 500 system is setting new standards in patient care during cardiac surgery.

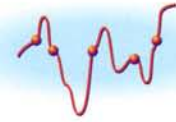


Less than one minute response time

The new CDI™ 500 system shunt sensor is designed to be placed in a shunt line where the blood is in direct contact with the system's sterile microsensors. This technological advancement eliminates the delays associated with the diffusion of blood gases and hydrogen ions through sterile membranes. The system's average response time for measured parameters pH, pCO₂, pO₂ and K⁺ is less than one minute.

Averaged response time of measured values, pH, pCO₂, pO₂ and K⁺, at 37°C with 90% equilibration in Terumo Cardiovascular Systems in vitro testing.





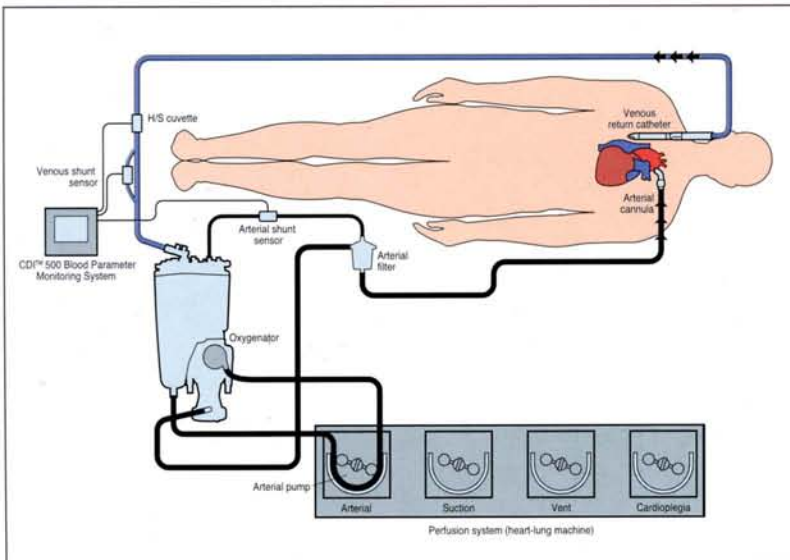
Accuracy comparable to laboratory analyzers

Clinical investigation demonstrates that the CDI 500 system provides values that are within the accepted accuracy parameters for laboratory analyzers. Advancements in optical fluorescent design account for the accurate results. The use of light emitting diodes (LEDs) reduces signal noise, drift and warm-up effects. New signal detection circuitry delivers high signal fidelity and eliminates the need for long fiber optic cables, providing increased reliability.

Easy to set up and calibrate

It takes less than one minute to set up the system for calibration.* There is no warm-up time required for installation or calibration. Installing the sensor in the shunt line requires a few, simple luer connections. The shunt sensor can be added after the initiation of bypass, facilitating set up in emergency cases.

Circuit diagram with the CDI™ 500 Blood Parameter Monitoring System



Fast, easy set up

The shunt sensor is placed in the probe head.



The probe head, with sensor attached, is placed in the calibrator.



The sensor, still attached to the probe head, is installed in the circuit with two luer connections.



The sensor allows placement in a variety of circuit locations.

**In clinical evaluations, the average time to set up calibration for the arterial shunt sensor was 37 seconds. Average time to install the calibrated sensor in the purge line was 22 seconds. (Calibration itself requires no user dedication and takes 10 minutes.)*

Clinical evaluation of the CDI™ 500 Blood Parameter Monitoring System validates lab quality accuracy and faster, more precise, clinical decision making.

Lab Quality Accuracy

During clinical evaluations with the CDI 500 system, investigators in four institutions concluded that values for arterial pH, pCO₂, pO₂ and K⁺ obtained by the system are as accurate as those obtained by traditional laboratory analyzers.

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 500 system 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.

Table 1

	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

Results

Table 1 shows the mean differences and standard deviations between the values measured by the CDI 500 system and the laboratory analyzers. The results of the study are shown in the bubble plots to the far right. The clinically acceptable

range for the accuracy of the values is shown as black lines in each bubble plot. For pH, pCO₂, 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.

