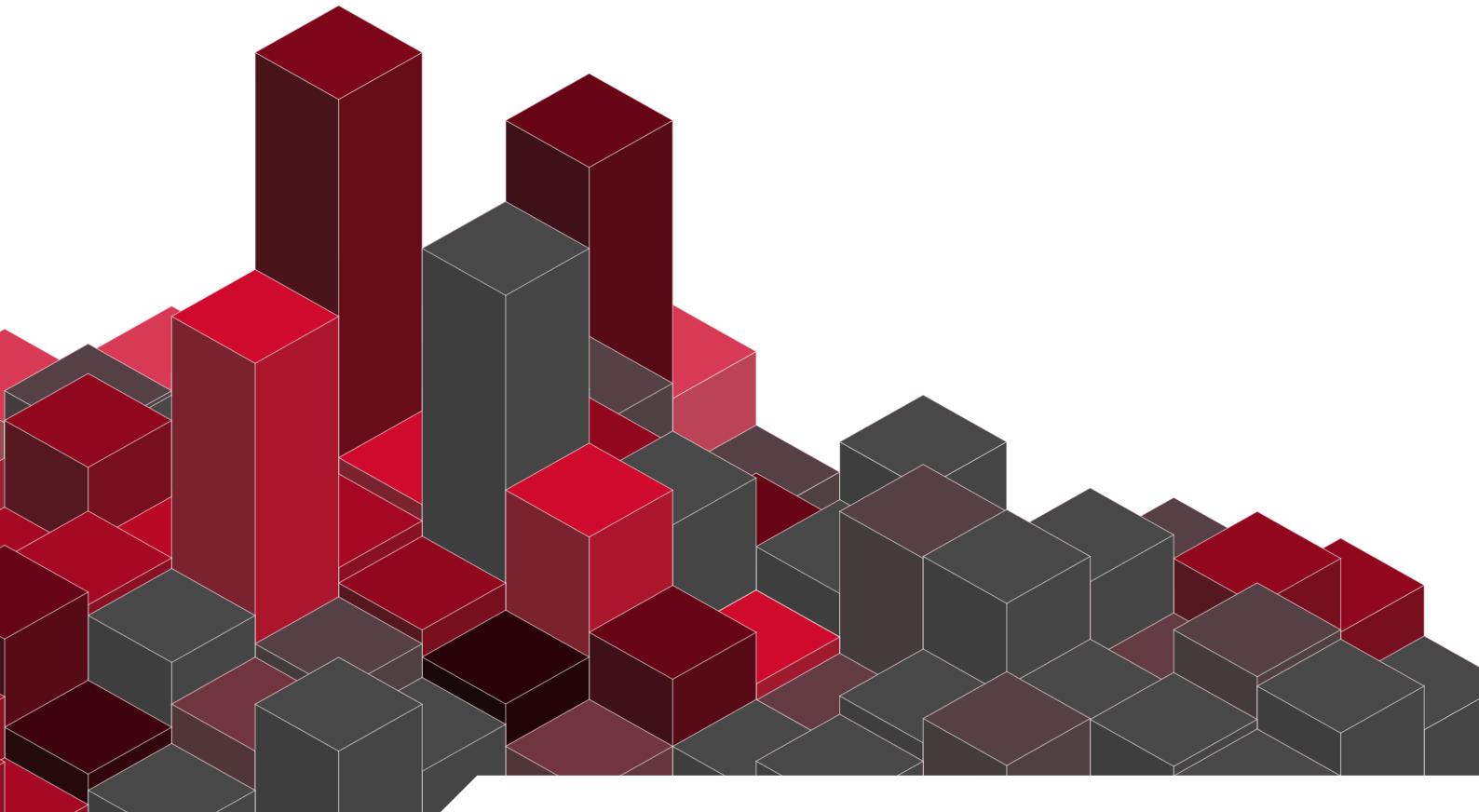




New Generation System M, leading the World
in the Non-Invasive Measurement of Critical
Real-Time Parameters.



Spectrum  *Medical*

Safer Solutions for Safer Hospitals

System M

Spectrum Medicals' total commitment to continuous product improvement is demonstrated with our New Generation System M. Upgraded features include an upgraded LCD Display Screen, Faster Processor Capabilities and new improved Software for greater ease of use.

The System M range of diagnostics monitors from Spectrum Medical is a proven solution for the continuous non-invasive diagnostic measurement of critical physiologic parameters during extracorporeal support. The proprietary range of measurement technologies share in the following "feature set" that enhances fast and accurate decision support.

Ease of Use:

Immediate access to key data without the need for multiple blood gas calibrations.

Non-Invasive:

Maintains the integrity of the bypass of ECMO circuit, improved infection control with a reduction in the risk of blood clotting and always vendor neutral.

