



DEPARTMENT OF HEALTH AND HUMAN SERVICES  
DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER  
GOVERNOR

MANDY COHEN, MD, MPH  
SECRETARY

MARK PAYNE  
DIRECTOR

March 14, 2017

Robert Leandro  
301 Fayetteville Street, Suite 1400  
Raleigh, NC 27601

**No Review**

**Record #:** 2160  
**Facility Name:** Swain Community Hospital  
**FID #:** 923480  
**Project Description:** Replace existing CT scanner  
**County:** Swain

Dear Mr. Leandro:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your letter of February 7, 2017 and email on March 9, 2017 regarding the above referenced proposal. Based on the CON law **in effect on the date of this response to your request**, the proposal described in your correspondence is not governed by, and therefore, does not currently require a certificate of need. However, please note that if the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective.

However, you need to contact the Agency's Acute and Home Care Licensure and Certification Section to determine if they have any requirements for development of the proposed project.

It should be noted that this determination is binding only for the facts represented in your correspondence. Consequently, if changes are made in the project or in the facts provided in your correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by this office. Changes in a project include, but are not limited to: (1) increases in the capital cost; (2) acquisition of medical equipment not included in the original cost estimate; (3) modifications in the design of the project; (4) change in location; and (5) any increase in the number of square feet to be constructed.

**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

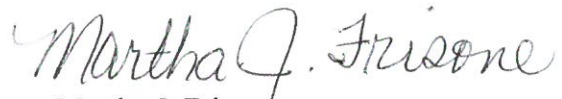


Please contact this office if you have any questions. Also, in all future correspondence you should reference the Facility ID # (FID) if the facility is licensed.

Sincerely,



Julie Halatek  
Project Analyst



Martha J. Frisone  
Assistant Chief, Certificate of Need

cc: Construction Section, DHSR  
Acute and Home Care Licensure and Certification Section, DHSR  
Paige Bennett, Assistant Chief, Healthcare Planning, DHSR

## Halatek, Julie F

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**From:** Halatek, Julie F  
**Sent:** Friday, March 10, 2017 7:59 AM  
**To:** 'Leandro, Robert A.'  
**Subject:** RE: Request for exemption from review - CT scanner - Swain Community Hospital

Thanks! I'll review and let you know if I have any questions.

**Julie Halatek, Esq.**

Project Analyst, Certificate of Need  
Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section  
North Carolina Department of Health and Human Services

919 855 3873 office  
[Julie.Halatek@dhhs.nc.gov](mailto:Julie.Halatek@dhhs.nc.gov)

809 Ruggles Drive  
2704 Mail Service Center  
Raleigh, NC 27699-2704

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**From:** Leandro, Robert A. [<mailto:robbleandro@parkerpoe.com>]  
**Sent:** Thursday, March 09, 2017 6:24 PM  
**To:** Halatek, Julie F <[julie.halatek@dhhs.nc.gov](mailto:julie.halatek@dhhs.nc.gov)>  
**Subject:** RE: Request for exemption from review - CT scanner - Swain Community Hospital

Julie,

Please find attached the information you requested. This includes our version of the chart you pointed to me online and the manufacture's quote. Let me know if you need anything else.

Robb

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**Robert Leandro**

Partner

Visit our healthcare blog:  
[healthlaw.parkerpoe.com](http://healthlaw.parkerpoe.com)



PNC Plaza | 301 Fayetteville Street | Suite 1400 | Raleigh, NC 27601  
Office: 919.835.4636 | Fax: 919.834.4564 | [vcard](#) | [map](#)

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**From:** Halatek, Julie F [<mailto:julie.halatek@dhhs.nc.gov>]  
**Sent:** Wednesday, February 08, 2017 3:59 PM  
**To:** Leandro, Robert A.  
**Subject:** RE: Request for exemption from review - CT scanner - Swain Community Hospital

It would be helpful if I actually included the link I said I was going to. Sorry about that!

<https://www2.ncdhhs.gov/dhsr/coneed/reviews/index.html>

**Julie Halatek, Esq.**

Project Analyst, Certificate of Need  
Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section  
North Carolina Department of Health and Human Services

919 855 3873 office  
[Julie.Halatek@dhhs.nc.gov](mailto:Julie.Halatek@dhhs.nc.gov)

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Raleigh, NC 27699-2704

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**From:** Leandro, Robert A. [<mailto:robbleandro@parkerpoe.com>]  
**Sent:** Wednesday, February 08, 2017 3:57 PM  
**To:** Halatek, Julie F <[julie.halatek@dhhs.nc.gov](mailto:julie.halatek@dhhs.nc.gov)>  
**Subject:** RE: Request for exemption from review - CT scanner - Swain Community Hospital

Julie,

I think I know what you need but can you direct me to the link you mentioned with examples? I can't seem to locate it.

