



NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

July 25, 2019

Elizabeth Kirkman
Elizabeth.kirkman@atriumhealth.org

Exempt from Review – Replacement Equipment

Record #: 2996
Facility Name: Atrium Health Cleveland
FID #: 953106
Business Name: Atrium Health Cleveland
Business #: 3072
Project Description: Replace vascular lab interventional x-ray equipment
County: Cleveland

Dear Ms. Kirkman:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of July 11, 2019, the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-184(a)(7). Therefore, you may proceed to acquire without a certificate of need the GE Innova IGS 540 interventional x-ray equipment to replace the GE Innova 4100 interventional x-ray equipment. This determination is based on your representations that the existing unit will be sold or otherwise disposed of and will not be used again in the State without first obtaining a certificate of need if one is required.

Moreover, you need to contact the Agency's Construction, Radiation Protection 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.

Sincerely,

[Handwritten signature of Ena Lightbourne]

Ena Lightbourne
Project Analyst

[Handwritten signature of Martha J. Frisone]
Martha J. Frisone
Chief

cc: Construction Section, DHSR
Radiation Protection Section, DHSR
Acute and Home Care Licensure and Certification Section, DHSR

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

LOCATION: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603
MAILING ADDRESS: 809 Ruggles Drive, 2704 Mail Service Center, Raleigh, NC 27699-2704
www.ncdhhs.gov/dhsr • TEL: 919-855-3873



Atrium Health



July 11, 2019

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

RE: Exemption Request for The Charlotte Mecklenburg Hospital Authority d/b/a Atrium Health Cleveland (“AH Cleveland”) to Replace Vascular Lab Interventional X-Ray Equipment

Dear Ms. Frisone:

Atrium Health Cleveland (“AH Cleveland”) is planning to replace existing vascular lab interventional x-ray equipment with new, technologically comparable equipment. AH Cleveland intends to purchase a GE Innova IGS 540 interventional x-ray system (“Replacement Equipment”) to replace the GE Innova 4100 interventional x-ray system (“Existing Equipment”) that is currently located in the vascular lab housed in room 1248 at AH Cleveland. The Existing Equipment, which was purchased in 2005, is beyond its useful life and is at risk for service interruptions due to downtime.

The Replacement Equipment will be located in the vascular lab housed in room 1248 at AH Cleveland. The Replacement Equipment will be used for the same types of procedures as the Existing Equipment and will not be used to provide a new health service. A chart comparing the Existing Equipment and the Replacement Equipment is included in Attachment A along with supporting documentation. The Existing Equipment is currently in use and documentation provided in Attachment B indicates 314 procedures were performed from June 2018 through May 2019.

The purchase price of the Replacement Equipment is \$751,488 (\$699,059 interventional x-ray equipment + \$52,429 tax). The projected total capital cost of the project is \$1,020,388 and includes the cost to acquire, install, and make operational the Replacement Equipment. The projected total capital cost also includes removal and replacement of the existing flooring and casework in the vascular lab, as well as enclosing the electrical trough. Attachment C provides the quote for the interventional x-ray equipment. Please see Attachment D for a letter documenting that the Existing Equipment will be taken out of service and removed from North Carolina. The total capital cost worksheet is provided in Attachment E.

The North Carolina Certificate of Need statutes provide a definition of replacement equipment in N.C.G.S. 131E-176(22a). The definition requires the replacement equipment be comparable to

the existing medical equipment and cost less than \$2,000,000 when installed. The statutes further provide in 131E-184(a)(7) an exemption from certificate of need review for replacement equipment projects if prior notice is provided to the CON Section.

Based on the above facts, the proposed project is exempt from CON review and this letter serves as prior notification of our intent to proceed with this project. We would appreciate your written concurrence that this project is exempt from CON review. If you have any questions or require further information regarding this project, please contact me at 704-446-8475.

Sincerely,

A handwritten signature in cursive script that reads "Elizabeth Kirkman".

Elizabeth Kirkman, Assistant Vice President
Atrium Health Strategic Services Group

Attachments

Attachment A

EQUIPMENT COMPARISON – AH Cleveland Vascular Lab Interventional X-Ray Replacement

