



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

JOSH STEIN • Governor

DEVPUTTA SANGVAI • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

August 29, 2025

Brighid Huber

Brighid.Huber@advocatehealth.org

Exempt from Review – Replacement Equipment

Record #: 4892

Date of Request: August 6, 2025

Facility Name: Carolinas Medical Center

FID #: 943070

Business Name: The Charlotte-Mecklenburg Hospital Authority

Business #: 1770

Project Description: Replace two pediatric heart-lung bypass machines

County: Mecklenburg

Dear Brighid Huber:

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-176(22a). Therefore, you may proceed to acquire without a certificate of need the two Spectrum Medical Quantum Perfusion Systems ("Replacement Pediatric Heart-Lung Bypass Machines") to replace two existing LivaNova S5 Heart-Lung Perfusion Systems ("Existing Pediatric Heart-Lung Bypass Machines"). This determination is based on your representations that the existing units 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,

Chalice L. Moore

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: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603

MAILING ADDRESS: 809 Ruggles Drive, 2704 Mail Service Center, Raleigh, NC 27699-2704

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AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

July 30, 2025

Ms. Micheala Mitchell, Chief
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
N.C. Department of Health & Human Services
809 Ruggles Drive
Raleigh, NC 27603

RE: Exemption Request for The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center to Replace Two Existing Pediatric Heart-Lung Bypass Machines

Dear Ms. Mitchell:

The Charlotte-Mecklenburg Hospital Authority (“CMHA”) d/b/a Carolinas Medical Center (“CMC”) seeks to acquire two Spectrum Medical Quantum Perfusion Systems (“Replacement Pediatric Heart-Lung Bypass Machines”) to replace two existing LivaNova S5 Heart-Lung Perfusion Systems (“Existing Pediatric Heart-Lung Bypass Machines”). The two Existing Pediatric Heart-Lung Bypass Machines were acquired in 2011. Both Existing Pediatric Heart-Lung Bypass Machines are at the end of their useful life. The two Existing Pediatric Heart-Lung Bypass Machines are currently housed in the surgical suite on the main campus of CMC at 1000 Blythe Boulevard, Charlotte, NC 28203.

The purpose of this letter is to provide the Agency with notice and to request a determination that CMC’s purchase of the Replacement Pediatric Heart-Lung Bypass Machines 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 1.¹

CMC’s proposal qualifies for this exemption.

A. Cost of the Replacement Equipment

The projected total capital cost of each Replacement Pediatric Heart-Lung Bypass Machine is \$380,406.57. There are no renovation costs or other costs associated with replacing each of the two Existing Pediatric Heart-Lung Bypass Machines. The quote for the Replacement Pediatric Heart-Lung Bypass Machines is provided in Attachment A.

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

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.

CMC intends to use the two Replacement Pediatric Heart-Lung Bypass Machines for substantially the same cardiovascular surgical procedures for which it currently uses the two Existing Pediatric Heart-Lung Bypass Machines. The Existing Pediatric Heart-Lung Bypass Machines are both LivaNova S5 Heart-Lung Perfusion Systems that have been in use since they were acquired.

The two Replacement Pediatric Heart-Lung Bypass Machines can and will perform all procedures currently performed on the two Existing Pediatric Heart-Lung Bypass Machines, although they possess some expanded capabilities due to technological improvements (see Attachment B for the Equipment Brochure). The Replacement Heart-Lung Bypass Machines are 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 two Existing Pediatric Heart-Lung Bypass Machines in operation at CMC were used in over 260 procedures in 2024.

C. Disposition of Equipment

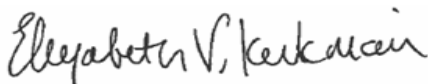
The two Existing Pediatric Heart-Lung Bypass Machines will be taken out of service and will not be re-sold or re-installed in North Carolina without appropriate Certificate of Need approval.

CONCLUSION:

Based on the foregoing information, CMC hereby requests that the Agency provide a written response confirming that the acquisition of the two Replacement Pediatric Heart-Lung Bypass Machines 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,



Elizabeth V. Kirkman

AVP, Core Market Growth Business Development

Attachment A

Prepared For:

Atrium Health - Carolinas Medical Center
 PO BOX 516
 Elmsford, New York 10523
 Attn: Mindy Couper
 Tel.: 740-442-1166

Quotation No: BGQC1729

Date: 14-Oct-2024
 Expiration Date: 15-Dec-2025

On Behalf of Spectrum Medical:
 Courtney Clark
 courtney.clark@spectrummedical.com

