



NC DEPARTMENT OF  
**HEALTH AND  
HUMAN SERVICES**

ROY COOPER • Governor

KODY H. KINSLEY • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

April 22, 2024

Lisa Griffin  
Llgriffin@novanthealth.org

**Exempt from Review – Replacement Equipment**

**Record #:** 4425  
**Date of Request:** April 12, 2024  
**Facility Name:** Novant Health Presbyterian Medical Center  
**FID #:** 943501  
**Business Name:** Novant Health, Inc.  
**Business #:** 1341  
**Project Description:** Replace electrophysiology lab #2  
**County:** Mecklenburg

Dear Ms. Griffin:

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 Philips Azurion 7 C12 electrophysiology lab to replace the GE INNOVA 2100-IQ, serial #5756149BU2, electrophysiology lab. 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,

*Gloria C. Hale*

Team Leader

*Micheala Mitchell*

Micheala Mitchell  
Chief

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

April 12, 2024



**Via Email**

Gloria Hale, Team Leader, Certificate of Need  
N.C. Department of Health Service Regulation  
809 Ruggles Drive  
Raleigh, North Carolina 27603

2085 Frontis Plaza Boulevard  
Winston-Salem, NC 27103

Re: Novant Health Presbyterian Medical Center  
Replacement of Existing Electrophysiology Lab #2 Equipment  
Charlotte, NC (FID: 943501; Mecklenburg County)

Dear Ms. Hale:

Pursuant to N.C. Gen. Stat. § 131E-184(f), this letter serves as prior written notice that Novant Health Presbyterian Medical Center (“NHPMC”) intends to replace an existing Electrophysiology (“EP”) Lab currently located in the Noninvasive Cardiology of NHPMC. NHPMC’s project meets the requirements set forth in N.C. Gen. Stat. 131E-184(f) for “replacement equipment” that exceeds two million (\$2,971,200) threshold in the following ways:

**Main Campus**

NHPMC is located at 200 Hawthorne Lane, Charlotte, North Carolina. COH is located at 1901 Randolph Road, Charlotte, North Carolina. The current location of the existing EP Lab and the location once replaced will be in the Noninvasive Cardiology Department located with the hospital.

**Previous Certificate of Need**

The existing EP Lab #2 equipment is a replacement of a unit that dates back to 2009; however, we are unable to find the documentation regarding its original certificate of need. NHPMC’s Annual License Renewal Application (“LRA”) indicated 3 EP Labs and this letter regards the replacement of Lab #2. The most recent LRA is included as support that this EP Lab has been in use and is still in use. **See Attachment A** for an excerpt of NHPMC’s 2024 LRA.

**Replacement Equipment**

The proposed project meets the definition of “replacement equipment” found in N.C.G.S. 131E-176(22a) and 10A N.C.A.C 14C.0303 for the reasons found on the following page:

- (1) NHPMC will replace the existing equipment with the proposed equipment that is functionally similar and will be used for the same diagnostic purposes, although it possesses expanded capabilities due to technological improvements.
- (2) The proposed equipment will not be used to provide a new health service.
- (3) The acquisition of the proposed equipment will not result in more than a 10% increase in patient charges or per procedure operating expenses within the first twelve months after the replacement equipment is acquired.
- (4) The existing equipment was not purchased second-hand nor was the existing equipment leased.
- (5) The existing equipment will be removed from North Carolina.

Ms. Gloria Hale  
April 12, 2024  
Page 2

The replacement involves the existing EP Lab equipment which was acquired in 2009 and is in need of an upgrade and would improve capacity in noninvasive cardiology services at NHPMC. **Attachment B** contains the Equipment Comparison Form.

See **Attachment C** for the Equipment Quote for the new EP Lab Equipment. The total capital cost for the proposed replacement equipment project is estimated to be \$3,027,375. See **Attachment D** – Project Capital Cost Form.

In support of our request, please find attached:

**Attachment A** – NHPMC 2024 LRA Excerpt  
**Attachment B** – Equipment Comparison Form  
**Attachment C** – Equipment Quote  
**Attachment D** – Projected Capital Costs Form

NHPMC's acquisition of the replacement EP Lab equipment does not require a certificate of need because none of the definitions of "new institutional health services" set forth in N.C.G.S. Section 131E-176(16) apply to the proposed project. As outlined above, the total cost for the project is \$3,027,375. The proposed capital cost includes equipment, as well as studies, surveys, designs, plans, working drawings, specifications, construction installation and other activities essential to making the equipment operational.

