



DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER
GOVERNOR

MANDY COHEN, MD, MPH
SECRETARY

MARK PAYNE
DIRECTOR

October 30, 2017

Lisa Griffin
Novant Health
2085 Frontis Plaza Boulevard
Winston-Salem, North Carolina 27103

Exempt from Review – Replacement Equipment

Record #: 2427
Facility Name: Novant Health Presbyterian Medical Center
FID #: 943501
Business Name: Novant Health, Inc.
Business #: 1341
Project Description: Replace existing, fixed CT scanner/simulator located on main campus of Novant Health Presbyterian Medical Center (NHPMC)
County: Mecklenburg

Dear Ms. Griffin:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of October 25, 2017 the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-184(a)(7). Therefore, you may proceed to acquire without a certificate of need the Toshiba Aquilion XT Scanner to replace the GE HiSpeed CT Scanner/Simulator located in the Radiation Oncology Department of NHPMC. This determination is based on your representations that the existing unit will be removed from North Carolina and will not be used again in the State without first obtaining a certificate of need.

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

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

Sincerely,

Handwritten signature of Gloria C. Hale in cursive.

Gloria C. Hale
Project Analyst

Handwritten signature of Martha J. Frisone in cursive.

Martha J. Frisone
Chief, Healthcare Planning and
Certificate of Need Section

cc: Construction Section, DHSR
Acute and Home Care Licensure and Certification Section, DHSR
Radiation Protection Section, DHSR
Sharetta Blackwell, Program Assistant, Healthcare Planning, DHSR

HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

WWW.NCDHHS.GOV

TELEPHONE 919-855-3873

LOCATION: EDGERTON BUILDING • 809 RUGGLES DRIVE • RALEIGH, NC 27603

MAILING ADDRESS: 2704 MAIL SERVICE CENTER • RALEIGH, NC 27699-2704

AN EQUAL OPPORTUNITY/ AFFIRMATIVE ACTION EMPLOYER



October 25, 2017

Via Email

Gloria Hale, Project Analyst, Certificate of Need
N.C. Department of Health Service Regulation
809 Ruggles Drive
Raleigh, North Carolina 27603



2085 Frontis Plaza Boulevard
Winston-Salem, NC 27103

Re: Novant Health, Inc. – Novant Health
Presbyterian Medical Center
Replacement of CT Simulator
Charlotte, NC (Mecklenburg County)



Dear Ms. Hale:

Novant Health, Inc. and Novant Health Presbyterian Medical Center (“NHPMC”) intend to replace an existing CT scanner currently located at the main campus of NHPMC in Charlotte, North Carolina. NHPMC will acquire a new Toshiba Aquilion XT Scanner for use in the Radiation Oncology department. See **Attachment A** for the Equipment Quote and a quote for the treatment planning guidance system. As part of the equipment cost, the vendor will provide onsite clinical training for the equipment. The total capital cost for the proposed replacement equipment project is estimated to be \$1,652,166¹. See **Attachment B** – Project Capital Cost. The existing CT scanner is to be sold to Radiology Oncology Systems for \$1 salvage value.

The proposed project meets the definition of “replacement equipment” found in G.S. 131E-176(22a) and 10A N.C.A.C 14C.0303 for the following reasons:

- (1) NHPMC will replace the existing CT scanner with the proposed CT scanner that is functionally similar and will be used for the same diagnostic purposes, although it possesses expanded capabilities due to technological improvements.
- (2) The proposed CT scanner will not be used to provide a new health service.
- (3) The acquisition of the proposed CT scanner will not result in more than a 10% increase in patient charges or per procedure operating expenses within the first twelve months after the replacement equipment is acquired.
- (4) NHPMC seeks to replace comparable medical equipment currently in use at project cost less than \$2 million.
- (5) The existing equipment was not purchased second-hand nor was the existing equipment leased.

In support of our request, please find attached:

- Attachment A** – Vendor Equipment Quotes (Toshiba; Vision RT; ROS)
- Attachment B** – Project Capital Cost
- Attachment C** – NC CON Equipment Comparison chart

¹ The project cost does not include sales, property or excise taxes as NHPMC is not subject to these taxes as a non-profit, tax-exempt organization.

Gloria Hale
RE: NHPMC Replacment of a CT Scanner
October 25, 2017
Page 2

NHPMC's acquisition of the replacement CT scanner does not require a certificate of need because none of the definitions of "new institutional health services" set forth in N.C.G.S. Section 131E-176(16) apply to the proposed project. As outlined above, the total cost for the project is \$1,652,166. The proposed capital cost includes equipment, as well as studies, surveys, designs, plans, working drawings, specifications, construction installation and other activities essential to making the equipment operational.

Based on the information provided, please confirm that NHPMC's replacement equipment request does not constitute a new institutional health service and is exempt from certificate of need review.

If you need additional information, please do not hesitate to contact me.

Sincerely,

A handwritten signature in cursive script that reads "Lisa Griffin".

Lisa Griffin
Manager, Certificate of Need
Novant Health, Inc.

Enclosures

Cc: Barbara Freedy, Director, CON, Novant Health

**ATTACHMENT A –
Equipment Quotes**



Made For life

TOSHIBA AMERICA MEDICAL SYSTEMS, INC.

QUOTATION/ORDER SUMMARY

DATE: 8/1/2017
SID #: 30042237
QUOTE #: 109151-1

PRESENTED TO:
NOVANT HEALTH PRESBYTERIAN MEDICAL
CENTER
200 HAWTHORNE LN
CHARLOTTE, NC. 28204

DELIVER TO:
NOVANT HEALTH PRESBYTERIAN MEDICAL
CENTER
200 HAWTHORNE LN
CHARLOTTE, NC. 28204

AQ/LB-SERIES/ONC/S.000
AQUILION LARGE BORE CT SCANNER - ONCOLOGY

AQ/LB-GEN1/CONSOLE-UPG.000
AQUILION LARGE BORE CONSOLE UPGRADE KIT (GEN1)

This quotation shall remain valid until December 29, 2017.

