

Flexible Solutions for all of your
Cardiopulmonary Bypass
Procedures



Quantum Perfusion Technologies

The ultimate representation of Performance,
Functionality and Ease of use.

The story of Spectrum Medical is now 20 years old and our total commitment to the care of our critically ill patients can be seen in every single one of our revolutionary technologies described within this brochure. Nothing is compromised, no technology is ever considered complete, and minor details matter in the pursuit of CPB perfection.

At Spectrum Medical we have one goal and that is to be your “trusted partner” both clinically and commercially. We understand that our new technologies do push the envelope, they do question current clinical practise and therefore, they drive new learning opportunities. Additionally, it is self-evident that for this process to work successfully a traditional vendor mentality by both parties is simply not fit for purpose.

In this brochure, we present to you three critical technologies as a unified solution. We begin the journey as a trusted partner and together we can change the current status quo and take patient safety, patient outcomes and healthcare efficiency to the next level.

At Spectrum Medical we are proud of where we started all those years ago with the development of non-invasive SO₂ technology to being a full solutions provider today. We have proven that CPB is an exciting place to integrate ground-breaking technology and Spectrum Medical is dedicated to its future.

Yours Sincerely,
Steve Turner
C.E.O & Founder



Quantum Perfusion Systems for the O.R.

Spectrum Medical proudly presents a modular range of Quantum Perfusion Modules and Patient Safety Systems for a wide range of ECLS procedures used in Cardiopulmonary Bypass.



The New York HLM Frame

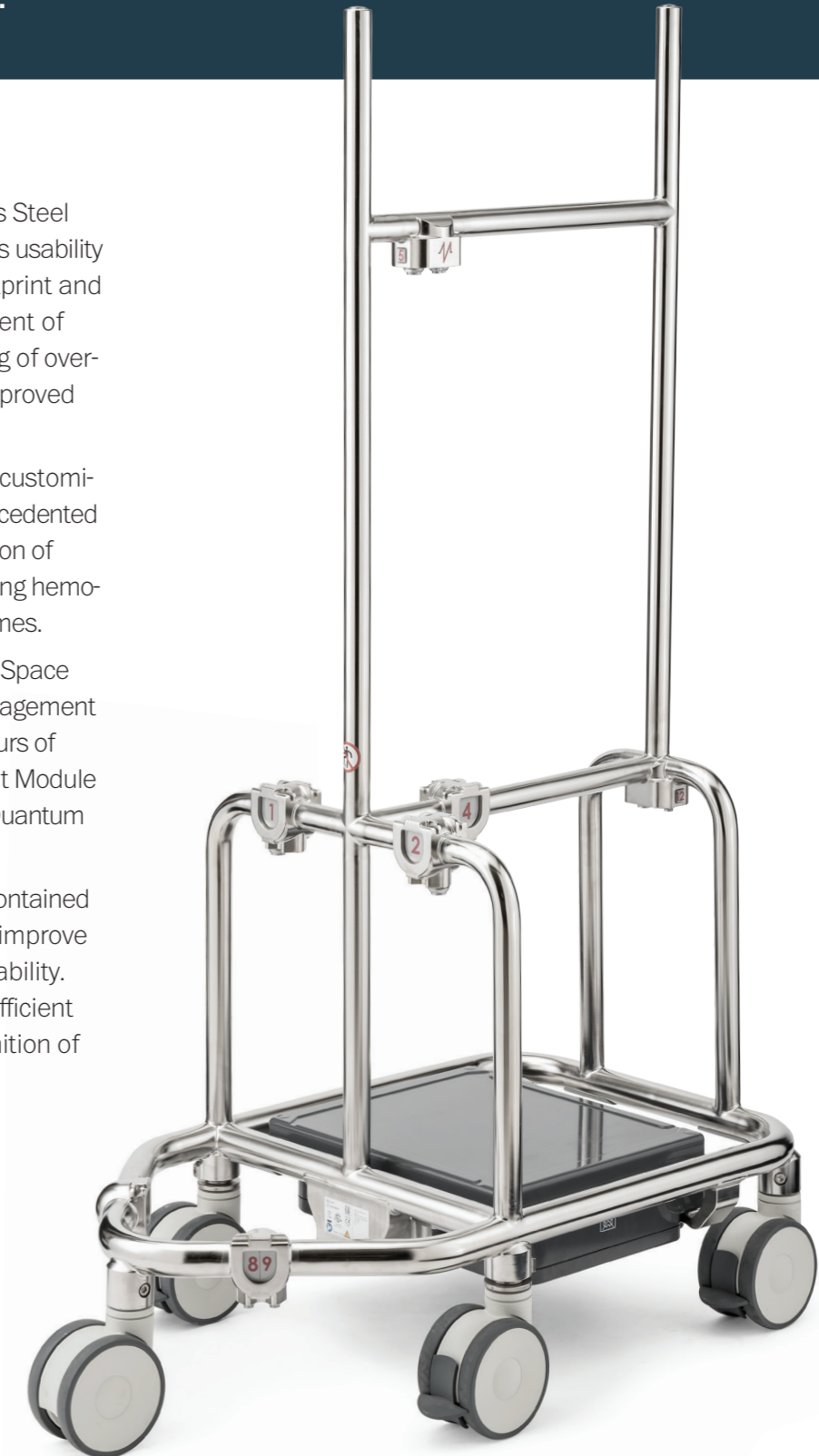


The Cheltenham HLM Frame

Quantum Space Frame Technology

Committed to Clinical Ergonomics and patient-centric solutions.

- The robust and compact Stainless Steel Space Frame construction improves usability by significantly reducing both footprint and weight. The independent placement of system modules allows fine-tuning of overall ergonomics, which leads to improved patient focus and safety.
- The compact modular design and customization opportunities offer an unprecedented degree of flexibility in the optimization of perfusion circuits focused on lowering hemodilution for improved patient outcomes.
- Integrated into the Stainless Steel Space Frame is the Quantum Power Management Module with approximately four hours of battery life. The Power Management Module can support a maximum of fifteen Quantum Modules.
- All power management cabling is contained within the stainless steel frame to improve both ergonomics and system durability. Integrated software provides for efficient power regulation and auto-recognition of connected Quantum Modules.



The Cheltenham HLM Frame

The Principles of Quantum Directed Perfusion (QDP)

Quantum Directed Perfusion (QDP) provides the next generation capabilities beyond basic Goal Directed Perfusion (GDP) techniques and the simplistic approach of measuring DO_2 .

This multifaceted approach to QDP provides the clinical team with the methodologies to improve the quality of bypass management that can lead to the reduction of AKI, and the higher costs associated with extended I.C.U. Time.^{1,2,3,4}

Real-Time Diagnostics:

The starting point for QDP is the use of Spectrum Medical's non-invasive diagnostic technology for the measurement of Oxygen Delivery (DO_2), Oxygen Consumption (VO_2), CO_2 Production (VCO_2), and multiple other calculations and indices. The monitoring of real-time total Oxygen Deficit is an entirely new and critically important concept to the world of Perfusion. The Quantum technology displays the real-time reporting of total time and percentage of case time when actual DO_2 is below target DO_2 .



Visualising Real-Time Information:

Spectrum Medical's Critical Care Scoring technology supports a proactive clinical risk assessment using recognized AKI markers such as age, gender, Pre-op Hct/Hb, EF, DM, and existing renal issues, and the subsequent deployment of an individual patient care strategy. Using Quantum Informatics and its LIVE VUE technology, patient care is improved with the seamless integration of "multiple information feeds" into a real-time display system.



Oxygen Deficit:

It is accepted that the potential of AKI is significantly increased with large DO_2 deficits.⁴ Calculating the Oxygen Deficit and then equating it to actual patient outcomes is a relatively straight forward process when using Spectrum Medical's Quantum Informatics technology. The Quantum Directed Perfusion calculation of Oxygen Deficit is expressed as the total "Area Under the Curve", and is a product of the accumulation of an actual deficit value (target DO_2 minus actual DO_2) multiplied by a unit of time.



Metabolic Compensation:

To further increase the precision of patient DO_2 requirements Spectrum Medical includes the capability to apply a percentage reduction per degree C to reflect decreasing metabolic activity as patients are cooled during Cardiac Bypass Surgery. The reduction per degree C is fully programmable and dependent on hospital based protocols. For example, if a DO_2 of 270mL/kg/m² at 37°C is the standard target and hospital protocols indicate a 7% / degree C as the change in Oxygen demand, the target DO_2 would be 251mL/kg/m² when the patient is at 36° C.

