



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

Pat McCrory  
Governor

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

Drexdal Pratt  
Division Director

March 14, 2014

Colleen Crowley  
K & L Gates LLP  
Post Office Box 14210  
Research Triangle Park, NC 27709

**Exempt from Review - Replacement Equipment**

Facility: Carolinas Medical Center  
Project Description: Replace existing PET/CT scanner located in the Morehead Imaging Center in the Morehead Medical Plaza (MMP) which is on CMC's main campus  
County: Mecklenburg  
FID #: 943070

Dear Ms. Kirkman:

In response to your letter of February 7, 2014 the above referenced proposal is exempt from certificate of need review in accordance with N.C.G.S 131E-184(f). Therefore, you may proceed to acquire, without a certificate of need, the Siemens Biograph mCT-64 PET/CT System to replace the existing Siemens Duo PET/CT System (Serial # 0301010/0301029). 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 Branch 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 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,

*Fatimah Wilson*  
Fatimah Wilson  
Project Analyst

*Martha J. Frisone*  
Martha J. Frisone, Interim Chief  
Certificate of Need Section

cc: Medical Facilities Planning Branch, DHSR  
Construction Section, DHSR  
Acute and Home Care Licensure and Certification Section, DHSR  
Radiation Protection Section, DHSR



**Certificate of Need Section**

www.ncdhhs.gov  
Telephone: 919-855-3873 • Fax: 919-733-8139  
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



K&L Gates LLP  
Post Office Box 14210  
Research Triangle Park, NC 27709-4210  
430 Davis Drive, Suite 400  
Morrisville, NC 27560  
T 919.466.1190 www.klgates.com

February 7, 2014

Colleen M. Crowley  
D 919.466.1189  
F 919.516.2189  
colleen.crowley@klgates.com

**Via Hand Delivery**

Martha J. Frisone, Chief  
Certificate of Need Section  
Division of Health Service Regulation  
N.C. Department of Health and Human Services  
809 Ruggles Drive  
Raleigh, NC 27603

Received by  
the CON Section  
FEB 7 2014

RE: Carolinas Medical Center – Exemption Notice for Acquisition of Replacement  
PET/CT System, Mecklenburg County

Dear Ms. Frisone:

Our client, The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center (“CMC”) (See Exhibit 1, CMC’s License), seeks to acquire a Siemens Biograph mCT S (64) PET/CT system from Siemens Medical Solutions USA, Inc. (“Siemens”) (“Replacement Equipment”). The Replacement Equipment will replace CMC’s current Siemens Biograph PET/CT system (“Existing Equipment”). The Existing Equipment is currently housed and in use in the Morehead Imaging Center in the Morehead Medical Plaza (“MMP”) on CMC’s main campus located at 1000 Blythe Boulevard in Charlotte. The Replacement Equipment will be located at the same location. The purpose of this letter is to provide the Agency with notice and to request a determination that CMC’s purchase of the Replacement Equipment is exempt from Certificate of Need (“CON”) review under the replacement equipment exemption provisions contained in Session Law 2013-360, Section 12G.3(b) and Session Law 2013-363, Section 4.6 (which are codified at N.C. Gen. Stat. § 131E-184(f)(1)-(3)).

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) 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.

Martha J. Frisone, Chief

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See N.C. Gen. Stat. § 131E-176(22a). Under the new provisions found at N.C. Gen. Stat. § 131E-184(f)(1)-(3), the CON Law provides:

- (f) The Department shall exempt from certificate of need review the purchase of any replacement equipment that exceeds the two million dollar (\$2,000,000) threshold set forth in G.S. 131E-176(22) if all of the following conditions are met:
  - (1) The equipment being replaced is located on the main campus.
  - (2) The Department has previously issued a certificate of need for the equipment being replaced. This subdivision does not apply if a certificate of need was not required at the time the equipment being replaced was initially purchased by the licensed health service facility.
  - (3) The licensed health service facility proposing to purchase the replacement equipment shall provide prior written notice to the Department, along with supporting documentation to demonstrate that it meets the exemption criteria of this subsection.

See Session Law 2013-360, Section 12G.3(b) and Session Law 2013-363, Section 4.6. The term "main campus" was defined in Session Law 2013-360, Section 13G.3(a) (codified at N.C. Gen. Stat. § 131E-176(14n)) as follows:

- (14n) "Main campus" means all of the following for the purposes of G.S. 131E-184(f) and (g) only:
  - a. The site of the main building from which a licensed health service facility provides clinical patient services and exercises financial and administrative control over the entire facility, including the buildings and grounds adjacent to that main building.
  - b. Other areas and structures that are not strictly contiguous to the main building but are located within 250 yards of the main building.

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In addition to the foregoing, to qualify for this exemption, the replacement equipment must be "comparable" to the equipment it replaces and must be "sold or otherwise disposed of when replaced." CMC's proposal qualifies for this exemption.

**A. Cost of the Replacement Equipment**

The total cost to acquire, install, and make operational the Replacement Equipment is \$2,067,135 which includes construction costs of \$236,000, furniture costs of 6,275, architect and engineering fees of \$55,000, equipment costs of \$1,726,975 (\$1,704,325 for the PET/CT scanner and \$22,650 for the injector)<sup>1</sup>, and a contingency of \$42,885. (See Exhibit 2, Quote for Replacement Equipment; Exhibit 3, Injector Quote; Exhibit 4, Proposed Total Capital Cost Sheet; Exhibit 5 Certified Cost Letter) The construction cost of \$236,000 for making the proposed equipment operational is indicated in a certified cost letter from Georgia E. Abernethy, AIA, IIDA from BBH Design (See Exhibit 5, Certified Cost Letter) No other construction-related costs will be incurred for this project. The cost for the removal of the Existing Equipment is included in the price quotation of \$1,704,325 for the Replacement Equipment itself. (See Exhibit 6, 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 \$2,067,135. There will be no other construction costs or other capital costs associated with this replacement project.

**B. Equipment Being Replaced is Located on the Main Campus and Currently in Use**

The Existing Equipment is currently located in the Morehead Imaging Center located within MMP on CMC's main campus in Pet Scan Room 1088 (Control Room 1078 and Chiller/Equipment Room 1089). (See Exhibit 7, Floor Plan at MMP) The Replacement Equipment will be placed in the same location. As the site plan, attached as Exhibit 8, shows MMP is part of the main campus, pursuant to N.C. Gen. Stat. § 131E-176(14n)(a). MMP is attached to Morehead Center Plaza ("MCP") which is attached to the main building of CMC. The buildings are attached via climate controlled sky bridges. As a result, MMP is part of the "main building" at CMC.

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<sup>1</sup> No taxes have been included for the equipment cost because CMC is entitled to a sales tax refund for under N.C. Gen. Stat. § 105-164.14(b) and 105-467. Any sales tax incurred on medical equipment by CMC in connection with this project will be refunded.

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Alternatively, MMP is also part of CMC's main campus pursuant to N.C. Gen. Stat. § 131E-176(14n)(b). MMP is located less than 250 yards from the main building at CMC. In fact, the distance between the buildings is approximately 327 feet. (See Exhibit 8, CMC Site Plan)

Clinical patient services are provided at the main campus of CMC, which is where the Existing Equipment is located. (See Exhibit 8, CMC Site Plan) Financial control of CMC is exercised from the main campus of CMC, which is where the Existing Equipment is located. (See Exhibit 8, CMC Site Plan) Administrative control of CMC is exercised from the main campus of CMC, which is where the Existing Equipment is located. (See Exhibit 8, CMC Site Plan)

The Existing Equipment is currently treating patients at CMC. In 2013, the Existing Equipment performed 1,381 procedures on patients. A break down of the number of procedures performed in 2013 by month is attached in Exhibit 9.

**C. Department Previously Issued CON for Equipment Being Replaced**

On July 18, 1990 CMC received a CON (Project ID # F-3602-89) to acquire a PET scanner and cyclotron ("PET Scanner A"). (See Exhibit 10a, CON for PET Scanner A) On June 24, 2003, CMC received a CON (Project ID # F-6781-03) to replace PET Scanner A with a PET/CT scanner ("PET Scanner B"). (See Exhibit 10b, CON for PET Scanner B) On November 10, 2003, CMC acquired PET Scanner B, a Siemens Biograph Duo PET/CT scanner which is currently in use. On October 7, 2005, CMC filed a Letter of No Review with the Agency advising the Agency of its plan to relocate PET Scanner B to MMP. (See Exhibit 10c, No Review Letter to relocate PET Scanner B to MMP) CMC seeks to replace the Existing Equipment, PET Scanner B, which it developed pursuant to a CON.

**D. 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).

CMC 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

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Biograph PET/CT system that was installed new at CMC in November 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 scans. (See Exhibit 11, Equipment Brochure) The Replacement Equipment is therefore "comparable medical equipment" as defined in Subsection (c).

Furthermore, CMC 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 12, 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 (See Exhibit 13). Moreover, CMC represents that use of the Replacement Equipment will not result in the types of expense or charge increase described in Subsection (d)(3).

**E. 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 6)

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**CONCLUSION**

Based on the foregoing information, CMC 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.

We thank you for your consideration of this notice.

Sincerely,

*Colleen M. Crowley*

Colleen M. Crowley

Martha J. Frisone, Chief  
February 7, 2014  
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**Exhibits**

Exhibit 1	CMC's License
Exhibit 2	Price Quotation (PET/CT System)
Exhibit 3	Price Quotation (Injector)
Exhibit 4	Proposed Total Capital Cost Chart
Exhibit 5	Certified Cost Letter
Exhibit 6	Existing Equipment Disposal Letter
Exhibit 7	Floor Plan at MMP
Exhibit 8	CMC Site Plan (includes measured distance)
Exhibit 9	Procedures Performed on Existing Equipment in 2013
Exhibit 10a	CON for PET Scanner A
Exhibit 10b	CON for PET Scanner B
Exhibit 10c	No Review Letter to relocate PET Scanner B to MMP
Exhibit 11	Equipment Brochure
Exhibit 12	Equipment Comparison Chart

# State of North Carolina

## Department of Health and Human Services Division of Health Service Regulation

*Effective January 01, 2014, this license is issued to  
The Charlotte-Mecklenburg Hospital Authority*

*to operate a hospital known as  
Carolinas Medical Center/Center for Mental Health  
located in Charlotte, North Carolina, Mecklenburg County.*

*This license is issued subject to the statutes of the  
State of North Carolina, is not transferable and shall remain  
in effect until amended by the issuing agency.*

*Facility ID: 943070*

*License Number: H0071*

**Bed Capacity: 1066**

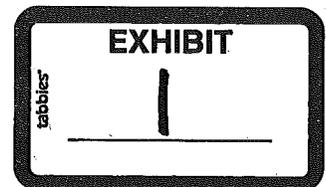
*General Acute 976, Rehabilitation 13, Psych 66, Substance Abuse 11,*

**Dedicated Inpatient Surgical Operating Rooms: 10**

**Dedicated Ambulatory Surgical Operating Rooms: 11**

**Shared Surgical Operating Rooms: 26**

**Dedicated Endoscopy Rooms: 9**



**Authorized by:**

*Adona Williams, M.D.*

Secretary, N.C. Department of Health and  
Human Services



*Dwight R. [Signature]*  
Director, Division of Health Service Regulation

**SIEMENS**

Siemens Medical Solutions USA, Inc.  
51 Valley Stream Parkway, Malvern, PA 19355



**SIEMENS REPRESENTATIVE**  
Donald Werner - (865) 548-6348

Customer Number: 0000035965

Date: 12/19/2013

**CAROLINAS HEALTHCARE SYSTEM**  
1000 BLYTHE BLVD  
CHARLOTTE, NC 28203

Siemens Medical Solutions, USA, Inc. is pleased to submit the following quotation for the products and services described herein at the stated prices and terms, subject to your acceptance of the terms and conditions on the face and back hereof, and on any attachment hereto.

**Quote Nr:** 1-7S13F2 Rev. 0

**Trade:** Siemens Biograph Duo : S/N P0005408-0301010

**Terms of Payment** 00% Down, 90% Delivery, 10% Installation  
Free On Board: Destination

**Purchasing Agreement** Premier

**Terms and Conditions** Premier terms and conditions apply

**Proposal Valid Until** 6/30/2014

**Siemens Biograph mCT-64 PET/CT System**

All items listed below are included for this system:

Qty	Part No.	Item Description
1	10248471	<b>Biograph mCT-S(64)</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, 20 - 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.