Table 2

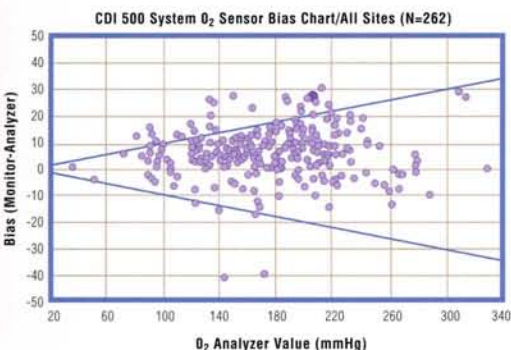
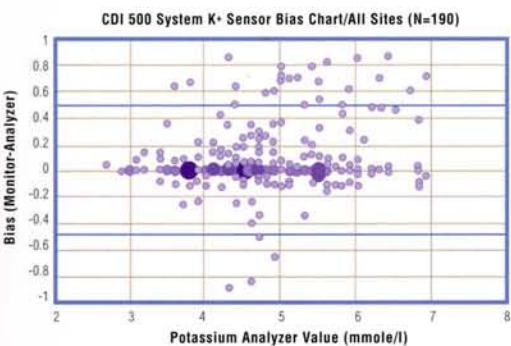
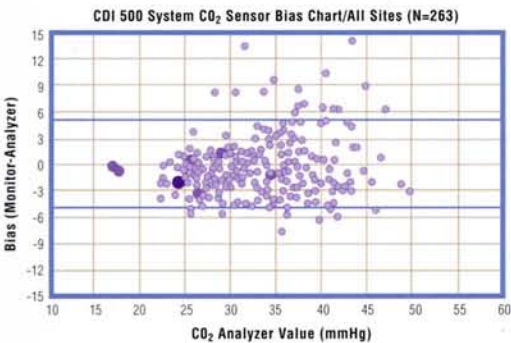
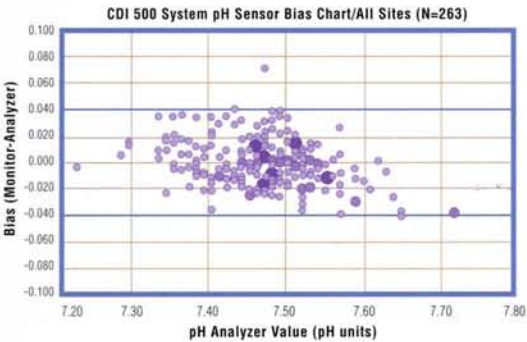
Blood Gas Parameters	CLIA '88 Mean Target Values	CDI 500 System Bias
pH	± .04 pH units	0.00 pH units
pCO ₂	± 5 mmHg	-0.3 mm Hg
pO ₂	± 3 standard deviations	NA
K ⁺	± 0.5 mmole/l	0.12 mmole/l

As indicated in Table 2, the CLIA target value could not be used for pO₂ values because it represents a variable range (± 3 standard deviations) as opposed to a fixed interval (e.g., ± 5 mm Hg). The investigators therefore used ± 10% of the reference, or laboratory analyzer, value to evaluate the performance of the pO₂ sensor. In each parameter measured, most data points fell within the limits of the target values. All investigators concluded that the CDI 500 system provides values that meet the accuracy standards for laboratory analyzers.

Results

In each graph below, the y-axis represents the bias, or difference, between the values obtained by the CDI 500 system and the value obtained by the lab analyzer. The x-axis represents the lab analyzer value for the same data points. For pH, pCO₂ and K⁺, upper and lower limits of CLIA mean target values are represented by the pair of parallel lines across the data field. For pO₂, the range of target values is defined by 10% of the laboratory analyzer value; as pO₂ increases, the acceptable variance from the laboratory analyzer value increases.

- 10 - 11 data points
- 7 - 9 data points
- 4 - 6 data points
- 1 - 3 data points



evaluators comment...

Faster, More Precise, Clinical Decision Making

In the customer satisfaction evaluation, all 30 participants concluded that continuous monitoring with the CDI 500 system leads to faster and more precise clinical decision making.

Save time on bypass.

During one case, the patient was hyperkalemic. When the surgeon called to come off pump at a lower K⁺ level, the perfusionist was able to adjust the patient's potassium value to the desired level within ten minutes (adding fluid to the circuit to dilute the potassium, using the hemoconcentrator to raise the hematocrit), and the patient came off the pump without incident. The perfusionist estimated that without accurate continuous in-line monitoring, it would have taken 10 to 20 minutes to correct and document the potassium level.

