



NC DEPARTMENT OF  
**HEALTH AND  
HUMAN SERVICES**

ROY COOPER • Governor  
MANDY COHEN, MD, MPH • Secretary  
MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

April 7, 2021

Elizabeth Runyon  
[Elizabeth.runyon@unchealth.unc.edu](mailto:Elizabeth.runyon@unchealth.unc.edu)

**Exempt from Review – Replacement Equipment**

**Record #:** 3517  
**Date of Request:** March 31, 2021  
**Facility Name:** University of North Carolina Hospitals  
**FID #:** 923517  
**Business Name:** University of North Carolina Hospitals at Chapel Hill  
**Business #:** 1900  
**Project Description:** Replace heart and lung bypass machine  
**County:** Orange

Dear Ms. Runyon:

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(a)(7). Therefore, you may proceed to acquire without a certificate of need the Mobile Spectrum Medical Quantum heart-lung bypass machine to replace the existing Mobile LivaNova 55 heart-lung bypass machine. 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,

Kim Meymandi  
Project Analyst

for  
Lisa Pittman  
Acting Chief, Certificate of Need

cc: Construction 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  
<https://info.ncdhhs.gov/dhsr/> • TEL: 919-855-3873

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER



March 31, 2021

VIA ELECTRONIC MAIL

Mike McKillip, Project Analyst  
Healthcare Planning and Certificate of Need Section  
Division of Health Service Regulation  
NC Department of Health and Human Services  
2704 Mail Service Center  
Raleigh, North Carolina 27699-2704  
mike.mckillip@dhhs.nc.gov

Re: UNC Hospitals Notice of Exemption for Replacement Equipment / Orange County

Dear Mr. McKillip,

UNC Hospitals (UNCH) provides this notice regarding a replacement heart and lung bypass machine and requests confirmation that the acquisition of such replacement equipment is exempt from certificate of need ("CON") review pursuant to NCGS § 131E-184 (a)(7) and the regulations set out in 10A NCAC 14C.0303. The existing heart and lung bypass machine is currently in use, and will be replaced with the new heart and lung bypass machine which is comparable medical equipment, as those terms are described in 10A NCAC 14C.0303.

### **Exemption from Review**

Pursuant to NCGS § 131E-184(a)(7): "The department shall exempt from certificate of need review a new institutional health service if it received prior written notice from the entity proposing the new institutional health service, when notice includes an explanation of why the new institutional health service is required for any of the following: ... To provide replacement equipment." (emphasis added) The acquisition of a new heart-lung bypass machine is a new institutional health service pursuant to NCGS § 131E-176(16)(f1).(5), but the acquisition of a heart-lung bypass machine that is replacement equipment is exempt from review as described herein.

"Replacement equipment" is defined by NCGS § 131E-176(22a) as equipment that costs less than \$2,000,000 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.

According to 10A NCAC 14C.0303, replacement equipment is "not comparable" if:

1. the replacement equipment to be acquired is capable of providing a health service that the equipment to be replaced cannot provide;
2. the equipment to be replaced was acquired less than 12 months prior to the date the written notice... is submitted to the CON Section and it was refurbished or reconditioned when it was acquired by the person requesting the exemption.

The proposed acquisition of the replacement heart- lung bypass machine does not meet either of these criteria, and thus it is comparable medical equipment to the existing heart and lung bypass machine.

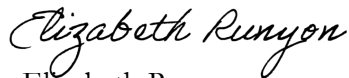
## Compliance

The acquisition of the replacement heart and lung bypass machine by UNCH is exempt from CON review because:

- The estimated project costs for the replacement heart and lung bypass machine are less than \$2,000,000. The vendor quote for the heart and lung bypass machine shows equipment costs of approximately \$286,910.00 (see Exhibit A) and with no other anticipated associated costs.
- The replacement equipment will be purchased for the sole purpose of replacing comparable medical equipment currently in use, which will be traded in for disposal and removal from North Carolina. A comparison of the existing and replacement equipment is provided in Exhibit B.
- The replacement equipment is functionally similar to the existing equipment and will be used for providing the same health service as the equipment currently in use.

UNC requests that the Agency confirm in writing that its acquisition of the replacement heart and lung bypass machine, as described herein, does not constitute a new institutional health service and is exempt from certificate of need review. Please don't hesitate to contact me at [elizabeth.runyon@unchealth.unc.edu](mailto:elizabeth.runyon@unchealth.unc.edu) if you require further information or have any questions regarding this correspondence.

