

North Carolina Department of Health and Human Services Division of Health Service Regulation

Roy Cooper Governor

Dempsey E. Benton Interim Secretary DHHS

Mark Payne, Director Health Service Regulation

CORRECTED

January 18, 2017

Dee Jay Zerman, Director of Regulatory Planning UNC Health Care System James T. Hedrick Building 211 Friday Center Drive, Suite G015 Chapel Hill NC 27517

Exempt from Review - Replacement Equipment

Record #:

2116

Facility Name:

Rex Hospital

FID #:

953429

Business Name:

Rex Hospital, Inc.

Business #:

1554

Project Description:

Replace cardiac catheterization equipment in Room 3

County:

Wake

Dear Ms. Zerman:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of December 9, 2016, the above referenced proposal 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 Philips FD20 Flexmove cardiac catheterization equipment to replace the Siemens Zee Ceiling cardiac catheterization equipment. This determination is based on your representations that the existing unit will be retained for use as a vascular lab and no longer used as cardiac catheterization equipment.

Moreover, you need to contact the Agency's Construction and Acute and Home Care Licensure and Certification Sections to determine if they have any requirements for development of the proposed project.

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.

Sincerel

Michael J. McKillip

Project Analyst

Martha J. Frisone

Assistant Chief, Certificate of Need

cc:

Construction Section, DHSR

Paige Bennett, Assistant Chief, Healthcare Planning, DHSR Acute and Home Care Licensure and Certification Section, DHSR

Healthcare Planning and Certificate of Need Section

www.ncdhhs.gov
Telephone: 919-855-3873 • Fax: 919-715-4413
Location: Edgerton Building • 809 Ruggles Drive • Raleigh, NC 27603
Mailing Address: 2704 Mail Service Center •Raleigh, NC 27699-2704
An Equal Opportunity/ Affirmative Action Employer



North Carolina Department of Health and Human Services Division of Health Service Regulation

Pat McCrory Governor

Richard O. Brajer Secretary DHHS

Mark Payne, Director Health Service Regulation

December 20, 2016

Dee Jay Zerman, Director of Regulatory Planning UNC Health Care System James T. Hedrick Building 211 Friday Center Drive, Suite G015 Chapel Hill NC 27517

Exempt from Review - Replacement Equipment

Record #:

2116

Facility Name:

Rex Hospital

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953429

Business Name:

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Moreover, you need to contact the Agency's Construction and Acute and Home Care Licensure and Certification Sections to determine if they have any requirements for development of the proposed project.

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.

Martha J. Frisone

Assistant Chief, Certificate of Need

Sincerely.

Minginga

cc:

Michael J. McKillip Project Analyst

Construction Section, DHSR

Paige Bennett, Assistant Chief, Healthcare Planning, DHSR

Acute and Home Care Licensure and Certification Section, DHSR

Healthcare Planning and Certificate of Need Section

www.ncdhhs.gov Telephone: 919-855-3873 • Fax: 919-715-4413 Location: Edgerton Building • 809 Ruggles Drive • Raleigh, NC 27603 Mailing Address: 2704 Mail Service Center • Raleigh, NC 27699-2704 An Equal Opportunity/ Affirmative Action Employer



James T. Hedrick Building 211 Friday Center Drive, Suite G015 Chapel Hill, NC 27517

December 9, 2016

Ms. Martha Frisone, Assistant Chief Healthcare Planning and Certificate of Need Section Division of Health Service Regulation 809 Ruggles Drive Raleigh, NC 27603



RE: Request for Exemption from Review to Replace Cath Lab at UNC REX Hospital

Dear Ms. Frisone:

Pursuant to N.C.G.S. 131E-184(a)(7)-Exemptions from Review-of the Certificate of Need Statute, I am writing to inform you of a project at UNC REX Hospital (Rex) to replace an existing unit of cardiac catheterization equipment.

Rex discussed this project with Ms. Martha Frisone and Mr. Mike McKillip in a meeting at the Healthcare Planning and Certificate of Need Section on June 2, 2016. Ms. Frisone and Mr. McKillip advised Rex to submit an exemption request as follows.

Pursuant to Project ID # J-8667-11, Rex is developing a new bed tower and will relocate all of its four existing cardiac catheterization labs. Please see Exhibit 1 for the Certificate of Need for Project ID # J-8667-11 which states "Rex Hospital, Inc. shall construct a new bed tower to replace no more than 115 acute care beds in a change in scope for Project ID # J-8532-10 (heart and vascular renovation and expansion project)/Wake County." Exhibit 1 also includes the Certificate of Need for Project ID # J-8532-10 which states "Rex Hospital, Inc. shall construct an addition to the hospital to expand and consolidate surgical and cardiovascular services and create a new main entrance and public concourse/Wake County."

One of the four cardiac catheterization labs approved to be relocated from the main hospital to the bed tower requires replacement. The equipment to be replaced, a Siemens Zee Ceiling, is located in Room 3 as shown on the line drawings in Exhibit 2. See Exhibit 3 for the vendor quote for the replacement equipment, a Philips FD20 Flexmove. The total costs related to the replacement of the cardiac catheterization lab are \$627,248.50 which includes equipment costs only. The cost for the development of the room that the equipment will be located in is included in the capital cost approved under Project ID # J-8667-11.

The proposed new cardiac catheterization lab is consistent with the replacement equipment definition at N.C.G.S. 131E-176(22a). The total capital cost of the project will be less than \$2,000,000 and the replacement equipment will be purchased for the purpose of replacing comparable medical equipment. "Comparable medical equipment" is defined under 10A NCAC 14C .0303(c) as "equipment which is functionally similar and which is used for the same diagnostic and treatment purposes." Further, replacement equipment is considered comparable to the existing equipment under the following circumstances as outlined under 10A NCAC 14C .0303(d):

- 1. it has the same technology as the equipment currently in use, although it may possess expanded capabilities due to technological improvements; and
- 2. it is functionally similar and is used for the same diagnostic or treatment purposes as the equipment currently in use and is not used to provide a new health service; and
- 3. the acquisition of the equipment does 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.

Rex's proposed new replacement unit is considered comparable pursuant to 10 NCAC 14C .0303 for the following reasons:

- 1. The proposed replacement equipment will be used for the provision of performing cardiac catheterization procedures, as is the existing equipment. The replacement equipment will perform all procedures currently performed on the existing equipment. Although the replacement equipment possesses some expanded capabilities due to technological improvements, the replacement equipment will perform the same general range of services. Essentially, the replacement equipment will have the same functionality as the equipment currently in use.
- 2. The function of, and diagnostic/therapeutic services provided by the replacement equipment will essentially be identical to the existing equipment. Rex intends to use the replacement equipment for the same

- procedures which are currently available on the existing equipment. No new health service will be provided as a result of the replacement.
- 3. The acquisition and operation of the replacement equipment will not result in an increase of more than 10 percent in patient charges or the operational cost per patient of providing the service within the first twelve months after the replacement equipment is acquired.

It is important to note that 10 NCAC 14C .0303 also defines equipment that is "not comparable" under subsection (e). Replacement equipment is not considered comparable if:

- 1. the replacement equipment is new or reconditioned, the existing equipment was purchased second-hand, and the replacement equipment is purchased less than three years after the acquisition of the existing equipment; or
- 2. the replacement equipment is new, the existing equipment was reconditioned when purchased, and the replacement equipment is purchased less than three years after the acquisition of the existing equipment; or
- 3. the replacement equipment is capable of performing procedures that could result in the provision of a new health service or type of procedure that has not been provided with the existing equipment; or
- 4. the replacement equipment is purchased and the existing equipment is leased, unless the lease is a capital lease; or
- 5. the replacement equipment is a dedicated PET scanner and the existing equipment is:
 - A. a gamma camera with coincidence capability; or
 - B. nuclear medicine equipment that was designed, built, or modified to detect only the single photon emitted from nuclear events other than positron annihilation.

Rex owns the existing cardiac catheterization equipment, which was new at the time of acquisition in 2011. The replacement equipment will be acquired more than three years after the installation of the existing unit and will be owned by Rex. As noted above, although the replacement equipment possesses some expanded capabilities due to technological improvements, the replacement equipment will perform the same general range of services as the existing unit. Therefore, the replacement equipment does not meet the definition of "not comparable."

The existing equipment has a fair market value of \$425,000. Rex proposes to retain this equipment for use as a vascular lab and will no longer use it as cardiac catheterization equipment, as defined as defined in N.C. GEN. STAT. § 131E-176(2)(f), As the fair market value of the existing equipment is less than the \$750,000 threshold for major medical equipment at N.C.G.S 131E-176(140), this

equipment is not regulated by the State Medical Facilities Plan or any statute in North Carolina. This interpretation is consistent with the Novant Health Matthews Medical Center Equipment Exemption Request included in Exhibit 4 and with the instructions provided to Rex by Ms. Frisone and Mr. McKillip at the meeting at the Healthcare Planning and Certificate of Need Section on June 2, 2016.

Based on the above facts, the proposed project is exempt from Certificate of Need review. We are requesting confirmation from your office to this fact.

Sincerely,

Dee Jay Zerman

Director of Regulatory Planning

UNC Health Care System

Attachment

Exhibit 1

Department of Health and Human Services
Division of Health Service Regulation

CERTIFICATE OF NEED

for

Project Identification Number # J-8667-11

FID # 953429

ISSUED TO: Rex Hospital, Inc. 4420 Lake Boone Trail Raleigh, NC 27607

Pursuant to N.C. Gen. Stat. § 131E-175, et. seq., the North Carolina Department of Health and Human Services hereby authorizes the person or persons named above (the "certificate holder") to develop the certificate of need project identified above. The certificate holder shall develop the project in a manner consistent with the representations in the project application and with the conditions contained herein and shall make good faith efforts to meet the timetable contained herein. The certificate holder shall not exceed the maximum capital expenditure amount specified herein during the development of this project, except as provided by N.C. Gen. Stat. § 131E-176(16)e. The certificate holder shall not transfer or assign this certificate to any other person except as provided in N.C. Gen. Stat. § 131E-189(c). This certificate is valid only for the scope, physical location, and person(s) described herein. The Department may withdraw this certificate pursuant to N.C. Gen. Stat. § 131E-189 for any of the reasons provided in that law.

SCOPE:

Rex Hospital, Inc. shall construct a new bed tower to replace no more than 115 acute care beds in a change of scope for Project I.D. # J-8532-10 (heart and vascular renovation and expansion project)/ Wake County

CONDITIONS:

See Reverse Side

PHYSICAL LOCATION: Rex Hospital

Rex Hospital 4420 Lake Boone Trail

Raleigh, NC 27607

MAXIMUM CAPITAL EXPENDITURE: \$285,072,367

TIMETABLE:

See Reverse Side

FIRST PROGRESS REPORT DUE:

August 1, 2013

This certificate is effective as of the 19th day of March, 2013

Chief, Certificate of Need Section Division of Health Service Regulation

CONDITIONS:

- 1. Rex Hospital, Inc. shall materially comply with all representations made in Project I.D. #J-8667-11, as amended by the conditions of approval.
- 2. Rex Hospital, Inc. shall not develop any additional acute care beds as part of this project.
- 3. The approved project capital cost for the project shall be \$285,072,367.
- 4. Rex Hospital, Inc. shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application and which would otherwise require a Certificate of Need.
- 5. Rex Hospital, Inc. shall develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant's representations in the written statement as described in paragraph one of Policy GEN-4.

TIMETABLE:

Completion of Preliminary Drawings	July 16, 2013
Completion of Final Drawings and Specifications	February 16, 2014
Approval of Final Drawings and Specifications	
by the Construction Section, DHSR	March 16, 2014
Contract Award	April 16, 2014
25% Completion of Construction	September 16, 2014
50% Completion of Construction	April 16, 2015
75% Completion of Construction	September 16, 2015
Completion of Construction_	April 16, 2016
Licensure of Facility	April 16, 2016
Occupancy/Offering of Services	June 16, 2016

STATE OF NORTH CAROLIA,
Department of Health and Human Services Division of Health Service Regulation

CERTIFICATE OF NEED

Project Identification Number # J-8532-10

FID # 945429

ISSUED TO: Rex Hospital, Inc. 4420 Lake Boone Trail Raleigh, NC 27607

Pursuant to N.C. Gen. Stat. § 131E-175, et. seq., the North Carolina Department of Health and Human Services hereby authorizes the person or persons named above (the "certificate holder") to develop the certificate of need project identified above. The certificate holder shall develop the project in a manner consistent with the representations in the project application and with the conditions contained herein and shall make good faith efforts to meet the timetable contained herein. The certificate holder shall not exceed the maximum capital expenditure amount specified herein during the development of this project, except as provided by N.C. Gen. Stat. § 131E-176(16)e. The certificate holder shall not transfer or assign this certificate to any other person except as provided in N.C. Gen. Stat. § 131E-189(c). This certificate is valid only for the scope, physical location, and person(s) described herein. The Department may withdraw this certificate pursuant to N.C. Gen. Stat. § 131E-189 for any of the reasons provided in that law.