---

**Robert Leandro**

Partner

Visit our healthcare blog:  
[healthlaw.parkerpoe.com](http://healthlaw.parkerpoe.com)



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Office: 919.835.4636 | Fax: 919.834.4564 | [vcard](#) | [map](#)

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**From:** Halatek, Julie F [<mailto:julie.halatek@dhhs.nc.gov>]  
**Sent:** Wednesday, February 08, 2017 3:42 PM  
**To:** Leandro, Robert A.  
**Subject:** Request for exemption from review - CT scanner - Swain Community Hospital

Mr. Leandro,

I am handling the exempt from review request that you submitted on behalf of Swain Community Hospital. In order to determine whether the equipment is comparable medical equipment as defined by statute, I need you to provide information about the current scanner and the proposed scanner. Additionally, please provide a quote from the product vendor showing the purchase price of the proposed CT scanner. Our website, linked below, has examples of requests for replacement equipment that provide appropriate documentation with

regard to equipment comparison and product pricing. Once I receive that information, I can continue reviewing the request. Please let me know if you need any additional information.

**Julie Halatek, Esq.**

Project Analyst, Certificate of Need  
Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section  
North Carolina Department of Health and Human Services

919 855 3873 office  
[Julie.Halatek@dhhs.nc.gov](mailto:Julie.Halatek@dhhs.nc.gov)

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Raleigh, NC 27699-2704

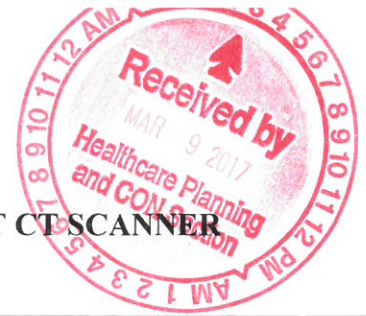
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**SWAIN COMMUNITY HOSPITAL  
INFORMATION FOR EXEMPTION OF REPLACEMENT CT SCANNER**



<b>Equipment Comparison</b>	<b>Existing Equipment</b>	<b>Replacement Equipment</b>
Type of Equipment	CT Scanner	CT Scanner
Manufacturer of Equipment	General Electric	General Electric
Model Name	Lightspeed Qx/i	Revolution EVO
Serial Number	287770CN2	To be determined
Provider's Method of Identifying Equipment	serial number	To be determined
Specify if Mobile or Fixed	Fixed	Fixed
Date of Acquisition of Each Component	June 2002	Exact date to be determined
Does Provider Hold Title to Equipment or Have a Capital Lease?	Title	Title
Specify if Equipment Was/Is New or Used When Acquired	New	New
Total Capital Cost of Project (Including Construction, etc.) <Use Attached Form>	Information not available	\$731,404.00
Total Cost of Equipment	Information not available	\$461,404.00
Fair Market Value of Equipment	Information not available	\$461,404.00
Locations Where Operated	Swain Community Hospital	Swain Community Hospital
Number Days in Use/To be Used in N.C. Per Year	365	365
Percent of Change in Patient Charges (by Procedure)	NA	No expected change in patient charges
Percent of Change in Per Procedure Operating Expenses (by Procedure)	NA	No expected change in per procedure operating expense
Type of Procedures Currently Performed on Existing Equipment	CT Scans	NA
Type of Procedures New Equipment is Capable of Performing	NA	CT Scans



GE Healthcare

Swain County Hospital  
45 Plateau St  
Bryson City NC 28713-4200

Attn: Steve Heatherly  
45 Plateau Street Sylva  
NC 28713-6784



Date: 08-10-2016  
Quote #: PR11-C58018  
Version #: 8

Customer Number : 1-23IA4U  
Quotation Expiration Date: 09-30-2016

This Agreement (as defined below) is by and between the Customer and the GE Healthcare business ("GE Healthcare"), each as identified herein. "Agreement" is defined as this Quotation and the terms and conditions set forth in either (i) the Governing Agreement identified below or (ii) if no Governing Agreement is identified, the following documents:

- 1) This Quotation that identifies the Product offerings purchased or licensed by Customer;
- 2) The following documents, as applicable, if attached to this Quotation: (i) GE Healthcare Warranty(ies); (ii) GE Healthcare Additional Terms and Conditions; (iii) GE Healthcare Product Terms and Conditions; and (iv) GE Healthcare General Terms and Conditions.

In the event of conflict among the foregoing items, the order of precedence is as listed above.

This Quotation is subject to withdrawal by GE Healthcare at any time before acceptance. Customer accepts by signing and returning this Quotation or by otherwise providing evidence of acceptance satisfactory to GE Healthcare. Upon acceptance, this Quotation and the related terms and conditions listed above (or the Governing Agreement, if any) shall constitute the complete and final agreement of the parties relating to the Products identified in this Quotation.

No agreement or understanding, oral or written, in any way purporting to modify this Agreement, whether contained in Customer's purchase order or shipping release forms, or elsewhere, shall be binding unless hereafter agreed to in writing by authorized representatives of both parties.

