

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

April 15, 2021

Ms. Brighid Huber Brighid.Huber@atriumhealth.org

Exempt from Review – Replacement Equipment				
Record #:	3530			
Date of Request:	April 12, 2021			
Facility Name:	Atrium Health Union West			
FID #:	180514			
Business Name:	The Charlotte-Mecklenburg Hospital Authority			
Business #:	1770			
Project Description:	Replace existing CT scanner			
County:	Union			

Dear Ms. Huber:

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(a)(7). Therefore, you may proceed to acquire without a certificate of need the GE Revolution Apex EL CT scanner to replace the GE Lightspeed VCT CT scanner ("existing unit"). This determination is based on CON Project ID #F-11618-18 which previously approved the relocation of one (1) CT scanner from Atrium Health Union to Atrium Health Union West and your representation that the existing unit has a fair market value of \$14,215.00 As such, the fair market value is below the \$750,000 threshold for "major medical equipment" as defined in N.C.G.S. 131E-176(14o) and thus, does not require a Certificate of Need application.

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,

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Misty L. Piekaar-McWilliams Project Analyst

fatumah Wilson for

Lisa Pittman Acting Chief, Certificate of Need

cc: Radiation Protection Section, DHSR Construction Section, DHSR

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

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

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

April 7, 2021

Ms. Lisa Pittman, Assistant Chief 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 d/b/a Atrium Health Union to Replace and Relocate a CT Scanner

Dear Ms. Pittman:

The Charlotte-Mecklenburg Hospital Authority ("CMHA") d/b/a Atrium Health Union ("AH Union") is planning to replace one of its existing CT scanners with new, technologically comparable equipment. AH Union intends to purchase a GE Revolution Apex EL CT scanner ("Replacement Equipment") to replace a GE Lightspeed VCT CT scanner ("Existing Equipment") that was installed in 2010. The Existing Equipment is currently located in the emergency department on the first floor of AH Union's main hospital building. The Replacement Equipment will be relocated to the radiology suite that will be on the ground floor of Atrium Health Union West ("AH Union West"), a new acute care hospital campus that will be a remote location and licensed as part of AH Union and is currently under development pursuant to previously approved Project ID #F-11618-18<sup>1</sup>.

While the Replacement Equipment possesses some expanded capabilities due to technological improvements, it will be used to perform the same types of procedures as the Existing Equipment and will not be used to provide a new health service. A chart comparing the Existing Equipment and the Replacement Equipment is included in Attachment A along with supporting documentation. The Existing Equipment is currently in use and documentation provided in Attachment B indicates that 16,495 scans were performed from March 2020 to February 2021.

The purchase price of the Replacement CT Scanner is 1,249,183 (1,192,538 CT Scanner and freight + 56,645 tax). The purchase price of the injector is 56,352 (53,425 injector + 390 freight + 2,537 tax). The projected total cost of this project is 1,390,850 and includes the cost to acquire and install the equipment. The cost of the development of the space that the equipment will be relocated to, which will be on the ground floor of AH Union West, is included in the capital

<sup>&</sup>lt;sup>1</sup>Pursuant to CON Project ID #F-11618-18, CMHA d/b/a AH Union was previously approved to relocate one fixed CT scanner from AH Union's main campus to AH Union West. The Replacement Equipment identified in this exemption request will be the CT scanner that is relocated to AH Union West.

cost approved under Project ID #F-11618-18. Attachment C provides the quotes for the Replacement Equipment and supporting equipment. The total capital cost worksheet is provided in Attachment D.

The Existing Equipment that is currently located in the emergency department on the first floor of AH Union's main hospital building has a maximum fair market value ("FMV") of \$14,215 (see Attachment E for FMV analysis). CMHA d/b/a AH Union proposes to retain the Existing Equipment since the FMV of this equipment is less than \$750,000, and it does not trigger the CON reviewability threshold for "major medical equipment" under N.C.G.S 131E-176(14o). The Existing Equipment will remain in its current location in AH Union's emergency department and will continue to be used for all primary CT applications.

The North Carolina Certificate of Need statutes provide a definition of replacement equipment in N.C.G.S. 131E-176(22a). The definition requires the replacement equipment be comparable to the existing medical equipment and cost less than \$2,000,000 when installed. The statutes further provide in 131E-184(a)(7) an exemption from certificate of need review for replacement equipment projects if prior notice is provided to the CON Section.

This letter serves as prior notification of our intent to proceed with this project. We would appreciate your written concurrence that this project is exempt from CON review. If you have any questions or require further information regarding this project, please contact me at 980-622-7049.

Sincerely,

Elepabeth V, Kerkaucan

Elizabeth Kirkman, Assistant Vice-President Atrium Health Strategic Services Group

Attachments

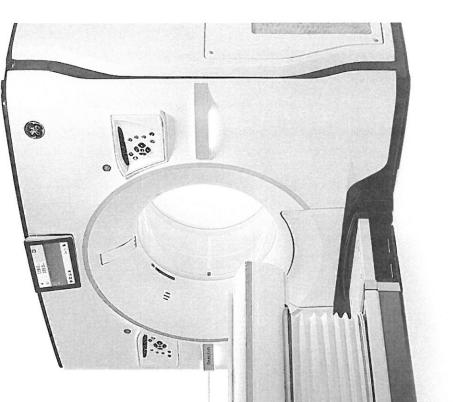
### Attachment A

EQUITIVIENT CUMPTANISUN - CIMPA U/D/A AN UNION CI REPLACEMENT & RELOCATION	eplacement & Relocation	
	Existing Equipment	Replacement Equipment
Type of Equipment (List each component)	CT Scanner	CT Scanner
Manufacturer of Equipment	GE	GE
Tesla Rating for MRIs	N/A	N/A
Model Number	LightSpeed VCT	Revolution Apex EL
Serial Number	414725CN2	Not Available Until Installed
Provider's Method of Identifying Equipment	Internal Asset # / Serial #	Internal Asset # / Serial #
Specify if Mobile or Fixed	Fixed	Fixed
Mobile Trailer Serial Number/VIN #	N/A	N/A
Mobile Tractor Serial Number/VIN #	N/A	N/A
Date of Acquisition of Each Component	2010	2021
Does Provider Hold Title to Equipment or Have a Capital Lease?	Title	Title
Specify if Equipment Was/Is New or Used When Acquired	New	New
Total Capital Cost of Project	\$284,306	\$1,390,850
Total Cost of Equipment	\$284,306	\$1,249,183
Fair Market Value of Equipment	\$14,215 (The current EMV of the Existing Equipment)	\$1,249,183
Net Purchase Price of Equipment	\$284,306	\$1,249,183
Locations Where Operated	AH Union ED (AH Union Main Campus, Level 01)	AH Union West Radiology Suite (AH Union West, Ground Level)
Number Days in Use/To Be Used in N.C. per Year	365 days / year	365 days / year
Percent of Change in Patient Charges (by procedure)	0%0	0%0
Percent of Change in Per Procedure Operating Expenses (by procedure)	0%0	0%0
Type of Procedures Currently Performed on Existing Equipment	All Primary CT Applications	N/A
Type of Procedures New Equipment is Capable of Performing	N/A	All Primary CT Applications

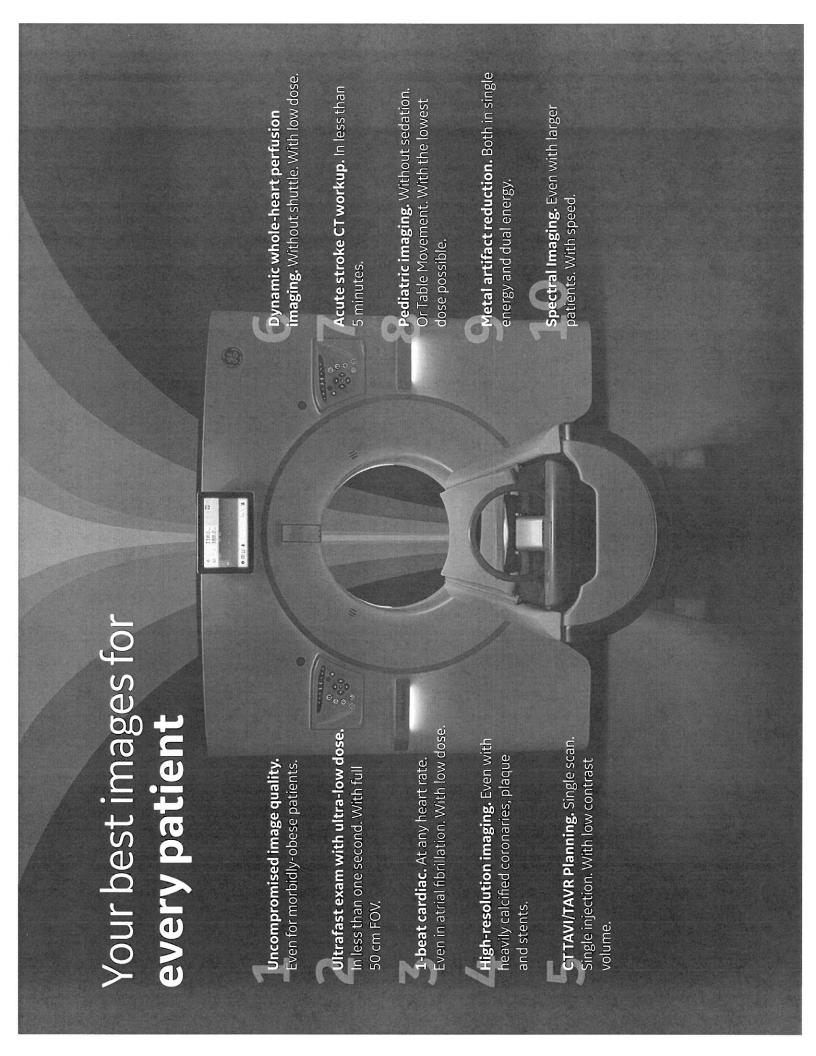
EOUIPMENT COMPARISON - CMHA d/b/a AH Union CT Replacement & Relocation



## Revolution Apex Uncompromised Clinical Solutions Elevate with



gehealthcare.com



## Coverage

Power + Deep Learning

Revolution Apex Elevating the capabilities of an uncompromised platform

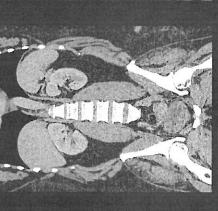
Spectral

Abdominal imaging: Reconstruction technologies comparison TrueFidelity on a BMI 62 patient (400 lbs, 1.73m)

## **Revolution Apex** Elevate with

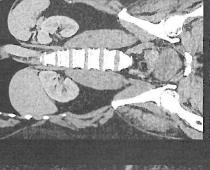
Uncompromised image quality. Even for morbidly-obese patients.

z-coverage Gemstone Clarity detector and TrueFidelity<sup>™</sup> Deep Learning Image including the Quantix 160 Tube, 16 cm can have superior image quality. Even With Revolution Apex, every patient the many capabilities of the system, the most challenging ones. Using uncompromised image quality, Reconstruction, clinicals show even for over-obese patients.