	Existing Equipment	Replacement Equipment
Type of Equipment (List each component)	Vascular Lab Interventional X-ray	Vascular Lab Interventional X-ray
Manufacturer of Equipment	GE	GE
Tesla Rating for MRIs	N/A	N/A
Model Number	Innova 4100	Innova IGS 540
Serial Number	Asset #000000001647	Not Available Until Installed
Provider's Method of Identifying Equipment	Internal Asset # / Serial #	Internal Asset # / Serial #
Specify if Mobile or Fixed	Fixed	Fixed
Mobile Trailer Serial Number/VIN #	N/A	N/A
Mobile Tractor Serial Number/VIN #	N/A	N/A
Date of Acquisition of Each Component	2005	2019
Does Provider Hold Title to Equipment or Have a Capital Lease?	Title	Title
Specify if Equipment Was/Is New or Used When Acquired	Refurbished	New
Total Capital Cost of Project (Including Construction, etc.)	\$976,608	\$1,020,388
Total Cost of Equipment	\$875,003	\$751,488
Fair Market Value of Equipment	\$43,750	\$751,488
Net Purchase Price of Equipment	\$875,003	\$751,488
Locations Where Operated	AH Cleveland Vascular Lab, Rm. 1248	AH Cleveland Vascular Lab, Rm. 1248
Number Days in Use/To Be Used in N.C. per Year	320 days/year	320 days/year
Percent of Change in Patient Charges (by procedure)	0%	0%
Percent of Change in Per Procedure Operating Expenses (by procedure)	0%	0%
Type of Procedures Currently Performed on Existing Equipment	Vascular procedures	N/A
Type of Procedures New Equipment is Capable of Performing	N/A	Vascular procedures

Innova IGS 540

Advanced visualization for complex interventional radiology & interventional oncology procedures

Advanced visualization and streamlined workflow

The IGS 550 brings the enhanced visualization, workflow integration and image clarity you need to address all IR and IO procedures, from routine diagnostic to complex liver, needle and EVAR procedures.

Extensive body coverage



GE's 41 x 41 cm panel:
41% greater FOV*

With its 41 x 41 cm (16.1 in) square flat-panel digital detector, the IGS 540 is among the largest in the industry. It provides 41% greater field-of-view versus common industry rectangular panels, helping to reduce the need table panning, potentially decrease number of runs which results in less dose, contrast and a shorter procedure.



panels

The large field of view is also enables large volume 3D acquisition.** As 3D cone-beam CT becomes increasingly required when completing complex interventional cases, the IGS 540 provides incredible 3D volume with

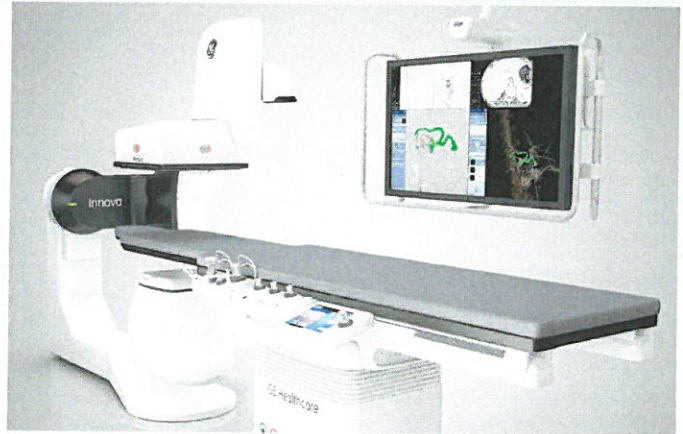
a single spin. The workflow is designed to be simple and intuitive with a test spin prior to the 3D acquisition to verify collisions are avoided.



*Compared to a 30 cm x 40 cm panel.

**Innova 3D is a purchasable option.

1. ASSIST solutions are composed of multiple medical devices. For more information, please refer to website www.gehealthcare.com/assist.
2. Needle ASSIST solution includes TrackVision 2 and requires AW workstation with Volume Viewer, Volume Viewer Interventional. These applications are sold separately.



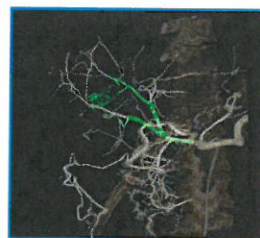
Simple, centralized, automated controls

Control your system and images with integrated, intuitive tableside controls. With simple menus, the central touchscreen lets you control most system functions, configure the system, modify imaging parameters, control your large display monitor, and manipulate advanced applications – all at the tableside.

ASSIST¹ portfolio of advanced applications

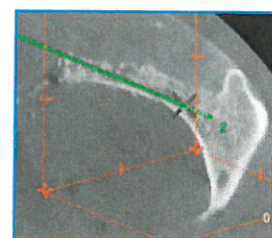
As the field of interventional radiology and oncology grows, so do the challenges for clinicians to plan, guide and assess complex minimally invasive procedures. To address these challenges, we have developed the ASSIST package of interventional imaging software. These tools are designed to help you grow your practice and accomplish more complex procedures with the same ease and confidence as routine procedures.

ASSIST applications for IR and IO:



Flight Plan for Liver, an ASSIST brand

Intuitive 3-step tool to help identify tumor-feeding vessels and to be selective in liver embolization procedures.



Needle ASSIST²

Designed to help you progress needles with precision and confidence during percutaneous access and potential ablation of spine, bone or lung tumors.

PCI ASSIST

Simplify complex coronary interventions with PCI ASSIST¹

PCI procedures are becoming more complex. Imaging new stents can be a challenge. PCI ASSIST is an integrated solution to help plan, guide and assess PCI procedures. It includes visibility improvements; StentViz and StentVesselViz.