# SIEMENS

Siemens Medical Solutions USA, Inc.  
51 Valley Stream Parkway, Malvern, PA 19355

**SIEMENS REPRESENTATIVE**  
Donald Werner - (865) 548-6348

Qty	Part No.	Item Description
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	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.
1	10504243	<b>PET Time-of-Flight-mCT (AWP)</b> Utilizing timing information (time-of-flight) between the two PET coincidence events, PET Time-of-Flight option provides improved image signal-to-noise which can be used to either enhance image quality and/or reduce patient acquisition time. With a system timing resolution of 555 ps, the PET Time-of-Flight option allows clinicians to realize the benefits of time-of-flight reconstruction.
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	14421151	<b>English Manual - mCT</b> Hardcopy of English Operator's Manual for Biograph mCT
1	MI_PET_PM	<b>MI PET Project Management</b> A Siemens Project Manager (PM) will be the single point of contact for the implementation of your Siemens 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	MI_PET_ADD_16	<b>Additional onsite training 16 hours</b> Up to (16) 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 if applicable. 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	MI_PET_ADD_32	<b>Additional onsite training 32 hours</b> 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 if applicable. 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	7568103L	<b>Project Mgmt/Site Planning (US only)</b>
1	NMPET_ADDL_RIGGING	<b>Additional Rigging NMPET \$7,400</b>
1	MIPET_BIOME_D_TRN	<b>Biomedical Training PET, XX1RADSFVC- (8 Hrs) virtual radiation \$1,500</b>
1	MIPET_BIOME_D_TRN	<b>Biomedical Training PET MI2BIOTRIN (4 Days) \$6,900.00</b>
1	MIPET_BIOME_D_TRN	<b>Biomedical Training PET MI2PHSLMAS (4 Days) \$6,000.00</b>

# SIEMENS

Siemens Medical Solutions USA, Inc.  
51 Valley Stream Parkway, Malvern, PA 19355

**SIEMENS REPRESENTATIVE**  
Donald Werner - (865) 548-6348

Qty	Part No.	Item Description
1	MIPET_BIOME D_TRN	<b>Biomedical Training PET MI2BIOSW (2 Days) \$3,000.00</b>
1	MIPET_BIOME D_TRN	<b>Biomedical Training PET MI1CTBASIC (5 Days) \$8,400.00</b>
1	MIPET_BIOME D_TRN	<b>Biomedical Training PET MI2CTDEF (5 Days) \$8,700.00</b>
1	MIPET_ELV_B 16	<b>Elev Bio16 (\$5,000)</b> Deinstall, freight, and/or scrapping is included in this offer.
1	MIP_RIEDEL_ CHILLIN	<b>MI PET Riedel Chiller Start-up by SBT</b>
1	MIPET_RECO N192	<b>mCT64 slice config.z-Sharp Techn. w.192</b> The unique STRATON X-ray source utilizes an electron beam that is accurately and rapidly deflected, creating two precise focal spots alternating 4,608 times per second. This doubles the X-ray projections reaching each detector element. The two overlapping projections result in an oversampling in z-direction. The resulting measurements interleave half a detector slice width, doubling the scan information without a corresponding increase in dose. Siemens' proprietary UFC (Ultra Fast Ceramic) detectors and the corresponding 64-slice detector electronics enable a virtually simultaneous readout of two projections for each detector element - resulting in a full 64-slice acquisition. This sampling scheme is identical to that of a 64x 0.3 mm allowing for reconstruction of 192 slices using 0.1 mm reconstruction interval increment. z-Sharp Technology, utilizing the STRATON X-ray sources and the UFC detectors, provides scan speed independent visualization of 0.33 mm isotropic voxels and a corresponding elimination of spiral artifacts in the daily clinical routine at any position within the scan field.
1	MIP_EOS_TM_ BONUS	<b>MI PET EOS Promo</b>
		<b>System Total: \$1,704,325</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.

Bayer HealthCare



**Quotation**

Quote To:  
Carolina's Medical Center  
1000 Blythe Blvd  
CHARLOTTE NC 28203-5871  
USA

Bayer HealthCare LLC  
c/o Medrad Inc

Order number: 0020007662  
Customer number: 0003142660  
Date: 01/17/2014  
PO Number: SCT 322  
Page: 1

Valid from: 01/17/2014 to 03/17/2014

Trey Karn  
Professional Sales Consultant  
864-415-2397  
trey.karn@bayer.com

PET/CT project

**We deliver according to the following terms and conditions:**

**Currency: USD**

**Terms of payment:** 30 d. w/o discount of inv. net  
**Terms of delivery:** Carriage paid FOB Destination

Item	Part No	Qty	Unit Price	UoM	Amount
1	81058881	1 PCE	49,500.00	1 PCE	49,500.00
	SYSTEM,DUAL,STELLANT WITH CERTEGRA WKS				
	Manual Item Discount				8,955.00-
	FLP Man.% Discount		41.00-		20,295.00-
2	84433765	1 PCE		PCE	
	OCS, 580mm CEILING MOUNT, PORTEGRA2				
3	INS SCT CS INF	1 NRQ	3,650.00	1 NRQ	3,650.00
	INSTALLATION - STELLANT W/CS-INFORMATICS				
	Manual Item Discount				1,250.00-
<b>Total</b>					<b>22,650.00</b>

**When applicable, State and Local taxes will be calculated on the order. If you are exempt from taxes, contact customer support at 1(800)633-7231**

**If pricing and terms of this order are based upon your current Group Purchasing Organization (GPO) affiliation, any change to your current affiliation may require a new quote or updated terms and pricing.**

**THANK YOU FOR YOUR ORDER**

Bayer HealthCare



## Quotation

**NOTE: If using signed quote as a purchase order please complete the following information:**

Print Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Title: \_\_\_\_\_

PO #: \_\_\_\_\_

Phone #: \_\_\_\_\_

**When applicable, State and Local taxes will be calculated on the order. If you are exempt from taxes, contact customer support at 1(800)633-7231**

**If pricing and terms of this order are based upon your current Group Purchasing Organization (GPO) affiliation, any change to your current affiliation may require a new quote or updated terms and pricing.**

**THANK YOU FOR YOUR ORDER**

# Bayer HealthCare



## BAYER PRODUCT TERMS AND CONDITIONS

If Customer is a member of a group purchasing organization ("GPO") who has a contract with Bayer, the terms of that GPO Agreement will supercede the terms herein.

The following terms and conditions will not apply to the license of Bayer's Radimetrics or Certegra products. Such products are subject to a separate license agreement.

1. **Modifications.** The prices and terms on this Quote are not subject to verbal changes or other agreements unless approved in writing by Bayer.
2. **Acceptance.** Bayer's products and services are sold only under the terms and conditions stated on this quotation. Acceptance of any Purchase Order is expressly and exclusively made conditional on your assent to these terms and conditions. Any different or additional terms and conditions that may appear in your Purchase Order or any other document sent by you, shall have no effect. Bayer expressly objects to and rejects all inconsistent or additional terms, conditions and limitations contained on any of your forms or other writings. If you do not communicate your objection to these terms and conditions in writing and within a reasonable time, or if you accept the goods covered by this Quote, you will be deemed to have accepted these terms and conditions and they will control in all instances. If the Products include embedded software or if you are purchasing software, **BY HAVING THE SOFTWARE INSTALLED AND USING THE SOFTWARE PURCHASED HEREUNDER, YOU AGREE TO BE BOUND BY THE TERMS OF THIS AGREEMENT. IF YOU DO NOT AGREE TO THE TERMS OF THIS QUOTE, DO NOT INSTALL OR USE THE SOFTWARE AND NOTIFY BAYER IMMEDIATELY.**
3. **Pricing.** Prices are based on costs and conditions existing on the date of this Quote and may be changed by Bayer before final acceptance. The pricing for products provided pursuant to this Quote may reflect or be subject to discounts, rebates, or other price reduction programs. Please be advised that you are obligated to: a) fully and accurately disclose the amount of any such discounts, rebates, or other price reductions in your cost reports or claims for reimbursement to Medicare, Medicaid, or health care programs requiring such disclosure and b) provide such documentation to representatives of the Secretary of the Department of Health and Human Services and state agencies upon request. Unless noted otherwise, the value of any product listed as \$0.00 on this Quote may constitute a discount that you should evaluate when filing such reports. You may request additional information from Bayer in order to meet your reporting or disclosure obligations, by writing to the address set forth in this Quote. All payments are due net thirty (30) days on the total invoiced amount. For all new customers Bayer requires a thirty percent (30%) pre-payment for all capital equipment orders, unless otherwise agreed to by Bayer. Bayer must approve any payment terms other than net thirty (30) days.
4. **Shipping.** All shipping dates are tentative. Bayer will make every reasonable effort to meet shipping dates referenced in this Quote. However, Bayer will not be liable for its failure to meet any such date.
5. **Installation.** The cost of installation is not included in the product price and is your responsibility unless otherwise stated. For details on equipment installation, you should consult with your Bayer Sales Representative or refer to your Products Manual, which is included with your equipment.

If this Quote includes installation of an overhead counterpoise system (OCS) it is your responsibility to ensure a suitable mounting location for the system. The counterpoise ceiling plate is required to be installed prior to Bayer installation of the counterpoise system and installed in accordance with the specifications listed in the installation manual. The OCS ceiling plate should always be installed by a qualified Structural Engineer and/or Architect. In addition, if applicable building codes require the use of a conduit, you are responsible for ensuring that a conduit is available prior to Bayer's installation.

If this Quote includes a Certo wireless network it is your responsibility to ensure the approval of the Information Technology Department to allow the operation of the wireless network at your site.

If this Quote includes a Spectris Solaris with an Integrated Continuous Battery Charging System (iCBC), installation will require a standard power outlet in the scan room, or authorization to install a filter through the penetration panel.
6. **License.** If the Products include embedded software, or if you are purchasing software, Bayer grants to you a non-exclusive license to use such software provided by Bayer, solely in connection with, or to operate, the Products. Use of the software for any other purpose is strictly prohibited. This license is effective on the date you begin using the Products and software and will continue in effect unless you return the Products or software or if the license is terminated because

**Please reference the quote number on your PO and fax to 412-406-0952**

# Bayer HealthCare



you breach any provision of these Terms. Upon termination you shall immediately cease use of all software and shall return the Products and software to Bayer. The software copyright is owned by Bayer and is protected by United States copyright laws and international treaty provisions. Bayer does not transfer title to the software to you, but retains the rights to make and license the use of all copies. You shall not copy, translate, disassemble, or decompile nor create or attempt to create, by reverse engineering or otherwise, the source code from the object code of the software. You are not permitted to modify or make derivative works of the software and ownership of any unauthorized modification or derivative work shall vest in Bayer.

7. Warranty. Bayer warrants that all new Bayer products are free from defects in workmanship or material under proper, normal use and service for a period of one year (12 months) from shipment, unless a longer period is provided on the warranty with the products, or as otherwise provided herein.

Bayer warrants that all refurbished Bayer products shall perform in accordance with the documentation provided, under proper, normal use and service for a period of the shorter of a) 90 days from installation or b) six months from shipment, unless a longer period is provided on the warranty with the products, or as otherwise provided herein.

If this Quote includes a Monitor, peripheral accessories on the Monitor such as pulse oximeter sensors, extension cables, power cables, fiber optic cables, ECG leads, capnography accessories (excluding patient connections), blood pressure cuffs, batteries, and extension tubing are warranted for a period of 90 days from the date of installation, but not to exceed six months from the date of shipment.

If this Quote includes disposable products or angiographic catheters, Bayer's warranty shall be limited to repair or replacement of any defective disposable product or angiographic catheter upon receipt of the defective product and a Bayer Return Goods Authorization. You acknowledge that the disposables and the equipment are a system and your actions regarding your equipment may invalidate your warranty on the disposables.

During the warranty period, there shall be no charge for any action deemed necessary by Bayer, including parts, travel, or labor to fulfill the terms of the warranty, during local business hours of 8:30 a.m. to 5:00 p.m., Monday through Friday, except holidays.

Your actions may invalidate this warranty. If Bayer determines that an equipment or disposable problem is due to any of the following, you agree to pay Bayer for all labor, travel, material handling and shipping at Bayer's, or Bayer's agents, standard rates:

- a) Malfunction or damage due to spillage of any type of fluid in or on the unit.
- b) Malfunction due to operator error, including failing to follow specified provisions of the Operations Manual.
- c) Malfunction or damage due to unauthorized modification or repair. Unauthorized actions may jeopardize functionality, reliability, or operator and patient safety. Therefore any unauthorized modification or repair shall render this warranty void and relieve Bayer from any further obligation. Bayer must review and authorize all modifications and repairs. This service may be obtained by contacting the Bayer Service Department.
- d) Malfunction or damage due to the use of non-Bayer or non-approved accessories. The use of accessories in connection with the equipment may jeopardize functionality, reliability or operator and patient safety. Therefore any use of non-Bayer or non-approved accessories (such as non-Bayer disposables or in the case of any PET/CT product, the use of vials or vial shields that are not approved by Bayer) shall render this warranty void and relieve Bayer from any further obligation.
- e) Damage by fire, floods, or other disaster commonly known as "Acts of God".
- f) If the Products include any Counterpoise system, any system malfunction, damage or failures due to improper installation or not meeting Bayer's specific requirements for level and plumb and/or loading as specified in the Bayer manuals.
- g) If the Products include any Counterpoise system, any ceiling or wall support structure used to mount or support an Injector Head Counterpoise System is excluded from Bayer's warranty. Bayer does not in any way warrant such structure.

8. Warranty Exclusions. EXCEPT AS PROVIDED IN THE ABOVE WARRANTY SECTION, BAYER EXPRESSLY DISCLAIMS ALL WARRANTIES OR CONDITIONS OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, IMPLIED WARRANTIES OF MERCHANTABILITY,

**Please reference the quote number on your PO and fax to 412-406-0952**

# Bayer HealthCare



NONINFRINGEMENT AND FITNESS FOR A PARTICULAR PURPOSE (WHETHER OR NOT BAYER IS AWARE OF YOUR INTENDED USE OF THE PRODUCT), AND ALL SUCH WARRANTIES ARE EXPRESSLY EXCLUDED. IN NO EVENT SHALL BAYER BE LIABLE FOR ANY LOST PROFITS OR INCIDENTAL OR CONSEQUENTIAL DAMAGES ARISING OUT OF OR IN CONNECTION WITH THE USE OR OPERATION OF BAYER'S PRODUCT OR SERVICE. Some states do not allow the exclusions on limitation of incidental or consequential damages, so the above limitations may not apply. This Limited Warranty gives you specific legal rights and you may also have other rights.

