

North Carolina Department of Health and Human Services Division of Health Service Regulation

Pat McCrory Governor Aldona Z. Wos, M.D. Ambassador (Ret.) Secretary DHHS

> Drexdal Pratt Division Director

July 17, 2015

Lisa Griffin Novant Health 2085 Frontis Plaza Drive Winston-Salem, NC 27103

Exempt from Review - Replacement Equipment

Record #:

1625

Facility Name:

Novant Health Presbyterian Medical Center (NHPMC)

FID #:

943501

Business Name:

Novant Health, Inc.

Business #:

1341

Project Description:

Replace CT scanner located in NHPMC's Radiology Department

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 June 19, 2015, the above referenced proposal is exempt from certificate of need review in accordance with G.S 131E-184(f). Therefore, you may proceed to replace the existing GE Lightspeed Pro 16-slice CT scanner, serial number 357459CN7, model number 2180689, located in the Radiology Department of NHPMC's main campus with a comparable CT scanner. This determination is based on your representations that the 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.



7.

Ms. Lisa Griffin July 17, 2015 Page 2

Sincerely,

Gloria C. Hale Project Analyst Martha J. Frisone,

Assistant Chief, Certificate of Need

cc:

Construction Section, DHSR

Acute and Home Care Licensure and Certification Section, DHSR

Radiation Protection Section, DHSR



Novant Health

2085 Frontis Plaza Drive Winston-Salem, NC 27103

July 15, 2015

Ms. Gloria Hale, Project Analyst
Healthcare Planning & Certificate of Need Section
North Carolina Department of Health & Human Services
809 Ruggles Drive
Raleigh, North Carolina 27603

Re: Response to Request for Additional Information re: Replacement Equipment Exemption Request for a CT Scanner at Novant Health Presbyterian Medical Center (NHPMC); Mecklenburg County

Dear Ms. Hale:

This letter is in response to our phone conversation on July 7, 2015 concerning the above referenced project. Per your request to provide documentation of the location of the CT Scanner #1 on the Main Campus of NHPMC, we have enclosed a line drawing of the First Floor of the hospital. In addition, a detail of CT Scanner Room #1's location within the Radiology Department is included. As indicated in the original replacement equipment exemption request, this project will replace the existing CT Scanner in the Radiology Department at NHPMC with a new CT Scanner in the Radiology Department at NHPMC.

Secondly, the original replacement equipment exemption request referenced N.C.G.S. 131E-184(f)(2) which states that the replacement equipment project may exceed two million dollars if "the Department has previously issued a certificate of need for the equipment being replaced. This subdivision does not apply if a certificate of need was not required at the time the equipment was initially purchased by the licensed healthcare facility." In this case, a Certificate of Need was not required for the CT Scanner purchased in 2004. Therefore, it meets this requirement and the total project costs are less than two million dollars.

Please let us know as soon as possible if you need additional information to assist in your consideration of this request. Thank you for your prompt consideration of this request.

Sincerely,

Lisa Griffin

Manager, Certificate of Need Financial Planning and Analysis

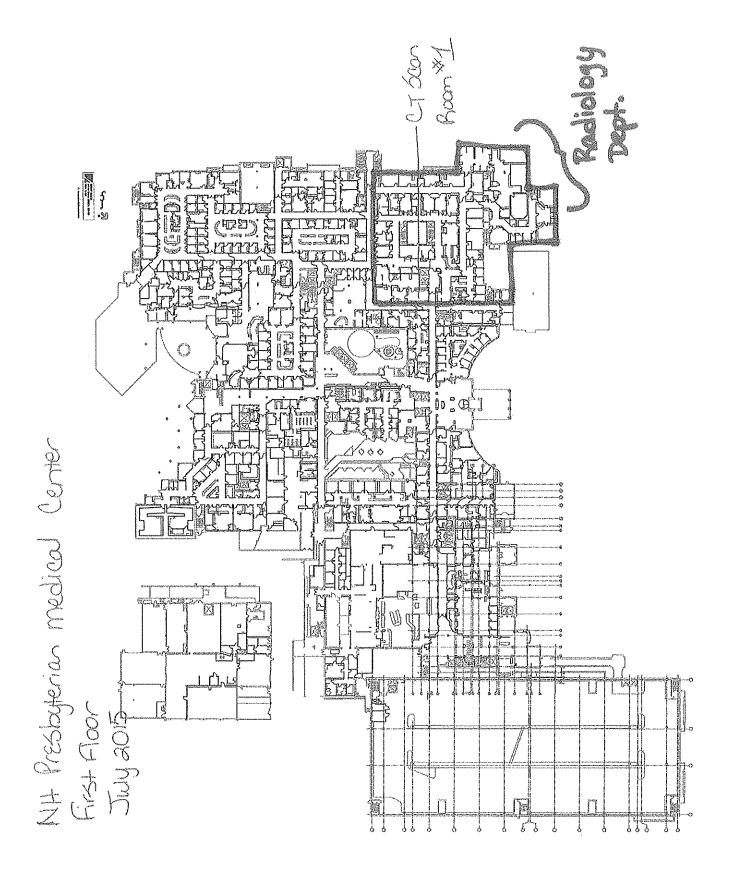
Novant Health, Inc.