In cardiology, one of the main challenge is the motion of the heart and the respiratory cycle. This motion makes it difficult to visualize small vessels and have a precise assessment of stent positioning. The movement of the heart and lungs can create blurring in the image, adding another level of complexity.

*PCI ASSIST helps improve visibility in moving anatomy up to +85% visibility at the same dose.**

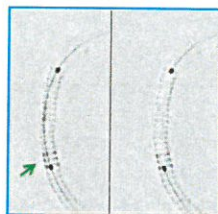
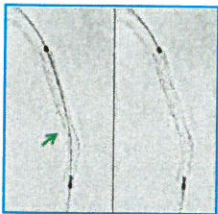
Obesity is increasing in the Western World. Obese patients place special needs upon imaging equipment and create technical challenges:

- Image quality degradation due to attenuation of the X-ray and photon scattering
- Increased radiation doses

*PCI ASSIST helps improve visibility in larger patients up to +75% visibility improvement on large patients at the same dose.**

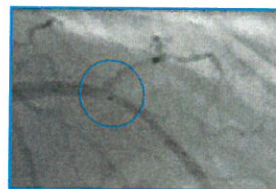
During PCI procedures, it can be difficult to assess the correct deployment of the stents. The new generation of stents, such as BVS, can be especially difficult to image. This has implications such as:

- Management of coronary artery bifurcation disease and potential risk of late stent thrombosis
- Residual lumen stenosis due to inadequate balloon expansion and elastic recoil
- Side branch complication after a single-stent crossover technique



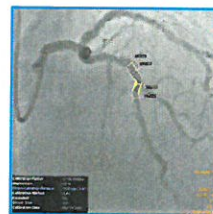
PCI ASSIST helps with stent deployment by enhancing visibility of the stent structure with StentViz.

It can be a challenge to visualize stents and their relation to the vessel and other stents. Visualizing the deployed stent can be difficult. The optimization of the stent overlap is important (no geographical miss, not too long of an overlap) and accurate positioning of a 2nd stent versus the side branch is critical.



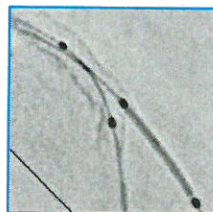
PCI ASSIST helps with stent positioning and evaluate deployment by enhancing the visibility of the stent in relation to the vessel or side branch with StentVesselViz.

Achieve clinical excellence in PCI



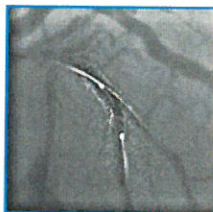
PLAN

Measure the vessel size and percent stenosis with OneTouchQA to help plan the optimal size stents required.



GUIDE

StentViz was used to guide the stents to reach minimal overlap.



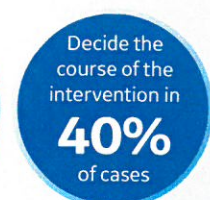
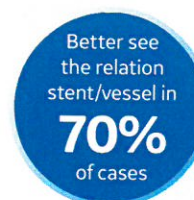
ASSESS

StentVesselViz enabled assessment of stent deployment in relation to the vessel wall.

* Improvement vs. same test without HCF option. IQ & visibility improvement is measured on Innova IGS 530 with phantoms using various Plexiglass.

1. PCI ASSIST refers to features of Innova IGS 520, Innova IGS 530 and Discovery™ IGS 730.
2. DOC1683165 – Clinical evidences generation study based on Columbia images. The Statements by GE's customers described here are based on results that were achieved in the customer's unique setting. Since there is no "typical" hospital and many variables exist, i.e. hospital size, case med, there can be no guarantee that other customers will achieve the same results. Method: Assessment of clinical benefit of StentVesselViz: Independent assessment of each sequence by 6 experienced interventional cardiologists; Assessment done in 2 steps by each reviewer: 1) conventional post-deployment angiogram alone x 11 clinical cases. 2) angio + SVV sequence x 11 same clinical cases. Results are based on Consensus of 5/6 operators.

PCI ASSIST helped:²



Attachment B

AH Cleveland Vascular Lab (Rm. 1248) Interventional X-Ray Volume

Month	Volume
Jun-18	28
Jul-18	40
Aug-18	29
Sep-18	26
Oct-18	26
Nov-18	24
Dec-18	17
Jan-19	31
Feb-19	25
Mar-19	21
Apr-19	20
May-19	27
Total	314

Attachment C



GE Healthcare

Date: 12-20-2018
Quote #: PR9-C128012
Version #: 2
Q-Exp-Date: 12-31-2018

Issued By:
GE Healthcare
FEIN: 14-0689340

Customer Address:
Atrium Health Cleveland
201 E Grover St
Shelby NC 28150-3917

Attention:
Tom Draper

This Agreement (as defined below) is by and between the Customer and the GE Healthcare business ("GE Healthcare"), each as identified herein. "Agreement" is defined as this Quotation and the terms and conditions set forth in either (i) the Governing Agreement identified below or (ii) if no Governing Agreement is identified, the following documents:

- 1) This Quotation that identifies the Product offerings purchased or licensed by Customer;
- 2) The following documents, as applicable, if attached to this Quotation: (i) GE Healthcare Warranty(ies); (ii) GE Healthcare Additional Terms and Conditions; (iii) GE Healthcare Product Terms and Conditions; and (iv) GE Healthcare General Terms and Conditions. In the event of conflict among the foregoing items, the order of precedence is as listed above.

