



North Carolina Department of Health and Human Services  
 Division of Health Service Regulation  
 Office of the Director

2701 Mail Service Center • Raleigh, North Carolina 27699-2701  
<http://www.ncdhhs.gov/dhsr/>

Pat McCrory  
 Governor

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

Drexdal Pratt, Director  
 Phone: 919-855-3750  
 Fax: 919-733-2757

March 19, 2013

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

**Exempt from Review - Replacement Equipment**

Facility: Rex Hospital  
 Project Description: Replace PET/CT system  
 County: Wake  
 FID #: 953429

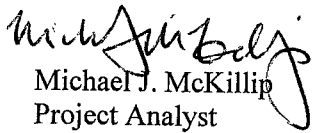
Dear Mr. Stewart:


In response to your letter of December 6, 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 Biograph Excel Edition PET/CT system to replace the existing Siemens Biograph PET/CT system [Serial # 0301021]. 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.

Moreover, you need to contact the Construction and the Acute and Home Care Licensure and Certification Sections 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: Acute and Home Care Licensure and Certification Section, DHSR  
 Construction Section, DHSR



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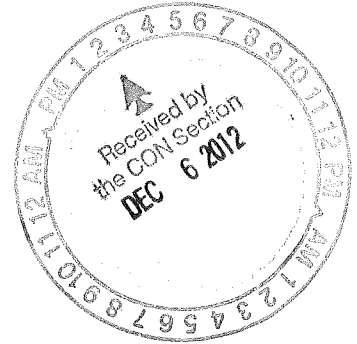
953429

December 6, 2012

William W. Stewart, Jr.  
D 919.466.1112  
F 919.516.2112  
bill.stewart@klgates.com

**Via Hand Delivery**

Craig R. Smith, Chief  
Certificate of Need Section  
Division of Health Service Regulation  
N.C. Department of Health and Human Services  
809 Ruggles Drive  
Raleigh, NC 27603



RE: Rex Hospital, Inc. – Exemption Notice for Acquisition of Replacement PET/CT System, Wake County

Dear Mr. Smith:

Our client, Rex Hospital, Inc. (“Rex”), seeks to acquire a Siemens Biograph mCT Excel Edition PET/CT system from Siemens Medical Solutions USA, Inc. (“Siemens”) (“Replacement Equipment”). The Replacement Equipment will replace Rex’s current Siemens Biograph PET/CT system (“Existing Equipment”). The Existing Equipment is currently housed in its own suite adjacent to Rex’s nuclear medicine department on the first floor in Rex Hospital located at 4420 Lake Boone Trail in Raleigh, North Carolina. The Replacement Equipment will be located in the same room. The purpose of this letter is to provide the Agency with notice and to request a determination that Rex’s purchase of the Replacement Equipment is exempt from Certificate of Need (“CON”) review under the replacement equipment exemption provisions contained in N.C. Gen. Stat. § 131E-184(a)(7).

The General Assembly has chosen to exempt certain, otherwise reviewable events from CON review. Among those exemptions is the acquisition of “replacement equipment,” defined as follows in the CON law:

“Replacement equipment” means equipment that costs less than two million dollars (\$2,000,000.00) 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.

See N.C. Gen. Stat. § 131E-176(22a).

To qualify for this exemption, the replacement equipment must (1) cost less than \$2,000,000 and (2) be “comparable” to the equipment it replaces. In addition, the existing

Craig R. Smith  
December 6, 2012  
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equipment must be “sold or otherwise disposed of when replaced.” Rex’s proposal qualifies for this exemption.