0.625 mm TrueFidelity image



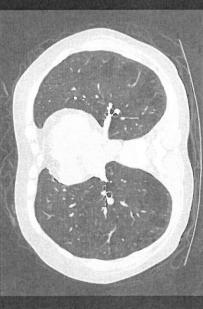


0.625 mm - TrueFidelity

# 0.6 mSv chest exam in less than 1 second with HyperDrive

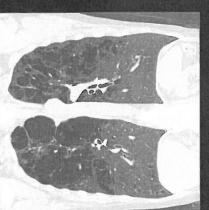
TrueFidelity images





Scan type: Helical Rotation time, s: 0.35 Pitch: 1.531 Slice, mm: 0.625 Scan length, mm: 331 Scan time, s: 0.9

kV: 120 mA: 55 DLP, mGy-cm: 45 Eff. dose, mSy: 0.6 k, \*DLP: 0.014

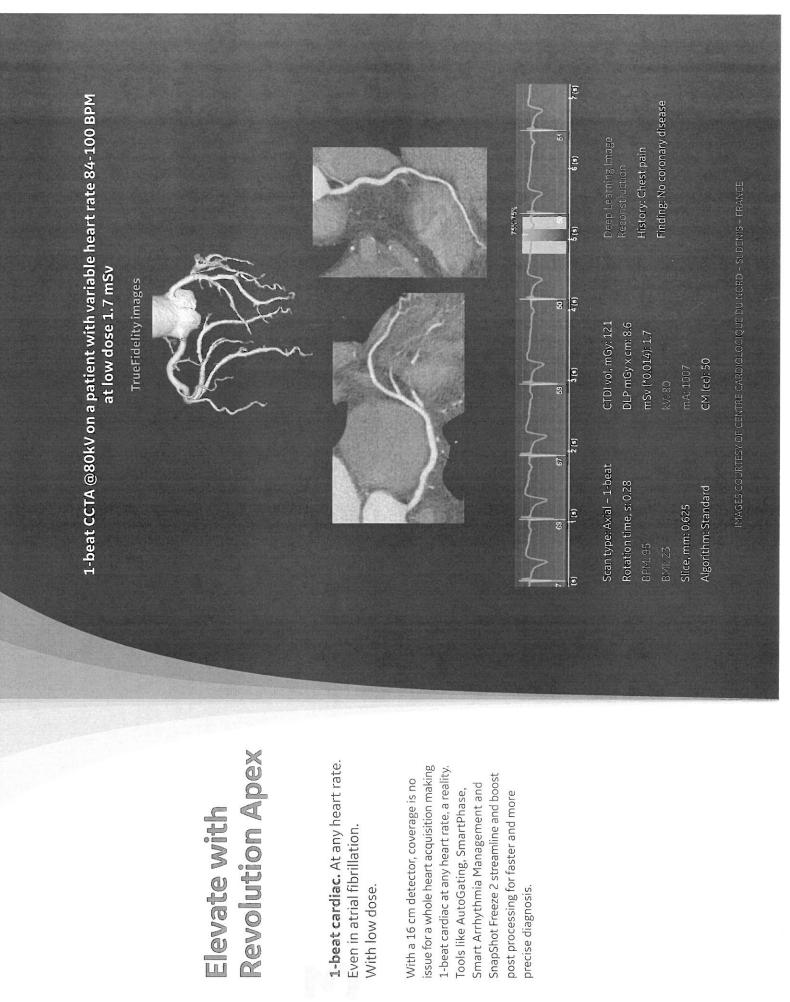


Deep Learning Image Reconstruction History: Tobacco use Follow up screening Findings: Stable solid <4 mm lingual node

### Elevate with Revolution Apex

Ultrafast exam with ultra-low dose. In less than one second. With full 50 cm FOV. Using HyperDrive, a 437 mm/s volumetric scan with 50 cm FOV and as low as 70 kV, Revolution Apex can acquire sub-second chest exams with ultra-low dose. Rely on TrueFidelity images for every exam, for the best image every time.

IMAGES COLINTESVIOF EROFDTERT & MEDICAL COLLEGE OF WISCONSIN



## TrueFidelity imaging. Even with heavily calcified coronaries. 1-beat CCTA with highly calcified coronaries

TrueFidelity

## Elevate with Revolution Apex

High-resolution imaging. Even with heavily calcified coronaries, plaque and stents. With high-definition imaging, Revolution Apex has best in class spatial resolution for better vessel visualization and reduced calcium blooming. This provides clear images to help the physician with tasks such as accurately quantifying stenosis in coronaries and other vascular structures. This could lead to increased speed and confidence in reporting.

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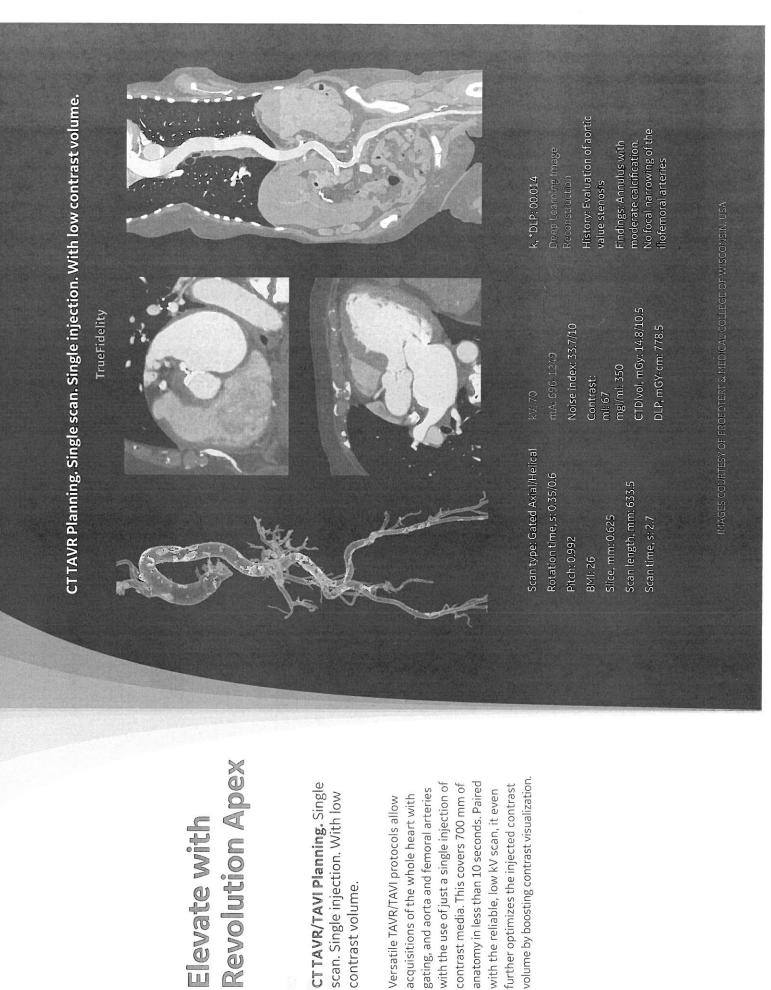
Scan type: Axial – 1-beat Rotation time, s: 0.28 Acquisition: High Resolution BPM: 20-69 BMI: 24 Slice, mm: 0.625

Algorithm: HD CTDI vol. mGy: 8.5 DLP mGy x cm: 119 mSv (\*0.014): 1.67 kv: 100

mA: 580

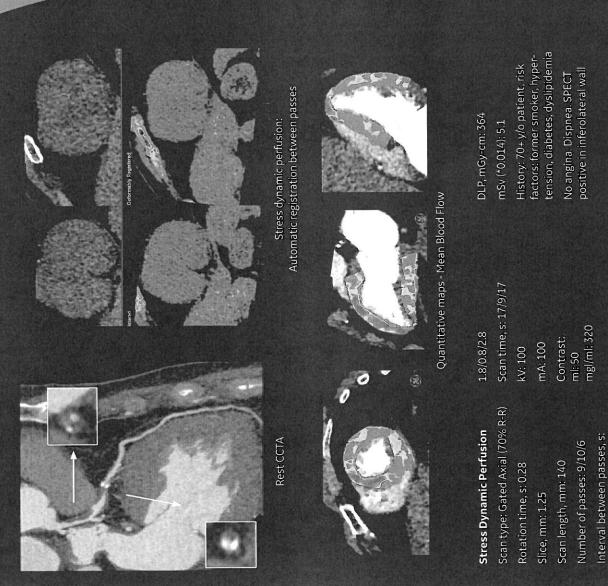
Deep Learning Image Reconstruction History: Asymptomatic pati with risk factors and high calcium score (941)

MAGES COURTESY OF CENTRE CARDIOLOGIQUE DU NORD - St DENIS - FRAN



contrast volume.

