

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

VIA EMAIL ONLY

March 4, 2022

Robbie Roberts, Manager, Market Planning Rroberts@wakemed.org

No Review	
Record #:	3836
Date of Request:	February 24, 2022
Facility Name:	WakeMed
FID #:	943528
Business Name:	WakeMed
Business #:	2018
Project Description:	Acquisition of a Siemens ARTIS pheno Surgery Pro imaging system to develop a
	hybrid operating room with no change in the total number of operating rooms
County:	Wake

Dear Mr. Roberts:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your correspondence regarding the project described above. Based on the CON law in **effect on the date of this response to your request**, the project as described is not governed by, and therefore, does not currently require a certificate of need. If the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective.

This determination is binding only for the facts represented in your correspondence. If changes are made in the project or in the facts provided in the correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by this office.

Please do not hesitate to contact this office if you have any questions.

Sincerely,

Michael J. McKillip, Project Analyst

Micheala Mitchell

Micheala Mitchell, Chief

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

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION

HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

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



3000 New Bern Avenue Raleigh, North Carolina 27610 919-350-8000

February 24, 2022

<u>Via Electronic Mail</u> Mr. Michael McKillip, Project Analyst Healthcare Planning and Certificate of Need Section Division of Health Service Regulation 2704 Mail Service Center Raleigh, NC 27699-2704

Re: Request for No Review to Acquire Hybrid OR Imaging Equipment at WakeMed Raleigh Campus/FID# 943528/Wake County

Dear Mr. McKillip:

This letter is to inform the Healthcare Planning and Certificate of Need Section of WakeMed's intent to acquire a Siemens ARTIS pheno imaging system, to be utilized within the existing surgical suite at WakeMed Raleigh Campus located at 3000 New Bern Avenue, Raleigh, NC 27610. This equipment will allow the space to function as a hybrid operating room in order to better enable surgeons to perform complex cardiovascular and endovascular cases, including TAVR (transcatheter aortic valve replacement) and FEVAR (fenestrated endovascular repair), as well as structural heart procedures such as heart valve corrections and septal defect closures. By acquiring this equipment, WakeMed will continue to provide quality of care and technology that meet the needs of its patients. WakeMed will install this new equipment in Operating Room 23. Please see Attachment 1 for line drawings showing the proposed location¹.

The proposed equipment does not constitute "major medical equipment" as defined by N.C.G.S. 131E-176(14o), which states:

Major medical equipment. – A single unit or single system of components with related functions which is used to provide medical and other health services and which costs more than two million dollars (\$2,000,000). In determining whether the major medical equipment costs more than two million dollars (\$2,000,000), the costs of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the major medical equipment shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater. Major medical equipment does not include replacement equipment. Beginning September 30, 2022, and on September 30 each year thereafter, the cost threshold amount in this

¹ Consistent with a separate written notice submitted to the CON Section, WakeMed proposes to construct Operating Room 23 as a replacement for the existing Operating Room 17. Upon completion of that project, Operating Room 17 will be decommissioned. There will be no increase in the number of licensed operating rooms at WakeMed Raleigh Campus.

subdivision shall be adjusted using the Medical Care Index component of the Consumer Price Index published by the U.S. Department of Labor for the 12-month period preceding the previous September 1.

Total cost of the new equipment is \$1,620,442. Please see Attachment 2 for the vendor quote. Because the total cost of the equipment does not exceed the statutory threshold for major medical equipment and the equipment is not otherwise regulated under the CON Act, this acquisition is exempt from certificate of need review.

WakeMed is requesting that the Healthcare Planning and Certificate of Need Section confirm that the proposed acquisition is exempt from CON review and that WakeMed may proceed with this equipment purchase without first obtaining a CON.

Thank you for your attention to this matter. If you have questions or require additional information, please contact me at 919-350-8023, or at <u>rroberts@wakemed.org</u>.

Sincerely,

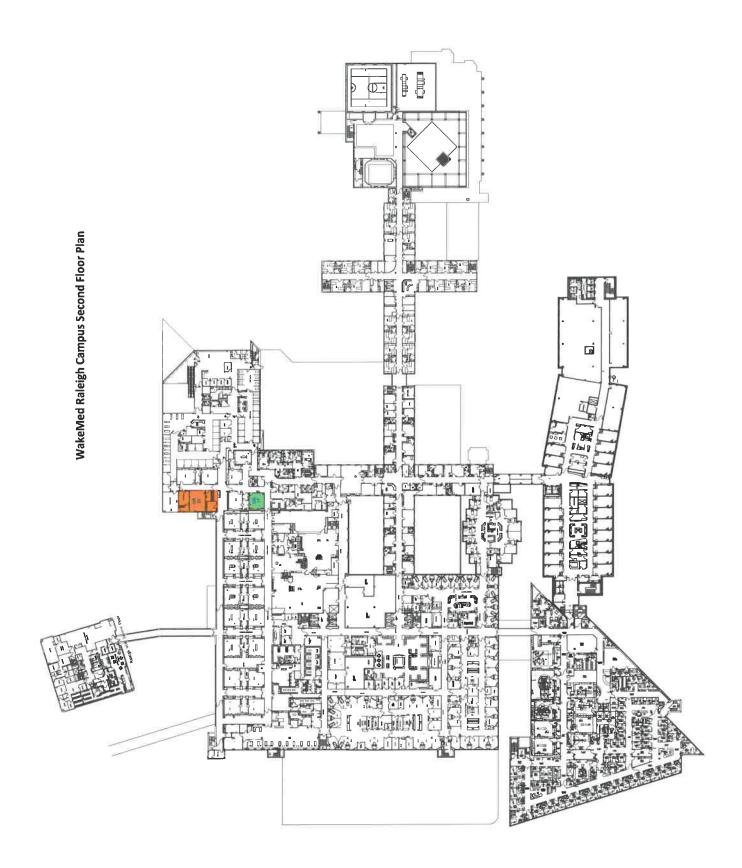
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Robbie Roberts Manager, Market Planning

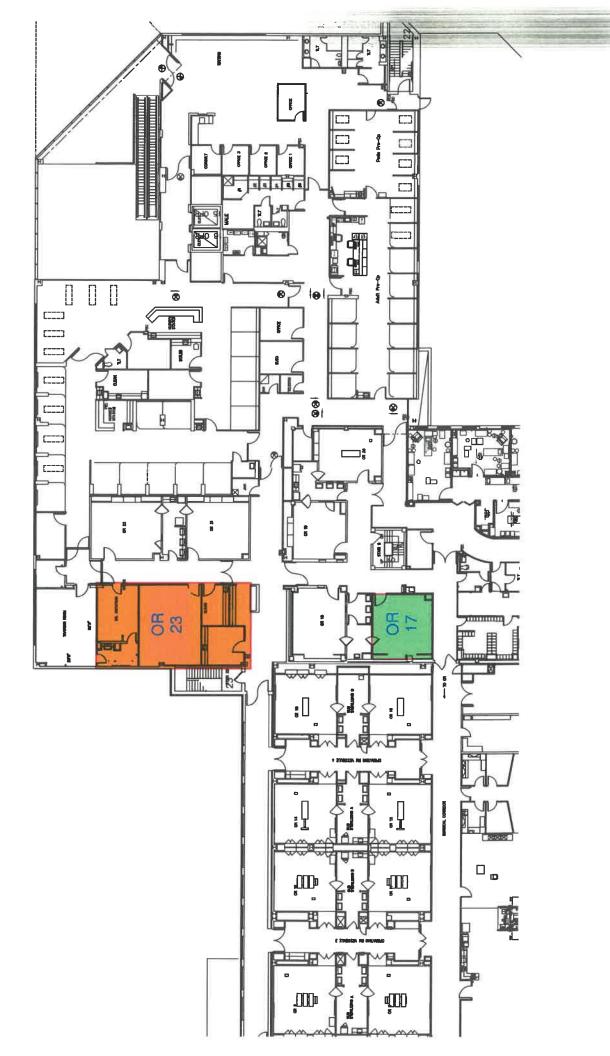
Attachments

ATTACHMENT 1

Line Drawings



WakeMed Raleigh Campus Operating Room Renovation Detail



ATTACHMENT 2

Equipment Quote from Vendor



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Stephen Argo - +1 (336) 210-6178 craig.argo@siemens-healthineers.com

Customer Number: 0000011224

Date: 01/19/2022

Pane

WAKEMED HEALTH AND HOSPITALS

3000 NEW BERN AVE RALEIGH, NC 27610

Siemens Medical Solutions USA, Inc. is pleased to submit the following quotation for the products and services described herein at the stated prices and terms, subject to your acceptance of the terms and conditions on the face and back hereof, and on any attachment hereto.