**A. Cost of the Replacement Equipment**

The total costs to acquire, install, and make operational the Replacement Equipment is \$1,726,850, which includes construction costs of \$131,850 and equipment costs of \$1,595,000. (See Exhibit 1, Quote for Replacement Equipment; Exhibit 2, Proposed Total Capital Cost; Exhibit 3, Existing Equipment Disposal Letter) The construction costs that are needed to install and make the Replacement Equipment operational are shown in quote for the Replacement Equipment on page three as “Design Construction Services – Site Modifications @ \$131,850.” (See Exhibit 1, Quote for Replacement Equipment; Exhibit 2, Proposed Total Capital Cost) No other construction-related costs will be incurred for this project. The remaining cost listed in the quote (\$1,595,000, which is derived from subtracting the construction costs of \$131,850 from total costs of \$1,726,850) is the cost of the Replacement Equipment itself. The cost for the removal of the Existing Equipment is included in the price quotation of \$1,595,000 for the Replacement Equipment itself. (See Exhibit 3, Existing Equipment Disposal Letter)

In combination, the cost for acquiring the Replacement Equipment, installation of the Replacement Equipment, and removal of the Existing Equipment represents a total capital cost of \$1,726,850. There will be no other construction costs or other capital costs associated with this replacement project. The cost is safely below the \$2,000,000 threshold.

**B. Comparable Equipment**

The CON rule codified as 10A N.C.A.C. 14C.0303 (the “Regulation”) defines “comparable medical equipment” in subsection (c) as follows:

“Comparable medical equipment” means equipment which is functionally similar and which is used for the same diagnostic or treatment purposes.

10A N.C.A.C. 14C.0303(c).

Rex intends to use the Replacement Equipment for substantially the same PET scans for which it currently uses the Existing Equipment. The Existing Equipment is a Siemens Biograph PET/CT system that was installed new at Rex in July 2003. This Existing Equipment has been used for PET scans since installation.

The Replacement Equipment will perform all procedures currently performed on the Existing Equipment. Although it possesses some expanded capabilities due to technological improvements, the Replacement Equipment will perform the same general range of PET

Craig R. Smith  
December 6, 2012  
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scans. The Replacement Equipment is therefore “comparable medical equipment” as defined in Subsection (c).

Furthermore, Rex does not intend to increase patient charges or per procedure operating expenses within the first 12 months after its acquisition. For further equipment comparison, please refer to Exhibit 4 (the Equipment Comparison Chart).

Subsection (d) of the regulation further provides:

(1) it has the same technology as the equipment currently in use, although it may possess expanded capabilities due to technological improvements; and

(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; and

(3) the acquisition of the equipment does 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.

10A N.C.A.C. 14C.0303(d). The Replacement Equipment will meet all three of the tests set out in Subsection (d). The Replacement Equipment satisfies the technology and functionality tests in Subsection (1) and (2) as discussed above and identified in the Comparison Chart (Exhibit 4). Moreover, Rex represents that use of the Replacement Equipment will not result in the types of expense or charge increase described in Subsection (d)(3).

**C. Disposition of Equipment**

As part of the proposal to acquire the Replacement Equipment from Siemens, Siemens will de-install and take possession of the Existing Equipment, which will not be re-sold or re-installed in North Carolina without appropriate CON approval. See Exhibit 3.

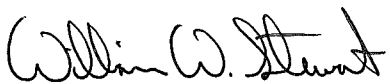
**CONCLUSION**

Based on the foregoing information, Rex hereby requests that the Agency provide a written response confirming that the acquisition of the Replacement Equipment described herein is exempt from CON review. If the Agency needs additional information to assist in its consideration of this request, please apprise us as soon as possible.

Craig R. Smith  
December 6, 2012  
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We thank you for your consideration of this notice.

