NC DEPARTMENT OF
HEALTH AND HUMAN SERVICES

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

VIA EMAIL ONLY

November 3, 2021

Elizabeth V. Kirkman
Elizabeth.Kirkman@atriumhealth.org

Exempt from Review – Replacement Equipment

Record #:	**3713**
Date of Request:	October 25, 2021
Facility Name:	Carolinas Medical Center
FID #:	943070
Business Name:	The Charlotte-Mecklenburg Hospital Authority
Business #:	1770
Project Description:	Replace existing interventional system and renovate existing space to accommodate replacement equipment
County:	Mecklenburg

Dear Ms. Kirkman:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that the above referenced project is exempt from certificate of need review in accordance with G.S. 131E-184(f). Therefore, you may proceed to acquire without a certificate of need the Siemens Icono Bi-Plane interventional system to replace the Siemens Artis Zee MP multi-purpose interventional system. This determination is based on your representations that the existing unit will be sold or otherwise disposed of and will not be used again in the State without first obtaining a certificate of need if one is required.

It should be noted that the Agency's position is based solely on the facts represented by you and that any change in facts as represented would require further consideration by this office and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

Julie M. Faenza

Julie M. Faenza
Project Analyst

Micheala Mitchell

Micheala Mitchell
Chief

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

October 25, 2021

Ms. Micheala Mitchell, Chief
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
N.C. Department of Health & Human Services
809 Ruggles Drive
Raleigh, NC 27603

RE: Exemption Request for The Charlotte-Mecklenburg Hospital Authority ("CMHA") to Replace Interventional Radiology Equipment located on the campus of Carolinas Medical Center ("CMC")

Dear Ms. Frisone:

The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center ("CMC") seeks to acquire a Siemens Artis Icono bi-plane interventional system ("Replacement Equipment"). Please see Attachment A for a copy of CMC's current hospital license. The Replacement Equipment will replace CMC's current Siemens Artis Zee multi-purpose interventional system ("Existing Equipment") that was acquired in 2012. The Existing Equipment is currently housed in interventional radiology ("IR") lab #3 in room 04L150 on the fourth floor of CMC's main hospital building located at 1000 Blythe Boulevard in Charlotte, NC 28203 (see Attachment B).

As part of this project, CMC plans to renovate and reconfigure IR lab #3 and adjacent support spaces in order accommodate the Replacement Equipment and comply with current code requirements. IR lab #3 and the adjacent support spaces will also undergo several aesthetic upgrades, including replacement of the existing flooring and ceiling as well as installation of new countertops, casework, and other finishes.

The purpose of this letter is to provide the Agency with notice and to request a determination that CMC's purchase of the Replacement Equipment is exempt from Certificate of Need ("CON") review under the replacement equipment exemption provisions contained in Session Law 2013-360, Section 12G.3(b) and Session Law 2013-363, Section 4.6 (which are codified at N.C. Gen. Stat. 131E-184(f)(1)-(3)).

The General Assembly has chosen to exempt certain, otherwise reviewable events from CON review. Among those exemptions is the acquisition of "replacement equipment," defined as follows in the CON law:

> "Replacement equipment" means equipment that costs less than two million dollars ($2,000,000) and is purchased for the sole purpose of replacing comparable medical equipment currently in use which will be sold or otherwise disposed of when replaced.

See N.C. Gen. Stat. 131E-176(22a). Under the provisions found at N.C. Gen. Stat. 131E-184(f)(1)-(3), the CON law provides:

(f) The Department shall exempt from certificate of need review the purchase of any replacement equipment that exceeds the two million dollar ($2,000,000) threshold set forth in G.S. 131E-176(22) if all of the following conditions are met:

(1) The equipment being replaced is located on the main campus.
(2) The Department has previously issued a certificate of need for the equipment being replaced. This subdivision does not apply if a certificate of need was not required at the time the equipment being replaced was initially purchased by the licensed health service facility.
(3) The licensed health service facility proposing to purchase the replacement equipment shall provide prior written notice to the Department, along with supporting documentation to demonstrate that it meets the exemption criteria of this subsection.

See Session Law 2013-360, Section 12G.3(b) and Session Law 2013-363, Section 4.6. The term "main campus" was defined in Session Law 2013-360, Section 13G.3(a) (codified N.C. Gen. Stat. 131E-176(14n)) as follows:

(14n) "Main campus" means all of the following for the purposes of G.S. 131E-184(f) and (g) only:

a. The site of the main building from which a licensed health service facility provides clinical patient services and exercises financial and administrative control over the entire facility, including the buildings and grounds adjacent to that main building.
b. Other areas and structures that are not strictly contiguous to the main building but are located within 250 yards of the main building.

The Existing Equipment is currently located in IR lab #3 in room 04L150 on the fourth floor of CMC's main hospital building located at 1000 Blythe Boulevard, Charlotte, NC 28203, which is the site from which CMC provides clinical patient services and exercises financial and administrative control over the entire facility (see Attachment B). CMC's Facility Executive's office is located on the second floor of the main hospital building. Please see a copy of CMC's license in Attachment A.

In addition to the foregoing, to qualify for this exemption, the replacement equipment must be "comparable" to the equipment it replaces and the equipment being replaced must be "sold or otherwise disposed of when replaced." CMC's proposal qualifies for this exemption.

A. Cost of the Replacement Equipment

The purchase price of the Replacement Equipment is $1,924,914 ($1,794,792 interventional system and injector + $130,122 Tax). Quotes for the Replacement Equipment and supporting equipment are provided in Attachment C. The projected total capital cost of the project is $3,030,755 (including taxes and freight) and includes the removal of the existing equipment and installation of the Replacement Equipment. The total capital cost for the proposed project is provided in Attachment D.

B. Equipment Being Replaced is Located on the Main Campus

The Existing Equipment is currently located in IR lab #3 in room 04L150 on the fourth floor of CMC's main hospital building (see Attachment B). The Replacement Equipment will also be located in IR lab #3 (see Attachment B).

C. Certificate of Need Issued for Equipment Being Replaced

The Existing Equipment was acquired in 2012. The cost to acquire the Existing Equipment was less than $750,000 and did not trigger the CON reviewability threshold for "major medical equipment" under N.C.G.S 131E-176(14o). A copy of the original purchase order for the Existing Equipment is not available due to system transition, however, internal documentation regarding the purchase price of the Existing Equipment can be found in Attachment E.

D. Comparable Equipment

The CON rule codified as 10A N.C.A.C. 14C.0303 (the "Regulation") defines "comparable medical equipment" in subsection (c) as follows:

> "Comparable medical equipment" means equipment which is functionally similar and which is used for the same diagnostic or treatment purposes.

CMC intends to use the Replacement Equipment for substantially the same interventional procedures for which it currently uses the Existing Equipment. The Existing Equipment is a Siemens Artis Zee multi-purpose interventional system that has been used to perform a range of body and neuro-related interventional procedures since its installation in 2012.

The Replacement Equipment can and will perform all procedures currently performed on the Existing Equipment, although it possesses some expanded capabilities due to technological improvements. The Replacement Equipment will have bi-plane capability which adds more versatility to the types of interventional procedures, specifically neuro-related procedures, that can be performed (see Attachment F for the Equipment Brochure). The Replacement Equipment is therefore "comparable medical equipment" as defined in Subsection (c).

Furthermore, CMC does not intend to increase patient charges or per procedure operating expenses more than 10 percent within the first 12 months after equipment acquisition. For further equipment comparison, please refer to Attachment G, the Equipment Comparison Chart.

Subsection (d) of the regulation further provides:

(1) it has the same technology as the equipment currently in use, although it may possess expanded capabilities due to technological improvements; and
(2) it is functionally similar and is used for the same diagnostic or treatment purposes as the equipment currently in use and is not used to provide a new health service; and
(3) the acquisition of the equipment does not result in more than a 10.0 percent increase in patient charges or per procedure operating expenses within the first twelve months after the replacement equipment is acquired.

The Replacement Equipment will meet all three of tests set out in Subsection (d). The Replacement Equipment satisfies the technology and functionality tests in Subsection (1) and (2) as discussed above and identified in the Comparison Chart (Attachment G). Moreover, CMC represents the use of the Replacement Equipment will not result in an expense or charge increase greater than 10 percent within the first 12 months after acquisition as described in Subsection (d)(3).

Documentation provided in Attachment H indicates that 960 procedures were performed from September 2020 to August 2021 on the Existing Equipment.

E. Disposition of Equipment

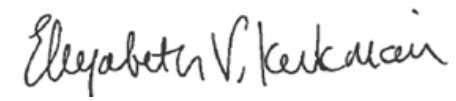
Please see Attachment I for a letter documenting the Existing Equipment will be taken out of service and will not be re-sold or re-installed in North Carolina without appropriate certificate of need approval.

CONCLUSION:

Based on the foregoing information, CMC hereby requests that the Agency provide a written response confirming that the acquisition of the Replacement Equipment described herein is exempt from CON review. If the Agency needs additional information to assist in its consideration of this request, please let us know.

Thank you for your consideration of this notice.

Sincerely,



Elizabeth V. Kirkman
Assistant Vice President
Atrium Health Strategic Services Group

Attachments

cc: Chan Roush, Vice President and Facility Executive, Carolinas Medical Center

Attachment A

State of North Carolina

Department of Health and Human Services
Division of Health Service Regulation

Effective January 01, 2021, this license is issued to

The Charlotte-Mecklenburg Hospital Authority

to operate a hospital known as

Carolinas Medical Center/Center for Mental Health

located in Charlotte, North Carolina, Mecklenburg County.

This license is issued subject to the statutes of the State of North Carolina, is not transferable and shall remain in effect until amended by the issuing agency.