All prices are F.O.B. destination.

Payment terms are: Cash - 0% down payment, 80% upon shipment, 20% net 45 days upon completion of installation and/or availability for first use, whichever is earlier.

This quotation/order will be subjected to the Agreement for Computed Tomography equipment products between Vizient Supply, LLC and Toshiba America Medical Systems, Inc., Reference contract no. XR0324

Please return signed quotation to Toshiba America Medical Systems by email OrderAdmin@tams.com or fax 714-441-9320.

ACCEPTED AGREED AND ORDERED:

PURCHASER'S SIGNATURE/TITLE

DATE

TOSHIBA REP / CONTACT

DATE

All information contained in this quotation is confidential and may not be disclosed to any third party without Toshiba's prior written consent.

EQUIPMENT SUMMARY:

AQ/LB-SERIES/ONC/S.000

AQUILION LARGE BORE CT SCANNER - ONCOLOGY

<u>PART NUMBER</u>	<u>QTY</u>	<u>DESCRIPTION</u>
	1	CT SCANNER AQ LB WITH EXTENDED COUCH
	1	ACCESSORY KIT FOR EXTENDED PATIENT COUCH
	1	CT PHANTOM
	1	CONSOLE DESK 65" X 36" X 30"
	2	CHAIR WITH ADJUSTABLE ARMS AND BACK
	5	MEDIA FOR DVD-RAM DRIVE (9.4 GB)
	1	NON-CORROSIVE FLOOR LEVELING EPOXY KIT
	1	DICOM 3 MODALITY WORKLIST MANAGEMENT (MWM) SERVICE CLASS USER (SCU) SYSTEM
AQ/PDU	1	TOSHIBA POWER DISTRIBUTION UNIT
CGS-53A/1B	1	SECOND CONSOLE FOR AQUILION RXL AND LB
CSTC-002A/2B	1	EXTENDED FIELD OF VIEW
TABLE-INSERT-EXT.100	1	CIVCO TABLE INSERT KIT FOR EXTENDED COUCH (AQUILION LB & LIGHTNING)
	1	TABLE TOP MOUNTING BRACKET FOR EXTENDED COUCH (BRACKET ONLY)
	1	CIVCO UNIVERSAL TABLE TOP INSERT FOR EXTENDED COUCH
CT-4-3-P/G	1	GREEN LASER ISOCENTER MARKING SYSTEM - POST MOUNTED
GAMMEX-467.100	1	GAMMEX PHANTOM KIT
	1	TISSUE CHARACTERIZATION PHANTOM
RESP-GATING/ONC.100	1	RESPIRATORY GATING ACQUISITION PACKAGE FOR ONCOLOGY
	1	PROSPECTIVE RESPIRATORY GATING SOFTWARE
	1	RETROSPECTIVE RESPIRATORY GATING SOFTWARE

AQ/LB-GEN1/CONSOLE-UPG.000 AQUILION LARGE BORE CONSOLE UPGRADE KIT (GEN1)

<u>PART NUMBER</u>	<u>QTY</u>	<u>DESCRIPTION</u>
AQLB/GEN1/2CONSOLE/H VG-UPG.100	1	AQUILION LARGE BORE CONSOLE UPGRADE KIT (GEN 1) (SEMAR INTEGRATED) SERIAL NUMBER 2040 TO 2164
	1	CONSOLE UPGRADE KIT FOR AQUILION LB GEN 1 (SEMAR INTEGRATED)
	1	SECOND CONSOLE DISPLAY KIT AQUILION LB (BEFORE V6.0)
	1	GENERATOR FOR GEN 1 AQUILION LARGE BORES REQUESTING SEMAR UPGRADE
APPS-ONSITE-16	1	ADDITIONAL ON-SITE APPLICATIONS TRAINING - 16 HOURS

TOTAL QUOTE PRICE
Applicable Sales Tax Additional**\$754,013.00**

AQ/LB-SERIES/ONC/S.000**AQUILION LARGE BORE CT SCANNER - ONCOLOGY**

Aquilion Large Bore Series (Aquilion LB), with Adaptive Iterative Dose Reduction 3D (AIDR 3D), is a large bore Computed Tomography (CT) scanner that provides improved patient positioning with outstanding image quality and clinical performance for today's radiology and oncology suites.

The system was designed for improved patient positioning and image quality necessary for CT simulation, oncology treatment planning, interventional radiology procedures and bariatric patients. This includes:

- Widest bore opening in the industry (90 cm) for easy patient positioning and maximum flexibility for treatment planning, and
- Largest true (non-extrapolated) field-of-view (70 cm), which covers more anatomy with greater accuracy than ever before by using Toshiba's PUREViSION PLUS Detector.

The Aquilion LB solves one of the biggest problems faced in oncology - the positioning of a large patient on a breast board with both arms up and the board tilted to its maximum (25%).

The Aquilion Large Bore Series scanner includes Aquilion's best-in-class, PUREViSION detector with 0.5mm elements. Aquilion LB's PUREViSION detector provides true isotropic resolution to radiology and oncology alike. Capable of reconstructing 32 unique slices with every rotation using Toshiba's proprietary coneXact algorithm. The Aquilion LB enables the user to scan in one plane and reconstruct information in another plane with the same image quality. This allows clinicians to use 3D volumetric information when needed. Aquilion LB's PUREViSION detector is the only detector to provide three slice-width combinations - 16x0.5, 16x1 and 16x2 mm - and it achieves an industry-leading, low-contrast resolution without using additional dose.

The combination of a high-speed scanner and a powerful, high-voltage generator meets every diagnostic requirement. Solid-state, multi-row detectors and optimal reconstruction techniques ensure high-quality images. A high-performance CPU, large color monitor, hybrid keyboard and refined Graphic User Interface (GUI) make the operating environment highly efficient.