SCOPE:

Rex Hospital Inc. shall construct an addition to the hospital to expand and consolidate surgical and cardiovascular services and create a new main entrance and public concourse/ Wake County

CONDITIONS:

See Reverse Side

PHYSICAL LOCATION: Rex Hospital

4420 Lake Boone Trail Raleigh, NC 27607

MAXIMUM CAPITAL EXPENDITURE: \$146,365,278

TIMETABLE:

See Reverse Side

FIRST PROGRESS REPORT DUE:

August 1, 2013

This certificate is effective as of the 28th day of March, 2013

Chief, Cerdificate of Need Section Division of Health Service Regulation

CONDITIONS:

- 1. Rex Hospital, Inc. d/b/a Rex Healthcare shall materially comply with all representations made in its application.
- 2. Rex Hospital, Inc. d/b/a Rex Healthcare shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application or which would otherwise require a certificate of need.
- 3. Rex Hospital, Inc. d/b/a Rex Healthcare shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to the issuance of the certificate of need.

A letter acknowledging acceptance of and agreeing to comply with all conditions stated in the conditional approval letter was received by the Certificate of Need Section on November 29, 2010.

TIMETABLE:

Completion of Preliminary Drawings	July 16, 2013
Completion of Final Drawings and Specifications	February 16, 2014
Completion of Final Drawings, Specifications and Site	
by Construction Section	March 16, 2014
Contract Award	April 16, 2014
25% Completion of Construction /25% of the Dollar Value of the	
Contract in Place	October 16, 2014
50% Completion of Construction	May 16, 2015
75% Completion of Construction	August 16, 2015
Completion of Construction_	April 16, 2016
Occupancy/Offering Services	June 16, 2016

Exhibit 2

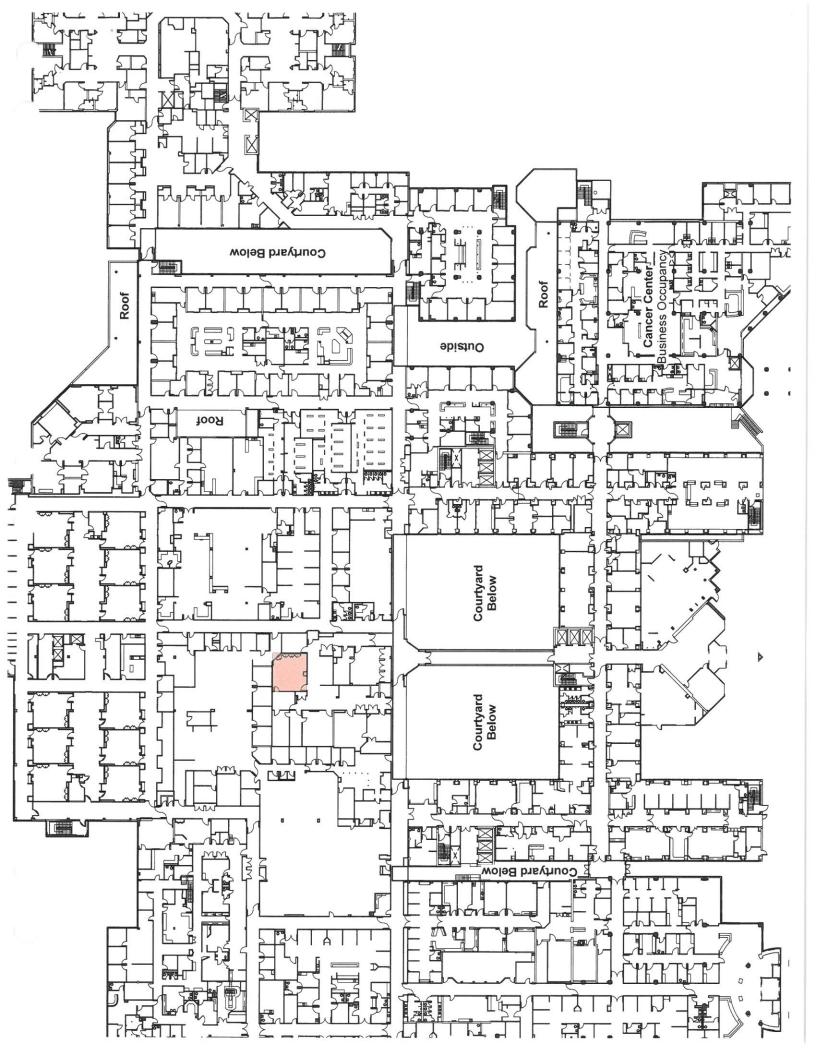


Exhibit 3

PHILIPS HEALTHCARE A division of Philips Electronics North America Corporation 22100 Bothell Everett Highway P.O. Box 3003 Bothell, Washington 98041-3003



Quotation #: 1-1GC4GVA Rev: 3 Effective From: 14-Jul-16 To: 12-Sep-16 Presented To: Presented By: **REX HEALTHCARE Tel:** (919) 677-9046 **Fax:** (919) 677-9047 Bethann Griffith-Subik Account Manager 4420 LAKE BOONE TRL RALEIGH, NC 27607-7505 Amy Morrow Tel: (828) 553-3118 Regional Manager Fax: Tel: Alternate Address: 14-Jul-16 **Date Printed:** Submit Orders To: 22100 BOTHELL EVERETT HWY BOTHELL WA 98021 Tel: (888) 564-8643 Fax: (425) 458-0390

This quotation contains confidential and proprietary information of Philips Healthcare, a division of Philips Electronics North America Corporation ("Philips") and is intended for use only by the customer whose name appears on this quotation. 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).

Quotation #: 1-1GC4GVA

Rev.: 3

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Quote Solution Summary			
Line #	Product	Qty	Price
	101824 FP Xper FD20	1	\$627,248.50
		Equipment Total:	\$627,248,50

Solution Summary Detail				
Product	Qty	Each	Monthly	Price
101824 FP Xper FD20	1	\$627,248.50		\$627,248.50

Buying Group: MEDASSETS SUPPLY CHAIN SYSTEMS INC. Contract #: MS03221

Addt'l Terms: Product Terms and Conditions of Sale (T&C) not printed with this solution. Refer to Contract # noted above for

applicable T&C details. If Service Agreement is quoted its T&C of Sale are printed

Each Quotation solution will reference a specific Buying Group/Contract Number representing an agreement containing discounts, fees and any specific terms and conditions which will apply to that single quoted solution. If no Buying Group/Contract Number is shown, Philips' Terms and Conditions of Sale will apply to the quoted solution.

Each equipment system 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.

Payment Terms: 0% Down, 80% Upon Delivery, 20% Due When the Product is Available for First Patient Use, Net due 30 days from date of invoice

Quote Summary 101824 FP Xper FD20

Qty	Product
1	NNAM076 FlashPoint-FD20 Ceiling
1	NNAJ581 DS FlexVision XL 8 Input Package
1	NNAM092 GSS PDU w/2k UPS
1	NDSA667 Non swivel, mounted IN floor
1	NDSA628 FlexVision XL,XperHD,Snapshot
1	NDSA508 Set of 2 additional 21in. LCDs
1	NDSA509 2ND REF for FlexVision XL
1	NDSA574 Cardiac
1	NDSA575 Vascular
1	NDSA383 Ceiling Height is 290cm
4	FDS0320 Xper live / ref slaving
1	NDSA654 Aut Pos Contr Xper sys & table
1	NDSA329 FD Rotational Angio
1	NDSA330 Subtracted Bolus Chase
1	NDSA078 CO2 VIEW TRACE
1	NDSA341 FD Smartmask
1	NDSA201 Full AutoCall
1	(Xper) NDSA177 Peripheral X-ray filter
1	NDSA403 Pivot for table base.
1	FDS0089 Mattress
1	FDS0291 Add.op-rail with cable ext.kit
2	FDS0034 Mon. cable carrier cliprail
1	NDSA441 Local solution for rackm. inj.
1	NDSA213 First Xper module is located in Examination Room
1	NDSA218 Second Xper module is located in Control room
1	980306640009 Black Anti-Fatigue Floor Mat w/ Blue Logo
1	980406190009 PIVOTING TABLE-MOUNTED RADIATION SHIELD
1	989801220158 Mark 7 Arterion, Table Mount
1	989600213942 AD5 TO XPER TABLE ADAPT. PLATE
1	SP019 Trade in Allowance

Quote Summary 101824 FP Xper FD20

Options

Qty 1	Product NDSA687 Wireless footswitch Monoplane
1	NDSA451 Xper Swing
1	NDSA340 Monoplane FD Dual Fluoro
1	NDSA394 Ventricular Quant.Sw pkg(Xper)
1	NDSA395 Coronary Quant.Sw pkg(Xper)
1	NDSA401 Xper Table Tilt
1	NDSA652 Interventional Tools Hardware
1	NDSA238 Real Time digital image link
1	NDSA683 2D Perfusion

System Type: Freight Terms: Remarketing

FOB Destination

Warranty Terms:

Part numbers beginning with two (2) asterisks (**) are covered by a system 12 Months Warranty unless otherwise

indicated. All other parts are third (3rd) party items.

Special Notations:

Contingencies must be removed 120 days before scheduled shipment to assure delivery on specified date.

Any rigging costs are the responsibility of the Purchaser.

Additional Terms:

Product Terms and Conditions of Sale (T&C) not printed with this solution. Refer to Contract # noted above for applicable

T&C details. If Service Agreement is quoted its T&C of Sale are printed

Line # Part #

1

Description

Qty

Each

Price

**NNAM076

FlashPoint-FD20 Ceiling

\$516,892.50

\$516,892.50

LIMITED AVAILABILITY BASED UPON RECEIPT OF CONTINGENT FREE ORDER AT THE FACTORY. CURRENT AVAILABILITY OF THIS OFFERING IS 120 DAYS ARO, SUBJECT TO AVAILABILITY AND PRIOR SALE.

NOTE: IF CUSTOMER IS UNABLE TO ACCEPT DELIVERY BY THE ABOVE STATED ARO DATE, THEN PHILIPS MAY DETERMINE A REVISED DELIVERY DATE.

FlashPoint FD20 Ceiling

Allura Xper FlashPoint systems are assembled from the ground up by Philips Engineers. The system geometry - composed of the stand, ceiling rails, and monitor ceiling suspension - is fully refurbished to look and perform like new. All major components – x-ray tubes, tables, detectors, monitors, user interfaces, and control cabinets - are brand new.

Allura Xper FD20 monoplane system is a state of art X-ray imaging system that can be customized to support a wide range of applications including peripheral, abdominal, cerebral, thoracic, cardiac and non-vascular interventional and diagnostic procedures.

The Allura Xper FD20 system uses an integrated single-host concept. The system is comprised of five functional building blocks: Geometry, X-ray Generation, User Interface, Image Detection, and Viewing. Each functional building block is explained in further detail.

GEOMETRY

The Allura Xper FD20 Stand

The Allura stand consists of a ceiling-mounted C-arm. The stand has the following capability:

- · The L-arm can be rotated and can be moved in longitudinal direction allowing a three-sided patient approach and total body coverage.
- L-arm rotation around the patient table: +90, 0, -90 degrees.
- L-arm longitudinal movement: 300 cm
- This movement features auto-stops at the parking position, cardio/neuro position and lower peripheral position.

The Allura stand allows a very wide range of projections, including PA and AP imaging.

- In the head position (0 degrees position, L-arm parallel to patient table):
 - C-arm rotation range (degrees): 120 LAO to 185 RAO
 - · C-arm angulation range (degrees): 90 CA to 90 CR
 - (Full angulation capability determined by patient position)
- In the side position (+90 / -90 degrees position, L-arm perpendicular to patient table):
 - C-arm rotation range (degrees): 90 LAO to 90 RAO
 - C-arm angulation range (degrees): 185 CA to 120 CR or 120 CA to 185 CR

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Line # Part #

Description

Qty

Each

Price

- (Full angulation capability determined by patient position)
- The stand provides fully motorized fast movements with variable and configurable maximum speed.
 - Variable C-arm rotation speed, up to 25 degrees per second
 - Variable C-arm angulation speed, up to 18 degrees per second
- L-arm rotation and longitudinal movement: motorized and manual
- C-arm depth is 90 cm
- The FD20 Dynamic Flat Detector features Xper Access which allows the flat detector to be positioned in either portrait or landscape imaging modes in 3 seconds.
- The variable source image distance between focus and Dynamic Flat Detector input screen is motorized from 86.5 to 123 cm.
- The stand features BodyGuard a capacitive sensing collision avoidance system for patient protection.

Patient support

The Xper Table

Patient support with flat carbon fiber tabletop

- Table top length of 319 cm, width 50 cm
- Metal-free overhang 125 cm
- Floating table-top movement of 120 cm longitudinal and 35 cm transversal range.
- Motorized height adjustment from 79 to 107 cm
- Maximum cantilever of 223 cm, for full patient coverage
- Maximum patient weight 250 kg with 25 kg of accessories plus 500 N for CPR in any longitudinal position of the table top
- Xper Geometry and Imaging Modules for exam room controls.
 - The operating modules can be attached to either side of the table.

