

Advanced Perfusion Systems for complex Cardiopulmonary Bypass Procedures



Quantum Perfusion Systems for the O.R.

Spectrum Medical proudly presents the world’s most advanced Perfusion System, delivering exceptional patient outcomes combined with a range of unique patient safety technologies, automation and real-time decision support systems.



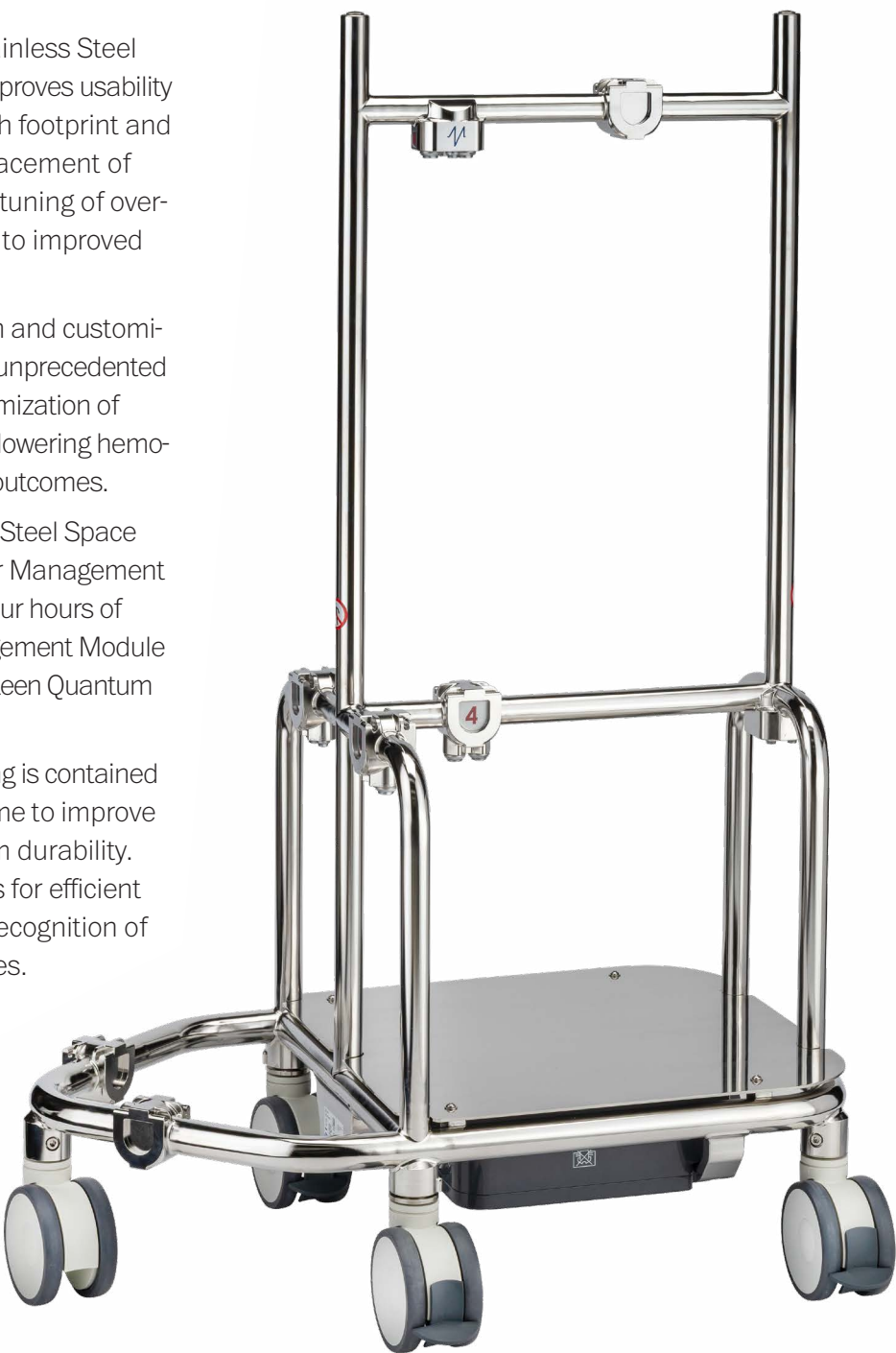
The New York Horizontal Frame System

The Cheltenham Vertical Frame System

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 Quantum Workstation

Your gateway into the management of the World’s most advanced Perfusion Patient Safety System. Highly configurable and advanced Quantum Modules extend perfusion management and functionality well beyond today’s conventional technologies.