Facility ID: 943070

License Number: H0071

Bed Capacity: *1211*

General Acute 1055, Rehabilitation 13 , Psych 132, Substance Abuse 11,

Dedicated Inpatient Surgical Operating Rooms: 9
Dedicated Ambulatory Surgical Operating Rooms: 11
Shared Surgical Operating Rooms: 42
Dedicated Endoscopy Rooms: 12

Authorized by:

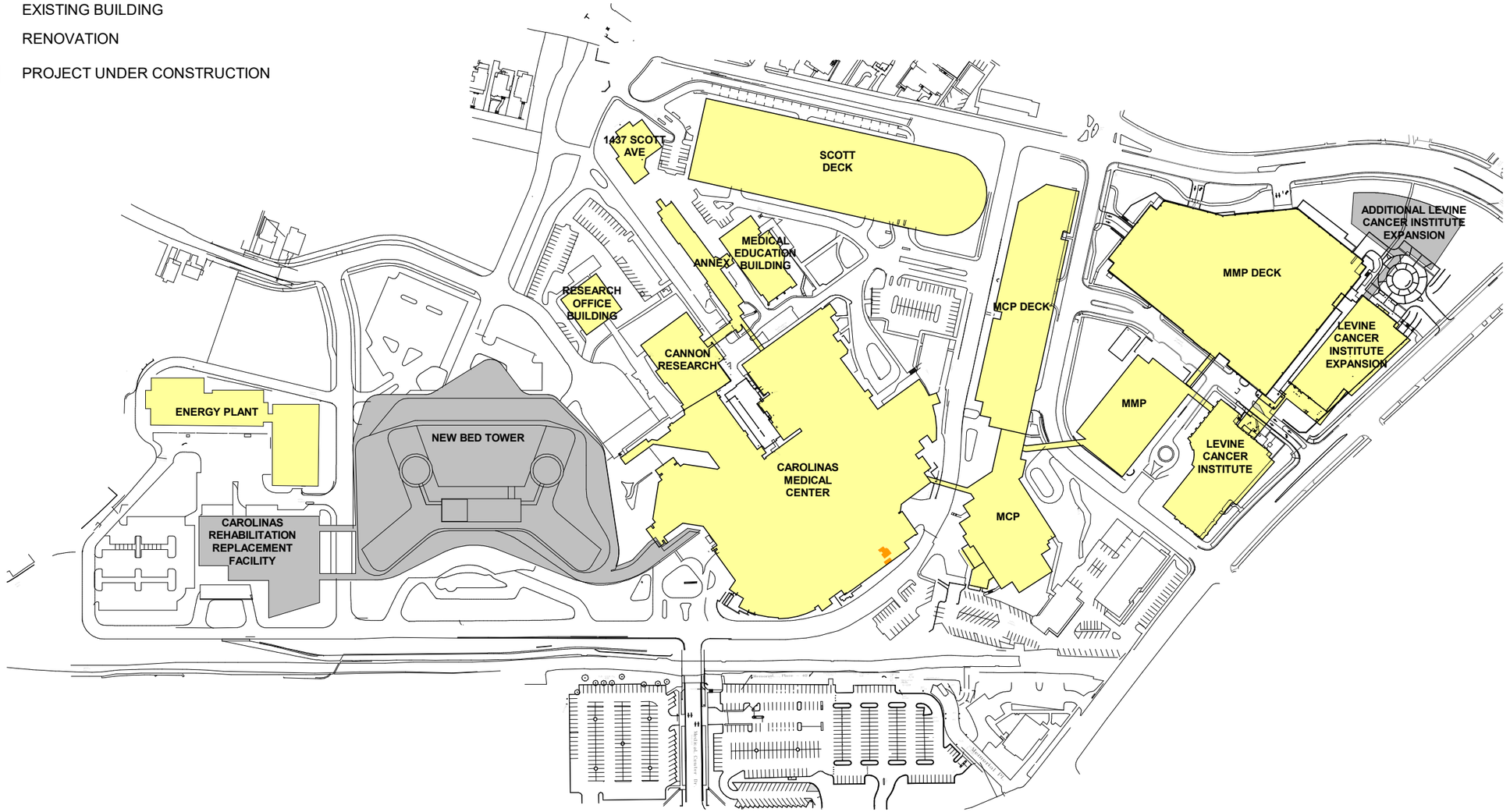
Secretary, N.C. Department of Health and Human Services