Table of Contents

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General Terms and Conditions	•••

Contract Total: \$ 1,620,442

(total does not include any Optional or Alternate components which may be selected)

Proposal valid until 04/19/2022

Estimated Delivery Date: TBD

Delivery dates and other contractual obligations of Seller may change due to the effects of the Covid-19 epidemic or other epidemic, including delays and disruptions in the supply chain, manufacturing, or execution as well orders by authorities and prioritization of (new and existing) orders of customers which are essential for the public healthcare. The magnitude of such changes cannot be predicted and might be substantial because it depends on the development of the Covid-19 epidemic or other epidemic.

Quotation is contingent on State CON approval. Should CON be denied, Customer may cancel without chage.

The Products described in this Quotation are governed by the terms and conditions of the VPFA effective September 23, 2020 between Siemens Medical Solutions USA, Inc. and WakeMed.

Included in this Quotation is \$50,000 to be held by Siemens Healthineers on account for the Customer ("Innovation Fund"). The Innovation Fund may only be used to purchase commercially available Siemens Healthineers products. This amount will not yield interest or other benefit to Customer. Any unused funds remaining will be refunded to the Customer as of the earlier of 24 months from the date of installation of the Products included in this Quotation or Siemens Healthineers' receipt of Customer's written request for return of the balance of the Innovation Fund.

This System quote CPQ-285890 must be purchased with Education quote CPQ-426440.



SIEMENS REPRESENTATIVE

Stephen Argo - +1 (336) 210-6178 craig.argo@siemens-healthineers.com

Accepted and Agreed to by:

Siemens	Medical Solutions USA Inc.	WAKEMED HEALTH AND HOSPITALS		
By (sign):	·	By (sign):		
Name:	Stephen Argo	Name:		
Title:		Title:		
Date:	×	Date:		

By signing below, signor certifies that no modifications or additions have been made to the Quotation. Any such modifications or additions will be void.

By (Sign):

SIEMENS REPRESENTATIVE

Stephen Argo - +1 (336) 210-6178 craig.argo@siemens-healthineers.com

Quote Nr:	CPQ-285890 Rev. 0
Terms of Payment:	00% Down, 80% Delivery, 20% Installation Free On Board: Destination
Purchasing Agreement:	VIZIENT SUPPLY LLC
	VIZIENT SUPPLY LLC terms and conditions apply to Quote Nr CPQ-285890
	Customer certifies, and Siemens relies upon such certification, that : (a) VIZIENT ANGIO-CARDIO - XR0313 is the sole GPO for the purchases described in this Quotation, and (b) the person signing this Quotation is fully authorized under the Customer's policies to choose and indicate for Customer such appropriate GPO.

ARTIS pheno VE2x Surgery Pro

P-CPQ-285890-0-11

All items listed below are included for this system:

Qty	Part No.	Item Description	Extended Price
1	14465090	 ARTIS pheno Surgery Pro Engineered to be truly patient-oriented, ARTIS pheno® is a unique floor mounted robotic C-arm system for individualized preprocedural planning, intraoperative guidance, and immediate checkup – regardless of patient condition or procedure complexity. The unique robotic design allows the positioning of the C-arm in virtually any patient position thanks to the flexible isocenter. The wide-space C-arm's usable clearance of 95.5 cm (37.5") grants more freedom during preparation and the procedure itself. Faster 3D imaging for patients with impaired kidney function. Case Flows offer faster workflows through procedural intelligence. For each procedure step a 1-click user interaction selects optimized global system settings, C-arm angulations, collimation, display layout an imaging preference. Simplified operation of ARTIS pheno with Touch2Move technology - functions that can be selected and invoked in a single step. CleanSurface: ARTIS pheno is sporting smooth surfaces; the seamless sealed covers protect against spills and simplify cleaning. CleanGuide, a comprehensive cleaning concept for ARTIS pheno. The CARE+OPTIQ package offers constant image quality at the lowest possible dose. The Iraeady contains the following functionalities: Live 2k Imaging, Fluoro Loop and Memory expansion (400k). Disclaime: The products/features (here mentioned) are not commercially available in all countries. Due to regulatory reasons their future availability cannot be guaranteed. Please contact your local Siemens organization for further details. Laser crosshairs	\$ 662,784 \$ 4,101
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1	14443011	Large Display diagn. Protection The high quality laminated glass protective screen protects the panel of the monitor against mechanical damage and fluid ingress on the front. It is suited for clinical image evaluation.	\$ 4,750
		Please note that components supplied by Siemens (displays, cables) can be installed on an existing third-party display holder only by the manufacturer of that holder. A connection kit for the large display is included.	
		In the event that the angiography system comes into contact with the third-party display holder, it must be possible to push away the holder in a horizontal direction with a force less than 50 N. Otherwise, there is a risk of crush injury to persons or material damage.	
		must meet the following criteria: To prevent injuring the patient when positioning the display holder above the table, it has to be possible to manually move the third-party display holder vertically with a force of up to 85 N.	
		Note: For safety reasons, third-party display holders in combination with Large Display	
1	14455574	Large Display (3rd party) Preparation for a large color flat screen display installed on a third-party display holder for the examination room.	\$ 48,786
1	14465015	Multimodality Viewing Supports the connection of external video sources such as Sensis/recording systems, PACS, HIS/RIS, Ultrasound, ECG, IVUS, OCT, external video, endoscope, mapping systems, and their visualization on the examroom display. Adapted to the local needs and depending on the availability of the cockpit option up to 24 external sources can be connected.	\$ 55,802
		The GIGALIX X-ray tube concentrates high pulse power on small, square-shaped focal spots (flat emitter technology for all focal spots). This provides unprecedented image quality for confidence in challenging situations.	¢ 55 000
		The as40HDR flat detector is optimized for the requirements of radiology and surgery.	
1	14465091	OPTIQ with as40HDR GIGALIX OPTIQ image chain with the following tube, collimator and flat detector configuration: as40HDR detector and GIGALIX tube	\$ 195,204
1	14432948	Automap Automatic stand positioning depending on the selected reference image and automatic reference image selection depending on the stand positioning.	\$ 1,297
		Dual architecture In order to provide highest level system availability, the imaging system consists of two independent computer systems that manage central tasks such as real-time image processing during fluoroscopy or acquisition as well as post-processing and networking functionality separately from one another. This ensures the best possible system performance and availability. Image storage capacity 100,000 images in 1k matrix with a size of 2 MB 25,000 images in 2k matrix with a size of 8MB	
1	14465043	preplanned puncture point and angle. Imaging System Image system computer for control of system operation and image acquisition.	\$ 63,065
		Laser cross for zen40HDR and as40HDR detector, integrated into the detector housing for simplified patient positioning and for syngo Needle Guidance marking	

