



NC DEPARTMENT OF  
**HEALTH AND  
HUMAN SERVICES**

JOSH STEIN • Governor

DEVDUTTA SANGVAI • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

October 27, 2025

Nicole Moore

[nicole.s.moore@advocatehealth.org](mailto:nicole.s.moore@advocatehealth.org)

**Exempt from Review – Replacement Equipment**

**Record #:** 4964  
**Date of Request:** October 8, 2025  
**Facility Name:** High Point Regional Health  
**FID #:** 943251  
**Business Name:** High Point Regional Health System  
**Business #:** 920  
**Project Description:** Replace heart-lung bypass machine  
**County:** Guilford

Dear Ms. Moore:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that the above referenced project is exempt from certificate of need review in accordance with G.S. 131E-184(f). Therefore, you may proceed to acquire without a certificate of need the Spectrum Medical Quantum Perfusion System to replace the Quest Medical MPS2 Heart-Lung Perfusion System. This determination is based on your representations that the existing unit will be sold or otherwise disposed of and will not be used again in the State without first obtaining a certificate of need if one is required.

It should be noted that the Agency's position is based solely on the facts represented by you and that any change in facts as represented would require further consideration by this office and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

Yolanda W. Jackson  
Project Analyst

Micheala Mitchell  
Chief

cc: Acute and Home Care Licensure and Certification Section, DHSR

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION  
HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

LOCATION: 1915 Health Services Way, Raleigh, NC 27607  
MAILING ADDRESS: 809 Ruggles Drive, 2704 Mail Service Center, Raleigh, NC 27699-2704  
<https://info.ncdhhs.gov/dhsr/> • TEL: 919-855-3873

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

October 8, 2025

Ms. Micheala Mitchell, Chief  
Ms. Yolanda Jackson, Project Analyst  
Healthcare Planning and Certificate of Need Section  
Division of Health Service Regulation  
809 Ruggles Drive  
Raleigh, NC 27603

RE: Exemption Request for High Point Regional Health d/b/a High Point Medical Center (HPMC) to Replace One Existing Heart-Lung Bypass Machine

Dear Ms. Mitchell:

High Point Regional Health d/b/a High Point Medical Center (“HPMC”) seeks to acquire one Spectrum Medical Quantum Perfusion System (“Replacement Heart-Lung Bypass Machine”) to replace one existing Quest Medical MPS2 Heart-Lung Perfusion System (“Existing Heart-Lung Bypass Machine”). The one Existing Heart-Lung Bypass Machine was acquired in 2011. The Existing Heart-Lung Bypass Machine is at the end of its useful life. The Existing Heart-Lung Bypass Machine is currently housed in the surgical suite on the third floor of HPMC’s main campus at 601 North Elm Street, High Point, NC 27262.

The purpose of this letter is to provide the Agency with notice and to request a determination that HPMC’s purchase of the Replacement Heart-Lung Bypass Machine is exempt from Certificate of Need (“CON”) review. The General Assembly has chosen to exempt certain, otherwise reviewable events from CON review. Among those exemptions is the acquisition of “replacement equipment,” defined in NCGS § 131E-176(22a) as follows in the CON law:

“Replacement equipment” means equipment that costs less than three million dollars (\$3,000,000) and is purchased for the sole purpose of replacing comparable medical equipment currently in use which will be sold or otherwise disposed of when replaced. In determining whether the replacement equipment costs less than three million dollars (\$3,000,000), the costs of equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the replacement equipment shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater. Beginning September 30, 2023, and on September 30 each year thereafter, the cost threshold amount in this subdivision shall be adjusted using the Medical Care Index component of the Consumer Price Index published by the U.S. Department of Labor for the 12-month period preceding the previous September 1.<sup>1</sup>

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<sup>1</sup> The current monetary threshold for replacement equipment is \$3,089,400.

HPMC's proposal qualifies for this exemption.

**A. Cost of the Replacement Equipment**

The projected total capital cost of the Replacement Heart-Lung Bypass Machine is \$672,641.05. There are no renovation costs or other costs associated with replacing the Existing Heart-Lung Bypass Machine. The quote for the Replacement Heart-Lung Bypass Machine is provided in Attachment A.

