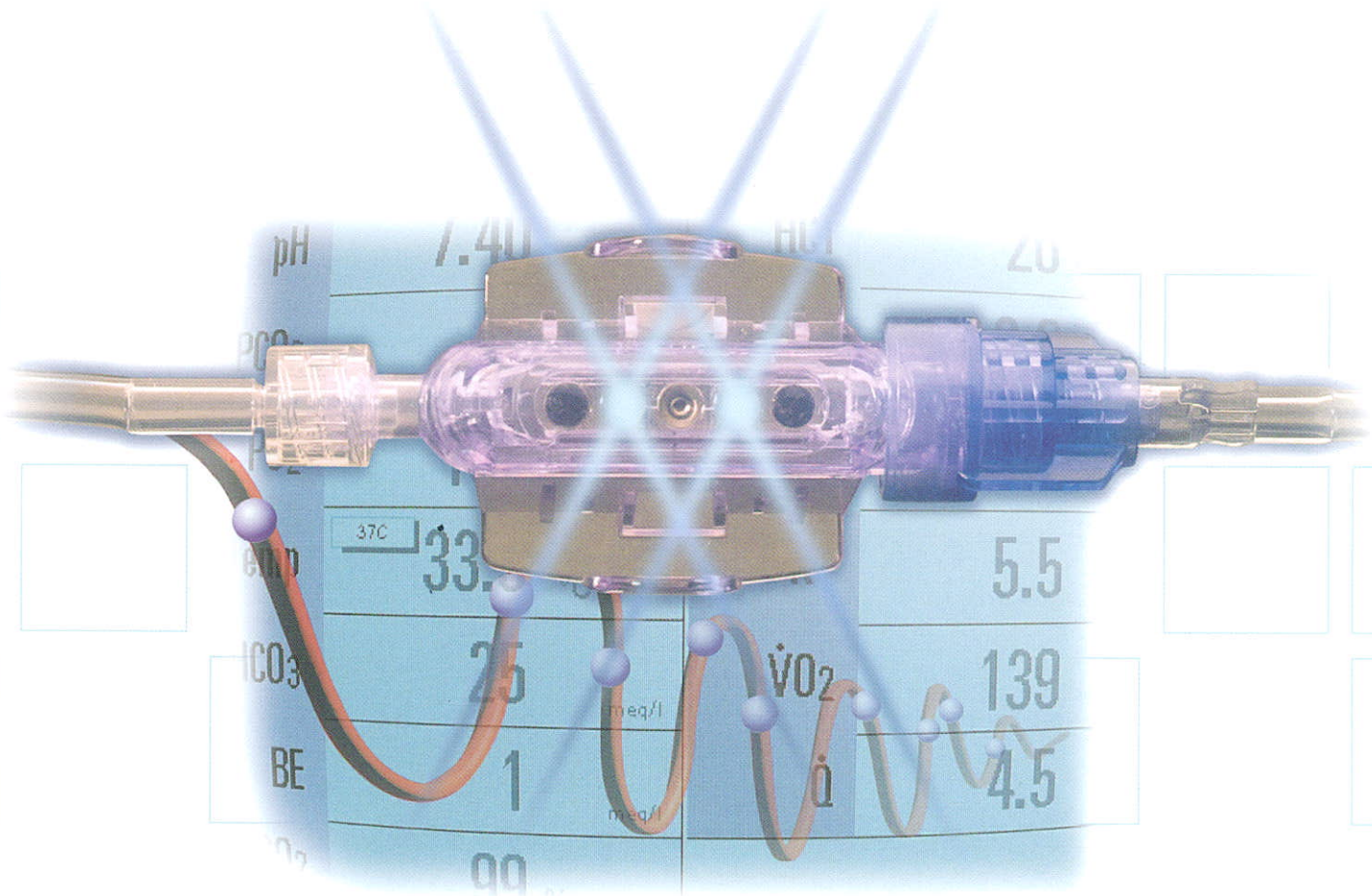
CDI™ 500 Blood Parameter Monitoring System

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



TERUMO
Cardiovascular Systems

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?