Director, Division of Health Service Regulation

Attachment B

COLOR KEY

- EXISTING BUILDING
- RENOVATION
- PROJECT UNDER CONSTRUCTION



SITE PLAN

INTERVENTIONAL RADIOLOGY ROOM #3 REPLACEMENT

ATRIUM HEALTH

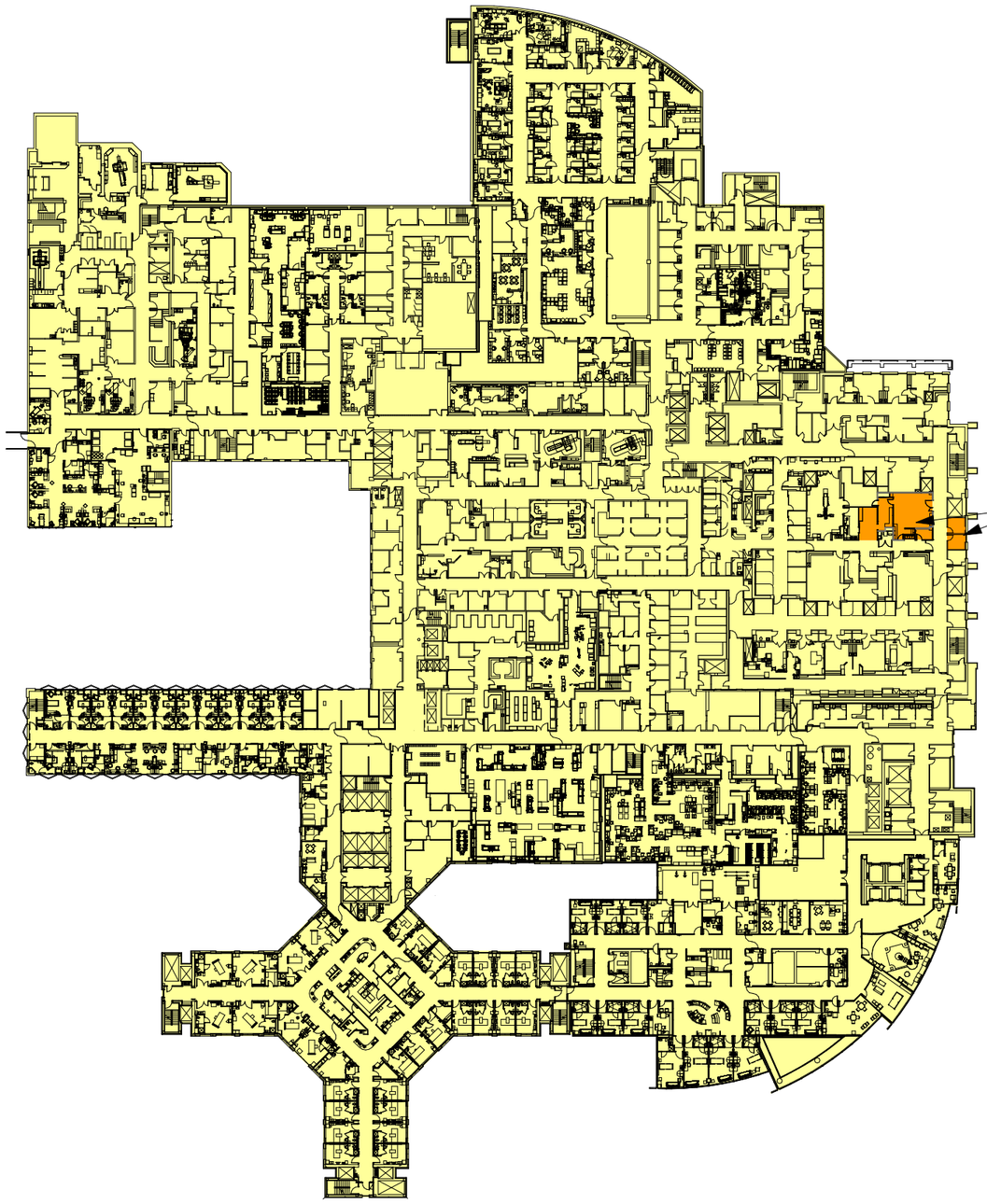
7/30/2021

CAROLINAS MEDICAL CENTER

COLOR KEY

EXISTING BUILDING

RENOVATION



EXISTING OVERALL FLOOR PLAN - LEVEL 04

INTERVENTIONAL RADIOLOGY ROOM #3 REPLACEMENT

ATRIUM HEALTH

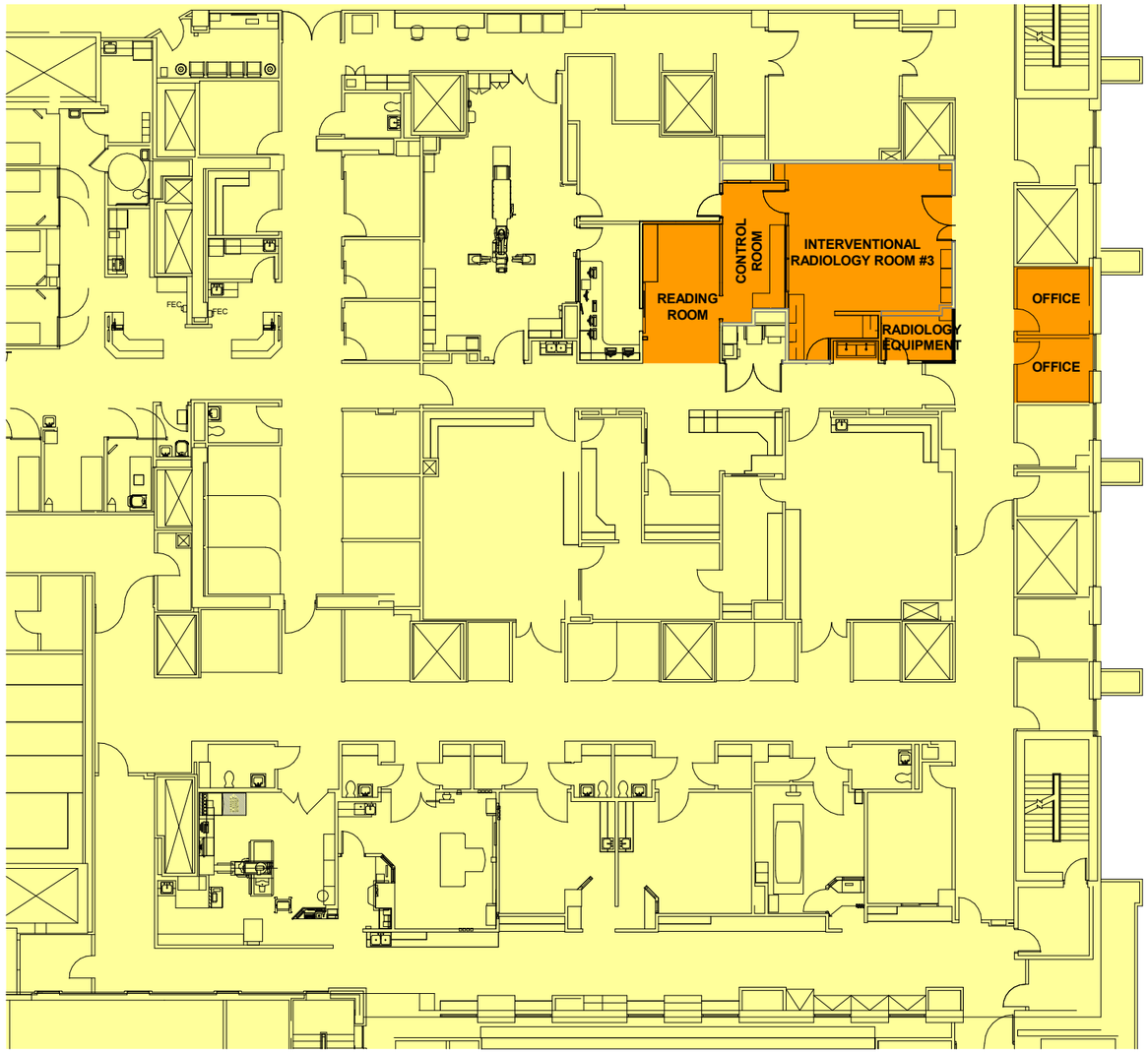
7/30/2021

CAROLINAS MEDICAL CENTER

COLOR KEY

EXISTING BUILDING

RENOVATION



ENLARGED EXISTING FLOOR PLAN - LEVEL 04

INTERVENTIONAL RADIOLOGY ROOM #3 REPLACEMENT

ATRIUM HEALTH

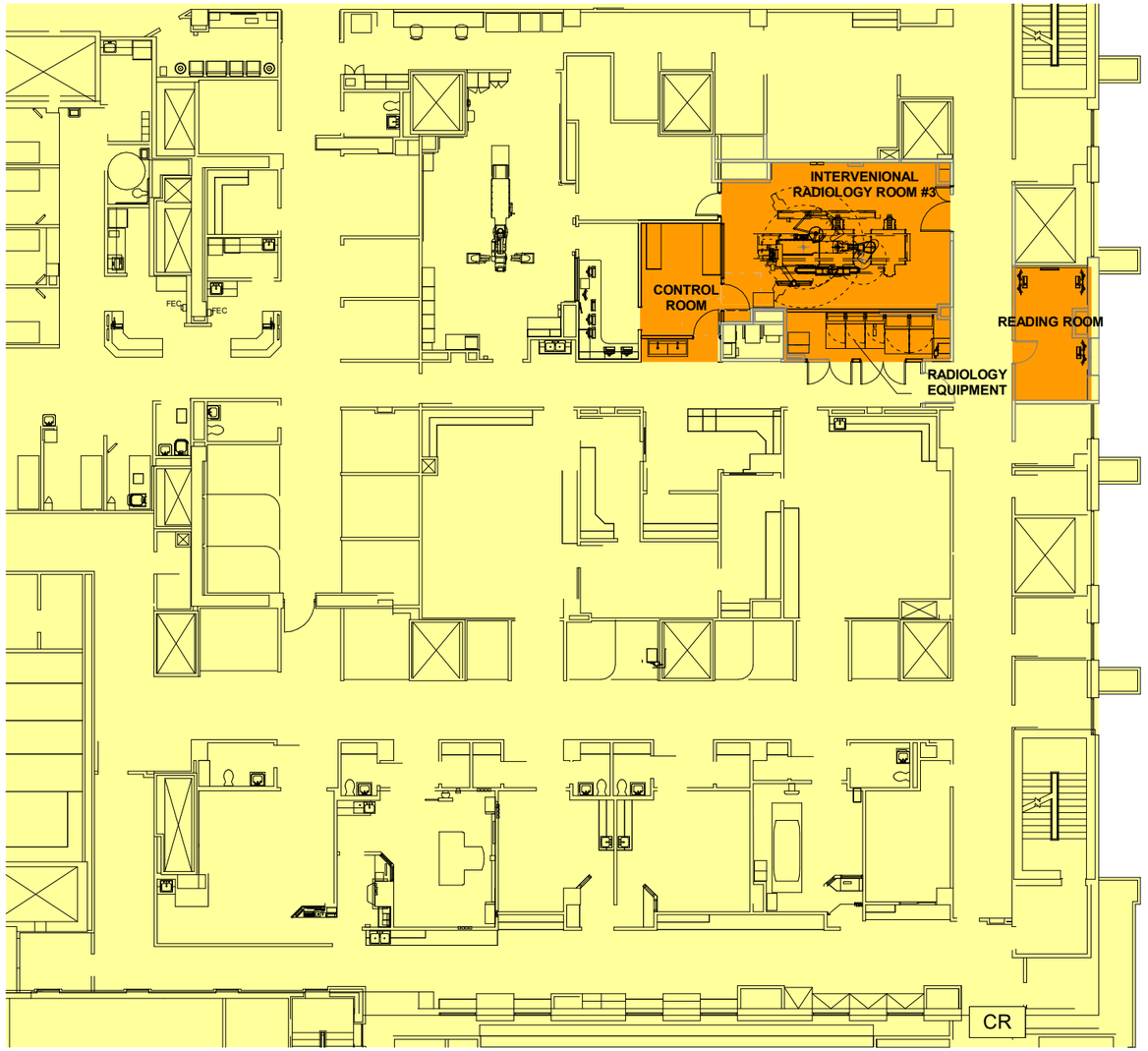
7/30/2021

CAROLINAS MEDICAL CENTER

COLOR KEY

EXISTING BUILDING

RENOVATION



ENLARGED PROPOSED PLAN - LEVEL 04

INTERVENTIONAL RADIOLOGY ROOM #3 REPLACEMENT

ATRIUM HEALTH

7/30/2021

CAROLINAS MEDICAL CENTER

Attachment C

Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard, Malvern, PA 19355

SIEMENS REPRESENTATIVE
Edwin Winicki
edwin.winicki@siemens-healthineers.com

Customer Number: 0000035965

Date: 02/05/2021

ATRIUM HEALTH
1000 BLYTHE BLVD
CHARLOTTE, NC 28203

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 **Page**

ARTIS icono biplane IR Pro (Quote Nr. CPQ-247249 Rev. 0) 3
General Terms and Conditions 11

Contract Total: $ 1,765,000
(total does not include any Optional or Alternate components which may be selected)

Estimated Delivery Date: 10/2021

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.

The parties hereby expressly agree that the Premier Healthcare Alliance, L.P. Group Purchasing Agreement—Imaging Products and Services effective October 1, 2015 (Contract Number(s) PP-IM272) and Siemens Terms and Conditions of Sale and Software License Schedule attached hereto shall govern the purchase of Products pursuant to this Quotation.

Pricing in this Quotation is contingent on Customer accepting Delivery of the Product prior to 150 days from date of order execution.

Payment Terms for this Quotation are 100% invoiced at installation completion.

Accepted and Agreed to by:

Siemens Medical Solutions USA Inc.		**ATRIUM HEALTH**	
By (sign):	_____	By (sign):	_____
Name:	Edwin Winicki	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.

Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard, Malvern, PA 19355

SIEMENS REPRESENTATIVE
Edwin Winicki
edwin.winicki@siemens-healthineers.com

By (Sign): _____

Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard, Malvern, PA 19355

SIEMENS REPRESENTATIVE
Edwin Winicki
edwin.winicki@siemens-healthineers.com

Quote Nr:	**CPQ-247249 Rev. 0**
Terms of Payment:	**Note in order Text Terms of payment** **Free On Board: Destination**
Purchasing Agreement:	PREMIER PURCHASING PARTNERS LP PREMIER PURCHASING PARTNERS LP terms and conditions apply to Quote Nr CPQ-247249 Customer certifies, and Siemens relies upon such certification, that : (a) PREMIER PP-IM-272 IR-CV 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 icono biplane IR Pro

All items listed below are included for this system: *(See Detailed Technical Specifications at end of Proposal.)*

Qty	Part No.	Item Description
1	14465009	**ARTIS icono biplane IR Pro** ARTIS icono biplane is a breakthrough in neuro interventions. The completely redesigned multi-axis floor stand and agile lateral plane revolutionize positioning flexibility and movement speed enabling imaging capabilities and workflow improvements that have never been seen before. At the same time ARTIS icono biplane was designed for multidisciplinary usage making different disciplines feel at home in the same interventional lab. The lateral plane can be swiveled by an automated drive with the click of a button to get to the preferred setting. Imaging two projections simultaneously saves time and contrast. Simplified operation of ARTIS icono with Touch2Move technology - functions that can be selected and invoked in a single step. The complete CARE+OPTIQ package offers constant image quality at a low dose. Digital acquisition technology and digital subtraction angiography with up to 7.5 f/s in 1k/16 bit matrix are available. OPTIQ Roadmap comes with enhanced image quality improvements at reduced radiation dose. Several directly accessible features ease the workflow and save time. The Pro system platform allows acces to unique features like syngo DynaCT Sine Spin, syngo DynaCT Multiphase and the preparation for 3D acquisitions with the agile lateral plane. It already contains the following functionalities: Live 2k Imaging, Fluoro Loop and Memory expansion (400k). Disclaimer: 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.
1	14465028	**Laser crosshairs (A&B)** Laser crosshairs integrated in the cover of the flat detector and tableside operation for easier, quicker and dose-saving positioning of the patient.
1	14465138	**Biplane Imaging system** Image system computer for control of system operation and image acquisition. 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 14432948

Automap

Automatic stand positioning depending on the selected reference image and automatic reference image selection depending on the stand positioning.

