Technical Compendium

CDI OneView™ Monitoring System

An overview of the CDI OneView Monitoring System and its industry leading technology.

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The CDI OneView Monitoring System Displays up to 22 Vital Patient Parameters.

The CDI OneView Monitoring System was designed and developed to enable continuous monitoring of in-line patient parameters during cardiopulmonary bypass (CPB) — potential of hydrogen (pH), partial pressure of carbon dioxide (pCO_2), partial pressure of oxygen (pO_2), potassium ion (K^+), temperature, oxygen saturation (SO_2), hematocrit (HCT), and hemoglobin (Hgb). In addition, the system offers continuous base excess (BE), bicarbonate (HCO_3^-), oxygen consumption (VO_2), oxygen delivery (DO_2), oxygen extraction ratio (O_2ER), cardiac index (CI), measured flow, visibility of cerebral saturations, and area under the DO_2i curve (AUC).

Using optical fluorescence and reflectance technologies with disposable Shunt Sensors and Cuvettes placed in the extracorporeal circuit, the CDI OneView System monitors and displays real-time changes in patient parameters. The system provides continuous results and reduces the need to obtain or dispose of blood samples as required with laboratory analyzers. Adoption of CDI OneView System technology allows constant visibility and provides early warning of dynamic changes.

By providing a comprehensive view of all relevant information, the CDI OneView System enables clinicians to gain valuable insights, make informed decisions, and drive strategic outcomes.