COMPONENTS

- Large-aperture, 90 cm, slip-ring gantry and extra-wide couch (47 cm)
- 72 kW High-frequency X-ray generator and 7.5 MHU high-heat-capacity X-ray tube
- Ergonomic operator console

- Volumetric image processor
- High-capacity hard disk
- CD-R / DVD-RAM Drive - 9.4 GBytes (double sided DVD RAM)
- Image data transfer link
- Patient comfort accessories
- Operator manuals and quality assurance phantoms

KEY FEATURES

Single-Energy Metal Artifact Reduction (SEMAR)

SEMAR (Single-Energy Metal Artifact Reduction) technology employs a sophisticated reconstruction algorithm to reduce artifacts caused by metal while improving visualization of the implant, its supporting bone and adjacent soft tissues for accurate imaging.

SEMAR can be used in routine low-dose scans, and the combination with AIDR 3D provides the best possible image quality without the need for a dedicated scan procedure or additional radiation exposure. It can be used with Helical scan mode. Toshiba will include SEMAR with each system as a value add.

** Bone structures near the metal-tissue interface may become distorted. Metal artifacts may not be completely removed in areas near the metal material. Comparison with the original images is suggested when performing diagnosis using SEMAR images.*

Improved Patient Positioning: The industry's largest aperture of 90 cm and the 70 cm true reconstruction field-of-view provides extreme flexibility during CT simulation and improved treatment planning.

Routine Fast Scanning: Using slip-ring technology, Aquilion LB is able to perform 0.32-second partial scans and 0.5-second routine scans to meet the demands of dynamic and helical examinations.

High Image Quality: The Aquilion LB features 994 channels in 40 rows of solid-state detectors; specialized, user-selectable, image-reconstruction algorithms; and a wide selection of slice thicknesses that provides 32 slices of high quality images. The system provides outstanding low-contrast resolution of 2 mm at 0.3% and high-contrast resolution of 0.35 mm.

High-Power Generator: Robust, high-voltage circuits generate 72 kW of power and 600 mA, providing support for the 7.5 MHU X-ray tube that makes possible helical scans up to 100 seconds and scans with metal-free scan range of up to 1,800 mm.

Multiple kV Selections: 80, 100, 120 and 135 kV.

Fast Image Reconstruction Time: Up to 22 images per second.

SURETechnology: Real-time helical display, which provides instantaneous visualization of acquired images, allows the operator to rapidly assess if additional images are needed. **SUREStart** bolus tracking software, which is included in the standard configuration, provides the ability to monitor contrast media in real-time.

Easy Operation: Perform easy operations using the 18-inch LCD monitor, mouse and hybrid keyboard. Scan automatically by programming procedures with eXam Plan and vocal instructions through VoiceLink™.

Optimal Space Utilization: The Aquilion LB has only three components – gantry, couch and console – with a footprint of only 27 square meters.

DOSE-REDUCTION FEATURES

Aquilion LB Series reinforces Toshiba's guiding principle of ALARA for every patient. To achieve this, Aquilion LB Series has an array of adaptive and integrated dose-reduction strategies that are implemented at every stage, from patient registration to image reconstruction. In addition, patient dose reduction is integrated into the console software, so it activates prior to turning on the x-ray beam.

Adaptive Iterative Dose Reduction 3D (AIDR 3D)

AIDR 3D is the third generation in the evolution of Toshiba's iterative reconstruction technology. AIDR 3D is an iterative algorithm intended to reduce pixel noise from the original data, the results analyzed, and the process repeated until the target level of noise-reduction is achieved. This iterative algorithm is superior in reducing background noise while preserving diagnostic information compared to non-iterative approaches.

AIDR 3D can be integrated into all acquisition modes for routine clinical use and is able to remove image noise resulting in dose reduction. This feature, a \$150,000 value, is included in each Aquilion LB Series at no additional charge.

SUREExposure3D (x, y, z automated mA modulation software)

Toshiba's SUREExposure3D software automatically adjusts the mAs based on patient anatomy to adapt to and compensate for changes in attenuation level.

Quantum Denoising Software - QDS (Adaptive Noise Reduction)

Toshiba's Quantum Denoising Software is an adaptive noise reduction algorithm that works in the image data space by preferentially smoothing areas of uniform density while preserving the edge information of the image. QDS works in both two and three dimensions and can drastically reduce image noise, thus lowering dose. Most importantly, QDS works in conjunction with the ^{SURE}Exposure3D software to adjust the mAs based on the expected noise reduction from QDS. In this way, patient dose reduction is totally integrated in the Aquilion console software prior to turning on the x-ray beam.

^{SURE}Exposure3D (x, y, z automated mA modulation software)

Toshiba's ^{SURE}Exposure3D software automatically adjusts the mAs rapidly during the scan to adapt to and compensate for changes in attenuation level produced by the non-uniformity of the anatomy being imaged. Therefore, as the scan moves from the shoulders to the lung, the mAs goes down, and as the tube rotates around the patient, less mAs is used anterior-posterior than laterally. Sure Exposure helps reduce dose while maintaining image quality.

Boost3D

Boost3D is an adaptive, three-dimensional algorithm that virtually eliminates degradation of image quality due to highly attenuating anatomical structures, such as the pelvis or shoulders. Without dose reduction algorithms, like Boost3D, these highly attenuating areas require increased mAs and kVp to overcome the low photon count. Instead, Boost3D seeks out portions of the raw-projection data where there is a disproportionate loss in x-ray signal and applies a three-dimensional algorithm locally to reduce the image noise and streak artifacts.

NEMA XR 25, XR 26 and XR 29

Aquilion PRIME Series ELITE meets the National Electrical Manufacturers Association's (NEMA) Medical Imaging & Technology Alliance (MITA) standards XR 25, XR 26 and XR 29.