Patient Support Accessories set

- · One cerebral filter
- · Three rail accessory clamps
- One IV stand
- One slow recovery foam mattress
- One Set of Arm Supports (FCV0248)
- One Set of Patient Straps (FCV0250)
- One Head Support (FCV0251)
- One Arm Support (FCV0258)
- · One Table-mounted Radiation Shield
- One anti-fatigue mat with Philips logo

X-ray Generation

The Allura Xper FD20 comprises an integrated dedicated X-ray system, micro-processor controlled Velara CFD generator based on high frequency converter technique. The user interface control of this X-ray Generator is incorporated in the Xper module, Xper Desktop Viewing Console, and the Xper on-screen displays. The Velara CFD generator comprises:

101824 FP Xper FD20 Qty

Each

Price

X-ray generator 100 kW

Line # Part #

- Voltage range is 40 125 kV
- Maximum current 1250 mA at 80 kV

Description

- Program selection
 - Pulsed X-ray for pulsed fluoroscopy; 3.75, 7,5, 15 and 30 frames/s
 - Pulsed X-ray for (subtracted) acquisition up to 6 frames/s for vascular applications
 - Minimum exposure time of 1 ms
 - Automatic kV and mA control for optimal image quality prior to run to save dose
 - An X-ray depth collimator with two semi-transparent wedged filters with manual and automatic positioning
 - SpectraBeam filtering of low energy radiation to optimize image quality and dose efficiency with MRC-GS 0407 X-ray tube.
 - Grid switching at dynamic pulsed fluoroscopy
 - Xper Beam Shaping, positioning of both shutters and wedges on the Last image Hold without the need for X-ray radiation

Fluoroscopy

- Three programmable fluoroscopy modes
 - Each mode can be set to different composition of dose rate, pulse speed, filter setting, and image processing (noise reduction, adaptive contour enhancement, and adaptive harmonization).
- Roadmap Pro
 - Roadmap Pro can be selected from the Xper imaging module and/or Xper module.
 - A vessel map is created and superimposed with (un)subtracted live fluoroscopy. Acquisition runs can be done during Roadmap without losing the vessel map. Roadmap Pro features Smart Settings in special clinical modes that are optimized to visualize special materials such as coils and glue. Live processing of the vessel map, the device map and the landmark map can be done on the Xper Module. Xres for vascular procedures is standard part of Roadmap Pro.
 - Disclaimer: AMC only corrects movement artifacts in two dimensions. Three dimensional movements such as swallowing or rotation of the head cannot be corrected.
 - In Roadmap Pro R2 "Automatic Motion Compensation" (AMC) is added to the roadmap functionality. During roadmap, small movements of the patient can lead to subtraction artifacts. These artifacts might conceal important clinical information. "Automatic Motion Compensation" compensates for rigid, uniform (skeletal/table) translations and is therefore very effective in interventional (neurology) applications where subtraction imaging is applied.

§ Disclaimer: AMC only corrects movement artifacts in 2 dimensions. 3 dimensional movements like swallowing or rotation of the head cannot be corrected.

Xper Fluoro Storage, a grab function allows storage and archiving of both a fluoro image and the last 20 seconds of Fluoroscopy, called Xper Fluoro Storage. These fluoro images or fluoro runs can be archived as a regular exposure run.

X-ray tube

The Allura Xper FD20 has the Maximus ROTALIX Ceramic grid switch tube assembly MRC 200 GS 0407 integrated in the C-arc. This MRC tube has an anode heat storage capacity of 2.4 MHU and 0.4/0.7 mm. nominal focal spot values. The tube has a maximal loading of 30 and 67 kW.

Quotation #: 1-1GC4GVA **Rev.:** 3 Page 7 of 35

Line # Part #

Description

Qtv

Each

Price

Dynamic pulsed fluoroscopy uses grid switching technology to eliminate soft radiation and improve image quality. SpectraBeam allows for filtration of the x-ray beam with (a combination of) 0.2, 0.5 or 1 mm CU-equivalent filters.

Tube housing ROT-GS 1004 is for oil-cooling and has a build-in thermal safety switch. A rotor control unit is build-in for continuous rotation of the anode disk. The heat exchanger CU 3101 is for direct and continuous forced cooling with oil.

IMAGE DETECTION

The Allura Xper FD20 comprises the following image detection chain:

- A 30 cm by 40 cm FD20 Dynamic Flat Detector with eight imaging modes.
 - 30 x 38, 30 x 30, 26 x 26, 22 x 22, 19 x 19, 16 x 16, 13.5 x 13.5, and 11 x 11 cm
- The digital output of the FD20 flat detector is 2k*2.5k image matrix at 14 bits depth for the largest mode
- The flat detector subsystem features Xper Access, the detector can be rotated over 90 degrees, it moves from portrait to landscape back & forth
- DQE (Detective Quantum Efficiency) >73 %
- The pixel pitch: 154 x 154 microns

Viewing

The Allura Xper FD20 comprises the following components in order to display the clinical images in the control and examination room:

Displays

Examination Room

Two 18-inch monochrome LCD monitors designed for medical applications. The first display is used for viewing live images. The second display is the reference monitor.

- 18-inch monochrome TFT-LCD display with a 160 degree viewing angle.
- Native format 1280x1024 SXGA
- 10-bit gray-scale resolution with gray-scale correction

These monitors are not delivered when FlexVision XL, EP Cockpit or EP Cockpit XL is selected.

The monitor ceiling suspension in the exam room can be configured to accommodate 3, 4, 6 or 8 LCD monitors and includes motorized height adjustment. The height-adjust feature is dependent on the room ceiling height. When FlexVision XL, EP Cockpit or EP Cockpit XL is selected the monitor ceiling suspension is configured for one of those options.

- Of the two medical monochrome LCD monitors included in the MCS, one is used for viewing of live images and the other serves as the first reference display. Reference images or runs are controlled by infra-red remote-control Xper ViewPad.
- The On-Screen Display provides status information on stand rotation, angulation, display of system messages, X-ray tube load status, selected fluoroscopy mode, selected detector Field of View, and both the rate and accumulation of the dose area product and skin dose.

Line # Part #

Description

Qty

Each

Price

For cardiac applications, the system also monitors and displays body zone specific Air Kerma data (10 zones).

Control Room

One 19-inch color LCD monitor used as a data monitor.

- · 19-inch color TFT-LCD display
- Native format 1280x1024 SXGA

One 18-inch monochrome LCD monitor (Xper review monitor) designed for medical applications.

- 18-inch monochrome TFT-LCD display
- Native format 1280x1024 SXGA
- 10-bit gray-scale resolution with gray-scale correction

These control room monitors are not delivered when EP Cockpit or EP Cockpit XL is selected. The Graphical User Interface on the monochrome monitor has the following features and functions:

- · Step through file, run, or images
- · File, and run overview
- · Contrast, brightness, and edge enhancement settings
- · Flagging of runs or images for transfer
- · Applying text annotation in images
- · Optional DICOM printing
- · Executing Quantitative Analysis Packages if available
- Subtraction functionality
- · Zoom/pan functionality
- Electronic shutters
- Video invert
- · View trace, stacking of images
- Landmarking

Acquisition

The acquisition segment coordinates the parameters for automatic exposure control. The program is selected via the Xper module or Xper Desktop Console.

Exposure techniques:

- Serial imaging for DA and DSA with automatic exposure setting
- · Single shot mode
- Acquisition frame rates: 0.5 to 6 images/s at 2048 x 2048, 12-bit matrix

The Allura Xper FD20 offers a storage capacity of:

- 50,000 images at matrix size of 1024 x 1024
- 12,500 images at matrix size of 2048 x 2048
- Maximum number of examinations is 999, with no limit to the maximum number of images per examination

Line # Part #

Description

Qtv

Each

Price

USER INTERFACE

Xper is comprised of three elements: 1) Xper Settings, which customizes the system to each user preferred settings. 2) Xper User Interface 3) Xper Integration, which makes advanced integration functionality available such as DICOM Query / Retrieve, background archiving, and Xper Fluoro Storage.

The Xper User Interface uses User Interface modules in the Examination Room with On-Screen Display.

The On-Screen Display is positioned on the left side of the reference monitor. The following system information is displayed

- X-ray indicator and X-ray tube temperature condition
- Gantry position in rotation, angulation, and Source Image Distance
- Detector field size display
- · General System messages
- · Selected Frame speed
- Fluoroscopy mode
- · Integrated fluoroscopy time
- · Skin Dose and Dose Area Product
- Stopwatch

The Xper ViewPad contains the preprogrammed function settings. The system is provides with two Xper Viewpads. The following functions are provided:

- Run and image selection
- · File and run cycle
- · File overview
- Store to Reference image file
- Copy image to photo file
- · Digital (fixed) zoom and panning
- Recall reference images
- Laser pointer, intended to point at regions of interest on the imaging monitors
 - LED indication of laser pointer on/off and battery low
- Subtraction on/off
- Remasking
- Landmarking

Remote Intercom

The separate intercom which is connected independently from the system that allows separate placement of the intercom at the preferred working position in the control room and examination room.

Table Side Modules

Two Xper Modules are provided for use. The first Xper Module is mounted tableside. The Second Xper Module (NCVA778) is located in the control room. These modules use a touch screen, which can be operated when draped with sterile covers. The Xper Module contains the following functionality:

Acquisition settings

Line # Part # Description Qty Each

- Selection of Xper Setting allows the user to set frame rates and X-ray generation settings applicable for the type of the preferred intervention
- · Image Processing

The Xper Geometry module can be positioned on all sides of the patient table, while keeping the button operation intuitive. The Xper Geometry module provides the following functionality:

- Tabletop float and table height position
- · Source Image Distance selection
- Longitudinal movement of the Gantry along the ceiling
- · Gantry rotation in an axis perpendicular to the ceiling
- · Store and recall of two scratch gantry positions including SID
- · Emergency stop button

The Xper Imaging module can also be positioned on three sides of the patient table, while keeping the button operation intuitive. The Xper Imaging module provides the following functionality:

- · Fluoroscopy Flavor selection defined per Xper Setting
- Shuttersand Wedge positioning
- · Xper Fluoro Storage and Grab
- · Selection of the Detector field size
- Shutter positioning
- Reset of the fluoroscopy buzzer

Pan Handle

· The Pan Handle is an extension of the control facility for floating movements of the tabletop.

Control Room

The control room comprises a Xper Review Module, Xper Desktop Module, a keyboard, and a mouse. The Xper Review Module offers the basic functions for review. The Xper Review Module contains the following functionality:

- · Power on/off
- · Tagarno wheel to control the review of a patient file
- File and run cycle
- Contrast, Brightness, and Edge enhancement settings
- File, Run, Image stepping and run and file overview
- Delete run
- Image invert and digital zoom
- Reset fluoroscopy timer and enable/disable X-ray

System information is displayed on the bottom of the data monitor:

- Stopwatch and Time
- System guidance information
- Dose Area Product (DAP) and Skin Dose, and accumulative dose
- · Frame speed settings, fluoroscopy mode, and accumulated fluoroscopy time
- Exposure and fluoroscopy settings as Voltage (kV), Current (mA) and pulse time (ms)
- · Geometry information as rotation, angulation, and SID

Price

Line # Part #

Description

Qty

Each

Price

Scheduling

The patients can be listed and selected per date, physician, and intervention type. Previous DICOM patient studies can be uploaded with the DICOM Query Retrieve function in the Allura system.

Patient management protocols are flexible and allow for multiple studies to be selected under one patient identification number. This means that new studies can be appended to an earlier patient file. Furthermore, each study can contain multiple examinations to allow for split administrative purposes. Each examination contains multiple files, like acquisition file, reference file, and QA results file.

Preparation

The preparation page provides the information of the room and patient preparation of each individual physician. The preparation page is customizable per Xper Setting and allows each physician to provide his own room protocols. This preparation page makes hard copies of the protocol instructions redundant.

Acquisition

The acquisition page contains information on the current selected patient.

Review

The review page allows for reviewing of patients:

- Previous examination cases
- · Review of other DICOM XA or DICOM SC studies

Radiation Dose Structured Report

Collection of dose relevant parameters and settings and export to a DICOM database (e.g. PACS, RIS), according IEC60601-2-43, 2nd Edition.

The reported data can be used for, for example:

- Quality improvement: evaluating trends in X-ray dose performance per facility, system and operator.
- RDSR enables analysis of average dose levels & variance for routinely performed exams and procedures.
- Typical system usage can be extracted from the data.

Vascular Quant.Sw pkg(Xper)

Functions:

- vessel diameter / stenotic index
- · automated vessel analysis
- · calibration routines

Line # Part #

Description

Qty

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Price

In addition the package allows manual measurements of line lengths (absolute and ratio's) and angulations. Multiple measurements in one image are possible.

Compatible with:

- Allura Xper FD10 Rel 3 and FD10/10 Rel 2 onwards
- Allura Xper FD20 Rel 2 and FD20/10 Rel 2 onwards
- Allura CV20 R1 onwards

RIS/CIS Dicom Interface

This package allows communication of the Allura Xper system with a local information system (CIS or RIS). The interfaceusesthe DICOM Worklist Management (DICOM WLM) and Modality Performed Procedure Step (DICOM MPPS) standards.

If a hospital has an Allura Xper system and an information system it can receive patient and examination request information from the information system and report examination results in order to:

- Eliminate the need for retyping patient information on the Allura Xper
- Prevent errors in typing patient names and registration numbers (ensuring consistency with IS information to prevent problems in archive clusters ortosearch for name in case of later retrieval)
- Inform the IS about the acquired images and radiation dose
- Upon request from the Allura Xper system the complete worklist with all relevant patient and examination data is returned from the IS to the Allura Xper system. For each patient the following information will be shown on the Allura Xper after it has been retrieved from the IS:

Patient Identification:

- · Patient name
- Patient ID
- · Birth date
- Sex

Examination/Request Information:

- Accession number
- Scheduled procedure step start time
- Scheduled performing physician's name

It is possible at all times to enter patient demographics information manually within the Allura Xper system in case of an emergency or in case the local Information System connection is down.