Dynamic whole-heart perfusion imaging. Without shuttle. With low dose.

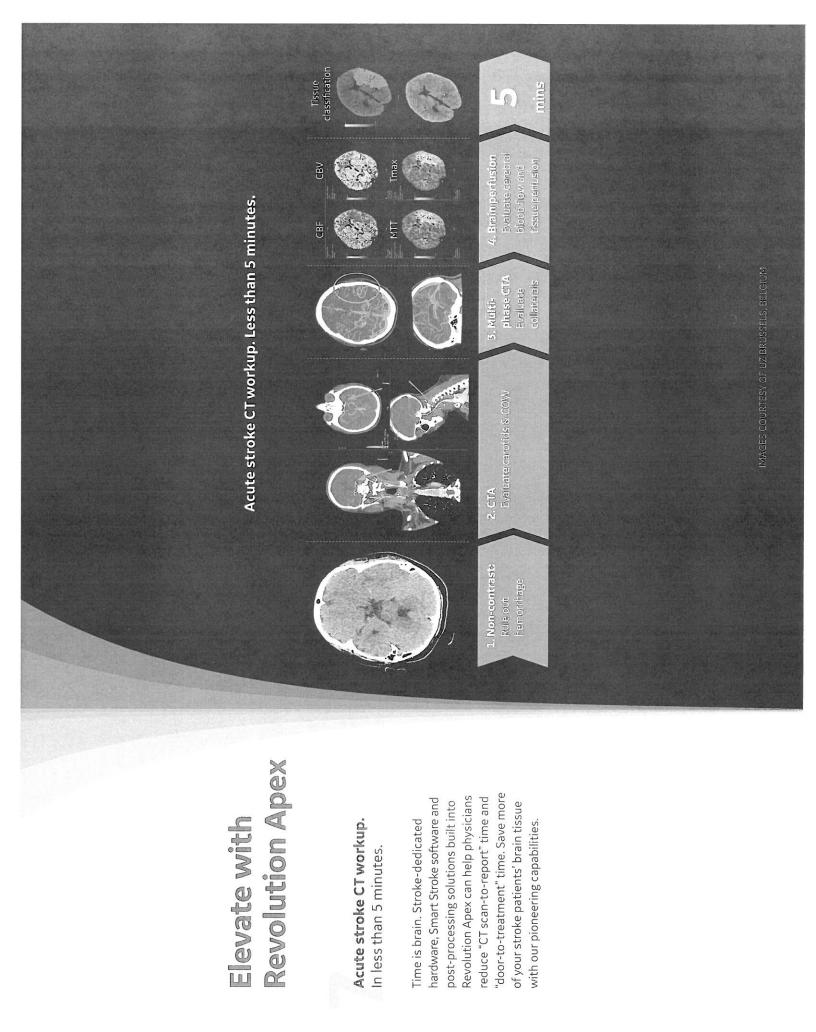


## Elevate with Revolution Apex

Dynamic whole-heart perfusion. Without shuttle. With low dose.

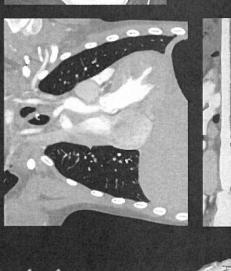
Revolution Apex, combining 16 cm wide coverage and 29 ms temporal resolution, enables whole-heart dynamic perfusion acquisition, without the need to shuttle the table. This enables an accurate whole-heart perfusion with uniform contrast and provides physicians both anatomical and functional information of obstructive CAD.

IMAGES COLIDIESVIOF CENTRO CARDIOLOGICO MONZINO ITAL



## Pediatric imaging. Without sedation. 3yo CTA Chest Aortic Stenosis 117bpm

**TrueFidelity images** 







CTDlvol, mGy: 1.3 Noise index: 27 mA: 383

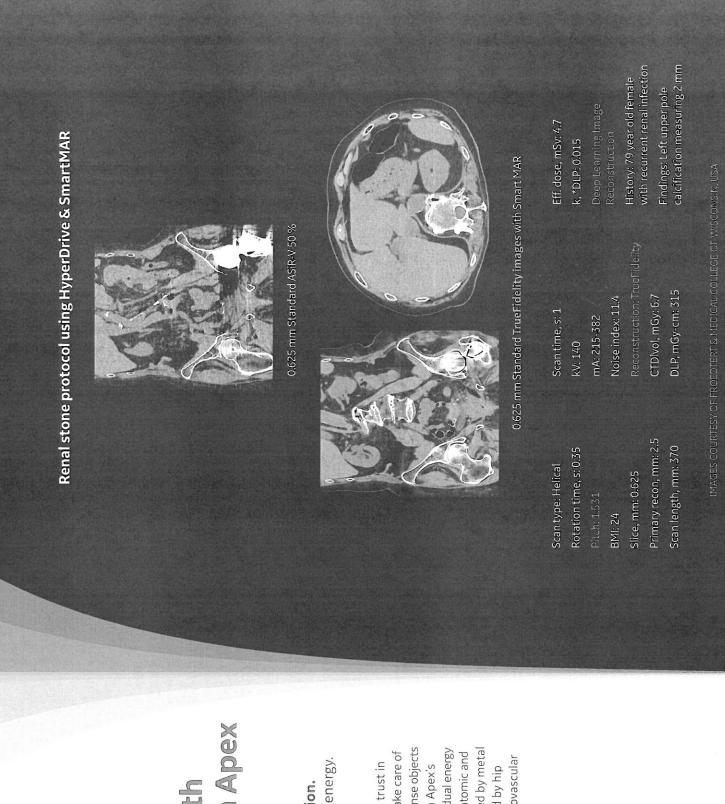
aortic stenosis. Ground glass opacities in right middle lobe Findings: Supravalvular

DLP, mGy-cm: 21.5

## **Revolution Apex** Elevate with

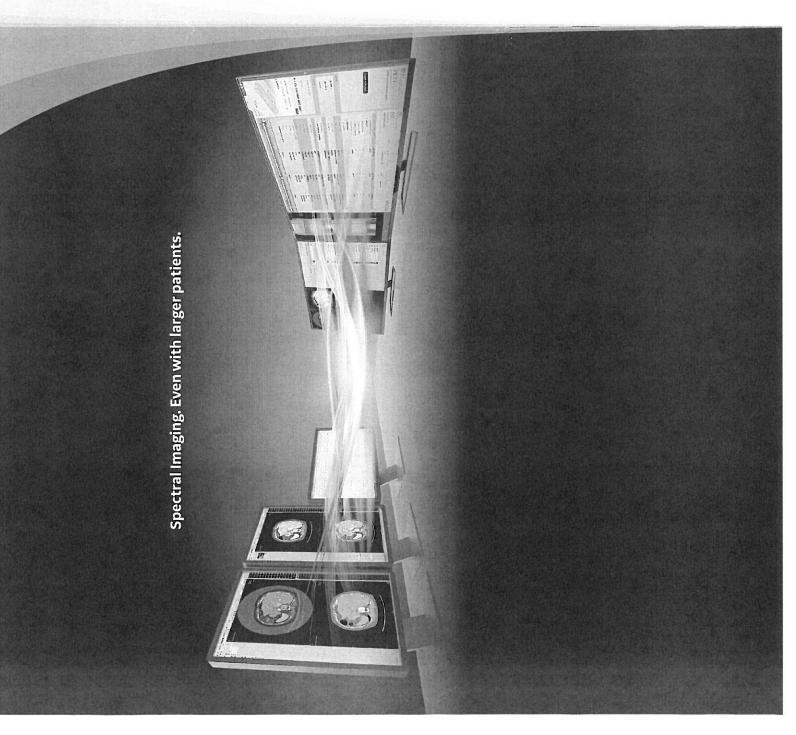
Without sedation. With the lowest dose possible. Pediatric imaging.

Revolution Apex's split-second volumetric scanning can potentially reduce the need repetition of scans in young children due for sedation and eliminate unnecessary and 70 kV scans allow you to minimize image quality and diagnostic confidence. to failed sedation. TrueFidelity images the radiation dose while improving



Elevate with Revolution Apex

Metal artifact reduction. Both in single and dual energy. No matter your acquisition, trust in metal artifact reduction to take care of the otherwise challenging dense objects in your patients. Revolution Apex's dedicated single energy and dual energy MAR solutions can reveal anatomic and pathological details obscured by metal artifacts in the body caused by hip implants, surgical clips, endovascular coils, dental fillings, etc.



### Elevate with Revolution Apex

Spectral Imaging. Even with larger patients. With speed.

The vision behind GSI Xtream has never wavered – a volume spectral imaging experience to help physicians diagnose disease with more confidence with a simplified workflow. Empowered by the Quantix 160 Tube, GSI Xtream on Revolution Apex takes that idea to the next level to enable spectral imaging on more challenging patients without the compromise on image quality and quantification accuracy. See the bigger picture with volume spectral CT.