- MITA XR 25 Computed Tomography Dose Check
 - Includes dose alerts and allows facilities to set dose notification values.
- MITA XR 26 Access Controls for Computed Tomography: Identification, Interlocks, and Logs
 - Provides access control ensuring only authorized operators can alter controls of the CT equipment.
- MITA XR 29 Standard Attributes on Computed Tomography (CT) Equipment Related to Dose Optimization and Management
 - Smart Dose standard bundles four important features to ensure that equipment produces high-quality diagnostic images while supporting patient safety:
 - DICOM Structured Reporting

- CT Dose Check
- Automatic Exposure Controls,
- Pediatric and adult reference protocols.

EQUIPMENT DESCRIPTION

Aquilion LB Gantry

The Aquilion LB gantry uses a direct-drive design to provide accurate alignment between beam and detector, and to reduce rotational noise for higher-quality images.

A low-voltage slip ring assures reliable, continuous power transfer.

- Digital signal transmission facilitated by innovative optical-coupling technology moves information to the volumetric image processor
- Generator is inside the gantry to conserve space

Other features include:

- Industry's largest aperture: 90 cm
- Five scan fields of view: 24, 32, 40, 55 and 70 cm
- Gantry controls on both sides (right and left)
- Patient positioning lights
- Wide range of scan times provides greater flexibility for optimal image quality (0.32 partial; 0.5, 0.75, 1, 1.5, 2 and 3 seconds full)
- Slice thickness selections of 16x0.5, 16x1 and 16x2 mm with the capability of stacking images to the desired slice thickness

CT Console

- Consists of hybrid keyboard, mouse, monitor and Navibox
- Controls the entire system, including power
- Image display
- Scanscope control
- Remote control of couch-top movement
- Window level and width adjustment
- Three preset windows can be stored in the eXam Plans
- Other mouse-operated, image-processing functions
- High line-rate, 18-inch LCD monitor
- Displays images in 512x512 or 1024x1024
- CT number display ranges from -1,536 to +8,191
- 32 programmable voice commands

* Dual console (optional)

X-ray Tube

The Aquilion LB is equipped with the MegaCool™ X-ray tube. This compact, high-performance tube was designed specifically to minimize tube-cooling delays in heavy patient-load conditions using 0.5-second scan time.

Other features include:

- Dual focal spots
- Anode capacity of 7.5 MHU
- Dissipation rate of 1,386 kHU per minute maximum

Detectors

The PUREViSION detector design allows Toshiba to generate a 70 cm true field-of-view - the largest in the industry - for improved positioning.

Other features include:

- PUREViSION solid-state detector array
- Low-contrast resolution of 2 mm at 0.3%
- 994 detector channels and 40 rows of detector elements
- 1,800 views per second to produce high-resolution images

Computer

- Two 64-bit processors
- Windows 7 Operating System
- Capable of simultaneous scanning, reconstructing, archiving and filming without interruption - true multi-tasking system
- Ultra-fast, 217 GB hard disk
- 100,000 images on both scan and display console
- 3,600 rotations of raw data maximum
- CD-R / DVD-RAM Drive - 9.4 GBytes (double sided DVD RAM)
- DICOM CD writer (*option*) - Archive up to 1000 images

PATIENT AND IMAGE MANAGEMENT**Patient Demographics Management**

- Enter individual patient information at the time of examination manually or imported from Modality Worklist Management query.
- On-line patient appointment file management

Image Management

Aquilion LB images can be stored on hard disk, magneto-optical disk or transferred via gigabit Ethernet connection using DICOM 3.0 standards.

DICOM 3.0 (Storage SCU)

- Allows the CT scanner to export images to CT simulation, 3D workstations or any other device on the network
- Consists of software only and utilizes pre-existing Ethernet ports on the CT scanner to connect to a coax-Ethernet-based network running TCP-IP communication protocols
- The system can be set to automatically transfer images to the network after an exam is complete

DICOM 3.0 (Print SCU)

- Allows the CT scanner to send image data that has been acquired and reconstructed to a film imager for printing via Ethernet in conformance with DICOM 3.0 standards

Image Display

- Display in multiple formats ranging from 1 to 16
- Overlay an inset scanogram for quick reference marking
- Add, subtract, rotate or filter images
- Adjust window width and level non-linearly, accommodating up to six built-in curves and six user-defined curves

IMAGE QUALITY ENHANCEMENTS

Automatic, 2-Pass, Beam-Hardening Correction (BHC): Compensates for the non-uniform, beam-hardening effect of bone for more accurate reconstruction. Reduction of streak artifacts in the posterior fossa and elimination of cupping artifact in the mid-brain.

Reconstruction Algorithms: Grouped by anatomical application, more than 50 algorithms are provided for customized image reconstruction according to the diagnostic information needed or physician preference.

HELICAL SCAN & FUNCTIONALITY

MultiView: Built into protocol for fast, multi-planar reconstruction in batch mode specifically for multislice data sets. Coronal, sagittal and axial images are created from isotropic volume data.

3D Imaging: Provides excellent image quality with surface shaded-renderings and volume-rendered 3D images. Provides zooming and panning over the 3D surface and performs distance measurements. Other features include:

- 3D surface display

- 3D shaded volume display
- Maximum intensity projection (Max - IP)
- Minimum intensity projection (Min - IP)
- Intensity volume rendering

Quantitative Analysis

- Profile display of CT numbers along a selected line in the axial plane
- Distance measurement and display
- CT number display
- Histogram display

Annotation

- Four lines of comments and arrow display
- 36 exam information fields that can be selectively masked or shown depending on site requirements

eXam Plan Protocols

- 684 eXam Plan protocols that can be adjusted while scanning
- Four preset reconstructions
- eXam Plan sets can be stored on optical disks and copied to other Toshiba scanners

Archiving

- Can be automated with each eXam Plan
- Data can be stored on and retrieved from MOD
- Raw data and image data can be protected to prevent deletion

Filming

- Auto filming can be set as part of the eXam Plan
- Images are displayed in 512x512 or 1024x1024

CUSTOMER CARE SERVICES**Toshiba CT ePROTECT Authentication and Malware Protection Device**

eProtect is the quickest, simplest, and most secure protection for Toshiba equipment. eProtect is a specially configured network device designed to isolate Toshiba medical products from hospital network traffic. eProtect will control and limit traffic into and out of Toshiba Products to allow DICOM services like Modality Worklist, Storage to PACS and workstations, Query & Retrieve, etc.