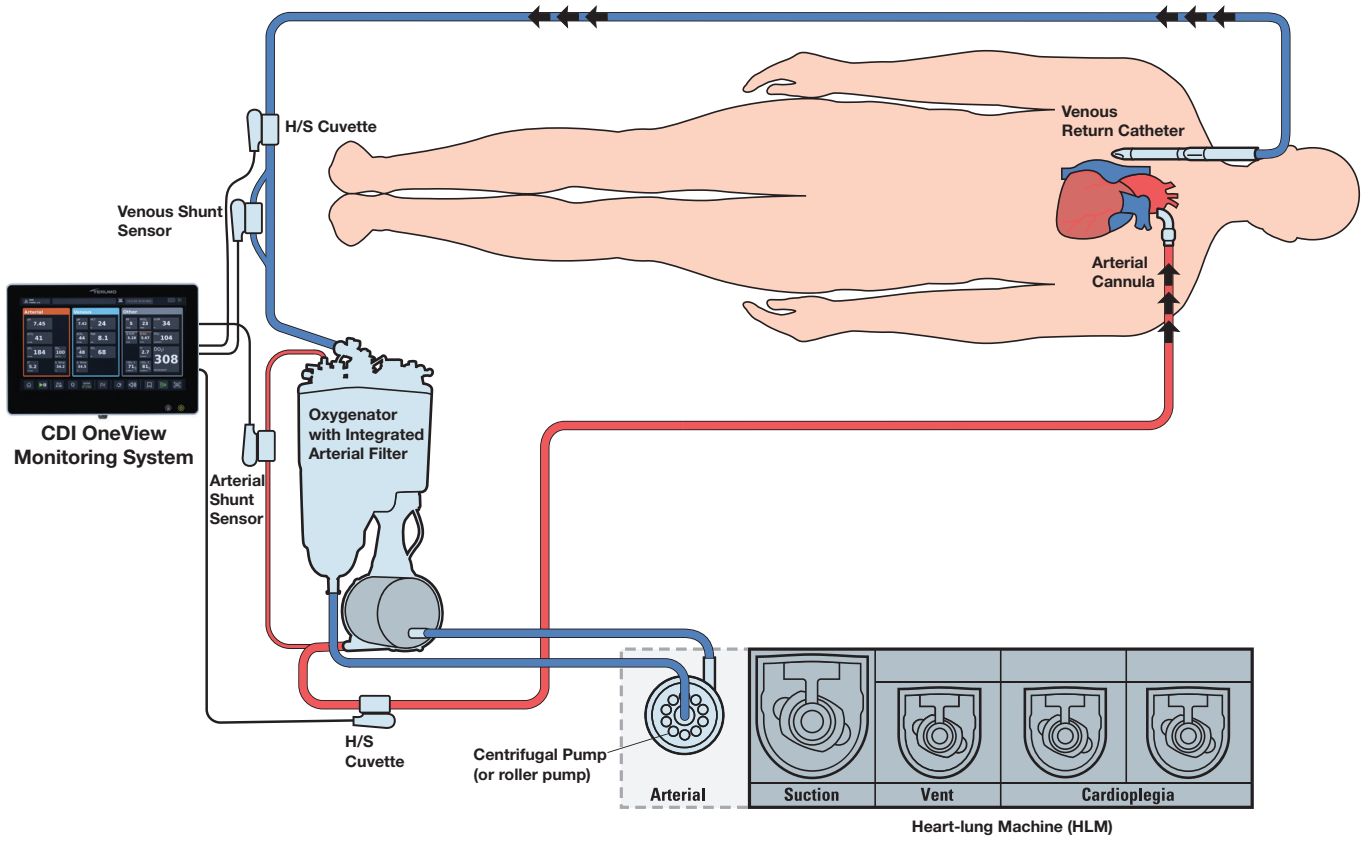

Figure 1: *The CDI OneView System Shunt Sensors and H/S Cuvettes are placed in the extracorporeal circuit, allowing real-time response to changes in patient parameters.*

System Accuracy Limits

The CDI OneView System has been subjected to rigorous bench tests to simulate clinical use and assess accuracy and precision over the system operating ranges. Blood samples taken from the test circuit were analyzed by conventional analyzer on a sample-by-sample basis and compared to values displayed by the CDI OneView System. The absolute values of the differences were then used to calculate error for each measurement.

$$Error = | CDI - Analyzer |$$

The population of errors for each sensor is summarized statistically using a Weibull Distribution.

Note: This analysis method using absolute value utilizes a different statistical approach from legacy CDI System products that is more suitable for the distribution of data across all operating conditions. Therefore, the statistical summary should not be used for direct comparison to legacy CDI System product performance specifications.

Sensor	Median Error	Standard Deviation
pH (pH units)	0.01	0.02
pCO_2 (mmHg)	1.35	0.96
pO_2 Arterial (>80 mmHg)	7.24	1.48
pO_2 Venous (<80 mmHg)	1.22	0.85
SO_2 (%)	0.69	0.85
Total Hgb (g/dL)	0.44	0.40
K^+ (mmol/L)	0.15	0.09
HCT Value	1.35	1.19
Flow Sensor Q		
1/4" x 1/16" (% of reading)	3.77	7.54
1/4" x 3/32" (% of reading)	4.26	6.76
3/8" x 3/32" (% of reading)	4.82	2.13

Table 1: *Mean measurement error and standard deviation differences found.*

Figure 2: *Components of the CDI OneView System.*

CDI OneView Monitoring System Technologies

System Overview

The CDI OneView System consists of a Central Processing Core, Touchscreen Display, a user-selected combination of Flow Sensors, Data Modules, Blood Parameter Modules (BPMs) and Hematocrit/Oxygen Saturation Probes (H/S Probes), disposable sterile Shunt Sensors and H/S Cuvettes, and a Calibrator.

The disposable Shunt Sensors and H/S Cuvettes are installed in the corresponding BPMs and H/S Probes at points in the circuit which will allow adequate exposure to blood (see Figure 1).

Clinicians select the combination of BPMs and H/S Probes depending on the parameters to be monitored (see Table 2). BPMs, which measure arterial and/or venous pH, pCO_2, pO_2, K^+, and temperature use optical fluorescence technology in conjunction with the disposable Shunt Sensor. The CDI OneView System calculates the following important parameters: arterial oxygen saturation (SaO_2), BE, HCO_3-, VO_2, DO_2, O_2ER, CI, and AUC. The H/S Probes, which measure HCT, Hgb, and arterial and/or venous SO_2, use optical reflectance technology in conjunction with the disposable H/S Cuvettes.

