



Flexible Solutions for all of your Cardiopulmonary Bypass Procedures

Spectrum / edical

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  $SO_2$  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 Technologies**

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



## Quantum Perfusion Systems for the O.R.

## Quantum Space Frame Technology

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

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 customi-
- zation 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<sub>2</sub>.

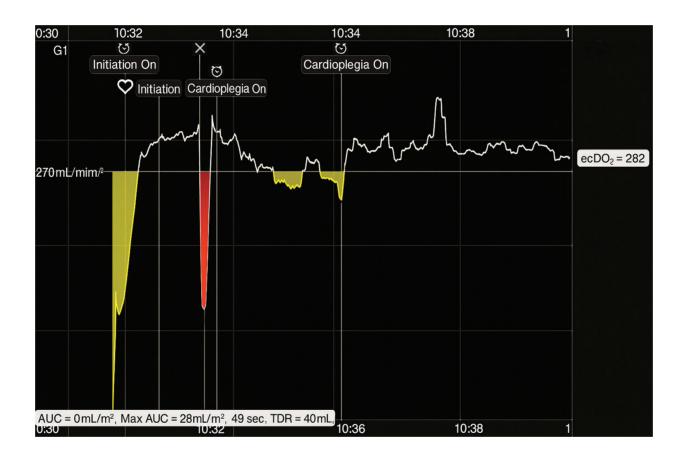
This multifaceted approach to QDP provides the clinical team with the methodologies to improve the quality of bypass management that can lead to the reduction of AKI, and the higher costs associated with extended I.C.U. Time. 1,2,3,4

#### Real-Time Diagnostics:

The starting point for QDP is the use of Spectrum Medical's non-invasive diagnostic technology for the measurement of a variety of channels; Oxygen Delivery (DO $_2$ ), Oxygen Consumption (VO $_2$ ), CO $_2$  Production (VCO $_2$ ), and multiple other calculations and indices. The monitoring of real-time supply and demand is an entirely new and critically important concept to the world of Perfusion. The Quantum technology displays the real-time variables based on the clinician's target values for these channels. By doing that we can create metrics in the form of data points and visuals that can help you make decisions, these are based on the latest literature<sup>4,5</sup>.

#### 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<sub>2</sub> deficits. <sup>4</sup> 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<sub>2</sub> minus actual DO<sub>2</sub>) multiplied by a unit of time.

Area Under the Curve (AUC) = This is the current active deficit being created for the single incident (please see TDR for total accumulation). This is accumulating based on your goal target- current channel value accumulating per second.

Maximum Area Under the Curve (MAX AUC) = This is the largest area of deficit between being at goal target, going under and coming back to goal target. We also give you a time between coming back to target and going back under target. This will tell you how long you were perfusing at your goal target after the incident before going back under.

Time Dose Response (TDR) = Total amount of deficit created, both time and depth. If our goal is 300ml/minute/m<sup>2</sup> for  $DO_2i$ , and you were at 250ml/minute/m<sup>2</sup> for 10 seconds, you would have created 500ml/m<sup>2</sup> of deficit.

#### Reference

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- 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.
- 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.

#### References

- 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.
- 5. Oshita T, Hiraoka A, Nakajima K, et al. A Better Predictor of Acute Kidney Injury After Cardiac Surgery: The Largest Area Under the Curve Below the Oxygen Delivery Threshold During Cardiopulmonary Bypass. J Am Heart Assoc. 2020;9(15):e015566. doi:10.1161/JAHA.119.015566
- 6. Hiroshi Mukaida, Satoshi Matsushita, Taira Yamamoto, Yuki Minami, Go Sato, Tohru Asai, Atsushi Amano, Oxygen delivery-guided perfusion for the prevention of acute kidney injury: A randomized controlled trial,
- 7. The Journal of Thoracic and Cardiovascular Surgery, Volume 165, Issue 2, 2023, Pages 750-760.e5,

## The Family of Quantum Workstations

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.



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  $\rm O_2$  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 3<sup>rd</sup> party device connectivity solution that enables the central display and transfer of critical real-time continuous clinical information.



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  $\rm O_2$  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<sub>2</sub> and PaCO<sub>2</sub> 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<sub>2</sub>, CO<sub>2</sub>, & Vacuum Channels
- O<sub>2</sub> and CO<sub>2</sub> Gas Concentrations & Pressures to the Oxygenator
- Overall Gas Flow to the oxygenator (SWEEP)
- CO<sub>2</sub> 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  $\mathrm{CO}_2$  removal when increasing or deceasing blood flow. This is not only critical during initiation and weaning but during the case when there is large 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 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 Motor Drive



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.

## The Quantum Sensor Module

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

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



The Quantum Smart Occluder is a revolutionary new approach to the management of flow and volume management during cardiopulmonary bypass surgery. We us 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 +/- 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

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  $DO_2$ .

The sensor module includes:

- Two 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 2025

#### 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 provided on the Quantum Workstation and secondarily on the QMCDS 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. This all encompassing system allows for the full range of delivery methods through a very intuitive interface that is completely integrated into the Spectrum Perfusion System.



