

ROY COOPER • Governor

MANDY COHEN, MD, MPH • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

## VIA EMAIL ONLY

January 27, 2021

Elizabeth Runyon, System Director of Regulatory Affairs and Special Counsel elizabeth.runyon@unchealth.unc.edu

**Exempt from Review - Replacement Equipment** 

**Record #:** 3470

Date of Request: January 22, 2021
Facility Name: Rex Hospital

FID #: 953429

Business Name: Rex Hospital, Inc.

Business #: 1554

Project Description: Replace CT scanner

County: Wake

Dear Ms. Runyon:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that the above referenced project is exempt from certificate of need review in accordance with G.S. 131E-184(a)(7). Therefore, you may proceed to acquire without a certificate of need the Siemens Drive CT scanner to replace the Siemens Definition AS64 CT scanner. This determination is based on your representations that the existing unit will be sold or otherwise disposed of and will not be used again in the State without first obtaining a certificate of need if one is required.

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

Sincerely,

Michael J. McKillip Project Analyst

Lisa Pittman

Assistant Chief, Certificate of Need

cc: Radiation Protection Section, DHSR

Construction Section, DHSR

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

LOCATION: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603

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

https://info.ncdhhs.gov/dhsr/ • TEL: 919-855-3873



January 22, 2021

#### VIA ELECTRONIC MAIL

Mike McKillip, Project Analyst
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
NC Department of Health and Human Services
2704 Mail Service Center
Raleigh, North Carolina 27699-2704
mike.mckillip@dhhs.nc.gov

Re: Rex Hospital Notice of Exemption for Replacement Equipment / Wake County

Dear Mr. McKillip,

Rex Hospital Inc. ("Rex") provides this notice regarding a replacement computed tomography (CT) scanner (the "CT Scanner"), and requests confirmation that the acquisition of such replacement equipment is exempt from certificate of need ("CON") review pursuant to NCGS § 131E-184 (a)(7) and the regulations set out in 10A NCAC 14C.0303. The existing CT scanner was acquired in 2012 and was the subject of a previous Replacement Equipment Exemption. See Exhibit A. The existing CT scanner currently in use will be replaced with the new CT Scanner which is "comparable medical equipment," as described in 10A NCAC 14C.0303.

## **Exemption from Review**

Pursuant to NCGS § 131E-184(a)(7): "The department shall exempt from certificate of need review a new institutional health service if it received prior written notice from the entity proposing the new institutional health service, when notice includes an explanation of why the new institutional health service is required for any of the following: ... To provide replacement equipment." (emphasis added) The acquisition of major medical equipment (as defined by NCGS § 131E-176(140)) is a new institutional health service pursuant to NCGS § 131E-176(16)(p), but the acquisition of a CT scanner that is replacement equipment is exempt from review as described herein.

"Replacement equipment" is defined by NCGS § 131E-176(22a) as equipment that costs less than \$2,000,000 and is purchased for the sole purpose of replacing comparable medical equipment currently in use which will be sold or otherwise disposed of when replaced.

According to 10A NCAC 14C.0303, replacement equipment is "not comparable" if:

- 1. the replacement equipment to be acquired is capable of providing a health service that the equipment to be replaced cannot provide;
- 2. the equipment to be replaced was acquired less than 12 months prior to the date the written notice... is submitted to the CON Section and it was refurbished or reconditioned when it was acquired by the person requesting the exemption.

The proposed acquisition of the replacement CT Scanner does not meet either of these criteria, and thus it is comparable medical equipment to the existing CT scanner.

## Compliance

The acquisition of the replacement CT Scanner by Rex is exempt from CON review because:

- The estimated project costs for the replacement CT scanner are less than \$2,000,000. The vendor quote for the CT Scanner shows equipment costs of approximately \$1,536,000 (see Exhibit B) and total project costs are estimated at \$1,808,785 (see Exhibit C).
- The replacement equipment will be purchased for the sole purpose of replacing comparable medical equipment currently in use, which will be traded in for disposal and removal from North Carolina. A comparison of the existing and replacement equipment is provided in <a href="Exhibit D">Exhibit D</a>.
- The replacement equipment is functionally similar to the existing equipment and will be used for providing the same health service as the equipment currently in use.