References

1. Alshaiikh, et al. Financial Impact of Acute Kidney Injury After Cardiac Operations in the United States. Ann Thoracic Surg. 2018 Feb;105(2):469-475.
2. de Somer, et al. O_2 Delivery and CO_2 Production During Cardiopulmonary Bypass as Determinants of Acute Kidney Injury: Time for a Goal-Directed Perfusion Management? Critical Care 2011; 15:R192.

References

3. Dasta JF, Kane-Gill SL, Durtschi AJ, et al. Costs and Outcomes of Acute Kidney Injury (AKI) Following Cardiac Surgery. Nephrol Dial Transplant. 2008;23:1970-1974.
4. Ranucci M, Romitti F, Isgro G, et al. Oxygen Delivery During Cardiopulmonary Bypass and Acute Renal Failure After Coronary Operations. Ann Thorac Surg. 2005;80:2213-20.

The Family of Quantum Workstations

Your gateway into the management of the World's most advanced Perfusion Patient Safety System. Highly configurable, integrated software applications (Apps) and advanced Quantum Modules extend perfusion management and functionality well beyond today's conventional technologies.



15" Quantum Workstation with optional Pump Control Module

The 15" Quantum Workstation

The 15" Quantum Workstation has been designed to support complex perfusion procedures utilized during Cardiac Surgery. Using its high-resolution touch screen technology the 15" Quantum Workstation supports the centralization of critical patient data, optional EMR generation and advanced perfusion management functions with single-level user navigation.

The 15" Quantum Workstation is supplied with Spectrum Medical's proven non-invasive measurement of O₂ Saturations and Hb/Hct and supports connectivity to a wide range of Quantum modules, including the Ventilation and Sensor modules.

Systems interoperability and patient safety are fundamental to Spectrum Medical and its commitment to partnering with customers to improve patient outcomes. The new 15" Quantum Workstation has an integrated 3rd party device connectivity solution that enables the central display and transfer of critical real-time continuous clinical information.



Quantum Pump Control Module

The system also includes a range of safety and best practice systems. Compliance is supported by the Best Practice App and patient safety through our Checklist and Complications Apps. Spectrum Medical's Live Vue technology and Critical Care Scoring systems functionality is available when the Quantum Workstation is network connected to a Quantum Informatics server installation.

The Quantum Pump Control Module

The Quantum Pump Control Module provides complete manual support of your Quantum Perfusion System with functionality that includes alarm management, pump management and the delivery of cardioplegia.

The Quantum Ventilation System

Finally, a fully integrated “single solution” Ventilator technology designed to provide the safe delivery of patient ventilation and the management of vacuum during Cardiopulmonary Bypass.



The Quantum Ventilation System

The second-generation Quantum Ventilation System is a world first solution designed to manage extracorporeal patient ventilation including the blending of gases, the management of vacuum, integrated patient safety systems, perfusion diagnostics, delivered anaesthesia gas concentration and a calculated MAC value.

The ultra-compact Quantum Ventilation System employs the very latest gas blending technologies to provide the user with Atmospheric or Hypobaric patient ventilation capability.

In Atmospheric mode, the Quantum Ventilation System delivers precision regulated FiO_2 , CO_2 with a sweep flow range from 0.025 to 10 L/m when flowing a single gas e.g. O_2 and up to a maximum flow rate of 20 L/m when modulating the delivery of two gases. e.g. 60% FiO_2 .

In Hypobaric mode, the Quantum Ventilation System regulates the delivery of two channels of O_2 to Spectrum Medical's new Ventilator technology with a sweep flow range of 0.025 to 10L/m per channel.

To ensure system performance and safety the ventilation system has a fully integrated secondary monitoring system that continuously compares actual measured values with user defined set-points and activates an alarm when the discrepancy between the two systems is greater than 10%.

In 'Patient Ventilation Mode' the Quantum Ventilation System, combined with its patented PaO_2 and PaCO_2 measurement technologies, provides a

decision support capability and an auto regulation function for the modulation of gas flows and gas concentrations when setting PaO_2 and PaCO_2 target values. The Quantum Ventilation System provides precision modulation and monitoring of WAG and VAVD.

To further improve patient safety the Quantum Ventilation System provides real-time monitoring of the following gas-ventilation parameters:

- Incoming Supply Pressures of Air, O_2 , CO_2 , & Vacuum Channels
- O_2 and CO_2 Gas Concentrations & Pressures to the Oxygenator
- Overall Gas Flow to the oxygenator (SWEEP)
- CO_2 concentrations measured from the WAG line

Integrated within the Quantum Ventilation System is Spectrum Medical's full range of Non-Invasive Diagnostic and Calculated Physiologic Measurements. To further improve usability, the system includes the measurement of Flow (including bubble detection), Pressure, Temperature and Reservoir Level Management.

The second-generation Ventilation System has been further modified to allow the hospital to connect to two independent vacuum sources for both WAG and VAVD. Furthermore, and to reduce routine servicing requirements, the system now includes a new “long-life” O_2 measuring technology.

The Quantum Centrifugal Pump CP37

The world's latest and most advanced Centrifugal Pump technology setting new standards for patient safety, hydraulic performance and hemolysis.

Spectrum Medical's next generation Quantum Centrifugal Pumps provide exceptional levels of performance along with significantly reduced prime volumes. The integration of a single sapphire bearing and patented hydro-dynamic balancing technology ensures levitation at low RPMs leading to significantly reduced heat generation and hemolysis.

The CP37 is integrated directly with the Quantum Perfusion System and can be connected to any port location within the Quantum Console to optimize the design of cardiopulmonary bypass circuits.



Quantum CP37 Hand Crank



Quantum CP37 Motor Drive

Perfusion Roller Pump

A Quantum leap in usability and perfusion systems' functionality.



The compact range of Quantum direct drive peristaltic roller pumps are provided with 4", 6" and 8" raceway diameters which maximize both flexibility and compactness when optimizing HLM design. In particular, the introduction of the mid-range 6" pump option eliminates the current compromise that compels users to use 8" pumps in medium flow applications.

The Quantum Universal Clamping System supports the mounting of pumps into multiple locations and pump change times of less than 60 seconds. Importantly, Quantum's pump detection software eliminates user intervention when adding or exchanging pumps.

Smart LEDs enable visual identification of pump function and color coordination with both the Quantum Workstation and the Quantum Pump Control Module.

Spectrum Medical's universal tube clamping system is designed to eliminate the frustration of using current tube clamping solutions and color coded plastic inserts. A single 'bobbin' solution allows for the clamping of all tubing diameters associated within the selected size of raceway.

Intelligent Tube Occlusion

Enhancing patient safety with precision solutions for complex phases of care during cardiopulmonary bypass.



The Quantum Smart Occluder is a revolutionary new approach to the management of perfusion-tube occlusion during bypass surgery. The Quantum Smart Occluder replaces the guess-work associated with conventional technologies by utilizing precise user inputs for the setting of flow; a critical requirement during certain phases of care.

The introduction of closed-loop flow control ensures flow control within +/- 2% of the requested set point. System-wide communication allows the user to combine the Smart Occluder with other Quantum

Modules to deliver levels of functionality new to the world of Perfusion, such as automated Initiation, Weaning and RAP.

Continuing the Quantum philosophy of seeking to improve system ergonomics, wherever possible, the Smart Occluder module includes two channels of flow measurement and bubble detection, two channels of pressure measurement and a two position reservoir level detection system.

An interlocking lid, color-coded LEDs and a mechanical override system maximize system safety.

The Quantum Sensor Module

Proven non-invasive measurement technologies provide flexible cost-effective management of Cardiopulmonary Bypass.



The Quantum Sensor Module

The Quantum Sensor Module is designed to provide the complete range of perfusion circuit parameters required for the safe management of Cardiopulmonary Bypass and the measurement of DO₂.

The sensor module includes:

- Three temperature measurements
- Three pressure measurements

- Three flow measurements (including emboli and bubble detection)
 - A two-position reservoir level detection system
- Offering complete flexibility, the Quantum Sensor Module can be connected directly to the Quantum Workstation or to any locations on the Quantum Perfusion Console.

Something New for 2022

2022
LOADING
...

New technology will be introduced early in 2022. Follow us on spectrummedical.com for any updates.

Heater-Cooler Technologies

A new future in patient safety.



A multi-level active patient safety strategy in a single system.

A Multi-Level Patient Safety Strategy

Guidance issued by the world's Regulatory Authorities has confirmed that current water-based heater-cooler systems have the potential to infect patients with Mycobacterium Chimera. Significant investigatory work has been undertaken to develop cleaning protocols to improve patient safety. However, anecdotal evidence indicates that these protocols are often ineffective and short term at best.