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 is 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.



15" Quantum Workstation with optional Pump Control Module



Quantum Pump Control Module

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 Physiologic 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 Physiologic 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 Quantum Ventilation System also allows the clinician to set a Sweep to Blood flow Ratio, which ensures consistent and predictable CO_2 removal when increasing or decreasing blood flow. This is not only critical during initiation and weaning but during the case when there are significant changes in blood flow that are expected and unexpected.

The Quantum Centrifugal Pump CP37

Perfusion Roller Pump

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

A Quantum leap in usability and perfusion systems' functionality.

Spectrum Medical's next generation Quantum Centrifugal Pump provides 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.

The CP37 is Spectrum Medical's most powerful Centrifugal Pump and is designed to support a wide range of clinical 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.



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 flow and volume management during cardiopulmonary bypass surgery. We use a closed loop algorithm with flow to create precise settings of the occluder, allowing precise volume management, which replaces the guesswork associated with conventional technologies.

The introduction of closed-loop flow control ensures flow control within $\pm 2\%$ of the requested set point. System-wide communication allows the user to combine the Smart Occluder with the Quantum ventilation System to unlock 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.

A next generation Mirco Cardioplegia Delivery System

Introducing “Pluto” the latest Quantum module from Spectrum Medical and setting new standards in the precision delivery of Mirco Cardioplegia.

The Quantum Micro-Cardioplegia Delivery System

The Quantum Micro-Cardioplegia Delivery System (QMCDs) is specifically designed to adapt to the variety of techniques used for myocardial protection during cardiac surgery and easily integrates with new and existing Quantum Perfusion Systems. The user friendly graphical interface allows for ease of use and improved safety during the delivery of cardioplegia. Specifically, the system is designed to interlock with a Quantum Roller Pump and allow the rates to stay consistent during the changing of flow through the cardioplegia system. This system's added safety includes monitoring of both inlet and outlet pressures, bubble detection, circuit blood flow and individual awareness of each syringe from being obstructed. Individual syringes for additive and arrest can be safely switched on the fly and rates can be individually set.



The Mr. Frosty Heater Cooler Technology

Introducing a world-first Heater Cooler technology that eliminates water from the O.R and the need for hazardous cleaning procedures.

Complete silence in the OR.

Guidance issues by the world’s regulatory Authorities have confirmed that current water-based heater-cooler systems have the potential to harm both patients and clinicians with the Mycobacterium Chimera bacterium. Hazardous and ineffective cleaning protocols combined with the disruption of sterile laminar air flow are known concerns that have proved problematic to resolve. A key principle with Spectrum Medical’s ground-breaking Mr Frosty technology is its full life-cycle integrated risk management strategy. The following two core technologies are fundamental to clinical risk management:

Containment

The concept of containment is the ultimate risk management strategy and central to the engineering technology of the Mr Frosty heater cooler. Mr Frosty is a sealed system with no open fluid storage tanks to atmosphere. Furthermore, Mr

Frosty does not use circulatory fans which guarantees the integrity of the sterile laminar air flow system whilst improving the OR environment with complete silence.

Heat Transfer Fluid

Spectrum Medical has replaced the use of water with a product called CoolFlow. Cool flow is a specifically formulated Biocidal Heat Transfer Fluid that not only stops the growth of Mycobacterium Chimera bacterium it eliminates the bacterium in the event of potential cross contamination. To support this formulation and to obtain Regulatory Approval Spectrum Medical has developed a proprietary range of standalone heat exchangers using high grade stainless steel. The Arterial and Cardioplegia heat exchangers are compact in design, with low priming volumes and pressure drops and suit all patient populations.



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 circuits. Simply connect the hoses to the single-use Quantum Stainless Steel heat exchangers and activate the prime function via the Workstation or Mr Frosty U.I.

System Charging

The simultaneous charging of two Mr Frosty units is accomplished by using Spectrum Medical’s “Igloo” chiller system. The required number of Igloo systems will be dependent on the number of Mr Frosty units in daily use. The maintenance of Spectrum Medical’s Heat Transfer Fluid is managed automatically during the re-charging phase.