Rex requests that the Agency confirm in writing that its acquisition of the replacement CT Scanner, as described herein, does not constitute a new institutional health service and is exempt from certificate of need review. Please don't hesitate to contact me at <a href="mailto:elizabeth.runyon@unchealth.unc.edu">elizabeth.runyon@unchealth.unc.edu</a> if you require further information or have any questions regarding this correspondence.

Sincerely,

Clizabeth Runyon
Elizabeth Runyon

System Director of Regulatory Affairs and Special Counsel

**UNC** Health



# North Carolina Department of Health and Human Services Division of Health Service Regulation Certificate of Need Section

2704 Mail Service Center • Raleigh, North Carolina 27699-2704 http://www.ncdhhs.gov/dhsr/

Drexdal Pratt, Director

Beverly Eaves Perdue, Governor Albert A. Delia, Acting Secretary Craig R. Smith, Section Chief Phone: (919) 855-3873 Fax: (919) 733-8139

July 17, 2012

William W. Stewart, Jr. K & L Gates, LLP P.O. Box 14210 Research Triangle Park NC 27709-4210

RE:

Exempt from Review - Replacement Equipment / Rex Hospital, Inc. / Replace existing Philips 16-channel computed tomography (CT) scanner with a new Siemens Somatom 64-slice CT scanner / Wake County

FID #: 953429

Dear Mr. Stewart:

In response to your letter of June 19, 2012, the above referenced proposal is exempt from certificate of need review in accordance with N.C.G.S 131E-184(a)(7). Therefore, you may proceed to acquire, without a certificate of need, the Siemens Somatom Definition AS 64-slice CT scanner to replace the existing Philips Brilliance 16 Channel CT scanner [Serial # 2073]. This determination is based on your representations that the existing unit will be removed from North Carolina and will not be used again in the State without first obtaining a certificate of need. Further please be advised that as soon as the replacement equipment is acquired, you must provide the CON Section and the Medical Facilities Planning Section with the serial number of the new equipment to update the inventory, if not already provided. In addition, you should contact the Construction Section to determine if they have any requirements for development of the proposed project.

It should be noted that this 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 Agency and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

Michael J. McKillip Project Analyst

Craig R Smith, Chief Certificate of Need Section

cc:

Construction Section, DHSR





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

#### PRELIMINARY PROPOSAL

Customer Number: 0000010805

Date: 09/10/2020

UNIV NORTH CAROLINA HEALTH CARE SYS

101 MANNING DR

CHAPEL HILL, NC 27514

Quote Nr:

CPQ-128151 Rev. 0

Trade:

Siemens AS-64 (400-412323)

**Terms of Payment** 

00% Down, 00% Delivery, 100% @ 6-months after

Installation

Free On Board: Destination

**Purchasing Agreement** 

Vizient

**Proposal Valid Until** 

9/30/2020

## Siemens Somatom Drive Dual Source CT for UNC-Rex

Qty Part No.

14460776

**Item Description** 

#### **SOMATOM Drive**

The SOMATOM Drive contains two new Straton MX Sigma tubes and Sigma generators to boost the power and enable an industry standard of low kV imaging with a significant step towards personalization with 10kV steps. Both tubes can be used with Tin Filters, for further dose reduction in non-contrast imaging and lung cancer screening.

This is in conjunction with two StellarInfinity Detectors & Integrated IR (Iterative Reconstruction), including key technologies TrueSignal and Edge Technology, the SOMATOM Drive routinely generates ultra-thin 0.5 mm slices e.g. for most accurate stenosis, plaque and stent analysis.

Available with 75 ms temporal resolution, faster than any conventional CT on the market, providing whole organ dynamic imaging and routine true Dual Energy scans.

All this power and precision is backed by three key technology areas-DistinCT Imaging: focused on providing the most specific parameters for best quality and lowest dose for each individual patient regardless of circumstances that they are in.