By signing below, each party certifies that it has not made any handwritten modifications.

Governing Agreement:	LifePoint Corporate Services
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:	\$432,232.73

INDICATE FORM OF PAYMENT:

If "GE HFS Loan" or "GE HFS Lease" is NOT selected at the time of signature, then you may NOT elect to seek financing with GE Healthcare Financial Services (GE HFS) to fund this arrangement after shipment.

Cash/Third Party Loan

GE HFS Lease

GE HFS Loan

Third Party Lease (please identify financing company) \_\_\_\_\_

By signing below, each party certifies that it has not made any handwritten modifications. Manual changes or mark-ups on this Agreement (except signatures in the signature blocks and an indication in the form of payment section below) will be void.

Each party has caused this agreement to be executed by its duly authorized representative as of the date set forth below.

CUSTOMER

\_\_\_\_\_  
Authorized Customer Signature                      Date

\_\_\_\_\_  
Print Name    Print Title

\_\_\_\_\_  
Purchase Order Number (if applicable)

GE HEALTHCARE

James Benecki    08-10-2016

\_\_\_\_\_  
Signature    Date

Product Sales Specialist

Email: Jim.Benecki@ge.com  
Office: +1 615 390 3634  
Mobile: (615) 390-3634  
Fax: (910) 401-1049



GE Healthcare



Date: 08-10-2016  
Quote #: PR11-C58018  
Version #: 8

<b>Total Quote Selling Price</b>	<b>\$473,232.73</b>
Trade-In and Other Credits	\$41,000.00
<b>Total Quote Net Selling Price</b>	<b>\$432,232.73</b>

**To Accept this Quotation**  
Please sign and return this Quotation together with your Purchase Order To:  
**James Benecki**  
Office: +1 615 390 3634  
Mobile: (615) 390-3634  
Email: Jim.Benecki@ge.com  
Fax: (910) 401-1049

**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

"Upon submission of a purchase order in response to this quotation, GE Healthcare requests the following to evidence agreement to contract terms. Signature page on quote filled out with signature and P.O. number.

\*\*\*\*\*OR\*\*\*\*\*

Verbiage on the purchase order must state one of the following: (i) Per the terms of Quotation # \_\_\_\_\_; (ii) Per the terms of GPO# \_\_\_\_\_; (iii) Per the terms of MPA # \_\_\_\_\_; or (iv) Per the terms of SAA # \_\_\_\_\_. Include the applicable quote/agreement number with the reference on the purchase order.

In addition, source of funds (choice of: Cash/Third Party Loan or GE HFS Lease or GE HFS Loan or Third Party Lease through \_\_\_\_\_), must be indicated, which may be done on the quote signature page (for signed quotes), on the purchase order (where quotes are not signed) or via a separate written source of funds statement (if provided by GE Healthcare)."





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Date: 08-10-2016  
Quote #: PR11-C58018  
Version #: 8

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
	<b>1</b>		<b>Revolution EVO**</b>			
1	1	S7880ES	<p>Today's healthcare environment is about creating new solutions to pressing needs. It's about understanding how one CT exam can improve patient outcomes while lowering the cost of providing care. Revolution EVO is designed with the purpose of operating in this new reality, while anticipating the challenges of tomorrow. It's designed to support the widest variety of patients and applications, from complex trauma or cardiac cases, to large patient backlogs in busy emergency departments that strain workflows and resources. The design of Revolution EVO is made for institutions that are unable to sacrifice advanced capabilities such as high resolution for daily productivity. It is well suited for those who need to provide the lowest dose possible. And it provides options to expand your referral physician base and the services you provide to your community.</p> <p>Revolution EVO is the next generation Volume CT with compact design and advanced technologies including Clarity Imaging system delivering up to 0.28mm of spatial resolution enabling you to see fine anatomical details, providing a pathway to a quick, confident diagnosis and delivering vastly improved image quality across the entire body enables you to broaden your clinical applications and potentially improve</p>	\$720,000.00	55.00%	\$324,000.00



Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
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treatment paths for diverse patient needs. Diagnostic images at the right dose add up to great care. Our innovative iterative reconstruction technologies are designed to reduce noise levels, improve low-contrast detectability and reduce dose for all patients.

Additional Smart Dose technologies like organ dose modulation and XR-29 capabilities help you monitor, measure and manage your dose delivery.

Often the only thing you can predict about your workday is how unpredictable it will be. Revolution EVO is designed to help you manage this unpredictability - quickly and compassionately. Revolution EVO Smart Flow technologies are designed to help you improve productivity by streamlining user workflow and access to information, enabling you to perform more studies in less time and manage your patient flow up to 40% more efficiently.