# Heater-Cooler Technologies

A new future in patient safety.



## The Mr. Frosty Patient Safety Strategy

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 through testing that the HTF is effective at eliminating M.chimaera.



#### 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.

## Quantum Heater-Cooler

#### 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  $2.1\,\mathrm{kW}.$ 



#### 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.



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## Sterile Technologies

A "Quantum leap" in Perfusion best practise



## 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 reduction of Gaseous Microemboli
- Improved Gross Air Management
- Anti-Thrombotic Strategies
- Low Hemolysis & Low Heat Generation
- Low Pressure Drop
- Minimal Blood Contacting Surface Area

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 small adult and large adult patients SuperPACs are supplied coated with Spectrum Medical's cross linked biocompatibility 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.

## The Quantum Dual Chamber Oxygenator

## 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.

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

#### Sizes available:

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  ${\rm FiO_2}$  or transition to a Physiologic Ventilation strategy.



#### Physiologic Ventilation - Future Innovations

Using the dual gas chambers with their own inlets we are able to create a physiologic environment in terms of arterial saturations while using 100% FiO<sub>2</sub>. The Quantum Dual Chamber Oxygenator creates a physiologic saturation and PaO<sub>2</sub> through managing gas flow within the independent chambers. The benefits of this technology is to create a more natural oxygen environment while reducing/eliminating nitrogen, which has the benefit of reducing gaseous micro emboli.

# 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.

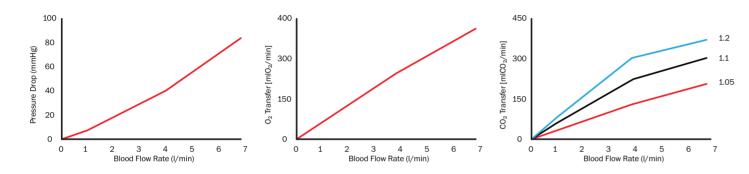
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## Centrifugal Pump

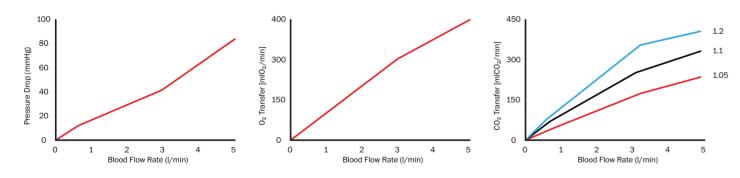
## Efficiency that makes a difference.

## CP37 - Low priming volume and high performance

## Quantum Perfusion Blood Oxygenator VT200



#### Quantum Perfusion Blood Oxygenator VT160



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



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.

## **Quantum Heat Exchangers**

# MIN THE COLUMN

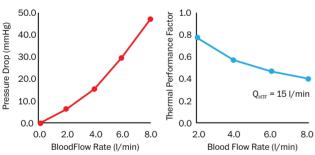
The Quantum range of sterile disposable heat exchangers have been designed by Spectrum Medical to provide the safest solution for eliminating the growth environment for the Mycobacterium Chimaera bacteria.

Specifically developed to operate exclusively with the Ouantum Heater-Cooler technology and its Glycol heat transfer fluid. Both the patient and the cardiopleagia 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
- Priming volume HTF side: 70 ml
- Exchange Surface: 0.12 m<sup>2</sup> • Maximum flow rate: 8 I/min



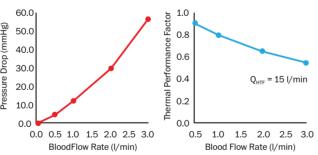
Pressure drop curves were generated using bovine blood (Hct: 32±2% - Hb: 12±1[g/dl]) at 37±1°C

#### Standard Heat Exchanger: Medium Flow (pediatric size)

• Priming volume blood side: 22 ml

Cardioplegia Heat Exchanger

- Priming volume HTF side: 38 ml
- Exchange Surface: 0.05 m<sup>2</sup> • Maximum flow rate: 3 I/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

0.0 0.2 0.4 0.6 0.8 1.0

- Priming volume HTF side: 22 ml
- Exchange Surface: 0.028 m<sup>2</sup>

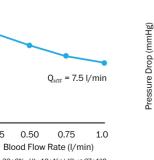
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15.0

10.0

5.0

- Maximum flow rate: 1 l/min
- Priming volume blood side: 22 ml • Priming volume HTF side: 22 ml • Exchange Surface: 0.028 m<sup>2</sup> • Maximum flow rate: 0.5 I/min
- Relief Valve Opening Pressure: 500 mmHg



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

0.6

0.4

0.2

0.25 0.50

#### 10.0 7.5 0.6 Q<sub>HTF</sub> = 7.5 I/min 5.0 2.5 0.2 0.0 0.125 0.25 0.375 0.5 0.25 0.375 0.125 BloodFlow Rate (I/min) Blood Flow Rate (I/min) Pressure drop curves were generated using bovine blood (Hct: 32±2% - Hb: 12±1[g/dl]) at 37±1°C