DistinCT Reading: focused on providing the quickest access to all diagnostic images regardless of the time of day, number of patients or the advanced nature of a study. DistinCT Function: focused on providing access to more quantitative data to enhance patient diagnosis and treatment outcomes.

SOMATOM Drive - provides the capabilities to "Drive Precision for all" patients.



**SIEMENS REPRESENTATIVE** 

Edwin Winicki

edwin.winicki@siemens-healthineers.com

| 222 | INCIDIA. | D.V | DDO | 00041 |  |
|-----|----------|-----|-----|-------|--|
| PKH |          | K Y | PKU | POSAL |  |

|   |          | PRELIMINARY PROPOSAL   |
|---|----------|--|
| 1 | 14447322 | ELEVATE R 40-/64-slice > Drive Elevate from 40-/64-slice configuration system to the SOMATOM Drive   |
| 1 | 14460584 | <b>DistinCT Imaging</b> We combine our market leading applications to make this the most Distinct scanner for our customers. Including SureView, Flash Spiral, Dual Adaptive Dose Shields, CARE Dose 4D, CARE kV, CARE Child, CARE Profile, CARE Dashboard, CARE Bolus, Dose MAP, FAST Adjust, XXL Mode 2cm and ADMIRE.  |
| 1 | 14460585 | DistinCT Imaging - Advanced  We combine the unique features of the SOMATOM Drive, to push the most distinct CT scanner to its maximum potential, including the full power of the Straton MX Sigma tube - DistinCT - Sigma High Power including, High Power 70 and High Power 80, Dual Power 4cm, 10kV Steps, X-CARE and CARE Contrast III.  Additionally Tin Filter scanning allows reaching new levels in low dose non-contrast scans.  |
| 1 | 14460778 | <b>DistinCT Reading</b> We combine our market leading applications to make reporting consistant, fast and simple for our customers. Includes VRT, Workstream 4D and Extended FoV.  |
| 1 | 14447380 | DistinCT Reading - Advanced  We combine our advanced applications to make reporting of complex and atypical anatomical structures faster and simpler.  Includes iMAR for anatomically driven metal artifact reduction, combines three successful approaches (beam hardening correction, normalized sinogram inpainting and frequency split). This allows to reduce metal artifacts caused by metal implants. FAST Spine, providing anatomically aligned preparation of spine recons with just a single click.  HD FoV Pro, designed to enable visualization of the human body parts and skin line located outside of the 50cm standard scan field of view, based on an algorithmic complement of missing detector data outside of the 50cm standard scan FoV. The image quality for the area outside the 50cm standard scan field of view does not meet the image quality of the area inside the 50cm standard scan field of view. Image artefacts may appear, depending on the patient setup and anatomy scanned. zUHR for functionality improved spatial resolution. |
| 1 | 14460588 | DistinCT Function - Cardiac  Cardiac scanning options to enable the simple to use, routine cardiac CTA and calcium scoring workflows, including beta blocker independent scanning, one heart beat scanning and flex scanning to enable functional imaging at low doses.  Includes: Heart View, Cardio Best Phase Plus and syngo Calcium Scoring CT.  |
| 1 | 14460589 | DistinCT Function - Dynamic  Adaptive 4D Spiral - a unique 4D Spiral scan mode that enables the SOMATOM  Drive to extend beyond restraints experienced when utilizing a static detector and allows for up to 48 cm (18.89") dynamic CT coverage. This enables use not only in perfusion but also for advanced 4D CT DSA evaluations.   |
| 1 | 14460587 | <b>DistinCT Function - DE</b> Dual Energy scanning options including Tin Filter modes and the applications to introduce Dual Energy as part of your routine daily workflow. Includes FAST DE results and FAST DE with Workstream 4D.   |
| 1 | 14460594 | Advanced Applications We combine our market leading applications to make positioning simple for our customers.  FAST Topo - enables faster scan speeds in topograms, which minimizes breathhold artifacts. It also has the potential to decrease the topogram dose.  FAST Planning - assists scan and reconstruction planning, based on a topogram, to provide an easier, faster and standardized workflow in CT scanning. FAST Planning   |
|   |          |  |