A key principle within a risk mitigation strategy is that it is required to be active for the life cycle of the product. A contamination event can occur at any time which means that formulating a patient safety strategy on a fixed cleaning cycle will be problematic. This is further complicated by the simple fact that there is no continuous monitoring technology that can alert the user when a contamination event has occurred.

Therefore, an implemented risk management process must eliminate the need for regular cleaning cycles and is continuous in operation.

The Mr. Frosty Patient Safety Strategy

The Spectrum Medical "Mr. Frosty" Heater-Cooler technology employs a multi-level safety strategy to minimize, if not eliminate, patient mortality rates associated with Mycobacterium Chimera infections.

Level 1) A "base-level" Bio Static Capability

To achieve a "base-level" Biostatic capability i.e., creating an environment that stops the growth of Mycobacterium Chimera colonies, Spectrum Medical has selected Glycol for its Heat Transfer Fluid (HTF). Glycol is a well-accepted technology used in applications requiring a Biostatic capability.

Level 2) A Mitigation Strategy in the event of Cross-Contamination

The Spectrum Medical solution is to reformulate its Biostatic HTF into a Biocidal HTF. This is accomplished with the addition of Monomeric Glutaraldehyde (MGA). Spectrum Medical has confirmed with long-term testing, equivalent to 6 years of clinical usage that Biocidal HTF performs in excess of Log 6 Reduction. Considering that for a fluid to be classified Biocidal, it needs to perform greater than Log 4 Reduction, this is a noteworthy achievement.

Level 3) Containment

The concept of Containment is the ultimate risk mitigation strategy which assumes that Safety Levels 1 and 2 have failed i.e., Mycobacterium Chimera can be detected, living, in the HTF.

However, in the unlikely event that there is cross contamination, a critical question that must be answered is whether the Mycobacterium Chimera within the HTF compromises patient safety by being released into the Operating Room and more importantly the sterile field?

Central to the Mr. Frosty technology is the concept of containment. To eliminate the potential unlikely aerosolization of Mycobacterium Chimera the hydraulic system has been designed to be a sealed system which operates without large circulatory fans.

Independent testing by Virginia Tech has confirmed a world first that there is NO detectable aerosolization from grossly contaminated Mr. Frosty Heater-Coolers. It's a fascinating report and well worth the read.

System Overview

The Quantum Heater-Cooler unit provides thermal energy to two independent circuits facilitating the simultaneous delivery of either hot or cold energy to both the patient and cardioplegia heat exchangers.

Simply connect the hoses to the single-use Quantum sterile heat exchangers using Spectrum Medical's drip-free connectors and with the simple and intuitive user interface, initiate the priming function. During the priming phase, the air contained within the single-use PureFlow heat exchangers will be replaced with Glycol heat transfer fluid.

To end the process, simply press the de-prime button and when the de-prime cycle is complete remove the hoses from the heat exchangers. The maintenance of the Glycol heat transfer fluid volume within Mr. Frosty is managed automatically during the re-charging process.

The Heater-Cooler is a fully functional standalone device or can be integrated within the Quantum Perfusion System and controlled directly from the Quantum Workstation.

Mr. Frosty works with both 110v and 220v AC supplies. In a fully charged condition, the stored cold energy is equivalent to 2.1 kW.



Quantum Heater-Cooler

Sterile Technologies

A “Quantum leap” in Perfusion best practise

System Charging

The recharging of the Heater-Cooler’s stored cold energy is accomplished by using Spectrum Medical’s “Igloo” Chiller system. The required number of chiller systems will be dependent on the number of Heater-Cooler systems in daily use and the customer specified Heater-Cooler re-charge times.

The Spectrum Medical Igloo Chiller system has been designed to support the simultaneous charging of two Quantum Heater-Cooler systems. Alternatively, and for larger hospital installations, the Igloo Chiller system can be integrated into a ring-main circuit with the expanded potential to support the simultaneous charging of up to five Quantum Heater-Cooler systems.

Ring main configuration and installation design is a “partnership process” between the hospital and Spectrum Medical’s engineering support team. Factors requiring consideration will be the number of Quantum Heater-Coolers in use, the available area within the hospital, power distribution, etc.



The Quantum CPB SuperPAC

The Quantum CPB SuperPAC represents Spectrum Medical's total commitment to patient safety, patient outcomes and the ultimate in Perfusion clinical best practice.

The Quantum SuperPAC is an uncompromising combination of innovative sterile technologies and a key system within Spectrum Medical's "Quantum Perfusion" strategy. What makes the SuperPAC different to currently available "tubing circuits" is the revolutionary approach to world first innovation and its integration with Spectrum Medical's Quantum CPB & Informatics Technologies.

- The elimination of Gaseous Microemboli
- Improved Gross Air Management
- Minimal Time to Prime
- Anti-Thrombotic Strategies
- No Blood Re-Circulation
- Low Hemolysis & Low Heat Generation
- Lowest Pressure Drop
- Minimal Blood Contacting Surface Area
- Integrated Pressure and Temperature Measurement
- Durable Bio Compatibility Coating

How we do all this is summarized in the following pages. Alternatively, for more detailed information please refer to the Spectrum Medical website.

SuperPAC Configuration

The Quantum SuperPAC is available in a range of sizes to support Adult, Paediatric and Neonate patient populations. SuperPACs are supplied coated with Spectrum Medical's cross linked bio compatibility PC1036. Superior adhesion qualities, elasticity and surface smoothness maximizes antithrombotic performance throughout the life of the product.

The SuperPAC is supplied with its own priming kit that is easy to use and duplicates current clinical practise.

For Reference: The Quantum Dual Chamber Oxygenator and the Quantum range of centrifugal pumps are not included within the SuperPAC and will need to be purchased separately.

The Quantum Dual Chamber Oxygenator

Spectrum Medical's Extracorporeal Membrane Ventilation Technology is another world first technology combining a revolutionary fluid path design with a dual chamber gas transfer technology.

Sizes available:

Large Adult	Small Adult
Paediatric (availability Q2 -2021)	Neonate (availability Q3-2021)

Spectrum Medical's revolutionary Dual Chamber Oxygenator technology takes patient ventilation to the next level. Working in conjunction with the Quantum Ventilation Module clinicians are offered the opportunity to continue current practice with the blending of FiO₂ or transition to a Hypobaric Ventilation strategy.



Hypobaric Ventilation – Future Innovations

When all the gases combined equal less than one atmosphere, it is called hypobaric. The Quantum Dual Chamber Oxygenator creates a hypobaric condition by only using oxygen and controlling Patient PaO₂ through a V/Q mismatch within the independent laminated fibre chambers. The V/Q mismatch supports the management of partial pressure significantly below atmospheric pressure, without the use of Nitrogen. This unique technology creates a large gas diffusion gradient and space within the patient's blood volume to absorb significant volumes of gaseous micro emboli.

The Quantum Dual Chamber Oxygenator

The Quantum Dual Chamber Oxygenator

Changing the world with safe ventilation for Patients undergoing CPB Support.

Total Surface Area (Ventilation Efficiency)

Spectrum Medical's revolutionary laminated membrane construction significantly increases gas exchange efficiency, minimizes pressure drop and priming volume. The unique construction eliminates the current compromise between fibre bundle compression and low priming volume. Individually all fibre layers within the fibre bundle are separated by ten microns, leading to a significant advantage in that, the individual fibres within the laminated bundle construction are in contact with flowing patient blood and providing gas exchange. This significant increase in gas transfer efficiency leads to a reduction in blood contact surface area, and by default, a lower priming volume and pressure drop.

Superior Air Handling

Spectrum Medical continues its commitment to patient safety with the integration of its patented Quantum Vortex Flow technology. This innovation in fluid dynamics ensures that blood flow passing through the laminated bundle construction is centrifugal in nature which generates a fluid vortex to support the separation of gross air from flowing patient blood. This separation of gross air from patient blood ensures almost instantaneous priming and minimizes or eliminates venous air being passed through to the arterial circuit.

Maximum Fluid Dynamic Performance

The elimination of low velocity sections and dead space within the fluid path has been at the forefront of Spectrum Medical's "anti-thrombotic" strategy. This unique design concept in conjunction with the Quantum Vortex Flow and Fibre Separation technologies guarantees that the total surface area of the laminated bundle construction is subjected to a circulating blood flow with a guaranteed total volume wash out of approximately 4 seconds when flowing blood at 5 lpm.