This Quotation is subject to withdrawal by GE Healthcare at any time before acceptance. Customer accepts by signing and returning this Quotation or by otherwise providing evidence of acceptance satisfactory to GE Healthcare. Upon acceptance, this Quotation and the related terms and conditions listed above (or the Governing Agreement, if any) shall constitute the complete and final agreement of the parties relating to the Products identified in this Quotation.

No agreement or understanding, oral or written, in any way purporting to modify this Agreement, whether contained in Customer's purchase order or shipping release forms, or elsewhere, shall be binding unless hereafter agreed to in writing by authorized representatives of both parties.

By signing below, each party certifies that it has not made any handwritten modifications.

Governing Agreement:	CSS-GEHC MVA July 15 2011
Customer Number:	1-2313PI
Terms of Delivery:	FOB Destination
Billing Terms:	100% billing at Ship Completion (Fulfillment) / Delivery
Payment Terms:	60 DAYS NET
Total Quote Net Selling Price:	\$699,059.02
Sales And Use Tax Status:	No Exemption Certificate on File

** The following ship to states do not impose a sales/use tax (AK, DE, MT, NH, OR). No exemption certificate required.

INDICATE FORM OF PAYMENT:	
If "GE HEF Loan" or "GE HEF Lease" is NOT selected at the time of signature, then you may NOT elect to seek financing with GE Healthcare Equipment Finance (GE HEF) to fund this arrangement after shipment.	
<input type="checkbox"/> Cash/Third Party Loan/Check	<input type="checkbox"/> GE HEF Loan
<input type="checkbox"/> GE HEF Lease	<input type="checkbox"/> Third Party Lease(please identify financing company) _____

By signing below, each party certifies that it has not made any handwritten modifications. Manual changes or mark-ups on this Agreement (except signatures in the signature blocks and an indication in the form of payment section below) will be void.

Each party has caused this agreement to be executed by its duly authorized representative as of the date set forth below.

CUSTOMER

Authorized Customer Signature Date

Print Name Print Title

Purchase Order Number (if applicable)

GE HEALTHCARE
Herbert Klann 12-20-2018

Signature Date

Imaging Account Manager
Email: Herb.Klann@ge.com
Office: +1 724 504 8778
Mobile: 724-504-8778



GE Healthcare

Date: 12-20-2018
Quote #: PR9-C128012
Version #: 2
Q-Exp-Date: 12-31-2018

Total Quote Selling Price	\$724,059.02
Trade-In and Other Credits	\$25,000.00

Total Quote Net Selling Price	\$699,059.02

To Accept this Quotation

Please sign and return this Quotation together with your Purchase Order To:

Herbert Klann
Office: +1 724 504 8778
Mobile: 724-504-8778
Email: Herb.Klann@ge.com

Payment Instructions

Please **Remit** Payment for invoices associated with this quotation to:

GE Healthcare
P.O. Box 96483
Chicago, IL 60693

To Accept This Quotation

- Please sign the quote and any included attachments (where requested).
- If requested, please indicate, your form of payment.
- If you include the purchase order, please make sure it references the following information
 - The correct Quote number and version number above
 - The correct Remit To information as indicated in "**Payment Instructions**" above
 - The correct SHIP TO site name and address
 - The correct BILL TO site name and address
 - The correct Total Quote Net Selling Price as indicated above

"Upon submission of a purchase order in response to this quotation, GE Healthcare requests the following to evidence agreement to contract terms. Signature page on quote filled out with signature and P.O. number.

*****OR*****

Verbiage on the purchase order must state one of the following: (i) Per the terms of Quotation # _____; (ii) Per the terms of GPO# _____; (iii) Per the terms of MPA # _____; or (iv) Per the terms of SAA # _____. Include the applicable quote/agreement number with the reference on the purchase order.

In addition, source of funds (choice of: Cash/Third Party Loan or GE HEF Lease or GE HEF Loan or Third Party Lease through _____), must be indicated, which may be done on the quote signature page (for signed quotes), on the purchase order (where quotes are not signed) or via a separate written source of funds statement (if provided by GE Healthcare)."