Sincerely,

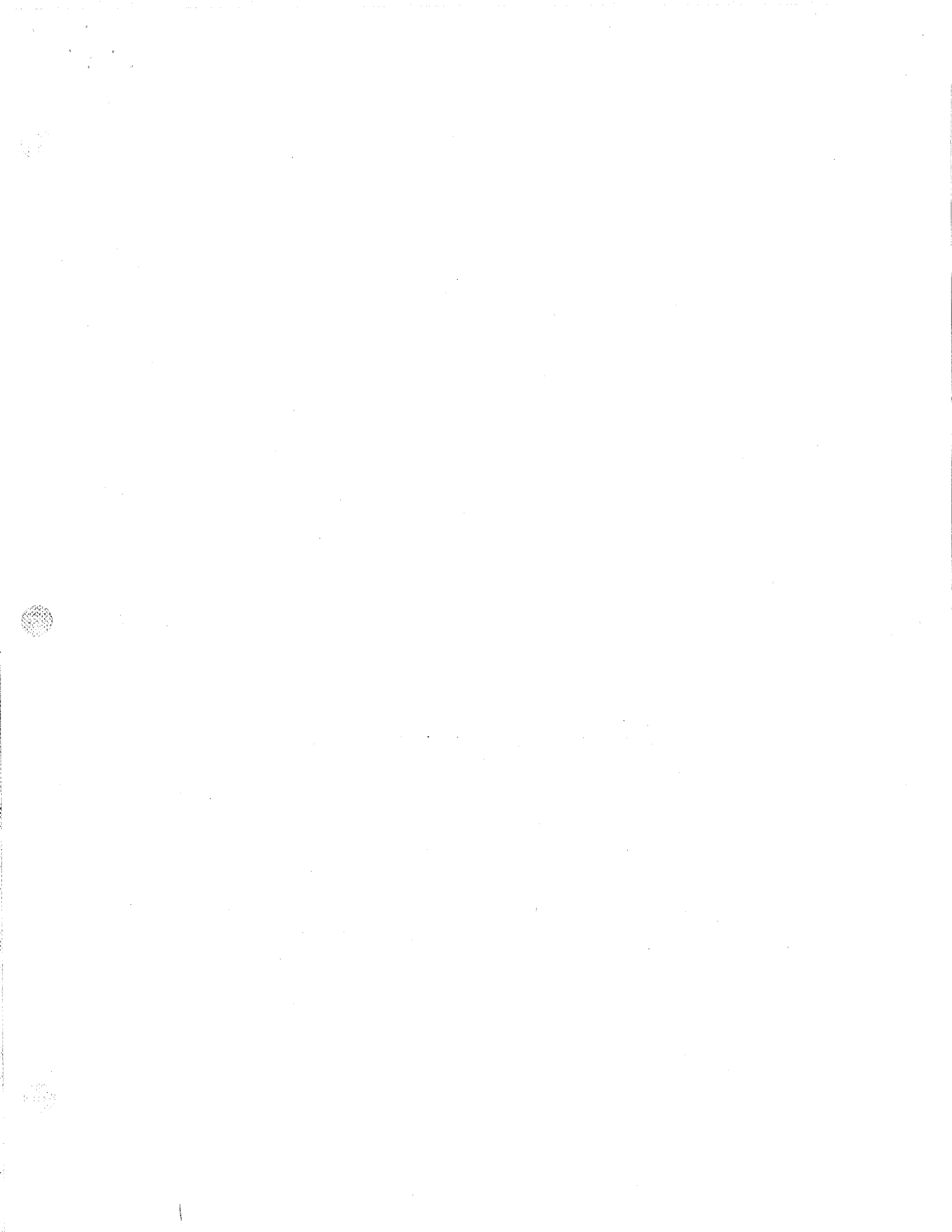
A handwritten signature in cursive script that reads "William W. Stewart". The signature is fluid and appears to be written in black ink.

William W. Stewart, Jr.

Craig R. Smith  
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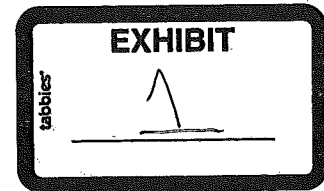
**Exhibits**

Exhibit 1	Price Quotation (PET/CT System)
Exhibit 2	Proposed Total Capital Cost Chart
Exhibit 3	Removal Letter from Siemens
Exhibit 4	Equipment Comparison Chart



# SIEMENS

Siemens Medical Solutions USA, Inc.  
51 Valley Stream Parkway, Malvern, PA 19355  
Fax: (866) 309-6992



SIEMENS REPRESENTATIVE  
Ed Winicki – (336) 688-0978

Customer Number: 0000009446

Date: 10/11/2012

**REX HOSPITAL**  
4420 LAKE BOONE TRAIL  
RALEIGH, NC 27607-7505

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<b>Quote Nr:</b>	<b>1-3DHTGZ Rev. 0</b>
<b>Terms of Payment:</b>	00% Down, 80% Delivery, 20% Installation Free On Board: Destination
<b>Purchasing Agreement:</b>	MedAssets