Revolution EVO is designed to help you compete in your market by helping to manage the health of your patient population today with precision, efficiency and the right dose. ASiR-V low-dose capabilities make it ideal for pediatric scans, oncology and chronic disease follow-up. At the same time, Revolution EVO can give you the flexibility to expand your services to the fastest growing procedures like



GE Healthcare

Date:  
Quote #:  
Version #:

08-10-2016  
PR11-C58018  
8

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
----------	-----	-------------	-------------	----------------	----------	----------------

advanced coronary CCTA and TAVI planning.  
 Revolution EVO is designed for you  
 Clarity Imaging Chain  
 Completely redesigned imaging chain resulting in the best spatial resolution in its class. Including wide coverage of 40 mm and high resolution so that you can see details as small as just 0.28 mm. Clarity's patented design integrates the data acquisition system directly with the photo diode reducing the size of this integrated system by 75%, improving signal to noise by 44% and power consumption by 50% compared to previous systems. The Performix 40 Plus tube delivers exceptional performance. The new liquid bearing and dual focal spot design improves precision and up to 0.35 second routine rotation enables faster scan times. This may allow for shorter breath holds, may reduce the need for sedation and reduce patient motion artifacts.  
 Clarity Imaging Chain provides the following:

- 40 mm of coverage at 1.25mm slice thickness
- Cable free between ASIC and Diode, and has a capability to reduce electric noise.
- Generation, up to 90% less heat compared with previous GE technology
- Improved signal to noise up up 44% compared with previous GE



GE Healthcare

Date:  
Quote #:  
Version #:

08-10-2016  
PR11-C58018  
8

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
----------	-----	-------------	-------------	----------------	----------	----------------

technology

- Optimized collimator to reduce scatter dose, noise and artifacts.
- Performix40\* Plus X-ray tube provides less focus movement.
- Using the 0.35sec rotation speed and higher pitch, a full-body trauma scan of 1000 mm can be acquired in as little as 6 seconds.

ASiR iterative reconstruction technology may enable reduction in pixel noise standard deviation (a measurement of image noise). The ASiR algorithm may allow for reduced mA in the acquisition of images, thereby reducing the dose required. ASiR iterative reconstruction technology also may enable improvement in low contrast detectability(\*\*)

(\*\*) In clinical practice, the use of ASiR may reduce CT patient dose depending on the clinical task, patient size, anatomical location and clinical practice. A consultation with a radiologist and physicist should be made to determine the appropriate dose to obtain diagnostic image quality for the particular clinical task.

ASiR-V optional  
Smart Technologies  
Smart Dose

Intelligent technology designed to help you acquire high-quality images using lower doses of radiation, contributing to more accurate diagnoses and lower exposures for patients. Includes dose management





GE Healthcare

Date:  
Quote #:  
Version #:

08-10-2016  
PR11-C58018  
8

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
			<p>tools such as organ dose modulation,            Organ dose modulation            Organ Dose modulation provides reduction of radiation dose via X-ray tube current modulation for sensitive tissues, such as breasts or eyes.            Revolution EVO is compliant with the NEMA XR 25, and XR 29 standards.            Including: Dose Check, DICOM Structured dose reporting. Adult and Pediatric reference protocols            Dose Check - Patient pre-scanning monitoring and alerts.            Receive notifications and alerts if your predetermined dose levels will be exceeded. You can correct and confirm the right settings before scanning to avoid unnecessary radiation dose to your patient. Dose check is based on standard XR 25-2010 published by The Association of Electrical and Medical Imaging Equipment Manufacturers (NEMA).            Dose Reporting: CT DIvol, DLP, Dose Efficiency are displayed to the user during scan prescription and at the end of the exam. The CT DIvol, DLP, and Phantom size used to calculate dose is automatically saved once the user selects End Exam.            DICOM Structured Dose Report generates a CT Dose Report, which can enable tracking of dose (CT DIvol and DLP) for the patient by the hospital radiation tracking system.            3D mA Modulation utilizing SmartmA</p>			



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Date:  
Quote #:  
Version #:

08-10-2016  
PR11-C58018  
8

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
----------	-----	-------------	-------------	----------------	----------	----------------

and AutomA.

3D mA Modulation allows you to personalize protocols and optimize dose for every patient – large and small. During the patient scan, in real-time, these automatic exposure controls, modulate dose in 3D helping you deliver consistent image quality because it automatically accounts for the changing dimensions of your patient's anatomy. 3D mA modulation acquisitions may reduce dose compared with fixed mA acquisitions. Auto mA modulation is designed to optimize the dose for the user prescribed noise index. Its effect on dose depends on the patient body habitus, and prescribed noise setting.

Dynamic Z-axis tracking

Dynamic Z-axis tracking provides automatic and continuous correction of the x-ray beam shape to block unused x-ray at the beginning and end of a helical scan to reduce unnecessary radiation.

DoseWatch Explorer\*§ Web based dose management solutions.

Analyze, identify, and optimize patient dose. Track and monitor patients' cumulative radiation dose over time and take steps to prevent excessive radiation dose.