Based on the information provided, please confirm that NHPMC's replacement equipment request does not constitute a new institutional health service and is exempt from certificate of need review as indicated above.

If you need additional information, please do not hesitate to contact me.

Sincerely,

*Lisa Griffin*

Lisa Griffin  
Manager, Strategic Planning

Enclosures

# ATTACHMENT A

# Novant Health Presbyterian - 2024 LRA

1. Does this facility provide cardiac catheterization on fixed units or electrophysiology services? Yes

\* Cardiac Catheterization procedures (as defined in G.S. § 131E-176 (2g))

Number of units of fixed cardiac catheterization equipment with a CON: 2

\* CON Project IDs for fixed equipment:

F-3472-98 and F-5975-99

\* Number of units of legacy fixed cardiac catheterization equipment (i.e., equipment obtained before a CON was required): 0

	Diagnostic Cardiac Catheterization**	Interventional Cardiac Catheterization***
Number of Procedures* Performed in Fixed Units on Patients Age 14 and younger:	0	0
Number of procedures* performed in fixed units on patients age 15 and older:	1119	971

- Electrophysiology procedures on dedicated electrophysiology equipment

\* Number of units of fixed dedicated electrophysiology equipment: 3

\* Number of procedures\* performed on dedicated electrophysiology equipment: 1245

2. Does this facility provide cardiac catheterization on mobile equipment? No

\* A procedure is defined as one visit or trip by a patient to a catheterization laboratory for a single or multiple catheterizations. If the visit includes both diagnostic and interventional procedures, count the interventional procedures only. For example, if a patient has both a diagnostic and an interventional procedure in one visit, Count all EP procedures separately.

\*\*\*a cardiac catheterization procedure performed for the purpose of detecting and identifying defects or diseases in the coronary arteries or veins of the heart, or abnormalities in the heart structure, but not the pulmonary artery."  
10A NCAC 14C .1601(9)

\*\*\*\*a cardiac catheterization procedure performed for the purpose of treating or resolving anatomical or physiological conditions which have been determined to exist in the heart or coronary arteries or veins of the heart, but not the pulmonary artery."  
10A NCAC 14C .1601(16)

Number of fixed or mobile units of legacy cardiac catheterization equipment owned by hospital (i.e., equipment obtained before a CON was required): 0

CON Project ID numbers for all non-legacy fixed or mobile units of cardiac catheterization equipment owned by hospital:

N/A

Name of Mobile Vendor, if not owned by hospital: N/A

# **ATTACHMENT B**

## EQUIPMENT COMPARISON

<i>NH Presbyterian Medical Center EP Lab 2</i>	<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)	Electrophysiology (EP) Equipment	Electrophysiology (EP) Equipment
Manufacturer	GE	Philips
Model number	INNOVA 2100-IQ	Azurion 7 C12
Other method of identifying the equipment (e.g., Room #, Serial Number, VIN #)	SN# 5756149BU2	TBD
Is the equipment mobile or fixed?	Fixed	Fixed
Date of acquisition	5/11/2009	
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>	NA	\$
Total cost of the equipment	NA	\$1,008,575
Location of the equipment <Attach a separate sheet for mobile equipment if necessary>	EP LAB 2	EP LAB 2
Document that the existing equipment is currently in use	See LRA Excerpt	NA
Will the replacement equipment result in any increase in the <b>average charge per procedure</b> ?	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 <b>average operating expense per procedure</b> ?	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 <Attach a separate sheet if necessary>	Electrophysiology	NA
Type of procedures the replacement equipment will perform <Attach a separate sheet if necessary>	NA	Electrophysiology

Date of last revision: 5/17/19

# **ATTACHMENT C**





**Sold to:**

Novant Health Presbyterian Medical Center  
200 Hawthorne Ln  
Charlotte, NC 28204-2515

**Presented By**

Hunter Pfister  
Philips Healthcare a division of Philips North  
America LLC  
414 Union Street  
Nashville, Tennessee 37219  
**Email:** hunter.pfister@philips.com

**Ship to:**

Novant Health Presbyterian Medical Center  
200 Hawthorne Ln  
Charlotte, NC 28204-2515

**Quote #:** Q-00274532

**Customer #:** 94024761

**Quote Date:**

**Valid Until:** 05/17/24

## Azurion 7 C12 - EP2 Lab Replacement

Dear Valued Customer,

I am pleased to submit the attached proposal for your consideration. Philips Healthcare is transitioning to a new quoting system and you will notice that this quote looks different than the ones you are used to receiving from us.