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## Siemens Biograph mCT-20 PET/CT System

Qty	Part No.	Item Description
1	14415398	<b>Biograph mCT 20 Excel</b>
1	14415351	<b>Install Kit with PDU – mCT</b> Items necessary for install. Includes power distribution unit for connecting entire system to a single 3-phase power drop.
1	14415353	<b>PET Gantry UPS – mCT</b> Uninterruptible Power Supply (UPS) option providing 10 minutes of backup power enabling proper shutdown of the PET system in the event of power loss. Specifications: 8.0 KVA, 230 Volts, 50/60 Hz.
1	10249096	<b>Cooling System Water/Air – mCT</b> Water-to-air heat exchanger for the dissipation of heat loss generated in the gantry to the outside air. System operating temperature: 20 - 26 degrees C, 15 - 75 % rel. humidity (not condensing). Ideal for installation far from the scan room. Cooling system contains to units, water/water exchanger close to the scan room and an additional remote water/air exchanger. Maximum distance between water/water unit and remote water/air exchanger up to 40 meters enabled by thin diameter of water transferring pipes.
1	10249267	<b>Cooling System US Install Kit – mCT</b> Kit for installation of the Cooling System Water/Air in US Includes: - Transformer for powering the Cooling System Water/Air - Service switch to shut off the outdoor cooling unit for maintenance or in case of emergency
1	10249560	<b>Biograph Ge-68 Sources</b> Calibration sources for the Biograph mCT. These sources are to be purchased with a new Biograph mCT scanner.
1	10097286	<b>Biogr. Uni. Phantom Shield-Fixed</b> Contains shield for the Biograph TrueV Uniform Phantom.
1	10249159	<b>Keyboard, English – mCT</b> Keyboard in the above-mentioned language.
1	10249167	<b>syngo Image Fusion (AWP) – mCT</b> Image Fusion package for spatial alignment and visualisation of image data of one patient where image data has been generated at different points in time or by different modalities. Support of optimal diagnosis (fusion of morphological and functional information) and therapy planning.



# SIEMENS

Siemens Medical Solutions USA, Inc.  
51 Valley Stream Parkway, Malvern, PA 19355  
Fax: (866) 309-6992

SIEMENS REPRESENTATIVE  
Ed Winicki – (336) 688-0978

Qty	Part No.	Item Description
1	14415354	<b>RTP Pallet</b> RTP Flat pallet for Biograph mCT. The carbon fiber table top utilizes a quick release latch for easy on/off. Varian Exact(tm) compatible indexing for accessories.
1	10412855	<b>Installation (US/CAN)</b>
1	10249181	<b>English Manual – mCT</b> Hardcopy of English Operator's Manual for Biograph mCT
1	10183139	<b>Elevate PET Senior systems</b> ELEVATE is the Siemens unique customer care solution that helps you get the most from your investment. Whether you're at the end of a product's lifecycle, the end of a lease, or the beginning of a new platform, the Elevate program rewards you as loyal customer with an attractive Bonus that makes it easy to transition from your current Siemens system to the new system.
1	MIPET_ELV_S NMCT20	<b>Elev PET Sen to mCT20 (-\$19,000)</b> Elevate Promo for Senior PET to a mCT20. Deinstall, freight, and/or scrapping is included in this offer.
1	10183117	<b>Elevate Service Bonus</b> Elevate – Managed system upgrade program Whether you're at the end of a product's lifecycle, the end of a lease, or the beginning of a new platform, Elevate can help you make the transition. We'll work with you through every phase of the process rewards you as loyal customer with an attractive Bonus that makes it easy to transition from your current Siemens system to the new system.
1	MI_PET_PM	<b>MI PET Project Management</b>
1	MI_PET_INITIA L_32	<b>Initial onsite training 32 hrs</b>
1	MI_PET_FLWU P_32	<b>Follow-up training 32 hrs</b>
1	7568103L	<b>Project Mgmt/Site Planning (US only)</b>
1	MIP_DEINSTA LL_EQP	<b>MI PET Deinstallation Equipment</b>
1	MIP_RIEDEL_ CHILLIN	<b>MI PET Riedel Chiller Start-up by SBT</b>
1	NU_PET_MISC _MATL	<b>Out of Scope Installation.</b>
1	ACRPHANTOM 464	<b>464 ACR Accreditation CT Phantom</b>
1	NUPET_FREIG HT_COST	<b>NU-Pet Freight Costs</b>
1	M2SCT212PET	<b>Stellant D PET/CT Inj. (ceiling)</b>
1	M2INTSYS200	<b>Medrad Intego PET Infusion System</b> M2INTSYS200 - Medrad Intego PET Infusion System Delivery of accurate doses of FDG and flushing solutions to patients as part of a PET or PET/CT procedure. Also intended to provide effective radiation shielding to medical personnel from radiation exposure during procedures. The Intego System: Contains an integrated ionization chamber that measures each FDG dose immediately prior to injection to enable more accurate delivery. Delivers each dose consistently within +/-2% of the measure dose. Has a saline test inject feature to verify vein patency. Automatically completes a saline flush to confirm that the entire FDG does is delivered to the patient, and to remove residual FDG from the line. Allows the user to enter a specific dose to deliver for each patient, or use MEDRAD's proprietary P3T technology to automatically calculate dose based on patient weight for easy set up. Automatically generates and prints per-patient and daily QC reports to reduce manual data logging and enable more accurate tracking of agent use. Includes installation, training and one year warranty through Medrad.
1	14415553	<b>Low contrast CT phantom – Biograph</b> Low contrast test phantom for system calibration and quality control.
1	10249558	<b>HI-REZ PET Processing # mCT (AWP)</b> Optimized image processing for maximum reconstructed image resolution for the most demanding clinical and research applications.