The Quantum SuperPAC

The New Paradigm

The Quantum SuperPAC represents Spectrum Medicals total 10-year commitment to advance world-first technologies that change clinical best practise and quantifiable patient outcomes.

Physiologic Ventilation the revolutionary new future for the management of Patient Ventilation.

The Quantum SuperPAC is an uncompromising combination of innovative Quantum sterile technologies that come together to represent a decades change in current Perfusion practice. As with all Spectrum Medical technologies the end result of product development must be a significant benefit to patient outcomes and safety and the SuperPAC is no different. Ten years ago, Spectrum Medical agreed an ambitious list of what we then defined as “Patient Outcomes Objectives”. These objectives were defined as follows:

Minimizing Inflammatory Response

- Reduce contact activation and blood-air interface exposure to minimize systemic inflammatory response syndrome (SIRS)

Neurologic Protection

- Reduce/eliminate gaseous micro emboli (GME) to minimize neurologic damage and preserve cognitive function.

Physiologic Perfusion

- Create optimal oxygenation conditions to improve systemic tissue perfusion by reducing hyperoxia induced vasoconstriction and reperfusion injury.

Eliminating Chimera

- Provide the capability to eliminate chimera infections, minimizing patient morbidity/mortality risk.

How we achieved these objectives is summarised in the following pages. However, and as with all new Spectrum Medical technologies they are new to the world of Perfusion, creating new

learning opportunities; therefore, please contact Spectrum Medical for further information.

Finally what makes the SuperPAC different to currently available “tubing circuits” is its integration within the “Quantum Eco System”. The Quantum SuperPAC is an integrated system working in conjunction with the Quantum Ventilation and Quantum Occlusion modules and it is for this reason that the SuperPAC is supplied exclusively to hospitals equipped with Spectrum Medical’s advanced Quantum Perfusion Systems.

SuperPAC Configuration

The Quantum SuperPAC is supplied non-custom in four configurations with ½" and ¾" drainage options, with and without an AV bridge. The SuperPAC includes the Perfusion Circuit, the Hybrid Reservoir, and the Dual Chamber Oxygenator. The optional Cardioplegia Circuit and the CP37 Centrifuge Pump is supplied separately.

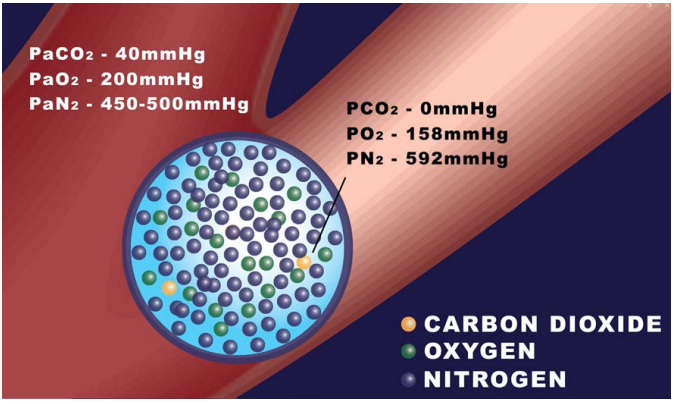
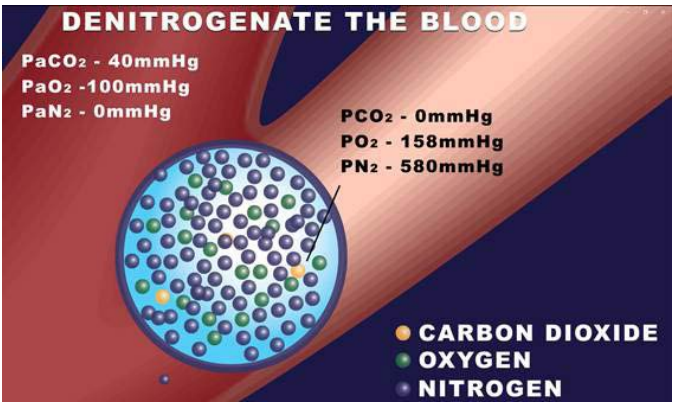
The Quantum SuperPAC is available to support low flow and high flow circuits, with a Paediatric option being available from 2027. SuperPACs are supplied coated with Spectrum Medical’s cross-linked PC1036. Superior adhesion qualities, elasticity and smoothness maximise antithrombotic performance throughout the Perfusion procedure.