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		Features: The laminated glass enforces high mechanical strenght and resistivity against mechanical impact, the special coating reduces reflections for a continuous image quality, excellent spectral transmisison of at least 98%, can be added to existing Artis Large Display installations. Weight: approx. 12kg (55") up to 16kg (60") Note: Observe the maximum permissible load of the display suspension, a combination with other options mounted to the display suspension might be	
1	14455574	restricted. Large Display (3rd party) Preparation for a large color flat screen display installed on a third-party display holder for the examination room.	\$ 48,786
		Note: For safety reasons, third-party display holders in combination with Large Display must meet the following criteria:	
		To prevent injuring the patient when positioning the display holder above the table, it has to be possible to manually move the third-party display holder vertically with a force of up to 85 N.	
		In the event that the angiography system comes into contact with the third-party display holder, it must be possible to push away the holder in a horizontal direction with a force less than 50 N. Otherwise, there is a risk of crush injury to persons or material damage.	
		Please note that components supplied by Siemens (displays, cables) can be installed on an existing third-party display holder only by the manufacturer of that holder.	
		A connection kit for the large display is included.	
1	14443011	Large Display diagn. Protection The high quality laminated glass protective screen protects the panel of the monitor against mechanical damage and fluid ingress on the front. It is suited for clinical image evaluation. Features: The laminated glass enforces high mechanical strenght and resistivity against mechanical impact, the special coating reduces reflections for a continuous image quality, excellent spectral transmision of at least 98%, can be added to existing Artis Large Display installations. Weight: approx. 12kg (55") up to 16kg (60")	\$ 4,750
		Note: Observe the maximum permissible load of the display suspension, a combination with other options mounted to the display suspension might be restricted.	
1	14465030	Large control room display Large control room display Panel 31.5" Resolution 3840 x 2160 Pixel size 0.181 x 0.181 mm Typical contrast max. 1000 : 1 Max. luminance 700 cd/m2 Calibrated luminance 400 cd/m2 Display area (diagonal) 800 mm Dimensions without stand (W x H x D) 761 x 471 x 90 mm	\$ 12,081
1	14465045	ARTIS multi-tilt table ARTIS multi-tilt table ensures optimal patient positioning regardless of the procedure and patient size. With an unprecedented level of material integrity, it is suitable for	\$ 126,979
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	 even the heaviest of patients. Maximum table load: 440 kg (970 lbs) consisting of 280 kg (617 lbs) for the patient, 100 kg (220 lbs) for accessories, plus 60 kg (132 lbs) for CPR Allows tilting in +15°/-20° and a +/-15° cradle The easy-float tabletop permits hassle-free positioning of the tabletop regardless of patient weight, mounted lower-body radiation protection and tableside modules Small table base allows upright and comfortable standing, close to the patient. The Siemens unique IsoTilt functionality keeps the C-arm projection during Trendelenburg tilting. Ball bearing mounted slidable accessory rails on both sides for easy positioning of control modules and accessories. 	
	Note: It is mandatory to provide UPS back up with this table option in order to comply with IEC 60601-2-43 CL. 201.15.101. Reason: In the event of power failure a neutral table position suitable for CPR must be reachable within 15 seconds. A suitable UPS from Siemens as required must be included in your order unless an existing / planned UPS provision for your installation site will satisfy the requirement.	
14455543	Tabletop - widePatient positioning tabletop made of carbon fiber in wide, straight design for universal use. The tabletop is straight all the way to the head area.Maximum patient weight: 280 kg / 617.3 lbWeight: 12.7 kg / 28.0 lbLength: 2287 \pm 1 mm / 90.1" \pm 0.04"Width: 525 \pm 0.5 mm / 20.7" \pm 0.02"	\$ 6,732
14455548	Intended only for use with ARTIS tables. Mattress - thick Matching, special-foam mattress, 7 cm, incl. a latex-free cover. This visco-elastic comfort mattress reacts to temperature and has the special property of adapting to the individual body shape under the influence of body weight and heat. Mattress thickness; 70 + 5 mm / 2.8" ± 0.2"	\$ 1,785
14465054	 Oper. contr. ARTIS table For an ideal workflow, full system operation can be performed directly at the table side. This includes complete system operation through modular control elements for controlling C-arm movements, patient table, and collimator. The illuminated controls and touch display are easy to use – even when covered with drapes for sterile operation. 	\$ 13,273
	Pilot module The pilot module provides comfortable and ergonomic operation of the system. It allows the control of system and table movements, imaging parameters, the selection of examination protocols, image acquisition and evaluation and many other functions. The touch screen can be configured to meet individual clinical requirements. The Touch2Move technology allows intuitive activation of system movements.	
	Table control module (with ARTIS multi-tilt table) The table operating module with panning knob for servo-assisted table movement enables virtually force-free movement of the patient regardless of table load and table inclination. Table control module (with ARTIS standard table) Table control module with panning knob for free-floating tabletop movement. Collimator control module The Collimator control module for controlling of all collimator functions, such as rectangular blade or wedge-shaped filters. Hand switch Multi-functional hand switch for acquisition control, switching acquisition frame rates and/or step movements. (This switch might not be available in all countries.)	
		 Advirum table load: 440 kg (970 lbs) consisting of 280 kg (917 lbs) for CPR. Allows tilting in +15'-20' and a +16' cradie The casy-float tableboy permits hassle-free positioning of the tabletop regardless of patient weight, mounted lower-body radiation protection and tableside modules Small table base allows upright and comfortable standing, close to the patient. The Siemens unique IsoTilt functionality keeps the C-arm projection during Trendelenburg tilting. Ball bearing mounted slidable accessory rails on both sides for easy positioning of control modules and accessories. Note: It is mandatory to provide UPS back up with this table option in order to comply with IEC 60601-2-43 GL. 2015. 101. Reason: in the event of power failure a neutral table position suitable for CPR must be reachable within 15 seconds. A suitable UPS from Siltemes as required must be included in your order unless an existing / planned UPS provision for your installation site will satisfy the requirement. 14455543 TabletOp - wide Patient positioning tabletop is straight all the way to the head area. Maximum patient weight. 200 Kg / 617.3 b Weight: 12.7 Kg / 28.0 b Length: 22.87 ± 1 mm / 90.1° ± 0.04' Weight: 32.7 ± 2.7 ± 0.2'' Intended only for use with ARTIS tables. 14455548 Mattress - thick Matching, special-foam mattress, 7 cm, ind. a latex-free cover. The side all workflow, full system operation can be performed directly at the table side. The side all workflow, full system operation can be performed directly at the table side. This includes complete system operation through modular control elements for control imodule motives and table movements, malging parameters, the selection of examination protocls, image acquisititon and evaluation and evaluation and evaluation and evaluati



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1	14465070	1st 4 pedal wireless footswitch Wireless 4-pedal footswitch for release of fluoroscopy, acquistion, and tabletop brake (with ARTIS table), as well as configurable control function.	\$ 4,064
1	14465048	2nd 4 pedal cable footswitch Additional wired 4-pedal footswitch for release of fluoroscopy, acquistion and tabletop brake (with ARTIS table), as well as configurable control function.	\$ 1,308
1	14465124	Operation in the control room Preparation for system operation from control room.	\$ 3,435
1	14465095	Op. ctrl handswitch (C-Room) Additional handswitch for radiation release and additional control functions.	\$ 644
1	14455566	Injector connection (C-Room) Interface in the control room for controlling the contrast medium injector. Injectors can be offered by Siemens Healthcare Accessory Solutions.	\$ 2,839
1	14440419	Cable clips ECG Cable clips for securing the ECG cable to the patient tabletop. It includes 10 cable clips.	\$ 35
1	14465062	Intended only for use with Artis / ARTIS tables Infusion bottle holder This infusion bottle holder can be mounted at the accessory rail of the patient table. It holds up to 4 infusion bottles. It includes an infusion bottle holder made of stainless steel with 4 retaining rings.	\$ 292
1	14440447	Intended only for use with Artis/ARTIS tables. Acc. rail module, wide tabletop This is an attachable module with accessory rails for placing the control modules near the patient's abdomen. It includes a carbon fiber module with accessory rails (45 cm / 17.7") attached to the right and left slides over the outer edges of the patient positioning tabletop. Length: 48 cm (18.9 ") Width (without accessory rails): 55 cm / 21.65" Width (with accessory rails): 61,8 cm / 24.33" Weight: 5.9 kg (13 lb)	\$ 2,550
		Intended only for use with Artis/ ARTIS wide tabletop.	
1	14440452	Catheter bracket This item can be positioned at the foot end of the patient table. It is made of stainless steel and attached at the accessory rail at the foot end. It includes a table extension.	\$ 885
1	14440459	Intended only for use with Artis / ARTIS tables. Arm rest Arm support used for the arm approach. Length: 1 m (39.4"). Slides underneath the patient mattress and is held in position by the patient's weight. Made of radiolucent carbon fiber material which is easy to clean. It includes two additional support pads of two different heights (4 and 7 cm). Length pad: 60 cm / 23.62" Width: 9 to 20 cm / 3.54" to 7.87" Maximum weight: 5 kg (11.02 lb) Weight (with pads): 2.1 kg / 4.63 lb	\$ 1,151
1	14440460	Intended only for use with Artis / ARTIS tables. Arm holder (pair)	\$ 423

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craig.argo@siemens-healthineers.com