Not for sale in all regions. May 2019 JB66934XX



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### Attachment B

AH Union ED CT Scanner				
Volume b				
Month	Volume			
Mar-20	1,348			
Apr-20	959			
May-20	1,269			
Jun-20	1,311			
Jul-20	1,451			
Aug-20	1,342			
Sep-20	1,344			
Oct-20	1,544	14		
Nov-20	1,487			
Dec-20	1,455			
Jan-21	1,530			
Feb-21	1,455			
Total	16,495			

### Attachment C



Carolinas HealthCare System Union 600 Hospital Dr Monroe, NC 28112-6000

This Agreement (as defined below) is by and between the Customer and the GE Healthcare business ("<u>GE Healthcare</u>"), each as identified below for the sale and purchase of the Products and/or Services identified in this Quotation, together with any applicable schedules referred to herein ("<u>Quotation</u>"). "<u>Agreement</u>" is this Quotation and either: (i) the Governing Agreement identified below; or (ii) if no Governing Agreement is identified, the GE Healthcare Terms and Conditions and Warranties that apply to the Products and/or Services identified in this Quotation. In the event of conflict, the Quotation supersedes.

GE Healthcare can withdraw this Quotation at any time before Customer: (i) signs and returns this Quotation or (ii) provides evidence of Quotation acceptance satisfactory to GE Healthcare ("Quotation Acceptance"). On Quotation Acceptance, this Agreement is the complete and final agreement of the parties relating to the Products and/or Services identified in this Quotation. There is no reliance on any terms other than those expressly stated or incorporated by reference in this Agreement and, except as permitted in this Agreement, no attempt to modify will be binding unless agreed to in writing by the parties. Modifications may result in additional fees and cannot be made without GE Healthcare's prior written consent.

Handwritten or electronic modifications on this Agreement (except an indication of the form of payment, Customer purchase order number and signatures on the signature blocks below) are void.

Governing Agreement:	CSS-GEHC MVA July 15 2011 a/k/a CSS-EQ-0031
Terms of Delivery	FOB Destination
Billing Terms	100% billing at Ship Completion (Fulfillment) / Delivery
Payment Terms	Net Due in 60 Days
Total Quote Net Selling Price	\$1,192,538.00
Sales and Use Tax Exemption	No Certificate on File

### IMPORTANT CUSTOMER ACTIONS:

Please select your planned source of funds. Source of funds is assumed to be cash unless you choose another option. Once equipment has been shipped, source of funds changes cannot be allowed.

\_\_\_ Cash

\_\_\_\_ GE HFS Loan

\_\_\_\_ GE HFS Lease

\_\_\_\_ Other Financing Lease

Other Financing Loan

Provide Finance Company Name

The parties have caused this Agreement to be executed by their authorized representative as of the last signature date below.

Carolinas Health	Care Syst	em Unior	l	
Signature:				
Print Name:				
Title:	1997			
Date:	a that is	ang ang ang ang	Charles of	
Purchase Order Numb	per, if applie	cable	2-0-2-01 1-0-2-01	

GE Precision H	ealthcare LLC, a GE Healthcare business
Signature: Herb	Klann
Title: Imaging	Account Manager
Date: April 2, 2	021



### To Accept This Quotation

Please sign and return this quotation together with your Purchase Order to:

Name: Herb Klann Email herb.klann@ge.com

Phone: 724-504-8778

Fax:

### **Payment Instructions**

Please **remit** payment for invoices associated with this quotation to:

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

FEIN: 83-0849145

Carolina	s HealthCare System Union	Addresses:
Bill To:	CAROLINAS HEALTHCARE SYSTEM UNION	CAROLINAS MEDICAL CENTER UNION, ACCOUNTS PAYABLE PO BOX 5003 MONROE, NC, 28111-5003
Ship To:	CAROLINAS HEALTHCARE SYSTEM UNION	600 HOSPITAL DR MONROE, NC, 28112-6000

### To Accept This Quotation

.

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

Upon submission of a purchase order in response to this quotation, GE Healthcare requests the following to evidence agreement to contract terms: Signature page on quote filled out with signature and P.O. number \*\*\*\* OR\*\*\*\* Verbiage on the purchase order must state one of the following:

(i)Per the terms of Quotation # \_\_\_\_\_, (ii) Per the terms of GPO #\_\_\_\_\_; (iii) Per the terms of MPA# \_\_\_\_\_; or (iv) Per the terms of SAA #

Include applicable quote/agreement number with the reference on the purchase order. In addition, Source of Funds (choice of Cash/Third Party Load or GE HFS Lease Loan or Third Party Lease through \_\_\_\_\_), must be indicated, which may be done on the Quote Signature Page (for signed quotes), or the Purchase Order (where quotes are not signed) or via a separate written source of funds statement (if provided by GE Healthcare)."



### **Catalog Item Details**

Line	Qty.	Catalog	
1	1.00	S7919AX	Revolution CT ES Digital – Cardiac Promotion

The Revolution CT ES Digital – Cardiac Promotion configuration is a premium CT scanner that brings the essence of Revolution CT experience into a scalable platform. Built upon ground-breaking and clinically proven Revolution CT hardware platform, it delivers HD image quality, fast volumetric scanning and lower dose with optimized contrast use. And it has scalability with its ability to be upgraded in-room to a 160mm detector coverage system, allowing you to grow its clinical capabilities with your needs. The Revolution CT ES delivers industry leading technical specifications for a premium CT system, including:

VHD reconstruction, 3D Collimator, and focal aligned detectors provide high-definition image quality, while overcoming the challenges of typical wide detector systems such as cone beam artifacts, HU uniformity, scatter and beam hardening artifacts.
 ASiR-V provides integrated advanced iterative reconstruction technology that reduces noise and reduces low-signal streak artifact at very low signal levels. This technology is designed to deliver reduced noise levels, improved low contrast detectability

and may enable a reduction in dose for all clinical applications. In clinical practice, the use of ASiR-V may reduce CT patient dose depending on the clinical task, patient size, anatomical location and clinical practice.

A consultation with a radiologist and a physicist should be made to determine the appropriate dose to obtain diagnostic image quality for the particular clinical task.

The Revolution CT ES Digital – Cardiac Promotion is sold as a Digital Model with Smart Subscription as part of the packaged solution. Smart Subscription is a new model from GE Healthcare that allows your CT to keep getting better by allowing you the ability to subscribe to different application packages ensuring that you always receive the latest technologies from GE Healthcare. Current offerings include software such as TrueFideltiy, Smart MAR, SnapShot Freeze 2 and much more.

### Clinical Highlights

High-Definition Imaging

The clinical needs for better image quality never stop. Visualizing the finest image details significantly enhances diagnostic confidence. Equipped with the 80 mm Gemstone Clarity Detector and the Performix® HDw tube, the Revolution CT ES achieves best-in-class 0.23 mm spatial resolution across all detector coverage, all FOV, all applications, even obese patients. • Low Dose Lung Cancer Screening

Empowered by low dose high definition image chain and new low-dose CT lung cancer screening protocols, Revolution CT ES can

deliver low dose, short scan times and sharp images for the detection of small lung nodules.

Contrast Optimized Scanning

X-ray radiation and iodine hazards have become the major concerns associated with CT scan with contrast enhancement. Due to increased use of iodinated contrast media in diagnostic imaging and interventional procedures, Contrast-induced nephropathy has become a significant source of hospital morbidity and mortality. Equipped with the ASiR-V and Low kVp scanning, Revolution CT ES addresses these two challenges with one unique solution: achieving lower dose scan with optimized contrast usage. • Fast Emergency & Trauma Imaging

The system allows for robust Triple RuleOut™ acquisition for all patients providing HD, motion free coronaries, PE & aortic dissection in a single exam covering the entire thorax. ECG gating and mA modulation along with flexible collimations enable low dose acquisition personalized to the patient.

80 mm helical mode combined with fast table speed of 300 mm/s allows for ultra-fast scanning, thus reducing the effect of breathing and other motion during the scan.

• Sedation-free Pediatric Scanning

Split second pediatric trauma acquisition of abdomen / pelvis is enabled by wide 80 mm z-coverage and fast table speed up to 300 mm/s, thus reducing the need for sedation and eliminating unnecessary repetition of scans in young children due to failed sedation, as is the case in 29% of conventional exams, shown in a large trial (British Journal of Anesthesia, 84 (6), 743-8 (2000)). 70kV scan mode allows for minimizing dose to pediatric patients while preserving excellent contrast to noise ratio and image quality.

### • Cardiac Acquisition

The system includes Cardiac Acquisition software and the CTM-400 Cardiac Trigger Module to support 2-Beat Coronary CT and 1-Beat Structural Heart acquisitions.

Neurology (To achieve the full benefits described below, an AW workstation with dynamic and perfusion post processing tools may be required. Please consult with your GE sales representative)

The single energy metal artifact reduction solution for Revolution CT is Smart MAR. It uses an automated, three-stage projectionbased process. Smart MAR is designed to reveal anatomic details obscured by metal artifacts by reducing photon starvation, beam hardening and streak artifacts caused by metal in the body, such as hip implants, surgical clips, endovascular coils, and dental



fillings. Smart MAR requires one single kV scan and can be enabled in secondary reconstructions, making the metal artifact reduction workflow fast and efficient.

Smart Stroke, the stroke-dedicated hardware, software and post-processing solution on Revolution CT, can help physicians to reduce "CT scan-to-report" time and "door-to-treatment" time, thus to save more brain tissue of patient with stroke.
Dual Energy Scanning

Revolution CT ES features protocols which allow easy configuration of back to back axial or helical scans of the same anatomy at two different X-ray energies (kVp's). To further improve registration accuracy patient immobilization may be utilized. The additionally acquired dual energy data can be post-processed on AW WS using Add/Sub function to gain additional clinical information.