Item No.	Qty	Catalog No.	Description
	1		IGS 5 - config 540
1	1	S18941EN	IGS 540 with Omega V
2	2	S18061TP	SmartBox for Innova IGS with Omega Tables New SmartBox for Simplified and Intuitive Joystick Control of Positioner and Table <ul style="list-style-type: none"> Anatomical and mechanical positioning Independent or simultaneous movement of all three positioner axes Remote SID Control Manual or motor assisted 4-way table panning Ergonomic design Hermetically sealed
3	1	S18061TA	Second TSSC Control for IGS with Omega Tables
4	1	S18061MB	2 Inch Comfort Table Mattress
5	1	S18061AZ	Head Extender
6	1	S18061MH	Head support widener for InnovaIQ Table with Tilt and OR Table
7	1	S18101CD	The 8kVA UPS allows to maintain gantry movements and Innova IQ table movements during mains power failure.
8	1	S18761PP	The Power Distribution Unit provides power for the components of the system and centralizes the ON/OFF function
9	1	S18751BR	Blended Roadmap Blended Roadmap is a vascular roadmapping application that superimposes a previously acquired vascular image over live fluoroscopy. Clinicians can select any DSA or bolus image as a reference roadmap image. By using it multiple times, it has the potential to minimize contrast media injections during roadmapping. Blended roadmap provides additional features to enhance roadmapping procedures: <ul style="list-style-type: none"> Adjustment of the subtraction level Adjustment of the vessels transparency Automatic resizing of the roadmap image to adapt to the fluoroscopic field of view Pixel shift of the vessel image to compensate for motion



Item No.	Qty	Catalog No.	Description
			Blended Roadmap is available on systems with either Omega V or InnovalQ tables. Blended Roadmap requires the Advanced Innova Software Package. On the biplane systems it can be applied to one frame at a time.
10	1	S18811PA	<p>Quantitative Analysis Package</p> <p>Stenosis Analysis Package on DL Digital System The Stenosis Analysis Package is an application designed for estimating vessel dimensions and relevant parameters of the arterial Stenosis morphology in X-Ray angiography. The system is capable of automatic detection of vessel edges and display of stenosis severity.</p> <p>Left Ventricular Analysis Package The Left Ventricular Analysis Package is an expert reporting tool designed to estimate wall motion dynamics of the left ventricle, and to perform Global Ejection Fraction Analysis in X-Ray angiography. The system is capable of providing Wall Motion and Global Ejection Fraction measurements. Wall Motion is built on the centerline method. GEF analysis is calculated using both Simpson's rule method and the Dodge-Sandler area-length method</p> <p>Cardiovascular Analysis Package (on DL system) The Cardiovascular Analysis Package includes both the Stenosis Analysis Package and the Left Ventricular Analysis Package. The Stenosis Analysis Package is an application designed to estimate vessel dimensions and relevant parameters of the arterial Stenosis morphology in X-Ray angiography. The system is capable of automatic detection of vessel edges and display of stenosis severity. The Left Ventricular Analysis Package is an expert reporting tool designed to estimate wall motion dynamics of the left ventricle, and to perform Global Ejection Fraction analysis in X-Ray angiography. The system is capable of providing Wall Motion and Global Ejection Fraction measurements (GEF). Wall Motion is built on the centerline method. GEF analysis is calculated using both Simpson's rule method and the Dodge-Sandler area-length method.</p>
11	1	S18741BX	InnovaBreeze lets the user follow the contrast using variable panning speed control in the control room while looking at subtracted images in real time
12	1	S18951DM	DOSE MAP
13	1	S18461NR	Large Display Solution with Video Server 10 inputs.
14	1	S18391PM	Mavig Monitor Suspension for Large Display Monitor with 36m Cable
15	1	S18461LV	Link Set for IVUS Volcano



Item No.	Qty	Catalog No.	Description
16	1	S18461LG	Link Set for Digital and Analog Ultrasound
17	1	S18461LY	Link Set Open 2 Suitable for anesthesia monitors, camera, etc.
18	1	S18461LX	Link Set Open 3 Suitable for Veran, anesthesia monitors, camera, etc.
19	1	S18461AD	Analog to Digital Converter Kit
20	1	M81521KC	AW VolumeShare 7 for Interventional with 32GB of RAM. DOES NOT include Volume Viewer. AW VolumeShare 7 is a multi-modality image review, comparison and post processing workstation built with simplicity and power at its core. Powerful software is optimized to take advantage of state of the art 64 bit technology and multiple cores to ensure leading edge performance. AW VolumeShare 7 features include: Hardware: o HP Z440 Workstation o CPU: Intel Xeon E5-1660v3 (Haswell) Eight-Core @ 3.0 GHz with 20MB L3 Shared Cache each with Dual QPI @ 8 GT/s o RAM: 32GB (8x4GB) Four-channel DDR4 ECC RSIMM @ 2133 MHz o GRAPHICS: NVIDIA Quadro NVS310 with 1 GB Video RAM o 1x 256GB SATA3 SSD for OS and Apps o 2x 512GB SATA3 SSD in RAID 0 for 1TB data storage o VGA Video Convert Kit