1 14465022

OPTIQ with as40HDR GIGALIX biplan

OPTIQ image chain with the following tube, collimator and flat detector configuration:
as40HDR detector and GIGALIX tube, in both planes
The as40HDR flat detector is optimized for the requirements of radiology and surgery.
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.

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.

1 14455573

Large Display (rail mount)

Large color flat screen display (including cables) for the examination room, with a panel diagonal of 55”. This large display version provides an excellent clinical image quality due to its new IPS panel technology.
The Large display is fixed on a ceiling-mounted, longitudinally movable, rotatable and height-adjustable display holder in the examination room.

1 14465012

Dual control room display

Live images are displayed on two 24“ color and gray scale image displays.

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 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.

1 14455548

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	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. 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.)
1	14465047	**1st 8 pedal wireless footswitch** Wireless 8-pedal footswitch for release of fluoroscopy, exposure and table brake, as well as configurable control function.
1	14465124	**Operation in the control room** Preparation for system operation from control room.
1	14465095	**Op. ctrl. - handswitch (C-Room)** Additional handswitch for radiation release and additional control functions.
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.
1	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" (l x h); one lower body radiation protection pivot swivel element (48 cm x 75 cm / 18.9" x 30.3" (l x h); one flip down element 57 cm x 33cm / 22.4" x 12.99" (l 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. 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	14434157	**Moveable upper body rad. protection** This radiation shield protects the user from scattered radiation. For room heights up to 290 cm / 114.2". 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.

1 14465037

syngo interv. Neuro Engine Pro

Application software for reconstruction, post-processing and handling of 3D information including specific 2D and 3D applications for interventional neuroradiology.

The package includes the following functionalities:

- 3D high-contrast and CT-like soft-tissue imaging (syngo DynaCT).

- 3D roadmap for dynamic overlay of planning data and 3D volumes on live images (fluoroscopy or roadmap).

- In-room control for table-side operation of advanced applications.

- 3D Wizard for expert step-by-step guidance in 3D acquisition.

- Parallel patient processing capabilities.

- Fusion functionality for integration of pre-interventional 3D datasets also from other modalities into the Angio-room.

- Marking of points or lines on the 3D geometry or MPRs and overlay of these markings on live images (e.g. fluoroscopy).

3D functional imaging providing physiologic blood volume information (syngo DynaPBV Neuro), dedicated workflow support and measurements for aneurysm analysis and 3D stenosis measurements.
- 2D functional imaging for visualization of blood flow characteristics (syngo iFlow).

1 14465145

Twin Spin

When acquiring a 3D volume with an according setup of start-position and acquisition program, the second plane will rotate in idle mode and does not need to be parked, saving time and improving the clinical workflow.

1 14465014

syngo DynaCT Sine Spin

syngo DynaCT Sine Spin helps neuroradiologists reduce cone beam CT artifacts in the basal part of the brain and close to the skull. Before performing thrombectomy and after all neurointerventions.

syngo DynaCT Sine Spin brings cone beam CT of the brain to the next level. A new double oblique trajectory for image acquisition was developed to overcome artifacts from bony structures especially in imaging the basal part of the brain and close to the skull.

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.

1 14446026

syngo Dyna4D

syngo Dyna4D enables the visualization of flow patterns in 3D.
With only one C arm scan it provides a view similar to virtually an unlimited number of DSA runs at no additional dose and contrast media.
syngo Dyna4D helps to expand clinical capabilities in the angio suite by optimizing patient selection and supporting individualized treatment strategies.

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

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.
1	14465096	**QVA Vascular analysis** Vessel analysis with determination of degree of stenosis, distance measurement and calibration.
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 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 restricted.
1	14455544	**Tabletop - narrow** Narrow-shaped carbon fiber patient positioning tabletop with head-end recess. Ideal for cardiological applications. Tabletop tapered in the thorax area for maximum freedom of C-arm angulation. Maximum patient weight: 280 kg / 617.3 lb Weight: 13 kg / 28.7 lb Length: 2287 ± 1 mm / 90.1" ± 0.04" Width head-end: 228 ± 0,5 mm / 9.0" ± 0.02" Width middle body: 480 ± 0.8 mm / 18.9" ± 0.03" Width lower body: 525 ± 0.5 mm / 20.7" ± 0.02" Intended only for use with ARTIS tables.
1	14440512	**LED Exam Light** Ceiling-mounted, flexible positionable examination light with focusable light system. It is fully integrated into the ceiling-installed radiation protection mounting unit. - Luminance: Min 60,000 Lux for 100 cm / 39.4" distance - Working distance: 70 to 140 cm / 27.6" to 55.1" - Color rendering index Ra at 4500 Kelvin: min. 95 - Color temperature: 4,100+-200 Kelvin - Focusable light field: 14 to 25 cm / 5.5" to 9.8" - Total input power: Max. 24 VA
1	AXA_RIG_ICONO_BP	**Standard Rigging icono BP**
1	AXA_EDU_INTNEURO	**Interventional Neuro Education Pkg** This Interventional Neurology education package includes Post-Go Live training: - Dedicated Siemens Education Consultant: partnering with your Education Coordinator to create a blended curriculum adapted to your facility’s individual needs. - Blended Learning: onsite, digital (immersive, online & virtual), and instructor-led classroom fortified by an ASRT approved checklist. - On-site Customization: optimizing system hardware, software, clinical workflow and operating safety consistent with the cleared use of the system. - Ongoing Educational Case Support: ability to request onsite case-support with a Siemens Clinical Education Specialist for your advanced procedures. This education package includes: - Go Live: Onsite clinical applications sessions, guiding staff members, reinforcing concepts and practices acquired during pre-training during operation. -

		Warranty / Post-Go Live: Continuation of the CEP delivery. Ongoing case support on advanced request and subject to availability. Parties will mutually agree on deliverables and scheduling of the requested training.This educational offering must be utilized within 12 months following install end date. If this offering is not completed within the applicable time period, Siemens obligation to provide the training will expire without refund.
1	AXA_INITIAL_28	**Initial onsite training 28 hrs** Up to (28) hours of on-site clinical education training, scheduled consecutively (Monday – Friday) during standard business hours for a maximum of (4) imaging professionals. Training will cover agenda items on the ASRT approved checklist. Uptime Clinical Education phone support is provided during the warranty period for specified posted hours. This educational offering must be completed (12) months from install end date. If training is not completed within the applicable time period, Siemens obligation to provide the training will expire without refund
1	AXA_FOLLOWUP_28	**Follow-up training 28 hrs** Up to (28) hours of follow-up on-site clinical education training, scheduled consecutively (Monday – Friday) during standard business hours for a maximum of (4) imaging professionals. Uptime Clinical Education phone support is provided during the warranty period for specified posted hours. This educational offering must be completed (12) months from install end date. If training is not completed within the applicable time period, Siemens obligation to provide the training will expire without refund.
1	EPW935515UPS	**Eaton Powerware 9355 15 kVA UPS** Includes UPS, battery, maintenance bypass panel, and one year on-site parts and labor coverage (24x7) by Eaton Powerware. This UPS is recommended when protection and uninterruptible power is required for the Artis' C-arm and table. Emergency fluoroscopy is not available with this UPS. If emergency fluoroscopy is required, the 9390 - 160 kVA UPS is recommended for the full system. One UPS per lab. Additional seismic brackets are required to make this system OSHPD approved.
2	GEL104013660127 8	**Black anti-fatigue mat 36x60** Black NewLife EcoPro anti-fatigue mat (36 inches x 60 inches), 3/4 inch polyurethane foam, fluid and dirt resistant with anti-micorbial properties, matte textured surface. The ultimate employee benefit for workers who stand, are ergonomically designed to provide the perfect balance of premium comfort and optimal support. Proprietary Cellulon®Polyurethane Technology stands up to the tough demands of commercial environments while providing lasting comfort that won't bottom out over time. This eco-friendly line of anti-fatigue mats is certified by the National Floor Safety Institute for its high traction bottom surface.
1	AM0160C	**Adept STARSystem** Radial positioning equipment intended for clinicians working on the right. Includes STARBoard, leg arm support and STARTable. A key function of the STARBoard is its ability to present the patients wrist in the hyper-extended position whilst access is achieved, then simply return it to a more relaxed, medially-rotated position, for the duration of the procedure, allowing greater patient comfort. Crafted in carbon fiber for superior strength, radiolucency and durability, the STARBoard is light weight and compact. STARSupport connects to the STARBoard after radial access is gained facilitating left arm procedures for superior patient comfort. STARTable not only provides clinicians with an adjustable work surface, the vertical shield reduces X-ray scatter. Includes one year warranty through Adept.
1	AXA_SERV_CONTRACT	**AXA Service Contract-Evolve $52,000**

1	AXA_BUDG_ADDL_RIG	**Budgetary Add'l/Out of Scope Rigging $10,383**

System Total: $ 1,765,000.00

Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard, Malvern, PA 19355

SIEMENS REPRESENTATIVE
Edwin Winicki
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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 Helpdesk “Tell us” function at www.siemens.com/tell-us.

Upgrades/Options/Software packages purchased and requiring installation by Siemens must be installed 60 days post shipment. If Siemens’ access to the equipment on which such package(s) are to be installed is not made available within 60 days post shipment then invoicing will occur and payment will be due based upon contractual payment terms.

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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 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 1½% 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-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, 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 non-complying 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 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 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 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

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.

Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard, Malvern, PA 19355

SIEMENS REPRESENTATIVE
Edwin Winicki
edwin.winicki@siemens-healthineers.com

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

1. 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.
"**Documentation**" shall mean the documents and other supporting materials which are intended to support the use of an associated product, including (but not limited to) instructions, descriptions, flow charts, logic diagrams and listings of the Software, in text or graphic form, on machine readable or printed media.
"**Designated Unit**" shall mean a single control unit or computer identified on the first page of the Agreement, on which Software licensed hereunder may be used by Licensee.
2. SCOPE: The following terms and conditions shall apply to all Software and Documentation provided by Licensor to Licensee under the Agreement (whether included with other products listed in the Agreement or listed separately in the Agreement), together with any updates or revisions thereto which Licensor may provide to Licensee, and all copies thereof, except any Software and/or Documentation licensed directly by Licensor's supplier under a separate end-user license agreement accompanying the Software or the Documentation, in which case Licensee agrees to be bound by that license agreement as a condition to using the Software and/or Documentation. Except as expressly provided herein, and provided that in no event shall the warranties or other obligations of Licensor with respect to such Software or Documentation exceed those set forth in this Schedule, this Schedule shall be subject to the liability limitations and exclusions and other terms and conditions set forth in the Agreement. **ANY USE OF THE SOFTWARE, INCLUDING BUT NOT LIMITED TO USE ON THE DESIGNATED UNIT, WILL CONSTITUTE LICENSEE'S AGREEMENT TO THIS SOFTWARE LICENSE SCHEDULE (OR RATIFICATION OF ANY PREVIOUS CONSENT).**
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Revised 03/15/05

Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard, Malvern, PA 19355

SIEMENS REPRESENTATIVE
Edwin Winicki
edwin.winicki@siemens-healthineers.com

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.

Quotation

Quote No. Q-00044046

Sales Support
tel (800) 633-7231
fax (412) 406-0952
radiologysolutions.bayer.com

Bayer HealthCare LLC
1 Bayer Drive
Indianola, PA 15051

This quotation has been prepared for: Charlotte Mecklenburg Hospital Auth Atrium Health

Issued on 2/2/2021 **Valid until** 10/29/2021 **Trade-in required** No

Your Bayer Sales Team:

Angie Wood, , angie.wood@bayer.com
Anthony Capuzzi 704-534-9391, , anthony.capuzzi@bayer.com

Quotation Overview

PREMIER RADIOLOGY T1-T4 Pricing Applied

Bayer's diagnostic imaging products, software, and equipment service help healthcare teams in radiology address their critical performance, quality, uptime, and scheduling requirements.

Please note: If pricing and terms of this [order/quote] are based upon your current Group Purchasing Organization (GPO) affiliation, any change to your current affiliation may require a new quote or updated terms and pricing.

>See Products and Services Details in this quote, or refer to your invoice, for an itemized breakdown of quoted products.

Imaging Products and Services

Product Name	Total List Price	Total Discounts	YOUR PRICE
Arterion - Medrad® Mark 7 Arterion® Injection System	$39,783.75	$(9,991.85)	$29,791.90
TOTAL(Local taxes, shipping and/or handling to be invoiced when applicable)	$39,783.75	$(9,991.85)	**$29,791.90**

Additional Comments

All terms and conditions from Premier contract PP-IM-421 will solely govern this agreement.

All Pricing is in U.S. Currency.

Quotation continued

Quotation prepared for: Charlotte Mecklenburg Hospital Auth Atrium Health **Issued on** 2/2/2021 **Valid until** 10/29/2021

Products and Services Details

Arterion - Medrad® Mark 7 Arterion® Injection System and Related Products/Services

Item(s)	Catalog No.	Qty	Unit List Price	Contracted Price	Trade-In Amount	Multi-Unit Discount	Additional Discounts	YOUR PRICE
Medrad® Mark 7 Arterion® Table Mount System	ART700 TABL	1	$36,000.00	$26,438.40	$0.00	$0.00		$26,438.40
Installation - Medrad® Mark 7 Arterion® - Table Mount	INS ART 700-R	1	$1,830.00	$0.00	$0.00	$0.00		$1,830.00
Power unit floor mount bracket assembly	60765438	1	$240.00	$0.00	$0.00	$0.00		$240.00
Medrad® Mark 7 Arterion® 150mL syringe	ART 700 SYR	1	$375.00	$212.50	$0.00	$0.00		$212.50
Medrad® Mark 7 Arterion® free-standing fixed height pedestal on wheels	84180173	1	$1,338.75	$0.00	$0.00	$0.00	20%	$1,071.00

Subtotal $29,791.90

TOTAL **$29,791.90**

GRAND TOTAL (Local taxes, shipping and/or handling to be invoiced when applicable) **$29,791.90**

If your organization is tax exempt, please notify Sales Support at 1-800-633-7231.

Quotation continued

Quotation prepared for: Charlotte Mecklenburg Hospital Auth Atrium Health **Issued on** 2/2/2021 **Valid until** 10/29/2021

Quotation continued

Quotation prepared for: Charlotte Mecklenburg Hospital Auth Atrium Health **Issued on** 2/2/2021 **Valid until** 10/29/2021

Quotation continued

Quotation prepared for: Charlotte Mecklenburg Hospital Auth Atrium Health **Issued on** 2/2/2021 **Valid until** 10/29/2021

This quotation has been prepared for: Charlotte Mecklenburg Hospital Auth Atrium Health

Issued on 2/2/2021 **Valid until** 10/29/2021 **Trade-in required** No

Your Bayer Sales Team:

Angie Wood, , angie.wood@bayer.com
Anthony Capuzzi 704-534-9391, , anthony.capuzzi@bayer.com

If you are using this quote as a purchase order, please complete the Acceptance and Billing information below:

Acceptance and Billing

Your signature below indicates your acceptance of this Agreement, including the terms and conditions included as part of this document. Please complete the information below, along with your Purchase Order referencing Quote # Q-00044046, and email this form to Sales Support at risalessupport@bayer.com AND your Strategic Account Manager, Angie Wood, at angie.wood@bayer.com.

If pricing and terms of this order are based on your current Group Purchasing Organization (GPO) affiliation, any change to your current affiliation may require a new quote or updated terms and pricing.

Payment terms
30 days due net

Terms of Delivery
PITTSBURGH

Customer contact

Address
1000 Blythe Blvd
Charlotte, NC 28203

Billing Information
1000 Blythe Blvd
Charlotte, NC 28203

Customer Number
3827302

Phone

Additional Customer Comments

PO#
Write PO number

PO Amount
Write PO amount

Customer Approver
Write customer name

Customer Approver Title
Write customer title

Billing Email Address (if applicable)
Write email address

Customer Approver Signature
X
Please print and sign

Date
MM/DD/YYYY

Quotation continued

Quotation prepared for: Charlotte Mecklenburg Hospital Auth Atrium Health **Issued on** 2/2/2021 **Valid until** 10/29/2021

Bayer Product Terms and Conditions

Please click on the relevant product name below to review terms and conditions

DEVICES

Bayer Product Terms and Conditions

Quotation continued

Quotation prepared for: Charlotte Mecklenburg Hospital Auth Atrium Health **Issued on** 2/2/2021 **Valid until** 10/29/2021

Attachment D

PROPOSED TOTAL CAPITAL COST OF PROJECT

Project name: CMC IR Lab #3 Replacement

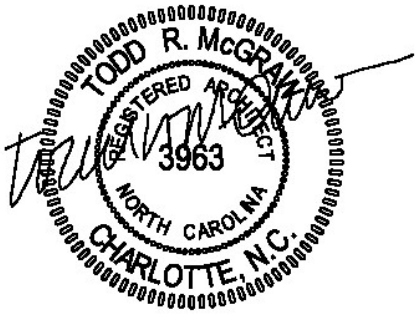
Provider/Company: Atrium Health

(1)	Purchase price of land	0
(2)	Closing costs	0
(3)	Site Preparation	0
(4)	Construction/Renovation Contract	$708,435
(5)	Landscaping	0
(6)	Architect/Engineering Fees	$212,283
(7)	Medical Equipment	$1,924,914.31
(8)	Non-Medical Equipment	0
(9)	Furniture	0
(10)	Consultant Fees (CON Fees, Legal Fees)	0
(11)	Financing Costs	0
(12)	Interest During Construction	0
(13)	Other (IS, Security, Internal Allocation)	$185,123
(14)	**Total Capital Cost**	$3,030,755.31

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

10/18/2021

(Signature of Licensed Architect or Engineer) *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 $130,122.41

Attachment E

Location	System	Final Offer	Notes
CMC-Main	Artis Zee MP	$ 571,500	Configured same as CMC-NE, except no injector or DSA as not bring used for Angio at CMC. Also, added some positioning aids.
System Total		$ 571,500	
Removal / Scrapping of Existing Polystar		$ 14,500	
Subtotal with Trade / Scrapping		$ 586,000	
Engineer Training for (1) Engineer (inexperienced) TBD - per Ron Padgett		$ 55,037	
Artis Zee Total with Scapping of Polystar and Engineer Training		$ 641,037	

Dec-12

Attachment F

ARTIS icono

A breakthrough in neuro interventions

Transforming care delivery
in image-guided therapy.

SIEMENS Healthineers

After the randomized controlled trials have proofed the positive outcomes of mechanical thrombectomy in ischemic stroke, interventional neuroradiology is confronted with an increasing number of procedures.

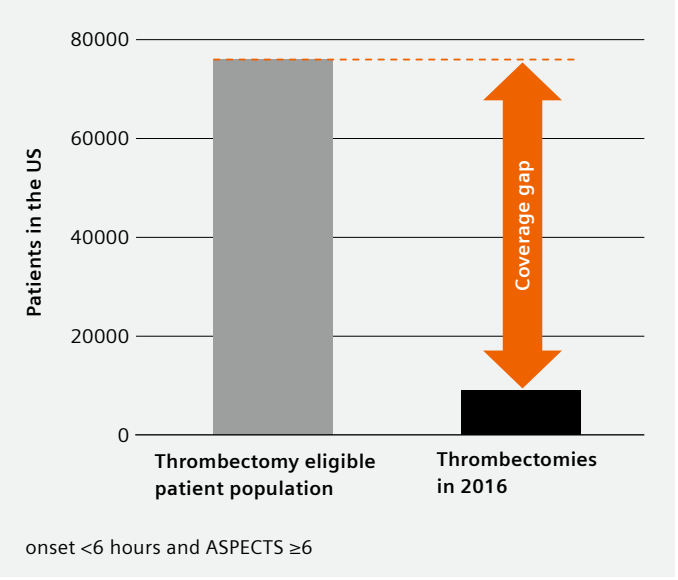
A typical human brain has 86 billion neurons. Let's fight for every one.