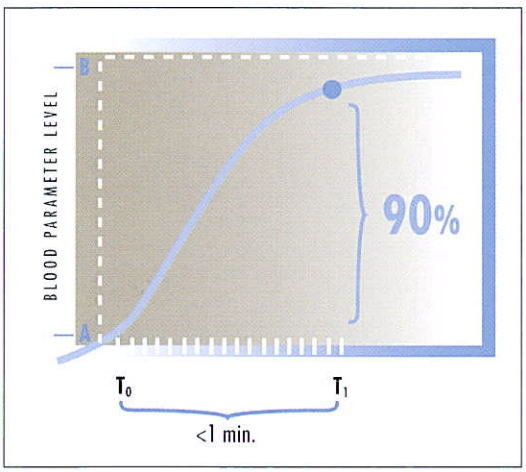
Based on optical fluorescence and reflectance technologies, the CDI 500 system continuously measures or calculates 11 critical blood parameter values during cardiopulmonary bypass. Access to continuous information is a key advantage in optimum patient management because it enables clinicians to react 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, pCO_2, pO_2, K^+, temp, SO_2, 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, pCO_2, pO_2 and K^+ is less than one minute.

Averaged response time of measured values, pH, pCO_2, pO_2 and K^+, at 37°C with 90% equilibration in Terumo Cardiovascular Systems in vitro testing.



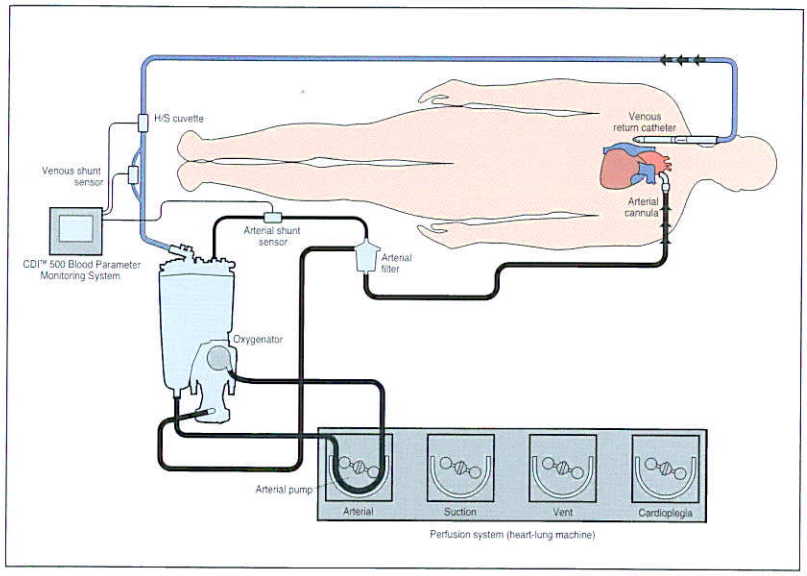
Accuracy comparable to laboratory analyzers

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.

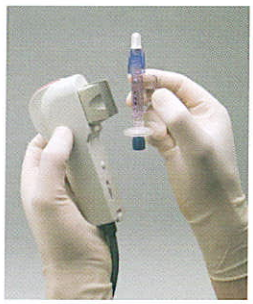
Easy to set up and calibrate

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



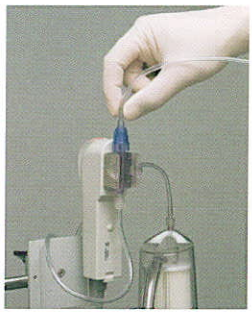
In clinical evaluations, the average time to set up calibration for the arterial shunt sensor was 37 seconds. Average time to install the calibrated sensor in the purge line was 22 seconds. (Calibration itself requires no user dedication and takes 10 minutes.)