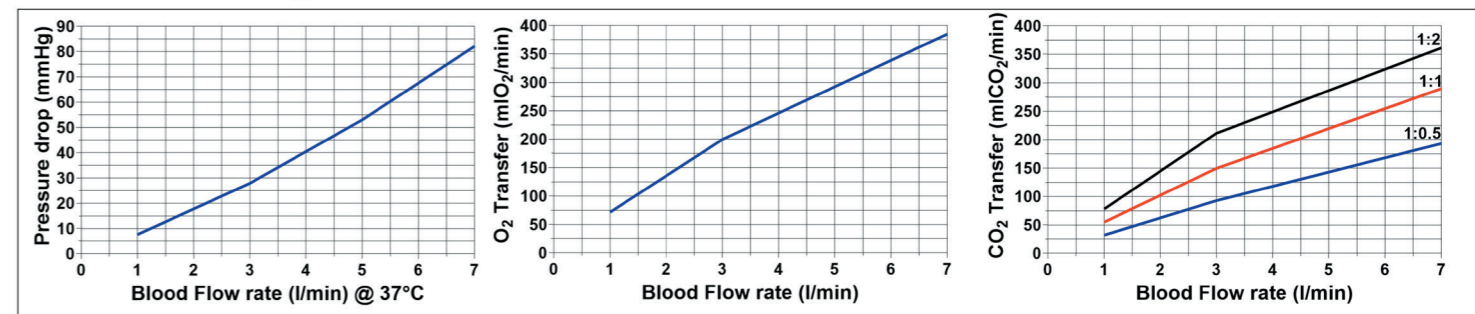
Biocompatibility

Resulting from significant process research, a world first is the application of PC1036 cross-linked biocompatibility coating to a fibre membrane construction. Superior adhesion qualities, elasticity and surface smoothness maximizes antithrombotic performance throughout the life of the product.

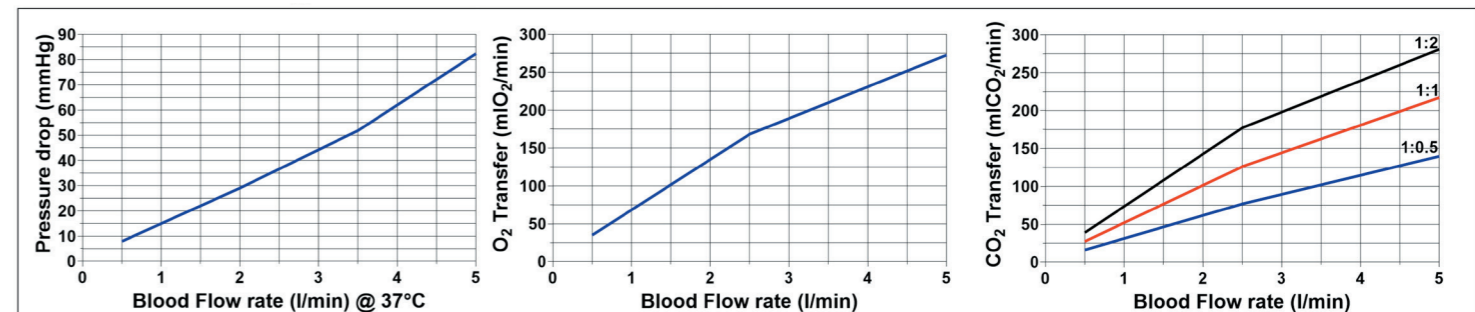
Materials free from DEHP

Commitment is again emphasised with all internal blood contacting surfaces being made from materials free from plasticizers.

Quantum Perfusion Blood Oxygenator ECC VT200



Quantum Perfusion Blood Oxygenator ECC VT160



Paediatric and Neonate Oxygenators coming soon. Continue checking our website for updates.

Centrifugal Pump



CP37

The CP37 is Spectrum Medical's most powerful Centrifugal Pump and is designed to support applications in the O.R.

With its 3/8 port and a prime volume of only 37cc, the CP37 is rated to 8 liters/min at 800 mmhg.

PC1036 biocompatibility coating and the availability of a hand crank further improves patient safety.

To support the introduction of the Quantum Heater-Cooler Technology and to minimise circuit complexity Spectrum Medical has integrated its stainless-steel PureFlow Venous heat exchanger and the CP37 Centrifugal Pump into a single disposable assembly.

Mounted directly to CP37 motor drive system, the CP37 with its integrated Venous heat exchanger is used exclusively with the Quantum Heater-Cooler technology and its Glycol heat transfer fluid.



CP37 with Integrated Heat Exchanger

Quantum Heat Exchangers



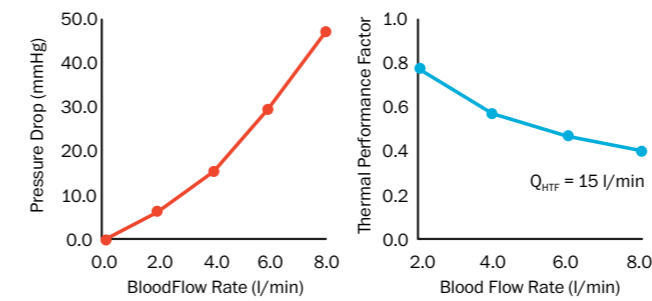
The Quantum range of sterile disposable heat exchangers have been designed by Spectrum Medical to provide the safest solution for eliminating the growth environment for the Mycobacterium Chimaera bacteria.

Specifically developed to operate exclusively with the Quantum Heater-Cooler technology and its Glycol heat transfer fluid. Both the patient and the cardioplegia heat exchangers are compact in design, with low priming volumes and minimal pressure drops.

Technical Specifications

Standard Heat Exchanger: High Flow (adult size)

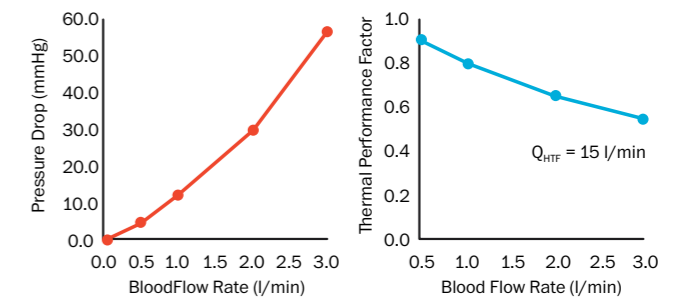
- Priming volume blood side: 55 ml
- Exchange Surface: 0.12 m²
- Priming volume HTF side: 70 ml
- Maximum flow rate: 8 l/min



Pressure drop curves were generated using bovine blood (Hct: 32±2% - Hb: 12±1[g/dl]) at 37±1°C

Standard Heat Exchanger: Medium Flow (pediatric size)

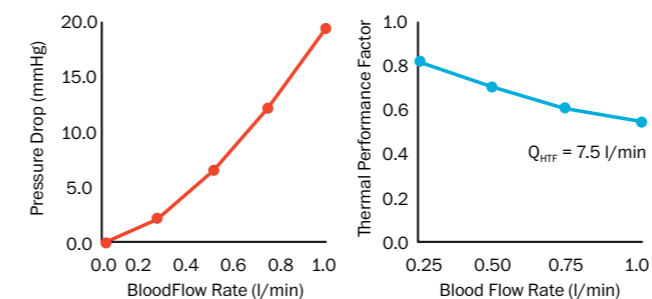
- Priming volume blood side: 22 ml
- Exchange Surface: 0.05 m²
- Priming volume HTF side: 38 ml
- Maximum flow rate: 3 l/min



Pressure drop curves were generated using bovine blood (Hct: 32±2% - Hb: 12±1[g/dl]) at 37±1°C

Standard Heat Exchanger: Low Flow (neonatal size)

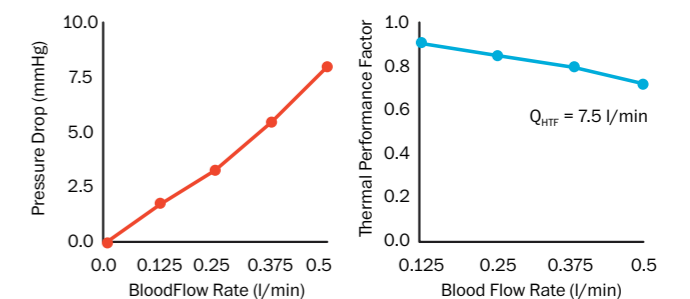
- Priming volume blood side: 11 ml
- Exchange Surface: 0.028 m²
- Priming volume HTF side: 22 ml
- Maximum flow rate: 1 l/min



Pressure drop curves were generated using bovine blood (Hct: 32±2% - Hb: 12±1[g/dl]) at 37±1°C

Cardioplegia Heat Exchanger

- Priming volume blood side: 22 ml
- Exchange Surface: 0.028 m²
- Relief Valve Opening Pressure: 500 mmHg
- Priming volume HTF side: 22 ml
- Maximum flow rate: 0.5 l/min



Pressure drop curves were generated using bovine blood (Hct: 32±2% - Hb: 12±1[g/dl]) at 37±1°C

Hybrid Reservoir

Quantum Informatics

Revolutionizing real-time patient safety and the development of clinical best practise.