Enclosures

cc: Barbara Freedy, Director, CON, Novant Health

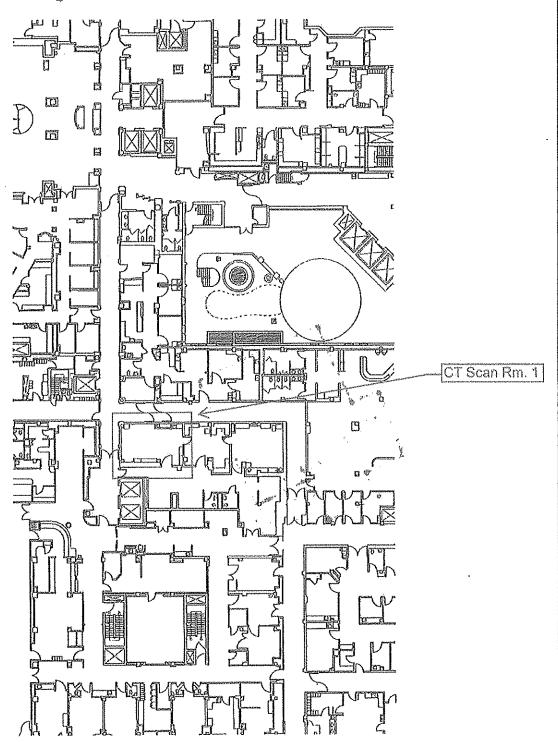
File: PMC CT REER RegForInfoResponse 07 15 15.doc

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NH Presbyterian medical Center Detail of CTSCANNER *1 Room July 2015





Novant Health

2085 Frontis Plaza Drive Winston-Salem, NC 27103

June 19, 2015

Ms. Martha Frisone, Assistant Chief
Healthcare Planning & Certificate of Need Section
North Carolina Department of Health & Human Services
809 Ruggles Drive
Raleigh, North Carolina 27603

Re: Replacement Equipment Exemption Request – CT Scanner at Novant Health Presbyterian Medical Center (NHPMC); Mecklenburg County

Dear Ms. Frisone:

This letter outlines Novant Health Presbyterian Medical Center's (NHPMC's) project to replace an existing 16-slice CT scanner located the hospital Radiology Department with a new GE Revolution (256-slice) CT Scanner. See Attachment A for the vendor quote from GE Healthcare. The costs related to the replacement of the CT Scanner are \$2,145,482 (including the new equipment cost of \$1,854,950). Also, included as Movable Equipment related to the purchase of the new CT is an injector. The quotes for this item is included in Attachment A). The project cost does not include: sales, property or excise taxes since NHPMC is a non-profit, tax-exempt organization and is not subject to these taxes. In addition, the expense for on-site training on the new unit for the radiology staff is covered by the vendor quote on Page 13. The existing equipment is to be removed from the Radiology Department by GE as part of the trade-in allowance (see Page 16) and will then be removed from the state by the vendor and not returned to North Carolina without appropriate certificate of need approval. Both the existing equipment and the replacement equipment are comparable medical equipment as explained on the following page. This project should be approved by the Agency as exempt pursuant to N.C.G.S. Section 131E-184(f) which states that a project is exempt from Certificate of Need review if it is more than \$2 million and meets the following requirements:

- The equipment is located on the main campus of the licensure acute care hospital, NHPMC;
- 2. The CON Department has previously issued a certificate of need for the equipment being replaced;
- 3. The facility proposing to acquire the replacement equipment shall provide prior written notice to the Department, along with supporting documentation to demonstrate that it meets the exemption criteria.

This exempt project will replace a functionally similar operational equipment item on the main campus of NHPMC in the Radiology Department and will not increase the inventory of CT scanners in Mecklenburg County. The proposed new CT scanner is consistent with the replacement equipment definition at N.C.G.S. Section 131E-

Ms. Martha Frisone
June 19, 2015
Replacement Equipment Request – NHPMC CT Scanner
Page 2

176(22a) which states that the replacement equipment is comparable to the equipment being replaced if it has the same technology as the equipment currently in use, although it may possess expanded capabilities due to technological improvements. The existing CT scanner is used for diagnostic CT imaging in the hospital Radiology Department and the replacement CT scanner will be used for diagnostic CT imaging in the hospital Radiology Department.

Pursuant to 10A NCAC 14C.0303 the proposed CT scanner constitutes replacement equipment because:

- 1. It is comparable to the equipment currently in use. It has the same technology as the equipment currently in use, although it does possess expanded capabilities due to the technological improvements.
- 2. It is functionally similar and is used for the same diagnostic or treatment purposes as the equipment currently in use and is not used to provide a new health service.
- 3. The acquisition of the new equipment 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. The existing equipment was not purchased second-hand nor was the existing equipment leased.
- 5. The replacement equipment is not capable of performing procedures that will result in the provision of a new health service or type of procedure that has not been provided with the existing equipment.

Attached for your convenience please find:

- 1) a vendor equipment price quote including moveable equipment items (Attachment A);
- project/capital cost schedule which identifies the components of the total project costs (Attachment B);
- 3) a certified estimate of related construction costs from an independent licensed North Carolina architect (Attachment C); and,
- 4) the NC CON equipment comparison form summarizing essential information about the proposed equipment purchase (Attachment D).

NHPMC's acquisition of the replacement CT scanner does not require a certificate of need because none of the definitions of "new institutional health service" set forth in N.C.G.S. Section 131E-176(16) is implicated. As discussed above, the total cost for the project is \$2,145,482. This includes the cost of the equipment, as well as studies, surveys, designs, plans, working drawings, specifications, construction installation and other activities essential to making the equipment operational (such as staff training).

In conclusion, based on the information described above, please confirm that NHPMC's replacement equipment request does not constitute a "new institutional health service"

Ms. Martha Frisone
June 19, 2015
Replacement Equipment Request – NHRMC MRI Scanner
Page 3

and does fit within the replacement equipment exemption definition. Therefore, the project is not subject to certificate of need review.

Please let us know as soon as possible if you need additional information to assist in your consideration of this request. Thank you for your prompt consideration of this request.

Sincerely,

Lisa Griffin

Manager, Certificate of Need Financial Planning and Analysis Novant Health, Inc.