Sincerely,



Elizabeth Runyon

System Director of Regulatory Affairs and Special Counsel  
UNC Health

## Quotation Prepared

UNC Hospital  
 Accounts Payable  
 4400 Emperor Blvd  
 Durham, NC 27703  
 Attn: Greg Griffin  
 Tel.: 984-974-4600, Mobile: 919-812-0739

## Quote Number: BCQ00637

Quotation Date: 23-Nov-2020  
 Quotation Expiration Date: 21-Feb-2021

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			
CHELTENHAM	Cheltenham Frame and Power Pack	1	49,750.00	49,750.00
	Quantum Modules			
51-000001-00	QWS 15"	1	42,000.00	42,000.00
51-000003-00	Quantum Console Module (5 Rotary Knobs)	1	6,525.00	6,525.00
51-000082-00	Quantum Ventilation G2-DISS	1	53,916.00	53,916.00
51-000011-00	Quantum Roller Pump - 4"	2	15,000.00	30,000.00
51-000013-00	Quantum Roller Pump - 6"	3	15,000.00	45,000.00
51-000008-00	Quantum Roller Pump - 8"	1	16,500.00	16,500.00
43-000954-00	4" Hand Crank Assembly	1	0.00	
43-000955-00	6" Hand Crank Assembly	1	0.00	
43-000956-00	8" Hand Crank Assembly	1	0.00	
51-000022-00	Quantum Smart Occluder - LH	1	19,035.00	19,035.00
MCAB-USA	Power cable and PSU (USA) non HLM	1	0.00	
	Quantum Mounting Systems			
52-000023-00	Mounting Arm Assy - LONG (Double)	1	2,878.00	2,878.00
43-000653-02	1.25 Vert. Tube Clamp - Single	3	1,200.00	3,600.00
43-000654-01	1.25 Vert. Tube Clamp - Double	3	2,150.00	6,450.00
52-000024-00	Horizontal Pole Mounting Arm - Hook Plate	1	1,200.00	1,200.00
	Quantum Accessories			
52-000013-00	Drip Stand Assy	2	1,300.00	2,600.00
52-000004-00	Tray Assy - 300x200x15mm Vienna	1	1,850.00	1,850.00
52-000017-00	Ball & T-Bar Hex Driver Kit	1	0.00	
	Sensor Kits			
43-000889-00	Level Sensor Assy	1	1,950.00	1,950.00
51-000135-00	QFS 9/16 x 1.2m (ID 3/8" x Wall 3/32")	1	3,656.00	3,656.00
				<b>Total</b>
Quantum Perfusion Technologies				286,910.00



**Spectrum Medical Inc**  
 481 Munn Road, Suite 180  
 Fort Mill SC  
 29715  
 United States  
 Tel: (800)265 2331  
 VAT Number: 20-8208460  
 www.spectrummedical.com  
 Quotation No: BCQ00637

Product Name	Service Level	Total Value	Service Cost
Quantum Perfusion Technologies - Product Support	Sentinel	286,910.00	28,691.00

Currency	Curr
All Prices Quoted are in	USD

**Payment Terms & Conditions - Perfusion 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.

**Sentinel Total Care**

**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.

**Annual Servicing**

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

**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.

**Accidental Damage**

Accidental damage on your Quantum Perfusion System including accessories (sensors, cables assemblies etc.). Quantum products beyond economic repair will be replaced with latest new build technologies.

**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.

**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.

**Emergency Loan Equipment**

For all products that cannot be repaired within 24 hours of being returned to Spectrum Medical Service Center.

**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.

**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.

**Quantum Workstation & Quantum Elite Specification**

<b>Hardware</b>	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 ISO 62304 and 60601.
<b>Software</b>	
OS	Windows 10 IoT Enterprise 2019 LTSC (Anti-Virus to be managed by Customer)
Application Code	Spectrum Medical proprietary Quantum application code.
<b>Electronics</b>	
Main Processor	Intel Atom E3845 Quad-Core 1.91 GHz
Memory	4GB DDR3, 64GB Solid State Drive, 2GB (or greater) SD Card
Battery	2 x 14.4V 6600 mAh Li-ion, Run-time: > 90 minutes
<b>Communications</b>	
Serial /USB	2 – USB /Serial



**Spectrum Medical Inc**  
481 Munn Road, Suite 180  
Fort Mill SC  
29715  
United States  
Tel: (800)265 2331  
VAT Number: 20-8208460  
[www.spectrummedical.com](http://www.spectrummedical.com)  
Quotation No: **BCQ00637**

Wired LAN	1 – 10/100Mbps
User Serial	4 – (RS232/RS485 up to 115200 bps)