Item No.	Qty	Catalog No.	Description
			<p>Software:</p> <ul style="list-style-type: none"> o GE Healthcare HELIOS 6 operating system o Demo Exams for training and exploration o Fast access to information you need through optional RIS integration & priors post-fetch o Efficient workflow through dynamic load, end review and Key Image Notes features o Productivity package to pre-process exams and allow up to 8 simultaneous sessions o Applications usage monitor to track and view usage of your system o Smart layouts with Volume Viewer General review protocol that optimizes comparison and single exam layouts o Enhanced multi-modality contouring tool with support for PET SUVs o Support for external DICOM USB media and preference management tool to exchange preferences across users o Support for optional, broad suite of multi-modality advanced applications
21	1	M80281AA	<p>AW VolumeShare 7 Monitors are two high-quality monitors offering bright and high contrast imagery suited to the display of medical images per the AW VolumeShare Indications for Use. Each provides a 19" 1280x1024 (5:4 aspect ratio) display that complies with international medical and patient safety standards and offers the following specifications:</p> <ul style="list-style-type: none"> • Maximum luminance (panel typical) : 330 nit • DICOM Part 14 calibrated luminance: 215 nit • Contrast ratio (panel typical) : 900:1 • An ambient light sensor • Brightness non-uniformity (measured as per DIN6868-157) : +/-25%
22	1	E4502SS	The X-Ray in use Warning and Room Lighting Control Panel provides an interface



Item No.	Qty	Catalog No.	Description
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between the X-Ray in use warning lights, interior room general lighting, and the X-Ray system. The X-Ray in use portion of the panel provides low voltage control of the X-Ray in Use Warning Lights and the room general lighting is controlled by a pre-wired foot switch

- Designed and tested for GEHC products, for use in CT, PET/CT and X-Ray applications
- Can eliminate procurement inconveniences and delivery delays often associated with acquiring individual components
- Improves servicing safety by the eliminating of the warning light/room general lighting circuit from the imaging control system cabinet.

NOTES:

- Customer is responsible for rigging and arranging for installation with a certified electrician
- ITEM IS NON-RETURNABLE AND NON-REFUNDABLE

23 1 E6220J

VIS-A-VIS Vitalinq Intercom System for X-ray

The VIS-A-VIS Vitalinq intercom system for X-ray is a two-way communication system that is designed to meet the specific needs that arise during diagnostic and interventional procedures. It enables physicians to have continuous two-way conversation with the control room operator during diagnostic and interventional procedures.

FEATURES/BENEFITS

- Capable of picking up conversation in a normal tone of voice, Vitalinq allows control room operators to respond immediately to physicians' requests
- Larger format and unique pyramidal construction of the microphones contribute to Vitalinq's high intelligibility, even within the acoustically active space of a full-functioning procedure room
- Designed to minimize the loss of articulation by reducing the potential echo path it gathers and transmits speech in a highly efficient manner

SPECIFICATIONS

- Dimensions: 24" x 24" x 20"
- Weight: 47 lbs.

NOTES:

- INSTALLATION IS THE RESPONSIBILITY OF THE CUSTOMER



Item No.	Qty	Catalog No.	Description
			<ul style="list-style-type: none"> Warranty Period 6 months - Exchange of non conforming products, which are returned to GE during warranty period. Installation, parts, application training and onsite service is the buyer's responsibility
24	1	E6420BL	<p>HB-2 Double Vertical Articulating Armboard</p> <p>This radiolucent, advanced composite armboard articulates in both the horizontal and vertical planes, allowing virtually unobstructed fluoroscopy of catheter placement. Advanced hinge design allows the user to set a vertical position of up to 45 degrees, with no metallic parts to corrupt the image. Radiolucent flat plate slides under the table pad, and is fastened securely in place by an angled lip on one side and a Velcro strap on the other. The plate fits most flattop, special procedure angiographic tables, and can quickly and easily be removed from the table by releasing the strap and sliding the armboard out from under the patient. A Velcro wrist strap and foam pad is included. A replacement pad set (E6420BN) is available separately</p>
25	1	E6420BN	Double Armboard Pad Set (2pcs)
26	2	E7018JZ	<p>Mavig 2.5m Ceiling Track without Cable Spooler</p> <p>The Ceiling Track is suited for use of ceiling guided accessories, including radiation protective shields, lamps, injectors, monitors, and other equipment.</p> <p>FEATURES AND BENEFITS</p> <ul style="list-style-type: none"> The unique structure profile ensures smooth running of the carriage With little force, the installed system can be moved and positioned The carriage glides smoothly, even after many years of routine use Adjustable cross-struts simplifies the system installation
27	1	E3053CM	Mavig Cable Holders and Stoppers for Ceiling Track (used with Cable Spoolers E3053CC, E3053LT)
28	2	E3053BC	<p>Portegra2 3600 Ceiling Column w/ Carriage 58 cm</p> <ul style="list-style-type: none"> Lower post allows 3600 rotation Upper fixed post is electric with 3300 rotation Each has a load capacity of 18 kg (40 lbs.)
29	2	E3053CH	Contour Shield 76 x 61 cm (with center connect)
30	2	E3053HB	LED130, focusable LED examination lamp