Quotation for: Quantum Perfusion Technologies



Quantum Perfusion Technologies

Part Number	Part Description	Quantity	Unit Price	Extended Price
	Quantum Frames			
51-000025-01	QPF2 - Cheltenham	1	28,481.00	28,481.00
51-000021-00	Quantum Power Supply	1	21,200.00	21,200.00
	Quantum Modules			
51-000093-00	QWS 15" HR Std	1	38,000.00	38,000.00
51-000003-00	Quantum Console Module (5 Rotary Knobs)	1	7,980.00	7,980.00
51-000082-00	QVM2-D-HM - Quantum Ventilation Module	1	98,576.00	98,576.00
51-000011-00	Quantum Roller Pump - 4"	4	15,618.00	62,472.00
51-000013-00	Quantum Roller Pump - 6"	2	15,618.00	31,236.00
51-000008-00	Quantum Roller Pump - 8"	1	16,538.00	16,538.00
43-000954-00	4" Hand Crank Assembly	1	358.00	358.00
43-000955-00	6" Hand Crank Assembly	1	375.00	375.00
43-000956-00	8" Hand Crank Assembly	1	430.00	430.00
	Quantum Mounting Systems			
52-000009-00	Mounting Arm Kit 115mm	1	1,837.00	1,837.00
52-000059-00	Mounting Arm Assy Short 300mm - Hook Mounts x1	1	2,756.00	2,756.00
52-000053-00	Mounting Arm Assy - QCM Only	1	3,237.00	3,237.00
52-000041-00	Mounting Arm Assy Short 270mm - Hook Mounts x2	2	2,878.00	5,756.00
43-000653-02	1.25 Vert. Tube Clamp - Single	6	1,378.00	8,268.00
52-000082-00	DB7-BiVAD QR Device Bracket	1	2,800.00	2,800.00
	Quantum Accessories			
52-000013-00	Drip Stand Assy	2	1,300.00	2,600.00
52-000078-00	Tray Assy - 300x200x15mm (StSt)	1	2,625.00	2,625.00
52-000068-00	Tray with 3x Hooks Assy - 300x135x15mm (StSt)	1	2,940.00	2,940.00
52-000020-00	Cable Clips - 1.25 in 6.5/9,5mm T1/T3 Double(10)	1	206.57	206.57
52-000017-00	Ball & T-Bar Hex Driver Kit	1	75.00	75.00
52-000075-00	Quick Release Hook Plate - Std	5	522.00	2,610.00
52-000097-00	Dual Tube 6" Bobbin Kit - O/d3/8" x2	1	980.00	980.00
	Sensor Kits			
0395-2584:L24	Transducer Cable to Edwards TruWave (8-pin)	3	840.00	2,520.00
43-000889-00	Level Sensor Assy	1	1,950.00	1,950.00
51-000064-00	QFS 5/16 x 2.0m (ID 3/16" x Wall 1/16")	1	3,850.00	3,850.00
51-000065-00	QFS 3/8 x 2.0m (ID 1/4" x Wall 1/16")	3	3,850.00	11,550.00
51-000067-00	QFS 9/16 x 2.0m (ID 3/8" x Wall 3/32")	3	3,850.00	11,550.00
51-000038-00	Hb-SO2 Twin 2.0m Sensor 7/16"(1/4 x 3/32)	1	3,325.00	3,325.00
51-000037-00	Hb-SO2 Twin 2.0m Sensor 9/16"(3/8 x 3/32)	1	3,325.00	3,325.00
	SAP Cables			
				Total



Spectrum Medical Inc
481 Munn Road, Suite 180
Fort Mill SC
29715
United States
Tel: (800)265 2331
www.spectrummedical.com
BGQC1729

Quantum Perfusion Technologies	380,406.57
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Additional Components

Part Number	Part Description	Quantity	Unit Price	Extended Price
SA-FOC-CREDIT	Free of Charge Credit	1.00	-22,824.39	-22,824.39

Total for Products

	Total Before Tax	Total Inc. Tax
Total for Products	357,582.18	357,582.18

Annual Product Support

Product Name	Support Level	Total Value	Support Cost
Quantum Perfusion Technologies - Product Support	Sentinel	380,406.57	30,432.53

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.

Quantum Workstation & Quantum Elite Specifications	
Hardware	Manufactured from medical grade aluminium materials and with the latest capacitance 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.
Software OS Application Code	Windows 10 IoT Enterprise 2019 / 2021 LTSC (Anti-Virus to be managed by customer using required exemptions) Spectrum Medical proprietary Quantum application code.
Electronics Main Processor Memory Battery	Intel Atom E3845 Quad-Core 1.91 GHz 4GB DDR3, 64GB (or greater) Solid State Drive, 2GB (or greater) SD Card 2 x 14.4V 6600 mAh Li-ion, Run-time: > 90 minutes
Communications Serial /USB Wired LAN User Serial	2 - USB /Serial 1 - 10/100Mbps 4 - (RS232/RS485 up to 115200 bps)