**B. Comparable Equipment**

The CON rule codified as 10A N.C.A.C. 14C.0303 (the "Regulation") defines "comparable medical equipment" in subsection (c) as follows:

"Comparable medical equipment" means equipment which is functionally similar and which is used for the same diagnostic or treatment purposes.

HPMC intends to use the Replacement Heart-Lung Bypass Machine for substantially the same cardiovascular surgical procedures for which it currently uses the Existing Heart-Lung Bypass Machine. The Existing Heart-Lung Bypass Machine is the Quest Medical MPS2 Heart-Lung Perfusion System that has been in use since it was acquired.

The Replacement Heart-Lung Bypass Machine can and will perform all procedures currently performed on the Existing Heart-Lung Bypass Machine, although it possesses some expanded capabilities due to technological improvements (see Attachment B for the Equipment Brochure). The Replacement Heart-Lung Bypass Machine is therefore "comparable medical equipment" as defined in Subsection (c).

For further equipment comparison, please refer to Attachment C, which contains the Equipment Comparison Charts.

The Existing Heart-Lung Bypass Machine has been in operation at HPMC for the past twelve months.

**C. Disposition of Equipment**

The Existing Heart-Lung Bypass Machine will be taken out of service and will not be re-sold or re-installed in North Carolina without appropriate Certificate of Need approval.

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Core Market Growth & Business Development

Medical Center Blvd

Winston-Salem, NC 27157

O: 336.716.6968

[Nicole.S.Moore@AdvocateHealth.org](mailto:Nicole.S.Moore@AdvocateHealth.org)

**CONCLUSION:**

Based on the foregoing information, HPMC hereby requests that the Agency provides a written response confirming that the acquisition of the Replacement Heart-Lung Bypass Machine described herein is exempt from CON review. If the Agency needs additional information to assist in its consideration of this request, please let us know.

Thank you for your consideration of this notice.

Sincerely,

*Nicole Moore*

Nicole Moore

# **Attachment A**

**Prepared For:**

Atrium Health-Wake Forest Baptist Medical Center  
 1 Medical Center Drive  
 Winston-Salem, NC 27157  
 Attn: Scott McGee  
 Tel.: 336-713-2894

**Quotation No: BHQC0923**

Date: 22-May-2025  
 Expiration Date: 31-Oct-2025

On Behalf of Spectrum Medical:  
 Tom McCarthy  
 tom.mccarthy@spectrummedical.com  
 Tel: +1 (803) 322 6884