9. Software Warranty. If the Products include embedded software or if you are purchasing software, Bayer warrants that the software will substantially conform to the functional specifications contained in the Operations Manual for one year following delivery. This warranty shall not apply if you use the software in a manner that is not authorized or not in accordance with the user instructions or if you modify the Products or the software or if a party other than Bayer provides service to the Products or software. Bayer does not warrant that the software will operate uninterrupted or that it will be free from minor defects or errors that do not materially affect its performance. Your sole and exclusive remedy for any damages or loss in any way connected with the software whether due to Bayer's negligence or breach of any other duty shall be, at Bayer's option: i) to bring the performance of the software into substantial compliance with the functional specifications or ii) return of an appropriate portion of any payment by you with respect to the portion of the software that is not functioning.

10. Indemnification. Bayer agrees to indemnify, defend and hold you harmless from any liability, loss, expense, cost, claim or judgment (including attorneys fees), arising out of any claim for property damage, or personal injury or death where the product is alleged to have caused or contributed to the damage, injury or death, provided that this indemnification does not extend to injuries, damages or death to the extent caused by the negligence, reckless disregard or intentional acts of you or any third party.

11. Force Majeure. Bayer will not be responsible for delays or non-performance directly or indirectly caused by any acts of God, fire, explosion, flood, war, accident, action by governmental authority, inability to procure supplies and raw materials, delays in transportation, work stoppage, court order, and other causes beyond Bayer's reasonable control.

12. Compliance With Laws/Export. In addition to any rights and remedies specifically identified here in this Quote, Bayer shall have all rights and remedies conferred by law. Bayer shall not be required to perform its obligations under this Quote if you have defaulted (e.g. failed to pay) under this Quote or any other contract involving Bayer. This Agreement shall be construed in accordance with the laws of the Commonwealth of Pennsylvania, United States of America. You warrant that you are and will remain in compliance with all export and reexport requirements, laws and regulations of the United States of America and any other applicable export and reexport laws and regulations.

13. HIPAA. Bayer represents that it is not a Business Associate as defined in the Health Insurance Portability and Accountability Act ("HIPAA"). The functions Bayer is required to perform hereunder do not require the use or disclosure of Protected Health Information ("PHI"). To the extent any disclosure of PHI does occur, it is incidental and covered under the incidental disclosure rule found in 45 CFR 164.502(a)(1). In addition, to the extent any such incidental disclosure does occur, Bayer agrees to keep all such information confidential.

**Please reference the quote number on your PO and fax to 412-406-0952**

**Attachment 4 - PROPOSED TOTAL CAPITAL COST OF PROJECT**

**Project name:** 2606859 CMC PET/CT Equipment Replacement, MMP I

**Provider/Company:** BBH Design, PA

**A. Site Costs**

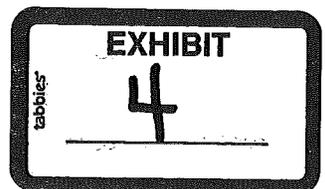
(1) Full purchase price of land	_____	
Acres	_____	
Price per Acre	\$ _____	
(2) Closing costs	_____	
(3) Site Inspection and Survey	_____	
(4) Legal fees and subsoil investigation	_____	
(5) Site Preparation Costs		
Soil Borings	_____	
Clearing-Earthwork	_____	
Fine Grade for Slab	_____	
Roads-Paving	_____	
Concrete Sidewalks	_____	
Water and Sewer	_____	
Footing Excavation	_____	
Footing Backfill	_____	
Termite Treatment	_____	
Other (Specify)	_____	
Sub-Total Site Preparation Costs	_____	
(6) Other (Specify)	_____	
(7) <b>Sub-Total Site Costs</b>	_____	<b>\$0</b>

**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) <b>Sub-Total Construction Contract</b>	_____	<b>\$236,000</b>

**C. Miscellaneous Project Costs**

(12) Building Purchase	_____	
(13) Fixed Equipment Purchase/Lease	_____	<b>\$1,726,975</b>
(14) Movable Equipment Purchase/Lease	_____	
(15) Furniture	_____	<b>\$6,275</b>
(16) Landscaping	_____	
(17) Consultant Fees		
Architect and Engineering Fees	_____	<b>\$55,000</b>
Legal Fees	_____	
Market Analysis	_____	
Other (Specify)	_____	
Other (Abatement)	_____	
Sub-Total Consultant Fees	_____	
(18) Financing Costs (e.g., Bond, Loan, etc.)	_____	<b>0</b>
(19) Interest During Construction	_____	<b>0</b>
(20) Other (Contingency)	_____	<b>\$42,885</b>
(21) <b>Sub-Total Miscellaneous</b>	_____	<b>\$1,831,135</b>
(22) <b>Total Capital Cost of Project (Sum A-C above)</b>	_____	<b>\$2,067,135</b>



Attachment 4 - PROPOSED TOTAL CAPITAL COST OF PROJECT

**Project Name:** CMC PET/CT Scan Replacement  
**Provider/Company:** DesignStrategies

*I certify that, to the best of my knowledge, the above construction related costs of the proposed project named above are complete and correct.*



---

*(Signature of Licensed Architect or Engineer)*

September 27, 2013

Mr. Jack Chamblee  
Carolinas HealthCare System  
PO Box 32861  
Charlotte NC 28232-2861

P.O. Box 33308  
Charlotte  
North Carolina 28233

T 980 321 4400  
F 980 321 4399  
www.bbh-design.com

**Re: Carolinas HealthCare System  
Carolinas Medical Center  
P1306.00 CMC PET/CT  
*Certificate of Need Application***

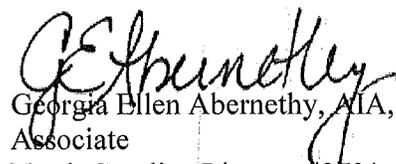
Dear Mr. Chamblee,

Having worked with Carolinas HealthCare System to develop the design for the referenced project, BBH Design is pleased to provide the cost certification letter.

The estimated cost of construction is based on our experience, the input of Tyler 2 Construction, and their recent construction experience with Carolinas HealthCare System. Based on this collective information, BBH Design PA certifies a construction cost of \$236,000.00.

Please contact our office if you have any questions.

Sincerely,  
BBH Design, PA

  
Georgia Ellen Abernethy, AIA, IIDA  
Associate  
North Carolina License #9731

g



# SIEMENS

January 27, 2014

Carolinas Healthcare System  
Attn: Mr. Jeff Aho  
Associate Vice President  
Carolinas Medical Center  
1000 Blythe Boulevard  
Charlotte, NC 28203

Dear Jeff Aho,

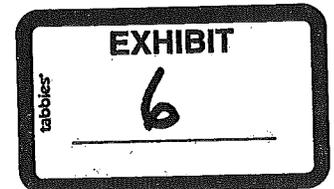
The purpose of this letter is to confirm that Siemens Medical Solutions USA, Inc. (Siemens) will be responsible for removing your existing Siemens Biograph Duo with Serial Number 0301010 ("existing equipment") as part of your purchase of the Siemens Biographs mCT-64 for Carolinas Medical Center. The cost for the deinstallation and removal is included in the price quotation for the replacement equipment, which totals \$1,704,325.

The system will be removed from Service by a broker designated by Siemens for either resale purposes or parts. The system will not be placed into Service by Siemens in North Carolina without proper state approvals.

Sincerely,



Edwin Winicki  
Key Account Executive  
Siemens Healthcare, USA



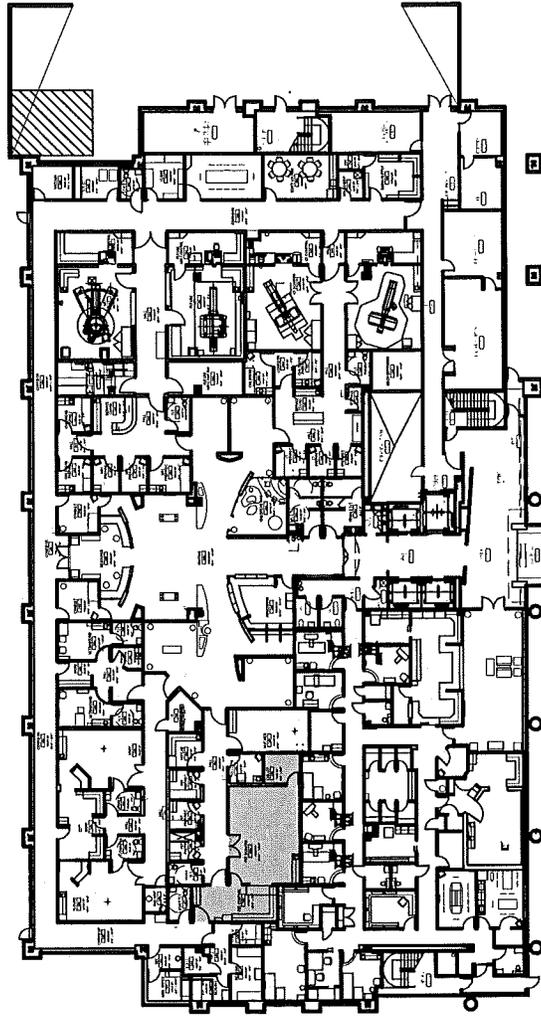
Siemens Healthcare, USA  
51 Valley Stream Parkway  
Malvern, PA 19351

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

COLOR KEY

EXISTING BUILDING

RENOVATION



# MMP FIRST FLOOR

MOREHEAD MEDICAL PLAZA (MMP) PET/CT REPLACEMENT

Carolinas HealthCare System

JANUARY 21, 2014

Charlotte, NC





**CAROLINAS**  
**HEALTHCARE SYSTEM**  
 PROJECT & CONSTRUCTION MANAGEMENT  
 4829 Airport Center Parkway  
 Charlotte, NC 28226

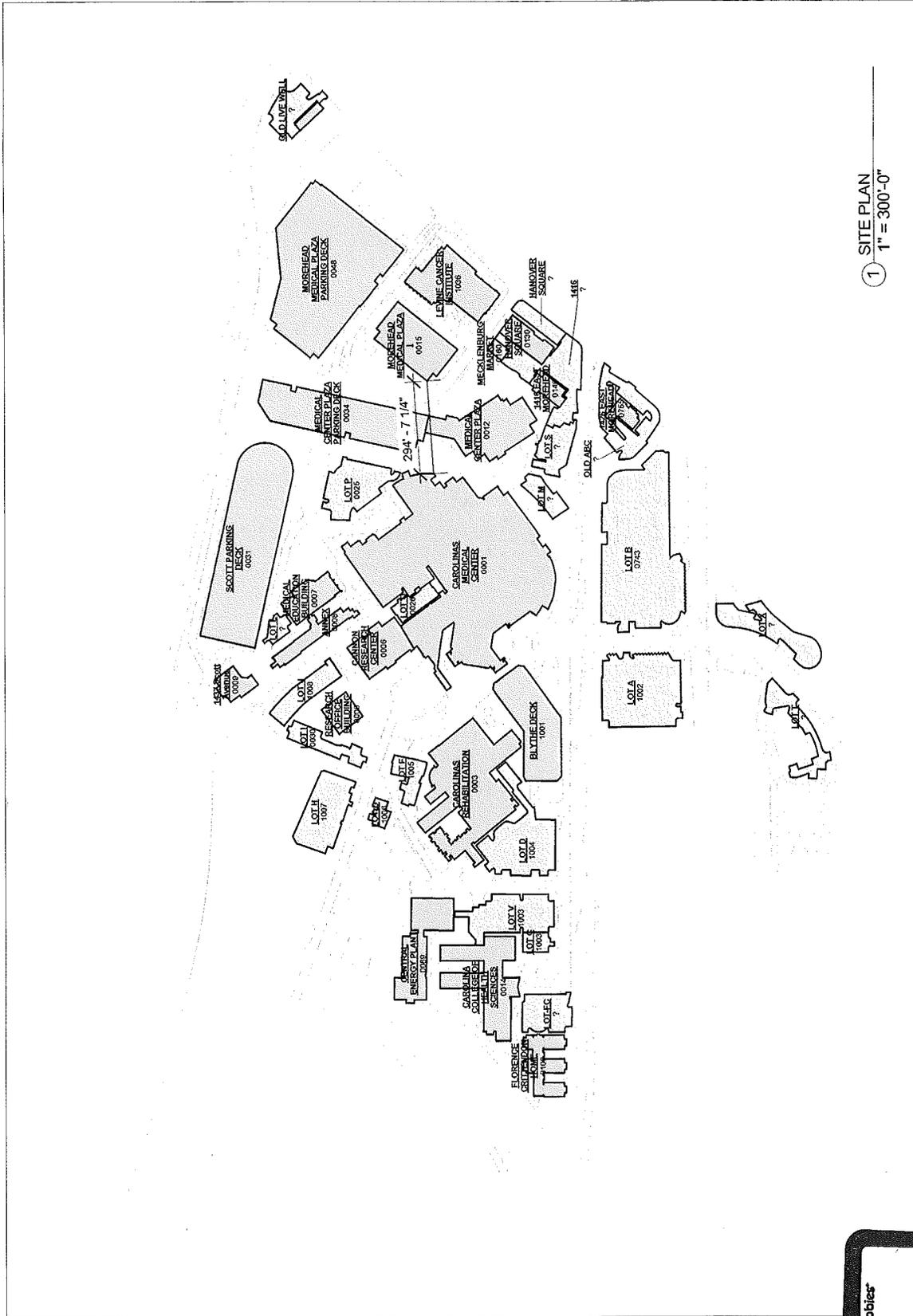
9/10/2013 3:52:28 PM

9/10/2013 3:52:28 PM

CAROLINAS MEDICAL CENTER  
 CHS Facility #1 0001  
 1000 Byrnes Boulevard  
 Charlotte, NC 28226

SHEET NAME  
 SITE PLAN

SHEET NUMBER  
 SP-2



① SITE PLAN  
 1" = 300'-0"

tabbles

**EXHIBIT**

**8**

Morehead Imaging Center - CMC Campus 2013 PET Scan Statistics

2013

January	123
February	92
March	112
April	118
May	124
June	120
July	121
August	112
September	91
October	127
November	125
December	116
<b>Total</b>	<b>1381</b>



EXHIBIT  
10a

# State Of North Carolina

## Department Of Human Resources Division Of Facility Services Certificate Of Need

Project Identification Number F-3602-89 Effective Date July 18, 1990

Issued to: Carolinas Medical Center, Inc.  
1000 Blythe Boulevard  
Charlotte, NC 28232

The North Carolina Department of Human Resources, pursuant to the North Carolina Health Planning and Resource Development Act of 1978, G.S. § 131-175, et seq., as amended and recodified, G.S. §131E-175, et seq., hereby finds and certifies that the new institutional health service proposed by the person listed above is consistent with, or as conditioned is consistent with the plans, standards, and criteria prescribed by the Act and the rules and regulations promulgated thereunder. The findings of the Department are attached hereto and incorporated by reference.