At the same time, eProtect restricts unnecessary network traffic from reaching the medical device. This unnecessary network traffic could be, but is not limited to viruses, malware, and malicious attacks. Toshiba has found

this to be the best form of malware protection for Toshiba imaging equipment. eProtect is provided *free of charge to Toshiba warranty and service agreement customers*. This feature, a \$20,000 value, is included in each Aquilion at no additional charge.

InnerVision™ Plus

Remote system diagnostics are available around-the-clock to help identify problems and provide potential solutions before care is interrupted or an engineer can arrive. InnerVision Plus is included at no charge and connected while any CT is under warranty, or any service agreement including Full Service, In-House Support, Partnership and/or VISN Master Service Agreement

Image Maker Express

Image Maker Express is an online marketing resource that helps Toshiba customers build demand for imaging service by growing their referring physician and patient relationships. Image Maker Express includes:

- Easy-to-use marketing resources and tools developed exclusively for Toshiba customers to bring together effective marketing strategies and tactics.
- A wealth of collaterals and content to create high-quality brochures, print ads and more to help market the Toshiba customer's new imaging capabilities.

Image Maker Express Materials available include:

- Product images and logos
- Clinical images and videos
- PowerPoint presentations and promotional videos
- Brochure samples
- Customizable press releases and media tips
- Marketing strategy tutorials

**Offerings may vary per product*

APPLICATION TRAINING

Each system includes a two phase education program and the industry exclusive Performance Pro guarantee.

Performance Pro is a unique approach to education utilizing blended learning with the promise of technical proficiency and optimal productivity. If for any reason the customer is not satisfied with any portion of the training, Toshiba will conduct that portion of the training again, at no charge.

Choice of two (2) Medical Imaging Consultants self-study programs; The CT CrossTrainer and/or The CT Registry Review Program.

The CT CrossTrainer is designed to acquaint the less-experienced technologist with important CT principles, technology and clinical exams. The program consists of 6 comprehensive StudyModules that have been accredited for 17 Category A CE credits; credits are earned by passing a post test for each StudyModule.

The CT Registry Review Program is designed to help the experienced CT technologist prepare to pass the ARRT's post-primary exam in CT. The course consists of 8 comprehensive StudyModules that have been accredited for 19 Category A CE credits; credits are earned by passing a post-test for each StudyModule.

Phase I: An initial thirty-two (32) hours, of on-site education will be provided at the customer facility following system go-live. This training is provided for up to four (4) imaging including to focus on maximizing CT simulation scanning techniques and protocols for radiation therapy planning. Training is scheduled consecutively, Monday through Friday, with Monday mornings and Friday afternoons scheduled as travel time for the applications specialist. CE credits are earned by participants that attend the Phase II training event in its entirety.

Phase II: An additional twenty-four (24) hours of on-site education will be provided for the same four (4) imaging professionals, which participated in Phase I training, approximately 6-8 weeks following installation to optimize staff proficiency and system productivity.

Note: Toshiba personnel are not responsible for scanning patients, patient safety, any actual patient contact, or operation of equipment during education sessions. Toshiba will only demonstrate proper equipment operation.

The training is offered to the Customer at no charge, providing that it is completed no later than one (1) year after the warranty start date.

Additional onsite training is available for purchase.

Applications support is available by phone on the toll-free ASSIST line, 1-800-521-1968.

COMPONENT SUMMARY:

<u>PART NUMBER</u>	<u>QTY</u>	<u>DESCRIPTION</u>
	1	CT SCANNER AQ LB WITH EXTENDED COUCH
	1	ACCESSORY KIT FOR EXTENDED PATIENT COUCH Includes each of the following items: <ul style="list-style-type: none">• "The Shield" Table Pad• Rolled Edge Foot Extension Pad• Protective Table Cover• Wide & Medium Security Straps• Chin Strap• Forehead Strap with Adult Pad• Adult Head Rests• Tilt Wedge• Knee Wedge• Coronal Head Positioner• Pediatric Lift Pad• Rail, Detachable, 69"
	1	CT PHANTOM Measures image quality to ensure compliance to Toshiba standards for: <ul style="list-style-type: none">• High-contrast resolution• Low-contrast resolution• Slice thickness• Noise• Contrast scale
	1	CONSOLE DESK 65" X 36" X 30" Measures 65" x 36" x 30"
	2	CHAIR WITH ADJUSTABLE ARMS AND BACK
	5	MEDIA FOR DVD-RAM DRIVE (9.4 GB) <ul style="list-style-type: none">• 9.4 GB• Two-sided
	1	NON-CORROSIVE FLOOR LEVELING EPOXY KIT

- 1 **DICOM 3 MODALITY WORKLIST MANAGEMENT (MWM) SERVICE CLASS USER (SCU) SYSTEM**
Allows the CT system to obtain details of patients and scheduled examinations electronically from the HIS/RIS system, avoiding the potential mistakes of manual entry.

Note: This option does not include a DICOM gateway for the HIS/RIS system.

AQ/PDU

- 1 **TOSHIBA POWER DISTRIBUTION UNIT**
The PDU is engineered to address common power problems found in the hospital environment and to isolate the CT system components to meet IEC 60601-1 Third Edition requirements. This is important to assure optimal reliability and performance of CT systems. Customer is responsible for complying with Toshiba's site specifications for electrical power.

This device provides most of the electrical site preparation requirements of Toshiba CT systems. The PDU contains a low impedance isolation step-down transformer with a shielding plate between primary and secondary.