Smart Flow

Designed to help you improve productivity and patient experience by streamlining your workflow and access to information.

Smart Flow technologies:



GE Healthcare

Date:  
Quote #:  
Version #:

08-10-2016  
PR11-C58018  
8

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
			<p>Silent design of Revolution EVO gantry allows significant reduction of audible noise compared with previous GE technology.</p> <p>Xtream Display is a multi-purpose touch LCD screen on the Revolution EVO gantry. .Xtream Display can show the user basic patient information as well as enable advanced capability of One Stop ED mode and instructional or distraction videos. The user can confirm patient information in the scan room, improving workflow improvement with preset positioning (Default Patient positioning) on gantry display.</p> <p>Fast, hands-free patient positioning</p> <p>Xtream Display provides workflow improvement with preset positioning (Default Patient Positioning) on the gantry display. Default Patient Positioning provides user friendly positioning. After patient is positioned on the table, the operator touches the selects the anatomical reference on the Xtream Display. The table is transferred to that anatomical reference simply by the foot pedal has been pressed by the user.</p> <p>One stop scanning mode - Exam prescription from the patient's side,</p> <p>Revolution EVO's exceptional one stop scanning mode provides a streamlined workflow on the Xtream Display. From the Xtream display at the gantry the user can: 1. select the patient from the worklist, 2. Select the appropriate protocol, 3, Confirm the</p>			



GE Healthcare

Date:  
Quote #:  
Version #:

08-10-2016  
PR11-C58018  
8

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
----------	-----	-------------	-------------	----------------	----------	----------------

firm the 1st within the selected protocol. All without having to leave the patients side.

Image Check - Real-time reconstruction during the scan:

With Image Check, up to 55 images are reconstructed and available per second. Reconstructing images in real time helps you focus solely on the well being and diagnosis of your patient.

Instructional or Distraction videos

Instructional videos are to assist the user in explaining the CT examination to patients. This is very useful when the user and patient do not speak the same language. Distraction videos are for young patient to help keep them distracted during exam prep and scanning.

Additional the Movie Change feature allows you to upload your own video

10 PMRs

For trauma patients, when the extent of the injuries is unknown, you can prospectively prescribe up to 10 multiphase reconstructions and easily prioritize which one you need first.

Protocol management

GE's protocol management is improved with the addition of a workflow improvement feature, which allows easy configuration of back to back Axial or helical scans of the same anatomy at two different X-ray energies (kVps). To further improve registration accuracy,





GE Healthcare

Date:  
Quote #:  
Version #:

08-10-2016  
PR11-C58018  
8

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
			<p>patient immobilization may be utilized. The additionally acquired dual energy data can be post-processed on console or AW workstation using Add/Sub function to gain additional clinical information. Access to advanced applications right on the console.</p> <p>Smart IQ</p> <p>IQ Enhance pitch booster - Scan a chest in as fast as two seconds with 175 mm/sec acquisition speed to help shorten patient breath-holds while maintaining image quality. Requires 0.35 second rotation speed capability to achieve 175mm/sec..</p> <p>Adaptive Enhance Level Adjustment (AELA) may improve visual spatial resolution while maintaining pixel noise standard deviation and artifact.</p> <p>Direct MPR with Auto-Batch feature, affording automatic real-time direct reconstruction and transfer of fully corrected multi-planar images, also allows users to move from routine 2D review to prospective 3D image review of axial, sagittal, coronal, and oblique planes while enabling automated protocol-driven batch reformats to be created and networked to their desired reading location.</p> <p>Scan mode: Helical</p> <ul style="list-style-type: none"> <li>• Helical Scan Speeds: Full 360° rotational scans: 0.7, 0.8, 0.9, 1.0 second</li> <li>• Helical Pitch (nominal): 0.516 to 1.531</li> </ul>			



GE Healthcare

Date: 08-10-2016  
Quote #: PR11-C58018  
Version #: 8

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
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- Cardiac Pitch: 0.16 to 0.325 (with cardiac option)
- Selectable kV: 80, 100, 120, 140
- Selectable mA: 10 to 560, 5mA increments
- Reconstruction Algorithms: Soft Tissue, Standard, Detail, Chest, Bone, Bone Plus, Lung, Ultra, Edge, Edge Plus
- Scan Mode: Axial & Cine
- Scan Speeds: 0.7, 0.8, 0.9, 1.0, and 2.0 second full scans (360° acquisition).
- Selectable kV: 80, 100, 120, 140
- Selectable mA: 10 to 560, 5mA increments
- Scan Plane Geometry: ± 30° gantry tilt, 0.5° increments
- Reconstruction Algorithms: Soft Tissue, Standard, Detail, Chest, Bone, Bone Plus, Lung, Ultra, Edge, Edge Plus
- System Components:  
Gantry Advanced slip ring design continuously rotates the generator, Performix\*40 Plus, Clarity detector and data acquisition system around the patient.
- Aperture: 70 cm
- Maximum SFOV: 50 cm
- Tilt: +/- 30 degrees, speed 1 degree/sec
- Multi-purpose LCD touch screen display with workflow features
- Integrated start scan button with countdown timer to indicate when



Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
			<p>x-ray will turn on.</p> <p>X-ray Tube: Performix*40 plus liquid metal bearing tube unit offers an optimized design for exams requiring a number of scans without tube cooling.</p> <ul style="list-style-type: none"> <li>• Performix*40 Plus with 7.0MHU of storage and capability of 72 kw operation provides increased helical performance with greater patient throughput</li> <li>• Wide range of technique (10 mA to 400 mA, in 5 ma increments) gives technologist and physician flexibility to tailor protocols to specific patient needs for optimizing patient dose.</li> <li>• Heat storage capacity: 7.0MHU(Performix*40 Plus)</li> <li>• Dual Focal Spots: <ul style="list-style-type: none"> <li>o Small Focal Spot: 0.7 (W) x 0.6 (L) Nominal Value; (IEC 60:193)</li> <li>o Large Focal Spot: 0.9 (W) x 0.9 (L) Nominal Value; (IEC 60:193)</li> </ul> </li> </ul> <p>High Voltage Generator: High Frequency on-board generator allows for continuous operation during scan.</p> <p>400mA based system</p> <ul style="list-style-type: none"> <li>• kV: 80, 100, 120, 140</li> <li>• Max Power: 48kW (72kW optional)</li> <li>• mA: 10 to 400 mA 5mA increments (up to 600mA option),</li> </ul> <p>Clarity Hilight Detector: 64 slice system 40 mm Clarity Hilight Detector system is comprised of 54,272</p>			



GE Healthcare

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Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
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individual elements providing 20mm of 0.625mm slice coverage and 40mm of 1.25mm slice coverage. Data is acquired either as thin slice at 0.625mm or as thicker slices at 1.25mm with the ability of thicker slices from image reconstruction or processing. 98% absorption efficiency.

Clarity DAS (Data Acquisition System):  
The Clarity DAS dramatically reduces noise and improves image performance.

- 2,460 Hz maximum sample rate.
- 861 - 1968 views per rotation.

Revolution EVO computer system:

- 2,100GB Disk (system, image, scan disks) stores up to 460,000 512x512 images and 3520 scan rotations at 64 slice mode or up to 1,500 scan data files, or up to 300 exams.
- Reconstruction speed with  
Standard reconstruction: Up to 55 frames per second with Image Check and Up to 35 frames per second in full 512 matrix

Warranty: The published Company warranty in effect on the date of shipment shall apply. The Company reserves the right to make changes.

General Electric Company reserves the right to make changes in specifications and features shown herein, or discontinue the product described at any time without notice or obligation.

Laser alignment devices contained within this product are appropriately





GE Healthcare

Date:  
Quote #:  
Version #:

08-10-2016  
PR11-C58018  
8

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
			labeled according to the requirements of the Center for Devices and Radiological Health. Asterisk*: Trademark of General Electric Company			
2	1	B7590EN	English Keyboard Kit	Incl.	Incl.	Incl.
3	1	B7660MR	System standard cable set	Incl.	Incl.	Incl.
4	1	B7880AB	The Optima 1700 table enables volume scanning. Key features of this 1700 table include: easy patient access by lowering to <17 inches from the floor, 500lb weight capacity, up to 1700mm scannable range, 137.5 mm/sec travel time, real-time Z-axis position feedback between gantry and table.	Incl.	Incl.	Incl.
5	1	B7900LC	This option provides lung screening reference protocols that are tailored to the CT system, patient size (small, average large), and the most current recommendations from a wide range of professional medical and governmental organizations. Now, qualified GE Healthcare CT scanners with this option are formally indicated for, and can be confidently used by physicians for low dose CT lung cancer screening of identified high-risk patient populations. These protocols deliver low dose, short scan times, and clear and sharp images for the detection of small lung nodules. Early detection from an annual lung screening with low dose CT in high-risk individuals can	Incl.	Incl.	Incl.



GE Healthcare

Date:  
Quote #:  
Version #:

08-10-2016  
PR11-C58018  
8

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
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prevent a substantial number of lung cancer-related deaths.ii  
 All new GE 64-slice and greater CT scanners, and virtually all of the 16-slice CT scanners that GE Healthcare sells are qualified for this screening option. This solution is also available to thousands of qualified GE CT scanners currently in use, increasing access to the quality scanners that satisfy both patient and physician needs. The new protocols, do include the choice for the user to be able to utilize GE Healthcare's industry-leading technologies such as ASiRTM, ASiR-VTM and VeoTM that are designed to reduce image noise, which is undesirable for physicians looking for small nodules. This option contains two documents. Lung Cancer Screening Option Reference Protocol Guide, and the Lung Cancer Screening Option User Manual / Technical Reference Manual