#### SIEMENS REPRESENTATIVE

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#### PRELIMINARY PROPOSAL

features the selection of the anatomical region of interest from a list prospectively defined scan and reconstruction ranges, automatic detection of the scan region(s) of interest and proposal of corresponding scan range(s) in the topogram (in a narrow or wide lateral FoV), optimized FoV and automatic iso-center adaptation for Head

FAST 3D Align - automatically corrects misalignment of anatomic structures, organs of the patient. It aligns those to fit it to the selected reconstruction plane for a highly automated reconstruction workflow. Additionally it minimizes the black area in the image by automatically adjusting the recon field of view. FAST 3D Align works in combination with Workstream 4D.

## 14447337 Multi-purpose table The Multi-Purpose table is especially designed for multi-disciplinary use, while still

enabling ultra-fast spiral scanning up to 458 mm/s. Its flexible design allows exchange of table tops for routine radiology, Trauma or bariatric use. Table load capacity up to 307 kg / 676 lbs. with bariatric table top (High Capacity Patient & Trauma Table Top). Physiological Measurement Module included.

#### 14410230 Mat for MPT Standard Table Top Replacement for the positioning mattress for Standard Multi Purpose Table Top. 14408231 High Cap. Patient & Trauma Tab.Top

The high capacity and trauma table top offers the capability to support up to 307 kg/676 lbs of patient weight. It allows easy positioning and transfer from and to the table, due to its flat surface. Special accessories and an extended table top width of 530 mm ensure a safe and comfortable positioning for obese patients.

14408232 High Cap. Patient & Trauma Acc Kit

The High capacity and Trauma accessory kit contains additional Patient restraint set with a width of 400mm and additional table extensions for feet and head.

14447335 Rear cover incl. Touch Panels

Standard CT rear gantry cover, including two Touch Panels, for additional access to the positioning of the patient from both sides of the gantry.

14460582 1 **FASTIRS** 

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FAST reconstruction computer for the preprocessing and reconstruction of the CT raw data. The reconstruction computer contains a cluster of high-performance GPU boards performing the preprocessing and reconstruction of the CT data.

14447370 Ring Light

> SOMATOM Drive offers a gantry ring mood light (LED) in different, preset, adjustable colors. Designed not only for aesthetics, they can be used to help create a relaxing atmosphere for your patients.

SURE\_VIEW SureView

> Provides exceptional image quality at any pitch setting, enabling you to scan faster because you can scan at any pitch without degrading image quality

CT LUNGIMAG Lung Imaging DRIVE

For well over a decade, CT has been recognized and used as the standard of care for lung nodule detection and sizing. This is due to CT's spatial resolution, geometric accuracy, and ability to create various reconstructions and 3D views. The high contrast environment in the chest between the lungs and the nodules makes for a relatively easy detection task for clinicians using CT images. Recent advances in CT technology have allowed these scans to be effectively performed at lower doses, higher resolutions, and faster scan times.

The SOMATOM Drive CT is indicated for use in low dose lung cancer screening for high risk populations\*. The Drive is delivered with two specific scan protocols to provide low dose lung cancer screening exams at approximately 0.33 mGy CTDI for a standard size adult. These default protocols utilize Siemens proprietary dose reducing features such as CARE Dose4D™, automatic exposure control technology



SIEMENS REPRESENTATIVE Edwin Winicki

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#### PRELIMINARY PROPOSAL

that modulates and adapts dose for every patient, for high image quality at low dose.

\*As defined by professional medical societies.

1 ACCESS\_PROT ECT

PROT Access Protection

Scan Protocols are password protected allowing only authorized staff members to

access and permanently change protocols

1 NEMA\_XR-29

**NEMA XR-29 Standard** 

This system is in compliance with NEMA XR-29 Standard Attributes on CT Equipment Related to Dose Optimization and Management, also known as Smart

Dose.

1 CT UPS\_DRIVE

Standard UPS for SOMATOM Drive

The standard partial system uninterruptible power supply (UPS) is built directly into the power distribution cabinet (PDC) and supports the critical circuits for table and gantry electronics, console computer, image reconstruction system, and the internal Ethernet switch (to ensure connectivity). This enables safe removal of patient if

outage occurs during scanning.