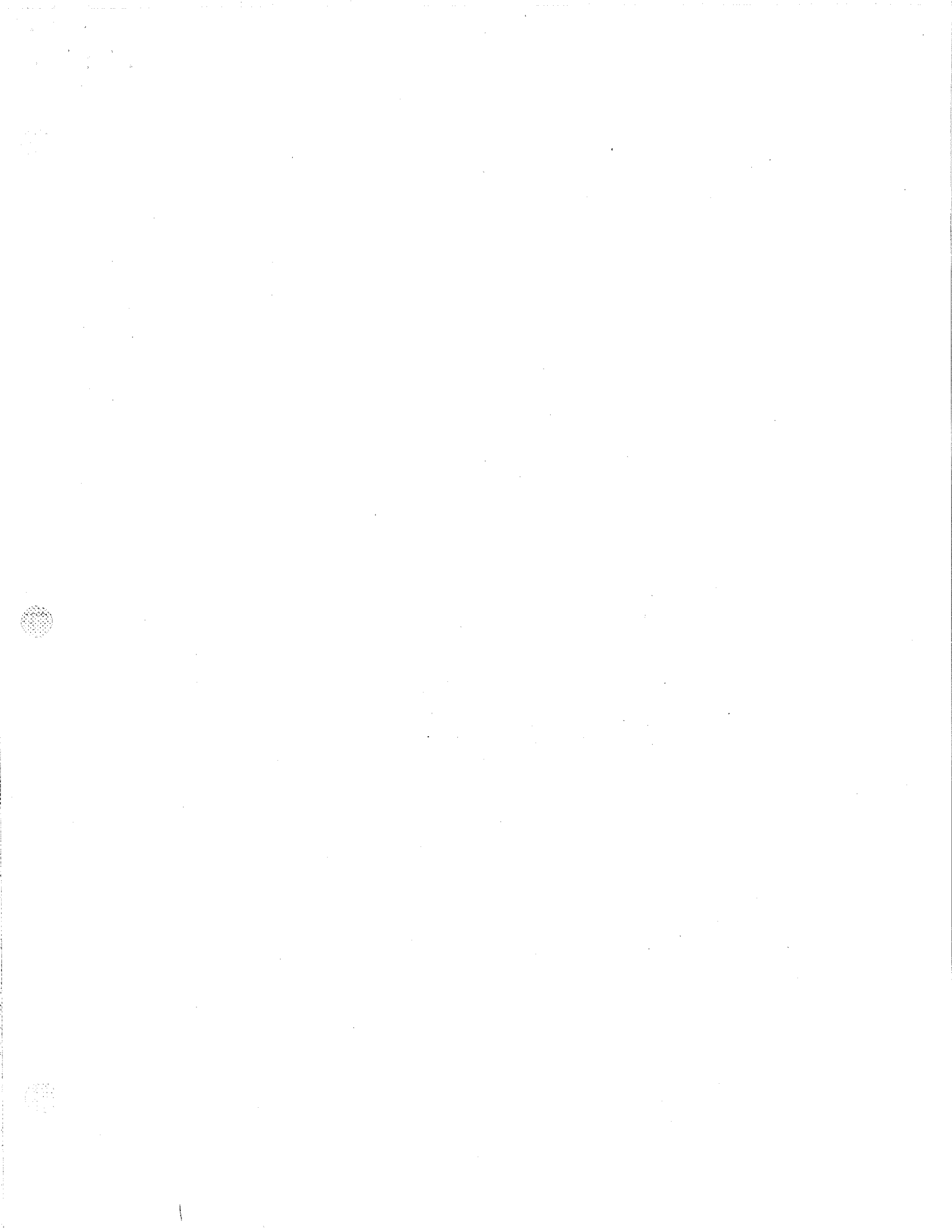
# SIEMENS

Siemens Medical Solutions USA, Inc.  
51 Valley Stream Parkway, Malvern, PA 19355  
Fax: (866) 309-6992

**SIEMENS REPRESENTATIVE**  
Ed Winicki – (336) 688-0978

Qty	Part No.	Item Description
1	08728912	<b>PET ACR Quality Phantom</b> ACR (American College of Radiology/Essex) Quality Phantom provides the ability to evaluate tumor detectability, attenuation and scatter correction.
1	DCS_Misc	<b>Design Construction Services – Site Modifications @ \$131,850</b> Site Modifications per DCS Proposal 12-26-1334 dated 9/20/2012 for Biograph mCT
		<b>Solution Total: \$1,726,850</b>

**FINANCING:** The equipment listed above may be financed through Siemens. Ask us about our full range of financial products that can be tailored to meet your business and cash flow requirements. For further information, please contact your local Sales Representative.



**PROPOSED TOTAL CAPITAL COST OF PROJECT**

**Project Name:** PET Scanner Replacement

**Provider/Company:** Rex Hospital, Inc.

**A. Site Costs**

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

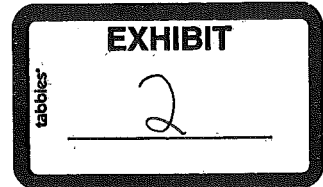
**B. Construction Contract**

- (8) Cost of Materials
  - General Requirements \$ \_\_\_\_\_