**Quotation for:  
 Quantum Perfusion Technologies**



**Quantum Perfusion Technologies**

Part Number	Part Description	Quantity	Unit Price	Extended Price
	Quantum Frames			
51-000059-01	QPF4 - New York	2	35,259.00	70,518.00
51-000021-00	Quantum Power Supply	2	23,296.87	46,593.74
	Quantum Modules			
51-000022-02	Quantum Smart Occluder - LH	2	20,257.65	40,515.30
51-000093-00	QWS 15" HR Std	2	42,825.30	85,650.60
51-000003-00	Quantum Console Module (5 Rotary Knobs)	2	8,379.00	16,758.00
51-000082-00	QVM2-D-HM - Quantum Ventilation Module	2	103,504.80	207,009.60
51-000011-00	Quantum Roller Pump - 4"	4	16,785.56	67,142.24
51-000013-00	Quantum Roller Pump - 6"	6	16,950.93	101,705.58
43-000954-00	4" Hand Crank Assembly	2	375.90	751.80
43-000955-00	6" Hand Crank Assembly	2	393.75	787.50
51-000062-00	Quantum Centrifuge Drive - CP37	2	13,781.25	27,562.50
52-000028-00	Centrifugal Hand Crank - CP37	2	3,616.20	7,232.40
	Quantum Mounting Systems			
43-000653-02	1.25 Vert. Tube Clamp - Single	6	1,446.90	8,681.40
43-000654-01	1.25 Vert. Tube Clamp - Double	2	2,410.80	4,821.60
52-000009-00	Mounting Arm Kit 115mm	2	1,928.85	3,857.70
52-000014-00	Horizontal Pole Mounting Arm - G Clamp	2	1,470.00	2,940.00
52-000023-00	Mounting Arm Assy Long 485mm - Hook Mounts x2	2	3,021.90	6,043.80
52-000041-00	Mounting Arm Assy Short 270mm - Hook Mounts x2	2	3,021.90	6,043.80
52-000053-00	Mounting Arm Assy - QCM Only	2	3,398.85	6,797.70
52-000059-00	Mounting Arm Assy Short 300mm - Hook Mounts x1	2	2,893.80	5,787.60
52-000060-00	G-Clamp to Hook Plate Adaptor Assy	2	1,745.10	3,490.20
	Quantum Accessories			
52-000013-00	Drip Stand Assy	4	1,365.00	5,460.00
52-000020-00	Cable Clips - 1.25 in 6.5/9,5mm T1/T3 Double(10)	2	206.57	413.14
52-000068-00	Tray with 3x Hooks Assy - 300x135x15mm (StSt)	2	3,087.00	6,174.00
52-000078-00	Tray Assy - 300x200x15mm (StSt)	4	2,756.25	11,025.00
52-000097-00	Dual Tube 6" Bobbin Kit - O/d3/8" x2	6	1,029.00	6,174.00
	Sensor Kits			
0395-2584:L24	Transducer Cable to Edwards TruWave (8-pin)	6	840.00	5,040.00
43-000889-00	Level Sensor Assy	2	2,047.50	4,095.00
51-000037-00	Hb-SO2 Twin 2.0m Sensor 9/16"(3/8 x 3/32)	2	3,491.25	6,982.50
51-000067-00	QFS 9/16 x 2.0m (ID 3/8" x Wall 3/32")	6	4,042.50	24,255.00
51-000068-00	QFS 11/16 x 2.0m (ID 1/2" x Wall 3/32")	2	4,042.50	8,085.00
	SAP Cables			
54-000013-00-0500	Cable Assy White 0.50m - SAP Type 1	2	567.00	1,134.00



**Spectrum Medical Inc**  
 481 Munn Road, Suite 180  
 Fort Mill SC  
 29715  
 United States  
 Tel: (800)265 2331  
 www.spectrummedical.com  
**BHQC0923**

**Quantum Perfusion Technologies**

Part Number	Part Description	Quantity	Unit Price	Extended Price
54-000013-00-0850	Cable Assy White 0.85m - SAP Type 1	4	567.00	2,268.00
54-000014-00-0300	Cable Assy White 0.30m - SAP Type 3	6	615.30	3,691.80
54-000014-00-1000	Cable Assy White 1.00m - SAP Type 3	2	615.30	1,230.60
54-000017-00-0850	Cable Assy White 0.850m - SAP Type 3:SAP Type 1	2	615.30	1,230.60
54-000039-00-0450	Cable Assy White 0.45m SAP Type 3-2	2	615.30	1,230.60
54-000039-00-1200	Cable Assy White 1.20m SAP Type 3-2	2	615.30	1,230.60
				<b>Total</b>
Quantum Perfusion Technologies				810,410.90

**Additional Components**

Part Number	Part Description	Quantity	Unit Price	Extended Price
SA-FOC-CREDIT	Free of Charge Credit	1.00	-137,769.85	-137,769.85

**Total for Products**

	Total Before Tax	Total Inc. Tax
Total for Products	672,641.05	672,641.05

**Annual Product Support**

Product Name	Support Level	Total Value	Support Cost
Quantum Perfusion Technologies - Product Support	Sentinel	810,410.90	64,832.87

Currency	Curr
All prices quoted are in	USD

## Payment Terms & Conditions - Perfusion & Thermal Technologies

### Payment Terms

Payments are due 30 days from date of invoice. 75% with purchase order, 25% on delivery of hardware to customer location.

### Quotation Number

When placing purchase orders, please ensure that the Spectrum Medical quotation number is referenced. Regrettably, purchase orders cannot be accepted without this quotation number.

### Please Note

Spectrum Medical cannot accept new purchase orders for any Quantum Perfusion Technology Modules unless accompanied by a supporting purchase order for a non-optional Support Contract.