Voltage Conversion

Wiring costs are significantly reduced since the PDU accepts a single, 480V delta input, supplying 200V to the generator and the various other parts of the system.

Distribution

The PDU comes prepackaged with the distribution breakers needed for each system feed. Having all system breakers in one location also makes it easier for service personnel to remove power.

Installation

Installation is much faster, more predictable, and less expensive with a factory-assembled and tested system.

CGS-53A/1B

- 1 **SECOND CONSOLE FOR AQUILION RXL AND LB**
This ergonomic, second console upgrades the Aquilion system* to a dual-console configuration. The scan console (scan system monitor) and the display console (image processing monitor) can be operated independently or in parallel in order to improve workflow and efficiency.

This is a genuine multi-tasking system for multi-slice and volume data sets.

- Includes user-friendly keyboards, mouse, monitors and CPU cabinet
- High line-rate, 19-inch, color monitor displays images in a 512x512 or 1024x1024 matrix using mouse and ergonomic keyboard

**Aquilion RXL and Aquilion LB systems ONLY*

CSTC-002A/2B

1 EXTENDED FIELD OF VIEW

This software identifies the extent to which the patient body and patient immobilizing devices are visualized outside the XL scan field of view (70 cm) in Large Bore CT Scanner.

- For reconstruction, a reconstruction field with a diameter of up to 850 mm can be specified for the raw data acquired with an FOV of XL
- The anatomy of the patient that extends outside the XL FOV can be visualized

Prerequisite: Software V3.1ER000 or higher

TABLE-INSERT-
EXT.100

1 CIVCO TABLE INSERT KIT FOR EXTENDED COUCH (AQUILION LB & LIGHTNING)

The TABLE-INSERT-EXT kit includes the table mounting bracket and a Universal Couchtop™ with an IPPS™ CT Couch Overlay.

1 TABLE TOP MOUNTING BRACKET FOR EXTENDED COUCH (BRACKET ONLY)

The table top mounting Bracket is used for securing CIVCO High Capacity Table Top insert.

Note:

- Applies to the Aquilion Lightning and Aquilion Large Bore Extended 1800 mm couches
- When table top mounting bracket (CAFT-021A/1B) is sold separately a Universal Couchtop™ (MT-IL 6521) may be required.

1 CIVCO UNIVERSAL TABLE TOP INSERT FOR EXTENDED COUCH

The Universal Couchtop Overlay is designed to provide rapid, accurate, and repeatable patient setup and localization. The Civco Prodigy 2 (every 7 cm) indexing system provides convenient and consistent orthogonal alignment.

- Optimum patient comfort
- Treatment flexibility
- Quick set-up and ease-of-use
- Highly repeatable patient positioning

Note:

- Applies to Aquilion Lightning and Aquilion Large Bore 205 kg 1800 mm couches.
- When Universal Couchtop Overlay (MT-IL 6520) is sold separately a mounting bracket (CAFT-021A/1B) may be required.

CT-4-3-P/G	1	<p>GREEN LASER ISOCENTER MARKING SYSTEM - POST MOUNTED The CT-4-3 consists of a single overhead moving line laser to project the sagittal plane, two moving lateral lasers to project the coronal plane, and fixed lasers to project the axial plane.</p>
GAMMEX-467.100	1	<p>GAMMEX PHANTOM KIT</p> <p>1 TISSUE CHARACTERIZATION PHANTOM</p>
RESP- GATING/ONC.100	1	<p>RESPIRATORY GATING ACQUISITION PACKAGE FOR ONCOLOGY</p> <p>1 PROSPECTIVE RESPIRATORY GATING SOFTWARE</p> <p>1 RETROSPECTIVE RESPIRATORY GATING SOFTWARE</p>
AQLB/GEN1/2CON SOLE/HVG- UPG.100	1	<p>AQUILION LARGE BORE CONSOLE UPGRADE KIT (GEN 1) (SEMAR INTEGRATED) SERIAL NUMBER 2040 TO 2164</p> <p>1 CONSOLE UPGRADE KIT FOR AQUILION LB GEN 1 (SEMAR INTEGRATED) Console upgrade for Aquilion Large Bore Generation 1 (TSX-201/A1) includes system software V6.3 provides new clinical features such as SEMAR (Single Energy Metal Artifact Reduction), Phase Average scan integration and improved time MIP functionality. Reconstruction speed is improved considerably. Additionally, all enhancements included with Large Bore VeloCT are included as well. Features such as:</p> <ul style="list-style-type: none"> • Cone Exact- 16 Slice to 32 Slice Upgrade, allowing 32 individual slices reconstructed per rotation • AIDR 3D-True Iterative Dose Reduction System • NEMA XR-29 Compliance including Dose Check, Dose Alert and structured Dose Reporting • Windows 7 Upgrade-Base Operating Software at Windows 7 Operating System <p>SEMAR utilizes a sophisticated reconstruction algorithm to reduce artifacts caused by metal while improving visualization of the implant, supporting bone and adjacent soft tissues* for accurate imaging. SEMAR can be retrospectively applied to a routine low-dose scan, including volumetric and helical scans, combined with AIDR 3D to achieve the best possible image quality without the need for additional exposure dose or a dedicated scan procedure.</p>

** Bone structures near the metal-tissue interface may become distorted. Metal artifacts may not be completely removed in areas near the metal material.*

Comparison with the original images is suggested when performing diagnosis using SEMAR images.

1 SECOND CONSOLE DISPLAY KIT AQUILION LB (BEFORE V6.0)

1 GENERATOR FOR GEN 1 AQUILION LARGE BORES REQUESTING SEMAR UPGRADE

APPS-ONSITE-16

1 ADDITIONAL ON-SITE APPLICATIONS TRAINING - 16 HOURS

Two (2) days, sixteen (16) hours, of additional onsite applications support. Training is scheduled consecutively, Monday through Friday, with Monday mornings and Friday afternoons scheduled as travel time for the applications specialist.