Parameters Measured	Components	Technology Utilized
pH, pCO_2, pO_2, K^+	BPM w/ Shunt Sensor	Optical fluorescence
HCT, Hgb, SO_2	H/S Probe w/ H/S Cuvette	Optical reflectance
Q Flow Rate	Flow Module w/ Flow Sensor	Ultrasonic

Table 2: *The CDI OneView System allows calculation of the following important parameters:*

BE, HCO_3-, VO_2, VO_2i, DO_2, DO_2i, CI, AUC. The system calculates SaO_2 and SvO_2 if not measured.

Optical Fluorescence with the CDI Shunt Sensor

The CDI OneView System 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. Temperature is measured at the Shunt Sensor site and does not represent the patient's actual temperature. The microsensors are in direct contact with the blood, enabling rapid response time.

The Shunt Sensor can be placed in any arterial or venous shunt or purge line with continuous flow (see Figure 1). A minimum blood flow requirement of 35 mL/min is necessary for proper measurement.

During normal operation of the CDI OneView System, light emitting diodes (LEDs) in the BPMs 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 presented on the Touchscreen Display.

The pH, pCO_2, and pO_2 measurements are taken every second. The K^+ measurement is taken every six seconds.

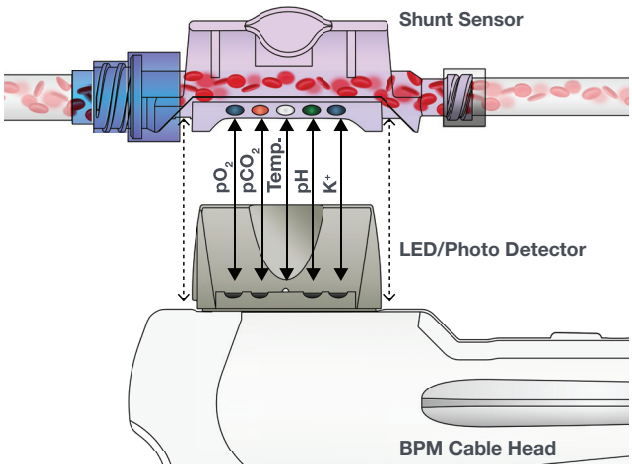

Figure 3: *Optical fluorescence: CDI Shunt Sensor and BPM.*

H/S Cuvettes.

Optical Reflectance with the CDI System H/S Cuvette

The CDI OneView System uses optical reflectance technology with the H/S Probes to measure oxy- and deoxy- forms of hemoglobin.

The flow-through H/S Cuvette is placed directly in the CPB circuit. A window in the H/S Cuvette allows optical measurement without blood contact (see Figure 4).

LEDs in the H/S Probe direct light pulses of specific wavelength at the blood through the optical window in the H/S Cuvettes (see Figure 4). The intensity of the resulting reflections are analyzed (on the basis of the characteristic spectra of the oxy- and deoxy- forms of hemoglobin) to determine the oxygen saturation, hematocrit, and hemoglobin. These measurements are taken every 18 milliseconds and are displayed on the monitor's Touchscreen Display.