Product Support - Perfusion & Thermal Technologies	Sentinel
<b>Comprehensive 24/7 Support</b> Spectrum Medical's innovative 24-hour live messaging support platform enables users to have immediate access to an extensive knowledge-based product library, frequently asked questions and troubleshooting tips. Additionally, the 24-hour support platform supports immediate communication with Spectrum Medical's global support team which comprise, service technicians, clinical consultants and system application experts via a dedicated phone number, email address or Spectrum Medical 24-hour live messaging service.	Y
<b>Quantum eLearning</b> Includes access to Spectrum Medical web-based electronic Learning Management System (or LMS) to streamline product training and to complement your current training practice and recertification.	Y
<b>Annual Servicing</b> Includes all required servicing visits performed by dedicated Spectrum Medical's service personnel.	Y
<b>Replacement Parts</b> Includes the cost of any replacement parts/repairs arising from a service.	Y
<b>Emergency Loan Equipment</b> For all products that cannot be repaired within 24 hours of being returned to Spectrum Medical Service Center.	Y
<b>Extended Warranty</b> Total warranty on your Quantum Perfusion System including associated accessories (sensors, cable assemblies etc.). Quantum products beyond economic repair will be replaced with latest new build technologies.	Y
<b>Time Expired Sterile Products</b> 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.	Y
<b>Accidental Damage</b> Accidental damage on your Quantum Perfusion System including accessories (sensors, cables assemblies, third party device connectivity related equipment etc.). Quantum products beyond economic repair will be replaced with latest new build technologies.	Y
<b>Remote On-Line Support</b> Integrated within the VISION Server System and with VPN access, the Sentinel maintenance application provides a capability to support the remote monitoring and fault diagnosis of all Quantum systems network connected to the local VISION server.	Y
<b>Software Updates</b> During the service visit Quantum Software will be maintained to latest standards, including changes to user functionality, updates to enhance maintainability, reliability and protocol changes to 3rd party device driver software at no cost to the customer. Software deployment is subject to prior customer approval and training via webinar or in-house at Spectrum Medical is included free of charge.	Y

Quantum Workstation & Quantum Elite Specifications	
<b>Hardware</b>	Manufactured from medical grade aluminium materials and with the latest capacitive touch-screen technologies, the Medically Approved Quantum Workstation complies with the very latest medical and safety regulations in accordance with IEC EN ISO 60601-1 and IEC EN 62304.
<b>Software</b> OS Application Code	Windows 10 IoT Enterprise 2021 LTSC (Anti-Virus to be managed by customer using required exemptions) Spectrum Medical proprietary Quantum application code.
<b>Electronics</b> Main Processor Memory Battery	Intel Atom x6425E Quad-Core 3.0 GHz 16GB DDR3, 240GB (or greater) Solid State Drive, 2GB (or greater) SD Card 2 x 14.4V 6600 mAh Li-ion, Run-time: > 90 minutes
<b>Communications</b> USB Wired LAN User Serial	2 - USB 1 - 10/100Mbps 4 - (RS232/RS485 up to 115200 bps)

Year 1 Sentinel Service Coverage Free of Charge per Advocate Health Agreement.

# **Attachment B**

## Quantum Perfusion Systems



# Quantum Perfusion Systems

Spectrum Medical proudly presents a modular range of Quantum Perfusion Modules and Patient Safety Systems in combination with flexible space frame solutions for all ECLs procedures used in Cardiopulmonary Bypass.

- 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 offers 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 which contains a four-hour battery pack and can integrate up to thirteen Quantum modules to support changing clinical practice.
- This system can also drive two centrifugal pumps with no change in overall footprint. The Quantum Perfusion System can be upgraded at any time, with the addition of an external drive motor, to support the integration of centrifugal pumps into your clinical practice.
- All power management cabling is contained within the stainless steel frame to improve both ergonomics and system durability.



The Vienna Frame



The Cheltenham Frame



The New York Frame

# Quantum Workstations

The window to intuitive control of the most advanced and safest perfusion technology available.



12" Quantum Workstation

## The 12" Quantum Workstation

The 12" Quantum Workstation is a direct replacement for the System M Monitoring system and an optional alternative to the 15" Quantum Workstation. The 12" Workstation with its high-resolution LCD screen has been designed to provide customers with a reduced spatial envelope and a simplified graphical user interface.