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



GE Healthcare

Date: 08-10-2016  
Quote #: PR11-C58018  
Version #: 8

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
6	1	B7880MR	<p>Revolution.  ii Moyer V. Screening for Lung Cancer: U.S. Preventive Services Task Force Recommendation Statement. Ann Intern Med. 2014;160:330-338. <a href="http://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/lur">http://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/lur</a></p> <p>MAR (Metal Artifact Reduction) software</p> <p>MAR helps reduce photon starvation, beam hardening and streak artifacts caused by high Z materials in the body, such as hip implants.</p> <p>The clarity of MAR images is addressing the challenges posed by metal artifacts, helping clinicians accurately contour targets and critical organs.</p> <p>MAR offers:  Exceptional image quality.  MAR is based on the latest in GE Healthcare smart technology, which uses a novel three-step, sinogram-based iterative algorithm.</p> <p>Streamlined workflow.  MAR requires only one scan, making the process of obtaining a corrected image fast and efficient.  Dose conscious.</p>	\$60,000.00	55.00%	\$27,000.00



GE Healthcare

Date: 08-10-2016  
Quote #: PR11-C58018  
Version #: 8

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
			MAR requires only one acquisition. Patient comfort. The efficient, single-scan process helps to reduce patient time inside the scanner. Versatility. MAR is designed to enhance clarity across a range of images including scans of hip implants, dental fillings, screws and other metal objects.			
7	1	B7880CH	The 72kW power option upgrades the maximum allowable mA selection of the on-board high frequency generator by 40% from 400 mA max to 560 mA, or 600mA with cardiac options. More mA can be used to image large patient or at faster rotation times you can maintain the mAs prescribed.	\$160,000.00	55.00%	\$72,000.00
8	1	B7810LW	VariSpeed Scanning Option Enables 0.5, 0.6, 0.7, 0.8, 0.9, 1.0 second rotation acquisitions	\$36,000.00	55.00%	\$16,200.00
9	1	B7880CJ	Provides the capability of a 360-degree rotation in 0.4 seconds. This additional rotation time will enhance the user's ability reduce exam times and potentially lower patient breath-holds. Enabling up to 153 mm/sec acquisition speeds	\$20,000.00	55.00%	\$9,000.00
10	1	B77292CA	Service cabinet for system	Incl.	Incl.	Incl. 18/23



GE Healthcare

Date: 08-10-2016  
Quote #: PR11-C58018  
Version #: 8

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
11	1	E4502KY	<p>accessories storage</p> <p>The 10 KVA Partial UPS has been specifically designed to coordinate with GE Healthcare CT and PET/CT scanners. In the event of a power outage, a partial system UPS provides continuous backup power to the scanner host and control computers, thus assuring no loss of usable scan data.</p> <ul style="list-style-type: none"> <li>• Critical circuits in the gantry and table remain powered which facilitate the safe of the patient from the scanner.</li> <li>• If power is restored within the battery hold-up time, the operator can continue scanner operations without the need to reboot the system.</li> <li>• When longer power outages are anticipated, the UPS provides time for the operator to to complete an orderly shutdown of the system software.</li> <li>• Maintains system electronics and allows critical scanner operations to continue for 10 minutes (typical) after loss of power</li> <li>• Protects electronics from under voltage, brownouts, line sags, over voltage and transients</li> <li>• Dimensions (H x W x D): 32.7" x 12" x 32"</li> <li>• Weight: 350 lbs.</li> </ul>	\$23,648.00	21.00%	\$18,681.92



GE Healthcare

Date:  
Quote #:  
Version #:

08-10-2016  
PR11-C58018  
8

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
			<ul style="list-style-type: none"> <li>Output Frequency: 50 or 60 Hz, auto-sensing</li> </ul>			
			NOTES:			
			<ul style="list-style-type: none"> <li>ITEM IS NON-RETURNABLE AND NON-REFUNDABLE</li> </ul>			
12	1	E4502AB	<p>The 90Amp 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.</p> <ul style="list-style-type: none"> <li>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 power off are combined into a single panel)</li> <li>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</li> </ul>	\$7,569.00	21.00%	\$5,979.51





GE Healthcare

Date: 08-10-2016  
Quote #: PR11-C58018  
Version #: 8

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
			<ul style="list-style-type: none"> <li>Designed and tested for GEHC CT products</li> </ul> <p>Specifications:</p> <ul style="list-style-type: none"> <li>Automatic restart incorporates an adjustable time delay to delay main power until the power has stabilized for 5 seconds</li> <li>One flush wall mounted remote emergency off pushbutton furnished with each system</li> <li>UL, cUL and CE labeled</li> </ul>			
13	1	E8016AZ	CT Table Slicker with Cushion - 1700 Systems (2 Piece Set)	\$420.00	21.00%	\$331.80
			<p>FEATURES/BENEFITS</p> <ul style="list-style-type: none"> <li>Two-piece, sealed slicker cushion set has comfort pads enclosed inside the slicker cover and extender cover</li> <li>Durable, clear PVC plastic cover facilitates faster, more thorough cleanup of blood and fluids</li> <li>Increase system uptime by protecting table from spills and particulate contaminants</li> <li>Thermo-sealed seams and flaps prevent contaminate buildup in hard to clean areas</li> </ul> <p>COMPATIBILITY</p> <ul style="list-style-type: none"> <li>VCT with GT 1700 Table, CT HD750</li> </ul>			
14	1	E8016BA	CT Footswitch Slicker - 2000 & 1700 Systems	\$50.00	21.00%	\$39.50