\*\* With the purchase of the first Quantum Heart Lung Machine ("HLM") in FY2021, UNC Health will receive a rebate on their current Dx Module valued at \$45,750. That rebate has been applied to this quotation. Subsequent Quantum HLM purchases executed in a subsequent fiscal year will include a rebate calculated by assessing a 20% reduction each fiscal year from the original rebate amount of \$45,750. [For example, the rebate for FY2022 shall be \$36,600 (\$45,750 - (\$45,750 x 20%)) for each HLM purchased. The rebate for FY2023 shall be \$27,450 (\$45,750 - (\$45,750 x 40%)), etc.] The total rebate received by UNC Health shall not exceed the Dx Modules full replacement amount of \$183,000 (the purchase price of the four Dx Modules at UNC). UNC Health shall return a Dx Module to Spectrum Medical, Inc. at the time they receive a HLM. \*\*

**UNC Hospitals Heart-Lung Bypass Machine  
EQUIPMENT COMPARISON**

	<b>EXISTING EQUIPMENT</b>	<b>REPLACEMENT EQUIPMENT</b>
Type (e.g., Cardiac Catheterization, Gamma Knife®, Heart-lung bypass machine, Linear Accelerator, Lithotripter, MRI, PET, Simulator, CT Scanner, Other Major Medical Equipment)	<b>Heart-lung bypass machine</b>	<b>Heart-lung bypass machine</b>
Manufacturer	<b>LivaNova</b>	<b>Spectrum Medical</b>
Model number	<b>S5</b>	<b>Quantum</b>
Other method of identifying the equipment (e.g., Room #, Serial Number, VIN #)	<b>48E00622</b>	
Is the equipment mobile or fixed?	<b>Mobile</b>	<b>Mobile</b>
Date of acquisition	<b>12/2007</b>	<b>Pending</b>
Was the existing equipment new or used when acquired? / Is the replacement equipment new or used?	<b>New</b>	<b>New</b>
Total projected capital cost of the project <Attach a signed Projected Capital Cost form>		<b>\$286,910</b>
Total cost of medical equipment	<b>\$148,231</b>	<b>\$286,910</b>
Location of the equipment <Attach a separate sheet for mobile equipment if necessary>	<b>UNC Medical Ctr Operating Room</b>	<b>UNC Medical Ctr Operating Room</b>
Document that the existing equipment is currently in use	<b>n/a</b>	
Will the replacement equipment result in any increase in the <b>average charge per procedure</b> ?		<b>No</b>
If so, provide the increase as a percent of the current average charge per procedure	<b>n/a</b>	<b>n/a</b>
Will the replacement equipment result in any increase in the <b>average operating expense per procedure</b> ?		<b>No</b>
If so, provide the increase as a percent of the current average operating expense per procedure		
Type of procedures performed on the existing equipment <Attach a separate sheet if necessary>	<b>CPB procedures</b>	
Type of procedures the replacement equipment will perform <Attach a separate sheet if necessary>		<b>CPB procedures</b>

**From:** [Mckillip, Mike](#)  
**To:** [Waller, Martha K](#)  
**Subject:** FW: [External] UNC Hospitals Exemption Request  
**Date:** Wednesday, March 31, 2021 1:00:22 PM  
**Attachments:** [HL Bypass Machine Exemption Request 3.31.21.pdf](#)  
[Exhibit A - Spectrum Medical Heart & Lung Bypass Machine Quote.pdf](#)  
[Exhibit B - Equipment Comparison Form.pdf](#)

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For you.

**Michael McKillip**

Project Analyst

Division of Health Service Regulation, Healthcare Planning and Certificate of Need

[NC Department of Health and Human Services](#)

Office: 919-855-3877

[mike.mckillip@dhhs.nc.gov](mailto:mike.mckillip@dhhs.nc.gov)

809 Ruggles Drive, Edgerton

2704 Mail Service Center

Raleigh, NC 27699

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**From:** Delong, Natasha <Natasha.Delong@unchealth.unc.edu>

**Sent:** Wednesday, March 31, 2021 12:23 PM

**To:** Mckillip, Mike <mike.mckillip@dhhs.nc.gov>

**Cc:** Runyon, Elizabeth <Elizabeth.Runyon@unchealth.unc.edu>

**Subject:** [External] UNC Hospitals Exemption Request

**CAUTION:** External email. Do not click links or open attachments unless you verify. Send all suspicious email as an attachment to [Report Spam](#).

Mike,

I hope to find you well.

Please see the attached heart and lung bypass machine Exemption Request for UNC Hospitals.

Let us know if you have any questions.



Sincerely,

**Natasha Bonett DeLong** | Strategy Analyst  
Strategic Planning  
UNC Health  
211 Friday Center Drive, Chapel Hill, NC 27517  
p (984) 974-1205 | m (919) 961-1706  
[natasha.delong@unchealth.unc.edu](mailto:natasha.delong@unchealth.unc.edu)

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