Enclosures

cc: Barbara Freedy, Director, CON, Novant Health

Laura MacFadden, Senior Director, Design & Construction, Novant Health

File: PMC CT REER Cover Letter 06 19 15.doc

Attachment A



Date: Quote #: 06-17-2015 PR5-C40067

Version #:

29

Novant Health Presbyterian Hospital

Attn: Shelly Hall

Customer Number:

200 Hawthorne Ln

200 Hawthorne Ln Charlotte

Quotation Expiration Date: 09-14-2015

Charlotte NC 28204-2515

NC 28204-2515

The terms of the Master Purchasing Agreement, Strategic Alliance Agreement or GPO Agreement referenced below as the Governing Agreement shall govern this Quotation. No additional or different terms shall apply unless agreed to in writing by authorized representatives of both parties.

Governing Agreement:

Novation

Terms of Delivery:

FOB Destination

Billing Terms:

80% on Delivery/ 20% on Acceptance or First Patient Use

Payment Terms:

NET 30

Total Quote Net Selling Price:

\$1,799,950.00

| INDICATE FORM OF PAYMENT: | | | |
|---|-----------------------|---|--|
| If "GE HFS Loan" or "GE HFS Lease" is Services (GE HFS) to fund this arrange | | of signature, then you may NOT elect to seek financing with | GE Healthcare Financial |
| Cash/Third Party Loan | | yada yada, kada yaya, kada wa da wa | duser na sembar kandidose e dosdus a chinadori sant kadin menderiri sa menera sembanos senda e embed |
| GE HFS Lease | | | |
| GE HFS Loan | | | |
| Third Party Lease (please identify | y financing company) | | |
| | | | |
| | | nade any handwritten modifications. Manual change d an indication in the form of payment section below) | |
| Each party has caused this agree | ment to be executed b | y its duly authorized representative as of the date set | forth below. |
| CUSTOMER | | GE HEALTHCARE Joel Fleury | 06-17-2015 |
| Authorized Customer Signature | Date | Signature | Date |
| Print Name | Print Title | Zone Modality Leader East NUC | |
| Purchase Order Number (if applica | able) | Email: Joel.Fleury@med.ge.com Mobile: +1 704 408 4181 Fax: 7043212115 | |



06-17-2015 PR5-C40067

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Total Quote Selling Price Trade-In and Other Credits **\$1,854,950.00** \$55,000.00

Total Quote Net Selling Price

\$1,799,950.00

To Accept this Quotation

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

Mobile: +1 704 408 4181 Email: Joel,Fleury@med.ge.com

Fax: 7043212115

Payment Instructions

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

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

To Accept This Quotation

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



06-17-2015

Date: Ouote #: Version #: 06-17-2015 PR5-C40067

NOFIGE:REGARDING-COMPUTED-FOMOGRAPHY-("CT")-PRODUCTS::This notice applies only to the following CE-Healthcare products: CT: Revolution CT and EVO, Optima 680 CT and Optima 520 CT, GE Healthcare has reclassified several advanced software tools and associated documentation to a GE Healthcare Technical Service Technology package that GE Healthcare feels will bring greater value and interest to our customers. GE Healthcare will continue to provide trained Customer employees with access to the GE Healthcare Technical Service Technology package under a separate agreement. GE Healthcare will continue to provide customers and their third party service providers with access to software tools and associated documentation in order to perform basic service on the CT, MR and NM products listed above upon a request for registration for such access. This will allow GE Healthcare to react faster to the future service needs of GE Healthcare customers. If you have any questions, you can contact your sales Service

This product offering is made per the terms and conditions of Novation/GE Healthcare GPO Agreement # XR11013 (CT) and # XR11031 (PET-CT),

For access to the applicable Novation Agreement and Contract Summary, please login to the Novation Marketplace website. If you require assistance or are experiencing issues please contact one of the following for support:

Novation Customer Service (888) 7-NOVATE NOVCustomerService@novationco.com

Web Site Technical Support (800) 327-8116 NovationTechSupport@novationco.com



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Date: Quote #: Version #: 06-17-2015 PR5-C40067

| ltem No. | Qty | Catalog No. | Description |
|---|--|--|---|
| | 1 | | Revolution CT |
| 1 manadamiskapahaniski | 1. | S7919A indiplomentarion transministrativo de provincia en * | GE's Revolution(TM)CT delivers uncompromised image quality & clinical capabilities through the convergence of coverage, spatial resolution and temporal resolution – all in one. Key technology enablers include unique image chain and reconstruction hardware, 80cm bore and Gemstone (TM) scintillator. Together, these enablers overcome the challenges of typical wide detector systems such as cone beam artifacts, HU uniformity, scatter & beam hardening artifacts. The next generation of iterative reconstruction technology, ASiR-V(1), is designed to reduce dose by up to 82%, improve low contrast detectability by up to 135%, reduce image noise by up to 91% and reduce streak artifacts. In addition, the Revolution CT provides the best effective temporal resolution enabled by 0.28s rotation speed combined with intelligent motion correction for excellent cardiac imaging at any heart rate. |
| *************************************** | ortho (west was not as to a local or to l | | (1) 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. |
| | | | Thanks to its innovative design, Revolution CT delivers breakthrough clinical applications for all anatomies: |
| | | | Cardiac |

- 1-Beat High definition, motion free coronary images at any heart rate with intelligent motion correction
- 1-Beat, comprehensive cardiac assessment for every patient at low dose coronaries, rest / stress perfusion & function
- Smart Cardiac acquisition modes that allow for robust cardiac exams for patients with high or irregular heart rates, arrhythmia, atrial fibrillations, PVC's, etc.