This Certificate affords the person listed above the opportunity to proceed with development of the proposed new institutional health service in a manner consistent with the plans, standards, and criteria prescribed by the Act and the rules and regulations promulgated thereunder. This Certificate includes and is limited to:

SCOPE: Construction of a new diagnostic center utilizing one cardiac positron emission tomography scanner, one rubidium generator, and one cyclotron/Mecklenburg County

CONDITIONS: See Reverse Side

PHYSICAL LOCATION: 1000 Blythe Blvd  
Charlotte, NC

MAXIMUM CAPITAL EXPENDITURE: \$5,121,769

**TIMETABLE:**

Contract Award	February, 1991	Completion of construction	June, 1991
25% completion of construction	March, 1991	Offering of Services	August, 1991
50% completion of construction	April, 1991		
75% completion of construction	May, 1991		

FIRST PROGRESS REPORT DUE:  
October 1, 1990

This Certificate is limited to the person listed above and is not transferable or assignable. This Certificate may be withdrawn as provided in G.S. §131E-189, and the rules and regulations promulgated thereunder.

Issuance of this Certificate does not supplant provisions or requirements embodied in codes, ordinances, statutes other than G.S. §131E-175, et seq., rules regulations or guidelines administered or enforced by municipal, state or federal agencies or the agent thereof.

*[Signature]*  
Assistant Director  
Chief, Certificate of Need Section  
Division of Facility Services

Conditions

1. Charlotte Memorial Hospital and Medical Center, Inc. shall materially comply with all representations made in the Certificate of Need application with the exception of those changes necessitated by the conditions stated herein.
2. Charlotte Memorial Hospital and Medical Center, Inc. shall acquire and operate one Cardiac Positron Emission Tomography Scanner, one Rubidium Generator, and one Cyclotron.
3. Charlotte Memorial Hospital and Medical Center, Inc. shall not renovate or construct more space than is required for the operation of the equipment approved by this decision.
4. Charlotte Memorial Hospital and Medical Center, Inc. shall submit to the Certificate of Need Section quarterly utilization data for this project commencing with the end of the first quarter or December 31, 1990, whichever is later, to document actual utilization of the equipment, actual payor mix, sources of reimbursement for this service, volume of scans performed, average scan duration, and specific indicators of patient selection for this service (e.g. ability to pay, primary diagnosis, marketing tool).
5. Prior to the issuance of the Certificate of Need, Charlotte Memorial Hospital and Medical Center, Inc. shall provide documentation that the medically underserved and patients without health insurance coverage for this specific service will have equal access to the PET scanner and cyclotron.
6. The approved capital expenditure shall be \$5,121,765.
7. Prior to the issuance of the Certificate of Need, Charlotte Memorial Hospital and Medical Center, Inc. shall submit confirmation from a commercial insurance provider and HCFA that reimbursement will be provided for the provision of Cardiac PET Scanner, Rubidium Generator and Cyclotron services or shall submit documentation that the hospital's inability to secure reimbursement for the proposed services, at this time, will not result in an incremental increase in charges in the hospital.
8. The proponent shall acknowledge acceptance and compliance with all conditions stated herein to the Certificate of Need Section in writing prior to the issuance of the certificate of need.

The conditions that were required to be met prior to the issuance of the certificate of need were met with correspondence received by the Certificate of Need Section on July 18, 1990.

# STATE OF NORTH CAROLINA

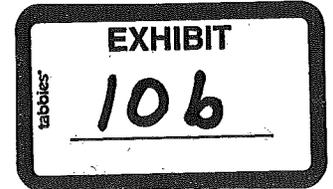
Department of Health and Human Services

Division of Facility Services

## CERTIFICATE OF NEED

for

Project Identification Number F-6781-03  
FID#944734



**ISSUED TO:** The Charlotte Mecklenburg Hospital Authority  
d/b/a Carolinas Medical Center  
P.O. Box 32861  
Charlotte, NC 28262

Pursuant to N.C. Gen. Stat. § 131E-175, et. seq., the North Carolina Department of Health and Human Services hereby authorizes the person or persons named above (the "certificate holder") to develop the certificate of need project identified above. The certificate holder shall develop the project in a manner consistent with the representations in the project application and with the conditions contained herein and shall make good faith efforts to meet the timetable contained herein. The certificate holder shall not exceed the maximum capital expenditure amount specified herein during the development of this project, except as provided by N.C. Gen. Stat. § 131E-176(16)e. The certificate holder shall not transfer or assign this certificate to any other person except as provided in N.C. Gen. Stat. § 131E-189(c). This certificate is valid only for the scope, physical location, and person(s) described herein. The Department may withdraw this certificate pursuant to N.C. Gen. Stat. § 131E-189 for any of the reasons provided in that law.

**SCOPE:** Carolinas Medical Center shall replace its existing positron emission tomography scanner with a PET/CT scanner/Mecklenburg County

**CONDITIONS:** See Reverse Side

**PHYSICAL LOCATION:** Carolinas Medical Center  
1000 Blythe Boulevard  
Charlotte, NC 28203

**MAXIMUM CAPITAL EXPENDITURE:** \$2,302,335

**TIMETABLE:** See Reverse Side

**FIRST PROGRESS REPORT DUE:** October 1, 2003

This certificate is effective as of the 24<sup>th</sup> day of June, 2003.

A handwritten signature in black ink, appearing to read "Lee B. Hoffman".  
\_\_\_\_\_  
Chief, Certificate of Need Section  
Division of Facility Services

## CONDITIONS

1. The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center shall materially comply with all representations made in its certificate of need application.
2. The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application or that would otherwise require a certificate of need.
3. The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center shall acknowledge acceptance and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.

A letter acknowledging acceptance and compliance with all conditions stated in the conditional approval letter was received by the Certificate of Need Section of June 12, 2003.

## TIMETABLE

Completion of final drawings and specifications	May 26, 2003
Contract Award	August 18, 2003
25% completion of construction	September 2, 2003
50% completion of construction	September 17, 2003
75% completion of construction	October 2, 2003
Completion of construction	October 22, 2003
Occupancy/offering of service(s)	January 2, 2004
Ordering equipment	July 24, 2003



North Carolina Department of Health and Human Services  
Division of Facility Services  
Certificate of Need Section

2704 Mail Service Center ■ Raleigh, North Carolina 27699-2704

Michael F. Easley, Governor  
Carmen Hooker Odom, Secretary

<http://facility-services.state.nc.us>

Lee Hoffman, Section Chief  
Phone: 919-855-3873  
Fax: 919-733-8139

January 24, 2006

Greg S. Bass  
Carolina HealthCare System  
PO Box 32861  
Charlotte, NC 32861-2861

RE: No Review/ Carolina Medical Center/ Develop outpatient imaging center, in Morehead Medical Plaza, to be licensed and operated as part of the hospital/ Mecklenburg County

Dear Mr. Bass:

The Certificate of Need (CON) Section received your letter of January 19, 2006, 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.

It should be noted that this determination is binding only for the facts represented by you. 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 the Certificate of Need Section. 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.

Sincerely,

  
Lee B. Hoffman, Chief  
Certificate of Need Section

cc: Medical Facilities Planning Section, DFS





# Carolinan HealthCare System

*James E.S. Hynes*  
Chairman

*Michael C. Tarwater, FACHE*  
President & CEO

January 18, 2006

Ms. Lee B. Hoffman, Chief  
Certificate of Need Section  
Division of Facility Services  
701 Barbour Drive  
Raleigh, North Carolina 27626-0530

**RE: Morehead Medical Plaza Imaging Center**

Dear Ms. Hoffman:

In our phone conversation today you requested additional information relating to the ownership of the outpatient imaging center Carolinas Medical Center (CMC) plans to develop on the first floor of the Morehead Medical Plaza building, a new multi-story medical office building on the CMC campus. The imaging center and equipment will be owned and operated by CMC and imaging services will be billed under the hospital's provider number.

As I described in my letter on October 7, 2005, the project will include the purchase of equipment and the relocation of equipment from the existing hospital-owned imaging center at Medical Center Plaza and from the radiology department on the fourth floor of CMC. The total capital cost for the project is estimated to be \$1,921,151 as was documented by the certified cost estimate attached to previous letter.

Based upon the project as described above, the project does not represent a new institutional health service as defined in N.C.G.S. §131E-176 (16) and does not require a Certificate of Need. As such, this letter serves as notification of our intent to proceed with the project. If you have any questions or require further information regarding this project, please call me at 704-355-0314.

Sincerely,

A handwritten signature in cursive script that reads "Greg S. Bass".

Greg S. Bass, Director  
CHS Management Company

Letter of No Review



# Carolinan HealthCare System

James E.S. Hynes  
Chairman

Michael C. Tarwater, FACHE  
President & CEO

October 7, 2005

Ms. Lee B. Hoffman, Chief  
Certificate of Need Section  
Division of Facility Services  
701 Barbour Drive  
Raleigh, North Carolina 27626-0530

**RE: Morehead Medical Plaza Imaging Center**

Dear Ms. Hoffman:

Carolinan Medical Center (CMC) is planning to develop an outpatient imaging center on the first floor of the Morehead Medical Plaza building, a new multi-story medical office building on the CMC campus. The project will include the purchase of new equipment and the relocation of existing equipment from the imaging center at Medical Center Plaza, an existing medical office building on the campus, and from the radiology department on the fourth floor of CMC.

Morehead Medical Plaza is being developed by an independent developer. CMC will lease the space for the imaging center. The total capital cost for the upfit of the medical office building space is estimated to be \$1,469,720. The cost for new equipment and the relocation of existing equipment is estimated to be \$451,431, resulting in a total project cost of \$1,921,151. A certified cost estimate is attached for your review (please see Attachment 1).

Based upon the project as described above, the project does not represent a new institutional health service as defined in N.C.G.S. §131 E-176 (16) and does not require a Certificate of Need. As such, this letter serves as notification of our intent to proceed with the project. If you have any questions or require further information regarding this project, please call me at 704-355-0314.

Sincerely,

A handwritten signature in cursive script that reads "Greg S. Bass".

Greg S. Bass, Director  
CHS Management Company

Attachments

**ATTACHMENT 1**

**Certified Capital Cost of Project**

Project name: Morehead Medical Plaza Imaging Center OSR # 2083269

<b>A. Site Costs</b>		
(1) Full purchase price of land		N/A
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		N/A
(6) Other (Specify) _____		
(7) Sub-Total Site Costs		N/A
<b>B. Construction Contract</b>		
(8) Cost of Materials		
General Requirements	_____	
Concrete/Masonry	_____	
Woods/Doors & Windows/Finishes	_____	
Thermal & Moisture Protection	_____	
Equipment/Specialty Items	_____	
Mechanical/Electrical	_____	
Other - Information Systems	\$87,825	
Sub-total Cost of Materials		included
(9) Cost of Labor		
(10) Other (Specify) _____		\$1,081,895
(11) Sub-Total Construction Contract		1,169,720
<b>C. Miscellaneous Project Costs</b>		
(12) Building Purchase		
(13) Fixed Equipment Purchase/Lease		\$361,431
(14) Movable Equipment Purchase/Lease		
(15) Furniture		90,000
(16) Landscaping		0
(17) Consultant Fees		
Architect and Engineering Fees	\$200,000	
Legal Fees	_____	
Market Analysis	_____	
Other (Specify) _____		
Other (Specify) _____		
Sub-Total Consultant Fees		200,000
(18) Financing Costs (e.g., Bond, Loan, etc.)		
(19) Interest During Construction		
(20) Contingency		100,000
(21) Sub-Total Miscellaneous		751,431
(22) Total Capital Cost of Project (Sum A-C above)		\$1,921,151

I certify that, to the best of my knowledge, the above construction related costs of the proposed project named above are complete and correct.