When a stroke occurs, every second counts in the battle to minimize neurological deficit. Many large vessel occlusion patients can benefit from interventional stroke management, where imaging and mechanical thrombectomy go hand-in-hand. This streamlined workflow has the potential to significantly enhance patient outcomes – and with more and more randomized controlled trials confirming the safety and success of mechanical thrombectomy, the number of stroke patients eligible for the procedure is growing steadily.

Procedure growth & coverage
So far, however, most of these eligible patients will not actually receive mechanical thrombectomy. To close the gap, more and more hospitals are now introducing comprehensive stroke services. As a result, the global growth rate for mechanical thrombectomy procedures is currently 26 percent per year*.

* Source: Decision Resources Group Medtech 360, CAGR 2017 – 2022

Coverage gap in mechanical thrombectomy



onset <6 hours and ASPECTS ≥6

AT Procedure Data Tool, based on registries and market reports.
Source: Rai AT, et al., J Neurointervent Surg (9) 2017

ARTIS icono – Advancing therapy outcomes in neuro interventions

With the number of thrombectomy eligible stroke patients rising steadily, you and your colleagues face a double challenge: treating more patients overall, and treating each one faster.

Our ARTIS icono system is specially designed to help you do both. With next-generation features, this icon of innovation can help you streamline procedures and exploit new growth fields – by literally expanding precision medicine.

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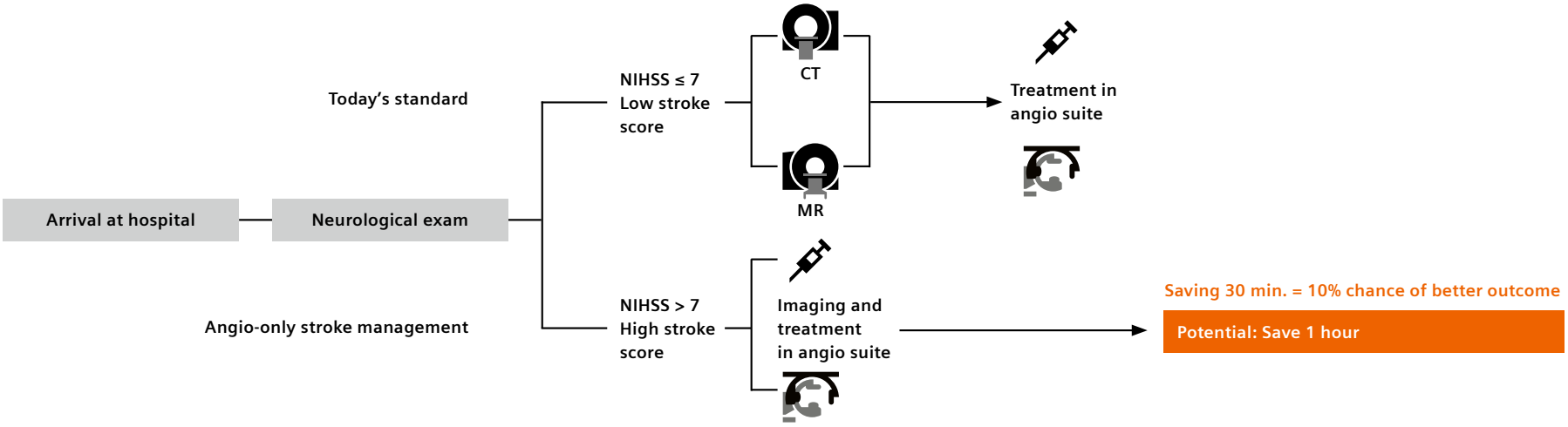
To a stroke patient, 30 minutes may be a lifetime

Switch smoothly and seamlessly between 2D and 3D imaging. Acquire CT-like images of unprecedented quality in moments. When every second counts, ARTIS icono delivers – fast.

Thanks to visualization of bleedings in the angio room, many patients with suspected stroke (NIHSS > 7, high stroke score) may no longer require conventional preliminary imaging. Instead, initial studies have shown that you can take them straight to the angio lab for diagnosis and subsequent intervention, possibly reducing time-to-thrombectomy by 34 minutes on average.

The Siemens Healthineers stroke workflow – "time is brain"



Faster and easier *syngo* DynaCT acquisition

syngo DynaCT High Speed reduces acquisition times significantly while raising the bar in CT-like image quality. In addition motion artifacts are reduced in *syngo* DynaCT with uncooperative patients by compensating movements. With the new Twin Spin feature you can smoothly switch between 2D biplane and 3D imaging and save precious time, and also reduce the risk of collisions with equipment (e.g., anaesthesia). You can now use biplane fluoroscopy to perform AP and lateral isocentering in a single step – no need to move the c-arm.

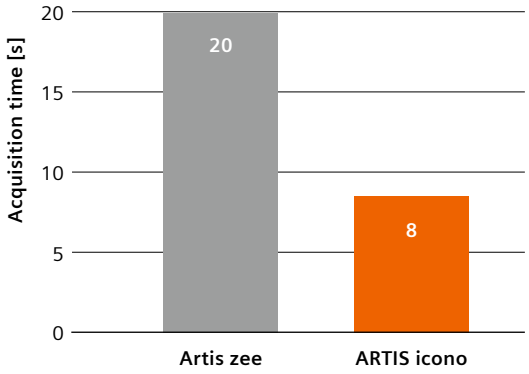
OPTIQ – A new approach to image quality and dose

Regardless of procedure, patient size or C-arm angulation, OPTIQ provides image quality according to your personal flavor. This innovative system uses big data to maintain your image quality presets automatically throughout the procedure. For maximum dose efficiency without user interaction, OPTIQ uses a contrast-driven technique based on automatic parametrization supported by intelligent, self-adjusting algorithms.

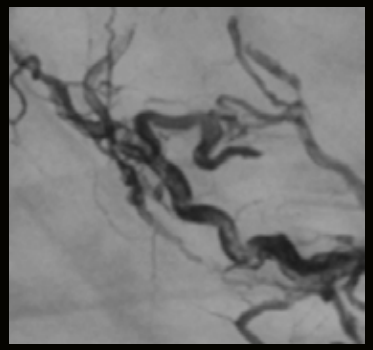
- Siemens Healthineers exclusive 5-parameter-driven exposure control
- SID and collimation settings are factored in automatically
- Constant image quality at a new ALARA benchmark

Faster diagnosis for faster treatment

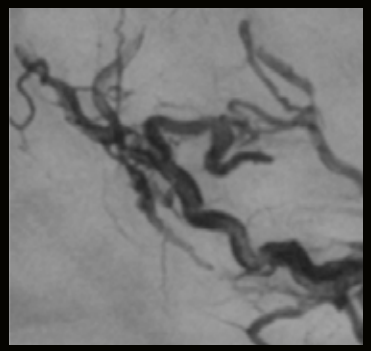
ARTIS icono acquires DynaCT images in less than half the time



Designed for faster diagnosis and faster treatment, ARTIS icono is a pioneer in the field of angio-only stroke therapy.

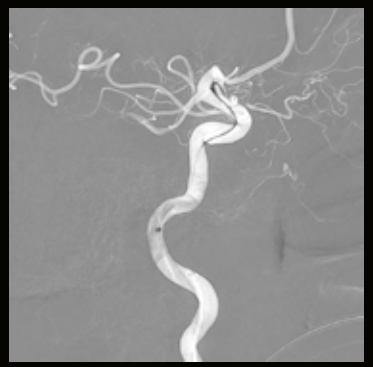


Conventional system with conventional dose



82% less dose with OPTIQ

Conventional system with conventional dose vs. OPTIQ with less dose (AVM treatment using tantalum containing material, same patient)
Prof. Bernhard Meyer, MD, Hanover Medical School, Hanover, Germany



DSA Roadmap with OPTIQ
Jan Gralla, MD, Inselspital Bern, Switzerland

syngo DynaCT Sine Spin: A combined LAO/RAO and CRAN/CAUD trajectory

Clear and consistent 3D imaging from cranium to basal

ARTIS icono delivers the consistent 3D whole-brain imaging quality you need for confident stroke diagnosis, treatment and optimal patient outcomes. With time-dynamic perfusion imaging tools at your fingertips, swift, smooth workflows become possible.

***syngo* DynaCT Sine Spin*: Visualize bleeding even near bony structures**

syngo DynaCT uses a new double oblique trajectory to overcome artifacts from the massive bony structures that surround the basal part of the brain. With a homogeneous soft tissue resolution from cranium to basal, ARTIS icono takes whole-brain soft tissue imaging to new levels of quality and consistency. *syngo* DynaCT Sine Spin is ideal before performing thrombectomy, and after all neuro interventions.

***syngo* DynaCT Multiphase* – Cerebral collateral vessel visualization without transferring to CT**

By making collateral status imaging an integral part of your interventional suite, *syngo* DynaCT Multiphase supports sound treatment decisions before mechanical thrombectomy. Rather than transferring the patient to CT, you can now save time by using time-resolved DynaCT instead.

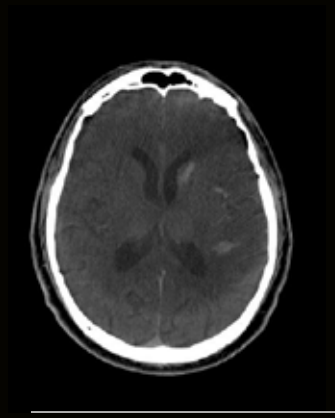
syngo DynaCT Multiphase depicts up to 10 different time points within a period of ~60 seconds or less. The images can be processed with the RAPID™ software by iSchemaView**.