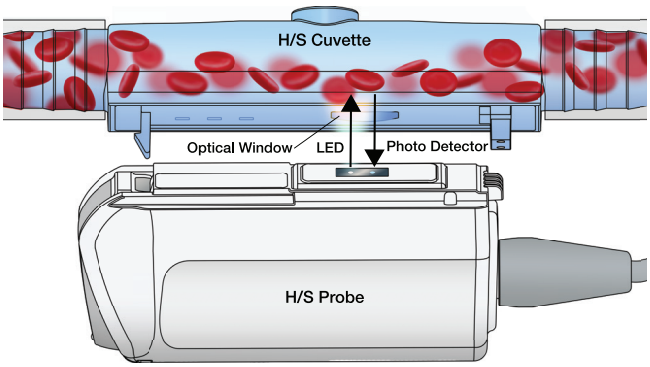

Figure 4: *Optical reflectance: CDI H/S Cuvette and H/S Probes.*

Cuvette Blood Flow Rates

The CDI OneView System should only be used where there is blood flow through the extracorporeal circuit. To perform accurately, reference the minimum and maximum blood flow rates (Q) as listed in the H/S Cuvette Instructions for Use. Restoration of blood flow above the minimum through the H/S Cuvette will restore performance of the system.

Ultrasonic Technology with the CDI Flow Sensor

The flow sensor uses ultrasonic "transit-time" technology to measure flow through a clamp-on sensor specifically designed for use with flexible plastic tubing. Ultrasonic transducers pass signals back and forth, alternately intersecting the flowing fluid in upstream and downstream directions. The transit-time it takes for the wave of ultrasound to travel from one transducer to the other is proportional to flow, and the difference between the upstream and downstream transit times is used to calculate the flow rate.

Placing H/S Probe onto H/S Cuvette.

CDI OneView Monitoring System Calibration of the Microsensors

Shunt Sensors in the BPM placed within the Calibrator.

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 Model 740 Calibrator and two canisters of calibration gases, Gas 1 and Gas 2. The calibration gases contain precise, defined levels of carbon dioxide (CO_2) and oxygen (O_2) gases (see Table 3). During calibration, the Shunt Sensors (attached to the BPM) 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 CO_2 and O_2 values.

	Gas 1 Model CDI746	Gas 2 Model CDI747
pH	7.171 pH units	7.599 pH units
CO_2	7.5% ± 0.1% (55.6 mmHg)	2.8% ± 0.1% (20.8 mmHg)
O_2	24.0% ± 0.1% (177.9 mmHg)	4.0% ± 0.1% (29.7 mmHg)

Table 3: *Calibrating gas values for the CDI OneView System. Balance of gas mixture is nitrogen (N_2). Gases measured at 1 atm and 21 °C.*

To perform the calibration, the system measures the fluorescent intensities emitted by a microsensor as it is exposed to Gas 1 and then Gas 2. It then plots the two fluorescent measurements as a function of the predefined values of the calibration gases (see example for pO_2 in Figure 5). The system uses the two points to create a slope and a y-intercept for that parameter. During CPB, 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.

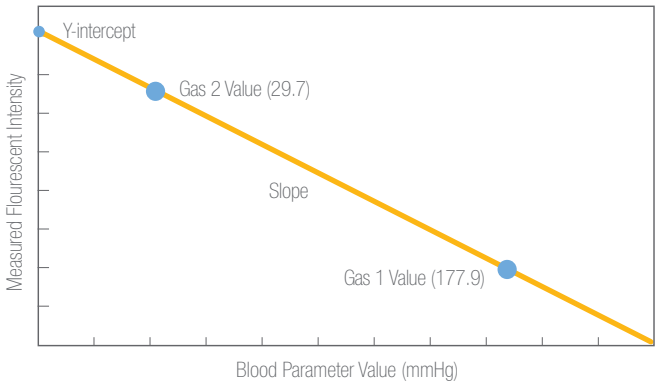

Figure 5: *Example of a 2-point calibration for pO_2 sensor.*

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 Shunt Sensor. This is the K^+ code on the Shunt Sensor pouch which is entered during the initial calibration sequence (as described in the CDI OneView Monitoring System Operator's Manual). The intercept point is obtained after the initiation of CPB using the K^+ level in a patient blood sample. The sample is drawn, the CDI OneView System K^+ reading is stored in the system, the sample is processed using the laboratory analyzer, and the analyzer's value is entered into the CDI OneView System to recalibrate the stored reading.