		The patient's arms can be comfortably placed along the body using these two arm holders. They slide underneath the patient mattress and is held in position by the patient's weight. It includes two pairs of arm holders of different length (540 mm / 690 mm - 21.2" / 27.2") and height (85 mm / 115 mm - 3.35" / 4.53"), suitable both for thick and thin patient mattresses.	
		Intended only for use with Artis / ARTIS tables.	
2	14465056	Abdomen radiation prot. IR This radiation shield protects the user from scattered radiation when standing at the table side. It can be attached to the accessory rails either on the right or on the left side of the patient positioning table. It provides the user an additional accessory rail. It includes a basic unit (89 cm x 75 cm / 35" x 29.5" (I x h); one lower body radiation protection pivot swivel element (48 cm x 75 cm / 18.9" x 30.3" (I x h); one flip down element 57 cm x 33cm / 22.4" x 12.99" (I x h), and two clip-on units (27 cm x 33 cm / 10.6" x 12.99", and 27 cm x 25 cm / 10.6" x 9.8") with a lead of 0.5 mm / 0.02" Pb.	\$ 10,240
		The maximum load of the accessory rails is 20 kg (44.1 lb).	
		Intended only for use with ARTIS tables. It provides a dictance of 7cm to prevent the collision with the table base in case of maximum penning.	
1	14432926	Card acq. mode w/high speed Card Highspeed enables image acquisition with up to 30 frames per second and helps visualizing a moving heart.	\$ 13,541
1	14465096	QVA Vascular analysis Vessel analysis with determination of degree of stenosis, distance measurement and calibration.	\$ 5,050
1	14465016	Cockpit Option Up to eight different external image sources can be displayed on the control- and examroom displays and controlled via a common keyboard and mouse in the control room.	\$ 32,646
1	14455607	syngo iFlow syngo iFlow allows the visualization and analysis of the flow and perfusion in the examined organs. This information is based on the time-to-peak calculations from a routine DSA acquisition. The calculations can be shown as a color-map of the whole organ. It is also possible to analyze the flow and perfusion of regions of interest (ROIs) defined by the user and this information can be displayed with graphics, which might further help in understanding the flow dynamics of these ROIs.	\$ 4,178
1	14465077	syngo EVAR Guidance Engine Application software for reconstruction, post-processing and handling of 3D information including applications for endovascular treatment of aortic aneurysms.	\$ 105,056
		The package includes the following functionalities:	
		- 3D high-contrast and CT-like soft-tissue imaging (syngo DynaCT)	
		- 3D Wizard for expert step-by-step guidance in 3D acquisition	
		- 3D roadmap for dynamic overlay of planning data and 3D volumes on live fluoroscopy	
		- Fusion functionality for integration of pre-interventional 3D datasets also from other modalities into the Angio-room (syngo 3D/3D Fusion and syngo 2D/3D Fusion)	
		- Marking of points or lines on the 3D geometry or MPRs and overlay of these markings on live fluoroscopy	
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1	AXA_RIG_PHE NO	Standard Rigging pheno	\$ 20,200
1	14465097	LV Analysis Analysis of the left ventricular function of the heart.	\$ 8,097
		The application enables the planning of one or multiple needle paths based on intraoperative syngo DynaCT images, or a preoperative 3D volume of a CT, PET/CT or MR system, in combination with Fusion functionality. Optimal progression views for easy control during needle insertion are calculated and suggested by the system and the planned needle path is overlaid on the live 2D image for easy guidance. Interventions such as vertebroplasties, kyphoplasties, pedicle screwing, biopsies, drainages and ablations can be performed on the angiography system with greater confidence.	¢ 9.007
1	14446029	syngo NeedleGuidance A software module for planning and control of needle procedures.	\$ 12,574
1	14440411	Intercom - Comfort Intercom system for communication between examination room and control room. It includes - a microphone with a control box for the control room - a microphone with an adaptive acoustic filter for background noise suppression for the examination room - a footswitch for conversation selection for the examination room	\$ 903
1	14465055	Cable footswitch (C-Room) Wired footswitch for control-room.	\$ 905
		For ARTIS standard table: Table control module with panning knob For ARTIS multi-tilt table and Surgery table: Table control module with Joystick	\$ 2,057
1	14465094	Op. ctrl table mod. (C-Room) Additional table control module	\$ 1,122
1	14465093	Op. ctrl syst. mod. (C-Room) Additional collimator and pilot control module for system movements, imaging parameters as well as review and many other functions.	\$ 3,787
1	14465137	Mentice Interface Th Mentice simulator is a non-medical device.	\$ 1,393
1	14465132	Third Party Broker Interface to relevant 3rd party applications. Easy and simplified integration of 3rd party systems via safe and open standard protocols.	\$ 6,956
1	14434325	syngo Aortic ValveGuide syngo Aortic ValveGuide is an application that supports TAVI procedures.	\$ 12,825
1	14434323	syngo Dyna3D HighSpeed syngo Dyna3D HighSpeed enables acquisitions to be generated down to less than 3 seconds. As a result unintended patient motion and moving organs such as the lungs can be displayed with a lot fewer artifacts.	\$ 0
		Cardiac. syngo DynaCT Cardiac uses the proven syngo DynaCT 3D reconstruction algorithms for 3D visualization of ventricles and vessels of the heart from projection images of a rotational angiography from an ARTIS system.	
1	14465125	3D image guidance during EVAR procedures. Upgrade DynaCT Cardiac Upgrade of a system with enhancement of the DynaCT functionality to DynaCT	\$ 1,514
		syngo EVAR Guidance – a dedicated and optimized workflow facilitating the use of	
		- Parallel patient processing capabilities,	
		- In-room control for table-side operation of advanced applications	



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1	NEMPEA0221	PRESS DUO elite AG pedestal 230V Nemoto's PRESS DUO elite is intended to be used for injecting contrast media and common flushing solution into the vascular system for angiographic procedures.	\$ 35,500
		This PRESS DUO elite model consists of the following components: Powerhead Powerhead pedestal Powerhead cable X-Ray interface cable Main unit (interface) Console Handswitch Console cable	
		This model is the 230 volt version.	
		The package includes installation (continental US), training and a two year warranty through Nemoto	
1	NEMOTO_YR2_ WARR	Nemoto Injector - 2nd year of warranty	\$ 0
2	AX_INNO_ASS UR	AX Innovation Assurance Fund	\$ 50,000
1	AXA_ADDL_RIG GING	Additional Rigging AXA \$25,000	\$ 25,000
		System Total	\$ 1,620,442



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OPTIONS on Quote Nr: CPQ-285890 Rev. 0

OPTIONS for ARTIS pheno VE2x Surgery Pro

All items listed below are OPTIONS and will be included on this system ONLY if initialed: (See Detailed Technical Specifications at end of Proposal.)

Qty Part No.		Item Description	Extended Price	Initial to Accept
1	E93PM150UAX	Eaton 93PM-150 kW UPS Complete system backup without interruption. One UPS per lab.	+ \$ 56,909	<u>X</u>
		Includes the following:		
		Eaton 93PM UPS Electronics Cabinet w/integrated maintenance bypass sidecar Eaton 93PM Single Battery Cabinet System (Full load back-up time @ 150kW of 7.1 minutes.) Eaton 93PM Remote Monitoring Panel Network Card Eaton 24x7 start-up One year (24x7) warranty through Eaton Corp.		
		Not approved for sites that require OSHPD.		
		Shipment is to customer's dock. Customer is responsible for logistics from the dock to inside location.		
1	14434157	Moveable upper body rad. protection This radiation shield protects the user from scattered radiation. It includes a ceiling rail (4 m / 157.5"), a ceiling mounted and movable stand (80 cm or 57 cm / 31.5" or 22,4"), a support arm (94 cm x 91 cm / 37" x 35.8") and an acrylic glass. The shield is made of acrylic glass with lead equivalent of 0.5 mm (w x h: 61 cm x 76 cm / 24" x 29.9"), which can pivot and rotate around a fixed point with a range of 360 degrees. The operation range is limited when used with Artis floor/biplane MN. Max. weight: 18 kg / 39.68 lb.	+ \$ 8,272	<u>X</u>
1	14465082	syngo DynaCT Multiphase With syngo DynaCT Multiphase it is for the first time possible to assess the collateral status with time resolved DynaCT, depicting 8 different time points within a period of 50 seconds. The seamless integration of collateral status imaging into the interventional suite leads to time savings (no transfer to CT) and sounder decisions.	+ \$ 78,240	<u>X</u>
1	14465136	Rapid Interface This interface provides the possibility to connect ARTIS to a RAPID server, which has to be purchased separately.	+ \$ 0	X
		With this combination it is possible to send reconstructed syngo DynaCT Multiphase volumes via DICOM transfer to a RAPID server (operated by iSchemaView Inc.). RAPID is not commercially available in all countries. Due to regulatory reasons the future availability cannot be guaranteed. Verification of mutual compatibility of medical devices combined in a system according to Article 12 of Directive 93/42/EEC on		
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		Medical Devices is pending. The product is not commercially available in the European Union.		
1	14455601	syngo TrueFusion syngo TrueFusion efficiently integrates True Volume TEE guidance into structural heart disease procedures. Based on the co-registration of an Artis angiography and an ACUSON SC2000 PRIME ultrasound system syngo TrueFusion enables fusion of TEE landmarks and valve models with live fluoroscopy for target oriented device navigation. The relevant TEE structures for guidance can be marked directly on the US system through the Echo expert and sent for fusion. Additionally the co-registration information can be used to synchronize the image orientation of X- ray and echo images to facilitate communication and potentially save fluoro time and contrast dye.	+ \$ 18,000	X
		Disclaimer for Application Software VD2: The products/features (here mentioned) are not commercially available in all countries. Due to regulatory reasons their future availability cannot be guaranteed. Please contact your local Siemens organization for further details.		v
1	14443020	syngo CTO Guidance Expand your procedure mix by treating more CTO patients Treating Chronic Total Occlusions (CTOs) is one of the most challenging procedures in interventional cardiology. Incomplete crossing of the lesion is a high risk. syngo CTO Guidance enables better planning with automatic segmentation of coronaries coming from the CTA. This helps to get a better understanding of the lesion and planning the procedure. Further, it provides additional information during the procedure and guidance with color-coded COROwave to avoid foreshortening. This enables more physicians to treat complex CTO cases and helps to expand the hospital's procedure mix.	+ \$ 17,940	x
4	4 4 4 9 5 4 9 4	syngo CTO Guidance provides industry-leading support and guidance during CTO revascularization procedures.	± ¢ 0 012	х
1	14465134	syngo Embolization Guidance syngo Embolization Guidance is an application for planning and performing embolizations. By manually marking a proximal start- and one or multiple distal target vessel point(s) in a syngo DynaCT, CTA or MRA dataset, the algorithm determins the course of the vessel (tree) that connects the start with the target point(s). Functionality for tumor segmentation with automatic tumor volume computation is available in addition. Segmented structures can be overlaid with live 2D imaging for guidance during the procedure. In combination with syngo DynaCT (≥200° acquisition) or CT dataset with intra-arterial injection, the easy one-click syngo Embolization Guidance application automatically detects and highlights tumor-feeding vessels for targeted embolization of the liver – supporting complete tumor embolization, which is important for an effective and safe treatment.	+ \$ 9,012	Δ