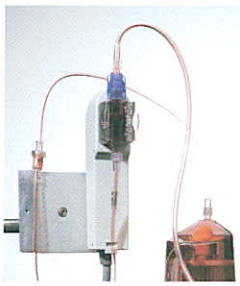
Fast, easy set up

The shunt sensor is placed in the probe head.

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



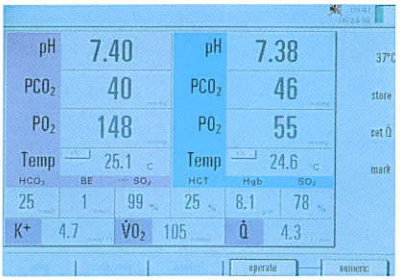
The sensor, still attached to the probe head, is installed in the circuit with two luer connections.



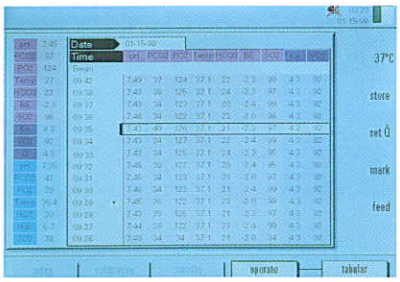
The sensor allows placement in a variety of circuit locations.

The ability to deliver continuous information quickly, accurately and easily is the result of the CDI™ 500 Blood Parameter Monitoring System's breakthrough technology and advanced features.

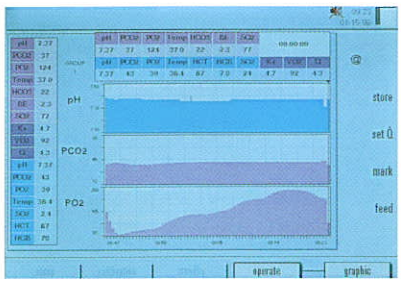
Numeric Format
Arterial and venous blood gases, K+, venous SvO_2 and Hct/Hgb.



Tabular Format
All parameters



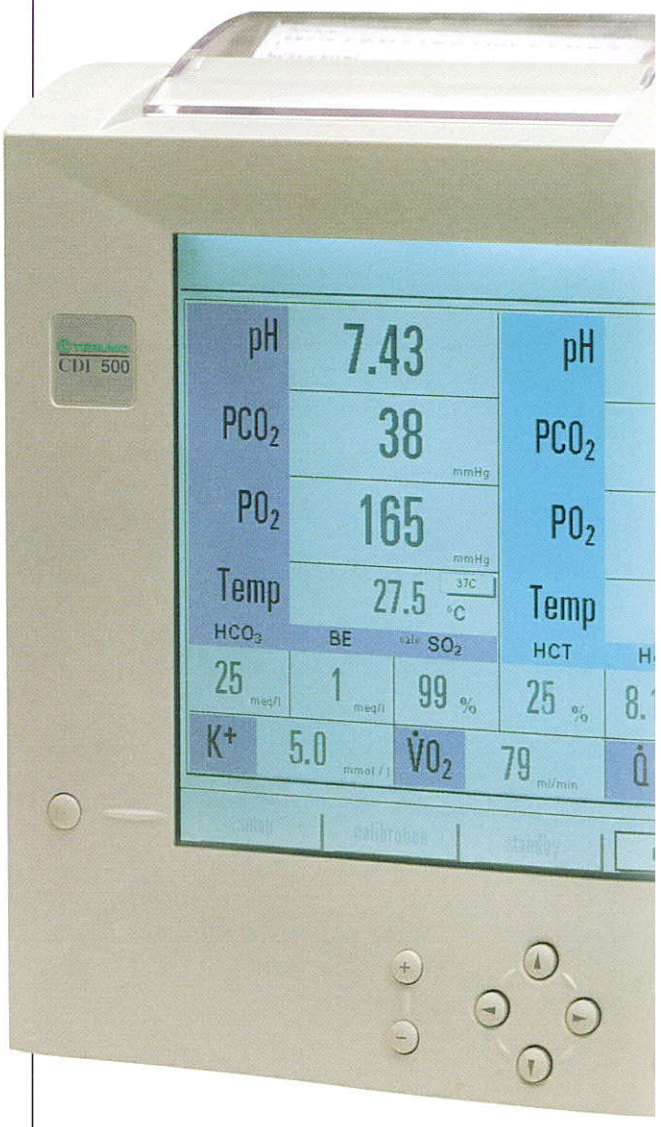
Graphical Format
All parameters available (pH, pCO_2, pO_2 currently displayed)