H/S Probe

Each H/S Probe is precalibrated at the factory for SO_2, HCT, and Hgb values; and further calibration is not required before going on CPB. A color chip test is performed at system startup. To meet system accuracy limits, perform an in vivo re-calibration as outlined in the CDI OneView Monitoring System Operator's Manual.

CDI OneView Monitoring System.

Glossary of Acronyms and Abbreviations

AKI	Acute Kidney Injury
AUC	Area Under the DO_2i Curve
BE	Base Excess
BPM	Blood Parameter Module
BSA	Body Surface Area
CI	Cardiac Index
CPB	Cardiopulmonary Bypass
DMS	Data Management System
DO_2	Oxygen Delivery
DO_2i	Indexed Oxygen Delivery
EMR	Electronic Medical Records
GDP	Goal-Directed Perfusion
H/S	Hematocrit/Oxygen Saturation
HCO_3^-	Bicarbonate
HCT	Hematocrit
Hgb	Hemoglobin
HL	Hyperlactatemia
HLM	Heart-lung Machine
ICU	Intensive Care Unit
K^+	Potassium Ion
O_2	Oxygen
O_2ER	Oxygen Extraction Ratio
paO_2	Arterial Partial Pressure of Oxygen
pCO_2	Partial Pressure of Carbon Dioxide
pH	Potential of Hydrogen
pO_2	Partial Pressure of Oxygen
Q	Blood Flow Rate
rSO_2	Cerebral Regional Oxygen Saturation
SaO_2	Arterial Oxygen Saturation
SO_2	Oxygen Saturation
SvO_2	Venous Oxygen Saturation
VO_2	Oxygen Consumption
VO_2i	Indexed Oxygen Consumption

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Product Specifications

Parameters	Display Range	Resolution
pH	6.50 to 8.50	0.01
pCO_2	10 to 200 mmHg 1.3 to 26.7 kPa	1 0.1
pO_2	10 to 700 mmHg 1.3 to 93.3 kPa	1 0.1
K^+	1.0 to 9.9 mmol/L	0.1
Shunt Temp	1.0 to 45.0 °C	0.1
SO_2	35 to 100%	1%
HCT	12 to 45%	1%
Hgb	4.0 to 15.0 g/dl	0.1
Q	0 to 10.00 L/min	0.001 < 1.00 L/min 0.01 ≥ 1.00 L/min
CI	0.1 to 10.0 L/min/m^2	0.1
BE	-25 to 25 mEq/L	1
HCO_3^-	0 to 50 mEq/L	1
VO_2	1 to 400 mL/min	1
VO_2i	1 to 1000 mL/min/m^2	1
DO_2	1 to 3000 mL/min	1
DO_2i	1 to 1000 mL/min/m^2	1
rSO_2	Match source device	Match source device
Q (from HLM)	Match source device	Match source device
O_2ER	0.00 to 100%	1%
SaO_2calc	35 to 100%	1%
SvO_2calc	35 to 100%	1%

Component	Part #	Dimensions	Weight
Core	CDI750	22.2 cm x 27.2 cm x 8.3 cm	3 kg
Display + Backplate	CDI751	30 cm x 20.5 cm x 9.5 cm	2.4 kg
Calibrator	CDI740	23 cm x 21 cm x 18 cm	3.3 kg
Core Bracket	CDI780	21 cm x 15.5 cm x 12 cm	1.6 kg
Display Bracket	CDI781	47 cm x 28 cm x 9 cm	1.7 kg
Calibrator Bracket	CDI782	32.4 cm x 18.6 cm x 8.2 cm	1 kg
BPM Bracket	CDI783	19.2 cm x 9 cm x 5.8 cm	1 kg

System Power Requirements and Specifications

100-240 VAC, 50/60 Hz

14.4-volt backup battery

Model CDI510H Shunt Sensor

Sterile, heparin-treated
Priming volume 1.2 mL

System Display Update

Every 1 second

System Measurement Cycle Time

pH, pCO_2, pO_2, SO_2, HCT, Hgb, Q = one measurement per second

K^+ = one measurement per six seconds

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

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