The 12" Quantum Workstation retains a range of capabilities that supports connectivity to the

Quantum Ventilation System, Quantum Diagnostics Module and third party physiologic monitors for the central display of critical clinical information. Additionally, it includes a range of Best Practice Apps and associated alert systems and network connectivity to Spectrum Medical's LIVE VUE remote monitoring technology.

The 12" Quantum Workstation does not support the Quantum HLM Pump Manager App.

## The 15" Quantum Workstation

The 15" Quantum Workstation is the gateway into the management of the World's most advanced Perfusion Management System.

Integrated software applications (Apps) supported by a unique range of advanced Quantum System Modules extend both Perfusion management and Perfusion functionality well beyond today's conventional technologies.

With a commitment to both patient and physician safety the Quantum Workstation with its high resolution 15" LCD screen has been designed to allow the centralization of critical patient data and perfusion management functions into a single user interface.

The Quantum software system is totally configurable to the needs of individual customers. Apps can be selected from the Quantum App Store and integrated into the practice work flow to provide the following functionalities:

- Blood Flow Management, the Delivery of Cardioplegia and Patient Weaning
- Patient Ventilation, Gas Blending and Vacuum Management
- Vitals Management and Diagnostic Alarm Settings
- Quantum EMR and Quantum System Settings



15" Quantum Workstation with optional Pump Control Module

# The Quantum Ventilation and Diagnostic Modules

Spectrum Medical's advanced technologies - a breakthrough in the safe delivery of patient ventilation and non-invasive diagnostics.

## Quantum Ventilation System

The 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 and perfusion diagnostics.

The ultra-compact Quantum Ventilation System employs the very latest gas blending technologies to ensure the precision delivery of  $\text{FiO}_2$ ,  $\text{CO}_2$  and sweep flow rates. The System provides a sweep flow range from 0.025 to 10 L/m when flowing a single gas e.g.  $\text{O}_2$  and up to a maximum flow rate of 20 L/m when modulating the delivery of at least two gases e.g. 60%  $\text{FiO}_2$ .

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 requirements 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  $\text{PaO}_2$  and  $\text{PaCO}_2$  measurement technologies, provides a decision support capability that will assist the clinician in the setting of gas flows and gas concentrations when setting  $\text{PaO}_2$  and  $\text{PaCO}_2$  target values.

The Quantum Ventilation System provides precision modulation and monitoring of two independent vacuum channels.





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

**Incoming Gas Concentrations and System Pressures:**

- Air, O<sub>2</sub>, CO<sub>2</sub>, Vacuum Incoming Supply Pressures
- O<sub>2</sub> and CO<sub>2</sub> Gas Concentrations to the Oxygenator
- Overall Gas Flow to the oxygenator (SWEEP)
- CO<sub>2</sub> concentrations measured at the primary exhaust port

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.

## Quantum Diagnostic System

The 'entry level' Quantum Diagnostics sensor-module is designed to provide the complete range of perfusion circuit parameters required for the safe management of extracorporeal circulation. The sensor module includes three measurement channels of pressure and flow (including emboli & bubble detection), two temperature channels and a reservoir level detection system.

The Quantum Diagnostics module integrates the entry level sensor module capabilities with Spectrum Medical's proven System M non-invasive Diagnostic technology as well as its complete range of Calculated Physiologic indices. New to Spectrum Medical is the capability for a single configuration to measure with high accuracy a gas flow range from 0.025 to 10.00 L/m.

Offering complete flexibility, the Quantum Diagnostics module can be connected directly to the Quantum Workstation and to multiple locations on the Quantum Pump Console.

# Perfusion Roller Pump

A Quantum leap in patient safety and perfusion systems' functionality.



The compact range of Quantum direct drive peristaltic roller pumps are provided with 4", 6" and 8" raceway diameters which maximizes both flexibility and compactness when optimizing HLM design. In particular, the introduction of the mid-range 6" 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 colour coded plastic inserts. A single 'bobbin' solution allows for the clamping of all tubing diameters associated within the selected size of race-way.

# Intelligent Tube Occlusion



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 with 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 and weaning.

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 channel reservoir level detection system.

An interlocking Lid, Color-coded LEDs and a mechanical override system maximizes system safety.

# Quantum Directed Perfusion

The tools to help improve outcomes.