\$4,000, inclusive of application specialist's expenses.

Note: Toshiba personnel are not responsible for scanning patients, patient safety, any actual patient contact, or operation of equipment during education sessions. Toshiba will only demonstrate proper equipment operation.

Education expires two (2) years from the later of purchase date or warranty start date.



Vision RT Inc
 8840 Stanford Boulevard
 Suite 3200
 Columbia, MD 21045
 Tel: 866 778-2379
 Fax: 651 229-3531
 Email: sales@visionrt.com

Prepared For: Ms. Karen Johnson (Presbyterian),
 Manager Radiation Oncology

Customer: Novant Health
 Novant Health Presbyterian Medical
 Center
 200 Hawthorne Lane
 Charlotte NC 28204
 USA

Date Issued: 02 May 2017

Reference: TTH1702396V6

Date: 01 August 2017

Revised:

Prepared By: Trip Thomas

Email: tthomas@visionrt.com

Mobile:

Offer Expires: 01 December 2017

Summary of offer	Site	Qty
AlignRT and GateRT system for patient setup, surveillance (including advanced treatments) and respiratory gating. Includes three camera units and interface to Varian's MMI (Motion Management Interface) which allows automated beam hold on the Varian Clinac.	Novant Health Presbyterian Medical Center	1
Stereotactic calibration phantom, levelling plate and software. Allows direct calibration of AlignRT to MV iso-centre.	Novant Health Presbyterian Medical Center	1
3D Photo: Monochrome texture mapping to overlay photo-realistic texture-map of patient on 3D surface.	Novant Health Presbyterian Medical Center	1
The AlignRT Real Time Coach is a visual coaching tool to indicate to a patient when their vertical breathing motion and postural alignment are within the user-defined position for delivery of treatment.	Novant Health Presbyterian Medical Center	1
AlignRT Offline workstation and software for remote planning and data preparation	Novant Health Presbyterian Medical Center	1
GateCT tracking solution for facilitating 4D CT reconstruction (Toshiba).	Novant Health Presbyterian Medical Center	1
A range of materials for download and use in marketing the clinic's use of AlignRT to patients and referrers.	Novant Health Presbyterian Medical Center	1

Code #	Description	Qty	Price
ALRT-PS-STD	AlignRT: Real Time Patient Positioning, Tracking and Surveillance	1	Included

	<i>Including</i>		
	AlignRT camera unit	2	Included
	AlignRT workstation; Remote console in control room	1	Included
	AlignRT v.5.x Patient Tracking Software	1	Included
	DICOM RT Import Module	1	Included
	AlignRT calibration plate	1	Included
	PSU for AlignRT HD Camera	1	Included
	Portable device to allow the remote control of key functions of AlignRT software	3	Included
ALRT-4DC-VAR	Interface to Varian 4D Integrated Treatment Console	1	Included
	<i>Including</i>		
	Interface to Varian 4D ITC (see note 2)	1	Included
ALRT-AS-VAR	Advanced Surveillance - including interface to MMI	1	Included
	<i>Including</i>		
	AlignRT camera unit	1	Included
	AlignRT software upgrade: 3 camera support	1	Included
	Vision RT's Gating (Beam Hold) Interface to the Varian Clinac Linac.	1	Included
	Customer must purchase the MMI interface from Varian. See note below. (see note 3)		
		1	Included
GRT-STD	GateRT® Software (only)	1	Included
	<i>Including</i>		
	GateRT software	1	Included
SRS-CALIB-STD	Stereotactic calibration phantom, levelling plate and software	1	Included
	<i>Including</i>		
	Stereotactic calibration module: includes analysis software	1	Included
	Stereotactic calibration phantom and levelling plate (see note 4)	1	Included
ALRT-3DP	3D Photo	1	Included
	<i>Including</i>		
	3D Photo: Monochrome texture mapping to overlay photo-realistic texture-map of patient on 3D surface	1	Included
ALRT-RTC	Real Time Coach	1	Included
	<i>Including</i>		
	Real Time Coach: Wireless couch mounted patient feedback unit.	1	Included
ALRT-RPW	Workstation hardware for Offline Workstation	1	Included
	<i>Including</i>		
	Workstation hardware for Offline Workstation	1	Included
	AlignRT v.5x software for Offline Workstation	1	Included
GCT-TOSH	GateCT®: Real time tracking for 4D CT reconstruction	1	Included
	<i>Including</i>		
	GateCT Workstation (remote)	1	Included
	Gating interface to Toshiba CT scanner	1	Included
	Calibration plate	1	Included
	PSU for AlignRT HD Camera	1	Included
	AlignRT camera unit	1	Included
DM-ALRT-MKT	AlignRT Marketing Pack	1	Included
	<i>Including</i>		
	Online access to digital media pack.	1	Included
	Installation and training for all items quoted (see note 1)		

*** The above price excludes shipping costs, import duties and any applicable sales taxes.**

Notes:

- 1 Standard or Vision RT modified Product mounting brackets are provided by Vision RT as part of the normal installation of the Product. Any additional mounting or fixing mechanism or construction cost required to use the Product in treatment room(s) shall be the responsibility of the customer
- 2 There are certain Varian system pre-requisites for the 4DITC to operate correctly with AlignRT. In order to establish these requirements and any related pricing, please consult your local Varian sales representative.
- 3 This requires the installation of Varian's Motion Management Interface (MMI), which needs to be purchased directly from Varian. There are certain Varian system pre-requisites for this interface to operate correctly. In order to establish these requirements and any related pricing, please consult your local Varian sales representative.
- 4 The Stereotactic module may only be used on AlignRT systems that utilise the HD camera platform.

This Quotation is subject to Vision RT's standard terms and conditions of sale (the "Terms and Conditions") as attached. Defined Terms in this Quotation shall have the same meaning as given to them in the Terms and Conditions.