Arterial blood gases, K+, SvO_2 and Hct/Hgb.

Arterial blood gases and K+

The CDI 500 system monitor displays blood parameter values in either graphic, numeric or tabular formats on its color LCD screen. You can select the format you prefer for easy interpretation of continuous information on your patient.



System Features

Self-diagnostic system verifies proper functioning of electronics and optics.

System alerts provide visual and audible indicators when parameters fall outside user-specified limits.

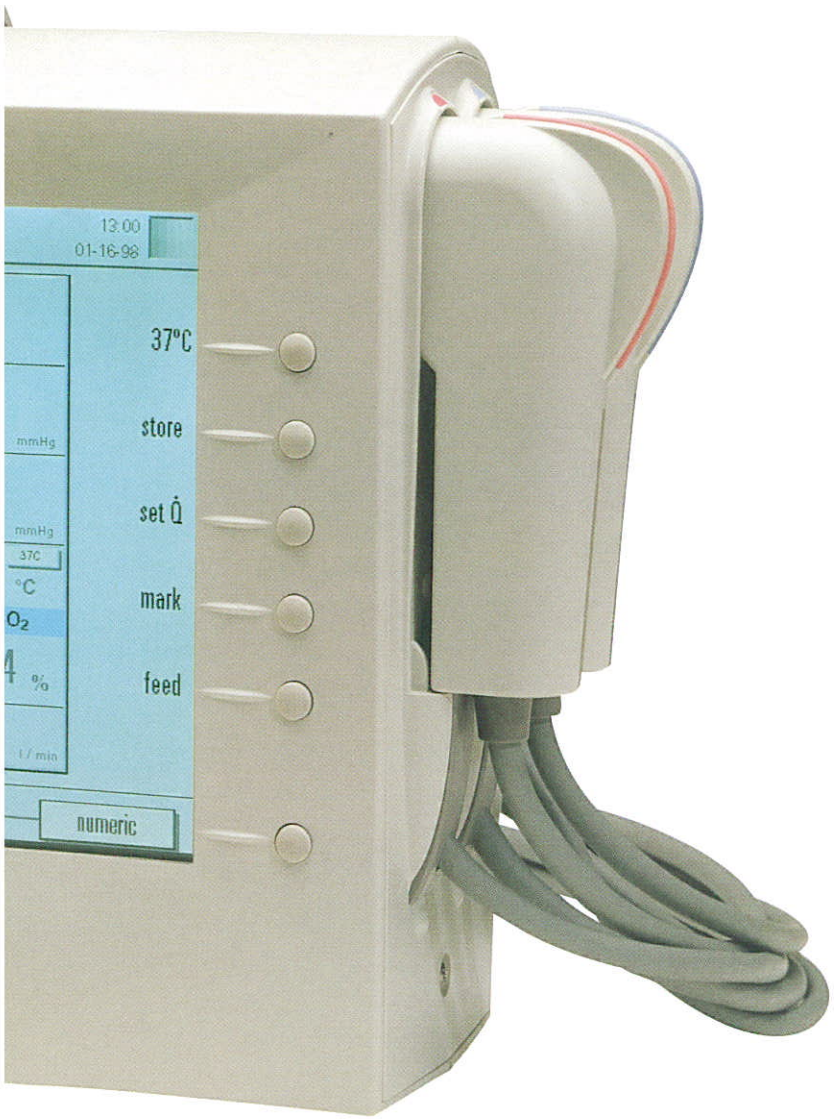
Monitor

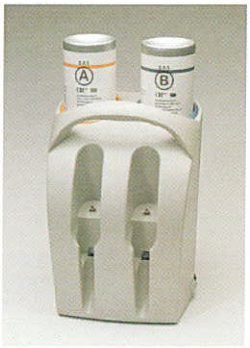
Modular probes allow user to configure system to meet specific monitoring requirements.