Dynamic volume acquisitions

- Whole organ dynamic volume perfusion acquisitions for any organ/tissues with uniform contrast and integrated beam hardening reduction.
- Flexible aperture size and sampling rate, which is particularly beneficial in localizing anatomy of interest.
- 4D imaging to acquire morphology and perfusion information from a single exam.

Neurology

 Neuro perfusion and CTA of the brain in a single exam to enable comprehensive stroke workup, function & anatomical assessment of the brain.



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Item No. Qty Catalog No.

Description

- Dedicated HD cardiovascular and head / neck angio in a single low dose exam for comprehensive stroke workup
- Routine head scans performed in less than a second single rotation with excellent gray white matter and bone/brain interface separation. VHD reconstruction with integrated artifact reduction reduces beam-hardening artifacts in the posterior fossa region.

Body Imaging

 Fast body scans enabled by multi-volume 16cm acquisition with excellent image quality allows for reduced breath hold times and shallow breathing.
 Smart collimation allows the ability to personalize the collimations for each patient between 5cm to 16cm.

Emergency & Trauma

 Split second scanning up to 16cm combined with fast table speed of 300mm/s allows for ultra fast scanning, thus reducing the effect of breathing and other motion during the scan.

TAVI assessment

 Rapid & comprehensive TAVI planning with dedicated protocols allowing ECG gated and non-gated acquisitions in a single exam.

Pediatrics

Split second pediatric acquisitions are enabled by wide 16cm coverage, thus
reducing the need for sedation. 70kV scan
mode allows for minimizing dose to pediatric patients while preserving excellent
contrast to noise ration and image quality.

Musculoskeletal imaging

 Acquire high definition bone images with excellent detail & significantly reduced artifacts from metal objects such as screw and plates. Volume 4D imaging mode can acquire kinetic studies to assess joint articulation up to 16cm coverage.

Technology engineered to wow

Gemstone Clarity Detector

• The Gemstone Clarity Detector is a next generation detector design with groundbreaking technology. It features a unique focally aligned layout of the detector sub-modules and a 3D collimator (post patient) that reduces scatter to primary ratio by more than 50%. Combined together, the Gemstone Clarity detector minimizes scatter artifacts, ensure HU uniformity & reduce beam hardening artifacts associated with wide coverage systems. Combined with the VHD reconstruction technology, the system delivers excellent image quality at



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Item No. Qtu

Catalog No.

Description

full 16cm coverage.

- The Gemstone scintillator enables high definition imaging, setting a new standard in scintillator primary speed, afterglow and performance.
- 98% efficient at 120 kV
- Fastest primary speed in the industry
- 20 times less radiation damage than GOS
- Isotropic ceramic with a cubic structure

Gemstone Clarity data acquisition subsystem The Gemstone Clarity data acquisition subsystem (DAS) features 3 times faster trigger rates capable of supporting features such as high. definition imaging.

- 16cm z-coverage/360 degree rotation
- 512 slices
- 256 detector rows
- Up-to-2,496 views-per-rotation-(at-fastest-rotation-speeds)

Volume High Definition reconstruction (VHD) VHD reconstruction is 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 16cm coverage. It further reduces variation in iodinated contrast HU uniformity across the full 16xm coverage, typically caused due to heel effect.

Artifact Reduction

In conjunction with the 3D collimator, Revolution CT's unique VHD reconstruction
with Multi-Material Artifact Reduction (MMAR) models system physics and
incorporates material characteristics to significantly reduce typical artifacts
such as beam hardening caused due to dense objects such as bone, iodine, and
metal.

Performix(TM)HDw x-ray tube

- Performix HDw 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
 optimizing the focal spot to deliver consistent beam quality across the full 16cm
 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 kV switching.
- Generator maximum peak power: 103kW
- Tube current range: mA 10-740 in 5mA increments



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Item No. Qty

Catalog No.

Description

Tube voltage: kV 70, 80, 100, 120, 140

Whisper drive gantry and contactless slip ring Revolution CT's gantry platform has
been designed from the ground up and tested to support rotation speeds as fast as

0.2s/rotation(2). The whisper drive system reduces audible noise during gantry
rotation at 0.28s by more than 50% compared to a typical belt drive system, thus
improving patient

comfort. The gantry also features a wide 80cm bore diameter to facilitate scanning larger patients and to ensure flexible access and patient positioning in the gantry. In addition, the contactless slip ring transfers power and data to and from the rotating side of the gantry to the stationary side through contactless RF technology at a transfer rate of 40Gbps.

(2)0,2s/rotation is an option that may be available in the future.

Gantry Display and controls

- LCD display-that-shows patient-information and ECG-data. This display-can-alsobe configured to show patient videos.
- Built-in breathing lights and countdown timer
- · Cardiac gating indicator light
- Start scan button with x-ray countdown timer
- Flexible cable management system to help reduce floor clutter. Gantry specifications
- Bore size: 80 cm
- Scan FOV: 50 cm
- Rotation time: VariSpeed technology: 360 degrees in 0.28s to 1s
- · Data chain bandwidth: 40 Gbps

Patient Table

- Foot pedals on both sides of table for fast elevation
- 10 times more stiffness to reduce deflection
- Integrated ECG module, IV pole and tray
- Vertical range: 50cm to 100.1cm (scannable 73.1cm to 100.1cm)
- Horizontal range: 200cm
- Horizontal speed: 300mm/s
- Load capacity: 227kg (500lb) +/- 0.06% positional precision over the entire scannable range

Smart Technologies Better patient care, improved efficiency, expanded applications.

Smart Technologies is a suite of intelligent CT tools designed to help you achieve these



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Item No. Qty

Catalog No.