Hybrid System

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

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

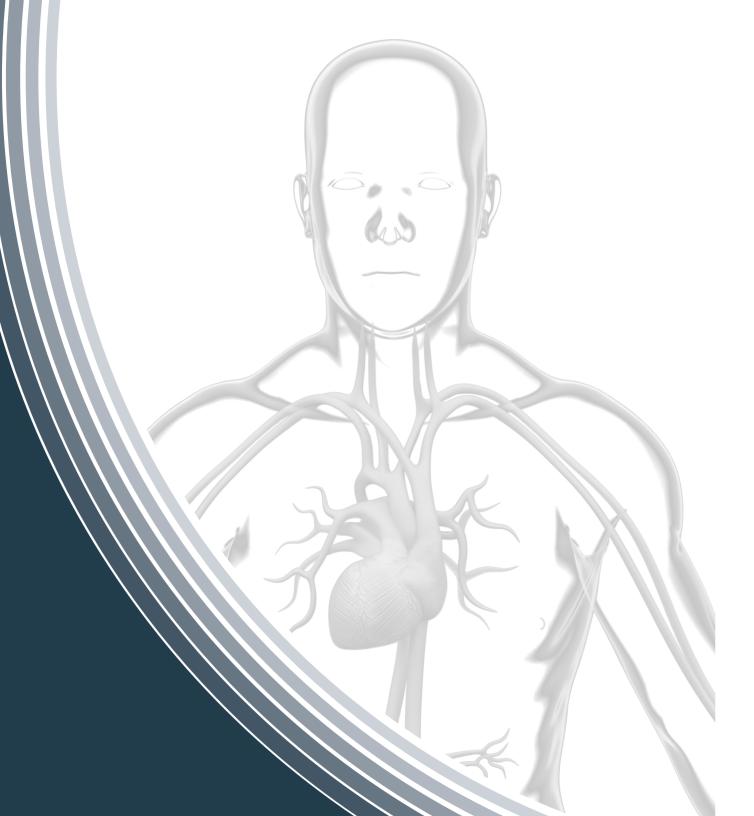
The Hybrid Cardiotomy-Venous System is as easy to use as a traditional hard shell system. It primes quickly and familiar Vacuum Assist approaches are easily used. The Hybrid System also provides the inherent safety of a soft bag while minimizing the need for manual air removal techniques.

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.



# Quantum Informatics - 24

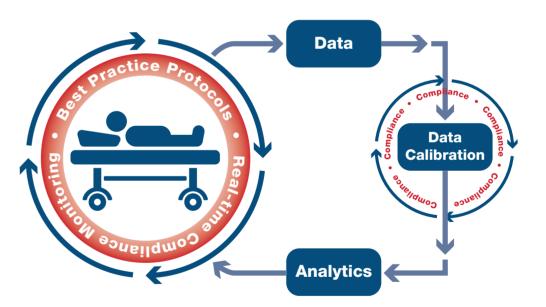
Revolutionizing real-time patient safety and the development of clinical best practise.



## Quantum Informatics - 24

Quantum Informatics - 24 is Spectrum Medical's latest generation software solution that revolutionizes real-time patient safety and the future development of clinical best practice for Cardiopulmonary Bypass.

Real-time compliance reporting systems combined with various Best Practice and Evidenced Based Protocol Apps provide a flexible approach to the consistent delivery of quality and safe patient care. The functionality of the Quantum Informatics technology ensures that clinicians are made aware of best practice violations as they happen and in near real-time. Intra-case compliance tools ensure that non-compliance data can be analysed in near-real time during clinically relevant time periods, such as change of shift or following clinical interventions.



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 3<sup>rd</sup> 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 3<sup>rd</sup> party middle ware solution. The VISION server application can support connectivity to the following systems:

- 3<sup>rd</sup> 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.

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## 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 additiona 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.

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

#### 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, OuantumChat.

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.

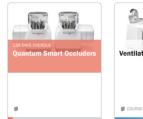
#### **Quantum Sterile Products Support:**

Partnering with hospitals in the provisioning of care is at the core of the Sentinel relationship and providing dedicated customer support for sterile disposable technologies is another exciting world first for Spectrum Medical.

Quantum sterile products supplied by Spectrum Medical that have exceeded their expiration date can be returned to Spectrum Medical for full credit against future purchases.

#### On-Line Learning Support (Quantum eLearning):

All users have access to Spectrum Medical's webbased 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 PO<sub>2</sub> and PCO<sub>2</sub>. Quantum eLearning is an easily accessible resource library. Access Quantum eLearning day













or night, on any device, from Loan Equipment any location with an 99% Up Time internet connection. gninis7T I<sub>GNOi</sub>; Educational Material Evidence Based



UK Headquarters: Call +44 (0) 1242 650120 enquiries@spectrummedical.com US Headquarters: Call 800 265 2331 ussales@spectrummedical.com ANZ Headquarters: Call +613 9562 8063 Sales.ANZ@spectrummedical.com

www.spectrummedical.com