Spectrum Medical continues to provide new technologies specifically designed to improve performance and therefore improve patient outcomes.

The Hybrid Cardiotomy-Venous Reservoir is as easy to use as a traditional hard shell system. It primes quickly and familiar Vacuum Assist approaches are easily used. The Hybrid Reservoir also provides the inherent safety of a soft bag while minimizing the need for manual air removal techniques.

Whether a Team currently uses Mini-bypass, has not yet attempted Mini-bypass, uses a Soft-bag or a Hard-shell reservoir, all will appreciate the easy to use Hybrid Reservoir Technologies. The improvements provide: gross venting of venous line air, control of patient volume, options to separately handle vented and suctioned blood, utilization of common Vacuum assist techniques while avoiding the complexity of a kinetic venous assist device, and elimination of the difficulties of converting from a Mini-bypass circuit to full drainage during unpredictable clinical situations. The Hybrid Reservoir is developed to successfully address a wide variety of challenging clinical situations.



Quantum Informatics is an all-encompassing patient safety system for the complex high acuity space focused on patient-clinician connectivity in the I.C.U. and the O.R.

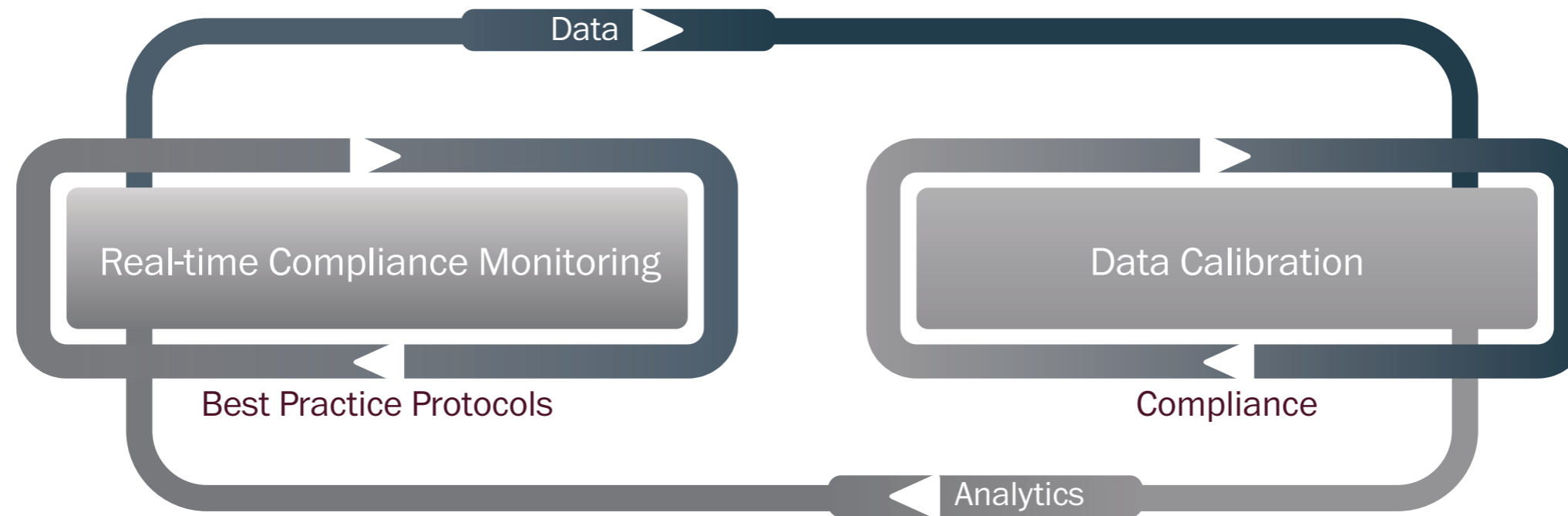
Quantum Informatics revolutionizes patient-clinician connectivity in the high acuity space with a patient-safety Informatics Platform that empowers the front-line clinical staff with a range of capabilities that can improve Patient Care, Patient Outcomes and Patient Safety. Of equal importance is the necessity to maintain usability within a complex space and therefore, Quantum Informatics philosophy can be understood in a simple four-stage process.

Stage 2

Unique to the Quantum Informatics technology is its ability to report QA indexes for compliance to hospital objectives encapsulated within the active Patient Safety System. Compliance is considered a function of time within Quality Objectives compared to the total time that care is provided. QA indexes can be broadly based on departmental index's or more granular segments of time and the team.

Stage 1

At the heart of the Quantum Informatics is seamless connectivity to data, and to ensure seamless connectivity, Quantum Informatics integrates with Quantum Workstations, 3rd Party Gateway Servers, Hospital Information Systems and a wide range of Patient Physiologic Monitors in the O.R. and I.C.U. setting.



Stage 4

An active Patient Safety Strategy is a significant new development within the Quantum Informatics Technology. Within this system, the patient is continuously monitored against several deployed best practice and evidence-based protocols that can communicate non-compliance via a central display system and physician alert systems. This system allows active QA/QI goals to become real-time clinical practice.

Stage 3

The use of analytics is an essential element in the QA/QI improvement process and wholly dependent on having access to clinical data for both large patient populations and discreet data for individual patients. To support the QA/QI process, the Quantum Informatics technology facilitates the transfer of clinical interventions and diagnostic data to the VISON server SQL database, where a wide range of reporting tools can be used for "post-op" investigation and the continuous improvement of the active Patient Safety System.

Active Patient Safety System

Active Patient Safety System

The Compliance, Complications, and Checklists applications combine clinical best practice and evidence-based protocols into a real-time Patient Safety System that supports the consistent delivery of quality and enhanced patient safety.

Best Practices

Measurement	Level	Critical Low	Critical High	Sustained Low	Sustained High	Decrease Rate	Increase Rate	Latest Value
Art Flow (L/min)	L1		7.5	2L/min / 2.0min				
CVP (mmHg)	L1							
FEMMean (mmHg)	L1	50	110					
LRADMean (mmHg)	L1	50	110					
MAP (mmHg)	L1	50	110	50mmHg / 2.0min				
SaO ₂ (%)	L1	70						
SvO ₂ (%)	L1	50	80	59% / 60s				
Art Flow (L/min)	L2	0.5	4.5					
CVP (mmHg)	L2	-25	25					
FEMMean (mmHg)	L2	50	85					
LRADMean (mmHg)	L2	50	85					
MAP (mmHg)	L2	50	85					
SaO ₂ (%)	L2	70						
SvO ₂ (%)	L2	50	100					

Compliance

The Best Practice app is an integral part of Quantum's active Patient Safety System which supports the real-time deployment of a bedside, patient-specific surveillance profile. Multiple surveillance profiles can be created within a hospital and stored within the Quantum Informatics System. Furthermore, clinicians with system privileges can make changes to a surveillance profile in real-time to further enhance individual care strategies and reduce alarm fatigue.

Creating surveillance profiles is a simple process in which real-time physiological data and discreet blood gas data is combined with a specific alerting strategy to create an individual surveillance profile. Alerting parameters can be configured individually or in combination using high/low limits, sustained limits or percentage rates of change limits.

LIVE VUE

Perfusion

Location C - QD100027

Location A - VV2

Set Compliance Limits

Measurement	Critical Low	Critical High	Sustained Low	Sustained High	Decrease Rate	Increase Rate
Art Flow (L/min)		8				
Blk Temp (°C)	23	37.5		35	90	
Card. Press (mmHg)	40	3				
FiO ₂ (%)	40	100	30			
Line Press (mmHg)	1	300	300	30	5	60
PCO ₂ (mmHg)	30	55		50	60	
PO ₂ (mmHg)	130	600		10	10	60
Pump Flow (l/min)		7.5				
Swamp (l/min)	1	6				

Complications

The Complications application provides a real-time capability that combines the surveillance of multiple information feeds with a range of complication algorithms. When activated, the complication algorithm generates a Complication Alert which is supported by a pre-agreed Complication Response.

Complication Specific Algorithms and a Complication Response are easily configured using a "decision tree" format or a checklist. Complication alerts can be triggered automatically via the active Patient Safety System or manually by the clinician. In both cases the clinician gains access to the pre-configured Complication Response. Furthermore, the alert is communicated to all active participants within the Clinician Alert System.