Description

goals, delivering diagnostic confidence with lower levels of radiation, Smart Dose

ASiR-V: The next generation of iterative reconstruction technology, ASiR-V(3), is designed to reduce dose by up to 82%, improve low contrast detectability by up to 135%, reduce image noise by up to 91% and reduce streak artifacts. In addition, the Revolution CT provides the best effective temporal resolution enabled by 0.28s rotation speed combined with intelligent motion correction for excellent cardiac imaging at any heart rate.

(3) 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.

- 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 the
 enhanced dose reduction while the overall image noise is still maintained.
- KV Assist: Makes it easy to select optimal kV settings for the patient being scanned. Recommends tube voltage and current to achieve the lowest dose while meeting desired image quality.
- 70 kV scanning: 70kV scan mode to enable low dose pediatric and small patient scans.
- ECG automated gating: Prospective ECG dose modulation automatically adjusts
 the mA to minimize the patient's exposure to x-ray reducing dose outside the
 prescribed phase ranges. Up to 3 phase ranges can be selected within a heart
 cycle with different levels of mA.
- SmartTrack: Advanced hardware and software for x-ray beam tracking minimizes
 patient dose.
- SmartBeam: Optimizes x-ray beam filtration independently for body, head, and cardiac applications.
- Dose computation, display, and reporting: CTDIvol, DLP, and dose efficiency
 computation and display during scan prescription provide dose information to
 the operator. Dose reporting saves CTDIvol, DLP, and phantom type in a DICOM
 structured dose report and a secondary screen capture. Series and cumulative
 exam values are saved and can be networked, and archived.
- DoseCheck: Provides the user with tools to help manage CT dose in clinical practice and is based on the standard XR 25-2010 published by The Association (NEMA)



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Item No. Otu

Catalog No.

Description

- CT 4Kids: Dose optimized procedure based protocols for pediatric imaging.
- Color Coding for Kids: Provides pediatric scan protocols based on the Broselow
 Luten(TM) Pediatric System. This color coding system is incorporated into the
 protocol selection on the operator's console and is designed to facilitate
 pediatric emergency care and reduce medical errors.

Smart Flow

- SmartStart(TM): In-room start scan and countdown display.
- AutoScan(TM): Fully automates longitudinal table movement and start of each helical scan.
- Auto SmartPrep: Real-time monitoring of contrast enhancement at a prescribed location and automatically transitions scan when the preset threshold is reached.
- Prospective multiple-thickness reconstruction: In addition to the initial reconstructed slice thickness, the operator has the option to prospectively specify up to 9 additional reconstructions from a single raw data set.
- Queued Reconstruction: Requests will be processed continuously and simultaneously with other processes on the system including scanning.
- Prospective and Retrospective reconstruction: Operator may initiate full reconstructions at any table location in increments of 1/10 the image thickness; image thickness remains constant.
- · Reconstruction speed: Up to 55 frames per second
- Exam Split: Allows multi-anatomical exams to be split in to separate anatomic sections.
- Trauma patient entry: Allows patient scans and image display/analysis without entering patient data before scanning.

Clarity Operator Environment The new Clarity Operator Environment is designed with your everyday needs in mind. The environment allows simultaneous scanning, image reconstruction, display, processing and analysis, as well as networking and archival. 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.
- Seamless multi-tasking through ability to have multiple patient sessions open with one active patient for acquisitions 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



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Item No. Qtu Catalog No. Description technologist intervention. Prospectively prescribe multi planar reconstructions for anatomies such as spine as part of the protocol, thus automating the workflow seamlessly. Manage your patient flow better with the ability to prepare scan prescription for the next patient while the current patient is getting off the table. Quickly select scan protocols through global search, anatomical selection or user specific favorites to the newly designed protocol management system. Facilitates protocol consistency by controlling access to changes and simplifying inputs required. Integration with AW Server allows access to advanced applications on the console. Better dose awareness through clearly visible real time projected dose indicator. Console specifications - Host Computer CPU: Dual Intel Six Core Xeon 2.66GHz 5650 Processors RAM 48GB DDR3-1333MHz ECC DIMM Total system storage: up to 700,000 512 images and with 1 TB for scan data files Additional storage: USB 2.0 Port for external hard disk drive connectivity Peripheral-components-24in 1920x1200 Monitor 104-key USB 2.0 Keyboard quality is important in providing quality 3-Button USB 2.0 Mouse

- 3-Button USB 2.0 Trackball (optional)
- DVD-ROM, DVD-R, DVD-RW, DVD+R, DVD+RW, CD ROM, CD-R, CD-RW, DVD+R DL
- 5.25in media
- 8.5 GB Double Sided DVD Media Capacity
- 16X DVD / 40X CD read speed
- Scan Control Interface

Image networking

- Exam Transfer up to 16 frames per second on dedicated 1 Gbit connection
- Standard auto-configuring Ethernet (UTP connection) 1000/100/10 BaseT
- Direct network connection; multi-suite ethernet card not required for gateway out of suite
- Protocols supported: DICOM network send (one IP address at a time) and receive, pull/query, and storage commitment push

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Item No. Qty

Catalog No.

Description

- Data Export capabilities to convert clinical images into PC-friendly formats like .jpeg, .mpeg, and .avi.
- Exams can be selected and moved between the Revolution CT and any imaging system supporting the DICOM protocol for network send, receive and pull/query.
- Image transfer times using DICOM protocols are > 16fps on a 1000baseT network.

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 without 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-

For US and Canadian Customers, this quotation includes access to the DoseWatch Explore application for a period of time concurrent with the system warranty. 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.

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 29-2013 / MITA Smart Dose Standard.