Warranty period is 12 months as per the attached Terms and Conditions of Sale.

Full product support during the Warranty Period and during any subsequent service plan will only be available if the customer provides internet access to Vision RT to allow Axeda support.

CONDITIONS OF PAYMENT

The terms of payment are as follows:

- 30% due within 14 days of order confirmation**
- 60% due within 30 days of shipment**
- 10% due within 30 days of completion certificate**

**ATTACHMENT B –
Project Capital Cost Form**

PROPOSED CAPITAL COSTS

10/25/2017

Project Name: **PMC Radiation Oncology (Project 17-4542)**

Proponent: **Novant Health Presbyterian Medical Center**

A. Site Costs

(1)	Full purchase price of land	\$	_____	-
	Acres _____ Price per Acre	\$	_____	-
(2)	Closing Costs	\$	_____	-
(3)	Site Inspection and Survey	\$	_____	-
(4)	Legal fees and subsoil investigation	\$	_____	-
(5)	Site Preparation Costs (Specify)			
	Soil Borings	\$	_____	-
	Clearing Earthwork	\$	_____	-
	Fine Grade For Slab	\$	_____	-
	Roads Paving	\$	_____	-
	Concrete Sidewalks	\$	_____	-
	Water and Sewer	\$	_____	-
	Footing Excavation	\$	_____	-
	Footing Backfill	\$	_____	-
	Termite Treatment	\$	_____	-
	Sub-Total Site Preparation Costs	\$	_____	-
(6)	Other (specify)	\$	_____	-
	Sub-Total Other	\$	_____	-
(7)	Sub-Total Site Costs	\$	_____	-

B. Construction Contract

(8)	Cost of Materials (Specify)			
	General Requirements	\$	28,295	
	Concrete/Masonry	\$	3,705	
	Woods/Doors & Windows/Finishes	\$	19,733	
	Thermal & Moisture Protection	\$	7,001	
	Spequipment/Specialty Items	\$	8,191	
	Mechanical/Electrical/Plumbing	\$	69,471	
	Miscellaneous Metals	\$	35,966	
	Sub-Total Cost of Materials	\$	_____	172,361
(9)	Cost of Labor GC Labor	\$	_____	92,810
(10)	Other (Specify)			
	Other Construction Contingency (GC)	\$	22,066	
	Other Demo & Final Clean	\$	7,467	
	Other General Liability	\$	3,203	
	Other Subcontractor Bonds	\$	3,437	
	Other Builders Risk	\$	801	
	Other Misc. Applied Costs (IT, Office, etc.)	\$	1,281	
	Other Allowance Permit	\$	801	
	Other Fee	\$	16,013	
	Sub-Total Other	\$	_____	55,089
(11)	Sub-Total Construction Contract	\$	_____	320,260

C. Miscellaneous Project Costs

(12)	Building Purchase	\$	_____	-
(13)	Fixed Equipment Purchase/Lease (+ \$1 Sale of Existing Equipment)	\$	754,014	
(13)	Fixed Equipment Purchase/Lease	\$	463,900	
(14)	Movable Equipment Purchase/Lease	\$	_____	-
(15)	Furniture	\$	_____	-
(16)	Landscaping	\$	_____	-
(17)	Consulting Fees			
	Architect and Engineering Fees	\$	34,000	
	Market Analysis	\$	_____	-
	Sub-Total Consulting Fees	\$	_____	34,000
(18)	Financing Costs (e.g. Bond Loan, etc)	\$	_____	-
(19)	Interest During Construction	\$	_____	-
(20)	Other (Specify)			
	Other Nurse Call	\$	1,500	
	Other A&E Reimbursable expenses	\$	1,500	
	Other DHSR review fee	\$	2,500	
	Other Permitting Special Inspections	\$	5,000	
	Other Pre/Post Construction TAB	\$	2,500	
	Other Construction Contingency	\$	32,026	
	Other FF&E Contingency	\$	_____	-
	Other Signage	\$	500	
	Other Telecom	\$	350	
	Other Voice / Data / CATV Cabling	\$	1,500	
	Other IT Contingency	\$	185	
	Other Capitalized Labor	\$	32,431	
	Sub-Total Other	\$	_____	79,992
(21)	Sub-Total Miscellaneous	\$	_____	1,331,906
(22)	Total Capital Cost of Project (Sum A-C above)	\$	_____	1,652,166

**ATTACHMENT C –
NC Equipment Comparison Form**

**Equipment Comparison Form
Novant Health Presbyterian Medical Center – CT Scanner
Replacement**

	Existing Equipment	Replacement Equipment
Type of Equipment (List Each Component)	CT Scanner/Simulator	CT Scanner/Simulator
Manufacturer of Equipment	GE	Toshiba
Tesla Rating for MRIs	N/A	N/A
Model Number	HiSpeed	Acquillon
Serial Number	2247001	TBD
Provider's Method of Identifying Equipment	Internal Asset Numbering System	Internal Asset Numbering System
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	2000	2017
Does Provider Hold Title to Equipment or Have a Capital Lease?	Own	Own
Specify if Equipment Was/Is New or Used When Acquired	New	New
Total Capital Cost of Project	\$800,000 (Estimated)	\$1,652,166
Total Cost of Equipment	\$490,318	\$1,217,914
Fair Market Value of Equipment	\$1	\$790,000
Net Purchase Price of Equipment	\$1	\$790,000
Locations Where Operated	NHPMC Rad Onc Dept.	NHPMC Rad Onc Dept.
Number of Days in Use/To be Used in NC per Year	365	365
Percent of Change in Patient Charges by Procedure	N/A	No increase
Percent of Change in Per Procedure Operating Expenses by Procedure	N/A	No increase
Type of Procedures Currently Performed on Existing Equipment	CT Scans/Treatment Planning	N/A
Type of Procedures New Equipment is Capable of Performing	N/A	CT Scans/Treatment Planning