Product Support - Perfusion & Thermal Technologies	Sentinel
Comprehensive 24/7 Support 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
Quantum eLearning 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
Annual Servicing Includes all required servicing visits performed by dedicated Spectrum Medical's service personnel.	Y
Replacement Parts Includes the cost of any replacement parts/repairs arising from a service.	Y
Emergency Loan Equipment For all products that cannot be repaired within 24 hours of being returned to Spectrum Medical Service Center, a loaner or replacement will be despatched. Upon receipt of the emergency loan or replacement equipment, the customer will be required to swap over the module and package the faulty part for return.	Y
Extended Warranty 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
Time Expired Sterile Products Partnering with hospitals in the provisioning of care is at the core of the Sentinel relationship. Quantum sterile products supplied by Spectrum Medical that have exceeded their expiration date can be returned to Spectrum Medical and exchanged for new replacement products free of charge.	Y
Accidental Damage 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
Remote On-Line Support 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
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 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

This quote is for purposes of the CON exemption letter.

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 FiO_2 , 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. 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% 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 PaO_2 and 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 PaO_2 and 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, O₂, CO₂, Vacuum Incoming Supply Pressures
- O₂ and CO₂ Gas Concentrations to the Oxygenator
- Overall Gas Flow to the oxygenator (SWEEP)
- CO₂ 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 $\pm 2\%$ 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.^{1,2,3,4}

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.⁴ 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

USA and Canada:

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ussales@spectrummedical.com

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

SMM-005 v3

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, etc.)	Heart-Lung Bypass Machine	Heart-Lung Bypass Machine
Manufacturer	LivaNova	Spectrum Medical
Model name/number	S5 Perfusion System	Quantum Perfusion System
Other method of identifying the equipment (e.g., Serial Number, VIN #)	48E01760	Not Available Until Installed
Is the equipment mobile or fixed?	Mobile	Mobile
Date of acquisition	2011	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	NA	\$380,406.57
Total cost of the equipment	Not available due to system transition	\$380,406.57
Location of the equipment	Carolinas Medical Center	Carolinas Medical Center
Document that the existing equipment is currently in use	Pediatric heart-lung bypass machines were used in over 260 procedures performed at CMC/LCH during CY2024	NA
Will the replacement equipment result in any increase in the average charge per procedure ?	NA	No
If so, provide the increase as a percent of the current average charge per procedure	NA	NA
Will the replacement equipment result in any increase in the average operating expense per procedure ?	NA	No
If so, provide the increase as a percent of the current average operating expense per procedure	NA	NA
Type of procedures performed on the existing equipment	Heart-Lung Bypass	NA
Type of procedures the replacement equipment will perform	NA	Heart-Lung Bypass

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, etc.)	Heart-Lung Bypass Machine	Heart-Lung Bypass Machine
Manufacturer	LivaNova	Spectrum Medical
Model name/number	S5 Perfusion System	Quantum Perfusion System
Other method of identifying the equipment (e.g., Serial Number, VIN #)	48E01771	Not Available Until Installed
Is the equipment mobile or fixed?	Mobile	Mobile
Date of acquisition	2011	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	NA	\$380,406.57
Total cost of the equipment	Not available due to system transition	\$380,406.57
Location of the equipment	Carolinas Medical Center	Carolinas Medical Center
Document that the existing equipment is currently in use	Pediatric heart-lung bypass machines were used in over 260 procedures performed at CMC/LCH during CY2024	NA
Will the replacement equipment result in any increase in the average charge per procedure ?	NA	No
If so, provide the increase as a percent of the current average charge per procedure	NA	NA
Will the replacement equipment result in any increase in the average operating expense per procedure ?	NA	No
If so, provide the increase as a percent of the current average operating expense per procedure	NA	NA
Type of procedures performed on the existing equipment	Heart-Lung Bypass	NA
Type of procedures the replacement equipment will perform	NA	Heart-Lung Bypass

From: [Huber, Brighid K](#)
To: [Stancil, Tiffany C](#); [Moore, Chalice L](#)
Subject: [External] Exemption Request for The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center
Date: Wednesday, July 30, 2025 4:16:07 PM
Attachments: [2025 CMHA dba CMC Exemption Request to Replace Existing Peds Heart-Lung Bypass Machines.pdf](#)

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Good afternoon,

I hope you both are doing well! Please find attached an exemption request submitted by The Charlotte-Mecklenburg Hospital Authority ("CMHA") d/b/a Carolinas Medical Center ("CMC") to replace two existing pediatric heart-lung bypass machines.

Thank you, and please let me know if you have any questions.

Best,

Brighid

Brighid Knoll Huber, MHA, ATC

Core Market Growth Business Development

Mobile: 724-986-6214

Atrium Health

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