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

11/17



Date: Quote #: Version #: 06-17-2015 PR5-C40067

| ltem No. | Qty | Catalog No. | Description |
|--|-----|-------------|--|
| | | | Ст. |
| 2 | 1 | B7918EN | Rev CT English kybd |
| 3 | 1 | B7919AE | Standard cable set for Revolution CT system |
| 4 | 1 | 87919AY | REVOLUTION DESK - ADJ |
| 5 | 1 | B7716WR | Xtream Injector Interface kit - Class IV |
| 6 | 1 | E8016DA | The GEHC Revolution CT table slicker is specifically designed to maximize contaminant protection. Manufactured to be used in conjunction with the table restraining belts, this slicker adds versatility to your CT procedures. Latex free, it is strongly suggested that the slicker is cleaned with a water/bleach solutioj prior to every procedure. |
| | | | Features: |
| landoren missississan, | | | Table gray cushion sealed in vinyl slicker Dimension 2403 x 788 |
| • | | | Table extender gray cushion sealed in vinyl slicker Dimension 406 x 788 |
| | | | Cover for catheter bag hanger |
| | | , | Increase system uptime by protecting table from spills and particulate contaminants |
| مو د و مديد در استان | | | Easy to install and comfortable for patients |
| | | | Will not interfere with normal operation of CT table |
| | | • | Clear PVC plastic facilitates faster cleanup of blood and fluids |
| | | | Prevents contaminant build up in hard to clean areas |
| | | | Thermosealed seams and flaps |
| | | | Recommended for trauma centers and sites concerned about exposure to blood and fluid-borne disease |
| 7 | 1 | E8016DC | The GEHC Revolution CT Foot Switch slicker is specifically designed to maximize contaminant protection. Latex free, it is strongly suggested that the slicker is cleaned with a water/bleach solutioj prior to every procedure. |
| 8 | 1 | E4502AE | The 125 Amp CT System Main Disconnect Panel (MDP) serves as the main facility power disconnect source installed ahead of the system PDU. The MDP will disconnect system power on first loss of incoming power, helping to prevent damage to system components. It also includes an automatic restart control circuit which restores power to the CT System PDU after a power outage. |
| | | | Can reduce installation time and cost by eliminating delays in obtaining individually enclosed components and on site assembly (ex: main circuit breaker, feeder overcurrent devices, magnetic contactors and UPS emergency |



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Item No. Qty

Catalog No.

Description

power off are combined into a single panel

- Configuration flexibility can be used as a stand-alone main disconnect or with
 the optional partial system UPS. (On systems where the optional partial system
 UPS is used the main disconnect panel also provides NEC mandated emergency
 power off control to both the PDU and UPS
- Designed and tested for GEHC CT products

SPECIFICATIONS

- Automatic restart incorporates an adjustable time delay to delay main power until the power has stabilized for 5 seconds
- One flush wall mounted remote emergency off pushbutton furnished with each system
- · UL, cUL and CE labeled

1 W0124CT

Revolution CT Customer Excellence Training

The Revolution Experience: Clinical Education Program

22 Days Onsite and 16 Hours of TiP Virtual Assist (TVA)

This training will begin with a Revolution Partnership Meeting, approximately 4-6 weeks prior to the first onsite training week. The purpose of this meeting is to identify the core group of technologists and radiologists who will participate in onsite training, understand the site's level of prior GE experience, discuss key factors necessary to ensure successful training, identify critical needs and clinical areas of focus, and discuss the preferred timeline and content for the first year of onsite training.

Initial training will include 8 days during a 2 week turnover. The Clinical Applications Specialist will work with staff to introduce them to the Revolution Clarity user interface, review the system components and how they impact clinical scanning, discuss the Revolution protocols and begin patient scanning. Protocol and image quality review will be completed with the radiologists.

The timing and content of the follow up visits will be customized to the clinical priorities of the site. Follow up visits will include advanced features and imaging for specific clinical applications such as cardiac and perfusion. Results of technologists assessments at the end of each of the initial training sessions will also be used as a guide for the content and focus of the follow up training. TiP Virtual Assist training will also be used to provide access to GE Clinical Applications Specialists who can answer questions as well as perform virtual troubleshooting, remote observation, image quality checks and to provide additional training.

This training program must be scheduled and completed within 12 months after the



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Item No. Qty Catalog No. Description

date of product delivery. Onsite training and TVA are delivered Monday through Friday between 8AM and 5PM.

10 B78921RB CardiQ Xpress Reveal is an integrated post processing image analysis software for Cardiovascular CT on GE's Advantage Workstation.

The optional CardiQ Xpress Reveal software can be used to effectively display,

The optional CardiQ Xpress Reveal software can be used to effectively display, reformat and analyze 2D, 3D, and GSI CT images for qualitative or quantitative assessment of the anatomy of the heart and coronary artery vessels from single or multiple cardiac phase image data sets. When used with CardiQ Function, CardiQ Xpress Reveal can also provide functional assessment including relative perfusion information.

CardIQ Xpress Reveal can be launched directly or from within Volume Viewer applications using axial, helical or GSI CT images; including images created using the SnapShot Freeze intelligent motion correction option. It provides the user with both single and multiple cardiac phase analysis protocols for single energy and spectral energy CT images.

The software includes a variety of different 2D, 3D or reformatted protocols including: display of the coronary vessel tree, angiographic view, 2D and 3D rendering of single or multiple coronary artery vessels or grafts, automatic reformation of cross sectional cardiac images into planes along short or long axis of the heart, one-touch cath views for 3D or reformatted images, 3D angiographic view phase registration, color mapped plaque density measurements, IVUS-like views, 3D ejection fraction, 4D aortic and Mitral valve views, relative perfusion, transparency views and beating heart images from single or multiple cardiac phase image data sets.