GE Healthcare

Date: 08-10-2016  
Quote #: PR11-C58018  
Version #: 8

Item No.	Qty	Catalog No.	Description	Contract Price	Discount	Ext Sell Price
			The footswitch slicker for CT VCT 2000 and 1700 systems is made of durable, clear PVC plastic that protects the footswitch and facilitates faster, more thorough cleanup of contamination caused by blood and other body fluids. Cover is held securely in place with Velcro...H			
15	1	R23053AC	Standard level 3 service package delivered for the warranty period	Incl.	Incl.	Incl.

**Quote Summary:**

<b>Total Contract List Price:</b>	<b>\$1,027,687.00</b>
<b>Total Discount:</b>	<b>(\$554,454.27)</b>
<b>Total Extended Selling Price:</b>	<b>\$473,232.73</b>
<b>Lightspeed 16 Trade-in</b>	
<b>Total Quote Net Selling Price</b>	<b>\$432,232.73</b>

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

### Options

(These items are not included in the total quotation amount)

Item No.	Qty	Catalog No.	Description	Ext Sell Price
16	1	W0100CT	6 Day CT TiP Onsite System Training CT Onsite Training for a new CT system <ul style="list-style-type: none"> <li>One 4 day onsite visit to coincide with system start-up.</li> <li>One 2 day onsite follow-up visit 6-8 weeks post system start up.</li> </ul>	\$13,300.00



GE Healthcare

Date: 08-10-2016  
Quote #: PR11-C58018  
Version #: 8

Item No.	Qty	Catalog No.	Description	Ext Sell Price
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During the first visit, the applications specialist will work with the medical and technical staff on system operation and patient procedures. The training produces the best results when a dedicated core group of 2-4 CT technologists complete the session with a modified patient schedule. It is suggested that key physicians are available to participate in the protocol implementation and image quality review sessions. By the end of this visit, the core group should be able to perform the routine patient procedures.

The 2 day revisit is suggested after the staff has run the system for 6-8 weeks, however this is flexible based on the site needs. The training will focus on the intermediate and advanced functions of the system or special needs of the customer. The training produces the best results when the same dedicated core group of 2-4 CT technologists from the initial visit complete the session with a modified patient schedule.

This training program must be scheduled and completed within 12 months after the date of product delivery.

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



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Columbia, SC  
Greenville, SC  
Raleigh, NC  
Spartanburg, SC

February 7, 2017

**VIA U.S. MAIL AND ELECTRONIC MAIL**

Martha Frisone  
Assistant Chief  
Healthcare Planning and Certificate of Need Section  
North Carolina Department of Health and Human Services  
2704 Mail Service Center  
Raleigh, NC 27699-2704  
[Martha.Frisone@dhhs.nc.gov](mailto:Martha.Frisone@dhhs.nc.gov)



Re: Request for No Review Determination

Dear Ms. Frisone:

This letter is intended to provide notice to the Healthcare Planning and Certificate of Need Section (the "Agency") that our client, Swain Community Hospital is planning to replace the Computed Tomography Scanner ("CT Scanner"), which was originally purchased in 2002. The approximate cost of the replacement equipment, including construction, planning, surveys, designs and other activities contemplated by N.C. Gen. Stat. § 131E-176(22a) is approximately \$731,404.00. See Attachment A. The existing CT Scanner will not be used in North Carolina without first obtaining a Certificate of Need ("CON").

Based on the amount at issue, we believe that Swain Community Hospital's replacement project is exempt from CON review under N.C. Gen. Stat. § 131E-184(a)(7). Accordingly, Swain Community Hospital requests that the Agency confirm that this acquisition is not subject to CON review and that it issue a written determination so that it could move forward with replacing this equipment.

I greatly appreciate your attention to this matter. If you have any questions, please feel free to contact me directly.

Sincerely,

A handwritten signature in black ink that reads "Robb A. Leandro".

Robb Leandro

RAL:klb

Enclosure

PPAB 3574487v1

**ATTACHMENT A**

Swain Community Hospital

<b>Expenditure</b>	<b>Cost</b>
CT Scanner	\$ 461,404.00
Design/Planning	\$ 70,000.00
Construction	\$ 200,000.00
<b>Total:</b>	<b>\$ 731,404.00</b>