Real-Time:

Second to second system updates using the latest technology to offer clinicians accurate information without delays.

Accuracy:

Critical real-time parameters that maintain accuracy over short and long term cases despite changes in temperature, hemodilution or blood flow.

System M Model Code	O ₂ Saturation and Hct/Hb	Flow and Emboli Detection	Calculated Physiologic Indices	Ventilation Diagnostics
System M Model Code 2	✓			
System M Model Code 3	✓	✓	✓	
System M Model Code 4	✓	✓	✓	✓



The sensors used with System M are non-invasive and require less than one minute set-up time.





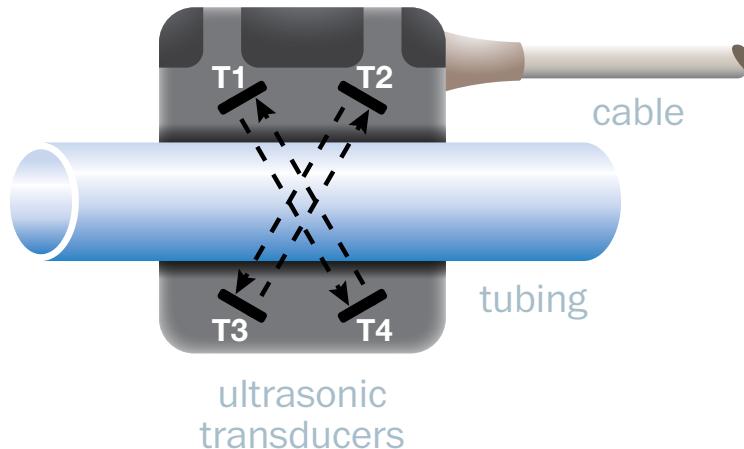
The System M monitors are portable, lightweight, fit easily on the pump, and come with up to 45 minutes of battery life.

The measurement of Blood Flow

To provide the accurate measurement of blood flow Spectrum Medical uses the latest ultrasonic technologies and the proven concept of “transit time”.

Transit time is the name given to the “phase delay” between a pair of opposing Ultrasonic transmitters and receivers. Pair one will measure the upstream transit time and pair two will measure the downstream transit time.

Clamp-on Probe Body

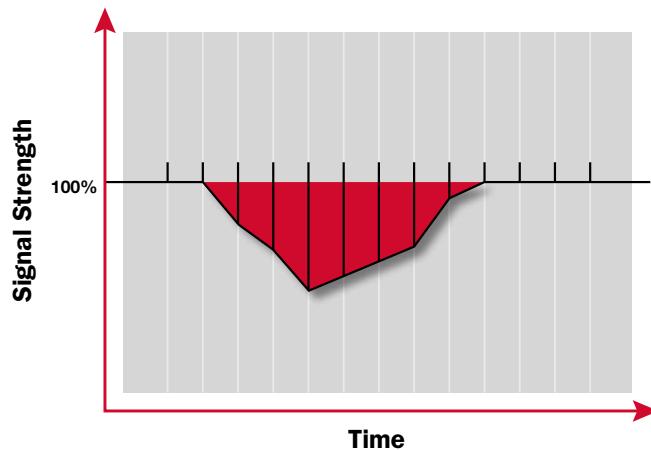


The transit time of the ultrasonic signal is decreased when traveling downstream with the blood flow and increased when traveling upstream against the blood flow. The phase delay between the integrated transit times is a measure of flowing blood.

If the transit times were equal in both the upstream and downstream sensing systems this would indicate that blood flow was static.

The Measurement of Emboli and Gross Emboli (bubbles)

Unlike blood flow, which is detected by changes in signal phase, emboli or gross Emboli (bubbles) is measured by detecting reductions in Ultrasonic signal strength. Gas as opposed to flowing blood is a poor conductor of ultrasonic energy and as emboli pass through the sensing elements the ultrasonic signal is reduced.



The level of emboli volume within the flowing blood will be dependent on the level of signal reduction multiplied by the number of signal reduction events.

Using ultra low-noise electronic technologies maximizes system sensitivity and speed of measurement. With channel specific samplings speeds now in excess of 2500 times per second Spectrum Medical has ensured system sensitivity to the presence of Emboli or Gross Emboli (bubbles).

Non-Invasive Measurement of SaO_2 , SvO_2 & Hemoglobin

The Measurement of SaO_2 and SvO_2

The Measurement of O_2 saturation is achieved by analyzing a specific region of the oxy-hemoglobin absorption curve. The use of this non-invasive optical shape recognition technology ensures the measurement of O_2 is highly accurate and extremely repeatable to its pre-shipped calibrations over the lifetime of the product.