Clinical applications include: imaging of cardiac morphology, coronary artery imaging and assessment of relative perfusion, assessment of plaque, bypass graft patency, post intervention follow-up and functional assessment.

CardIQ Xpress Reveal combines simplified user workflow with SnapShot Freeze intelligent motion correction imaging.

- Pre-processing the images & models including SnapShot Freeze exams, for faster review
- Loading images into the auto launch area area for real-time review of multiple exams
- · Easy switching from one protocol to the other without exiting the application
- · Single click one-touch cath views
- · Batch movie output within cardiac reformat
- · User defined layouts within vessel analysis for simplified viewing and filming

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06-17-2015 PR5-C40067

29

Item No. Qtu

Catalog No.

Description

Multi-phase load to single phase review

The CardIQ Xpress reveal option allows the user to:

- Rendering and display of 2D/3D coronary vascular tree images with automatic vessel tracking & labeling with single click of a protocol. Images can be reviewed in axial, reformat, curved, oblique MPVR, and cross section views
- Measurements of coronary arteries including stenosis and stenosis length, and densitu
- PlaqID to color code non-calcified and calcified plaque with volume measurements.
- 2D reformat review with predefined views to review all coronary vessels.
- Color enhanced relative perfusion defect pattern recognition for detection of ischemic heart disease with 4 color patterns
- Automatically render data for streamlined reading to include: 3D rendered heart,
 angiographic view, tree VR, and ejection fraction.
- Reformat standard axial CT images of single or multiple cardiac phases automatically into short, long and two chamber long axis of the heart for easy review
- Perform functional evaluation of the heart and cine capabilities for multiphase
 beating-heart-images with one easy-click
- Extraction of the left ventricle and automated ejection fraction and volume measurements
- 4D aortic valve and mitral valve views with one touch
- Ability to select different protocols without exiting the application
- · Pre-defined VR IVUS-like views for virtually determining plaque compositions
- One touch angiographic view protocol display coronary vessel tree and myocardium with automatic removal of heart chambers for cath comparative
- Heart transparency model allowing for full visualization of coronaries in relations to the heart chambers with the ability to fade out the chambers of the heart
- Oblique reformat views in the standard cath angles for easy analysis of the coronary vessels
- Load multi-phase images, review the data and decide which phase or phases will be reviewed for further processing by dropping the non-essential phases
- Phase registration ability to register images from different cardiac phases into a unique data set. The data set can then be saved as a 3D object and/or used for further analysis



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Item No. Qty

Catalog No.

Description

For Revolution CT customers who have SSF in 18 CardIQ Xpress Reveal 2.0 and CardIQ Xpress Process. This catalog provides the required upgrade for CardIQ Xpress Process, enabling it to work with Revolution CT datasets note its mandatory that the AW or AWS have a minimum of 24GB or RAM for Revolution CT datasets to correctly process with SSF.

System requirements:

- AW Workstation with VolumeShare6 on HP 8400 or later with a minimum of 16GB RAM or a HP Z800 with 24GB of RAM
- · Auto Launch and Preprocessing Option
- 2 monitor configuration
- Color Landscape monitor

Quote Summary:

Trade in of LSPro 16

Total Quote Net Selling Price

(\$55,000,00) \$1,799,950.00

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

① \$1,799,950 + \$55,000 Net Trade Ix

= 1,854,950

Bayer HealthCare



_Currency: USD_____

Quotation

Quote To: PRESBYTERIAN:HOSPITAL dba Novant Health Presby Med Ctr 200 Hawthorne Ln **CHARLOTTE NC 28204-2515** USA

Bayer HealthCare LLC

Quotation number: 0020015138 Customer number: 0003424904 Date: 04/14/2015

Page:

04/14/2015 to Valid from: 09/15/2015

We deliver according to the following terms and conditions:

30 d. w/o discount of inv. net Terms of payment:

Terms of delivery: Carriage paidFOB DESTINATION

| Item | Part No Qty | | |
|---|--------------------------------------|-----------|-----------|
| 1 | 81058881 | | |
| • | SCT 322 1PCE | • | |
| | SYSTEM, DUAL, STELLANT WITH CWKS/OCS | 3 | |
| 2 | 60339129 | | |
| | 1PCE | | |
| | SW APP, P3T ABDOMEN, 1.X | | |
| 3 | 59943360 | | |
| | INS SCT CS 1PCE | | |
| | INSTALLATION - STELLANT WITH OCS | | |
| | | | |
| *************************************** | | Sub Total | 31,150.00 |

Total 31,150.00

If pricing and terms of this order 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.

Attachment B

PROPOSED CAPITAL COSTS

Project Name:

CT-1 and Control Renovation

June 19, 2015

Proponent:

Novant Health Presbyterian Hospital

| A. | Site C | Costs | | | |
|------------------------------------|-------------------------------|--|--|---|--|
| | (1) | Full purchase price of land | | \$ - | |
| | | Acres Price per Acre | | \$ - | |
| rana et essa d'assance, se reliana | (2) | Closing Costs | A Committee of the Comm | \$ | Kalinalis konsenius kurish mash usa kurish kanna di kuri |
| raig comea glassocopungeas | (3) | Closing Costs Site Inspection and Survey | anotespaninoas per montal su canapas en conscien | \$ - | A Satana tanàna dia kaominina mpikambana mpikambana mpikambana mpikambana mpikambana mpikambana mpikambana mpi |
| | (4) | Legal fees and subsoil investigation | | \$ - | |
| | (5) | Site Preparation Costs \$ | i | | |
| | | Soil Borings \$ | | | |
| | | Clearing Earthwork \$ | | | |
| | | Fine Grade For Slab \$ | | | |
| | | Roads Paving \$ | | • | |
| | | Concrete Sidewalks \$ | <u>,, ,, ,, ,, ,, ,, ,, ,, ,, ,, ,, ,, ,, </u> | | |
| | | Water and Sewer \$ | + - | | |
| | | Footing Excavation \$ | | | |
| | | Footing Backfill \$ | | | |
| | | Termite Treatment \$ | 44 | | |
| | | Sub-Total Site Preparation Costs | | \$ | |
| | (6) | Other (specify) | | \$ | |
| | (7) | Sub-Total Site Costs | | \$ | |
| B. | Cons | truction Contract | | | |
| | (8) | Cost of Materials | | | |
| | | General Requirements \$ | 24,766.00 | | |
| | · embouchersum/enermyerenembe | Concrete/Masonry \$ | 5,507.00 | فرسيون ليفقن والرضوطة والأوقاء والموافقة الماسيسة المواة والمسامسوي الموطان بيهران فللمست | |
| | | Woods/Doors & Windows/Finishes \$ | 68,625.00 | | |
| | | Thermal & Moisture Protection \$ | 913.00 | | |
| | | Equipment/Specialty Items \$ | 10,654.00 | | |
| | | Mechanical/Electrical \$ | 34,693.00 | | |
| | | Other \$ | 1,029.00 | | |
| | | Sub-Total Cost of Materials | | \$ 146,187.00 | • |
| | (9) | Cost of Labor GC Labor | | \$ 17,856.00 | • |
| | (10) | Other - (Specify) | | \$ | • |
| | (11) | Sub-Total Construction Contract | | \$ 164,043.00 | • |
| C. | Misce | ellaneous Project Costs | | | |
| | (12) | Building Purchase | | \$ - | |
| | (13) | Fixed Equipment Purchase/Lease | | \$ 1,854,950.00 | • |
| | ` ' | Other (contingency) | | \$ - | • |
| | (14) | Movable Equipment Purchase (Injector) | | \$ 31,150.00 | • |
| | (15) | Furniture | | \$ - | • |
| | (16) | Landscaping | | \$ - | • |
| | (17) | Consult Fees | | | • |
| | , , | Architect and Engineering Fees \$ | 15,339.00 | | |
| | | Market Analysis \$ | * | , | |
| | | Other - Structural Allowance \$ | 80,000.00 | | |
| | | Sub-Total Consultant Fees | | \$ 95,339.00 | |
| | (18) | Financing Costs (e.g. Bond Loan, etc) | | \$ - | |
| | | Interest During Construction | | \$ - | |
| | (19) | intercet baring concuration | | | |
| | (19) (20) | Other (SPECIFY) | | \$ - | |
| | | | | \$ - | • |
| | | Other (SPECIFY) | | Married Communication (1971) | • |

Attachment C



June 18, 2015

Ms. Martha Frisone, Assitant Chief Certificate of Need Section Division of Health Service Regulation 809 Ruggies Drive Raleigh, NC 27603

Re: Presbyterian Hospital Main, CT-l and Control Renovation

Dear Ms. Frisone:

Ec,a Architecture has reviewed the proposal submitted by Revels Contracting Services, Inc. for the remedial construction of a 746 square foot MR suite in the existing Presbyterian Hospital building in Charlotte, North Carolina.

It is our opinion, that the scope of the work is adequate to complete the project as discussed and outlined by this proposal. Furthermore, the construction estimate of \$164,043 (plus a structural allowance of \$80,000) is reasonable, for the proposed scope of work for the project, when compared to other similar projects in North Carolina. The construction is estimated at \$164,043 and \$15,339 for A&E drawings for a total cost of \$179,382.00 + \$80,000.00 allowance for structural

If you should have any avertions regarding this project, please do not hesitate to contact me. Thank you.

Sincerely,

Eric Cebula,

Ec,a Architecture, PC

Eric J. Cebula, AIA PO Box 30183 Charlotte, NC 28230 704.849.6748 (tel) 800.652.0689 (fax) 704.906.6752 (cell) eca-cebula@carolina.rr.com

Attachment D

| Replacement of CT Scanner at Novant Health Presbyterian Medical Center | EQUIPMENT | REPLACEMENT EQUIPMENT |
|---|--|--|
| Type of Equipment (List Each Component) | Lightspeed Pro 16 slice CT | Revolution CT |
| Manufacturer of Equipment | GE C | GE |
| Tesla Rating for MRIs | n/a | n/a |
| Model Number | 2180689 | n/a |
| Serial Number | 357459CN7 | Cat. # S7919A |
| Provider's Method of Identifying Equipment | Internal Asset Number | Internal Asset Number |
| 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 | 11/29/2004 | TBD |
| Does Provider Hold Title to Equipment of Have a Capital Lease? | Holds Title | Will Hold Title |
| Specify if Equipment Was/Is New or Used When Acquired | New | New |
| Total Capital Cost of Project (Including Construction, etc.) < Use Attached Form> | \$1,175,675 | \$2,145,482 |
| Total Cost of Equipment | \$1,023,04 | \$1,854,950 |
| Fair Market Value of Equipment | \$55,00 | \$1,854,950 |
| Net Purchase Price of Equipment | n/a | \$1,799,950 |
| Locations Where Operated | PMC Radiology Dept. | PMC Radiology Dept. |
| Number Days In Use/To be Used in N.C. Per Year | 365 | 365 |
| Percent of Change in Patient Charges (by Procedure) | None | None |
| Percent of Change in Per Procedure Operating Expenses (by Procedure) | None | Моде |
| Type of Procedures Currently Performed on Existing Equipment | CT Scans | P. 100 P. |
| Type of Procedures New Equipment is Capable of Performing | reserve Assessed | CT Scans |
| | 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1 | |

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|---|---|--|---|--|
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