Physiologic Ventilation

Spectrum Medical’s revolutionary Dual Chamber Oxygenator technology combined with the patented functionality of the Quantum Ventilation System takes patient ventilation into the future.

The combination of these two revolutionary technologies allows clinical best practise to transition between, decades old ventilation practise of blending with FiO₂ into a Physiologic Ventilation strategy. Using the dual gas chamber technology with its two independent chambers, clinicians can now create a Physiologic Environment which achieves Normoxia levels of PO₂ during bypass using 100% Oxygen.

Eliminating the use of room air eliminates the partial pressure of N₂ from the TOTAL patient blood volume, creating significant pressure delta between physiologic blood and nitrogen from the gas bubble to absorb Gaseous Micro Emboli (GME).



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.

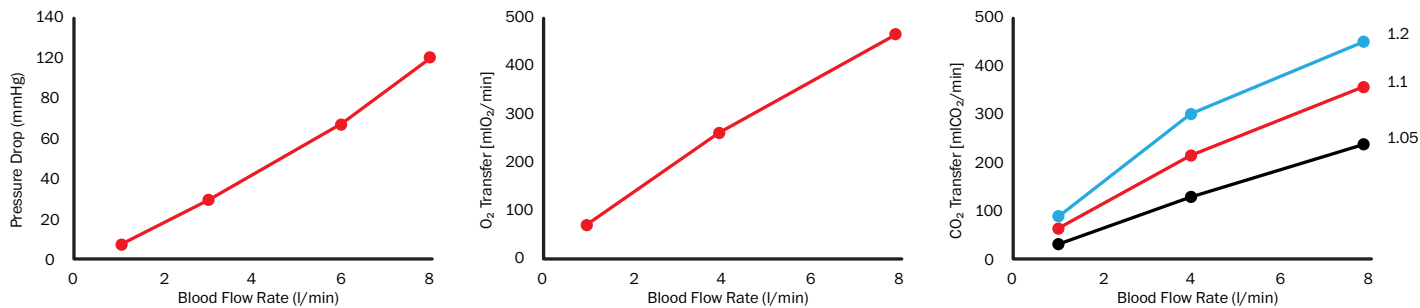
Biocompatibility

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.

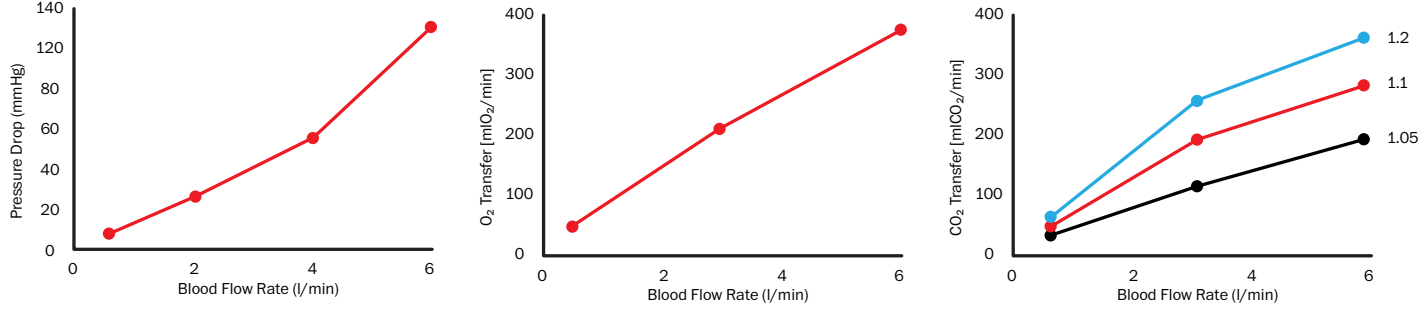
The Quantum Dual Chamber Oxygenator

Efficiency that makes a difference.

Quantum Perfusion Blood Oxygenator VT200



Quantum Perfusion Blood Oxygenator VT160



Performance of the device were obtained in agreement with ISO 7199 Standard (37 °C)



Hybrid System

Quantum Informatics - 26

Next generation System, bringing benefits of Mini-CPB to everyday usage.