• Dual Energy Scanning

### Key Hardware Components

### Gemstone Clarity Detector

The Gemstone Clarity detector features a unique focally aligned layout of the detector sub-modules and a 3D collimator (post patient) to minimize scatter artifacts, ensure HU uniformity & reduce beam hardening artifacts associated with wide coverage systems. Combined with VHD reconstruction technology, the system delivers excellent image quality at full 80 mm coverage. The Gemstone Clarity detector also features a revolutionary ultra-low capacitance photo diode with new ASIC technology that redefines electronic noise at the quantum limit to less than 3 photons @ 120 keV (3100 electrons). The detector includes acquisition electronics which allow 4x faster bandwidth and 3x faster trigger rate than previous generations and reduces electronic noise by 25% which may improve image quality and reduce artifacts in low signal conditions as may be encountered in large patients. 3D Collimator Scatter Reduction Technology reduces scatter to primary ratio by more than 50% (R Melnyk, J Boudry, X Liu, and M Adamak, "Anti-scatter grid evaluation for wide- cone CT," Proc. of SPIE, Vol. 9033, 90332P1-7, 2014) and results in significant improvement in image quality and reduction in beam hardening and metal artifacts.

Gemstone Clarity detector specifications:

- Z-Coverage/360 degree rotation: 80 mm
- Number of slices: 256
- Number of detector rows: 128
- Number of detector elements: 106,496 cells with individual electronic/DAS channels
- Sampling rate: Up to 2,496 views per rotation (Up to 8914 Hz)
- Electronic noise: less than 3 photons noise (3100 electrons)
- Effective analog to digital conversion range >2,000,000:1
- Scintillator speed: 0.03us (100 times faster than GOS)
- Afterglow: 0.001% (4 times lower than GOS)
- Radiation damage: 0.03% (20 times less than GOS)
- Scatter to Primary Ratio: <10%
- Detection efficiency: 98% @ 120 kV

### Performix HDw tube

The Performix HDw tube is a next generation anode-grounded, metal-ceramic x-ray tube. The tube enables improved spatial resolution via dynamic in-plane focal spot deflection and independent control of the focal spot size in both X and Z-axis which optimizes the focal spot to deliver consistent beam quality across the full 80 mm Z-axis coverage, making it one of the most innovative CT tubes offered today. The design is optimized for exams requiring a large number of scans without tube cooling. It is powered by an onboard high frequency generator capable of ultra-fast kVp switching. Due to the ultrashort exposure times associated with wide coverage scanning, traditional metrics related to tube cooling such as anode heat content & cooling rate lose their relevance. The GE Performix HDw tube includes a standard license that automatically enables the use of tube dependent advanced applications. The use of a third party X-ray tube will require an additional license for the activation of these features.

### Ultra-fast kV Switching Generator

The new generator features 3x faster rise and fall times for kV switching compared to previous generator. This would allow for more time to be spent at the target energy levels and result in better energy separation between the datasets acquired at different kV levels using fast kV switching.

- Generator maximum peak power: 103 kW
- Tube current range: 10-740 mA with 5 mA increments

• Tube voltage: 70, 80, 100, 120, 140 kV. Automatically selected through kV Assist based on patient body habitus and examination type

- Max x-ray tube assembly heat content: 5.0 MJ (6.8 MHU)
- Max continuous heat dissipation: 3.0 kW
- Focal spot size according to IEC 60336/2005: 1.0 x 0.7mm, 1.6 x 1.2mm, 2.0x1.2mm



### Gantry and Slipring

Revolution CT's gantry platform has been designed from the ground up to support the demands of today's scanning environment. Exclusive Whisper Drive system technology reduces audible noise during gantry rotation at 0.28s by more than 50% compared to a typical belt driven system thus improving patient comfort (audible gantry noise is measured at 69 dBA).

The contactless slipring transfers power and data to and from the rotating side of the gantry (slip ring) to the stationary side through contactless RF technology. This eliminates carbon dust due to brush wear- out in typical CT systems thereby increasing the reliability of the system. In addition, the gantry frame features redundant fail-safe mounts for all major components that is designed and tested to stringent standards to ensure safe and reliable operation even at fast rotation speeds.

• Aperture: 80 cm

• Focus-to- detector Distance: 109.7 cm

• Focus-to- isocenter Distance: 62.6 cm

Scan FOV: 50 cm

Rotation speeds: 0.28s, 0.35s, 0.5s, 0.6s, 0.7s, 0.8s, 0.9s, 1.0s per 360° acquisition

• Temporal resolution: 140ms cardiac temporal resolution without using SnapShot Freeze. 29ms effective temporal resolution using SnapShot Freeze. (As demonstrated in mathematical phantom testing)(Cardiac Acquisition software and AW workstation or server with CardIQ Xpress 2.0 required to process SnapShot Freeze data)

• Data chain bandwidth: 40 Gbps

• Table and gantry control panels: Define both internal and external scan planes to +/- 1 mm accuracy. Activated any time during exam (with tube stationary)

• Front and rear integrated gantry LCD Display: Display patient information, ECG data from the integrated ECG module (optional), built-in patient breathing lights and countdown timer, cardiac gating indicator light and patient information videos

• Flexible cable manage system with coordinated straps attached to the gantry sides to keep cables connected to the gantry away from the floor and to reduce clutter

The system is shipped with the NG2000V Heavy Table which has the ability to support patient weights up to 675 lbs.

### **Operator** Console

The Revolution CT scanner desktop allows simultaneous scanning, image reconstruction, display, processing and analysis, as well as networking and archival.

It features the new "Clarity Operator Environment" designed with your everyday needs in mind. The environment allows for more real time adaptive capabilities thus enabling dramatically improved timing with Smart Prep including automatically transitioning to acquisition in as quickly as 1 second when the set HU threshold is reached. The benefits provided by the new interface include:

• Smart prescription workflow automates scan set up by recommending scan parameters specific to the patient based on scout attenuation and ECG information, in the case of cardiac, to enable consistent image quality & dose performance across scans, irrespective of the technologist expertise level

• Seamless multi-tasking through ability to have multiple patient sessions open with one active patient for acquisition and the rest for post-acquisition tasks

• "Plan ahead" task list as part of scan setup automates repetitive tasks such as reconstructions, image transfer, image processing, etc. without requiring technologist intervention

• Ability to prospectively prescribe multi planar reconstructions for anatomies such as spine as part of the protocol, thus automating the workflow seamlessly

• Clear status visibility across all automated patient tasks without any interaction enables you to focus on the primary task at hand

• Manage your patient flow better with the ability to pre-pare scan prescription for the next patient while the current patient is aetting off the table

• Quickly select scan protocols through global search, anatomical selection or user specific favorites in the new-ly designed protocol management system

• Facilitates protocol consistency by controlling access to changes and simplifying inputs required

• Integration with AW allows prescribing automatic image processing steps to be performed on the AW / AW Server post acquisition

• Better dose awareness through clearly visible real time projected dose indicator for the selected protocol

Operator console specifications

• Intel Xeon performance processor: 2.60GHz/8-Core CPU (or equivalent)

- Nvidia high performance GPU (or equivalent)
- 64 GB DDR3 unbuffered ECC (or equivalent)
- 24 inch dual monitors with screen resolution of 1920x1200
- Image data storage up to 700,000 uncompressed DICOM images (512x512)
- Scan data storage of 1 TB (up to 1500 scan files are supported)
- DVD-ROM (supports DVD-R, DVD-RW, DVD+R, DVD+RW, DVD+R DL, CD-R, CD-RW)
- USB 3.0 Port for External Hard Disk Drive Connectivity (scan data storage and image data storage are supported)
- Recon Server Xtream enables recon task parallelism and achieves up to 1.8x faster reconstruction throughput than Recon Server



### Pro

• Image reconstruction speed up to 65 fps with FBP and up to 25 fps with ASiR-V.

System Software

Smart Flow

Simplified, automated scan prescriptions, personalized to the patient and easy-to-use reference protocols make the Revolution CT fast and efficient in patient set-up, prescription & scanning. The following features further help you streamline your workflow. • Protocol Management System

Protocols can be copied, built and edited intuitively using the Protocol Management System.

• GE Reference Protocol: A set of predefined protocols for adult patients that cannot be modified but can be copied and used. These protocols are factory installed. They have been developed in collaboration with clinical partners to provide users with a convenient and clinical relevant starting point for tailoring your departmental protocols.

Recently Scanned Protocols: A copy of the last 90 proto- cols reside exactly as they were used for review purposes only. These
protocols can also be copied and used within into your departmental protocols.

Anatomical Selector: Use the Anatomical Selector area to select a specific anatomical region to show only protocols related to that region.

• Favorites: A user can add to a list of favorite protocols commonly used by your site.

### **Clinical ID**

Clinical ID is designed to streamline the clinical application specific workflow from protocol setup to reconstruction prioritization and automated reformatted views for timely diagnostic decisions.

### AutoVoice™

Auto Voice provides recorded breathing instructions for the patient. Consistent breathing instructions assist with more precise timing during an exam. Auto Voice also provides a pre- message in the SmartPrep feature. The system also comes equipped with microphones at the console and gantry for communicating with the patient. The system has three, pre-recorded messages in ten selectable languages that cannot be deleted. You can also record up to 17 additional messages for each language. Default language options include: Chinese, English (Female), English (Male), French, German, Italian, Korean, Japanese, Spanish (European), Spanish (Latin America).

### **Smart Patient Centering**

The smart patient centering feature helps to detect suboptimal centering prior to the diagnostic scan. When scout is acquired, the system will assess patient centering. If the patient is off-centered greater than 2 cm, the system will display the table height location and an up or down arrow to indicate the elevation needed to reach that height.

### SmartStartTM

- Gantry-mounted start scan button and countdown dis- play,
- Facilitates single-technologist operation by allowing start of scan at the gantry, with a visual reminder of time until X-ray initiation

### SmartPrepTM with Dynamic Transition

Enables real-time monitoring of IV contrast and a user-selectable mode to dynamically transition to the diagnostic scan phase when a user entered Enhancement Threshold is reached in the Transition ROI.