Item No.	Qty	Catalog No.	Description
31	1	E3053J	Mavig Double Pivot Lower Body Protector Provides convenience, flexibility and enhanced protection for medical personnel. Helps shield technicians against scatter radiation from sources beneath the tabletop and also helps to protect the lower extremities. Flexible 0.5 mm lead equivalent curtains attached to aluminum alloy pivoting arm. The entire lower body protector can be easily and quickly removed from the table. Warranty Code H- 6 Months: Exchange of non-conforming products, which you return to us during the warranty period. Note: Installation, parts, applications training and on-site service is the buyer's responsibility. o Pivotal, flexible shield: 65W90cm (25W35in) o Easy-on upper protective shield: 25W65 cm o Includes one set of wall storage holders o Convenient and flexible system
32	1	E3053JH	Mavig Mobile Height-Adjustable Lead Acrylic Shield with Patient Cutout, 0.5 mm lead equivalent . . .H Warranty Period- 6 months- Exchange of non conforming products, which are returned to GE during warranty period Note: Installation, parts, application training and on-site service is the buyer's responsibility
33	1	E7058A	<p>GE Anti-Fatigue Floor Mat</p> <p>FEATURES/BENEFITS</p> <ul style="list-style-type: none"> • Ingenious device for those who spend a lot of time on their feet on concrete or tile surfaces • Cradles feet in cushiony comfort, minimizing stress and fatigue • Sealed to prevent moisture absorption and facilitate cleanup - ideal for medical environments <p>SPECIFICATIONS</p> <ul style="list-style-type: none"> • Dimensions (L x W x D): 60" x 36" x 0.5" • Weight: Approx 22 lbs. • Blue/White Marble Color <p>COMPATIBILITY</p> <ul style="list-style-type: none"> • Cath Labs, Angiography, R&F rooms • Mammography • Ultrasound
34	2	W0004CV	<p>4 Days Interventional X-ray On-site System Training</p> <p>Four full week days (1 day = 8 hours) of on-site training for an Interventional X-ray System, to be used Monday through Friday. Training expires 12 months from the date of go-live of equipment or purchase, whichever is the latest. Days provided consecutively.</p>



Item No.	Qty	Catalog No.	Description
35	1	W4010CV	HQ Class for Innova Single Plane or with AW Tuition for one student to attend one three-day class for Innova Single Plane at the GE Healthcare Institute in Waukesha, WI. Tuition includes air transportation, local ground transportation, hotel and meals to include breakfast and lunch. Training expires 12 months from the date of go-live of equipment or purchase, whichever is the latest. This course will focus on both the Innova IGS Single Plane and Advantage Workstation and is intended for the customer who desires training on both systems to include 3DCT/3DCT HD. This course is not recommended for customers who have purchased an Innova IGS System without the purchase and/or use of the Advantage Workstation.
36	1	S18101TT	OMEGA 5 OR ELEGANCE TABLE
37	1	S18121RF	In Board Rails, 186 inches long, to be used with 6 or 8 LCD Monitor Suspensions
38	1	S18121RD	In Board Rails, 228 inches long, to be used with LCD Monitor Suspensions
39	1	S18111BC	7 ft. 9 in. Inboard Monitor Bridge
40	1	S18111BD	9'6"- INBOARD MONITOR BRIDGE
41	1	S18101AT	TEMPLATE
42	1	S18101AE	Base Plate LC - Ground Floor Kit
43	1	S18101AJ	Base Plate LC - Through Floor Kit

Quote Summary:

INNOVA 4100 ANGIO 704487CR41

Total Quote Net Selling Price

\$699,059.02

(Quoted prices do not reflect state and local taxes if applicable. Total Net Selling Price Includes Trade In allowance, if applicable.)



GE Healthcare

Date: 12-20-2018
Quote #: PR9-C128012
Version #: 2
Q-Exp-Date: 12-31-2018

Options

(These items are not included in the total quotation amount)

Item No.	Qty	Catalog No.	Description	Ext Sell Price	Initial To Accept
44	1	E7100RS	<p>Includes:</p> <ul style="list-style-type: none"> o 1 - E7100RA Raysafe i2 o 4 - E7100RB Additional Raysafe Dosimeter o 1 - E7100RC Raysafe Dose Manager Software o 1 - E7100RD Additional Raysafe Rack <p>RaySafe i2 dosimetry system provides real-time, accurate and easy-to-interpret dose information. It helps healthcare workers to better understand scatter radiation and decide when it is time to adjust their working behavior to avoid unnecessary exposure. By continuous control of exposure data it is possible to reduce dose to the personnel. Clinical studies have indicated around 30-40% staff dose reduction.</p>	\$44,849.00	X_____

(Quoted prices do not reflect state and local taxes if applicable. Total Net Selling Price Includes Trade In allowance, if applicable.)