Informatics - 26 is Spectrum Medical's latest generation software solution that revolutionizes real-time patient safety and the future development of clinical best practice for Extracorporeal Life Support.

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

The Hybrid Cardiotomy-Venous System is as easy to use as a traditional hard shell system. It primes quickly and familiar Vacuum Assist approaches are easily used. The Hybrid System 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 System 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 System is developed to successfully address a wide variety of challenging clinical situations.



System Architecture & H.I.S. Integration (VISION)

About VISION Server - VISION is the gateway to Quantum Informatics. It automates software, Windows and security updates, provides web-based remote access, and manages user privileges. VISION runs on a hospital-supplied server and integrates with Active Directory.

Two-way H.I.S. and 3rd party gateway communication is delivered via a MIRTH-supplied interface engine. A built-in SQL database stores patient data long-term and streams active data to LIVE VUE and bedside Patient Safety Systems.

Medical Device Connectivity - A world-leading connectivity solution, built in - eliminating the need for 3rd party middleware. VISION supports:

- 3rd Party Gateway Servers (e.g. Philips, GE)
- Direct connectivity to Physiologic Monitors, Ventilators, etc.
- Middleware solutions
- Hospital Information Systems (via Mirth)
- The Quantum Workstation Platform

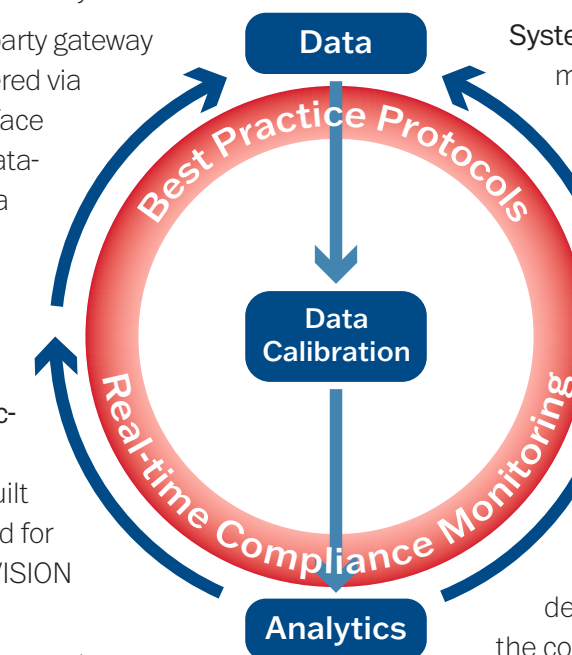
Analytics, Administration & Reporting

Case Playback - Retrospectively replay stored patient data from the VISION SQL database in real-time - waveforms, physiological trends, blood gases. With H.I.S. integration, playback can also include medications, alerts and personnel activity. Ideal for training and Morbidity & Mortality meetings.

System Administration - Day-to-day management at the physician level. VISION's web interface handles real-time profile creation, modification and deployment of the active Patient Safety System.

Dashboards & Reporting - Partnered with LOGI Analytics - a recognised leader in data visualisation - the LOGI tool-set is now a standard module within Quantum Informatics - 26, delivering clinical analytics across the continuum of care.

Real-time Compliance - QI-26 closes the loop between Data, Calibration, Compliance and Analytics, surfacing Best Practice Protocols directly at the point of care.



Sentinel Total Care

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

Software Updates:

Spectrum Medical is committed to the continuous improvement of your Quantum technologies. We continually review, enhance, and add software functionality driven by evidence-based clinical usage and trends. Any software deployment is subject to prior customer approval and training via Spectrum Medical.

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 configuration support to enhance your clinical practice. Using dedicated Product Specialists as opposed to traditional service personnel is a unique strategy with Sentinel Total Care covering 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

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 maximise equipment uptime our loan equipment stays with you until you receive a repaired or new replacement module from Spectrum Medical.

Quantum Sterile Products Support:

Quantum Sterile products including Centrifuge Pumps, Oxygenators and Cannulas supplied that have exceeded their expiration date can be return to Spectrum Medical for exchange. Please note Quantum SuperPACs are not covered by this clause.



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