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FINANCING: The equipment listed above may be financed through Siemens. Ask us about our full range of financial products that can be tailored to meet your business and cash flow requirements. For further information, please contact your local Sales Representative.

ACCESSORIES: Don't forget to ask us about our line of OEM imaging accessories to complete your purchase. All accessories can be purchased or financed as part of this order. To purchase accessories directly or to receive our accessories catalog, please call us directly at 1-888-222-9944 or contact your local Sales Representative.

COMPLIANCE: Compliance with legal and internal regulations is an integral part of all business processes at Siemens. Possible infringements can be reported to our communication channel "Let Us Know".

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Siemens Medical Solutions USA, Inc. General Terms and Conditions

1. GENERAL

1.1 Contract Terms and Acceptance. These terms and conditions constitute an integral part of any contract between Seller and Purchaser identified on the first page hereof and shall govern the sale of the products identified in such contract ("Products"). Purchaser acknowledges that this is a commercial and not a consumer transaction. Purchaser shall be deemed to have assented to, and to have waived any objection to, this Agreement upon the earliest to occur of any of the following: Purchaser's completion or execution of this Agreement; Purchaser's acceptance of all or any part of the Products; Purchaser's issuance of a purchase order for any Products identified on Seller's quotation or proposal; or delivery of the Products to the common carrier for shipment pursuant hereto.1.2 Refurbished/Used Products. For Products identified on this Agreement as used or refurbished Products, these Products have been previously owned and used. When delivered to Purchaser, such Products will perform in accordance with the manufacturer's specifications. Since pre-owned Products may be offered simultaneously to several customers, the availability of such Products to Purchaser cannot be guaranteed. If the Products are no longer available. Seller will use its best efforts to identify other suitable products in its inventory. If substitute products are not acceptable to Purchaser, then Seller will cancel the order and refund to Purchaser any deposits previously paid. The warranty period for any used or refurbished Products will be separately stated on the quotation. 1.3 Third Party Products. If this Agreement includes the sale of third party products not manufactured by Seller, then Purchaser agrees and acknowledges that (a) Purchaser has made the selection of these products on its own. (b) the products are being acquired by Seller solely at the request of and for the benefit and convenience of Purchaser, (c) no representation, warranty or guarantee has been made by Seller with respect to the products, (d) the obligation of Purchaser to pay Seller for the products is absolute and unconditional, (e) use of the products may be subject to Purchaser's agreement to comply with any software licensing terms imposed by the manufacturer; and (f) unless otherwise indicated by Seller in writing, Seller is not responsible for any required installation, validation,

product recall, warranty service, maintenance, complaint handling, or any other applicable FDA regulatory requirements, and the Purchaser will look solely to the manufacturer regarding these services and will assert no claim against Seller with respect to these products.

2. PRICES

2.1 Quotations. Unless otherwise agreed to in writing or set forth in the quotation, all prices quoted by Seller and amounts payable by Purchaser are in U.S. dollars, and include Seller's standard packaging. The prices quoted to Seller assume that the Seller is located in, and will use the Products in, the U.S. If not, such quotation will be void. Unless otherwise stated, the quotation shall only be valid for forty-five (45) days from the date of the quotation.2.2 Delay in Acceptance of Delivery. Should the agreed delivery date be postponed by Purchaser, Seller shall have the right to deliver the Products to storage at Purchaser's risk and expense, and payments due upon delivery shall become due when Seller is ready to deliver.

3. TAXES

3.1 Any sales, use or manufacturer's tax which may be imposed upon the sale or use of Products, or any property tax levied after readiness to ship, or any excise tax, license or similar fee (excluding the Medical Device Excise Tax as set forth in Section 4191 of the Internal Revenue Code of 1986, as amended) required under this transaction, shall be in addition to the quoted prices and shall be paid by Purchaser. Notwithstanding the foregoing, Seller agrees to honor any valid exemption certificate provided by Purchaser.

4. TERMS OF PAYMENT; DEFAULT

4.1 Payments; Due Date. Unless otherwise set forth in the quotation, Purchaser shall pay Seller as follows: an initial deposit of 10% of the purchase price for each Product is due upon submission of the purchase order, an additional 80% of the purchase price is due upon delivery of each Product, and the final 10% of the purchase price is due upon completion of installation or when the Products are available for first patient use, whichever occurs first. Unless otherwise agreed, all payments other than the initial deposit are due net thirty (30) days from the date of invoice. Seller shall have no

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obligation to complete installation until the payment due upon delivery is received. Partial shipments shall be billed as made, and payments for such shipments will be made in accordance with the foregoing payment terms 4.2 Late Payment. A service charge of 11/2% per month, not to exceed the maximum rate allowed by law, shall be made on any portion of Purchaser's outstanding balance which is not paid when due. Payment of such service charge shall not excuse or cure Purchaser's breach or default for late payment.4.3 Payment of Lesser Amount. If Purchaser pays, or Seller otherwise receives, a lesser amount than the full amount provided for under this Agreement, such payment shall not constitute or be construed other than as on account of the earliest amount due Seller. No endorsement or statement on any check or payment or elsewhere shall constitute or be construed as an accord or satisfaction. 4.4 Where Payment Due Upon Installation or Completion. Should any terms of payment provide for either full or partial payment upon completion of installation or thereafter, and completion of installation is delayed for any reason for which Seller is not responsible beyond the installation date set forth in the Notice to Manufacture Letter issued by Seller, as applicable, then the balance of payments shall be due on the day following such installation date 4.5 Default; Termination. Each of the following shall constitute an event of default under this Agreement: (i) a failure by Purchaser to make any payment when due; (ii) a failure by Purchaser to perform any other obligation under this Agreement within thirty (30) days of receipt of written notice from Seller; or (iii) the commencement of any insolvency, bankruptcy or similar proceedings by or against Purchaser. Upon the occurrence of any event of default, at Seller's election: (a) the entire amount of any indebtedness and obligation due Seller under this Agreement and interest thereon shall become immediately due and payable; (b) Seller may suspend the performance of any of Seller's obligations hereunder, including, but not limited to, obligations relating to delivery, installation and warranty services; (c) Purchaser shall put Seller in possession of the Products upon demand; (d) Seller may sell or otherwise dispose of all or any part of the Products and apply the proceeds thereof against any indebtedness or obligation of Purchaser under this Agreement; (e) if this Agreement or any indebtedness or obligation of Purchaser under this Agreement is referred to an attorney for collection or realization, Purchaser shall pay to Seller all costs of collection and realization (including, without limitation, a reasonable sum for

attorneys' fees); and Purchaser shall pay any deficiency remaining after collection of or realization by Seller on the Products. In addition, Seller may terminate this Agreement upon written notice to Purchaser in the event that Purchaser is not approved for credit or upon the occurrence of any material adverse change in the financial condition or business operations of Purchaser. **4.6 Financing**. Notwithstanding any arrangement that Purchaser may make for the financing of the purchase price of the Products, the parties agree that any such financing arrangement shall have no effect on the Purchaser's payment obligations under this Agreement, including but not limited to Sections **4.1** and **4.2** above.