On request of the clinical user the Integris will report the following information about the selected patient to the IS:

Patient Identification:

- Patient name
- Patient ID
- Birth date
- Sex

Examination/Request Information:

Line # Part # Description Qty Each Price

- Accession number
- · Performed procedure step status start/end date and time
- · Performing physician's name
- · Referenced image sequence

Radiation dose:

- Total time of fluoroscopy
- · Accumulated fluoroscopy dose
- Accumulated exposure dose
- Total dose
- · Total number of exposures
- · Total number of frames

Further detailed information can be found in the Allura Xper DICOM Conformance Statement.

The interface requires an EasyLink (hardware and software) if the IS is not compliant withDICOM Work List Management and Modality Performed Procedure Step

Archive

Continuous Autopush

Continuous Autopush is an archive accelerator, which ensures that background archiving continues with minimal disruptions.

Clinical studies can be archived to a CD or a PACS. The archive process can be completely automated and customized with Xper Settings. Parameters like multiple destinations, archive formats can be selected to the individual needs and wishes for programming under the Xper Settings,

The Xper DICOM Image Interface enables the export of clinical images to PACS. The export formats are based on DICOM 3.0 protocols. The system exports clinical studies in Cardiac DICOM XA Multi-Frame or DICOM Secondary Capture formats.

- The export format is configurable in 512x512, 1024x1024 2048 x 2048 (unprocessed) matrix.
- The examination can be sent to multiple destinations for archiving and reviewing purposes.
- The Xper DICOM Image Interface provides DICOM Storage and DICOM Storage Commitment Services.
- The DICOM Query/Retrieve function allows older DICOM XA MF and DICOM SC studies to be uploaded in the system. Furthermore, additional information can be appended to a study, while keeping the patient identification the same.

Remote Service

Access to the system from a Remote location is possible via network or modem connection. Remote access to a system can shorten the time needed for e.g. changing system settings or problem diagnosis.

Clinical Education Program for Allura Systems

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Line # Part #

Description

Qty

Each

Price

Essentials OffSite Education: Philips will provide up to two (2) Cardiovascular Technologists, Registered Technologists Registered Nurses, or other system operator as selected by customer, with in-depth didactic, tutorial, and hands-on training covering basic functionality and work-flow of the cardiovascular imaging system. In order to provide trainees with the ability to apply all fundamental functioning on their system, and to achieve maximum effectiveness, this class should be attended no earlier than two weeks prior to system installation.

In the event that an EP Navigator workstation has also been ordered, the offsite training course will be tailored to focus on the electrophysiology functionality of the FD system and the EPN workstation.

In the event that your main FD system will be dedicated to Cardiac applications your offsite training course will be tailored to focus on the Cardiac functionality.

This twenty-eight (28) hour class is located in Cleveland, Ohio, and is scheduled based on your equipment configuration and availability. Due to program updates, the number of class hours is subject to change without notice. Customer will be notified of current, total class hours at the time of registration. This class is a prerequisite to your equipment handover OnSite Education. CEU credits may be available for each participant that meets the guidelines provided by Philips. Please refer to guidelines for more information. Travel and lodging are not included, but may be purchased through Philips. It is highly recommended that 989801292102 (CV Full Travel Pkg OffSite) is purchased with all OffSite courses.

Handover OnSite Education: Philips Education Specialists will provide twenty-eight (28) hours of education for up to four (4) students, selected by customer, including technologists from night/weekend shifts if necessary. Students should attend all 28 hours, and must include the two OffSite education attendees. CEU credits may be available for each participant that meets the guidelines provided by Philips. Please refer to guidelines for more information. Note: Site must be patient-ready. Philips personnel are not responsible for actual patient contact or operation of equipment during education sessions except to demonstrate proper equipment operation. It is highly recommended for systems that are fully loaded or for customers with a large number of staff members to also purchase 989801292099 (CV Add OnSite Clin Educ 24h).

2 **NNAJ581

DS FlexVision XL 8 Input Package

\$10,300.50

\$10,300.50

The FlexVision XL8 input package provides eight isolated wall connection boxes and eight legacy converters.

Education expires one (1) year from equipment installation date (or purchase date if sold

Isolated Wall Connection Box

separately). Ref #106107-110915

This Isolated Wall connection Box facilitates connection of the video source via standard DVI cable/connector and lossless

transfer of the video signal over the approximate 30 m cable distance. It can be mounted in the exam room or in the control room, depending on the location of the video source.

The quantity of the VWCB's has to be calculated as follows:

For each video signal to FlexVision XL on Vascular System: 8 VWCB Note:

No VWCB is required in case a video signal is connected directly to a dedicated LCD from the following sources:

- 1) Xper Live/ref Slaving
- 2) Interventional HW (XtraVision), ViewForum, Xcelera (only if workstations are powered by Allura Xper)
- 3)Xper IM

Line # Part #

Description

Qty

Each

Price

Legacy Video Convertor

The Legacy Video Convertor enables conversion from VGA towards DVI for supported input resolutions as listed in the table below.

Signal type Native resolution Image Aspect Ratio

VGA 640x480 4:3

SVGA 800x600 4:3

XGA 1024x768 4:3

SXGA 1280x1024 5:4

SXGA+ 1400x1050 4:3

UXGA 1600x1200 4:3

WXGA 1280x800 16:10 (8:5)

WSXGA 1440x900 16:10 (8:5)

WSXGA+ 1680x1050 16:10 (8:5)

WUXGA 1920x1200 16:10 (8:5)

2K 2048x1080 19:10

TV1080I/P 1920x1080 16:9

TV 480I 720x480 4:3

TV 480P 704x480 4:3

3 **NNAM092

GSS PDU w/2k UPS

1

\$0.00

\$0.00

989801220072 GSS PDU

Model GSS PDU without UPS: power rating of 200kVA (I), 400/480VAC input, 400/480VAC output, voltage and current monitoring, communication and control. No UPS is included in this product. No transformer included in this product.

4 **NDSA667

Non swivel, mounted IN floor

1

5 **NDSA628

FlexVision

1

\$92,358.00

\$92,358.00

XL,XperHD,Snapshot FlexVision XL with XperHD

FlexVision XL for Allura Xper Release 7 systems with large 56-inch high resolution color LCD in the Exam Room.

FlexVision XL is an integrated viewing solution designed to give you full control over your viewing environment.

The FlexVision XL provides the ability to:

- Display 2 to 8 screens simultaneously from up to 16 sources (incl. third party systems) on the Philips 56-inch color LCD in the Exam Room.
- · Resize and/or enlarge information at any stage during the case.
- Select and customize viewing lay-outs of the Philips 56-inch color LCD via the Allura Xper table-side module

XperHD on FlexVision XL brings High Definition viewing for clinical images. Native resolution of FD20 can be displayed. Excellent sharp and crisp clinical images can be displayed at full size without digital zoom.

Xper HD brings:

101824 FP Xper FD20				
Line # Part #	Description	Qty	Each	Price

- High Definition imaging
 - Sharp images at full size without zoom
- · High Definition display at native resolution
 - Up to 2k*2k image display fully integrated
- · High Definition for the ultimate detail
 - Enhanced small vessel visualization
- Overview connected equipment (incl. third party systems) from a single location.

The FlexVision XL consists of:

- MediaWall Controller for the large screen display
- OmniSwitch
 - OmniSwitch allows the user to direct and switch the video output of all connected medical equipment to specific sub windows of the Philips 56-inch color LCD in the Exam Room.
 - OmniSwitch is a 16 channel video-switch operated from the Allura Xper tableside module. 16 channels are available for a mix of up to 7 internal and up to 9 external inputs.
 - OmniSwitch supports a wide variety of display formats (up to 1600x1200).
 - External inputs are connected to OmniSwitch via Wall Connection boxe(s).
- Medical grade, high resolution color LCD in the Exam Room
 - This display supports the image quality requirements for monochrome X-ray images as well as color images and replaces all displays normally delivered with an Allura Xper system for the Exam Room.
 - Main characteristics are:
 - 56 inch, 8 Megapixel color LCD
 - · Native resolution: 3840x2160
 - Brightness: Max: 450 Cd/m2 (typical) stabilized: 350 Cd/m2
 - · Contrast ratio: 1200:1 (typical)
 - Wide viewing angle (approx. 176 degrees)
 - Constant brightness stabilization control
 - Lookup tables for gray-scale, color and DICOM transfer function
 - · Full protective screen
 - Ingress Protection: IP-21
- Large color LCD control (Xper Module)
 - Resize and/or enlarge information at any stage during the case via the Allura Xper tableside module in the Exam or Control Room
 - Select viewing lay-outs via the Allura Xper table-side module in the Exam Room
 - Create new layouts by matching inputs to desired locations on preset templates.
- Monitor Ceiling Suspension
 - Monitor ceiling suspension for use in the Exam Room carries the 56 inch color LCD, providing highly flexible viewing capabilities. The monitor ceiling suspension is heightadjustable and moveable along ceiling rails. It can be positioned on either side of the table.
- Isolated Wall Connection Boxes
 - Up to 8 Isolated Wall Connection Boxes can be connected to FlexVision XL.
 - Through Isolated Wall Connection Boxes, 3rd party equipment can be connected to the FlexVision Omniswitch.

Line # Part #

Description

Qty

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Price

- Snapshot
 - The snapshot function allows the user to store/save a screen-capture of any image on any EP cockpit display as a DICOM Secondary Capture image to a connected PACS. The snapshot-all function allows the user to store/save a screen-capture for each displayed image in the Exam Room / Control Room as seperate DICOM Secondary Capture images.

6 **NDSA508

Set of 2 additional 21in. LCDs

1

\$9,247.50

\$9,247.50

Two 21inch additional displays are located on top of the monitor ceiling suspension frame which carry the 56 inch large screen color LCD display.

These 2 additional LCD's can be used to display additional video sources or used as display back up for Hemo and Xray Live images. These LCD's have a fixed content.

Main characteristics of back-up displays are:

- 21.3 inch, 2 Megapixel color LCD display
- Max. resolution: 1600x1200
- Brightness: 450 Cd/m2
- · Contrast ratio: 550:1
- Wide viewing angle (approx. 170 degrees)
- · Constant brightness stabilization control
- · Independently selectable brightness settings for monochrome and color images
- · Independently selectable lookup table for gray-scale, color and DICOM transfer function

FDS0320 Xper live / ref slavingrequired when displaying X-Ray Live as back-up.

7 **NDSA509

2ND REF for FlexVision XL

1

\$4,522.50

\$4,522.50

2nd REF for FlexVision XL is optional on FlexVision XL. Second Ref images will be displayed on the large screen monitor.

8 **NDSA574

Cardiac

1

Diagnostic and interventional vascular angiography procedures (e.g. abdominal, thoracic and peripheral interventions)

9 **NDSA575

Vascular

- 1

Diagnostic and interventional vascular angiography procedures (e.g. abdominal, thoracic and peripheral interventions)

10 **

**NDSA383

Ceiling Height is 290cm

1

Ceiling height is 290cm

11

**FDS0320

Xper live / ref slaving

4

\$5,238.00

\$20,952.00

Line # Part #

Description

Qty

Each

Price

Xper Live/Ref Slaving

The Xper Live/Ref Slaving will enable the option to slave the Live or Ref video source from the Allura Xper. The total amount of Xper Live/Ref Slaving that can be selected is max 4.

Xper Live/Ref Slaving is possible:

- In Control Room icw FCV0011(B/W monitor in Control Room)
- In Philips MCS (additional monitor excluded from this option)
- Icw FCV0519 1 or 2 MCS from Skytron/Steris

12 **NDSA654

Aut Pos Contr Xper sys & table

1

\$7,623.00

\$7,623.00

This Automatic Position Controller (APC) combines APC for Allura Xper FD10 and FD20 systems with table APC.

System APC provides two modes of operation:

Preset Position Sequence: the sequence of projections is determined through personnalized Xper Settings. Each set contains a maximum of 10 positions. Positions can be recalled in sequence or directly. The projection sequence comprises rotation angulation and SID settings related to the selected reference image.

Reference driven positioning: The projections on the reference monitors can be recalled with the push of a button. The reference driven positioning recollects the C-arm rotation angulation Flat detector image format and SID.

Table APC

The Automatic Position Controller (APC) for the table provides two modes of operation:

Auto positioning. The tabletop position and table height will be adjusted automatically to the pre-defined default point of interest. This to save time and x-ray dose at the start of an exam or for setting up the system for rotation scans.

Store/recall of a position of the table top. This includes the height-, longitudinal- and lateral position of the table top.

13 **NDSA329

FD Rotational Angio

1

\$18,189.00

\$18,189.00

Rotational Angiography provides real-time 3D impressions of complex vasculature and coronary artery tree. It acquires multiple projections with just one contrast injection via a fast rotational scan of the region of interest.

Rotational Angiograpy can be used during screening procedures to quickly determine the optimal projection for the study as the angle (rotation/angulation) of the projection is indicated on each image.

Compared with traditional angiography, Rotational Angiography can save considerable time, dose and contrast, while providing image detail required for diagnostic and therapeutic decisions.

A rotational scan is possible both with the Allura Xper systems in the side position (ceiling mounted systems) and in the head position, providing the flexibility to perform procedures virtually from head to toe.

C-arm in side position:

Max. rotation Speed: 30 degrees/s Max. rotation Angle: 180 degrees

C-arm in head position:

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Max. rotation Speed: 55 degrees/s Max. rotation Angle: 305 degrees

Max. Frame speeds are given by the framespeed specifications of the system configuration.

The speed and range of rotation are the highest available (see table). The very high speed allows using less contrast, whereas the very wide rotation range provides a complete evaluation of the anatomy.

A contrast run can be followed up with a mask run, to allow image/run subtraction.