Color LCD display provides high visibility at a variety of viewing angles.

Built-in handle for transportability.

Integrated lead acid battery provides emergency power for 45 minutes (with no printing).



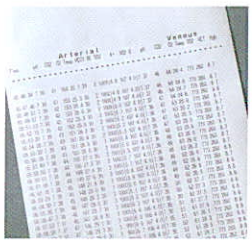


Calibrator

Small footprint and built-in handle for transportability.

Mountable onto monitor pole clamp.

Provides fast, automatic 2-point gas tonometered calibration.



Integral Monitor Printer

Delivers documentation of system's self-diagnostics, calibration verification as well as displayed values.

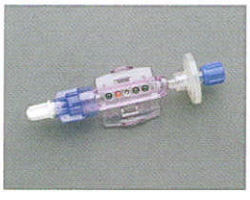
H/S Cuvette

Disposable cuvette clips easily to hematocrit/ saturation probe and requires no calibration.

RS-232 Serial Interfaces

Takes inputs from pumping system to use and display blood flow.

Provides outputs to data management systems or transmission to other external devices.



Innovative Shunt Sensor

Direct contact with blood for fast response time.

Can be added after initiation of bypass.

Treated with covalently bound, non-leaching heparin.

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, pCO_2, pO_2 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, 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.

Table 2

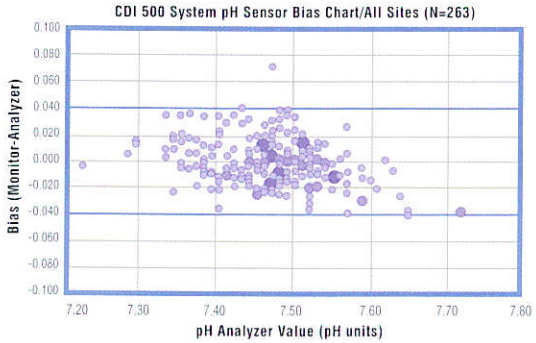
Blood Gas Parameters	CLIA '88 Mean Target Values	CDI 500 System Bias
pH	± .04 pH units	0.00 pH units
pCO_2	± 5 mmHg	-0.3 mm Hg
pO_2	± 3 standard deviations	NA
K+	± 0.5 mmole/l	0.12 mmole/l

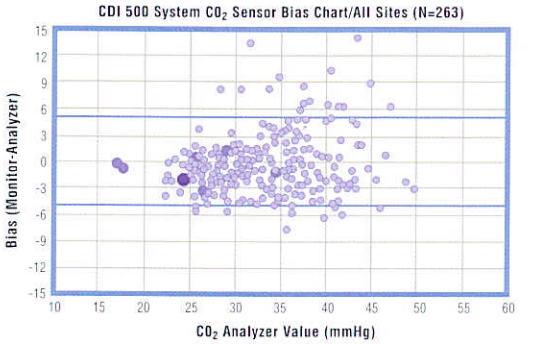
As indicated in **Table 2**, the CLIA target value could not be used for pO_2 values because it represents a variable range (± 3 standard deviations) as opposed to a fixed interval (e.g., ± 5 mm Hg). The investigators therefore used ± 10% of the reference, or laboratory analyzer, value to evaluate the performance of the pO_2 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.