5. EXPORT TERMS

5.1 Unless other arrangements have been made, payment on export orders shall be made by irrevocable confirmed letter of credit, payable in U.S. dollars against Seller's invoice and standard shipping documents. Such letter of credit shall be in an amount equal to the full purchase price of the Products and shall be established in a U.S. bank acceptable to Seller. Purchaser shall have sole responsibility to procure all necessary permits and licenses for shipment and compliance with any governmental regulations concerning control of final destination of Products.5.2 Purchaser agrees that Products shall not at any time directly or indirectly be used, exported, sold, transferred, assigned or otherwise disposed of in a manner which will result in non-compliance with applicable export Control and US Sanction laws and regulations. If Purchaser purchases a Product at the domestic price and exports such Product, or transfers such Product to a third party for export, outside of the U.S., Purchaser shall pay to Seller the difference between the domestic price and the international retail price of such Product. Purchaser shall deliver to Seller, upon Seller's request, written assurance regarding compliance with this Section in form and content acceptable to Seller.

6, DELIVERY, RISK OF LOSS

6.1 Delivery Date. Delivery and installation dates will be established by mutual agreement of the parties as set forth in the Notice to Manufacture Letter issued by the Seller, as applicable. Seller shall make reasonable efforts to meet such delivery date(s).6.2 Risk of Loss; Title Transfer. Unless otherwise agreed to in writing, the following shall apply: (a) For Products that do not require installation by Seller, and for options and add-

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on products purchased subsequent to delivery and installation of Products purchased under this Agreement, delivery shall be complete upon transfer of possession to common carrier, F.O.B. Shipping Point, whereupon title to and all risk of loss, damage to or destruction of the Products shall pass to Purchaser. (b) For Products that require installation by Seller, delivery shall be complete upon delivery of the Products to Purchaser's designated site, F.O.B. Destination; whereupon title to and all risk of loss, damage to or destruction of such Products shall pass to Purchaser upon completion of delivery. (c) All freight charges and other transportation, packing and insurance costs, license fees, custom duties and other similar charges shall be the sole responsibility of Purchaser unless included in the purchase price or otherwise agreed to in writing by Seller. In the event of any loss or damage to any of the Products during shipment, Seller and Purchaser shall cooperate in making any insurance claim.

7. SECURITY INTEREST/FILING

7.1 Purchaser grants to Seller a security interest in the Products until payment in full by Purchaser. Purchaser shall sign any financing statements or other documents necessary to perfect Seller's security interests in the Products. Purchaser further represents and covenants that (a) it will keep the Products in good order and repair until the purchase price has been paid in full, (b) it will promptly pay all taxes and assessments upon the Products or the use thereof, (c) it will not attempt to transfer any interest in the Products until the purchase price has been paid in full, and (d) it is solvent and financially capable of paying the full purchase price for the Products.

8. CHANGES, CANCELLATION, AND RETURN

8.1 Orders accepted by Seller are not subject to change except upon Seller's written agreement.**8.2** Orders accepted by Seller are non-cancellable by Purchaser except upon Seller's written consent and payment by Purchaser of a cancellation charge equal to 10% of the price of the affected Products, plus any shipping, insurance, inspection and refurbishment charges; the cost of providing any training, education, site evaluation or other services completed by Seller; and any return, cancellation or restocking fees with respect to any Third Party Products ordered by Seller on behalf of Purchaser. Seller may retain any payments received from Purchaser up to the amount of the cancellation charge. In no event can an order be

cancelled by Purchaser or Products be returned to Seller after shipment.**8.3** Seller reserves the right to change the manufacture and/or design of its Products if, in the judgment of Seller, such change does not alter the general function of the Products.

9. FORCE MAJEURE

9.1 Seller shall not be liable for any loss or damage for delay in delivery, inability to install or any other failure to perform due to causes beyond its reasonable control including, but not limited to, acts of God or the public, war, civil commotion, blockades, embargoes, calamities, floods, fires, earthquakes, explosions, storms, strikes, lockouts, labor disputes, or unavailability of labor, raw materials, power or supplies. Should such a delay occur, Seller may reasonably extend delivery or production schedules or, at its option, cancel the order in whole or part without liability other than to return any unearned deposit or prepayment.

10. WARRANTY

10.1 Seller warrants that the Products manufactured by Seller and sold hereunder shall be free from defects in material or workmanship under normal use and service for the warranty period. The final assembled Products shall be new although they may include certain used, reworked or refurbished parts and components (e.g., circuit boards) that comply with performance and reliability specifications and controls. Seller's obligation under this warranty is limited, at Seller's option, to the repair or replacement of the Product or any part thereof. Unless otherwise set forth in the Product Warranty attached hereto and incorporated herein by reference ("Product Warranty"), the warranty period shall commence upon the earlier of the date that the Products have been installed in accordance with Section 12.5 hereof (which date shall be confirmed in writing by Seller) or first patient use, and shall continue for twelve (12) consecutive months. Seller makes no warranty for any Products made by persons other than Seller or its affiliates, and Purchaser's sole warranty therefor, if any, is the original manufacturer's warranty, which Seller agrees to pass on to Purchaser, as applicable. The warranty provided by Seller under this Section 10 extends only to the original Purchaser, unless the Purchaser obtains the Seller's prior written consent with respect to any sale or other transfer of the Products during the term of the warranty.10.2 No warranty extended by Seller shall apply to any Products which have been damaged by fire, accident, misuse,



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abuse, negligence, improper application or alteration or by a force majeure occurrence as described in Section 9 hereof or by the Purchaser's failure to operate the Products in accordance with the manufacturer's instructions or to maintain the recommended operating environment and line conditions; which are defective due to unauthorized attempts to repair, relocate, maintain, service, add to or modify the Products by the Purchaser or any third party or due to the attachment and/or use of non-Seller supplied parts, equipment or software without Seller's prior written approval; which failed due to causes from within non-Seller supplied equipment, parts or software including, but not limited to, problems with the Purchaser's network; or which have been damaged from the use of operating supplies or consumable parts not approved by Seller. In addition, there is no warranty coverage for any transducer or probe failure due to events such as cracking from high impact drops, cable rupture from rolling equipment over the cable, delamination from cleaning with inappropriate solutions, or TEE bite marks. Seller may effectuate any repairs at Purchaser's facility, and Purchaser shall furnish Seller safe and sufficient access for such repair. Repair or replacement may be with parts or products that are new, used or refurbished. Repairs or replacements shall not interrupt, extend or prolong the term of the warranty. Purchaser shall, upon Seller's request, return the noncomplying Product or part to Seller with all transportation charges prepaid, but shall not return any Product or part to Seller without Seller's prior written authorization. Purchaser shall pay Seller its normal charges for service and parts for any inspection, repair or replacement that falls outside of Seller's warranty. Seller's warranty does not apply to consumable materials, disposables, supplies, accessories and collateral equipment, except as specifically stated in writing or as otherwise set forth in the Product Warranty.10.3 This warranty is made on condition that immediate written notice of any noncompliance be given to Seller and Seller's inspection reveals that Purchaser's claim is covered under the terms of the warranty (i.e., that the noncompliance is due to traceable defects in original materials and/or workmanship).10.4 Purchaser shall provide Seller with both on-site and remote access to the Products. The remote access shall be provided through the Purchaser's network as is reasonably necessary for Seller to provide warranty services under this Agreement. Remote access will be established through a broadband internet-based connection to either a

Purchaser owned or Seller provided secure end-point. The method of connection will be a Peer-to-Peer VPN IPsec tunnel (non-client based) with specific inbound and outbound port requirements.10.5 Warranty service will be provided without charge during Seller"s regular working hours (8:30-5:00), Monday through Friday, except Seller's recognized holidays. If Purchaser requires that service be performed outside these hours. such service can be made available at an additional charge, at Seller's then current rates. The obligations of Seller described in this Section are Seller's only obligations and Purchaser's sole and exclusive remedy for a breach of product warranty.10.6 SELLER MAKES NO WARRANTY OTHER THAN THE ONE SET FORTH HEREIN AND IN THE PRODUCT WARRANTY. SUCH WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO ANY EXPRESS **OR IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSES, AND** SUCH CONSTITUTES THE SOLE AND EXCLUSIVE WARRANTY MADE WITH RESPECT TO THE PRODUCTS, SERVICE OR OTHER ITEM FURNISHED UNDER THIS AGREEMENT.10.7 In the event of any inconsistencies between the terms of this Section 10 and the terms of the Product Warranty, the terms of the Product Warranty shall prevail.