The stand is designed for a very high mechanical stability. It offers precise positioning and high reproducibility, assuring you of high quality images and excellent subtraction studies.

Operation of Rotational Angiograpy is extremely easy. The procedure is selected, set up and executed virtually in a matter of seconds, supporting the highest patient throughput. A set of dedicated acquisition programs is available on the Xper Module and can be selected at the touch of a button. The rotation end- and start-positions are easily selected. The procedure is controlled from the exposure hand- or footswitch.

14 **NDSA330 Subtracted Bolus Chase 1 \$19,039.50 \$19,039.50

For visualisation of vessel structures when the blood flow is difficult to estimate, in particular in the lower peripherals.

Bolus Chase solves the problem of cumbersome step movements, the mismatch between blood flow and selected program, and lack of real-time image information.

During digital acquisition in non-subtracted mode with uninterupted real-time image display, the contrast bolus is followed (chased) interactively by a motorized table scan movement using a hand-hold speedcontroller to adapt the speed of the table scan to the contrast flow.

The framespeed can be adapted as well.

The bolusrun is followed with a maskrun while using the same speedcurve and framespeed as generated during the bolusrun. Viewing is possible in the subtracted and non-subtracted mode. If subtracted viewing is not required, the maskrun can be skipped.

Subtracted Bolus Chase gives fast, accurate results for increased patient throughput and improved patient management. Automated exposure control and precise speed control assure a high quality images and excellent subtraction studies.

Comprising:

- tabletop motordrive and hand-held speed controller
- automatic exposure control

15 **NDSA078 CO2 VIEW TRACE 1 \$2,713.50 \$2,713.50

Software package enabling tracing (stacking) of images acquired with CO2 injections. This function can be used during postprocessing next to view trace of images acquired with iodine injections.

16 **NDSA341 FD Smartmask 1 \$10,147.50 \$10,147.50

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Line # Part #

Description

Qty

Each

Price

SmartMask simplifies the roadmapping procedures by overlaying on the live monitor fluoroscopy with a selected reference image.

The reference image can be faded in/out with variable intensity, controlled from tableside.

SmartMask uses the reference image displayed on the reference monitor.

Any previously acquired image can be used as reference.

SmartMask facilitates pre- and post- intervention comparisons to assess treatment results.

17 **NDSA201

Full AutoCall

1

\$3,420.00

\$3,420.00

(Xper)

The Auto call option is a software package to be used in conjunction with quantitative analysis software packages. It provides an auto calibration procedure for an object to be analyzed that is placed in the iso-center. When the object to be analyzed (e.g. Left Ventricle Vessel Segment) is placed in the iso-center Autocal avoids the need to:

- acquire an additional image series containing a sphere or grid for calibration purposes or
- calibrate manually on a calibration object (e.g. catheter) displayed in the image or image series to be analyzed.

18 **NDSA177

Peripheral X-ray filter

1

\$1,192.50

\$1,192,50

Set of flexible x-ray filters provides a uniform density in angiographic examinations of the lower peripheral area.

Includes:

- 1 Central filter at the top edge provided with sizing markersevery 5 cm --length: 1m;
- Two side filters --length: 1 m.

19 **NDSA403

Pivot for table base.

1

\$4,230.00

\$4,230.00

For angiographic- and interventional procedures of the upper peripherals.

Provides improved table access for patient transfer.

Allows pivoting of the table base around its vertical axes.

Pivot range from -90 degrees to + 180 degrees (or -180 to +90 degrees) with locked positions on 0, -13/+13 (facilitating arm-angiography) and -90/+90 and 180 degrees.

Comprising:

· pivot device with graduated scale.

To be mounted on the universal floor plate of the table.

Compatible with Xper Table

**FDS0089

20

Mattress

1

\$423.00

\$423.00

21 **FDS0291

Add.op-rail with cable ext.kit

1

\$3,217.50

\$3,217.50

Qty

Each

Price

Line # Part # Description

The content of the additional OP-Rail kit is:

A. One additional OP-Rail (mechanical), similar to FCV4893 (length = 30cm)

- B. Cable Extension set for OP-Rail
 - One Extension cable for Geo Module: length = 1.3 m
 - One Extension cable for Imaging Module: length = 1.3 m
 - One connection box (wherein the extension cables are coupled with the UI-Module cables.

Ad A: An extension for the table op-rail (30cm).

The additional op-rail can be mounted at the both sides of the tabletop part where no op-rails are mounted as standard. The additional op-rail is compatible with AD5 and Xper Table (cardio and neuro) patient-tabletops. The op-rail has the same profile /dimensions as the current standard op-rail. The maximum load (downwards) on the additional op-Rail is 100 N (F=100N) (this is limited by the tabletop of the Patient Table) The maximum mechanical moment on the additional op-Rail is 40Nm downwards and 20Nm upwards (this is limited by the tabletop of the Patient Table)

22 **FDS0034 Mon. cable carrier cliprail 2 \$243.00 \$486.00

Additional monitor cable carrier for Cliprails.

This is an extra monitor cable hose relief between the MCC and the ceiling inlet. For instance if the ceiling inlet cannot be placed in the middle of the cliprails (due room restrictions).

This item is not suitable for Monitor Ceiling Carriage (MCC) mounting or for Stand hose.

23 **NDSA441 Local solution for rackm. inj. 1

24 **NDSA213 First Xper module is located in 1 Examination Room

First Xper module is located in Examination Room

25 **NDSA218 Second Xper module is located 1 in Control room

Second Xper module is located in Control room

26 **980306640009 Black Anti-Fatigue Floor Mat w/ 1 \$180.00 \$180.00 Blue Logo

Blue Anti-Fatigue Floor Mat w/ Logo

27 **980406190009 PIVOTING TABLE-MOUNTED 1 \$2,524.50 \$2,524.50 RADIATION SHIELD

Table-mounted radiation shield for additional protection of physician and staff against scatter radiation. The shield consists of two protective parts: a lower shield and an upper shield. The shield is specially designed for use with the AD5 patient table.

The table mounted radiation shield provides the following features:

Mounting to either the right orleft tableaccessory rails;

Line # Part

Description

Qty

Each

Price

- Pivoting into the required working position;
- Pivoting into the parking underneath the tabletop facilitating patient preparation;
- The upper shield can be positioned upright providing optimal protection or can be folded down for free access to the patient.

The table mounted radiation shield includes:

- Lower shield measuring 70 cm high 80 cm wide 0.5 mm Pbequivalence;
- Upper shield measuring 40 cm high 50 cm wide 0.5 mm Pbequivalence;
- · Mounting clamp;

Docking device for wall mounting.

28 **989801220158 Mark 7 Arterion, Table Mount

1

\$25,650.00

\$25,650.00

The Mark 7 Arterion Injection System is the latest in MEDRAD's "Mark" series of angiographic injectors. Compared to earlier systems, the Mark 7 Arterion injector head is lighter and easier to use so you can focus more on the patient.

The clear and intuitive user interface guides you through proper set-up, and highlights the information you need to perform safe procedures.

Unique to the market, the front load system simplifies set-up and makes for a cleaner tear down.

The clear syringe provides a higher level of confidence that you are ready to inject.

Made from a clear material, the Mark 7 Arterion syringe (Catalog ART 700 SYR) allows you to easily view the inside of the syringe for smoother purging of air. And MEDRAD's famous fluid dots are still there to help-round for fluid, oval for air.

The table mount injector solution ensures the contrast injector is conveniently placed and always available when it is needed. It provides a clean workspace without occupying valuable floor space. System includes:

- Table Mount
- display control panel
- · 6 ft. coiled hand switch
- operation manual (CD)
- 10 ft. head cable
- syringe heat maintainer
- imaging system interface cable for the Allura / Allura Xper
- · consumables starters kit

For the MEDRAD Mark7 Injector system Philips is only the distributor. MEDRAD provides the service as well as the application support of both versions unless stated differently in the Philips Service Agreement

System Specifications:

- Flow Rate 0.1-45.0 ml/s in 0.1 ml increments
- · 0.1-59.9 ml/m in 0.1 ml increments
- Volume 1-150 ml in 1 ml increments
- Pressure Limit 100-1200 psi in 1 psi increments
- (150ml syringe) 689-8273 kPa in 1 kPa increments
- Rise Time 0.0-9.9 seconds in 0.1 increments

Qty

Delay Time 0.0-99.9 seconds in 0.1 increments

Description

- Fill Speed 1-20 ml/s
- Fill Volume 1-150 ml
- Syringe Size 150 ml
- Syringe Heat Maintainer 35 °C (95 °F) ± 5 °C (9 °F)
- Protocol Memory 40 Protocols
- Injection Memory History

29 **989600213942 AD5 TO XPER TABLE ADAPT.

\$1,939.50

Each

\$1,939.50

Price

PLATE

30 SP019

Line # Part #

Trade in Allowance

(\$78.000.00)

(\$78,000.00)

Customer represents and warrants that (i) Customer has, and shall have when title passes, good and marketable title to the equipment being traded in and (ii) has the authority to effect such trade in.

Product: 100215.000 Allura Xper FD20 Serial Number: 722003:1911

Manufacturer: PHILIPS HEALTHCARE

Trade-In authorization number:

40614

Trade-In Value:

\$78,000.00

De-install Date:

Customer will be trading-in equipment that is described on the attached System Disclosure Form (the "Trade-In"), which Trade-In the parties agree (i) will be removed on the De-install Date and (ii) is currently in the condition as represented on the System Disclosure Form. In addition, the parties agree as follows:

- 1. Customer represents and warrants that Customer has good and marketable title to the Trade-In as of the date of this Quotation and will have good and marketable title when Philips removes the Trade-In from Customer's site (the "Removal Date");
- 2. Title to the Trade-In shall pass from Customer to Philips on the Removal Date, unless otherwise agreed by Philips and the Customer;
- 3. Notwithstanding anything to the contrary in any Business Associate Addendum, Customer represents and warrants that as of the Removal Date all Protected Health Information will have been deidentified or removed from the Trade-In;
- 4. Philips may test and inspect the Trade-In prior to de-installation. If the condition of the Trade-In is not substantially the same on the Removal Date (ordinary wear and tear excepted) as it is identified on the System Disclosure Form, then Philips may reduce the price quoted for the Trade-In:
- 5. If the removal date is delayed until after the De-Install Date, unless Philips causes the delay, then Philips may reduce the price quoted for the Trade-In by six percent (6%) per month.
- 6. Philips is responsible for normal de-installation costs of the Trade-In.
- 7. The trade-in value will not include costs associated for any facility modifications and/or rigging required for de-installation and must be accounted for separately.
- 8. Customer is responsible for all plumbing necessary to properly drain coolant from chiller system and cap the lines.
- 9. Prior to the Removal Date, Customer shall remove from the room all equipment that is not being deinstalled.

******PROMOTIONS******

Promotion Name

Description

Mono Closer 2016-Q3

Philips is pleased to offer this special promotional discount of \$50,000 with the purchase of a monoplane Allura system. To be eligible for this promotion, orders must be received by September 30, 2016.

Quotation #: 1-1GC4GVA

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LIST PRICE
DISCOUNT
TRADE IN AMOUNT
NET PRICE

\$1,678,330.00 \$973,081.50 (\$78,000.00) \$627,248.50

Buying Group:

MEDASSETS SUPPLY CHAIN SYSTEMS INC.

Contract #:

Addt'l Terms: Product Terms and Conditions of Sale (T&C) r

MS03221

Product Terms and Conditions of Sale (T&C) not printed with this solution. Refer to Contract # noted above for applicable T&C details. If Service Agreement is quoted its T&C of Sale are printed

Each Quotation solution will reference a specific Buying Group/Contract Number representing an agreement containing discounts, fees and any specific terms and conditions which will apply to that single quoted solution. If no Buying Group/Contract Number is shown, Philips' Terms and Conditions of Sale will apply to the quoted solution.

Each equipment system 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.

Price above does not include any applicable sales taxes.		
The preliminary delivery request date for this equipment i	s:	
If you do not issue formal purchase orders indicate by init		
Tax Status:		
Taxable Tax Exempt		
If Exempt, please indicate the Exemption Certification Nu the certificate.	mber:	_, and attach a copy o
Delivery/Installation Address:	Invoice Address:	
Contact Phone #:	Contact Phone #:	
Purchaser approval as quoted:	Date:	
Title:		

This quotation is signed and accepted by an authorized representative in acknowledgement of the system configuration, terms and conditions stated herein.

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OPTIONS

SELECTION OF ANY OPTION WILL INCREASE THE CONTRACT PRICE BY THE AMOUNT SHOWN IN THE PRICE COLUMN. OPTIONAL EQUIPMENT PRICING VALID ONLY IF PURCHASED IN CONJUNCTION WITH EQUIPMENT QUOTED.

Line ?	# Part #	Description	Qty	Each	Price	Initial
1	**NDSA687	Wireless footswitch	1	\$6,664.50	\$6,664.50	

The wireless footswitch is an option for our Allura systems. It provides the possibility to have one wireless footswitch in the exam room.

A wireless footswitch provides workflow optimization, flexibility at table-side, removes cable clutter on the floor and provides easier cleaning of the footswitch.

The mono-plane wireless footswitch is a 3 pedal version; one pedal for fluoroscopy, one for exposure and one to control the roomlight/single shot. The pedals can be configured according customers preferred lay-out.

The wireless footswitch is working via RF technology and is fully tested and released for medical use. It has an active range up to 10 meters, depending on structures within this range.