Quantum Directed Perfusion provides the next generation capabilities beyond traditional Perfusion monitoring and basic Goal Directed Perfusion (GDP) techniques. Quantum Directed Perfusion (QDP) from Spectrum Medical goes well beyond the simplistic approach of measuring  $DO_2$ . This multifaceted approach to QDP provides the clinician team with the methodologies to develop best practice strategies that can lead to the reduction of AKI, and the higher costs associated with extended I.C.U. Time.<sup>1,2,3,4</sup>

## The Principles of Quantum Directed Perfusion (QDP)

- 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 a completely 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  $DO_2$ . Having this information intra-operatively and in real-time significantly increases the quality of bypass management.

However, more importantly Quantum Directed Perfusion calculates Oxygen Deficit or a total "area under the curve" calculation which is generated by the accumulation of an actual deficit value (i.e. target  $DO_2$  minus actual  $DO_2$ ) multiplied by a unit of time.

It is accepted that the potential of AKI is significantly increased with large  $DO_2$  deficits.<sup>4</sup> Calculating the Oxygen Deficit and then equating it to outcomes is a relatively straight forward process using Quantum's Informatics technology. Such an analysis is useful in determining intra-op best practice.

- Spectrum Medical's Critical Care Scoring technology supports a pro-active 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.
- Quantum Informatics and its LIVE VUE technology improve patient care with the seamless integration of "multiple information feeds" into central viewing systems that are available to everybody in the Operating Room.

### References

1. Alshaikh, et al. Financial Impact of Acute Kidney Injury After Cardiac Operations in the United States. *Ann Thorac 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.
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.

# I.T. Solutions for Perfusion, ECMO and the I.C.U.



## Quantum Informatics, I.T. Solutions for Perfusion, ECMO and the I.C.U.

Quantum Informatics is a revolutionary new methodology for the provision of specialized health informatics solutions for the critical care space including the I.C.U. and the O.R. The real-time integration of physiologic data facilitates the real-time implementation of Best Practice and Evidence Based Protocols that can support the identification of adverse events before they become adverse outcomes. Quantum Informatics is highly configurable and can easily integrate within existing Hospital Information Systems, clinical workflows and diverse care locations. The overall system consists of the following three modules:

**VIPER EMR** – VIPER EMR is the clinical interfacing software that uses an App based architecture for easy integration into the individual work-flow needs of a hospital. VIPER EMR can run on either the 12" or 15" Quantum Workstation or a Quantum Tablet.

**VISION** – Spectrum Medical's VISION server application provides system-wide maintenance of software, system-wide communication, the creation and transfer of patient records (end of case and real-time) and bi-directional HL7 communication to the



H.I.S. using a Mirth Interface Engine. VISION's SQL database is used for the storage of critical patient information and is supported by a comprehensive analytics package to support improved quality outcomes.

**LIVE VUE** – LIVE VUE is Spectrum Medical's web-based near real-time remote monitoring solution. Highly configurable graphical presentation systems and integrated best practice alert systems provide clinicians with instant access to live patient data from a variety of care locations to enhance patient safety and rapid decision support.

# Total Customer Support

With an absolute dedication to customer support and a total solutions approach to maximizing equipment availability within the hospital, Spectrum Medical has designed a two-tier customer support program called Sentinel Total Care and Vigilance Total Care.

## Sentinel Total Care:

**Extended Warranty:** Full warranty on your Quantum Perfusion System including Associated Accessories (sensors, cable assemblies) for its 10-year life at no cost to the customer. Quantum products beyond economic repair will be replaced with latest 'new build' technologies.

**Annual Servicing:** Includes all required servicing visits performed by dedicated Spectrum Medical's service personnel and the cost of all servicing items.

**Accidental Damage:** Accidental damage including accessories (sensor, cable assemblies) for the 10-year life of your Quantum Product at no cost to the customer. (Available with Vigilance in US Markets).

**Emergency Loan Equipment:** Loan equipment provided at no cost if the defective equipment cannot be rectified within 24 hours of being returned to Spectrum Medical.

**Annual Software Updates:** During the service visit Quantum Software will be maintained to latest standards, including changes to user functionality, updates to enhance maintainability, reliability and protocol changes to third party device driver software at no cost to the customer. Software deployment is subject to prior customer approval and training via webinar or in-house at Spectrum Medical is included free of charge.