Franklin H. [Signature]  
 (Signature of Licensed Architect or Engineer)

Oct 3, 2005  
 (Date)

**ATTACHMENT 2**

**Equipment Costs**

## Morehead Medical Plaza Imaging Center Medical Equipment List

### Existing Equipment Moved

Equipment Type	Current Location	Equipment Number	Serial Number	Relocation Cost
CT	MCP	162829	2801	\$32,000
Fluoro	CMC Fluoro #2	76958	993070	\$22,000
Fluoro	MCP	38930	973060	\$22,000
Nuc Med	CMC 4th Floor	126675	8776	\$20,000
PET	CMC 4th Floor	301010	0301010	\$35,000
<b>TOTAL</b>				<b>\$131,000</b>

### Used Equipment Purchased

Equipment Type	Vendor	Model Number	Serial Number	Purchase Price
CT	GE	Qxi		\$100,000

### New Equipment Purchased

Equipment Type	Vendor	Purchase Price
Miscellaneous	Miscellaneous	\$130,431

<b>Total</b>	<b>\$361,431</b>
--------------	------------------

Notes: MCP = Medical Center Plaza

**ATTACHMENT 3**

**Used Equipment Quote**

GE Healthcare  
**Technologies**

Medical Equipment  
**EXCHANGE**

GE Healthcare Technologies  
Medical Equipment Exchange  
3114 N. Grandview Blvd (W-544)  
Waukesha, WI 53188  
Fax 262-513-4185

**PURCHASE AGREEMENT**

THE GENERAL ELECTRIC COMPANY, THROUGH ITS GE HEALTHCARE TECHNOLOGIES MEDICAL EQUIPMENT EXCHANGE DIVISION, hereby offers to sell GE QXI CT scanner, located at Carolinas Medical Center, 1000 Blythe Blvd, Charlotte, NC 28203 and "BUYER" "Carolinas Medical Center, 1000 Blythe Blvd, Charlotte, NC 28203" agrees to purchase the following equipment according to the terms and conditions as set forth within the attached STANDARD CONDITION OF PURCHASE FOR GE HEALTHCARE TECHNOLOGIES MEDICAL EQUIPMENT EXCHANGE.

**DESCRIPTION OF EQUIPMENT:**

GE QXI CT scanner installed at Carolinas Medical Center. System ID 704355CTB

**PAYMENT TERMS:** Full payment due now.

Unit Price: \$100,000.00 (ref#: 2536844) Cashiers Check will NOT be accepted as form of payment.

**Send Payment To:**

GE HEALTHCARE TECHNOLOGIES - GoldSeal/MEE Attn: Rob Kearney  
(mail stop W-544), 3114 N. Grandview Blvd. Waukesha WI 53188.

ACCEPTANCE: GE and BUYER have carefully read the STANDARD CONDITIONS OF PURCHASE FOR GE HEALTHCARE TECHNOLOGIES MEDICAL EQUIPMENT EXCHANGE. Signature below by both parties constitutes a binding purchase agreement according to all its terms and conditions.

GE HEALTHCARE TECHNOLOGIES  
MEDICAL EQUIPMENT EXCHANGE

Name: Rob Kearney

Title: Trade/Sales Specialist

Date: \_\_\_\_\_

\_\_\_\_\_  
Signature

BUYER  
Carolinas Medical Center

Name: MICHAEL RUSH

Title: DIRECTOR, MATERIALS RESOURCE MGT

Date: 9/29/05

Michael Rush

\_\_\_\_\_  
Signature

# GE Healthcare Technologies

Medical Equipment  
**EXCHANGE**

GE Healthcare Technologies  
Medical Equipment Exchange  
3114 N. Grandview Blvd (W-644)  
Waukegan, WI 53188  
Fax 262-513-4185

## STANDARD CONDITIONS OF PURCHASE FOR GE HEALTHCARE TECHNOLOGIES MEDICAL EQUIPMENT EXCHANGE

These conditions apply to the GE Healthcare Technologies Medical Equipment EXCHANGE Equipment ("Equipment") listed in the Purchase Agreement. The Equipment is pre-owned and sold AS IS and with no warranties, as described below. The Purchase Agreement is the multi-page numbered document that has been typed with the name and address of the buyer ("Buyer"), these Standard Conditions of Purchase, and any applicable special terms.

### FORMATION OF CONTRACT

The Purchase Agreement is a request for an offer of purchase from Buyer. By signing the Purchase Agreement and returning it to the General Electric Company, through its GE Healthcare Technologies Medical Equipment EXCHANGE division ("Seller") with a deposit in the amount specified in the Purchase Agreement, Buyer makes an offer to purchase the Equipment under the terms and conditions specified in the Purchase Agreement. Seller accepts Buyer's offer by the signature of a Sales Manager and by the credit approval of Seller's customer credit department.

The Purchase Agreement is intended to be the complete and exclusive statement of the terms of the contract between both parties. Seller's acceptance of Buyer's offer is expressly made conditional on Buyer's assent to all of Seller's terms. No prior proposals, statements, course of dealing or usage of the trade will be part of the contract. After the contract has been formed, it may be modified only in writing, signed by Seller's Sales Manager and by Buyer.

### PRICE, TAXES AND UPGRADES

The price Buyer will pay is stated in the Purchase Agreement. **The price quoted does not include tax. Any applicable taxes will be billed upon final invoicing, unless a valid tax exemption certificate is received prior to processing.**

### PAYMENT

The payment terms are stated in the Purchase Agreement. If any payment depends on an event (e.g., de-installation) that is delayed for a reason for which Buyer is responsible, Buyer will make the payment when the event was first scheduled to occur. Buyer grants to Seller a purchase money security interest in all items listed in the Purchase Agreement until Seller receives full payment. Late payments will be subject to a late fee equal to 1% per month (or the amount allowed by law, whichever is less) on the outstanding amount.

### EQUIPMENT AVAILABILITY; NOTICE OF SALE

Because the Equipment may be offered simultaneously to several customers, its sale to Buyer is subject to its continued availability at the time Buyer offer to purchase it. If the Equipment is no longer available, (1) Seller will attempt to identify other pre-owned equipment in Seller's inventory that meets Buyer's needs, and (2) if substitute equipment is not acceptable to Buyer, Seller will cancel Buyer's order and refund any deposit Buyer has paid Seller for the cancelled order. This is Seller's sole liability and Buyer's sole remedy. Equipment availability dates are approximate. Seller is not liable for delays in performance or delivery due to a cause beyond Seller's reasonable control. These causes include, without limitation, the failure of any third party to make the Equipment available, as well as government priorities and labor or transportation problems. If such a delay occurs, Seller may extend the performance or availability date for a period of time equal to the delay.

Closing of this sale is conditioned upon: (1) notice of the disposition of the Equipment having been provided to all necessary parties, if legally required, and (2) prior to the sale closing date, Seller not having been enjoined, stayed or otherwise legally prohibited from closing this sale as a result of bankruptcy, redemption, etc.

### INSPECTION

The Equipment specifications contained in the Purchase Agreement are based solely on the representations made to Seller by the Equipment's prior owner. Buyer is entitled to conduct a complete inspection of the Equipment (at Buyer's cost) within 5 days of the date that Buyer signs the Purchase Agreement ("Inspection Period"), unless a different Inspection Period is specified in the Purchase Agreement, and Seller will assist Buyer in a reasonable manner to make arrangements to conduct the inspection. If Buyer elects not to conduct an inspection during the Inspection Period, Buyer is deemed to have waived Buyer's right of inspection.

If, during Buyer's inspection, Buyer determines that the Equipment materially deviates from the specifications described in the Purchase Agreement, Buyer will notify Seller in writing within 48 hours of the date of inspection. Seller will have the option to do one of the following, which will be Seller's sole liability and Buyer's sole remedy: (1) renegotiate the price to be paid with respect to such Equipment; or (2) terminate this Agreement and return to Buyer all monies Buyer has paid with respect to such Equipment.

# GE Healthcare Technologies

Medical Equipment  
**EXCHANGE**

GE Healthcare Technologies  
Medical Equipment Exchange  
3114 N. Grandview Blvd. (WV-544)  
Waukesha, WI 53188  
Fax 262-513-4185

#### **DE-INSTALLATION, PICK-UP, TRANSPORTATION, AND INSTALLATION**

Seller will notify Buyer when Buyer may take possession of the Equipment. Buyer is responsible for de-installation, pick-up, rigging, crating, transportation, and installation of the Equipment, at Buyer's cost. Buyer may retain Seller to provide these services, under a separate agreement. Buyer assumes sole liability for property damage or personal injury related to Buyer's obligations under this contract. It is the Buyer's sole responsibility to coordinate the de-installation with the Seller's Installation Team and to insure the specific date and time for de-installation. Any deviations from the agreed upon schedule, caused by Buyer, which result in additional costs to either Seller or the site will be paid by Buyer. Buyer will take possession of the Equipment in a timely manner, and leave the de-installation and pick-up areas in a clean and orderly condition. It is expected that the removal will be conducted in a professional and courteous manner designed to cause no undue disruptions in the sites daily workflow. If Buyer delays taking possession of the Equipment or performing any other obligations, and Seller deinstalls, transports, and/or stores the Equipment, Buyer will be responsible for such costs, and will pay them within 10 days of receipt of Seller's invoice. In addition, if Buyer delays taking possession of the Equipment by more than 10 days after the date it is available for possession, Seller may, at Seller's option, terminate this contract, retain any deposit or other payments made in order to compensate Seller for costs associated with Buyer's default, and sell the Equipment to another party to help offset any remaining deficiency. On Seller's request, Buyer will provide Seller with a certificate of insurance naming Seller as an additional insured, evidencing coverage against damage or injury resulting from acts or omissions by Buyer or Buyer's agents while carrying out Buyer's responsibilities under this contract.

#### **TITLE AND RISK OF LOSS**

Seller represents that Seller has full right, title, and authority to sell the Equipment. Title to the Equipment will pass to Buyer upon Seller's receipt of Buyer's payment in full of the purchase price. Risk of loss will pass to Buyer on the date the Equipment is available for Buyer to take possession of it or the date Seller gives Buyer notice of its availability, whichever is later. From that point forward, Buyer bears all risk of loss associated with the Equipment, including the risk of loss or damage during de-installation, rigging, transportation, storage, and installation. Until such time as the risk of loss passes to Buyer, in the event of loss or damage to the Equipment, Seller has the option to do one of the following, which will be Seller's sole liability and Buyer's sole remedy: (1) renegotiate the price to be paid with respect to lost or damaged Equipment; or (2) terminate this Agreement and return to Buyer all monies Buyer has paid with respect to such Equipment.

#### **SOFTWARE AND OTHER LICENSES NOT INCLUDED**

Buyer has the sole responsibility to contact the manufacturer of the Equipment and obtain any necessary licenses to use any software or any other licensed products embedded in the Equipment.

#### **NON-CIRCUMVENTION**

To facilitate Buyer's inspection of the Equipment, Buyer will be provided with the location of the Equipment and the identity of the current owner. If Buyer purchases the Equipment directly or indirectly from a party other than Seller for a period of 2 years from the date of this Purchase Agreement, Buyer will pay Seller a finder's fee of 30% of the price Buyer paid for the Equipment to compensate Seller for locating the Equipment for Buyer.

#### **REGULATORY MATTERS**

Buyer acknowledges that the Equipment is a prescription medical device regulated by the U.S. Food and Drug Administration ("FDA") and may only be used by or on the order of a licensed health care provider. If Buyer re-sells the Equipment to a third party, Buyer (1) is responsible for ensuring that the Equipment complies with all applicable FDA regulations at the time it is delivered to a health care provider for use and for compliance with all applicable FDA product locator and other regulations; and (2) will indemnify Seller against any damages or costs incurred by Seller that are attributable to Buyer's failure to ensure that the Equipment is sold in accordance with FDA regulations applicable at the time the Equipment is delivered to such third party.

#### **PURCHASE FOR EXPORT**

Buyer will comply with all applicable U.S. and local laws, including the Foreign Corrupt Practices Act, and warrant that the Equipment will not be exported to the Republic of China. If Buyer is purchasing the Equipment for export, Buyer is responsible to obtain any required export or import licenses or documentation.

#### **DISCLAIMER OF WARRANTIES**

The Equipment is provided AS IS, with no warranties and with all faults, obvious and latent, that may be discovered before or after Buyer's purchase. Seller did not inspect, recondition, alter, modify, or manufacture the Equipment. Buyer represents that Buyer had the option to inspect the Equipment, as described above. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES, INCLUDING BUT NOT LIMITED TO ANY WARRANTY REGARDING THE ACCURACY OF EQUIPMENT SPECIFICATIONS OR OPERABILITY, NOR ARE THERE ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

# GE Healthcare Technologies

Medical Equipment  
**EXCHANGE**

GE Healthcare Technologies  
Medical Equipment Exchange  
3114 N. Grandview Blvd (W-544)  
Waukesha, WI 53188  
Fax 262-513-4185

#### **LIMITATIONS OF REMEDIES AND DAMAGES**

THE TOTAL LIABILITY OF SELLER AND SELLER'S REPRESENTATIVES TO BUYER AND BUYER'S EXCLUSIVE REMEDY RELATING TO THE PURCHASE AGREEMENT AND THE ITEMS LISTED IN IT IS LIMITED TO THE PRICE STATED IN THE PURCHASE AGREEMENT FOR THE PRODUCT OR SERVICE WHICH IS THE BASIS FOR THE CLAIM. Buyer agrees that Seller and Seller's representatives have no liability to Buyer for (1) any punitive, incidental or consequential damages such as lost profit or revenue, or (2) anything occurring after risk of loss passes to Buyer. Buyer will be barred from any remedy unless Buyer gives Seller prompt written notice of the problem complained of.