The wireless footswitch has a lithium battery which only needs to be recharged once per week. During recharging the footswitch still can be used and is fully functional. In parallel, a wired footswitch can also be used.

The status of the battery is indicated by an LED-indication on the footswitch itself, so that the user can decide when the footswitch needs to be recharged.

The wireless footswitch can easily be cleaned in water. It has the highest water ingress protection standard (IPX8).

The wireless footswitch has an on/off switch. It can be switched off when not in use. When the footswitch is active, but not in use, it will go into a sleep-mode. It will be re-activated when touched or when one of the pedals is pressed.

2 **NDSA451 Xper Swing 1 \$11,425.50 \$11,425.50

The XperSwing option is an extention of Rotational Scan, providing real-time 3D impressions of the coronary artery tree. It acquires multiple projections with just one contrast injection via a fast dual axis rotational scan of the region of interest. So, rotation and angulation movements are combined in one complete scan trajectory, using the maximum rotation and angulation speed of the system. (up to 55 resp 30 degr/sec)

Swing can be used during screening procedures to quickly determine the optimal projection for the study as the angle (rotation/angulation) of the projection is indicated on each image.

Compared with traditional angiography, XperSwing can save considerable time, patient dose and contrast medium, while providing image detail required for diagnostic and therapeutic decisions. In total seven pre-programmed trajectories are available: two for Right Coronary imaging, three for Left coronary imaging and two generic trajectories. The choice depends on size and weight of the patient. These trajectories are designed to fully cover most if not all conventional projections for a diagnostic coronary angiography, much more complete then the single axis Rotational Scan.

The Swing scan is possible both with the Allura Xper systems in the side position (ceiling mounted systems) and in the head position, providing the flexibility to perform procedures virtually from head to toe.

Max. Frame speeds are given by the framespeed specifications of the system configuration.

OPTIONS

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Line # Part #

Description

Qty

Each

Price Initial

The speed and range of rotation are the highest available (see table). The very high speed allows using less contrast, whereas the very wide rotation range provides a complete evaluation of the anatomy.

The stand is designed for a very high mechanical stability. It offers precise positioning and high reproducibility, assuring you of high quality images and excellent subtraction studies.

Operation of the XperSwing is easy. The procedure is selected, set up and executed virtually in a matter of seconds, supporting the highest patient throughput.

The set of dedicated acquisition programs with the trajectories is available on the Xper Module and can be selected at the touch of a button. The rotation end- and start-positions are easily selected. The acquisition procedure is controlled from the exposure hand- or footswitch.

3 **NDSA340

Monoplane FD Dual Fluoro

\$16,668.00

\$16,668.00

Dual Fluoro for Flat Detector systems

The Dual Fluoroscopy mode allows digitally processed fluoroscopy in parallel with trace subtract fluoroscopy, providing a non subtracted reference fluoro image for complex interventions.

This option provides an additional fluoro channel in parallel to the default fluoro channel. The Dual Fluoroscopy mode is selected via the Xper module.

The trace subtracted fluoro image will be displayed on the exam monitor, the non-subtracted fluoro image is displayed on the reference monitor.

In Dual Floro mode, the fluoroscopy image on the exam montitor can be zoomed digitally with a factor 2, providing a larger view of the region of interest for complex interventions. The fluoro zoom function is controlled via the Xper module.

4 **NDSA394

Ventricular Quant.Sw pkg(Xper)

1

\$9,486.00

\$9,486.00

Left Ventricular Quantification Software Package. Software package for the analysis of single plane Left ventricular angiograms. Calculates the Ejection fraction and local wall motion parameters in different formats.

Functions:

- Various LV-volumes
- · Ejection Fraction
- Cardiac Output
- Centerline Wall Motion
- Slager Wall Motion
- Regional Wall Motion
- Calibration routines

In addition the package allows manual measurements of line lengths (absolute and ratio's) and angulations. Multiple measurements in one image are possible.

Comprising:

OPTIONS

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Line # Part #

Description

Qty

1

Each

Price Initial

software license

Compatible with:

- Allura Xper FD10 Rel 3 and FD10/10 Rel 2 onwards
- Allura Xper FD20 Rel 2 and FD20/10 Rel 2 onwards
- Allura CV20 R1 onwards

5 **NDSA395

Coronary Quant.Sw pkg(Xper)

\$6,651.00

\$6,651.00

Functions:

- · diameter measurement along the selected segment
- cross sectional area
- %-stenosis
- · pressure gradient values
- · stenotic flow reserve
- · calibration routines

In addition the package allows manual measurements of line lengths (absolute and ratio's) and angulations. Multiple measurements in one image are possible.

Comprising:

software license

Compatible with:

- Allura Xper FD10 Rel 3 and FD10/10 Rel 2 onwards
- Allura Xper FD20 Rel 2 and FD20/10 Rel 2 onwards
- · Allura CV20 R1 onwards

6 **NDSA401

Xper Table Tilt

1

\$17,343.00

\$17,343.00

This innovating SyncraTilt enhances the accuracy and efficiency of gravity-oriented procedures. It is available as an option for the Xper table in Allura Xper series systems.

SyncraTilt is ideal for interventional, myelography, phlebography and head down procedures because it provides more precise imaging of contrast medium, blood, or objects in the body.

With SyncraTilt, the isocentre is automatically located at the isocentre of rotation and angulation of the stand. If the longitudinal position of the stand changes, the tilt isocentre is changed to match with the new stand position. As a result, the region of interest is always centred. As the table tilts, the X-ray beam automatically coordinates to the movement.

The table floats even when tilted, and the region of interest can be followed by panning the tabletop.

When combined with the Bolus Chase option, SyncraTilt enables phlebography to be performed with a head-up tilted patient.

OPTIONS

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Line # Part #

Description

Qty

Each

rice Initia

The option provides:

- · maximum tilt range:
 - -17 degrees (head down) to +17 degrees (head up).

tilt speed: 2 degrees/sec

- · automatic safeguarding system with manual override
- panning range in tilted plane: equal to the standard tabletop specifications (longitudinal 120cm, lateral 35cm)
- · easy to use controls

Comprising:

· Tilt drive with user controls `

Compatible with:

- Xper table in Allura Xper FD series Rel 3 onwards (monoplane versions) and Rel 2 onwards (biplane verions)
- · Bolus Chase
- · Pivot for table base
- · swivel for table base

7 **NDSA652

Interventional Tools Hardware

\$7,695.00

\$7.695.00

The Interventional hardware is the hardware for the 3D interventional tools and enables import and viewing of DICOM compatible data from other imaging modalities.

The Interventional Hardware comprises at least:

- · Computer Workstation
- CR 19" display
- 16 GB memory
- 2 TB disk for the operating system, application software and application data
- · Internal CD-Rom / DVD writer
- Mouse tablet to interact with all the interventional tools at the table side.

Conditionally:

FD Calibration Tool Kit for 3D-RA

8 **NDSA238

Real Time digital image link

\$11,749.50

\$11,749.50

Real Time digital image link to an off-line Allura Interventional Hardware station.

This applies on the applications 3D-RA, StentBoost and 3D-CA on the Interventional Hardware. This dedicated digital link sends raw or processed image data (depending on the application) real time during monoplane exposures to the connected Interventional Hardware station, to allow instant results of

the applicable reconstruction after the exposure run.

In biplane systems, this digital link is available for the frontal channel only.

9 **NDSA683

2D Perfusion

\$26,370.00

\$26,370.00

Quotation #: 1-1GC4GVA

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OPTIONS

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Line # Part

Description

Qty

Each

Price Initial

2D Perfusion brings functional imaging in the interventional suite and therefore allows assessing tissues perfusion during the intervention. It is based on a digital subtraction angiography (DSA) and it calculates the transit time of the contrast trough the vessels, displaying it as a full color image.

2D Perfusion can be used for the identification of perfusion alterations in tissue in case of vascular pathologies or to verify perfusion behavior in case of tumors and AVM. It helps identifying the areas

which are at risk of being hypo-perfused (or hyper perfused) and it allows to compare side by side pre, peri, and post-procedural perfusion images to identify treatment end point and to verify procedure outcome.

2D perfusion allows to draw a region of interest (ROI) and to study the perfusion within the ROI thanks to the time density curve.

Once the ROI is selected, the time density curve is generated real time and the average value of the selected parameter is calculated and displayed.

When comparing pre and post intervention images, it's possible to draw a region of interest and it will be automatically drawn in the comparative image. It will also calculate the time density curve of both images, to easily evaluate pre and post intervention differences.

The functional parameters available are:

- 1. Mean Transit Time
- 2. Arrival Time
- 3. Time to Peak
- 4. Wash-in Rate
- 5. Width
- 6. Area Under Curve

The color legend indicates for which functional parameter each color represents in the displayed image.

- 2D Perfusion runs are acquired on a compatible with Allura Xper FD system release 7.2.3.3/ 7.2.5/ 7.6.3/ 7.8.1/ 7.7.1/ 8
- 2D Perfusion can run on Interventional Tools Hardware: Radisys 8 and DELL T5500. In field extensions, replacement hardware can be ordered.
- 2D Perfusion supports subtracted X-ray exposure runs acquired with a 2D Perfusion protocol. (While acquiring a run with the 2D Perfusion protocol, the subtracted run is shown on the X-ray modality screen.)
- 2D Perfusion supports runs acquired on the frontal channel or on the lateral channel.
- The 2D Perfusion protocol acquires up to 173 images at 3 frames per second.
- 2D Perfusion supports runs of 5 images or more
- Runs can be transferred to 2D Perfusion over the DICOM network or over the Real Time Image Link (option).
- 2D Perfusion provides different options for exploring the time-to-density curve, which
 describes the presence of contrast at a certain point in time.
- It allows to draw 2 different types of ROI: an elliptical ROI or to draw a freeform ROI. If you
 make changes to the ROI (elliptical ROI only), the curve in the analysis graph is updated
 automatically.

OPTIONS

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Line # Part

Description

Qty

Each

Price Initial

- In procedures where it's required to compare left and right hemispheres, you can draw a mirror line, and analyze the perfusion behaviors in the ROI between the hemisphere suspected to have a perfusion alteration, with the normo-perfused hemisphere.
- 2D Perfusion includes 3 new EPX's for Neuro, Abdominal and Peripheral examinations. 2D
 perfusion allows to select the frames where the presence of contrast is detected, in order to
 reduce the motion artifacts.

Clinical Education Program for 2D Perfusion

IXR 2D Perfusion OnSite Education: Philips Education Specialists will provide sixteen (16) hours of education for up to four (4) students, selected by customer, including technologists from night/weekend shifts if necessary. CEU credits may be available for each participant that meets the guidelines provided by Philips. Please refer to guidelines for more information. Note: Site must be patient-ready. Philips personnel are not responsible for actual patient contact or operation of equipment during education sessions except to demonstrate proper equipment operation.

Education expires one (1) year from equipment installation date (or purchase date if sold separately). Ref # 6034-20131218

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PHILIPS PRODUCT WARRANTY

This product warranty document is an addition to the terms and conditions set forth in the quotation to which this warranty document is attached. The terms and conditions of the quotation are incorporated into this warranty document. The capitalized terms herein have the same meaning as set forth in the quotation.

TWELVE-MONTH SYSTEM WARRANTY

Philips warrants to Customer that the Philips Vascular and Cardiac Systems (the "System") as delivered to Customer will perform in substantial compliance with its performance specifications for a period of twelve (12) months upon first patient use. Any glassware or flat detectors provided with the System is subject to special warranty terms set forth below.

PLANNED MAINTENANCE

During the warranty period, Philips personnel will schedule planned maintenance visits, in advance, at a mutually agreeable time on weekdays, between 8:00 A.M. and 5:00 P.M. local time, excluding Philips observed holidays.

Any commercially available upgrade to the System which is hereafter installed by Philips during the original term of the System warranty shall be subject to the warranty terms contained in the first paragraph of this warranty, except that such warranty shall expire on the later of: a) upon termination of the initial twelve (12) month warranty period for the System on which the upgrade is installed or b) after ninety (90) days for parts only from the date of installation.

MRC X-RAY TUBES

Philips warrants to Customer, for the warranty periods further specified in this section, that the Philips X-Ray tube will be substantially free from defects in material and manufacturing workmanship, which impair performance under normal use as specified in Philips product descriptions and specifications

The warranty period for MRC tubes provided with Customer's purchase of a new or refurbished X-ray system shall be the shorter of thirty-six (36) months after installation or thirty-eight (38) months after date of shipment from Philips. The warranty period for purchases of replacement tubes shall be the shorter of twelve (12) months after installation or fourteen (14) months after date of shipment from Philips.

MRC TUBE WARRANTY EXCLUSION

The above warranty shall not apply to X-ray tubes outside the United States and Canada. Phillips' obligations under the product warranty do not apply to any product defects resulting from: improper or inadequate maintenance or calibration by Customer or its agents; Customer or third party supplied software, interfaces, or supplies, use or operation of the product other than in accordance with loss, or damage in transit; improper site preparation; unauthorized maintenance or Philips' applicable product specifications and written instructions; abuse, negligence, accident, modifications to the product; or, to viruses or similar software interference resulting from the connection of the product to a network

If a tube is found to fail during the warranty period, and if, in the best judgment of Philips, the failure is not due to neglect, accident, improper installation, use contrary to instructions, or the exclusions stated above, Philips' tube warranty liability hereunder is limited to, at Philips option, the repair or replacement of the tube. Any replacement tube would have a warranty period equal to the balance of the warranty period left on the tube replaced.