1 4SPAS014

Low Contrast CT Phantom & Holder

1 PSPD250480Y3

**Surge Protective Device (SPD)** 

K

CTSP4002

CT Slicker

Thermoseal seams and flaps deflect fluids, reducing contaminant penetration into the cushion and table. Contaminants are retained on the tabletop or shunted to the floor. Cleanup is faster, more thorough, and contaminant build-up is reduced. Built using heavy, clear, micro matte vinyl, and top grade hook and loop fastening strips (Velcro) to better fit the specified table. Custom vinyl resists tears and minimizes radiologic interference. Latex free. Set includes CT Skirts.

Includes warranty from RADSCAN Medical.

1 M2ISI900SI

Medrad ISI900 interface,w/install

1 CT\_PM

**CT Project Management** 

A Siemens Project Manager (PM) will be the single point of contact for the implementation of your Siemen's equipment. The assigned PM will work with the customer's facilities management, architect or building contractor to assist you in ensuring that your site is ready for installation. Your PM will provide initial and final drawings and will coordinate the scheduling of the equipment, installation, and rigging, as well as the initiation of on-site clinical education.

1 CT\_ADDL\_RIG GING Additional Rigging CT

1 CT\_BTL\_INSTA

**CT Standard Rigging and Installation** 

1 CT\_PR\_ELV\_D RIVE

**CT Drive Elevate Bonus** 

1 CT\_TRADE\_IN\_ ALLOW

Trade-in of existing Definition AS64 @ \$82,900

1 CT\_EDUOPTIO N5 Clinical Education & Training: Option 5

Siemens offers multiple options for clinical education and training on your new system. These options enable a more personalized approach to the introduction to system operation, features, and benefits and will help ensure that your technologists and physicians have the opportunity to engage in the level of training that best meets your current clinical needs and business objectives.

The following items are the education and training modules are highly

recommended for the operation of your new Siemens system and are most effective for sites where technologists and/or physicians have limited experience on Siemens' systems. In addition to covering routine procedures, this option also provides

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#### PRELIMINARY PROPOSAL

additional opportunities to learn more specialized procedures and further increase efficiencies.

#### 1 CT\_INITIAL 32

#### Initial onsite training 32 hrs

Up to (32) hours of on-site clinical education training, scheduled consecutively (Monday – Friday) during standard business hours for a maximum of (4) imaging professionals. Training will cover agenda items on the ASRT approved checklist. Uptime Clinical Education phone support is provided during the warranty period for specified posted hours. This educational offering must be completed (12) months from install end date. If training is not completed within the applicable time period, Siemens obligation to provide the training will expire without refund.

#### 1 CT\_FOLLOWUP \_16

#### Follow-up training 16 hrs

Up to (16) hours of follow-up on-site clinical education training, scheduled consecutively (Monday – Friday) during standard business hours for a maximum of (4) imaging professionals. Uptime Clinical Education phone support is provided during the warranty period for specified posted hours. This educational offering must be completed (12) months from install end date. If training is not completed within the applicable time period, Siemens obligation to provide the training will expire without refund.

#### CT\_FOLLOWUP \_24

## Follow-up training 24 hrs

Up to (24) hours of follow-up on-site clinical education training, scheduled consecutively (Monday – Friday) during standard business hours for a maximum of (4) imaging professionals. Uptime Clinical Education phone support is provided during the warranty period for specified posted hours. This educational offering must be completed (12) months from install end date. If training is not completed within the applicable time period, Siemens obligation to provide the training will expire without refund.

## 1 CT\_DEWSPTL

#### Dual Energy Workshop w/T&L

This workshop tuition for (1) attendee includes didactic lectures on physics, patient selection, scanning and protocols, post processing data sets, and interpretations. Economy airfare, lodging and lunch is included for (1) attendee. All arrangements must be arranged through Siemens designated travel agency. Workshop must be scheduled consecutively (Monday – Friday) during standard business hours. This educational offering must be completed by the later of (12) months from purchase or install end date. If training is not completed within the applicable time period, Siemens obligation to provide the training will expire without refund.