This is a commercial sales transaction. Any claim related to this contract will be covered solely by commercial legal principles. Seller, Seller's representatives and Buyer will have no tort or other liability to the other arising out of this contract.

This limitation does not affect claims by third parties for personal injury due to Seller's, Seller's representatives' or Buyer's negligence or product liability. Buyer will indemnify Seller and Seller's employees, agents, officers, and directors for any claim or loss directly or indirectly attributable to Buyer's acquisition, use, or sale of the Equipment, except to the extent that such claim or loss is caused by Seller's gross negligence or willful misconduct.

#### **CONFIDENTIAL INFORMATION**

Each party will treat patient information to which it may have access under this Purchase Agreement as confidential in accordance with applicable laws.

#### **GENERAL MATTERS**

Any assignment of this contract will be void without the other party's prior written consent, which will not be unreasonably withheld. Seller can hire a subcontractor to perform work under the contract. If any part of the contract is found invalid, the remaining part will be effective. Both parties expressly acknowledge that the laws of the state of New York, except its conflict of laws rules, will govern the relationship between the parties. In the event it is necessary for Seller to enforce any part of this Agreement, including payment obligations, Buyer will pay Seller's costs of enforcement, including reasonable attorneys' fees and collection costs.

#### **END OF PRODUCT LIFE**

If the product Buyer is purchasing has been previously announced by Seller or any other medical equipment manufacturer as end of product life, Seller makes no claims as to the future availability of parts, service contracts or hourly-billed service for this device.

**ATTACHMENT 4**

Line Drawing



The PET products described herein are developed and manufactured by CIS Innovations, a market leader in PET products, systems and solutions. CIS is headquartered in Knoxville, Tennessee and is a joint venture between Siemens Medical Solutions USA, Inc. and CTL, Inc.

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 Scatch, iMC, and ScanView are trademarks of Siemens AG, Medical Solutions.

Results may vary. Data on file.

Consistent with regional variations of sales rights and service availability, we cannot guarantee that all products included in this brochure are available through the Siemens sales organization worldwide. Any liability and packaging may vary by country and is subject to change without prior notice. Some of the features and products described herein may not be available in the United States.

The information in this document contains general technical descriptions of specifications and systems as well as standard and optional features which do not always have to be present in individual units.

Siemens reserves the right to modify the design, packaging, specifications and options described herein without prior notice. Please contact your local Siemens sales representative for the most current information.

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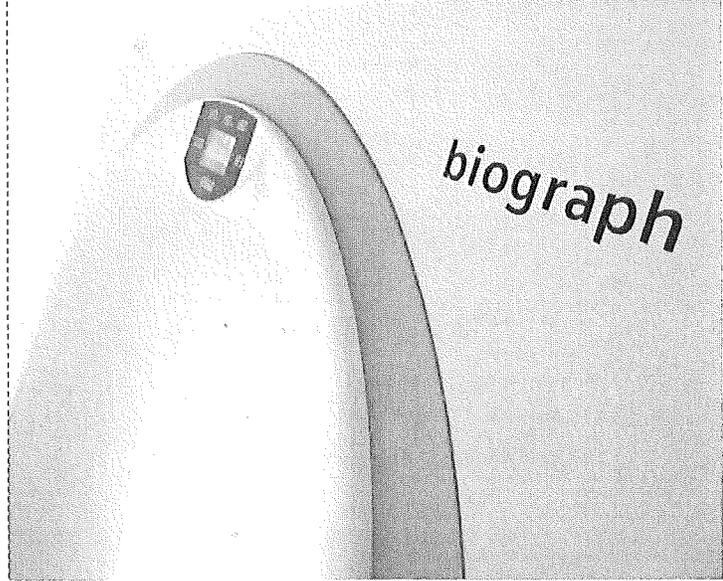
Siemens AG, Medical Solutions  
 Henkestr. 127, D-91052 Erlangen  
 Germany  
 Telephone: +49 9131 84-0  
 www.siemens.com/medical

Siemens Medical Solutions USA, Inc.  
 Nuclear Medicine Group  
 Positron Emission Tomography  
 10215 Technology Drive, Suite 101  
 Knoxville, Tennessee 37932  
 Telephone: (865) 218-6300

Siemens Medical Solutions USA, Inc.  
 Nuclear Medicine Group  
 2501 N. Barrington Road  
 Hoffman Estates, IL 60195  
 Telephone: (867) 304-7700

Siemens Medical Solutions that help

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Anyway you slice it, biograph gives you more

SIEMENS  
 medical

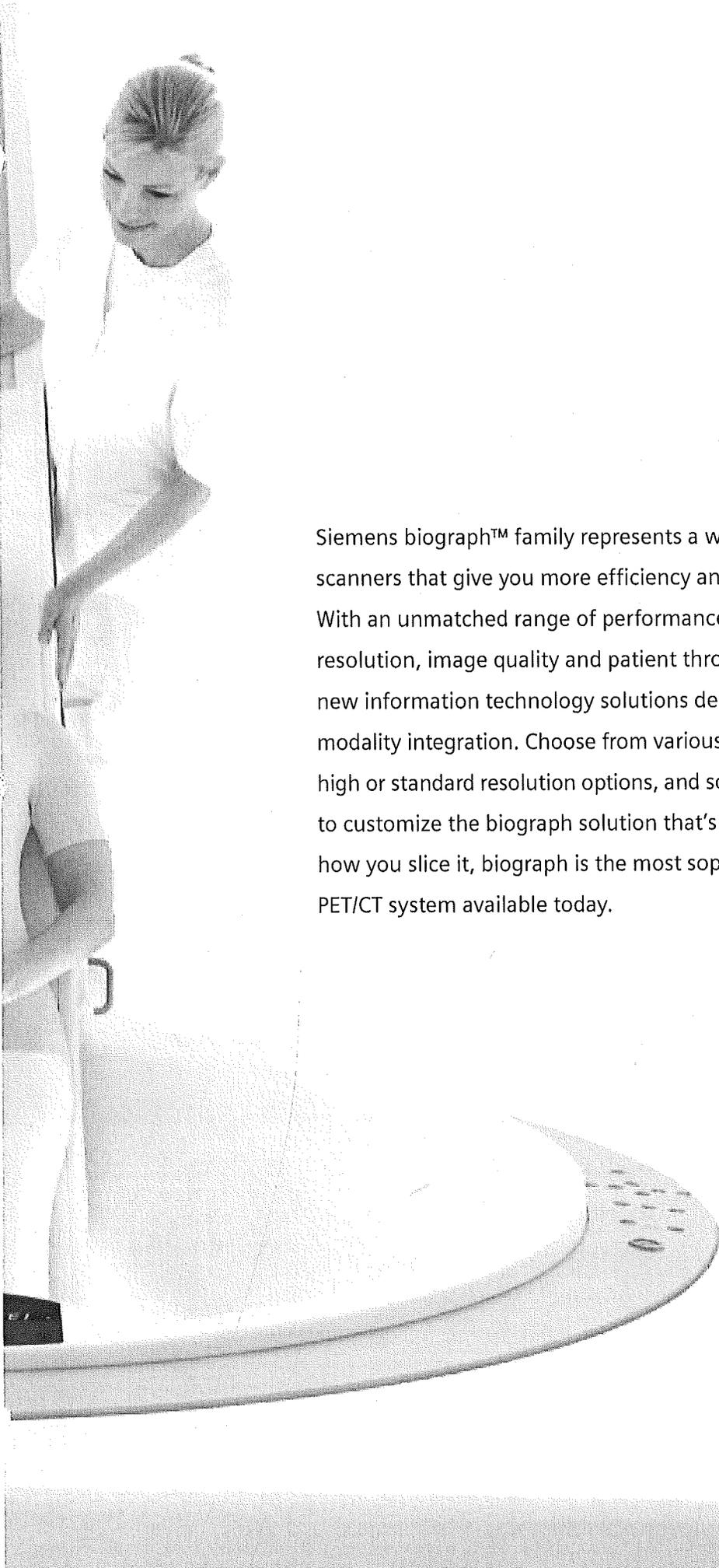
Proven Outcomes. This is what Siemens is helping your bottom line. Outcomes that lead to a level of care that feels exceptional to the patient and the care provider. Proven positive of the value of integrating medical technology, IT, management consulting, and services in a way that only Siemens can.



Take the lead in PET/CT

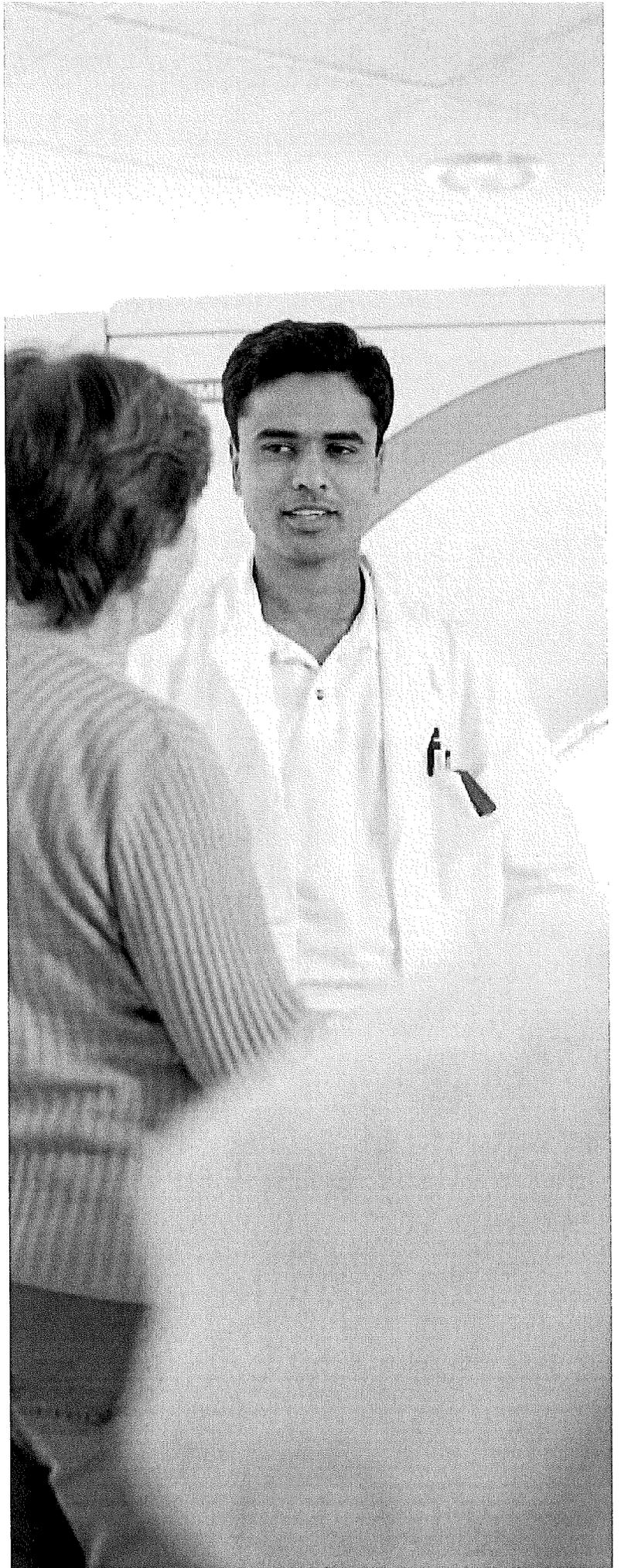


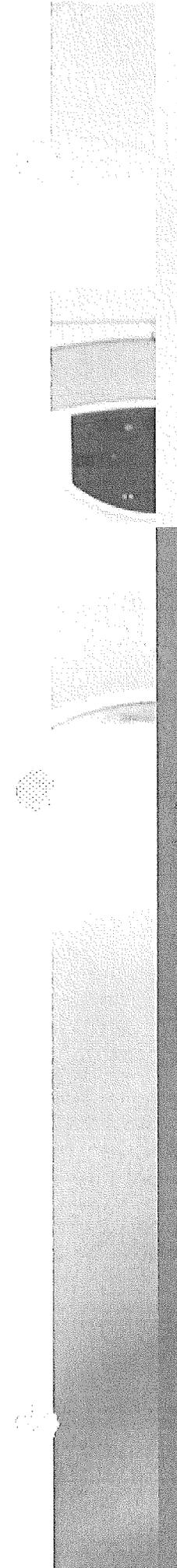
*biograph*

A black and white photograph of a woman in a white lab coat standing next to a Siemens biograph PET/CT scanner. She is adjusting a patient on the scanner's table. The scanner is a large, curved, white machine with a control panel on the side. The background is a plain, light-colored wall.