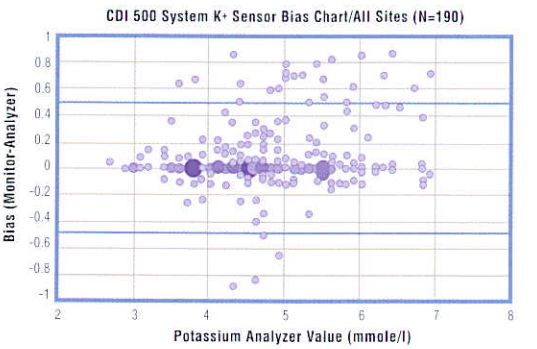
Results

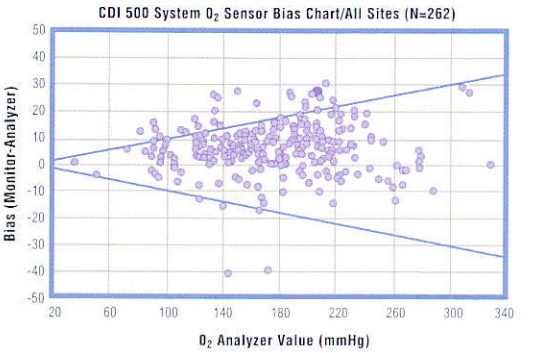
In each graph below, the y-axis represents the bias, or difference, between the values obtained by the CDI 500 system and the value obtained by the lab analyzer. The x-axis represents the lab analyzer value for the same data points. For pH, pCO_2 and K+, upper and lower limits of CLIA mean target values 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.

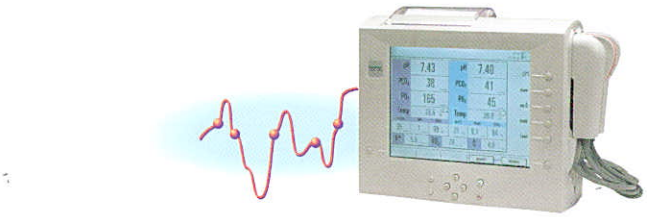
- 10 - 11 data points
- 7 - 9 data points
- 4 - 6 data points
- 1 - 3 data points











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 pO_2 and pCO_2 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.

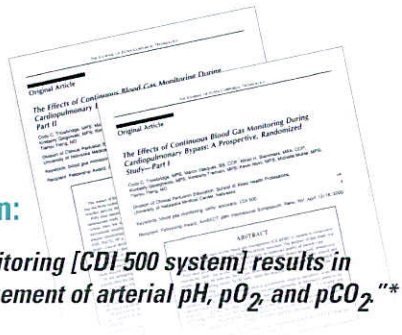
"The ability to continuously monitor potassium is an asset because it allows you to fine-tune your myocardial protection strategy during long cases like mitral valve repairs or cases with continuous retrograde cardioplegia."

Ian Shearer, CCP

Proactively manage pharmacological treatment.

"The real time O_2 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, pO_2, and pCO_2."*

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, 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

TERUMO
Cardiovascular Systems
PRECISION-FOCUSED TECHNOLOGY

For more information, contact:

TERUMO CARDIOVASCULAR SYSTEMS CORPORATION
6200 Jackson Road
Ann Arbor, Michigan 48103-9300
USA
734 663 4145 phone
734 663 7981 fax
800 521 2818 toll free

TERUMO CORPORATION
44-1, 2-chome
Hatagaya, Shibuya-ku
Tokyo 151-0072
Japan
81 3 3374 8111 phone
81 3 3374 8196 fax

TERUMO EUROPE N.V.
Authorized EC Representative
Interleuvenlaan 40 B-3001
Leuven
Belgium
32 16 38 12 11 phone
32 16 40 02 49 fax

TERUMO EUROPE N.V.
Cardiovascular Division
Hauptstrasse 87
D-65760 Eschborn
Germany
49 6196 8023 500 phone
49 6196 8023 555 fax

TERUMO LATIN AMERICA CORPORATION
8750 NW 36th Street, Suite 600
Miami, Florida 33178
USA
305 477 4822 phone
305 477 4872 fax
800 283 7866 toll free

www.terumo-cvs.com

801134