### Trauma Patient entry

Allows patient scans and image display/analysis without entering patient data before scanning.

### **Prospective Exam Split**

Prospective Exam Split allows operator to specify how to split images from a scan into separate requested procedures/accession numbers in protocol management. This capability is especially useful in cases of full body trauma or for chest, abdomen and pelvis exams. Prospective Exam Split works with primary, secondary and reformatted images.

### Smart DMPR

Smart DMPR can automatically generate reformatted views with prospectively set window width and window level and automatically transferring these image datasets to the designated PACS destination for fast review and diagnosis.

### Digital Tilt

The system has preset protocols that can be selected prospectively, which allows images to be reconstructed at a specified tilt angle. This capability, combined with organ dose modulation and tilted head holder accessory for the patient allows for reducing the dose to sensitive organs such as the eyes while also reducing dental artifacts.

### Enhanced Xtream Injector (Requires a compatible Bayer or Nemoto Injector system)

The Enhanced Xtream Injector provides synchronization of the start of the scan and the start of the contrast injector using the start scan button on the Scan Control Interface or the gantry controls. The Enhanced Xtream Injector also allows setting of the contrast



injector parameters within the CT scan protocol and creation of an Injector Report at End Exam of what was delivered by the injector. The system and injector are operated independently after the start scan button is pressed on the system.

### System Software

### Volume High Definition Reconstruction

The system features state of the art image reconstruction technology designed to mitigate cone beam artifacts associated with wide coverage systems. In addition, the algorithm preserves temporal uniformity and provides excellent image quality at full 80 mm coverage. It further reduces variation in iodinated contrast HU uniformity across the full 80 mm z-coverage, typically caused due to heel effect. In addition, Smart MAR technology utilizes material physics learnings from GSI incorporated in single energy acquisition. In conjunction with the 3D Collimator, this reduces beam hardening artifacts due to iron, bone, metal & other dense objects.

### Iterative Reconstruction: ASiR-V

Integrated advanced iterative reconstruction technology (ASiR-V) reduces noise, even at very low signal levels. The ASiR- V algorithm focuses primarily on the modeling of the system noise statistics, objects, and physics and de-emphasizes the modeling of the system optics. The most time-consuming portion of the IR process is the modeling of the system optics. By excluding the most time-consuming component, system optics, and focusing on the other terms during the IR process, significant image quality improvement can be achieved with- out paying a large penalty in reconstruction speed. The advanced system noise model includes the modeling of the data acquisition system (photon noise and electronic noise) as well as noise characteristics of the reconstructed images. The photon noise model includes characterization of the photon statistics as it propagates through the imaging chain. The modeling of the reconstructed image noise includes characterization of the scanned object, using information obtained from extensive phantom and clinical data. This technology is designed to deliver reduced noise levels, improved low contrast detectability and may enable up to 82% reduction in dose when compared to FBP for all clinical applications.

### Smart Dose technologies

### Automatic Exposure Control (AEC)

AEC is a versatile and powerful tool designed to tailor the scanner's radiation output to each patient based on the patient's size, age, shape and attenuation and the user's re- quested level of image noise/quality criterion. AEC technology uses estimated patient attenuation values to adjust the mA dynamically in order to achieve the requested level of image noise/quality criterion.

### 3D Dose Modulation Utilizing SmartmA

Volumetric knowledge prior to scanning allows you to personalize protocols and optimize dose for every patient, large and small. During the scan, real-time, 3D dose modulation helps deliver consistent image quality because it automatically accounts for the changing dimensions of your patient's anatomy. In addition, the system provides guidance to assist in centering the patient to maximize the benefit of mA modulation.

### Organ Dose Modulation

Organ Dose Modulation (ODM) builds on the SmartmA feature to enable even further patient dose reduction. By reducing the mA exposure profile as a function of the X-ray tube angle, radiosensitive organs towards the anterior surface of the patient, such as the eyes, breasts and thorax, can benefit from enhanced dose reduction while the overall image noise is still maintained.

### kV Assist

kV Assist makes it easy to select optimal kV settings for the patient being scanned. It recommends tube voltage and current to achieve the lowest dose while meeting desired image quality goals.

### 70 kV Scanning

70 kVp scan mode enables low dose pediatric and small patient scans

### ECG Modulated mA

For cardiac applications (optional), prospective ECG dose modulation automatically adjusts the mA to minimize the patient's exposure to X-rays – reducing mA, and thus dose, near the beginning and end of each prescribed phase range. Up to 3 phase ranges are selected within a heart cycle with different mA levels. The peak mA for the first phase range is automatically determined based on noise index set by the user. The user can also select the relative mA level for an optional second or third phase range, set as a percent of the mA level of the first phase range. This provides clear images and allows you to reduce dose yet provides motion free, high quality images for functional and anatomical analysis within a heart cycle

### Color Coding for Kids

Based on the Broselow-Luten Pediatric System, the Color Coding for Kids was developed to help operator to select the correct pediatric CT protocol. The system divides the protocols into nine color zones based on height and weight, and incrementally increases scan technique as the patient's size in- creases. This arrangement of protocols assists you in reducing the variations in pediatric protocol selection. If the patient weight is unavailable, a Broselow-Luten Tape can also be used to obtain the weight based



### on the length.

- DoseWatch Explore is an introductory dose management software application that provides you secure access, via any PC with internet access, to dose and protocol data from this system. An InSite connection to the system and completion of the registration process is required to use the DoseWatch Explore application. For US and Canadian Customers, this quotation includes access to the DoseWatch Explore application for a period of time concurrent with the system warranty. Smart Dose technologies

• Smart Track: Advanced hardware and software for X-ray beam tracking minimizes patient dose.

Smart Beam: Optimizes X-ray beam filtration independently for body, head, and cardiac applications.

• Soft Shutter: This capability reduces the over-beaming dose in helical scans by using an advanced reconstruction algorithm for helical scans that makes better use of acquired data through intelligent view weighting and back projection.

• Dose Check: Provides the user with tools to help them manage CT dose in clinical practice and is based on the standard XR-25-2010 published by The Association of Electrical and Medical Imaging Equipment Manufacturers Association (NEMA). Dose Check provides the following:

o Checking against a Notification Value if the estimated dose for the scan is above your site established value

o Checking against an Alert Value where the user needs spe- cific authority to continue the scan at the current estimated dose without changing the scan parameters if the estimated dose exceeds the alert value

o The ability to define Alert Values for Adult and Pediatric with age threshold

o Audit Logging and Review capabilities

o Protocol Change Control capabilities provided by robust protocol management interface

• Dose Computation, Display & Reporting: CTDIvol (CTDI volume), DLP (Dose Length Product), and Dose Efficiency computation and display during scan prescription provide dose information to the operator. Dose Reporting saves the CTDIvol, DLP, and phantom type in a DICOM Structured Dose Report and a secondary screen cap- ture. Series and cumulative exam values are saved. Saved values can be networked or archived.

### **DICOM Interchange**

DICOM Interchange allows the saving of any image from the database, along with a PC viewer using Internet Explorer, to a CD-R or DVD-R with- out marking the exam/series or image as archived for exam transfer between stations that are not networked or pass along to referring physicians or patients. For detailed information, please reference DICOM conformance statement.

- DICOM Storage Service Class
- Service Class User (SCU) for image send
- Service Class Provider (SCP) for image receive
- Service Class User (SCU) for storage commitment
- DICOM Query/Retrieve Service Class
- DICOM Modality Worklist
- DICOM Modality Performed Procedure Step

### Image Networking

Exams can be selected and moved between the Revolution CT and any imaging system supporting the DICOM protocol for network send, receive and pull/guery. Image transfer time using DICOM protocols is > 16fps on a 1000baseT network.

Warranty: The published Company warranty in effect on the date of shipment shall apply. The Company reserves the right to make changes. All specifications are subject to change. Regulatory Compliance: This product is designed to comply with applicable standards under the Radiation Control for Health and Safety Act of 1968. Laser alignment devices contained within this product are

appropriately labeled according to the requirements of the Center for Devices and Radiological Health.

This product complies with the performance standards of 21 CFR, sub-chapter J, and the applicable IEC 60601-1 series.

This product complies with NEMA Standard XR29-2013 / MITA Smart Dose Standard.

See the Pre-Installation manual for details of the siting requirements for GE Revolution CT.

Line	Qty.	Catalog	
2	1.00	B7919AE	Standard cable set for GEHC ultra-premium CT systems
Line	Qty.	Catalog	
3	1.00	B7918EN	English keyboard

GE GE	Healthca	re	April 2, 2021 Quote Number: <b>2007763296.2</b> Customer ID: <b>1-23I36A</b> Agreement Expiration Date: <b>7/1/2021</b>
Line	Qty.	Catalog	
4	1.00	B75062BE	Enhanced Xtream Integrated Injector Interface Kit - Class IV
Line	Qty.	Catalog	
5	1.00	B78552CA	CT Operator Console Desk

The Freedom workspace is an ergonomic working environment specifically designed for use with the GE Healthcare imaging systems. The sleek table design enables the efficient use of space while enhancing clinical workflow and technologist comfort.

The Freedom workspace provides a minimalist footprint to improve patient visibility and giving the user easier access to patients in the imaging suite.

It offers sit/stand and horizontal/vertical monitor flexibility. It can also help reduce noise and heat with remote location options of the console. The non-adjustable Freedom workspace version is 1300mm long x 895mm wide x 850mm height and weighs 55.8kg.