- Seamlessly integrate collateral status imaging into your interventional suite
- Sounder decisions based on time-resolved CTA information
- Save time by skipping the transfer to CT

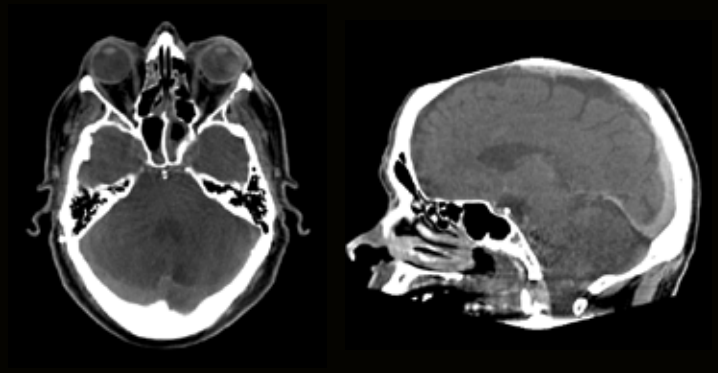
ARTIS icono and iSchemaView's RAPID™

RAPID ANGIO** provides clear, easy-to-interpret CT perfusion maps. These help you to identify brain regions with reduced cerebral blood flow and blood volume, as well as delayed contrast arrival. RAPID based on CT images was used in the DAWN and Defuse3 multicenter studies.

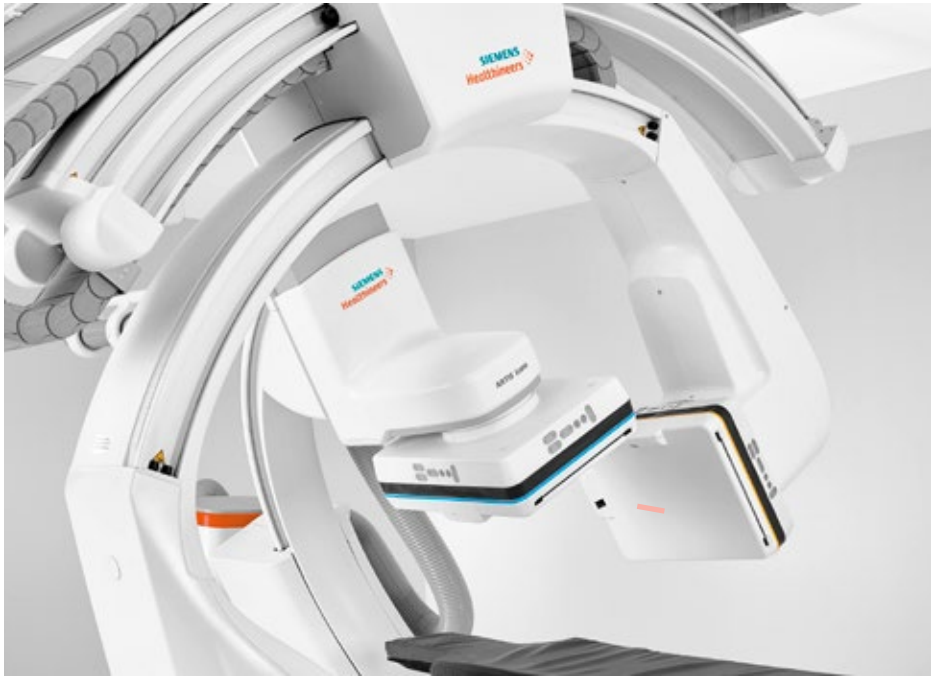
*optional feature
**Third party SW required.



Visualization of bleeding with *syngo* DynaCT Sine Spin
René Chapot, MD, Alfried Krupp Krankenhaus Essen, Germany



Homogeneous image quality with *syngo* DynaCT Sine Spin
René Chapot, MD, Alfried Krupp Krankenhaus Essen, Germany



"Over the years, for us the challenge for aneurysm treatment is to be able to treat more complex cases, smaller aneurysms and more complex anatomy."

Mani Puthuran MD, The Walton Centre, Liverpool, UK

Better patient outcomes in cerebral aneurysms

When you need to visualize flow characteristics clearly and identify regions with blood flow anomalies, ARTIS icono delivers.

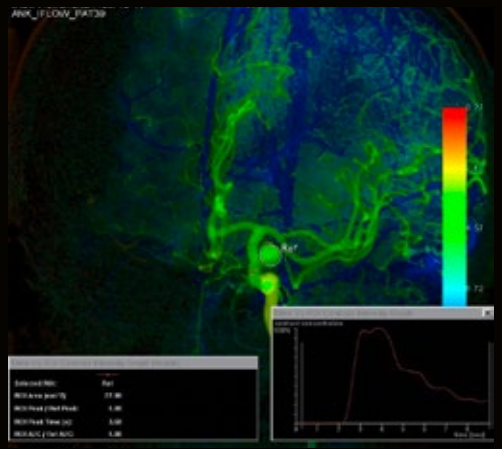
***syngo* iFlow – dynamic flow evaluation**
At the press of a button, *syngo* iFlow* visualizes a complete DSA run in a single, color-coded image. It can display flow curves (e.g. time to maximal opacification, area under curve) for regions of interest, and evaluates the in- and outflow of contrast both before and after flow diverter placement.

***syngo* Dyna3D – high-contrast 3D acquisition and visualization**
syngo Dyna3D* acquires high-contrast 3D visualizations in just three seconds, saving you time and helping to save contrast media. You can either view contrast media and devices separately, or together in different colors. *syngo* Dyna3D supports both subtracted and unsubtracted acquisition and visualization.

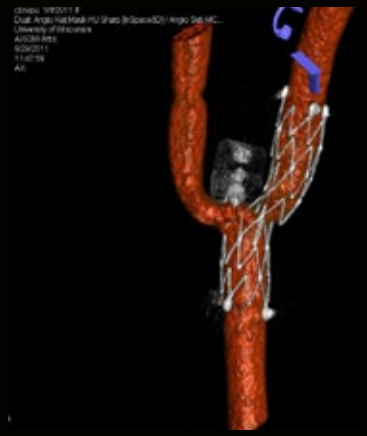
***syngo* DynaCT Micro – maximum resolution for very small vessels**
With an outstandingly high spatial resolution of approx 0.14 mm, *syngo* DynaCT Micro* optimizes spatial orientation in very small anatomies and devices. It harnesses the power of every detector pixel to boost the level of detail – and raises the bar in 3D imaging resolution.

***syngo* DynaCT SMART – see the full picture around metal stents**
syngo DynaCT SMART* reduces metal artifacts in a fully automated workflow in order to visualize regions in close vicinity of metal to make diagnosis possible. This makes it ideal for excluding in-stent stenosis or residual aneurysm filling.

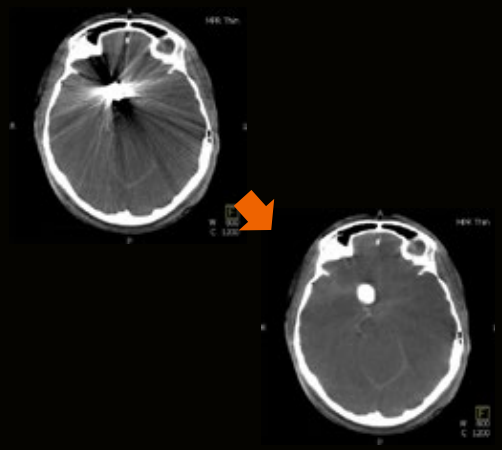
*optional feature



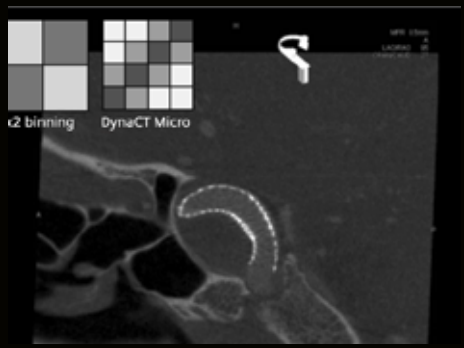
syngo iFlow
Saruhan Cekirge, MD, Hacettepe University, Ankara, Turkey



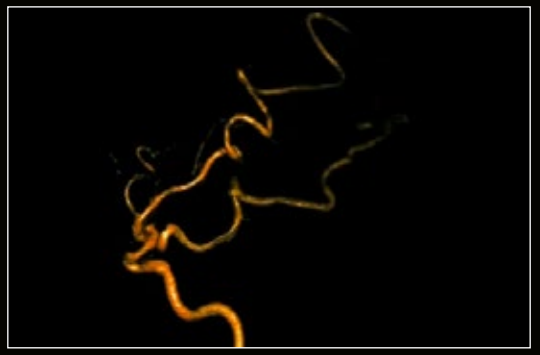
syngo Dyna3D with *syngo* DualVolume
Charles Strother, MD, Madison, Wisconsin, USA

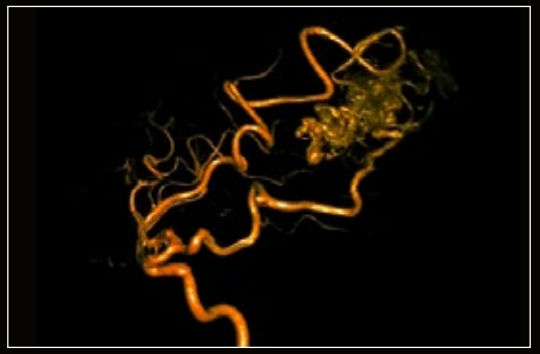


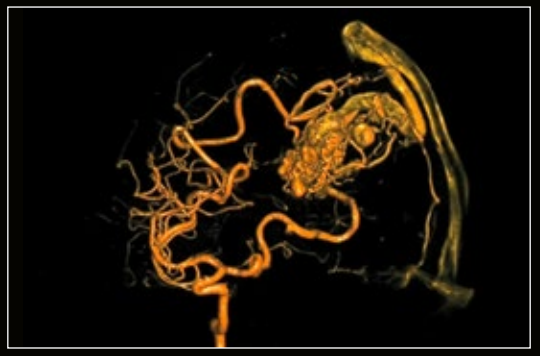
syngo DynaCT SMART
Demetrius K. Lopes, MD, Rush University Medical Centre, Chicago, USA



syngo DynaCT Micro
Martin Skalej, MD, University Hospital Magdeburg, Germany







syngo Dyna4D
Saruhan Cekirge, MD, Hacettepe University, Ankara, Turkey

Better patient outcomes in arteriovenous malformations

When you're planning AVM treatments, clarity is key. ARTIS icono adds a new dimension to simplify the treatment of complex vessel anatomies.