IMAGE INTENSIFIER TUBES

Philips warrants the image intensifier tubes provided with the System, if any, will be free from defects in material and manufacturing workmanship for twenty-four (24) months. Claims must be made within twenty-four (24) months after installation or twenty-seven (27) months after date of shipment from Philips, whichever occurs first. If an image intensifier tube fails to meet this warranty, as Customer's sole and exclusive remedy, upon return of the tube, Philips will provide a prorated credit towards the purchase of a replacement tube from Philips

USA	AGE		(CREDIT
0	to within	12	months	100%
12	to within	13	months	50%
13	to within	14	months	46%
14	to within	15	months	42%
15	to within	16	months	37%
16	to within	17	months	33%
17	to within	18	months	29%
18	to within	19	months	25%
19	to within	20	months	21%
20	to within	21	months	17%
21	to within	22	months	12%
22	to within	23	months	8%
23	to within	24	months	4%

Tubes received by Philips under this warranty that are found to meet all test specifications will be returned to the Customer and the warranty will continue as of the original date of installation. Examination of the returned tube may necessitate its destruction, but Philips' liability shall, in any case be limited to repair or replacement as aforesaid, only if in its sole opinion the tube has been properly used, installed and applied and has not been subjected to neglect, accident, or improper installation, or use. Transportation charges and risk of loss, both ways, of returned or replaced tubes shall be at the expense of the Customer

DYNAMIC FLAT DETECTORS

Philips warrants the flat detectors provided with the System, if any, will be free from defects in material and manufacturing workmanship for twelve (12) months. Claims must be made within twelve (12) months after installation or fifteen (15) months after date of shipment from Philips, whichever occurs first. If a detector fails to meet this warranty, as Customer's sole and exclusive remedy, upon return of the detector, Philips will provide Customer a replacement detector at no additional charge.

SYSTEM SOFTWARE AND SOFTWARE UPDATES

The software provided with the System will be the latest version of the standard software available for that System as of the 90th day prior to the date the System is delivered to Customer. Updates to standard software for the System that do not require additional hardware or equipment modifications will be performed as a part of normal warranty service during the term of the warranty.

All software is and shall remain the sole property of Philips or its software suppliers. Use of the software is subject to the terms of a separate software license agreement. Customer must sign all such license agreements prior to or upon the delivery of the product. No license or other right is granted to Customer or to any other party to use the software except as set forth in the license agreements.

Any Philips maintenance or service software and documentation provided with the product and/or located at Customer's premises is intended solely to assist Philips and its authorized agents to install and to test the System, to assist Philips and its authorized agents to maintain and to service the System under a separate support agreement with Customer, or to permit Customer to maintain and service the System. Customer agrees to restrict the access to such software and documentation to Philips' employees and those of its authorized agents, and to authorized employees of Customer only.

WARRANTY LIMITATIONS

Philips' obligations under the System warranty are limited, at Philips' option, to the replacement of the System or a portion thereof, or to a credit or refund of a portion of the purchase price paid by Customer. Any refund or credit will be paid to Customer when the System is returned to Philips. Certain of the parts used in the manufacture or installation of, or in the replacement parts for, this System may contain refurbished components. If such components are used, they will be subject to the same quality control and inspection procedures as all other components in the System. Any System warranty is made on condition that Philips receives written notice of a System defect during the warranty period, and within thirty (30) days following the discovery of the defect by Customer. Philips' obligations under the System warranty do not apply to any System defects resulting from: improper or inadequate maintenance or calibration by Customer or its agents; Customer or third party supplied software, interfaces, or supplies; use or operation of the product other than in accordance with loss, or damage in transit; improper site preparation, unauthorized maintenance or Philips' applicable product specifications and written instructions; abuse, negligence, accident, modifications to the System; or to viruses or similar software interference resulting from the connection of the product to a network. Philips does not provide a warranty for any such third party products furnished to Customer by Philips; however, Philips shall use reasonable efforts to extend to Customer the third party warranty for the product. The obligations of Philips' described above are Philips' only obligations and Customer's sole and exclusive remedy for a breach of a System warranty. Repairs or replacement parts do not extend the term of this warranty. parts do not extend the term of this warranty.

THE WARRANTIES SET FORTH IN THIS WARRANTY DOCUMENT WITH RESPECT TO THE SYSTEM (INCLUDING THE SOFTWARE PROVIDED WITH THE SYSTEM), GLASSWARE, AND DETECTORS ARE THE ONLY WARRANTIES MADE BY PHILIPS IN CONNECTION WITH THE SYSTEM, SOFTWARE, GLASSWARE, DETECTORS, AND THE TRANSACTIONS CONTEMPLATED BY THE QUOTATION, AND ARE EXPRESSLY IN LIEU OF ANY OTHER WARRANTIES, EXPRESS OR IMPLIED INCLUDING, WITHOUT THE SYSTEM OF ANY OTHER WARRANTIES, EXPRESS OR IMPLIED INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

ACCESS TO SYSTEM

Philips shall have full, free and safe access to the System and Customer's operation, performance and maintenance records for the System, on each scheduled or requested warranty service visit. Philips shall also have access to and use of any machine, service, attachment, features or other equipment required to perform the necessary service contemplated herein at no charge to Philips. Customer waives warranty service if it does not provide such access to the System and Customer's records. Should Philips be denied access to the System and Customer's records at the agreed upon time, a charge equal to the appropriate hourly rate will be accepted by Customer for "waiting time."

In the event it is not possible to accomplish warranty service within normal working hours (8:00 A.M. to 5:00 P.M., Monday through Friday, excluding Philips observed holidays), or in the event Customer specifically requests that warranty service be performed outside of Phillips normal working hours, Customer agrees to pay for such services at Phillips standard service rates in effect. Maintenance Agreements are available for extended coverage.

TRANSFER OF SYSTEM

In the event Customer transfers or relocates the System, all obligations under this warranty will terminate unless Customer receives the prior written consent of Philips for the transfer or relocation. Upon any transfer or relocation, the System must be inspected and certified by Philips as being free from all defects in material, software and workmanship and as being in compliance with all technical and performance specifications. Customer will compensate Philips for these services at the prevailing service rates in effect as of the date the inspection is performed. Any System which is transported intact to pre-approved locations and is maintained as originally installed in mobile configurations will remain covered by this

CONDITIONS

This warranty is subject to the following conditions: the System (a) is to be installed by authorized Philips representatives (or is to be installed in accordance with all Philips installation instructions by personnel trained by Philips), (b) is to be operated exclusively by duly qualified personnel in a safe and reasonable manner in accordance with Philips written instructions and for the purpose for which the products were intended, (c) is to be maintained and in strict compliance with all recommended and scheduled maintenance instructions provided with the System, and (d) Customer is to notify Philips immediately in the event the System at any time fails to meet its printed performance specifications.

LIMITATIONS OF LIABILITY AND DISCLAIMERS

The liability, if any, of Philips AND ITS AFFILIATES for damages whether arising from breach of the terms in the quotation, breach of warranty, negligence, indemnity, strict liability or other tort, or otherwise with respect to the products and services is limited to an amount not to exceed the price of the product or service giving rise to the liability.

IN NO EVENT SHALL PHILIPS OR ITS AFFILIATES BE LIABLE FOR ANY INDIRECT, PUNITIVE, INCIDENTAL, CONSEQUENTIAL, OR SPECIAL DAMAGES, INCLUDING WITHOUT LIMITATION, LOST REVENUES OR PROFITS, OR THE COST OF SUBSTITUTE PRODUCTS OR SERVICES WHETHER ARISING FROM BREACH OF THE TERMS IN THIS QUOTATION, BREACH OF WARRANTY, NEGLIGENCE, INDEMNITY, STRICT LIABILITY OR OTHER TORT, PHILIPS SHALL HAVE NO LIABILITY FOR ANY GRATUITOUS ADVICE PROVIDED TO THE CUSTOMER.

FORCE MAJEURE

Philips and Customer shall each be excused from performing its obligations arising from any delay or default caused by events beyond its reasonable control including, but not limited to; acts of God, acts of third parties, acts of the other party, acts of any civil or military authority, fire, floods, war, embargoes, labor disputes, acts of sabotage, riots, accidents, delays of carriers, subcontractors or suppliers, voluntary or mandatory compliance with any government act, regulation or request, shortage of labor, materials or manufacturing facilities.

Philips system specifications are subject to change without notice Document Number 4535 983 03234 999

Non Disclosure Agreement for Philips Confidential Pricing Information

The parties specified below agree to the following terms:

A. Philips

Name	Philips Healthcare, a division of Philips Electronics North America Corporation	
Address	22100 Bothell-Everett Highway, Bothell, WA 98021 United States of America	

B. Company

Name	REX HEALTHCARE
Address	4420 LAKE BOONE TRL RALEIGH, NC 27607-7505

C. Confidential Information

Authorized Purpose	To evaluate Philips' confidential information relating to pricing for imaging equipment ("Pricing") in connection with the potential purchase of such imaging equipment.
Period	Begins on the date Pricing is first disclosed and continues for 5 years from date Pricing is last disclosed.

D. Philips Contact

Name	Bethann Griffith-Subik	
Title		
Telephone	(919) 677-9046	
Fax	(919) 677-9047	
e-mail		
Signature		

Company Contact

Name	
Title	
Telephone	
Fax	
e-mail	
Signature	

- 1. The following terms and conditions (the "Agreement") apply to Pricing disclosed by Philips and its Affiliates ("Philips") to Company and its Affiliates ("Company"), in connection with the Authorized Purpose.
 - (a) Subject to Philips' prior written consent, Company may disclose, or request that Philips disclose, Pricing to Company's Affiliates that need to know the Pricing for carrying out the Authorized Purpose, provided they are advised of and agree to be bound by this Agreement. Company is responsible for any breach of this Agreement by its Affiliates.
 - (b) An Affiliate is any corporation, company, or other entity, that: (i) is under the Control of a party hereto; or (ii) has Control of a party hereto; or (iii) is under common Control with a party hereto. For this purpose "Control" means that more than fifty percent (50%) of the controlled entity's shares or ownership interest representing the right to make decisions for such are owned or controlled, directly or indirectly, by the controlling entity.
- 2. Philips may disclose Pricing to Company with respect to the Authorized Purpose in writing, orally, or otherwise. All information is assumed to be Pricing, and confidential, if the confidential or proprietary nature is reasonable under the circumstances.
- 3.All Pricing disclosed by Philips shall remain Philips' the property. Company does not, by implication, estoppel, or otherwise, acquire any intellectual property right, title, or ownership, nor a license to any such intellectual property right, with respect to any Pricing disclosed by Philips hereunder.
 - ALL PRICING IS PROVIDED ON AN "AS IS" BASIS, WITHOUT ANY WARRANTY WHATSOEVER. PHILIPS SHALL HAVE NO LIABILITY WHATSOEVER RESULTING FROM THE USE OF THE INFORMATION PROVIDED.
- 4. Company shall:
 - (a) not use the Pricing for any purpose other than the Authorized Purpose;
 - (b) not disclose the Pricing to any third party;
 - (c) protect the Pricing against disclosure in the same manner and with the same degree of care with which Company protects its own confidential information but not less than a reasonable degree of care; and
 - (d) limit circulation of the Pricing to Company's employees as have a need to know in connection with the Authorized Purpose. These obligations shall survive the termination of this Agreement. Philips may terminate this Agreement at any time by means of a written notice to Company. Company shall return to Philips, or certify destruction of, all Pricing, immediately upon termination or expiration of this Agreement.
- 5. Information disclosed by Philips to Company pursuant to this Agreement shall not be confidential to the extent that the information:
 - (a) is or becomes part of the public domain without violation of this Agreement or any other obligation of confidentiality;
 - (b) is known by Company prior to disclosure by Philips;
 - (c) is lawfully obtained by Company from a third party without any breach of confidentiality or violation of law; or
 - (d) is developed by Company completely independently of any such disclosure by Philips.
- 6. If Company is required, pursuant to administrative or judicial action or subpoena, to disclose the Pricing, Company shall use its best efforts to maintain the confidentiality of the Pricing, e.g. by asserting in such action any applicable privileges. Immediately after gaining knowledge or receiving notice of such action or subpoena, Company shall notify Philips and give Philips the opportunity to seek any other legal remedies so as to maintain such Pricing in confidence, including a reasonable protective order.
- 7. Company may not transfer or assign any or all of its rights and/or obligations or delegate the performance of any or all of its obligations under this Agreement, directly or indirectly, through acquisition, merger or otherwise, without the prior written consent of Philips. Any transfer, assignment or delegation in contravention of the foregoing shall be void.
- 8.Company shall not disclose, export or release the Pricing in contravention of any applicable laws or regulations.
- This Agreement shall be governed and construed in accordance with the laws of the State of New York, without giving effect to its conflict of laws provisions.
- 10. This Agreement contains the entire understanding of the parties and supersedes any previous understandings or agreements with respect to the subject matter hereof. This Agreement may be amended only in writing signed by authorized representatives of each party.

Pricing NDA ver1 - 8/9/07

Exhibit 4



North Carolina Department of Health and Human Services Division of Health Service Regulation

Pat McCrory Governor Richard O. Brajer Secretary DHHS

Drexdal Pratt Division Director

August 24, 2015

Lisa Griffin Manager Certificate of Need Business Planning Novant Health, Inc. 2085 Frontis Plaza Drive Winston-Salem, North Carolina 27103

Exempt from Review - Replacement Equipment

Record #:

1693

Facility Name:

Novant Health Matthews Medical Center (NHMMC)

FID #:

945076

Business Name:

Novant Health, Inc.