**Telephone Support:** Within standard working hours.

## Vigilance Total Care: additional support when using Spectrum Medical's Quantum Informatics and VISION Data Management System.

**Vigilance Server:** Vigilance Server is a revolution in customer support and uses current technology developed for Spectrum Medical's Perfusion Management System. Integrated within the VISION Server System the Vigilance maintenance application provides for the pro-active, real-time monitoring and reporting of electronic and functional sub-systems, real-time fault diagnosis, deployment of system wide software updates, and on-line system support. With access to a private VPN, this diagnostic information is communicated in real-time to Spectrum Medical.

**Quantum Instant Access:** To maximize operational uptime of the Quantum Perfusion System, Spectrum Medical will, at its discretion, deploy a 'bonded inventory' of critical Quantum modules within a secure hospital location. Customers will have immediate 24-hour access to this bonded stock and more importantly prior approval from Spectrum Medical will not be required.

Spectrum Medical must be notified as soon as practically possible that the bonded stock has been used.



UK Headquarters:

Call +44 (0) 1242 650120

[enquiries@spectrummedical.com](mailto:enquiries@spectrummedical.com)

USA and Canada:

Call 800 265 2331

[ussales@spectrummedical.com](mailto:ussales@spectrummedical.com)

[www.spectrummedical.com](http://www.spectrummedical.com)



SPECTRUM MEDICAL LIMITED  
Registered to:  
ISO 13485:2016  
File No. A14554

# **Attachment C**

## EQUIPMENT COMPARISON

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type (e.g., Cardiac Catheterization, Gamma Knife®, Heart-lung bypass machine, Linear Accelerator, Lithotripter, MRI, PET, Simulator, CT Scanner, Other Major Medical Equipment)	Heart Lung Bypass	Heart Lung Bypass
Manufacturer	Quest Medical	Spectrum Medical
Model number	MPS2	Quantum Perfusion System
Other method of identifying the equipment (e.g., Room #, Serial Number, VIN #)	2471, 2477	HPMC 3 <sup>rd</sup> floor OR
Is the equipment mobile or fixed?	Mobile	Mobile
Date of acquisition	03/07/2011	12/1/2025
Was the existing equipment new or used when acquired? / Is the replacement equipment new or used?	New	New
Total projected capital cost of the project <Attach a signed Projected Capital Cost form>	N/A	\$672,641.05
Total cost of the equipment	N/A	\$672,641.05
Location of the equipment <Attach a separate sheet for mobile equipment if necessary>	HPMC 3 <sup>rd</sup> floor OR	HPMC 3 <sup>rd</sup> floor OR
Document that the existing equipment is currently in use	Yes	N/A
Will the replacement equipment result in any increase in the <b>average charge per procedure</b> ?	N/A	No
If so, provide the increase as a percent of the current average charge per procedure	N/A	N/A
Will the replacement equipment result in any increase in the <b>average operating expense per procedure</b> ?	N/A	No
If so, provide the increase as a percent of the current average operating expense per procedure	N/A	N/A
Type of procedures performed on the existing equipment <Attach a separate sheet if necessary>	CABG MVR AVR	CABG MVR AVR
Type of procedures the replacement equipment will perform <Attach a separate sheet if necessary>	CABG, MVR, AVR	CABG, MVR, AVR

**From:** [Moore, Nicole](#)  
**To:** [Stancil, Tiffany C](#); [Waller, Martha K](#)  
**Cc:** [Jackson, Yolanda W](#); [Blake, Macy L](#)  
**Subject:** [External] HPMC Heart Lung Bypass Letter of No Review  
**Date:** Thursday, October 9, 2025 8:18:35 AM  
**Attachments:** [image001.png](#)  
[image002.png](#)  
[image003.png](#)  
[image004.png](#)  
[2025 1007 HPMC Heart Lung Bypass Machine Letter of No Review.pdf](#)

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Good morning,

Please find the attached letter of no review requested by High Point Regional Health (dba High Point Medical Center) for a heart lung bypass machine replacement. Please reach out if you have any questions.

Thank you,  
Nicole

**Nicole Moore**

Director, *Core Market Growth and Business Development* – Atrium Health  
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