11. LIMITATION OF LIABILITY

11.1 In no event shall Seller's liability hereunder exceed the actual loss or damage sustained by Purchaser, up to the purchase price of the Products. The foregoing limitation of liability shall not apply to claims for bodily injury or damages to real property or tangible personal property to the extent arising from Seller's negligence or a product defect 11.2 SELLER SHALL NOT BE LIABLE FOR ANY LOSS OF USE, **REVENUE OR ANTICIPATED PROFITS; COST OF** SUBSTITUTE PRODUCTS OR SERVICES; LOSS OF STORED, TRANSMITTED OR RECORDED DATA; OR FOR ANY INDIRECT, INCIDENTAL, UNFORESEEN, SPECIAL, PUNITIVE OR CONSEQUENTIAL DAMAGES WHETHER BASED ON CONTRACT, TORT, STRICT LIABILITY OR ANY OTHER THEORY OR FORM OF ACTION, EVEN IF SELLER HAS BEEN ADVISED OF THE POSSIBILITY THEREOF, ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT OR THE SALE OR USE OF THE PRODUCTS. THE FOREGOING IS A SEPARATE, ESSENTIAL TERM OF THIS AGREEMENT AND SHALL BE EFFECTIVE UPON

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THE FAILURE OF ANY REMEDY, EXCLUSIVE OR NOT.

12. INSTALLATION - ADDITIONAL CHARGES

12.1 General. Unless otherwise expressly stipulated in writing, the Products shall be installed by and at the expense of Seller except that Seller shall not provide rigging or site preparation services unless otherwise agreed to in writing by Seller for an additional charge. Seller will not install accessory items such as cabinets, illuminators, darkroom equipment or processors for X-Ray and CT equipment, unless otherwise agreed to in writing by Seller, 12.2 Installation by Seller. If Seller specifies it will install the Products, the following applies: subject to fulfillment of the obligations set forth in Section 12.3 below, Seller shall install the Products and connect them to the requisite safety switches and power lines to be installed by Purchaser. Except as otherwise specified below, if such installation and connection are performed by Seller's technical personnel, prices shown include the cost thereof, provided that the installation and connection can be performed within the Continental United States or Puerto Rico and during normal business hours. Any overtime charges or other special expenses shall be additional charges to the prices shown.12.3 Purchaser's Obligations. Purchaser shall, at its expense, provide all proper and necessary labor and materials for plumbing service, carpentry work, conduit wiring, and other preparations required for such installation and connection. All such labor and materials shall be completed and available at the time of delivery of the Products by Seller. Additionally, Purchaser shall provide free access to the installation site and, if necessary, safe and secure space for storage of Products and equipment prior to installation by Seller. Purchaser shall be responsible, at its sole cost and expense, for obtaining all permits, licenses and approvals required by any federal, state or local authorities in connection with the installation and operation of the Products, including but not limited to any certificate of need and zoning variances. Purchaser shall provide a suitable environment for the Products and shall ensure that its premises are free of hazardous conditions and any concealed or dangerous conditions and that all site requirements are met. Seller shall delay its work until Purchaser has completed the removal of any hazardous materials or has taken any other precautions and completed any other work required by applicable regulations. Purchaser shall reimburse Seller for any increased costs and expenses

incurred by Seller that are the result of or are caused by any such delay. In the event that Seller is requested to supervise the installation of the Products, it remains the Purchaser"s responsibility to comply with local regulations. Seller is not an architect and all drawings furnished by Seller are not construction drawings. If local labor conditions, including a requirement to use union labor, require the use of non-Seller employees to participate in the installation of the Product or otherwise causes delays or any additional expenses, then any such additional costs shall be at Purchaser's expense. 12.4 Regulatory Reporting. In the event that any regulatory activity is performed by anyone other than Seller's authorized personnel, then Purchaser shall be responsible for fulfilling any and all reporting requirements 12.5 Completion of Installation. Installation shall be complete upon the conclusion of final calibration and checkout under Seller's standard procedures to verify that the Products meet applicable written performance specifications. Notwithstanding the foregoing, first use of the Products by Purchaser, its agents or employees for any purpose after delivery shall constitute completion of installation.

13. PATENT, COPYRIGHT AND OTHER INFRINGEMENT CLAIMS 13.1 Infringement by Seller. Seller warrants that the Products manufactured by Seller and sold hereunder do not infringe any U.S. patent or copyright. If Purchaser receives a claim that any such Products, or parts thereof, infringe upon the rights of others under any U.S. patent or copyright, Purchaser shall notify Seller immediately in writing. Provided that Purchaser gives Seller information, assistance and exclusive authority to evaluate, defend and settle such claims, Seller shall at its own expense and option: indemnify and defend Purchaser against such claims; settle such claims; procure for Purchaser the right to use the Products; or remove or modify them to avoid infringement. If none of these alternatives is available on terms reasonable to Seller, then Purchaser shall return the Products to Seller and Seller shall refund to Purchaser the purchase price paid by Purchaser less reasonable depreciation for Purchaser's use of the Products. The foregoing states Seller's entire obligation and liability, and Purchaser's sole remedy, for claims of infringement.13.2 Infringement by Purchaser. If some or all of the Products sold hereunder are made by Seller pursuant to drawings or specifications furnished by Purchaser, or if Purchaser modifies or combines, operates or uses the Products other than as specified by Seller or with any product, data, software, apparatus Siemens Medical Solutions USA, Inc.

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or program not provided or approved by Seller, then the indemnity obligation of Seller under Section 13.1 shall be null and void.

14. DESIGNS AND TRADE SECRETS; LICENSE; CONFIDENTIALITY

14.1 Any drawings, data, designs, software programs or other technical information supplied by Seller to Purchaser in connection with the sale of the Products shall remain Seller's property and shall at all times be held in confidence by Purchaser.14.2 For all Products which utilize software for their operation, such "Applications Software" shall be licensed to Purchaser under the terms of Seller's Software License Schedule attached hereto.14.3 Seller and Purchaser shall maintain the confidentiality of any information provided or disclosed to the other party relating to the business, customers and/or patients of the disclosing party, as well as this Agreement and its terms (including the pricing and other financial terms under which the Purchaser will be purchasing the Products). Each party shall use reasonable care to protect the confidentiality of the information disclosed, but no less than the degree of care it would use to protect its own confidential information, and shall only disclose the other party's confidential information to its employees and agents having a need to know this information. The obligations of confidentiality set forth herein shall not apply to any information in the public domain at the time of disclosure or that is required to be disclosed by court order or by law.

15. ASSIGNMENT

15.1 Neither party may assign any rights or obligations under this Agreement without the prior written consent of the other, which shall not be unreasonably withheld. Any attempt to do so shall be void, except that Seller may assign this Agreement without consent to any subsidiary or affiliated company, and may delegate to authorized subcontractors or service suppliers any work to be performed under this Agreement so long as Seller remains liable for the performance of its obligations under this Agreement. This Agreement shall inure to and be binding upon the parties and their respective successors, permitted assigns and legal representatives.

16. COSTS AND FEES

16.1 In the event that any dispute or difference is brought arising from or relating to this Agreement or the breach, termination or validity thereof, the prevailing party shall be entitled to recover from the other party all

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reasonable attorneys' fees incurred, together with such other expenses, costs and disbursements as may be allowed by law.

17. MODIFICATION

17.1 This Agreement may not be changed, modified or amended except in writing signed by duly authorized representatives of the parties.

18. GOVERNING LAW; WAIVER OF JURY TRIAL

18.1 This Agreement shall be governed by the laws of the state where the Product(s) will be installed, without regard to that state's choice of law principles.**18.2 EACH OF THE PARTIES EXPRESSLY WAIVES ALL RIGHTS TO A JURY TRIAL IN CONNECTION WITH ANY DISPUTE UNDER THIS AGREEMENT.**

19. COST REPORTING

19.1 Purchaser agrees that it must fully and accurately report prices paid under this Agreement, net of all discounts, as required by applicable law and contract, including without limitation 42 CFR §1001.952(h), in all applicable Medicare, Medicaid and state agency cost reports. Purchaser shall retain a copy of this Agreement and all other communications regarding this Agreement, together with the invoices for purchase and permit agents of the U.S. Department of Health and Human Services or any state agency access to such records upon request.

20. INTEGRATION

20.1 These terms and conditions, including any attachments or other documents incorporated by reference herein, constitute the entire, complete and exclusive statement of agreement with respect to the subject matter hereof, and supersede any and all prior agreements, understandings and communications between the parties with respect to the Products. Purchaser's additional or different terms and conditions stated in a purchase order, bid documents or any other document issued by Purchaser are specifically rejected and shall not apply to the transactions contemplated under this Agreement.

21. SEVERABILITY; HEADINGS

21.1 No provision of this Agreement which may be deemed unenforceable will in any way invalidate any other portion or provision of this Agreement. Section headings are for convenience only and have no substantive effect.

22. WAIVER

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22.1 No failure and no delay in exercising, on the part of any party, any right under this Agreement will operate as a waiver thereof, nor will any single or partial exercise of any right preclude the further exercise of any other right.

23. NOTICES

23.1 Any notice or other communication under this Agreement shall be deemed properly given if in writing and delivered in person or mailed, properly addressed and stamped with the required postage, to the intended recipient at its address specified on the face hereof.