Business #:

1341

Project Description:

Replace vascular lab located at NHMMC

County:

Mecklenburg

Dear Ms. Griffin:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letters of July 15, 2015 and August 20, 2015, the above referenced proposal is exempt from certificate of need review in accordance with G.S 131E-184(a)(7). Therefore, you may proceed to replace the existing GE Vascular Lab, model number OED 9900 Elite, located in the Vascular Lab Room of NHMMC in Matthews, with a comparable vascular lab. The Agency understands, per your representations in additional correspondence received, that the existing GE Vascular lab will be relocated for use elsewhere in the state and that the total costs, including the fair market value of the existing GE Vascular Lab, will be under \$750,000, and therefore will not require a certificate of need.

Moreover, you need to contact the Agency's Construction and Acute and Home Care Licensure and Certification Sections to determine if they have any requirements for development of the proposed project.

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



Office of the Director

http://www.ncdhhs.gov/dhsr/ Phone: 919-855-3750 / Fax: 919-733-2757

Location: 809 Ruggles Drive, Dorothea Dix Hospital Campus, Raleigh, N.C. 27603 Mailing Address: 2701 Mail Service Center • Raleigh, North Carolina 27699-2701

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Lisa Griffin August 24, 2015 Page 2

separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

Gloria C. Hale Project Analyst Martha J. Frisone,

Assistant Chief, Certificate of Need

cc:

Construction Section, DHSR

loria C. Hale

Acute and Home Care Licensure and Certification Section, DHSR

Assistant Chief, Healthcare Planning

Hale, Gloria

From:

Griffin, Lisa L (CON) < llgriffin@novanthealth.org>

Sent:

Thursday, August 20, 2015 12:28 PM

To:

Hale, Gloria

Subject:

RE: Replacement Equipment Exemption Request for Vascular Lab at NHMMC

Attachments:

Vascular Lab Lifesafety Plan.pdf

Follow Up Flag:

Follow up Flagged

Flag Status:

Good afternoon, Gloria:

This email is in response to your email requesting additional information related to the Novant Health Matthews Medical Center Vascular Lab replacement equipment exemption request. In response to Item #1, I have attached a drawing of the 2nd Floor of NHMMC indicating the location of the Vascular Lab (enlarge to see lower left side of drawing). This is the only Vascular Lab at MMC and the new equipment is to be installed in that same location.

In response to Item #2, the existing vascular lab equipment is to be relocated to Novant Health Vascular Specialists in Salisbury, Rowan County, NC. Novant Health Vascular Specialists are a physician group employed by Novant Health. It is our understanding that since Vascular Lab equipment is not specifically regulated by an SMFP need determination or other statute in NC, that the existing equipment could be relocated within the state as long as the total costs of the relocation, including the FMV of the existing equipment, is under the \$750,000 threshold for Major Medical Equipment at NCGS 131E-176(14o). The total project cost for the relocation of the existing vascular lab equipment within the Novant Health system will be under \$750,000. In addition, on April 2, 2015, Barbara Freedy, Novant Health CON Director, discussed this matter with Martha Frisone and June Farrell, when they were at a CON medication session together. Barb's notes from that day indicate that Martha advised us that so long as the total capital cost of the project, including the FMV or purchase price of the vasc unit we hope to transfer to Salisbury/Rowan County, is less than \$750,000, we do not need to file any CON Application or submit prior written notice to the CON Agency based on the statutory language. We are not aware of any prior written notice language in the current definition of Major Medical Equipment. If the Agency's interpretation has changed, please let us know.

Please let me know if you have any other questions or need further information.

Lisa Griffin Manager, Certificate-of-Need/Business Planning Novant Health (704) 384 - 3462

From: Hale, Gloria [mailto:gloria.hale@dhhs.nc.gov]

Sent: Monday, August 17, 2015 4:48 PM

To: Griffin, Lisa L (CON)

Subject: RE: Replacement Equipment Exemption Request for Vascular Lab at NHMMC

Ok, I will try e-mail and if you have any questions about what we need, feel free to call me.

- 1 –Do you know what room number the vascular lab is in at NHMMC? Is there only one vascular lab there? Please provide.
- 2 The letter and appendices do not clearly indicate that the existing vascular lab that will be replaced will not be used again in the state and will be removed from North Carolina. Appendix B indicates that a company will relocate it to Salisbury. The existing unit cannot be relocated and used elsewhere in the state without a CON. So, please provide written clarification on Novant Health, Inc.'s intention in regard to the vascular lab unit to be replaced.

Thanks, Lisa.

Gloria C. Hale, MPH
N.C. Department of Health and Human Services
Project Analyst, Healthcare Planning and Certificate of Need Section - Division of Health Service Regulation 809 Ruggles Drive
Raleigh, NC 27603
(Office) 919-855-3873
gloria.hale@dhhs.nc.gov
www.ncdhhs.gov/dhsr

From: Griffin, Lisa L (CON) [mailto:llgriffin@novanthealth.org]

Sent: Monday, August 17, 2015 4:37 PM
To: Hale, Gloria <gloria.hale@dhhs.nc.gov>

Subject: RE: Replacement Equipment Exemption Request for Vascular Lab at NHMMC

Gloria,

I am not in the office tomorrow but working from home in the morning and then traveling and attending the FMC Mobile PET Hearing in Kernersville. You may call my cell at 704-351-1132 between 9 and 11 AM or email the questions to me.

Thanks, ---Lisa

----Original Message----

From: Hale, Gloria [gloria.hale@dhhs.nc.gov]

Sent: Monday, August 17, 2015 04:27 PM Eastern Standard Time

To: Griffin, Lisa L (CON)

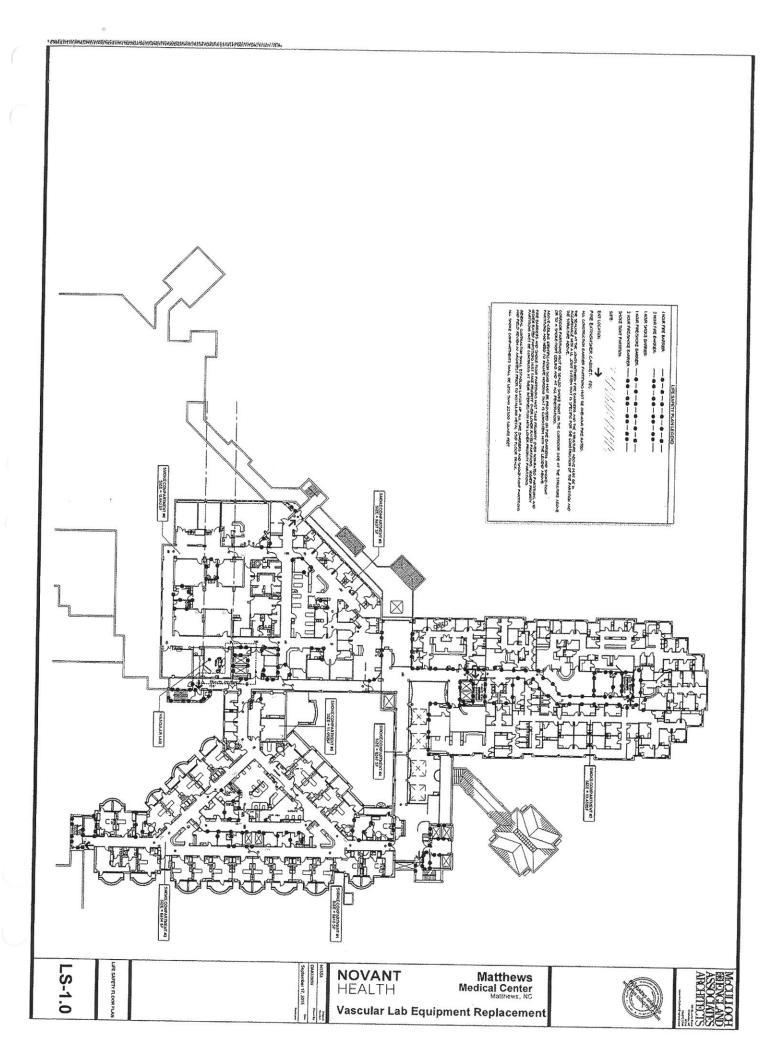
Subject: RE: Replacement Equipment Exemption Request for Vascular Lab at NHMMC

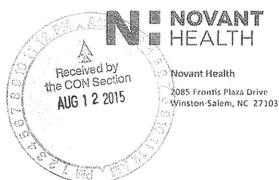
Lisa, I do need a couple of clarifications on this request afterall. I will call you.

Gloria C. Hale, MPH

N.C. Department of Health and Human Services

Project Analyst, Healthcare Planning and Certificate of Need Section - Division of Health Service Regulation 809 Ruggles Drive Raleigh, NC 27603





July 15, 2015

Ms. Martha Frisone, Assistant Chief Healthcare Planning & Certificate of Need Section North Carolina Department of Health & Human Services 809 Ruggles Drive Raleigh, North Carolina 27603

Re: Replacement Equipment Exemption Request for the Vascular Lab at Novant Health Matthews Medical Center (NHMMC); Mecklenburg County

Dear Ms. Frisone:

This letter outlines Novant Health Matthews Medical Center's (NHMMC's) project to replace an existing, operational vascular lab located in the hospital in Matthews, North Carolina. See Attachment A for the vascular lab unit vendor quote from Siemens Medical Solutions. The total costs related to the replacement of the Vascular Lab are \$1,274,888 (including the new Vascular Lab equipment cost of \$799,547). Also, included as Movable Equipment related to the purchase of the new Vascular Lab and found in Attachment A is an injector. In addition, a new server and software upgrade are included in the project costs and detailed in Attachment A. First Call Parts of Salem, Virginia, will remove the existing vascular lab from NHMMC for a cost of \$1,500 (see Attachment B.)

The project cost does not include sales, property or excise taxes since NHMMC is a non-profit, tax-exempt organization and is not subject to these taxes at the time this request was submitted. In addition, the expenses for on-site training on the new unit for the NHMMC vascular lab staff is covered by the vendor as indicated on pages 6 and 9 of vendor quote in **Attachment A**. Both the existing equipment and the replacement equipment are comparable medical equipment as explained on the following page. This project should be approved by the Agency as exempt pursuant to N.C.G.S. Section 131E-184(a)(7) which states that a project is exempt from Certificate of Need review if the facility provides prior written notice to provide replacement equipment.

This exempt project will replace a functionally similar operational unit of medical equipment at NHMMC. The inventory of vascular labs in Mecklenburg County will not increase as a result of this project.

Ms. Martha Frisone
July 15, 2015
Replacement Equipment Request – NHMMC Vascular Lab Replacement
Page 2

The proposed new Vascular Lab equipment is consistent with the replacement equipment definition at N.C.G.S. Section 131E-176(22a) which states that the replacement equipment is comparable to the equipment being replaced if it has the same technology as the equipment currently in use, although it may possess expanded capabilities due to technological improvements. The existing vascular lab equipment is used for vascular procedures at NHMMC and the replacement equipment will be used for vascular procedures at NHMMC. Also, the replacement equipment costs less than \$2 million dollars with total capital costs of the Vascular Lab replacement and relocation of \$1,274,888.

Pursuant to 10A NCAC 14C.0303 the proposed Vascular Lab equipment constitutes replacement equipment because:

- 1. It is comparable to the equipment currently in use. It has the same technology as the equipment currently in use, although it does possess expanded capabilities due to the technological improvements.
- 2. It is functionally similar and is used for the same diagnostic or treatment purposes as the equipment currently in use and is not used to provide a new health service.
- 3. The acquisition of the new 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 replacement equipment is not capable of performing procedures that will result in the provision of a new health service or type of procedure that has not been provided with the existing equipment.

Attached for your convenience please find:

- 1) a vendor equipment price quote including moveable equipment items (Attachment A);
- 2) a vendor quote regarding removal of existing NHMMC Vascular Lab equipment (Attachment B);
- project/capital cost schedule which identifies the components of the total project costs (Attachment C);
- 4) a certified estimate of related construction costs from an independent licensed North Carolina architect (Attachment D); and,
- 5) the NC CON equipment comparison form summarizing essential information about the proposed equipment purchase (Attachment E).

Ms. Martha Frisone
July 15, 2015
Replacement Equipment Request – NHMMC Vascular Lab Replacement
Page 3

NHMMC's acquisition of the replacement Vascular Lab equipment does not require a certificate of need because none of the definitions of "new institutional health service" set forth in N.C.G.S. Section 131E-176(16) is implicated. As discussed above, the total cost for the project is \$ 1,274,888. This includes the cost of the equipment, as well as studies, surveys, designs, plans, working drawings, specifications, construction installation, and, other activities essential to making the equipment operational (such as staff training).

In conclusion, based on the information described above, please confirm that NHMMC's replacement of Vascular Lab equipment does not constitute a "new institutional health service" and does fit within the replacement equipment exemption definition. Therefore, the project is not subject to certificate of need review.

Please let us know as soon as possible if you need additional information to assist in your consideration of this request. Thank you for your prompt consideration of this request.

Sincerely,

Lisa Griffin

Manager, Certificate of Need Financial Planning and Analysis

Novant Health, Inc.

Enclosures

cc:

Barbara Freedy, Director, CON, Novant Health, Inc.

Laura MacFadden, Vice President, Design & Construction, Novant Health, Inc.

File: MMC VascLab REER Cover Letter 07 15 15.doc