Complications - Cerebral Congestion

ID	Measurement	Critical Low	Critical High	Sustained Low	Sustained High	Decrease Rate (%)	Increase Rate (%)	Latest Value
1	CH1 - Cerebral tis. O ₂ Sat. (%)					15% / 30s		
2	CH2 - Cerebral tis. O ₂ Sat. (%)					15% / 30s		
3	CVP (mmHg)						20% / 30s	
4	Ven Flow (L/min)					25% / 30s		

Condition - (1 Or 2) And (3 Or 4)

(1 Or 2) And (3 Or 4)

Cerebral Congestion

Venous air lock

Venous line occlusion

Cannula Misplacement

VAVD

Summary

Emergent - Initial

Pump

Cardiotomy Reservoir

Pump Tubing

Arterial Filter

Oxygenator

Cardioplegia Delivery

Miscellaneous

Patient

Initiate CPB

Post CPB

SBAR, Handoff

Centrimag PostCL

Malignant Hyperthermia

Cerebral Congestion

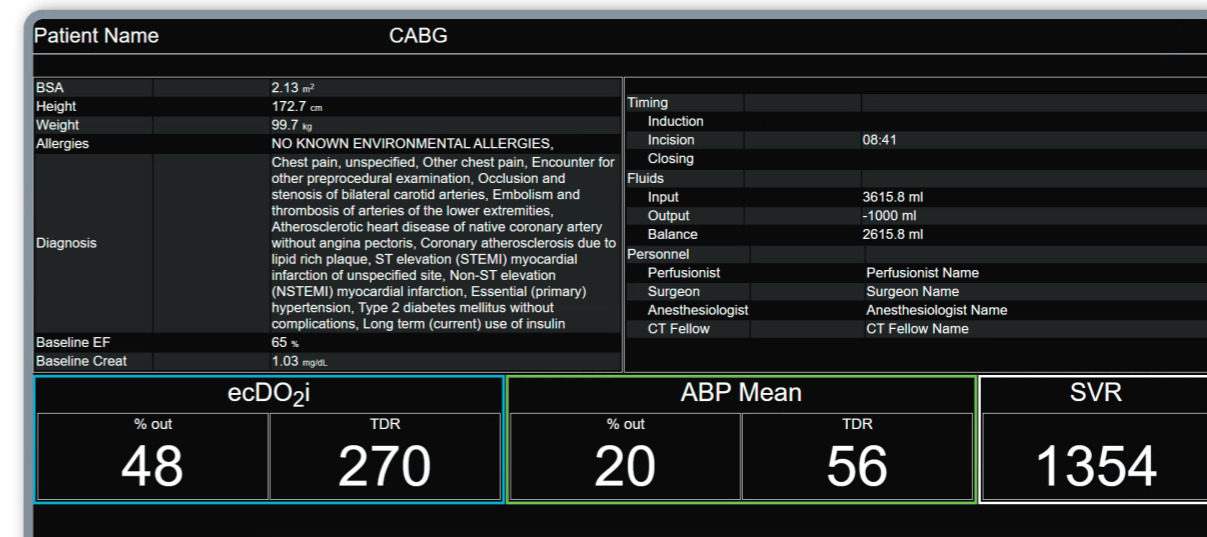
Checklists

A Checklist application within Quantum's active Patient Safety System supports the creation of multiple checklist formats and their real-time deployment to the bedside. Checklists can be configured to be triggered by any number of specific event types such as a complication alert, patient hand-off etc. Furthermore, Checklist functionality can be time-synchronized with a change of shift or current rounding practice.

Critical Care Scoring

Custom Dashboards for the I.C.U. and O.R.

Patient Safety Technologies, revolutionizing real-time clinician patient connectivity in the I.C.U. and O.R.



The Quantum Informatics Critical Care Scoring technology has been designed to support instant access to a highly visual representation of patient status and then to alert the clinical team via the Quantum Informatics' system when a patient status becomes critical.

At the heart of the Critical Care Scoring functionality is the development of a hospital configured scoring system that's specific to a physiologic system such as Renal, Respiratory, Cardiac etc. Analysing data at the system level allows the

instant summary of multiple data points to both speed response and patient triage.

Initial system configuration and subsequent modifications are both easy and only possible with Admin level access. Real-time data combined with ADT feeds from the Hospital Management System facilitates the active calculation of a patient system status. Additionally, ADT feeds allow the introduction of pre-specified patient weighting factors into the system scoring calculation.

Custom dashboards are used by the clinical team to visualize data that is critical to clinical practice and patient safety. Dashboards have been used in the operating room to create real-time custom views and clinical decision trees relevant to the surgical procedure. Dashboards have also been

used in the I.C.U. to allow clinical teams to monitor patients and share data to multiple clinicians to support real-time response to real-time adverse events. These dashboards can consist of live streaming data from 1st and 3rd party devices, ADT, Labs and information from the HIS.

Centralized & Remote Tele-Health and Integrated Alerting Systems

Centralized & Remote Tele-Health and Integrated Alerting Systems

With the seamless integration of “multiple information feeds” and the intuitive input of ADT data, Spectrum Medical is committed to maximizing patient safety with real-time responses to real-time adverse events.

When Spectrum Medical’s revolutionary app based Patient Safety System on the Quantum Workstation are integrated with our next generation server based Quantum Informatics technology, clinical safety and real-time physician response is taken to the next level.

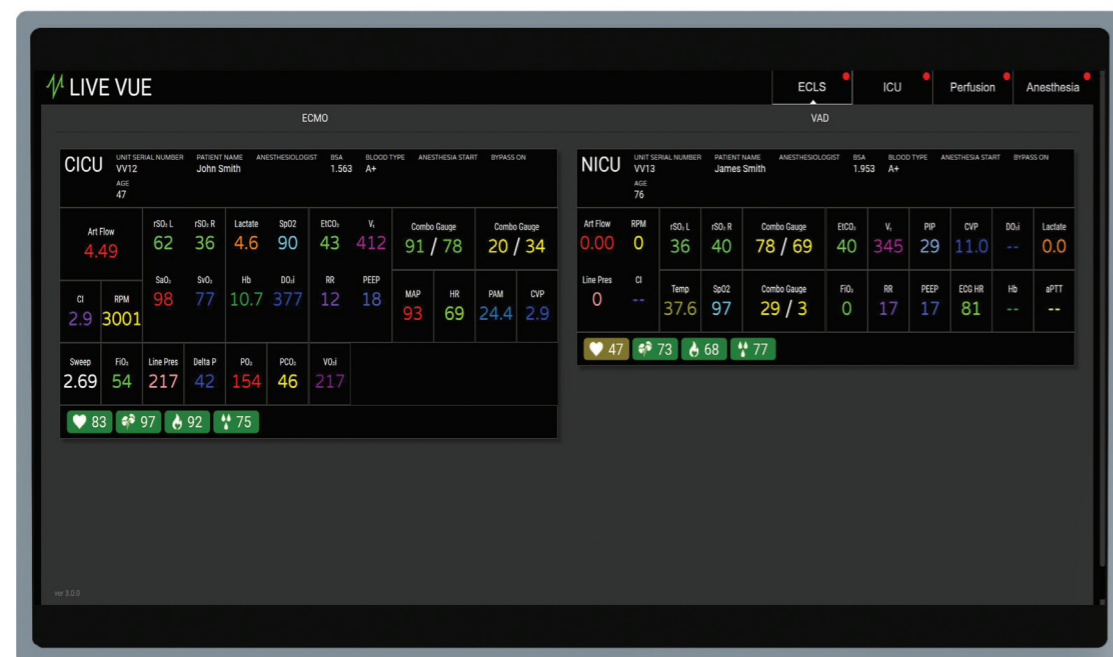
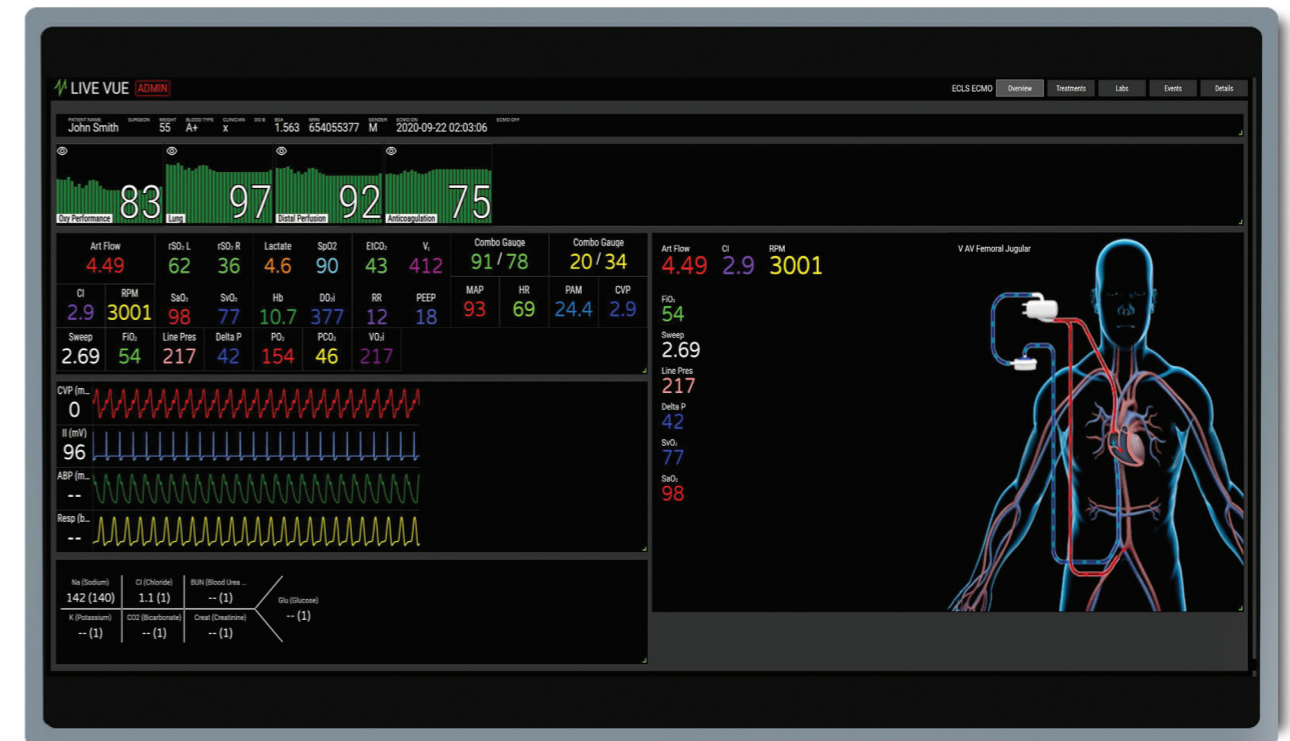
Quantum Informatics LIVE VUE is the name given to the software system designed to visualize real-time clinical information in both graphical and textual formats to clinicians within the clinical setting or from a remote location. LIVE VUE will provide the clinical team with a “wide area, real-time perspective” of all patients within the care setting. This presentation of data is further enhanced with the integration of system alerts associated with the deployed active Patient Safety System.