Line	Qty.	Catalog		
6	1.00	B7660B	Chair	

Chair for CT scanner

Line	Qty.	Catalog	
7	1.00	B77292CA	CT Service Cabinet

Service cabinet for system accessories storage

Line	Qty.	Catalog	
8	1.00	B7864PZ	Eaton 14.4 KVA 3-Phase Partial System UPS for GE CT and PET/CT Scanners

Eaton's 14.4 KVA 3-Phase partial system UPS (Uninterruptible Power Supply) has been specifically configured to coordinate with compatible GE CT and PET/CT scanners.

The partial system UPS provides clean, reliable, constant voltage power to the scanner electronics. It helps protect the system's sensitive electronic components from damaging power anomalies such as high frequency noise transients and over voltage and under voltage conditions.

Utilizing the Partial system UPS can help maintain user productivity and improve system reliability. It can also help to reduce service costs and prevent system downtime.

Specifications:

1. Rating: 14.4 KVA

2. Input voltage range: three phases; 102-132V/phase

3. Input frequency range: 45-65 Hertz

4. Input power factor: >95% typical



5. Output frequency: 50 or 60 Hertz, autosensing

- 6. Output regulation: <3% steady state for all conditions of line and load
- 7. Voltage distortion: <5% threshold
- 8. Overload capacity: 110% for 10 minutes; 125% for 1 minute; 149% for 5 seconds.
- 9. Efficiency: >90% typical
- 10. Battery backup time: >10 minutes typical
- 11. Battery recharge time: < 3 hours to 80% capacity typical
- 12. Operating temperature: 50°F 104°F (10°C 40°C)
- 13. Floor heat dissipation: 5122 BTU/hour typical @11.5 KVA
- 14. Humidity: 20-80% relative humidity, non-condensing
- 15. Audible noise (norm mode): <60 dBA @1 meter
- 16. Dimensions (H x W x D): 49 inches x 12 inches x 32 inches (1245 mm x 305 mm x 813 mm)
- 17. Weight: 620 lbs (277 kg)

NOTE: THE PARTIAL SYSTEM UPS HAS DIFFERENT INTERACTIONS WITH COMPATIBLE SCANNERS, BASED ON DIFFERENT SCANNER POWER ARCHITECHURE. REFER TO THE PARTIAL SYSTEM UPS PRODUCT DATA SHEET FOR DETAILS. NOTE: ITEM IS NON-RETURNABLE AND NON-REFUNDABLE NOTE: REMOVAL/DISPOSAL OF OLD UPS IS THE CUSTOMERS RESPONSIBILITY NOTE: CONTACT GE SERVICE OR EATON FOR START-UP ASSISTANCE

Line	Qty.	Catalog	
9	1.00	B7900LC	Low Dose CT Lung Screening Option with Indication For Use

This option provides lung screening reference protocols that are tailored to the CT system, patient size (small, average large), and the most current recommendations from a wide range of professional medical and governmental organizations. Now, qualified GE Healthcare CT scanners with this option are formally indicated for, and can be confidently used by physicians for low dose CT lung cancer screening of identified high-risk patient populations. These protocols deliver low dose, short scan times, and clear and sharp images for the detection of small lung nodules. Early detection from an annual lung screening with low dose CT in high-risk individuals can prevent a substantial number of lung cancer-related deaths.

All new GE 64-slice and greater CT scanners, and virtually all of the 16-slice CT scanners that GE Healthcare sells are qualified for this screening option. This solution is also available to thousands of qualified GE CT scanners currently in use, increasing access to the quality scanners that satisfy both patient and physician needs. The new protocols, do include the choice for the user to be able to utilize GE Healthcare's industry-leading technologies such as ASiRTM, ASiR-VTM and VeoTM that are designed to reduce image noise, which is undesirable for physicians looking for small nodules.

This option contains two documents. Lung Cancer Screening Option Reference Protocol Guide, and the Lung Cancer Screening Option User Manual / Technical Reference Manual

i) The following GE Healthcare CT scanners are qualified to receive the new low dose CT Lung Cancer Screening Option: LightSpeed 16, BrightSpeed Elite, LightSpeed Pro16, Optima CT540, Discovery CT590 RT, Optima CT580, Optima CT580 W, Optima CT590 RT, LightSpeed Xtra, LightSpeed RT16, LightSpeed VCT, LightSpeed VCT XT, LightSpeed VCT XTe, LightSpeed VCT Select, Optima CT660, Revolution EVO, Discovery CT750 HD, Revolution HD, Revolution CT, Revolution Frontier.

ii) Moyer V. Screening for Lung Cancer: U.S. Preventive Services Task Force Recommendation Statement. Ann Intern Med. 2014;160:330-338.

http://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/lung-cancer-screening

Line	Qty.	Catalog	
10	1.00	E4502BG	UL Main Disconnect Panel 380-480V 50/60Hz 175A for CT Rev2.0

The MDP (Main Disconnect Panel) and UPS Control Panels serve as the main facility power disconnect source installed ahead of the Revolution CT system. On systems where the optional partial system UPS is included in the system, the panel provides NEC mandated UPS emergency power-off control function via a UPS control cable included with the UPS. The MDP saves time,



installation labor, and valuable mounting space by consolidating the main circuit breaker, control power source and required indicator lights into a compact factory manufactured panel.

Applications For general installations of GE Revolution Apex™.

Designed for reliability and easy installation

• The MDP saves time, installation labor, and valuable mounting space by consolidating the main circuit breaker, the feeder overcurrent devices, magnetic contactors and UPS emergency power-off into one compact panel

• The system provides stock availability of otherwise special-order devices, saving time and installation costs

• Reduces installation time and cost by eliminating delays in obtaining individually enclosed components and by eliminating on site assembly

- UPS emergency power-off functions are included for future, partial system UPS addition
- Disconnects system power on first loss of incoming power, preventing damage to system components
- Provides a standardized platform for UPS or other future GE engineered modifications or upgrades

Built for investment protection

- UL, cUL listed
- Supplied with low voltage, cover mounted Push to Stop, Twist to Restore pushbutton and long life LED pilot lights
- Provides overcurrent and short circuit protection
- Suitable for use on systems with 25,000A of short circuit current. It is the installer's responsibility to verify that the available shout circuit current is 25,000A or less for compliance to all electrical codes.

• An optional partial system UPS provides clean uninterrupted power to the system computer, maintaining system integrity during power loss while also providing a solution to power quality problems.

• Emergency-off disconnects power to both the PDU and optional partial system UPS output, per National Electric Code

Main power disconnect operating handle can be padlocked in the Off position for servicing safety and OSHA lock out/tag out
 The door has provisions for padlocking

- Enclosure door is interlocked with On / Off disconnect handle to prevent unauthorized access if disconnect is in the On position
- Factory wired and tested
- Panel disconnect provides OSHA lockout / tag out provisions

• The main disconnect panel may be used as a stand-alone main disconnect, with the optional GE partial system UPS or with a GE full system UPS

Remote EPO (Emergency Power Off)

Includes two normally closed contact blocks attached to the back of the emergency off push button. Two are included with each MDP. NOTES:

- Customer is responsible for arranging for installation with a qualified party
- ITEM IS NON-RETURNABLE AND NON-REFUNDABLE

Line	Qty.	Catalog	
11	1.00	R21013AC	Standard Service License

GE Healthcare has reclassified its service tools, diagnostics and documentation into various classes (please refer to the Service Licensing Notification statement at the beginning of this Quotation). The Standard License provides access to service tools used to perform basic level service on the Equipment and is included at no charge for the warranty period.

Line	Qty.	Catalog	
12	1.00	W0301CT	TIP CT Scanner 1 Training Program

This training program is designed for customers purchasing a GEHC CT system to include Optima, EVO, or Cardiographe. GEHC will work with the designated Customer contact to agree upon a reasonable training schedule for a pre-defined group of core technologists that will leverage blended content delivery and may include a combination of onsite days and virtual offerings, to include TiP Virtual Assist, the GEHC Answerline and available on-demand courses ("Virtual Inclusions"). This blended curriculum with multiple delivery platforms promotes learner retention and allows for an efficient and effective skill development.

This program may contain:



• Onsite training (generally 10 days)

• Virtual Inclusions may include:

• Remote instructor-led training: Instructor leads a remote training session one-on-one or in a group, typically for 1 hour

• Answerline Support-Access to GEHC experts for clinical, non-emergency applications assistance via phone or by using the iLing button on the imaging console

• Tip Virtual Assist-Direct interactive access to a GEHC expert for enhanced support.

• On Demand courses-On healthcare learning system. Self-paced courses and webinars (CE and non-CE).

Training will be delivered at a mutually agreed upon time between the customer and GE Healthcare (excluding GE Healthcare holidays and weekends), are subject to availability and generally will not exceed 14 days. This training program has a term of six (6) months commencing on Acceptance, where all onsite training must be scheduled and completed within six (6) months of Acceptance and all Virtual Inclusions also expire at the end of such six (6) month period. Additional onsite days may be available for purchase separately.

All GEHC "Training" terms and conditions apply. Given the unique nature of this program, if this program is purchased as part of a purchase under a Governing Agreement, including any Master Purchase Agreement, Group Purchasing Organization Agreement, or Strategic Alliance Agreement, this program shall take precedence over any conflicting training deliverables set forth therein.