  - Concrete/Masonry \$ \_\_\_\_\_
  - Woods/Doors & Windows/Finishes \$ \_\_\_\_\_
  - Thermal & Moisture Protection \$ \_\_\_\_\_
  - Equipment/Specialty Items \$ \_\_\_\_\_
  - Mechanical/Electrical \$ \_\_\_\_\_
  - Other (Specify) \$ \_\_\_\_\_
- Sub-Total Cost of Materials..... \$ \_\_\_\_\_
- (9) Cost of Labor..... \$ \_\_\_\_\_
- (10) Other (Specify)..... \$ \_\_\_\_\_
- (11) **Sub-Total Construction Contract** \$ \_\_\_\_\_

**C. Miscellaneous Project Costs**

- (12) Building Purchase..... \$ \_\_\_\_\_
- (13) Fixed Equipment Purchase/Lease \$ 1,726,850 (includes \$1,595,000 equipment cost and \$131,850 for design construction services)
- (14) Movable Equipment Purchase/Lease \$ \_\_\_\_\_
- (15) Furniture \$ \_\_\_\_\_
- (16) Landscaping \$ \_\_\_\_\_
- (17) Consultant Fees
  - Architect and Engineering Fees \$ \_\_\_\_\_
  - Legal Fees..... \$ \_\_\_\_\_
  - Market Analysis..... \$ \_\_\_\_\_
  - Other (Specify) (Staff Costs) \$ \_\_\_\_\_
  - Other (Specify)..... \$ \_\_\_\_\_
- Sub-Total Consultant Fees..... \$ \_\_\_\_\_
- (18) Financing Costs (e.g. Bond, Loan, etc.) \$ \_\_\_\_\_
- (19) Interest During Construction. \$ \_\_\_\_\_
- (20) Other (Specify) \$ \_\_\_\_\_
- (21) **Sub-Total Miscellaneous..** \$ 1,726,850