I would like to point out a specific area of change to you. Promotions are applied to the line item price of individual items, instead of to the total net price as you are used to. As a result the line item prices appear lower than you might expect based on previous quotations. Please note that the list price of the system has not changed and promotion values are subject to availability.

I trust this meets your expectation, however should you have any queries or require further information or clarification, please do not hesitate to contact me using the details shown at the bottom of this letter.

Please note that all necessary initial applications training is included in the offer price. Further application training can be purchased separately by contacting our Customer Care Center.

Orders relating to this proposal should be sent to the address or fax number at the top of this document.

Thank you,

Hunter Pfister

This quotation contains confidential and proprietary information of Philips Healthcare, a division of Philips North America LLC ("Philips") and is intended for use only by the customer whose name appears on this quotation. Except as otherwise required by state or federal law after strict compliance with any applicable notification and procedural requirements therein, it may not be disclosed to third parties without the prior written consent of Philips.

**IMPORTANT NOTICE:** Health care providers are reminded that if the transactions herein include or involve a loan or discount (including a rebate or other price reduction), they must fully and accurately report such loan or discount on cost reports or other applicable reports or claims for payment submitted under any federal or state health care program, including but not limited to Medicare and Medicaid, such as may be required by state or federal law, including but not limited to 42 CFR 1001.952(h).

Philips Healthcare a division of Philips North America LLC  
414 Union Street  
Nashville, Tennessee 37219



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## 1. Financial Overview

Line	Article No.	Description	Qty	List Price	Net Price
1	722223	Azurion 7 M12	1	\$ 2,294,070.00	\$ 1,284,679.20
2	100133	CV Third Party Products	1	\$ 22,570.00	\$ 12,639.20
3	SP008	MAVIG offer no.: 762716	1	\$ 10,357.50	\$ 10,357.50
4	722135	Field Extensions Azurion 3	1	\$ 114,026.06	\$ 70,696.16

**Total Net Price**

**Total Price**  
**\$ 1,378,372.06**

DRAFT

## 2. Quote Summary

Line	Article No.	Description	Qty	Unit List Price	Net Price
<b>1</b>	<b>722223</b>	<b>Azurion 7 M12</b>			
1.1	NNAT206	Azurion 7 C12	1	\$ 1,500,020.00	\$ 840,011.20
1.2	989801229902	Low Load Fluoro (LLF) UPS - 5	1	\$ 89,150.00	\$ 49,924.00
1.3	NNAE675	Azurion Clinical Education Pkg	1	\$ 0.00	\$ 0.00
1.4	NCVD067	ClarityIQ	1	\$ 197,800.00	\$ 110,768.00
1.5	NCVD031	FlexVision XL + 2 LCD's	1	\$ 232,140.00	\$ 129,998.40
1.6	FCV0834	coupling to video switching	1	\$ 15,610.00	\$ 8,741.60
1.7	NCVD063	Switchable Monitors	1	\$ 74,230.00	\$ 41,568.80
1.8	NCVD064	extension to FlexVision Pro	1	\$ 83,510.00	\$ 46,765.60
1.9	FCV0588	Isolated Wall Connection Box	9	\$ 3,290.00	\$ 16,581.60
1.10	FCV0824	video WCB on rear side 1st MCS	2	\$ 12,680.00	\$ 14,201.60
1.11	NCVD097	DVD writer	1	\$ 640.00	\$ 358.40
1.12	NCVA082	Intercom	1	\$ 4,420.00	\$ 2,475.20
1.13	NCVA783	Pivot for table base.	1	\$ 10,300.00	\$ 5,768.00
1.14	FCV0510	Long mattress cardio	1	\$ 1,240.00	\$ 694.40
1.15	459801079651	Cabinet Rear Cover	4	\$ 1,050.00	\$ 2,352.00
1.16	989600213943	Patient table adaptation plate	1	\$ 7,870.00	\$ 4,407.20
1.17	459800938361	Clip rails for Monitor Ceiling Carriage (390cm, 153.5")	1	\$ 2,890.00	\$ 1,618.40
1.18	459800706722	MONITOR CEILING CARRIAGE	1	\$ 15,080.00	\$ 8,444.80
					\$ 1,284,679.20
<b>2</b>	<b>100133</b>	<b>CV Third Party Products</b>			
2.1	989801220012	Cable Spooler	1	\$ 810.00	\$ 453.60
2.2	989801229910	RAD SHIELD W/ARM (CONTOURED) 61X76	1	\$ 5,880.00	\$ 3,292.80
2.3	989801220388	Lower Body Protection	1	\$ 3,460.00	\$ 1,937.60
2.4	989801220420	Mavig 4 Meter Ceiling Track-FlexArm 80cm	1	\$ 12,020.00	\$ 6,731.20
2.5	989801220375	Black Anti-fatigue Floor Mat w/logo.	1	\$ 400.00	\$ 224.00
					\$ 12,639.20
<b>3</b>	<b>SP008</b>	<b>MAVIG offer no.: 762716</b>	1	\$ 10,357.50	\$ 10,357.50
<b>4</b>	<b>722135</b>	<b>Field Extensions Azurion 3</b>			
4.1	NNAE596	IXR StentBoost Imaging Systems OnSite Education	1	\$ 0.00	\$ 0.00