24. RIGHTS CUMULATIVE

24.1 The rights and remedies afforded to Seller under this Agreement are in addition to, and do not in any way limit, any other rights or remedies afforded to Seller by any other agreement, by law or otherwise.

25. END USER CERTIFICATION

25.1 Purchaser represents, warrants and covenants that it is acquiring the Products for its own end use and not for reselling, leasing or transferring to a third party (except for lease-back financings).

26. ACCESS TO BOOKS AND RECORDS

26.1 To the extent required by Section 1861(v)(1)(I) of the Social Security Act and the regulations promulgated thereunder, until the expiration of four (4) years after the furnishing of any Product or service pursuant to this Agreement, Seller shall make available, upon written request by the Secretary of Health and Human

Services (the "Secretary"), or upon request by the Comptroller General (the "Comptroller"), or any of their duly authorized representatives, copies of this Agreement and any books, documents, records or other data of Seller that are necessary to certify the nature and extent of any costs incurred by Purchaser for such Products and services. If Seller carries out any of its duties under this Agreement through a subcontract with a related organization involving a value or cost of ten thousand dollars (\$10,000) or more over a twelve (12) month period, Seller will cause such subcontract to contain a clause to the effect that, until the expiration of four (4) years after the furnishing of any Product or service pursuant to said contract, the related organization will make available upon the written request of the Secretary or the Comptroller, or any of their duly authorized representatives, copies of records of said related organization that are necessary to certify the nature and extent of cost incurred by Purchaser for such Product or service.

27. DISPOSITION OF PRODUCTS

27.1 Purchaser expressly agrees that should Purchaser sell, transfer or otherwise dispose of the Products, Purchaser shall notify Seller in writing and give Seller the opportunity to purchase such Products. With Purchaser's notice, Purchaser shall provide Seller with a copy of the third party's binding offer to purchase the Products and Seller shall have seven (7) days to notify the Purchaser of an offer to purchase the Products. 05/15 Rev.



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SIEMENS Healthineers

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Software License Schedule to the Siemens Medical Solutions USA, Inc. General Terms and Conditions

 DEFINITIONS: The following definitions apply to this Schedule: "Agreement" shall mean the attached (i) Quotation for Products and/or Services including the Terms and Conditions of Sale and applicable schedules; and/or (ii) Software License Agreement describing the software licensed herein and the specific system for which the license is issued. "Licensor" shall mean Siemens Medical Solutions USA, Inc.

"Licensee" shall mean the end-user to whom Licensor provides Software or Documentation for its internal use under the Agreement.

"Software" shall mean the software described in the attached Agreement, including the following as contained therein: (i) software programs consisting of a series of statements or instructions to be used directly or indirectly in a programmable controller or computer to bring about a certain result and (ii) databases consisting of systemized collections of data to be used or referenced directly or indirectly by a programmed controller or computer. Notwithstanding the foregoing, "Software" does not include "firmware" as such term is conventionally understood. Diagnostic/Maintenance Software also is not included within the scope of the Software licensed under this Schedule, and is available only as a special option under a separate Diagnostic Materials License Agreement and may be subject to a separate licensing fee.

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Siemens Medical Solutions USA, Inc.

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Revised 03/15/05

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TRADE-IN EQUIPMENT REQUIREMENTS

THE FOLLOWING APPLIES ONLY TO THE EXTENT THAT THE QUOTATION INCLUDES AN EQUIPMENT TRADE IN OR IF A TRADE-IN IS LATER ADDED TO THS QUOTATION VIA A CHANGE ORDER. THESE REQUIREMENTS ARE IN ADDITION TO ANY OTHER REFERENCED TERMS AND CONDITIONS OF THE QUOTATION AND SHALL REMAIN IN EFFECT REGARDLESS OF ANY CONTRARY LANGUAGE IN THE QUOTATION.

This Quotation includes the trade-in equipment described herein and referenced by either the Project Number identified in the Quotation hereof (non-Ultrasound) or the Trade In Part Number (Ultrasound) as further described in the associated Trade Sheet which is incorporated herein by reference. Purchaser certifies that the description of the trade-in equipment as set forth on the Trade Sheet is a true and accurate representation of the equipment, and that the equipment is in good working condition unless otherwise noted on the Trade Sheet.

The trade-in equipment must be made available for removal no later than turnover of the new equipment. Purchaser must vacate the room of all items not listed on the Trade Sheet, or otherwise clearly identify all items listed on the Trade Sheet, prior to the start of the de-installation. If this is not done, Seller will have no liability for items which are subsequently removed or scrapped. If the de-installation or return of the trade-in equipment is delayed by Purchaser for reasons other than a force majeure event, or if upon inspection by Seller it is determined that the equipment does not meet the manufacturer's operating specifications, or if any items listed as included on the Trade Sheet are not made available at the time of de-installation, then trade-in value will be re-evaluated and any loss in value or additional costs incurred by Seller shall be deducted from the established trade-in value and the pricing set forth on this Quotation will be adjusted by change order. In the event that access to the non-ultrasound trade-in equipment is denied past 14 days from turnover, or access to ultrasound trade-in equipment is denied past 30 days from turnover, then Purchaser shall pay to Seller a rental fee in the amount 3.5% of the total trade-in value plus any additional value provided by an Elevate/Promotional program included in this quotation (no less than \$1000) for each month, or part thereof, that access is denied. In addition, if the purchase and installation of the new equipment covered by this Quotation is not completed, then Seller shall invoice Purchaser for all costs and expenses incurred by Seller in connection with the de-installation and removal of the trade-in equipment, including but not limited to labor, materials, rigging out, and transportation, which costs shall be paid by Purchaser within thirty (30) days of the invoice date.

Purchaser further acknowledges and agrees that (i) the trade-in equipment will be free and clear of all liens and encumbrances including, but not limited to, unpaid leases and loans, and that upon request, it will execute a bill of sale or other documents reasonably satisfactory to Siemens to transfer title and ownership of the equipment to Seller, (ii) it is Purchaser's sole responsibility to delete all protected health information and any other confidential information from the equipment prior to de-installation, without damaging or cannibalizing the equipment or otherwise affecting the operation of the equipment in accordance with its specifications, (iii) the equipment, including all updates, upgrades, modifications, enhancements, revisions, software, S/W disks and manuals, shall be returned to Siemens in good operating condition, reasonable wear and tear excepted, and (iv) to the extent not prohibited by applicable law, Purchaser shall indemnify and hold Seller harmless from and against any and all claims, demands, causes of action, damages, liability, costs and expenses (including reasonable attorney's fees) resulting or arising from Purchaser's failure to comply with item (i) above.

FOR MR SYSTEMS: cryogen levels must be least 65% upon time of de-installation. FOR MOBILE SYSTEMS: system must be road worthy and a state issued title transferring ownership to Seller (or Designee) must be received prior to the removal of the mobile system. FOR MODALITY TRADE SYSTEMS (non-ultrasound): The trade-in equipment must be available for inspection within two weeks of the scheduled de-installation date. In addition, Purchaser must provide a clear path for the removal of the trade-in equipment and on the date of de-installation after final inspection and test by the Seller (or Designee) has occurred, the Purchaser must supply licensed tradespeople to disconnect the power and plumbing (including draining and removing and disposing of any hazardous materials including, but not limited to glycol from the chiller and oil from the transformer, as examples.) Any additional costs due to the need to use a larger rig (other than a standard 80 ton rig), as well as any construction activities, street closings, permits, etc., required to de-install/remove the equipment are out-of-scope costs and will be the responsibility of Purchaser. FOR ULTRASOUND SYSTEMS – Purchaser may provide transducers with the ultrasound unit being traded in, but will not receive additional credit for such transducers.

 From:
 Mckillip, Mike

 To:
 Waller, Martha K

 Subject:
 FW: [External] Letter of No Review Request

 Date:
 Thursday, February 24, 2022 2:21:39 PM

 Attachments:
 LONR WakeMed Raleigh Hybrid OR Equip.pdf

FYI

Michael McKillip

Project Analyst Division of Health Service Regulation, Healthcare Planning and Certificate of Need <u>NC Department of Health and Human Services</u>

Office: 919-855-3877 mike.mckillip@dhhs.nc.gov

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From: ROBBIE ROBERTS <RROBERTS@wakemed.org>
Sent: Thursday, February 24, 2022 2:10 PM
To: Mckillip, Mike <mike.mckillip@dhhs.nc.gov>
Subject: [External] Letter of No Review Request

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Mike:

I hope you have been doing well. Please see the attached Letter of No Review request for WakeMed Raleigh Campus. If you have questions or need anything else, please let me know. Thanks. RR

Robbie Roberts Manager, Market Planning WakeMed Health & Hospitals 919-350-8023 rroberts@wakemed.org