Total Quote Net Selling Price: \$1,192,538.00

If applicable, for more information on this devices' operating system, please visit GE Healthcare's product security portal at: <u>https://securityupdate.gehealthcare.com/en/products</u>



### **GPO Agreement Reference Information**

Customer:	Carolinas HealthCare System Union	
Contract Number:	CSS-GEHC MVA July 15 2011 a/k/a CSS-EQ-0031	
Billing Terms:	100% billing at Ship Completion (Fulfillment) / Delivery	
Payment Terms:	Net Due in 60 Days	
Shipping Terms	FOB DESTINATION	

Offer subject to the Terms and Conditions of the applicable Group Purchasing Agreements currently in effect between GE Healthcare and CSS-GEHC MVA July 15 2011 a/k/a CSS-EQ-0031

If applicable, for more information on this devices' operating system, please visit GE Healthcare's product security portal at: <u>https://securityupdate.gehealthcare.com/en/products</u>

### Quotation

Quote No. Q-00044648

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: Union West HospitalIssued on 2/23/2021Valid until 4/24/2021

Trade-in required No

Your Bayer Sales Team:

Anthony Capuzzi 704-534-9391, , anthony.capuzzi@bayer.com

### **Quotation Overview**

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	YOUR PRICE
Stellant FLEX - Medrad® Stellant® FLEX Injection System(s)		\$53,425.00
TOTAL(Local taxes, shipping and/or handling to be invoiced when applicable)		\$53,425.00

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

Medium OCS for this order



## Quotation continued Quotation prepared for: Union West Hospital

### Issued on 2/23/2021

Valid until 4/24/2021

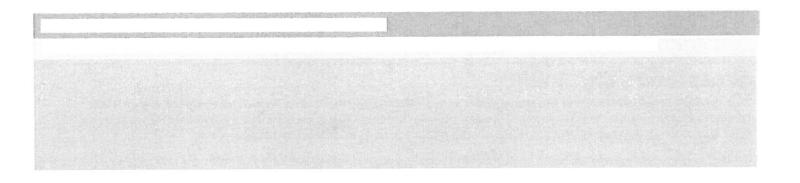
TOTAL	\$53,425.00
SHIPPING & HANDLING	\$389.66
GRAND TOTAL (Local taxes, shipping and/or handling to be invoiced when applicable)	\$53,814.66



## Quotation continued Quotation prepared for: Union West Hospital

Issued on 2/23/2021

Valid until 4/24/2021



# Quotation

Quote No. Q-00044648

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: Union West Hospital

Issued on 2/23/2021

Valid until 4/24/2021

Trade-in required No

Your Bayer Sales Team:

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-00044648, and email this form to Sales Support at <u>risalessupport@bayer.com</u> AND your SC, Anthony Capuzzi, at anthony.capuzzi@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. If your organization is tax exempt, please notify Sales Support at 1-800-633-7231.

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 Additional Customer Comments	Phone	
PO#	PO Amount	
Write PO number	Write PO amount	
Customer Approver	Customer Approver Title	Billing Email Address (if applicable)
Write customer name	Write customer title	Write email address
Customer Approver Signature		Date
х		
Please print and sign		MM/DD/XXXX

Please print and sign

MM/DD/YYYY

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Issued on 2/23/2021

Valid until 4/24/2021

# **Bayer Product Terms and Conditions**

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

DEVICES

**Bayer Product Terms and Conditions** 

# Attachment D

### PROPOSED TOTAL CAPITAL COST OF PROJECT

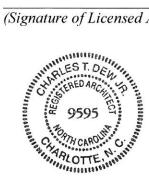
Project name:	Atrium Health Union West - Union CT Replacement & Relocation CON Exemption						
Provider/Company: Atrium Health							
(1) Purchase price of land		\$0.00					
		\$0.00					
(3) Site Preparation		\$0.00					
(4) Construction/Renovation	on Contract	\$0.00					
(5) Landscaping		\$0.00					
(6) Architect/Engineering I	Fees	\$0.00					
(7) Medical Equipment		\$1,305,535					
(8) Non Medical Equipmer	nt	\$0.00					
(9) Furniture		\$0.00					
(10) Consultant Fees (CON	0) Consultant Fees (CON Fees, Legal Fees)						
(11) Financing Costs	) Financing Costs \$0.						
(12) Interest During Constru	2) Interest During Construction \$0						
(13) Other (IS, Security, Inte	b) Other (IS, Security, Internal Allocation) \$85,31						
(14) Total Capital Cost		\$1,390,850					

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

March 9, 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 \$59,182.

# Attachment E

### **Capital** Guide

# **Fair Market Value Analysis**

## Total FMV Estimate = \$5,686 to \$14,215

### Configuration

Vendor **GE Healthcare** 

Device

Scanning Systems, Computed Tomography

Model LightSpeed VCT

### **Prepared For**

### **Prepared By**

**Carolinas HealthCare System** Chris Hollar

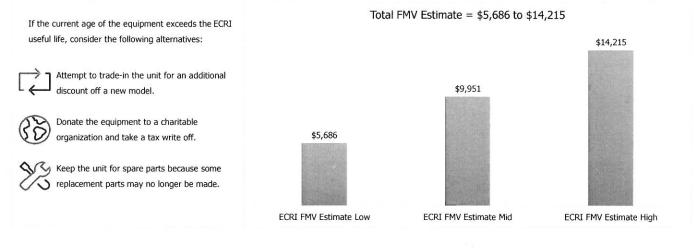
Christina Jarjisian Phone: (800) 998-3274 ext. 6202 Email: cjarjisian@ECRI.org Thursday, February 25, 2021

If you have any questions or require additional information, please do not hesitate to call the analyst.

Work Order: 1093620



### **FMV Analysis Details**



Vendor	Model	Generic Device Name	Current Age (yrs)	ECRI Useful Life (yrs)	Purchase Price	Price Source	Qty	ECRI FMV Estimate Low	ECRI FMV Estimate Mid	ECRI FMV Estimate High
GE Healthcare	LightSpeed VCT	ст	11	10	\$284,306	ECRI	1	\$5,686	\$9,951	\$14,215
				TOTALS	\$284,306		1	\$5,686	\$9,951	\$14,215

The ECRI useful life is the number of years we believe the product can typically be used and serviced. These expected useful lives are derived from a consensus of ECRI experts that have examined the real-world replacement intervals for capital equipment and information technology.

We utilize a useful life expectancy of ten (10) years for CT Systems. By way of comparison, the American Hospital Association (AHA) life span for this technology is five (5) years.

#### Discussion

The age of your LightSpeed VCT exceeds the expected useful life. Therefore, we expect the residual value of the equipment would be limited to 2% to 5% of the original purchase price. Your facility did not provide the original cost of the LightSpeed VCT. We utilized our PricePaid database to estimate a purchase price of \$284,306 in 2010. Based upon our assumptions, the FMV estimate for your LightSpeed VCT is between \$5,686 and \$14,215.

Please note that our FMV estimates do not take into account usage or condition of the equipment. Our analysis also does not account for any clinical value that the equipment may hold, but rather estimates what value the equipment may have in the used medical device marketplace. In order to most accurately determine the FMV of your equipment, we suggest that you:

- 1. Consider the availability of new technology.
- Determine if the equipment no longer meets government or safety standards.
- 3. Decide if it is more economical to repair or replace the equipment.
- 4. Ensure the availability of repair parts from original equipment manufacturer (OEM).
- 5. Ascertain if obsolescence impacts clinical/operational effectiveness.
- 6. Define the reliability/dependability of the equipment.

Many factors can enhance or detract from the FMV. Changes in demand due to reported problems and device recalls, as well as technological innovations can also have a significant impact.

Model-specific factors affecting the FMV:

Enhances FMV	
Large market share	
Model still in production	
Well known OEM	
Service available from OEM	
Service available from 3rd party	
Stable technology	
Detracts From FMV	
Small market share	
Discontinued model	
Little known OEM	
No longer serviceable by OEM	
Servicing restricted to OEM	
Volatile technology	



10 Year Useful Life

FMV	Yean 1	Year 2	Year 3	Yean 4	Vear 5	Venn 6	Year 7	Year 8	Year 9	Year 10
Max	90%	81%	72%	63%	54%	45%	36%	27%	18%	10%
Min	85%	76%	67%	58%	49%	40%	31%	22%	13%	5%

### DISCLAIMER

ECRI's FMV estimate is defined as the cash amount that a buyer may reasonably offer, and a seller accept, in exchange for capital medical equipment on the open market. Our estimate assumes that both the buyer and seller are reasonably knowledgeable and neither is being pressured into a transaction. ECRI's FMV estimate is not an imposed value. Due to the highly subjective nature of FMV's, our estimate is not in any manner a guarantee of value.

The member agrees to hold in strict confidence Capital Guide Custom Analyses, as well as the content of the other Products and Services offered under the Capital Guide Agreement, using them only for their intended purpose and within its own institution, and shall not transmit them to or share them with third parties without the prior written permission of ECRI in each instance. The provisions of this clause shall survive expiration or termination of this Agreement. In the event that member uses or attempts to use the Custom Analysis, or other Capital Guide Products and Services, in a manner that is contrary to the terms of the Capital Guide Agreement, it may result in an automatic termination of the usage rights granted herein and will give ECRI the right (in addition to any such remedies available to it) to injunctive relief enjoining those acts, it being acknowledged that legal remedies are inadequate.

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### Piekaar, Misty L

From:	Huber, Brighid K <brighid.huber@atriumhealth.org></brighid.huber@atriumhealth.org>
Sent:	Wednesday, April 7, 2021 11:22 AM
То:	Flores, Disraeliza; Fatimah.Wison@dhhs.nc.gov
Cc:	Kirkman, Elizabeth; Piekaar, Misty L
Subject:	[External] Exemption Request for CMHA d/b/a Atrium Health Union to Replace and
	Relocate a CT Scanner
Attachments:	2021 AH Union CT Replacement & Relocation Exemption Request_final.pdf

CAUTION: External email. Do not click links or open attachments unless you verify. Send all suspicious email as an attachment to Report Spam.

### Good morning,

Please find attached an exemption request submitted by The Charlotte-Mecklenburg Hospital Authority d/b/a Atrium Health Union to replace and relocate a CT scanner.

Thank you, 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

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