CDI OneView™ Monitoring System

An industry benchmark of excellence with real-time monitoring of up to 22 vital patient parameters.

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CDI OneView Monitoring System

Enhancing patient care and cost savings

In-line continuous monitoring of oxygen delivery (DO_2) is a key parameter clinicians use to reduce the risk of acute kidney injury (AKI), improve patient outcomes, and save hospital costs. The CDI OneView System allows you to bring DO_2 and any combination of 22 vital parameters into a single view. With a few touches of the screen, you have precise control over seeing parameters that matter most. Research shows that the largest area under the DO_2 curve (AUC) is an independent risk factor for AKI. Managing indexed oxygen delivery (DO_2i) in relation to oxygen extraction ratio (O_2ER) has been shown to reduce the incidence of hyperlactatemia (HL) during surgery as well as reduce postoperative serum creatinine, mechanical ventilation time, and intensive care unit (ICU) stay.

A comprehensive interface for enhanced monitoring

The CDI OneView System builds on the critical information clinicians have come to rely on with the addition of cerebral oximetry values and blood gases visible on the same screen. The system measures or calculates potential of hydrogen (pH), partial pressure of carbon dioxide (pCO_2), partial pressure of oxygen (pO_2), potassium (K^+), temperature, oxygen saturation (SO_2), hematocrit (HCT), hemoglobin (Hgb), base excess (BE), bicarbonate (HCO_3^-), cardiac index (CI), O_2ER, oxygen consumption (VO_2), DO_2, AUC, and measured flow. The system is designed for expansion as new parameters become available.

Intuitive control and advanced customization

The CDI OneView System also offers a full range of advanced features, including optical fluorescence technology, new probe design, and measured flow options. The user-friendly Touchscreen Display enables interaction with flexible customization and configurability for up to 12 case profiles — allowing intuitive navigation at the touch of a finger. User-defined thresholds provide alerts to ensure timely attention to potential concerns and make immediate adjustments if necessary.

Seamless connectivity and customizable data visualization

The modular system offers the flexibility to easily connect a variety of probes and devices such as Flow Sensors, regional cerebral oxygen saturation (rSO_2), and external data management devices. This flexibility extends to how the data can be viewed and analyzed, allowing users to observe the collected information in real-time and choose from numerical representations, multi-parameter or single graphical displays, and even customize the visualizations to suit specific needs and preferences.

Informed decision-making

Built on proven CDI System technology, the CDI OneView System delivers exceptional performance and convenience in real-time.

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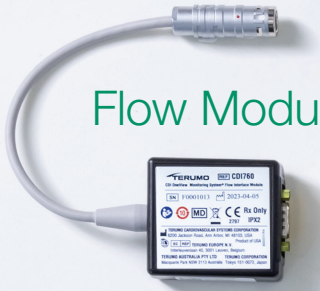
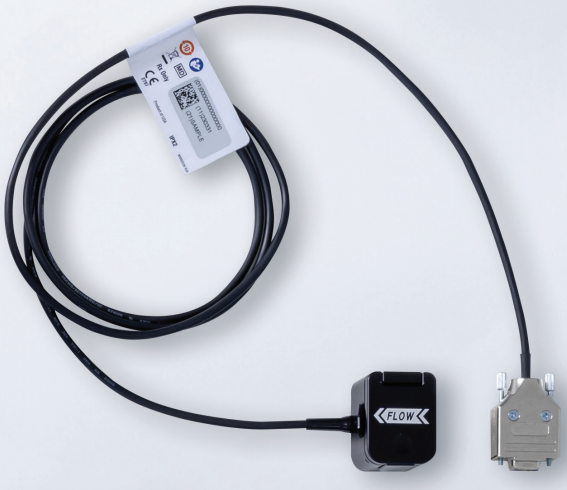


Flow Module

Touchscreen Display



Flow Sensor

Processing Core

Blood Parameter Modules (BPM)

Hematocrit/Oxygen Saturaton (H/S) Probe

Calibrator

Data Modules

BPM Bracket

Calibrator Bracket

Display Bracket

Core Bracket

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Arterial
pH 7.45
pCO2 41
pO2 184
SO2 100
K+ 5.2
S. Temp 34.2
Venous
pH 7.42
HCT 24
pCO2 44
Hgb 8.1
pO2 48
SO2 68
S. Temp 34.5
Other
BE 5
HCO3 23
O2ER 34
Q-HLM 5.19
Q-Art 5.67
VO2I 104
Q 2.7
DO2i 308
mL/min/m²
CDI OneView Monitoring System® Display Bracket
CDI OneView Monitoring System® Calibrator Bracket
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Designed for Maximum Configurability

CDI OneView Monitoring System Components

Touchscreen Display

- Graphical user interface and touchscreen technology provide quick access to clinician-defined customizable parameters and view configurations.
- Compact, low profile display lends to maximizing the view of the operative field.
- Self-diagnostic system verifies proper functions of electronics and optics — offering early notification of equipment function.*
- System alerts provide visual indicators and system alarms provide visual and audible indicators when parameters fall outside user-specified limits.
- Integrated camera for barcode scanning.
- Monitors blood temperature at either actual or 37 ˚C to allow for alpha-stat or pH-stat management.
- Displays parameter values in numeric and graphic formats.