System alerts for Complications, Compliance, Critical Care Scoring and Checklist, if active, will

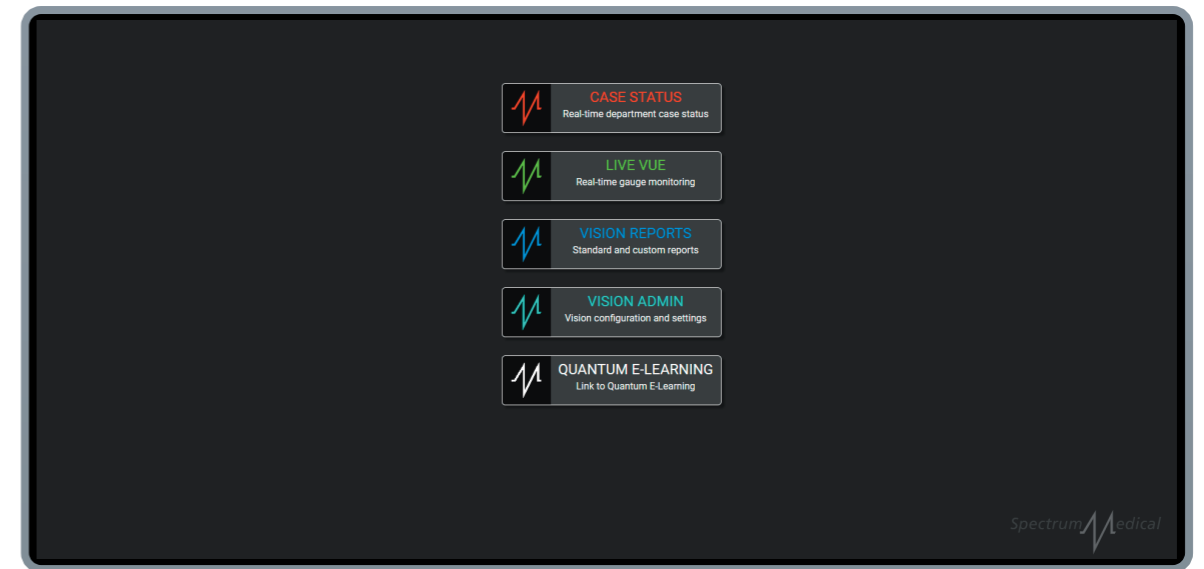
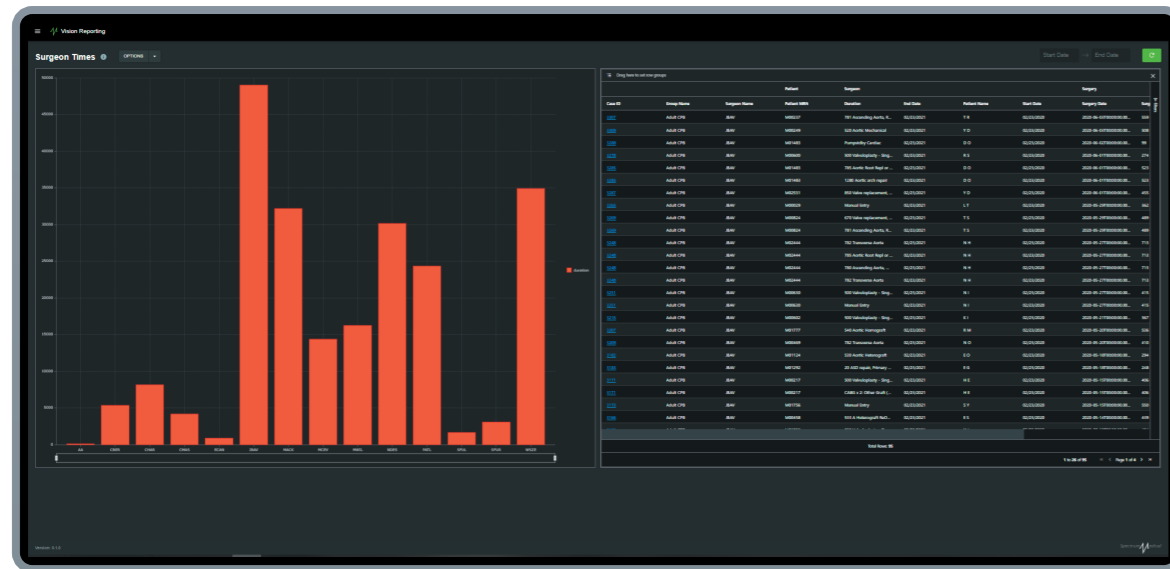
be communicated to the summary information screen and to the clinician’s personnel comms device in real-time.

Access to patient-specific granular trending information is made possible by selecting a patient displayed in the LIVE VUE dashboard. This data can include waveforms, trending physiologic data, intermittent blood gas data etc. In fact, the presentation of discreet patient data can be further enhanced by extending the exchange of information to include relevant data within the Hospital Information System.

The LIVE VUE interface is also used for the selection and deployment of both surveillance profiles and checklists. The LIVE VUE interface is also used for the individual setting of alerts within an active patient surveillance profile.



The Powerhouse behind Spectrum Medical's Quantum Informatics technology.



About VISION Server

VISION is a sophisticated server application that is the gateway into Spectrum Medical's Quantum Informatics Technology. VISION automates the system-wide distribution of software upgrades, windows and security updates, a web-based remote access capability plus the management of user passwords and system privileges. VISION will also support integration with Active Directory.

The VISION server application operates on a hospital supplied server. It supports two-way communication with the Hospital Information Systems (H.I.S.) and 3rd party gateway servers using an integrated communications interface engine supplied by MIRTH Inc. In addition to its system management functionality the VISION server application includes a SQL database for the long term storage of data and for the real-time distribution of active patient

data to both LIVE VUE and the clinician deployed active Patient Safety Systems.