Siemens biograph™ family represents a whole new class of PET/CT scanners that give you more efficiency and flexibility than ever before. With an unmatched range of performance options to enhance image resolution, image quality and patient throughput, biograph gives you new information technology solutions designed specifically for hybrid modality integration. Choose from various CT multislice configurations, high or standard resolution options, and software configuration options to customize the biograph solution that's just right for you. No matter how you slice it, biograph is the most sophisticated and powerful PET/CT system available today.

biograph gives you ...  
**More PET**





## Finer detail

### LSO HI-REZ imaging technology

Our new LSO HI-REZ technology takes full advantage of LSO's unique scintillator properties to deliver more PET resolution. Offering a 4-mm square LSO crystal and a resulting voxel size unmatched in the industry, the LSO HI-REZ technology improves volumetric resolution by more than 250% over the previous design. Leveraging advanced technologies, the biograph operates with ultrahigh system count rates, shorter patient scanning times, excellent volume sensitivity, high spatial sampling and isotropic spatial resolution. With its precise registration and fusion of high-resolution metabolic and anatomic information, the biograph gives clinicians the most powerful new diagnostic tool available.

## Superior image quality

### Pico-3D electronics

Our advanced Pico-3D feature provides ultrafast detector electronics that substantially improve system count rate performance, thus giving you better image quality, signal-to-noise ratio, and lesion detectability. With Pico-3D, biograph provides 70% more image statistics than conventional PET/CT systems. Combined with our patented LSO crystal technology, Pico-3D sets a new standard of excellence for all aspects of PET scanning with FDG and new tracers beyond FDG. Higher quality Pico-3D imaging allows optimum scanning flexibility across all doses and patient sizes, also offering superior energy and timing resolution, better noise rejection, and increased count rate with improved system dead time. Ultimately, more information produces superior image quality and higher patient throughput.

## Increased efficiency

### The lightning speed of LSO crystal detectors

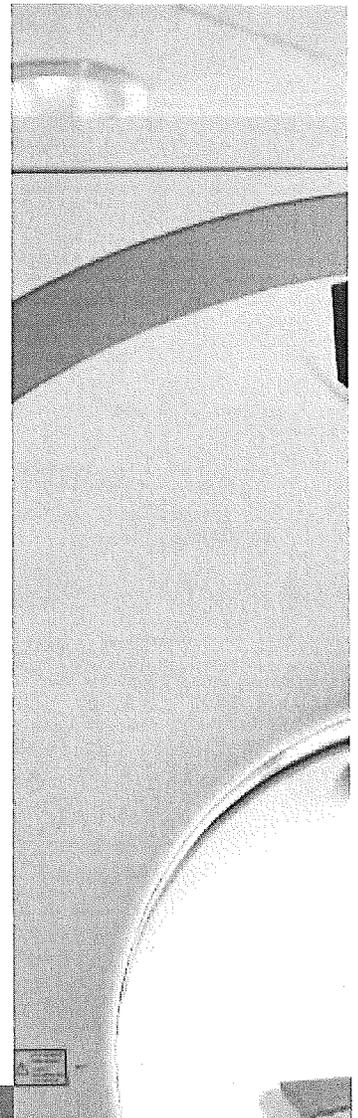
LSO has the fastest scintillation decay time of all crystals currently in use and offers the best combination of PET scintillator properties known today. LSO crystal technology allows fast coincidence timing with efficient rejection of random events to provide the very high count rates essential to high-speed PET scanning. The ultrafast LSO crystal technology brings significant advantages to high-throughput 3D acquisition, providing more flexibility for 3D acquisitions across a wide range of count rates to improve throughput at any dose level. In combination with high-speed electronics, accurate data correction and fast reconstruction techniques, LSO-based PET scanners deliver exceptional image quality in the shortest scanning time available today.

## Streamlined workflow

### e.soft and e.soft@LEONARDO

Siemens revolutionary e.soft™ nuclear medicine software suite delivers unmatched system power and clinical flexibility by combining PET, PET/CT and SPECT-CT software on a single workstation. e.soft offers 3D MIP with correlation to all orthogonal planes along with 2D ROI and 3D VOI SUV semiquantitative image analysis. e.soft is based on Siemens exclusive *syngo*® common medical imaging software platform that provides multimodality connectivity using the DICOM standard.

# biograph gives you ... **More CT**



## **Increased efficiency**

### **High-performance UFC Detectors**

Siemens modern Ultra Fast Ceramic (UFC™) Detector technology combines all the qualities of a first-class detector: very high degree of X-ray absorption, very high light conversion, and extremely short afterglow. These properties ensure high image quality with significantly reduced radiation exposure compared to other detector materials. Combined Applications to Reduce Exposure (CARE) offer a wide range of advanced dose reduction solutions that deliver optimized patient care and reduced operational costs. The CARE Dose4D™ feature enables you to achieve excellent imaging results, shorter examination times and the lowest possible radiation exposure to patient and user alike.

## **Finer detail**

### **Unmatched resolution**

Cutting-edge CT detector technology combined with advanced cone beam reconstruction techniques enable the most detailed and artifact-free images possible. Moreover, the biograph's fixed-fulcrum, cantilevered patient bed eliminates relative deflection between PET and CT, ensuring submillimeter registration accuracy.



## Streamlined workflow

### LEONARDO

The LEONARDO post-processing workplace provides unmatched clinical flexibility and efficiency by integrating more than 50 *syngo*-based multimodality processing applications within one logical user interface. Strict adherence to the DICOM standard provides smooth integration into clinical workflows and ensures cross-vendor compatibility. The LEONARDO workplace includes many *syngo* CT applications, such as LungCARE, InSpace, Perfusion CT, Calcium Scoring, Vessel View, and Colonography. Automated workflows reduce administrative work and accelerate clinical processes. The LEONARDO workplace lets you perform one-stop oncology and cardiac assessments.

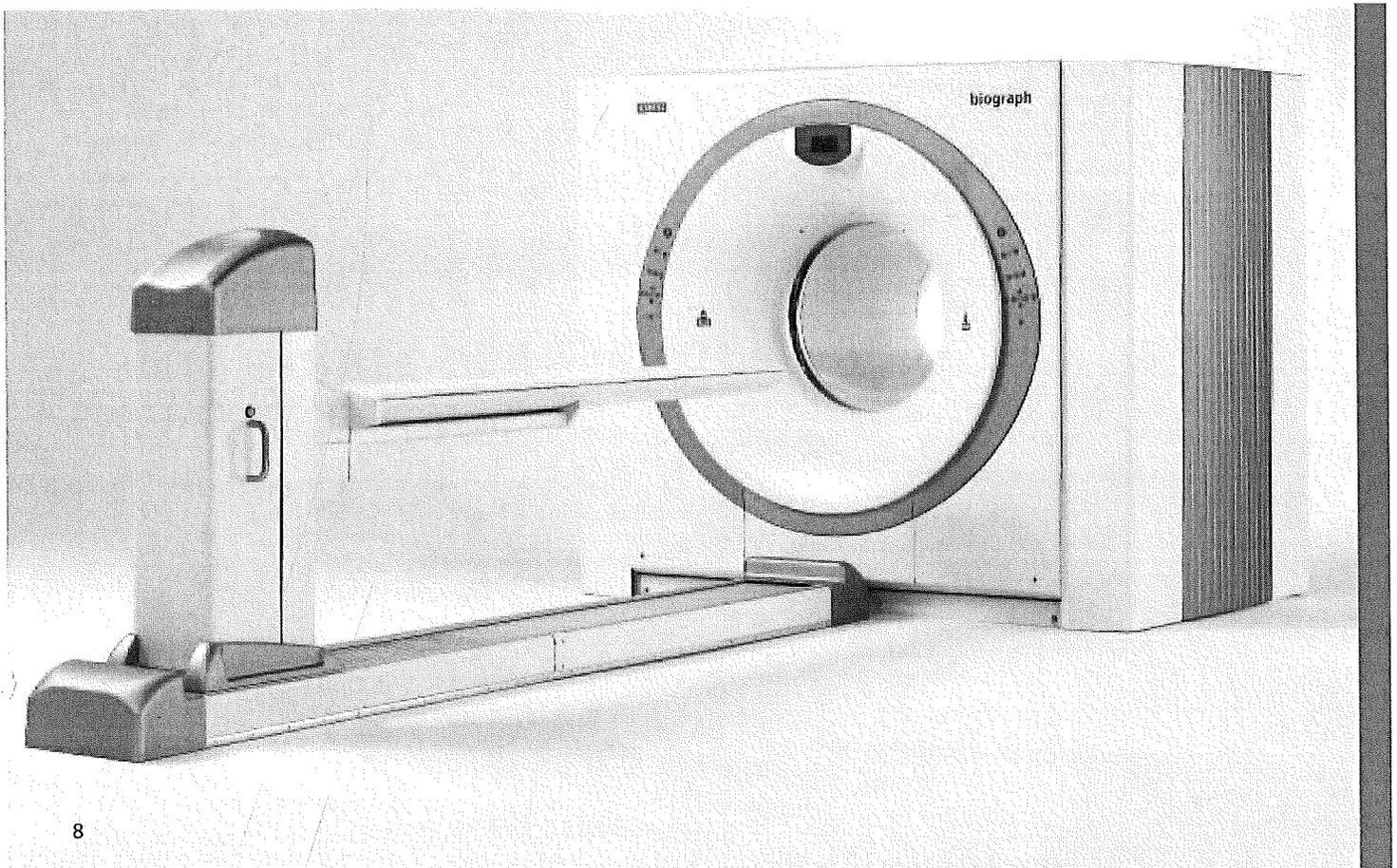
## Superior image quality

### SureView multislice image reconstruction

Our multislice scanners employ SureView™, a patented solution for multislice CT imaging with no compromise in image quality at any speed. SureView allows the CT scanner to automatically select the necessary pitch value to achieve the defined coverage and scan time, while keeping image quality constant, ensuring high quality imaging at any scanning speed. The SureView reconstruction protocol ensures high image quality independent of pitch, employing state-of-the-art cone beam reconstruction.

## More PET/CT

The world's first fully integrated  
PET/CT scanner





The merging of PET and CT technologies in the biograph molecular imager produced a precision imaging system unlike anything ever seen before. This ingenious scanning device makes it possible to see detailed anatomy and functional processes at the molecular level. Spectacular detail of internal organs and living tissue can be seen through a single, non-invasive diagnostic procedure.

# See more than ever before Siemens biograph family gives you more choices

See how much the Siemens biograph family can do for you. With proven quality and resolution in PET imaging combined with various multislice CT configurations, the possibilities are endless. The 2-, 6-, 16- and now 64-slice configuration options create unprecedented imaging potential in specialties such as cardiology and oncology.

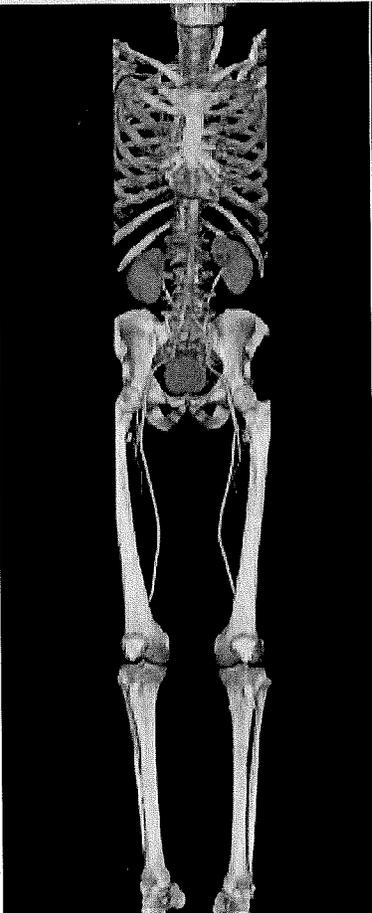


### **64-slice Cardiac CTA**

Cardiac CTA clearly demonstrated this abnormal origin of the right coronary artery. The 0.4 mm resolution and 0.33 s rotation speed enable the most robust cardiac CTA today.

### **64-slice CT Angiogram**

This CTA image demonstrates the speed available to capture a true arterial phase full-body CTA, with the necessary resolution to interrogate the renal arteries as a stand-alone exam.



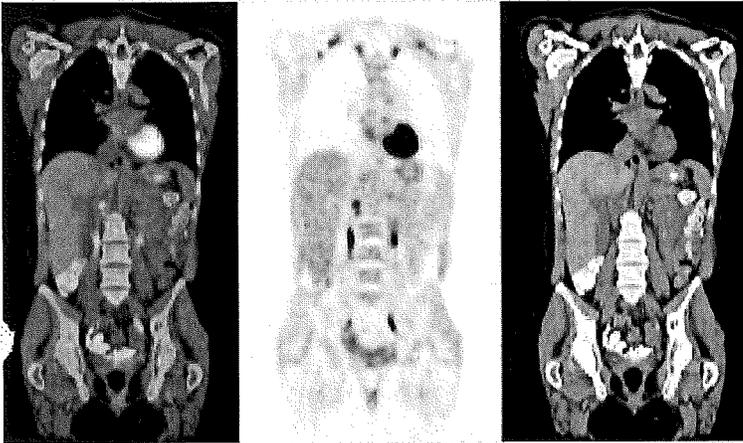
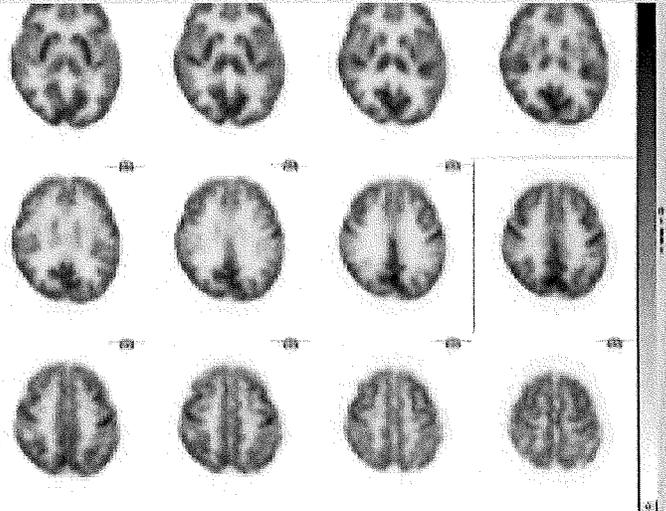
### **Cervical Cancer**

The biograph 2 used for initial staging demonstrated focally increased activity in the cervix consistent with the newly diagnosed cervical carcinoma with lymph node metastases in the right internal iliac chain.