4.2	NNAE597	IXR Dynamic Coronary Roadmap OnSite Education	1	\$ 0.00	\$ 0.00
4.3	NCVC542	Dynamic Coronary Roadmap	1	\$ 61,836.06	\$ 38,338.36
4.4	NCVC544	StentBoost Live	1	\$ 52,190.00	\$ 32,357.80
					<hr/>
					\$ 70,696.16
					<b>Total Price</b>
<b>Total Net Price</b>					<b>\$ 1,378,372.06</b>

DRAFT

## 3. Local Sales Terms and Conditions

Line	Product Code	Contract Name	Contract No.	Billing Plan
1	722223 Azurion 7 M12	Vizient Supply LLC XR0703	XR0703	0/80/20
2	100133 CV Third Party Products	Vizient Supply LLC XR0703	XR0703	0/80/20
3	SP008 MAVIG offer no.: 762716	NONE	NONE	0/80/20
4	722135 Field Extensions Azurion 3	Vizient Supply LLC XR0703	XR0703	0/80/20

Payment Terms US: Net 30 Days

INCO Terms: Carriage and Insurance Paid To Destination

This is a cash price quote, which includes ACH, check, and wire transfer. Any other form of payment will result in different price, which may be higher.

Billing Terms: Are as displayed under the Billing Plan table above. For each item, X/Y/Z milestones are defined as follows (unless an Agreement specifying alternative payment terms has been negotiated between the parties):

X is the percentage invoiced upon signed acceptance of quotation or upon receipt of Customer Purchase Order  
 Y is the percentage invoiced upon delivery of major components to Customer designated location or Philips warehouse.  
 Z is the percentage invoiced upon completion of installation or product available for first patient use, whichever occurs first.

If DEMO Equipment is included in this quotation it is sold under the Contact No. Contract Name/Contract Number ("Contract") of the products/solution included in this quotation.

All amounts in this quote are in USD

Additional Terms US:

This purchase is governed by the terms and conditions applicable to Customer Member of the specific Vizient Contract number identified above, as well as any Philips Standard Terms and Conditions of Sale and Software License, set forth below, to the extent not in conflict with the applicable Vizient Contract terms.



## 4. Signature Page

**Invoice to:**

Novant Health Presbyterian Medical Center  
200 Hawthorne Ln  
Charlotte, NC 28204-2515

**Ship to:**

Novant Health Presbyterian Medical Center  
200 Hawthorne Ln  
Charlotte, NC 28204-2515

Total Net Price

Total Price  
\$ 1,378,372.06

### Acceptance by Parties

Each Quotation solution is issued pursuant to and will reference a specific Contract Name/Contract Number ("Contract") representing an agreement containing discounts, fees and any specific terms and conditions which will apply to that single quoted solution. Any PO for the items herein will be accepted subject to the terms of that Contract. If no Contract is shown, Philips Terms and Conditions of Sale including applicable product warranty or Philips Terms of Service ("Philips Terms") located in the Philips Standard Terms and Conditions of the quotation shall solely apply to the quoted solution.