Using a miniature scanning spectrometer and infrared LED, the system measures the reflected amplitude of light at 100 discrete wavelengths.

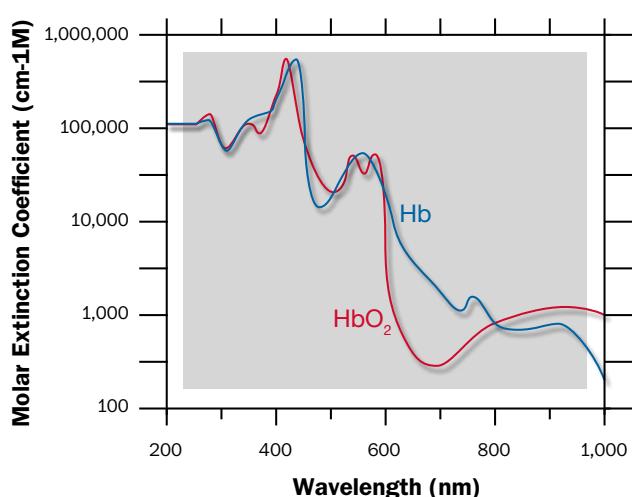
A specifically developed algorithm derives the relative contributions from both the fully oxygenated and the reduced oxygenated absorption curves to calculate an actual O_2 concentration.

The Measurement of Hematocrit and Hemoglobin

Spectrum Medical again uses non-invasive technology for the continuous reading of Hematocrit (15 to 50%) and Hemoglobin (5 to 17g/dl).

Infrared light from an LED is passed through a flowing tube of blood. A photodiode detects a receiving light level and converts the resultant light energy into a proportional electrical output.

The sensors are delivered pre-calibrated with a high and low concentration value. Software algorithms linearize this relationship and convert the incoming signal to an actual value of Hematocrit or Hemoglobin.



Perfusion Diagnostics

Now You can Measure Non-Invasively, in Real-Time, ALL of the Critical Care Parameters to enable Timely and Accurate Clinical Decision Support.

Calculated Physiologic Indices

The following measurements are available when using saturation monitoring, the measurement of Hct / Hb and the measurement of Arterial Flow.

Parameter	Units	Description
ecDO ₂	ml/min	Adequacy of tissue oxygenation. The amount of O ₂ bound to hemoglobin in arterial blood.
ecVO ₂	ml/min	Oxygen consumption: systemic oxygen uptake
ecO ₂ ER	%	O ₂ Extraction Ratio: the ratio of Oxygen consumption to Oxygen delivery.
ecDO ₂ i	ml/min/m ²	The amount of O ₂ bound to Hemoglobin in Arterial blood divided by BSA
ecVO ₂ i	l/min/m ²	The consumption of Oxygen divided by BSA
ecVCO ₂ i	ml/min/m ²	CO ₂ production divided by BSA
ecVCO ₂	ml/min	CO ₂ production

Ventilation Diagnostics (PaO₂/PaCO₂ etc...)

Spectrum Medical extends its diagnostic capabilities with patented technology that supports the non-invasive measurement of a wide range of parameters that enhance the overall-management of extracorporeal gas delivery and the optimization of Patient Ventilation.

By using real-time sensor inputs including inlet gas concentrations, gas flows and pressures to the inlet side of the oxygenator and oxygenator exit CO₂ values the proprietary algorithms will generate in real-time the non-invasive measurement of PaO₂ and PaCO₂.

Ventilation Parameters include:

Parameter	Units	Description
PaO ₂	mmHg/kPa	The partial pressure of O ₂ within the Arterial blood
PaCO ₂	mmHg/kPa	The partial pressure of CO ₂ within the Arterial blood
FiO ₂	%	The fraction of inlet O ₂ to the oxygenator
FiCO ₂	%	The fraction of inlet CO ₂ to the oxygenator
Sweep	l/min	Total gas flow to the oxygenator
FeCO ₂	%	The fraction of exit CO ₂ from the oxygenator
FeO ₂	%	The fraction of exit O ₂ from the oxygenator

Perfusion Data Management



From VIPER to VISION and LIVE VUE

VISION is a sophisticated server application that is the hub of Spectrum Medical's EMR technology. VISION automates the system-wide maintenance of software, the creation and transfer of patient records, and the storage and retrieval systems for complex clinical data sets.

LIVE VUE is Spectrum Medical's web-based near real-time remote access tool. System privileges allow for the remote viewing of live clinical data, while hardware configuration supports detailed and simultaneous viewing of multiple patients.



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MEDICAL ELECTRICAL EQUIPMENT
WITH RESPECT TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY
IN ACCORDANCE WITH UL 60601-1/CAN/CSA C22.2 No. 601.1

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