(22) **Total Capital Cost of Project (Sum A-C above)** \$ 1,726,850.00



I assure that, to the best of my knowledge, the above capital costs for the proposed project are complete and correct and that it is my intent to carry out the proposed project as described.

Bernard M. Spang  
(Signature of Officer Authorized to Represent Provider/Company)

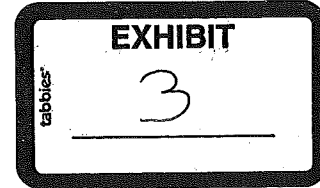
CFO  
(Title of Officer)



# SIEMENS

November 15, 2012

Rex Hospital  
Attn: Diana Massa  
Director of Heart and Vascular Services  
Rex Hospital  
Raleigh, NC 27607



Dear Diana Massa,

The purpose of this letter is to confirm that Siemens Medical Solutions USA, Inc. (Siemens) will be responsible for removing your Siemens Biograph PET/CT with Serial Number 3600214-01-0301021 ("existing equipment") installed at Rex Hospital in Raleigh, NC as part of your purchase of a Siemens Biograph mCT 20 Excel Edition PET/CT system. The cost for the deinstallation and removal is included in the price quotation for the replacement equipment, which totals \$ 1,595,000. There are no additional costs for deinstallation and removal.

We will work closely with you to ensure proper timing of the deinstallation. It is understood that Siemens will take possession of the existing equipment and will permanently remove it from the State of North Carolina. Siemens will not sell the existing equipment to any North Carolina facility unless the facility has the appropriate Certificate of Need approval as required by the State of North Carolina.

Sincerely,

A handwritten signature in black ink, appearing to read "Edwin Winicki".

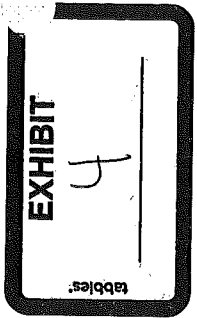
Edwin Winicki  
Key Account Executive  
Siemens Healthcare, USA

Siemens Healthcare, USA  
51 Valley Stream Parkway  
Malvern, PA 19351

[www.SiemensMedical.com](http://www.SiemensMedical.com)







EQUIPMENT COMPARISON

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	Siemens Biograph PET/CT System	Siemens Biograph mCT Excel Edition PET/CT System
Manufacturer of Equipment	Siemens	Siemens
Tesla Rating for MRIs	NA	NA
Model Number	3600214-01	Biograph mCT Excel Edition
Serial Number	0301021	Unknown
Provider's Method of Identifying Equipment	Serial number	Serial 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 of Each Component	July 2004	Pending Agency Approval
Does Provider Hold Title to Equipment or Have a Capital Lease?	Own	Own
Specify if Equipment was/Is New or Used When Acquired	New	New
Total Capital Cost of Project (Including Construction, etc.) <Use Attached Form>	Unknown	\$1,726,850 (includes \$1,595,000 equipment cost and \$131,850 for design construction services - site modifications)
Total Cost of Equipment		\$1,595,000
Fair Market Value of Equipment	Salvage	\$1,595,000
Locations Where Operated	Rex Hospital Raleigh, NC	Rex Hospital Raleigh, NC
Number of Days in Use/To Be Used in N.C. Per Year	365	365
Percent of Change in Patient Charges (by Procedure)	N/A	Less than 10%
Percent of Change in Per Procedure Operating Expenses (by Procedure)	N/A	Less than 10%
Type of Procedures Currently Performed on Existing Equipment	PET scans	
Type of Procedures New Equipment is Capable of Performing		PET scans