Each equipment system and/or service listed on purchase order/orders represents a separate and distinct financial transaction. We understand and agree that each transaction is to be individually billed and paid. This quotation contains confidential and proprietary information of Philips Healthcare, a division of Philips North America LLC ("Philips") and is intended for use only by the customer whose name appears on this quotation. Except as otherwise required by state or federal law after strict compliance with any applicable notification and procedural requirements therein, it may not be disclosed to third parties without the prior written consent of Philips.

This quotation provides contract agreement discounts and does not reflect rebates that may be earned by Customer, under separate written rebate agreements, from cumulative volume purchases beyond the individual quantity being ordered under this quote. Customer is reminded that rebates constitute discounts under government laws which are reportable by Customers.

The price above does not include sales tax.

Please fill in the below if applicable:

1. Tax Status: Taxable \_\_\_\_\_ Tax Exempt \_\_\_\_\_  
If Exempt, please indicate the Exemption Certification Number: \_\_\_\_\_, and attach a copy of the certificate.
2. Requested equipment delivery date \_\_\_\_\_
3. If you do not issue formal purchase orders indicate by initialing here: \_\_\_\_\_
4. Our facility does issue formal purchase orders; however, due to our business/system limitation, we cannot issue a formal purchase order until 90 days prior to standard warranty expiration. Initialed: \_\_\_\_\_

**CUSTOMER SIGNATURE**

by its authorized representative

Signature: \_\_\_\_\_

Print Name: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

**PHILIPS SIGNATURE**

by its authorized representative

Signature: \_\_\_\_\_

Print Name: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_



# **ATTACHMENT D**



**Projected Capital Cost Form**  
***PMC EP Lab 2 Replacement***

Building Purchase Price	NA
Purchase Price of Land	NA
Closing Costs	NA
Site Preparation	NA
Landscaping	NA
Construction/Renovation	\$ 934,318
Architect / Engineering / DHSR	\$ 87,543
Medical Equipment (EP Lab)	\$ 1,378,372
Medical Equipment	\$ 612,591
Non-Medical Equipment	\$ -
Furniture	\$ 6,300
DPS/IT Systems	\$ 8,250
Financing Costs	\$ -
Other: (Capitalized Labor)	\$ -
Other: Contingency	\$ -
<b>Total Capital Cost</b>	<b>\$ 3,027,375</b>

**CERTIFICATION BY A LICENSED ARCHITECT OR ENGINEER**

I certify that, to the best of my knowledge, the projected construction costs for the proposed project are complete and correct.

DocuSigned by:  
*Daniel Kinken*  
B7BA40864EE04D6

Date Signed: 04/08/2024 | 8:29:30 PDT

Signature of Licensed Architect or Engineer  
Daniel Kinken, McCulloch England

**CERTIFICATION BY AN OFFICER OR AGENT FOR THE PROPONENT**

I certify that, to the best of my knowledge, the projected total capital cost for the proposed project is complete and correct and that is our intent to carry out the proposed project as described.

DocuSigned by:  
*Matthew Stiene*  
9BCFAC883516459...

Date Signed: 04/08/2024 | 11:29:23 EDT

Signature of Officer/Agent

Senior Vice President, Construction & Facilities Svcs, Novant Health  
Title of Officer/Agent

**From:** [Griffin, Lisa L](#)  
**To:** [Hale, Gloria](#)  
**Cc:** [Cremeens, Cameron L](#); [Stancil, Tiffany C](#)  
**Subject:** [External] Replacement Equipment Exemption Notice - NH Presbyterian EP Lab  
**Date:** Friday, April 12, 2024 2:40:48 PM  
**Attachments:** [PMC EP Lab 2 REER to Agency 4.12.24.pdf](#)

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**CAUTION:** External email. Do not click links or open attachments unless verified. Report suspicious emails with the Report Message button located on your Outlook menu bar on the Home tab.

Hi Gloria,

Attached is a replacement equipment exemption notice regarding the replacement of an existing EP Lab located at Novant Health Presbyterian Hospital in Charlotte, NC. Please let me know if you have any questions or need additional information.

Have a wonderful weekend!

***Lisa Griffin***

Manager, Strategic Planning  
Novant Health | Internal Consulting Group  
(704) 351 – 1132

We are here to help you get the care you need. Visit [Novant Health](#) for up-to-date information.

Estamos aquí para ayudarle con el cuidado que usted necesita. Visite [Novant Health](#) para información actualizada.

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