Medical Device Connectivity

To ensure the seamless integration of clinical information, the Quantum Informatics VISION Server application includes a world leading Medical Device Connectivity solution that can eliminate the need for a 3rd party middle ware solution. The VISION server application can support connectivity to the following systems:

- 3rd Party Gateway Servers (e.g. Philips & GE)
- Direct device connectivity to a range of Physiologic Monitors Ventilators etc.
- Connectivity to middle ware solutions
- Hospital Information Systems (via Mirth)
- The Quantum Workstation Platform

System Analytics & Case Playback

Initially developed to support the training environment as well as Morbidity and Mortality meetings, the Case Playback technology provides the capability to retrospectively replay stored patient data from the VISION SQL database in real-time. Continuous information includes waveforms, trending physiological and blood gas data. Additionally and dependent on the H.I.S. integration, case playback can include case related events such as medication delivery, best practice alerts, personnel activity etc.

System Administration

Spectrum Medical has long recognised that the success of any deployed QA / QI platform is dependent on the maintenance of Physician engagement, which in itself is largely dependent

on utility and the ability to introduce system-wide changes quickly.

The day-to-day management of Quantum Informatics is at the physician level. VISION's web interface supports the real-time management of the active Patient Safety System, including, profile creation, profile modification and profile deployment.

Dashboards / Management Reporting

Spectrum Medical recognizes that dashboards and active reporting systems are core to delivering information and clinical analytics across the continuum of healthcare. To deliver this, Spectrum Medical has partnered with LOGI Analytics, a recognized leader in the field of data visualization and data analytics. The LOGI "tool-set" is now a standard module within Quantum Informatics.

Sentinel Total Care

Absolute dedication to customer support and a total solutions approach to a “trusted partner status”



In-service Customer Support

Sentinel Total Care defines Spectrum Medical’s approach to a total solutions support program that maximizes equipment availability with the very latest system functionality.

Software Updates:

Spectrum Medical is committed to the continuous improvement of both system functionality and the enhancement of capital value. We continually review, enhance, and add software functionality driven by evidence-based clinical usage and trends. Our 3rd party device driver software is regularly updated to ensure compatibility with both established and new systems. All software updates are included at no additional cost to the customer. Any software deployment is subject to prior customer approval and training via Spectrum Medical’s web-based electronic Learning Management System (Quantum eLearning).

On-Site Customer Support:

A Spectrum Medical Product Specialist will perform all required routine servicing to ensure optimum performance of your Quantum Perfusion System. Visiting Product Specialists will also provide additional user training and support changes to systems configuration to enhance clinical practice. Using dedicated Product Specialists as opposed to

traditional service personnel is a unique strategy within the CPB space. Additionally, Sentinel Total Care covers all associated service visit costs (travel, labour, and spare parts).

Extended Warranty:

Sentinel Total Care includes comprehensive protection in the event of any breakdown of your Quantum System. Coverage includes modules, sub-assemblies, and any associated accessories (sensors, cables, clamp assemblies, batteries, etc.). Quantum products beyond economical repair will be replaced with the latest ‘new build’ technologies at no additional cost.

Accidental Damage:

No questions asked, unintentional damage protection, including all Quantum accessories. Quantum products beyond economical repair will be replaced with the latest ‘new build’ technologies at no additional cost. Sentinel Total Care allows you to effectively manage your budget with no sudden large Purchase Order requirements.

In-service Customer Support

Real-Time Customer support 24 hours, seven days a week.

Remote Real-Time Support (QuantumChat):

Integrated, as part of Sentinel Total Care, users have access to Spectrum Medical's comprehensive 24/7 remote real-time support application, QuantumChat.

QuantumChat puts customers in direct contact with our product, clinical and technical specialists located globally. Ask a question anytime, anywhere and get an immediate response back. Share pictures, videos or even start a live video chat with a product expert using your mobile device. Each user is given a dedicated login and grouped within your clinical team. Follow or respond to questions asked by fellow team members. Get device information about your Quantum System by simply scanning the QR barcode found on any Quantum module/sensor. Accessed via the app, our knowledge-based libraries such as documents, manuals, software release notes and various troubleshooting help tips. QuantumChat makes troubleshooting and resolving issues easy and fast. QuantumChat supports multiple languages and is compatible with either Apple or Android mobile devices.

Additionally, with the inclusion of our VISION Server System and with VPN access, Spectrum Medical can provide remote monitoring and fault diagnosis of all Quantum system networks connected to the local VISION server intraoperatively.



Emergency Loan Equipment:

Spectrum Medical will dispatch complimentary loan equipment if your defective equipment cannot be rectified within 24 hours of being returned to a Spectrum Medical Service Centre. To maximize equipment uptime our loan equipment stays with you until you receive a repaired or new replacement module from Spectrum Medical.

Time Expired Sterile Products:

Partnering with hospitals in the provisioning of care is at the core of the Sentinel relationship.

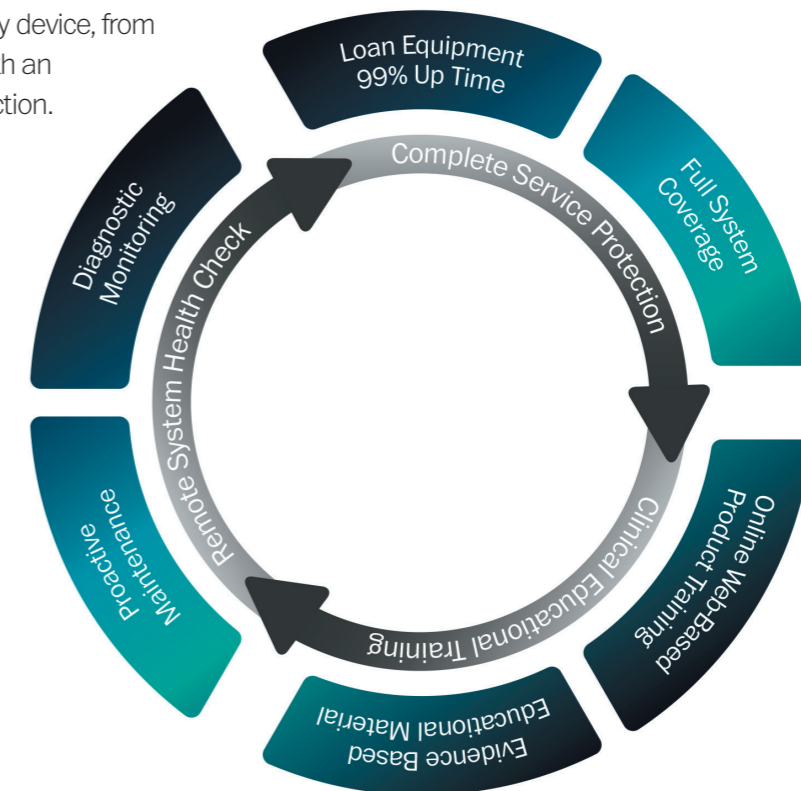
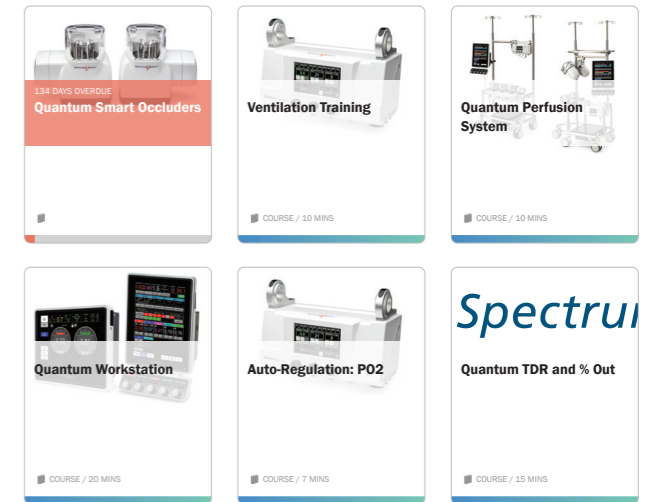
Quantum sterile products supplied by Spectrum Medical that have exceeded their expiration date can be returned to Spectrum Medical and exchanged for new replacement products free of charge.

In-service Customer Support

Sentinel provides access to a wide range of structured Training, Educational and Re-Certification resources.

On-Line Learning Support (Quantum eLearning):

All users have access to Spectrum Medical's web-based eLearning management platform, Quantum eLearning. Quantum eLearning will complement any existing training or re-certification program. Each Spectrum Medical module, product or technology, has its own dedicated course. Each course content is available in multiple languages and designed to ensure that the user's product and clinical knowledge is both relevant and up-to-date. Topics covered include clinical benefits of hypobaric oxygenation, safety features for Mini-Bypass mode, and auto-regulation of PO₂ and PCO₂. Quantum eLearning is an easily accessible resource library. Access Quantum eLearning day or night, on any device, from any location with an internet connection.





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