***syngo* Dyna4D – better orientation for AVM treatment**
syngo Dyna4D* is specially designed to help you plan AVM treatments with confidence. By combining 3D vessel tree and temporal blood flow information in a single visualization, it brings outstanding clarity.

- Combine temporal and 3D information
- Sounder AVM treatment planning

"The ARUBA trial conclusion that medical management is superior to medical management with interventional therapy for all unruptured AVMs could be repudiated."

Neurosurgery 2018 (391), The NASSAU (New Assessment of cerebral Arteriovenous Malformations yet Unruptured) Analysis

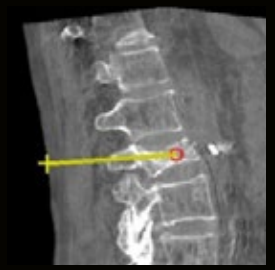
Better patient outcomes in spinal interventions

To enhance your flexibility, ARTIS icono biplane offers laser crosshairs in both planes.

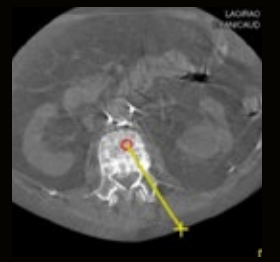
***syngo* Needle Guidance – faster, more comfortable needle procedures**
syngo Needle Guidance* displays the length and direction of the needle path on the fluoroscopy image. The C-arm positions automatically in bull's eye and progression view, while the integrated laser crosshair indicates both the planned entry point and the angle of the device.

Full body coverage of up to 210 cm

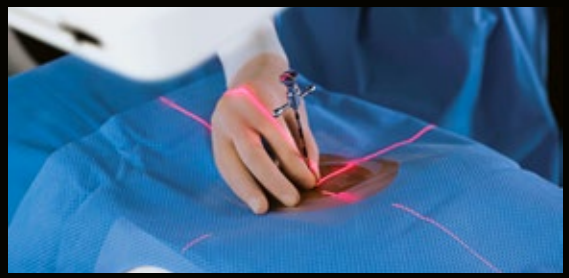
*optional feature



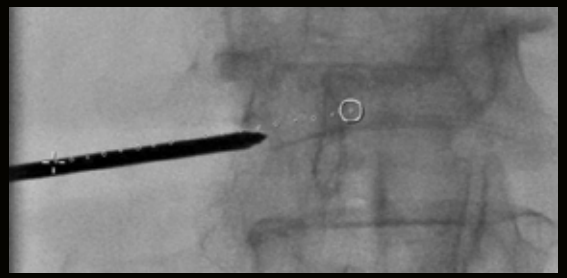
Needle path planning saggital



Needle path planning axial view



Laser crosshair



Progression view

Technical Data

Installation

ARTIS icono is available as a biplane and floor-mounted system

Required room size

ARTIS icono floor requires a minimum room size of 25 m² with the Standard Table and 29 m² with the Multi-tilt Table

ARTIS icono biplane requires a minimum room size of 27 m² with the Standard Table and 29 m² with the Multi-tilt Table

Multiaxis floor stand

- Flexible C-arm positioning at patient's head, left and right side
- Longitudinal coverage of 210 cm, lateral coverage of 190 cm
- C-arm angulation speed up to 100°/s

Agile lateral plane

- Swivel range of 270° to reach detector position on patient's left and right side
- C-arm rotation of +/-100° relative to lateral position for full 3D capabilities*
- C-arm angulation speed of up to 60°/s

Patient tables

ARTIS Multi-tilt Table
- Virtually no force required for repositioning
- Flexible tilting of +15° / -20° and Cradle: +15° / -15°
- Patient weight up to 280 kg

ARTIS Standard Table
- Free floating table top with lowest panning forces
- Patient weight up to 280 kg

OPTIQ imaging chain

- Offers constant image quality at a new ALARA benchmark. Regardless of procedure, patient size or C-arm angulation.
- Pre-set image quality level is maintained automatically throughout the procedure for maximum dose efficiency.
- Contrast driven technique based on automatic parametrization supported by intelligent, self-adjusting algorithms.

as40HDR flat detector

- 16-bit analog-digital conversion
- 65,000 differentiable gray levels
- Refresh rate of 270 Hz
- Images with a resolution up to 2480 × 1920 pixels

* not yet commercially available

Why Siemens Healthineers?

At Siemens Healthineers, our purpose is to enable healthcare providers to increase value by empowering them on their journey towards expanding precision medicine, transforming care delivery, and improving patient experience, all supported by digitalizing healthcare.

An estimated 5 million patients globally benefit from our innovative technologies and services every day in the areas of diagnostic and therapeutic imaging, laboratory diagnostics and molecular medicine, as well as digital health and enterprise services.

We are a leading medical technology company with over 170 years of experience and 18,000 patents globally. With more than 48,000 dedicated colleagues in 75 countries, we will continue to innovate and shape the future of healthcare.

The clinical overlay on the title is not that of the individual pictured. It was modified for better visualization.

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The information in this document contains general technical descriptions of specifications and options as well as standard and optional features that do not always have the present in individual cases.

The statements by Siemens' customers described herein are based on results that were achieved in the customer's unique setting. Since there is no "typical" hospital and many variables exist (e.g., hospital size, case mix, level of IT adoption) there can be no guarantee that other customers will achieve the same results.

The customers cited are employed by an institution that might provide Siemens product reference services, R&D collaboration, or other relationship for compensation pursuant to a written agreement.

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In the interest of complying with legal requirements concerning the environmental compatibility of our products (protection of natural resources and waste conservation), we recycle certain components. Using the same extensive quality assurance measures as for factory-new components, we guarantee the quality of these recycled components.

Note: Any technical data contained in this document may vary within defined tolerances. Original images always lose a certain amount of detail when reproduced.
Caution: Federal law restricts this device to sale by or on the order of a physician.

For accessories, go to: siemens.com/medical-accessories

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Attachment G

EQUIPMENT COMPARISON - Carolinas Medical Center IR Lab #3 Replacement

	EXISTING EQUIPMENT	**REPLACEMENT EQUIPMENT**
Type (e.g., Cardiac Catheterization, Gamma Knife®, Heart-lung bypass machine, Linear Accelerator, Lithotriptor, MRI, PET, Simulator, CT Scanner, etc.)	Interventional System	Interventional System
Manufacturer	Siemens	Siemens
Model name/number	Artis Zee MP	Icono Bi-Plane
Other method of identifying the equipment (e.g., Serial Number, VIN #)	157710	Not Available Until Installed
Is the equipment mobile or fixed?	Fixed	Fixed
Date of acquisition	2012	2021
Was the existing equipment new or used when acquired? / Is the replacement equipment new or used?	New	New
Total projected capital cost of the project <Attach a signed Projected Capital Cost form>	NA	$3,030,755
Total cost of the equipment	$641,037	$1,924,914
Location of the equipment <Attach a separate sheet for mobile equipment if necessary>	CMC, 4th Floor IR Lab #3 (Room # 04L150)	CMC, 4th Floor IR Lab #3 (Room # 04L150)
Document that the existing equipment is currently in use	Existing equipment performed 960 procedures from Sept. 2020 to Aug. 2021	NA
Will the replacement equipment result in any increase in the **average charge per procedure**?	NA	Yes
If so, provide the increase as a percent of the current average charge per procedure	NA	10%
Will the replacement equipment result in any increase in the **average operating expense per procedure**?	NA	Yes
If so, provide the increase as a percent of the current average operating expense per procedure	NA	10%
Type of procedures performed on the existing equipment <Attach a separate sheet if necessary>	Interventional procedures	NA
Type of procedures the replacement equipment will perform <Attach a separate sheet if necessary>	NA	Interventional procedures

Attachment H

CMC IR Lab #3 Volume by Month	
Month	**Volume**
Sep-20	85
Oct-20	69
Nov-20	50
Dec-20	48
Jan-21	42
Feb-21	55
Mar-21	84
Apr-21	100
May-21	109
Jun-21	111
Jul-21	105
Aug-21	102
Total	**960**

Attachment I

FIRST CALL PARTS
Redefining Replacement Medical Parts

Nolan Hamilton

First Call Parts

1351 Southside Dr, Salem, VA 24153

October 20, 2021

First Call Parts will remove a Siemens Artis Zee MP from Atrium Health Carolinas Medical Center.

In exchange, First Call Parts agrees to not re-install it in the State of North Carolina without the appropriate CON approval. Please contact us at 540-676-1511 with further questions.

Sincerely

Nolan W. Hamilton

Nolan Hamilton

From:	Faenza, Julie M
To:	Waller, Martha K
Subject:	FW: [External] Exemption Request for The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center
Date:	Monday, October 25, 2021 12:09:46 PM
Attachments:	2021 CMHA dba CMC Exemption Request to Replace IR Equipment.pdf

Julie M. Faenza, Esq.
Project Analyst, Certificate of Need
Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section
NC Department of Health and Human Services
Office: 919-855-3873 *(I am working remotely most of the time; email is the best way to reach me.)*
Julie.Faenza@dhhs.nc.gov
Pronouns: She/her/hers

Don't wait to vaccinate. Find a COVID-19 vaccine location near you at MySpot.nc.gov.

Twitter | Facebook | Instagram | YouTube | LinkedIn

From: Huber, Brighid K <Brighid.Huber@atriumhealth.org>
Sent: Monday, October 25, 2021 11:42 AM
To: Hunt, Tiffany C <Tiffany.C.Hunt@dhhs.nc.gov>
Cc: Kirkman, Elizabeth <Elizabeth.Kirkman@atriumhealth.org>; Faenza, Julie M <Julie.Faenza@dhhs.nc.gov>
Subject: [External] Exemption Request for The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center

Hello,

I hope this email finds you well. Please find attached an exemption request submitted by The Charlotte-Mecklenburg Hospital Authority ("CMHA") d/b/a Carolinas Medical Center ("CMC") to replace interventional radiology equipment located on 4th floor of the main hospital building.

Thank you very much, and please let me know if you have any questions.

Best,

Brighid

Brighid Knoll Huber, MHA, ATC
Strategic Services Group
Mobile: 724-986-6214

Atrium Health

Carolinas HealthCare System is Atrium Health

2709 Water Ridge Parkway, Suite 200, Charlotte, NC 28217