Calibrator

- Rapid two-point gas calibration ensures the Shunt Sensor is operating according to designated specifications.
- Small footprint and built-in handle for transportability.
- May be mounted either on a tabletop or to a bracket.

Processing Core

- Serves as a connectivity hub, routing information from the Blood Parameter Module (BPM), Hematocrit/Oxygen Saturation (H/S) Probe, and Flow Sensors to the Touchscreen Display. May be conveniently mounted vertically or horizontally to the heart-lung machine (HLM) or on a flat surface.
- Integrated battery pack ensures uninterrupted operation for at least 25 minutes.

Data Modules

- HLM Data Module accepts flow input from the pumping system to use for calculations and display blood flow ($\dot{Q}$).
- rSO_2 Module allows values to stream and display on the CDI OneView System Touchscreen Display from Medtronic INVOS™, Edwards ForeSight Elite®, and Nonin SenSmart®.
- Data Management System (DMS) Module allows the CDI OneView System data to stream to external data management systems or electronic medical records (EMR).
- Connectivity with EMR streamlines data management, potentially enhancing efficiency.
- Data management connectivity allows documentation of the system's self-diagnostics, calibration verification, and displayed values.

Flow Sensing

- Measured flow from the extracorporeal circuit is used to calculate critical goal-directed perfusion (GDP) parameters.
- In pediatric cases with multiple circuit shunts, measured flow is more accurate than calculated arterial flow from a roller pump.
- Flow sensors are available in three sizes: 3/8" x 3/32", 1/4" x 3/32", and 1/4" x 1/16".

BPM

- Capability to be employed in venous or arterial applications.
- The LED indicator lights display the assignment.
- Housings have been redesigned for usability allowing smooth insertion to the Calibrator slot.

H/S Probe

- Capability to be employed in venous or arterial applications.
- The LED indicator lights display the assignment.
- The spring clip was designed with user-friendliness in mind and can be detached for cleaning purposes.
- Color chip referencing can be performed when needed.

*Case summary provides documentation of the system's self-diagnostics and calibration verification, as well as displayed values.

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Profile: or2
14:11:33 05-22-2023
Arterial
pH 7.45
pCO2 41 mmHg
pO2 184 mmHg
SO2 100 Calc. %
K+ 5.2 mmol/L
S. Temp 34.2 °C
Venous
pH 7.42
HCT 24 %
pCO2 44 mmHg
Hgb 8.1 g/dL
pO2 48 mmHg
SO2 68 %
S. Temp 34.5 °C
Other
BE 5 mEq/L
HCO3 23 mEq/L
O2ER 34 %
Q̇-HLM 5.19 L/min
Q̇-Art 5.67 L/min
V̇O2i 104 mL/min/m²
CI 2.7 L/min/m²
ḊO2i 308 mL/min/m²
rSO2 -1 71 BL 95 L CERE %
rSO2 -2 81 BL 90 R CERE %
BSA 2.10
Q
pH-Stat
37° α-Stat

DO_2 Monitoring: Enhancing Perfusion Safety and Precision During Cardiopulmonary Bypass (CPB)

Precision Monitoring for Perfusion Safety and CPB

Ensuring constant in-line monitoring throughout CPB is a pivotal element in upholding perfusion safety and enhancing patient outcomes. Research has demonstrated that precise management of blood gas parameters is indispensable in preventing adverse outcomes associated with inadequate control of these parameters.

DO_2 Monitoring

DO_2 is an indicator of the amount of oxygen (O_2) being delivered to the patient during CPB and is a standard in patient parameter monitoring - refer to American Society of Extracorporeal Technology AmSECT Guidelines 7.4, 9.2, and 10.1. DO_2 is a calculated value based on the blood Hgb oxygen saturation (SaO_2), arterial flow, and the arterial partial pressure of oxygen (PaO_2). It can be indexed to the size of the patient by using body surface area (BSA) in the formula. The CDI OneView System allows the clinician to enter the patient's BSA. DO_2 is expressed in mL/min or mL/min/m^2 if indexed to BSA.

Preventing AKI

The kidneys are sensitive to the oxygen level in the blood as well as the flow rate. Less-than-optimal DO_2 can cause organ damage. AKI is a sudden or rapid decline in renal filtration function. It is kidney damage/failure that happens within a few hours or days and causes a build-up of waste products in the blood, making it difficult for the kidneys to keep the right balance of fluid in the body. Kidney injury can be chronic or acute and increases morbidity and mortality. AKI results in longer ICU/hospital stays and higher costs, most specifically when the patient requires dialysis.