GE Healthcare

This Price Hold Letter ("PHL") is entered into as of June 18, 2019, by and between Atrium Health Cleveland with an address at 201 E. Grover St., Shelby, NC 28150 ("Customer") and GE Precision Healthcare LLC, a GE Healthcare business, with an address at 3000 N. Grandview Blvd., Waukesha, WI 53188 ("GE Healthcare")

WHEREAS, GE Healthcare has provided Customer with certain Quotation PR9-C128012 v.2 dated December 20, 2019 (the "Quotation") concerning GE Healthcare's desire to sell to Customer, and Customer's agreement to purchase from GE Healthcare, certain GE Healthcare products and/or services listed on the Quotation in accordance with the terms and conditions set forth on the Quotation; and

WHEREAS, the parties now desire to agree to the terms and conditions set forth herein.

NOW THEREFORE, in consideration of the premises and the representations and mutual undertakings hereinafter set forth, and for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties agree to the foregoing and as follows:

1. Until December 31, 2019, GE Healthcare shall, upon Customer request, offer Customer the catalogue items for the Products identified on the Quotation that are commercially available at the prices listed in the Quotation ("Price Hold"). It is expressly understood that this Price Hold is limited to purchases of the specific Products listed in the Quotation with identical configuration and will not be extended to purchases of other GE Healthcare products or services.
2. Customer acknowledges that the information contained herein is subject to the confidentiality clause of the Quotation and agrees not to disclose this information except as permitted by the terms of the respective Quotation or with GE Healthcare's prior written consent. Notwithstanding the foregoing, Customer shall have the right to disclose confidential information, including pricing, and the terms and conditions of the Quotation to Customer's attorneys, accountants, and consultants solely for the purposes of advising the Customer and only in the event that those parties are (a) not competitors of GE Healthcare and (b) agree in writing to keep the information confidential.

IN WITNESS WHEREOF, Customer and GE Healthcare have caused this PHL to be executed by their duly authorized representatives as of the day and year first above written.

Atrium Health Cleveland

GE Healthcare

Signature: _____

Signature: _____

Print Name: _____

Print Name: _____

Title: _____

Title: _____

Date: _____

Date: _____

Attachment D

June 8th, 2019

Chris Hollar
Manager, Capital Acquisitions
Materials Resource Management
Atrium Health
Office: 704-512-7247

RE: 2005 INNOVA 4100 ANGIO (SID = 704487CR41)

Dear Chris,

Thank you for allowing General Electric Healthcare (GEHC) the opportunity to earn your business. Atrium Health (AH) Cleveland Regional Medical Center is a valued customer and we truly appreciate the partnership we share.

The purpose of this letter is to inform you that General Electric Healthcare will be responsible for removing your existing 2005 INNOVA 4100 ANGIO system as part of your upcoming GE Innova IGS 540 Vascular Lab purchase and estimate the de-installation and removal will be completed at no additional charge to AH. AH will be responsible for the cost of any scan room construction, renovation, clearing the rig path, rigging costs, and opening the Lab room access panel. We will work closely with your facilities planning department to insure proper timing of the de-installation. The system will be de-installed, removed, and shipped by our GE team to our Goldseal business in Waukesha, WI. We understand and confirm that this unit may not be returned to the State of North Carolina without proper authorization from the North Carolina Certificate of Need (CON) section of DHSR.

Thank you again for the opportunity to earn your business. If you have any additional questions, feel free to call me at any time.

Sincerely,

-Herb

Herb Klann
Account Manager, GE Healthcare
Diagnostic & Interventional Imaging

M 724-504-8778
Herb.Klann@GE.com

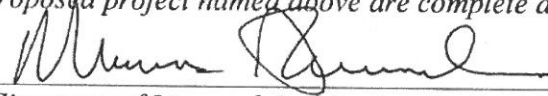
Attachment E

PROPOSED TOTAL CAPITAL COST OF PROJECT

Project name: CERP2019 AH CLEVELAND INTERVENTIONAL VASCULAR XRAY
Provider/Company: Atrium Health

(1) Purchase price of land	_____
(2) Closing costs	_____
(3) Site Preparation	_____
(4) Construction/Renovation Contract	\$180,800
(5) Landscaping	_____
(6) Architect/Engineering Fees	\$28,800
(7) Medical Equipment	\$751,488
(8) Non Medical Equipment	_____
(9) Furniture	_____
(10) Consultant Fees (CON Fees, Legal Fees)	_____
(11) Financing Costs	_____
(12) Interest During Construction	_____
(13) Other (IS, Security, Internal Allocation)	\$59,300
(14) Total Capital Cost	\$1,020,388

I certify that, to the best of my knowledge, the above construction related costs of the proposed project named above are complete and correct.


(Signature of Licensed Architect or Engineer)

7/8/19
DATE



Sales taxes have been included in these equipment costs. However, because Atrium Health is entitled to a sales tax refund under N.C. Gen. Stat. § 105-164.14(b) and 105-467, the sales tax that Atrium Health initially incurs for this medical equipment purchase will be refunded to Atrium Health, and thus will reduce the capital costs that Atrium Health actually incurs for the equipment by \$52,429.