"Patients don't always react as you expect. Consider that there are variations in the amount of blood from the pericardium that is introduced in the circuit. That factor alone can affect the systemic potassium level in a manner that is difficult to predict."

Robin Sutton, MS, CCP
Director, Life Support Department,
Medical University of South Carolina

Minimize risk of neurologic injury.

"Our heart team believes that careful control of pO₂ and pCO₂ can minimize the risk of neurologic injury. Even though open heart surgery is generally considered a safe operation with a relatively low mortality rate, there are a lot of variables that can affect morbidity. Clinicians shouldn't assume that cardiac surgery is predictable."

Ian Shearer, CCP
Chief, Perfusion Services, Duke University Medical Center

Fine-tune myocardial protection strategy during long cases.

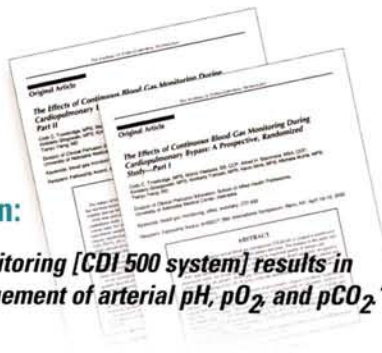
"The ability to continuously monitor potassium is an asset because it allows you to fine-tune your myocardial protection strategy during long cases like mitral valve repairs or cases with continuous retrograde cardioplegia."

Ian Shearer, CCP

Proactively manage pharmacological treatment.

"The real time O₂ consumption gives us a tool to identify the 'light' patient and has provided us with direction for the use of anesthetic agents and drugs."

Ralph Montesano, CCP
Senior Staff Perfusionist, Lehigh Valley Hospital



Studies have shown:

"The use of in-line monitoring [CDI 500 system] results in more consistent management of arterial pH, pO₂, and pCO₂."*
and

"As blood gas parameters fell outside of normal range more often, complication rates increased and more time was spent on mechanical ventilation, in the ICU, and in the hospital."*

Ask your Terumo Cardiovascular Systems representative for more information on these studies.

* Trowbridge C, Stammers A, et al. *The Effects of Continuous Blood Gas Monitoring During Cardiopulmonary Bypass: A Prospective, Randomized Study, Parts I and II.* J. Extra-Corp Tech, 2000; 32:120-137.

Ordering Information

Description	Catalog No.	Units/Case
Monitor Configurations		
Monitor with one blood parameter module	500A	1
Monitor with one blood parameter module & one Hct/Sat probe	500AHCT	1
Monitor with two blood parameter modules	500AV	1
Monitor with two blood parameter modules & one Hct/Sat probe	500AVHCT	1
Calibrator		
	540	1
Accessories for Use with CDI 500 System		
Gas A, calibration gas for use with Calibrator 540	CDI506	1
Gas B, calibration gas for use with Calibrator 540	CDI507	1
Printer paper	7310	5
Monitor pole clamp, 7" (17.8 cm) arm length, calibrator mount	CDI517	1
Monitor pole clamp, 4.5" (11.4 cm) arm length	CDI518	1
Cable head bracket	CDI519	1
Disposable Sensors for Use with CDI 500 System		
Shunt Sensor for use with 500 System, heparin treated	CDI510H	20
Disposable H/S Cuvettes for Use with CDI 500, 101 and 100 Systems		
1/4" x 1/4"	6914	20
3/8" x 3/8"	6913	20
1/2" x 1/2"	6912	20
1/4" x 1/4" with 6" (15.2 cm) extension tube	6934	10
3/8" x 3/8" with 6" (15.2 cm) extension tube	6933	10
1/2" x 1/2" with 6" (15.2 cm) extension tube	6932	10

CDI™ 500 Blood Parameter Monitoring System

Product Specifications

Displayed Parameters	System Operating Ranges	Resolution
pH	6.8 to 8.0	0.01
pCO ₂	10 to 80 mm Hg (1 to 11 kPa)	1 mm Hg (0.1 kPa)
pO ₂	10 to 500 mm Hg (1 to 67 kPa)	1 mm Hg (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 9.9/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

Model CDI510H Shunt Sensor

Sterile, heparin-treated
 Priming volume 1.2 ml

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

System display update

Every six seconds



For more information, contact:

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