The Critical Importance of DO_2 and VO_2 in CPB

DO_2 and VO_2 values provide the clinician valuable information for the maintenance of optimal metabolic performance of the patient while being supported on CPB — ensuring that the O_2 requirements of essential organs such as the brain, intestines, liver, and kidneys are being adequately fulfilled on an individual basis. The kidneys are particularly sensitive to even a short-term O_2 deficit. The CDI OneView System uses the AmSECT recommended formula to calculate DO_2. Numerous clinical studies have demonstrated that careful monitoring of DO_2 during cardiac surgery and maintaining a threshold level during CPB dramatically reduce AKI.

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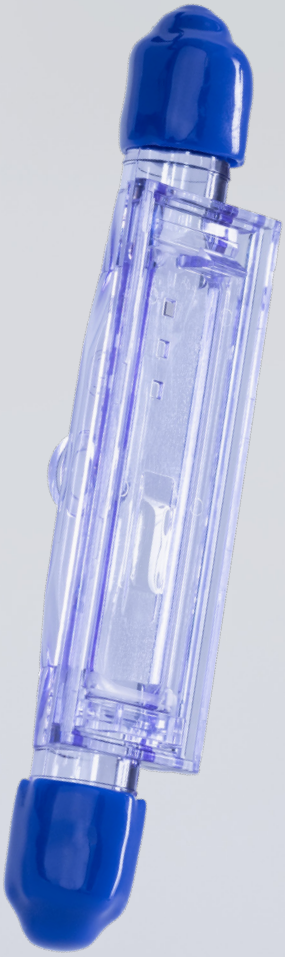
Proprietary Technology Ensuring Precision

The Shunt Sensor is placed in the BPM.

The H/S Cuvette is installed into the H/S Probe.

Shunt Sensor

- Proprietary optical fluorescence technology is used to measure pH, pCO_2, pO_2, and K^+.
- Simple installation into the shunt line using luer connections.
- May be added after the initiation of bypass, facilitating quick set up in emergency cases.
- Treated with covalently bound, non-leaching heparin.



H/S Cuvette

- Optical reflectance technology provides accurate readings of arterial and venous oxygen saturation (SO_2)/HCT/Hgb.
- The H/S Cuvette easily clips to the H/S Probe.
- Available in three sizes: ¼" x ¼", ⅜" x ⅜", and ½" x ½".

CDI OneView Monitoring System.

Glossary of Acronyms and Abbreviations

AKI	Acute Kidney Injury
AUC	Area Under the $\dot{D}O_2i$ Curve
BE	Base Excess
BPM	Blood Parameter Module
BSA	Body Surface Area
CI	Cardiac Index
CPB	Cardiapulmonary 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_2i	Indexed Oxygen Consumption

Product Components

Catalog #	Description	Units/Case
CDI750	Processing Core	1
CDI751	Touchscreen Display	1
CDI752	Display Cable	1
CDI753	Blood Parameter Module	1
CDI754	Hematocrit/Oxygen Saturation Probe	1
Calibrator Components		
CDI740	Calibrator	1
CDI741	Calibrator Cable	1
CDI746	Caliboration Gas 1	1
CDI747	Calibration Gas 2	1
Flow Sensors		
CDI763	Flow Sensor 3/8" x 3/32" (9.5 mm x 2.4 mm)	1
CDI764	Flow Sensor 1/4" x 3/32" (6.4 mm x 2.4 mm)	1
CDI768	Flow Sensor 1/4" x 1/16" (6.4 mm x 1.6 mm)	1
External Data Modules (EDMs)		
CDI760	Flow Interface Module	1
CDI770	HLM Interface Module	1
CDI771	DMS Interface Module	1
CDI772	RSO_2 Interface Module	1
Brackets		
CDI780	Core Bracket	1
CDI781	Display Bracket	1
CDI782	BPM Bracket	1
CDI783	Calibrator Bracket	1
Disposable Sensors		
CDI510H	Shunt Sensor, Heparin Treated	20
Disposable H/S Cuvettes		
6914	1/4" Connectors	20
6913	3/8" Connectors	20
6912	1/2" Connectors	20
6934	1/4" with 6" (15.2 cm) Extension Tube	10
6933	3/8" with 6" (15.2 cm) Extension Tube	10
6932	1/2" with 6" (15.2 cm) Extension Tube	10

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 to 45 °C	0.1
SO_2	35 to 100%	1%
HCT	12 to 45%	1%
Hgb	4.0 to 15.0 g/dL 40 to 150 g/L	0.1
Q	0 to 10.00 L/min 0 to 10,000 mL/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 in all four locations	Match in all four locations
Q (from HLM)	Match in all four locations	Match in all four locations
O_2ER	0.00 to 100%	1%
SaO_2calc	35 to 100%	1%
SvO_2calc	35 to 100%	1%

(*) When no unit is listed, the same unit as listed in the Display Range applies.

System Power Requirements and Specifications

100-240 VAC, 50/60 Hz

14.4-volt backup battery

Model CDI 510H 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

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