## 1 SY\_PR\_TEAMP LAY

#### teamplay Welcome & Registration Package

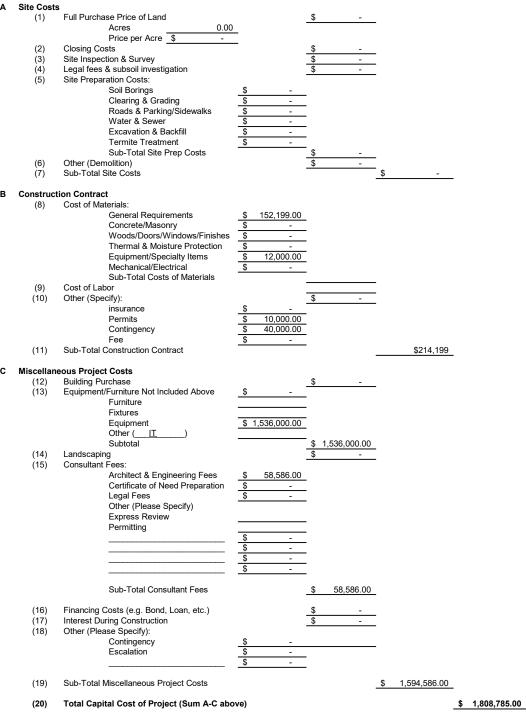
teamplay is a cloud-based network that brings together your imaging modality users, the systems' dose and utilization data, and the users' expertise to help you improve the delivery of care to your patients. Basic features are provided free of charge. Premium features (benchmarking, non-Siemens devices) are provided on a trial basis for three months at no charge, and may be used thereafter on a subscription fee basis.

To register: http://teamplay.siemens.com/#/institutionRegistration/1

System Total

\$1,536,000

## **CT1 Equipment Replacement**



Assumptions:

## **EXHIBIT D - EQUIPMENT COMPARISON**

|   | EXISTING<br>EQUIPMENT | REPLACEMENT<br>EQUIPMENT |
|---|-----------------------|--------------------------|
| Type (e.g., Cardiac Catheterization, Gamma Knife®, Heart-lung bypass machine, Linear Accelerator, Lithotriptor, MRI, PET, Simulator, CT Scanner, Other Major Medical Equipment) | CT scanner            | CT scanner               |
| Manufacturer  | Siemens               | Siemens                  |
| Model number  | Definition AS64       | Drive                    |
| Other method of identifying the equipment (e.g., Room #, Serial Number, VIN #)  | 7536                  |                          |
| Is the equipment mobile or fixed?   | Fixed                 | Fixed                    |
| Date of acquisition   | 2012                  |                          |
| Was the existing equipment new or used when acquired? / Is the replacement equipment new or used?   | New                   | New                      |
| Total projected capital cost of the project <attach a="" capital="" cost="" form="" projected="" signed=""></attach>  | NA                    | 1,808,785                |
| Total cost of the equipment   | \$769,336             | \$1,536,000              |
| Location of the equipment <attach a="" equipment="" for="" if="" mobile="" necessary="" separate="" sheet=""></attach>  | Main CT<br>department | Main CT<br>department    |
| Document that the existing equipment is currently in use  | Yes                   | NA                       |
| Will the replacement equipment result in any increase in the average charge per procedure?  | NA                    | no                       |
| If so, provide the increase as a percent of the current average charge per procedure  | NA                    | NA                       |
| Will the replacement equipment result in any increase in the average operating expense per procedure?   | NA                    | no                       |
| If so, provide the increase as a percent of the current average operating expense per procedure   | NA                    |                          |
| Type of procedures performed on the existing equipment <attach a="" if="" necessary="" separate="" sheet=""></attach>   | CT Scans              |                          |
| Type of procedures the replacement equipment will perform <attach a="" if="" necessary="" separate="" sheet=""></attach>  |                       | CT Scans                 |
|   |                       |                          |