**Brain Imaging**

The biograph 6 with HI-REZ technology provides a 250% increase in volumetric resolution over conventional PET systems, as demonstrated in this <sup>18</sup>F-FDG brain, where more definition of the sulci and gyri are demonstrated.



**Ovarian Cancer**

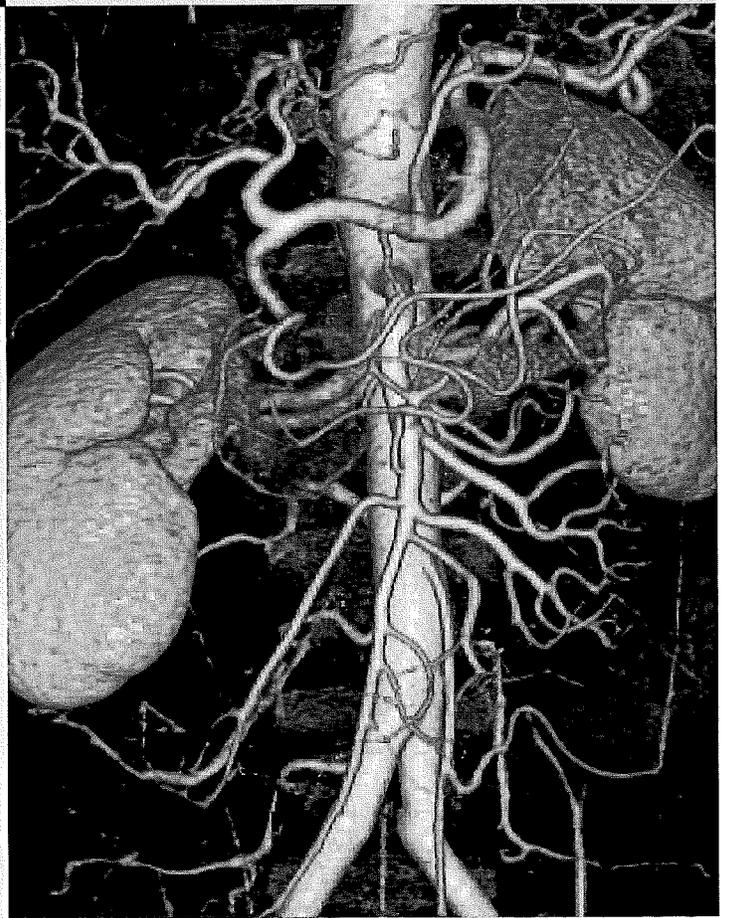
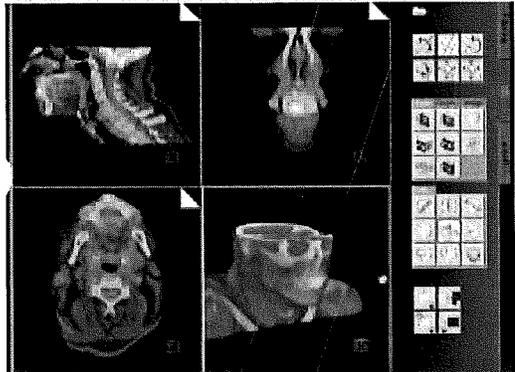
Two pericaval nodes, one approximately 10 mm and one 4 mm found in the lumbar region, posterior to the right kidney, consistent with metastatic disease. This small lesion detectability is only possible with HI-REZ technology.

**Lip Cancer**

A single focus of abnormal <sup>18</sup>F-FDG activity localized midline of lower lip. Using the HI-REZ technology enabled differentiation of soft tissue in the upper and lower lip on the PET images alone.

**Renal CT Angiogram**

Bilateral dual renal arteries are visible on this abdominal 16-slice CTA study done on a kidney donor prior to surgery.

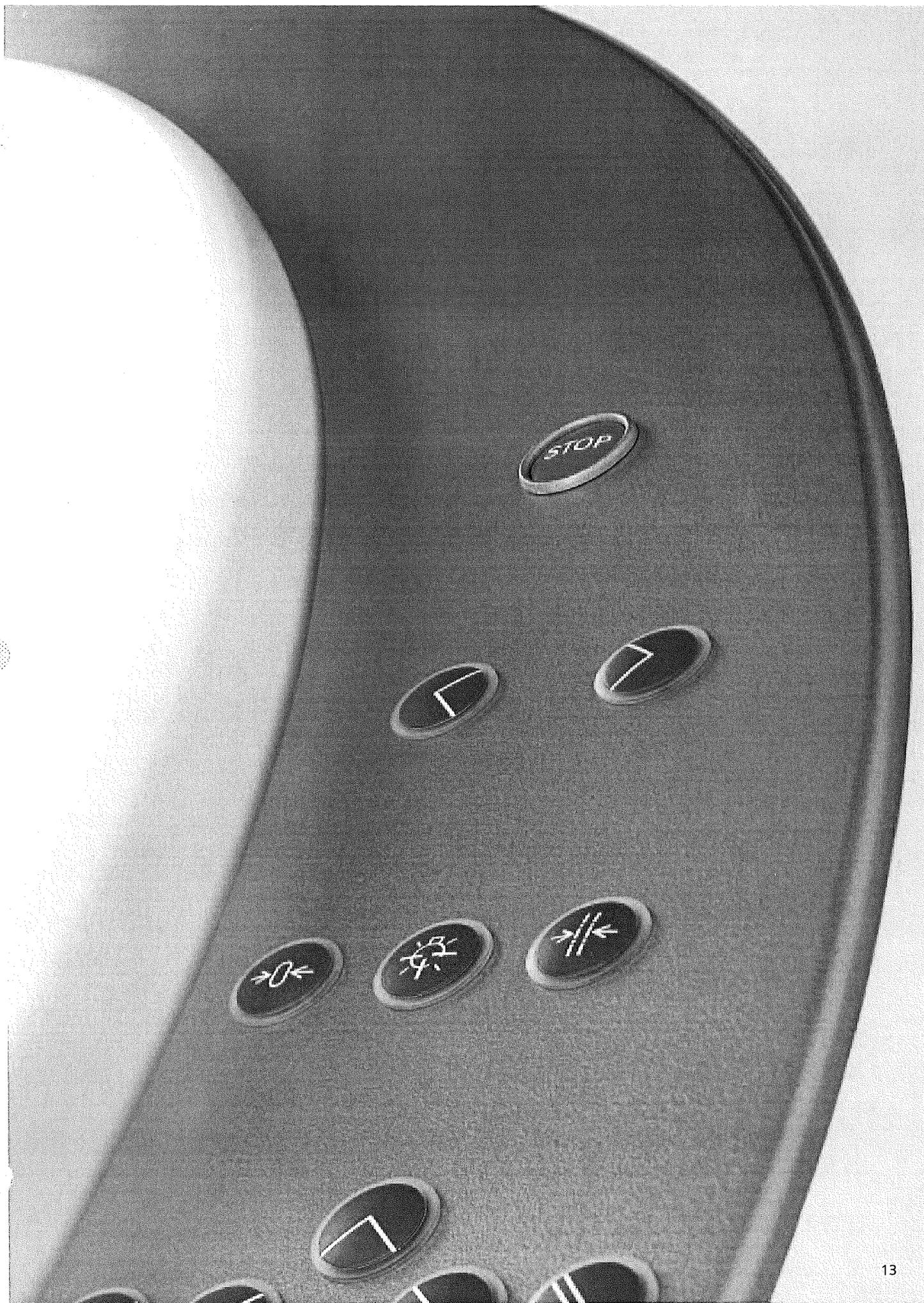


**We see a way to integrate anatomic and functional imaging  
with therapy planning and follow-up in a single workplace**

**We see a way to provide superior dose reduction  
in PET/CT using CARE Dose4D**

**We see a way to increase diagnostic confidence by combining  
CT and functional imaging with submillimeter accuracy**

**We see a way to integrate PET/CT acquisition, processing,  
image display and fusion in a single syngo console**



# Life

## The continuous development of your skills, productivity, and technology

### Skills

Skills helps you get the most value out of your system by maximizing your clinical know-how. With a full range of continuous learning programs – from extensive start-up and technical training to applications support. Designed to adapt to your needs, Life's personalized training includes web-based courses you can access at your convenience. And you can learn in our workshops, fellowships, and symposiums with our clinical partners.

The sharper your skills, the better your performance.

### Productivity

Life provides a complete and customizable range of offerings that cover virtually every facet of system availability. From safety checks and proactive remote services to preventive maintenance, quality assurance, updates, virus protection, corrective maintenance, and spare parts. It also offers services to support your in-house staff. Clinical network services for managing your entire PACS network. And integrated service management that relieves the burdens of planning and monitoring service and maintenance agreements.

It's all the support and data you need to maximize productivity.

### Technology

To keep you on top of software and hardware upgrades and updates, Life offers packages and service contracts to help you benefit from the latest workflow improvement, clinical application, and diagnostic functions. These updates and upgrades facilitate shorter examination times, enhanced productivity, and optimal system performance.

As your needs change, Life ensures that you have access to the latest, most promising clinical developments for all of your current equipment. Clinically speaking, Life helps you offer your patients more services and diagnostic capabilities. From a business perspective, it optimizes your investment and strengthens your competitive advantage.

As technology moves forward, we'll help you stay ahead.

June 26, 2013

Carolinas Healthcare System  
Attn: Mr. Jeff Aho  
Associate Vice President  
Carolinas Medical Center  
1000 Blythe Blvd.  
Charlotte, NC 28203

Dear Mr Aho,

The purpose of this letter is to describe the capabilities of the new PET/CT system as they compare to the system it is replacing.  
The best way to do that would be with a small chart of technical and clinical attributes to the systems.

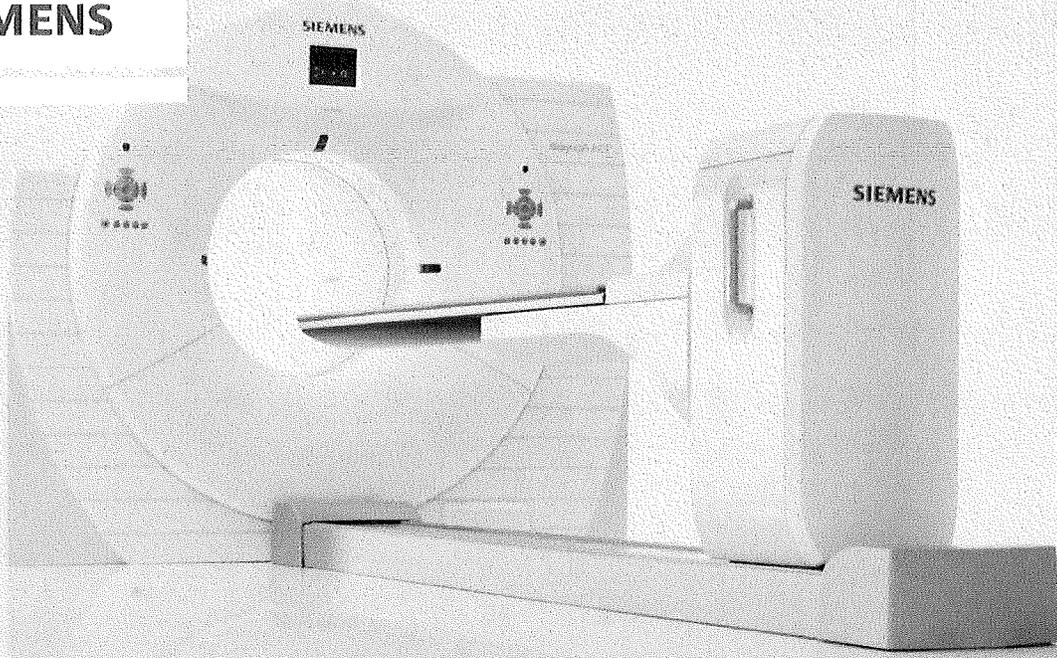
<b>Attribute</b>	<b>Biograph Duo (old)</b>	<b>Biograph mCT (new)</b>
<b>Average scan time</b>	20-40 min	10-15 min
<b>Patient table weight</b>	450 lbs	500 lbs
<b>Gantry bore size</b>	70 cm	78 cm
<b>PET resolution</b>	6.6 mm	4.2 mm
<b>CT Slices</b>	2 per rotation	40 per rotation
<b>CT resolution</b>	14 lp/cm	30 lp/cm
<b>Co-scan range</b>	174 cm	194 cm
<b>CT generator power</b>	40 kW	80 kW
<b>CT field of view</b>	50 CM	50, 64 and 78 CM

Also attached to this letter are the two brochures for the systems.

Sincerely,

Don Werner  
Product Sales Executive, PET/CT  
Siemens HealthCare, USA.

SIEMENS

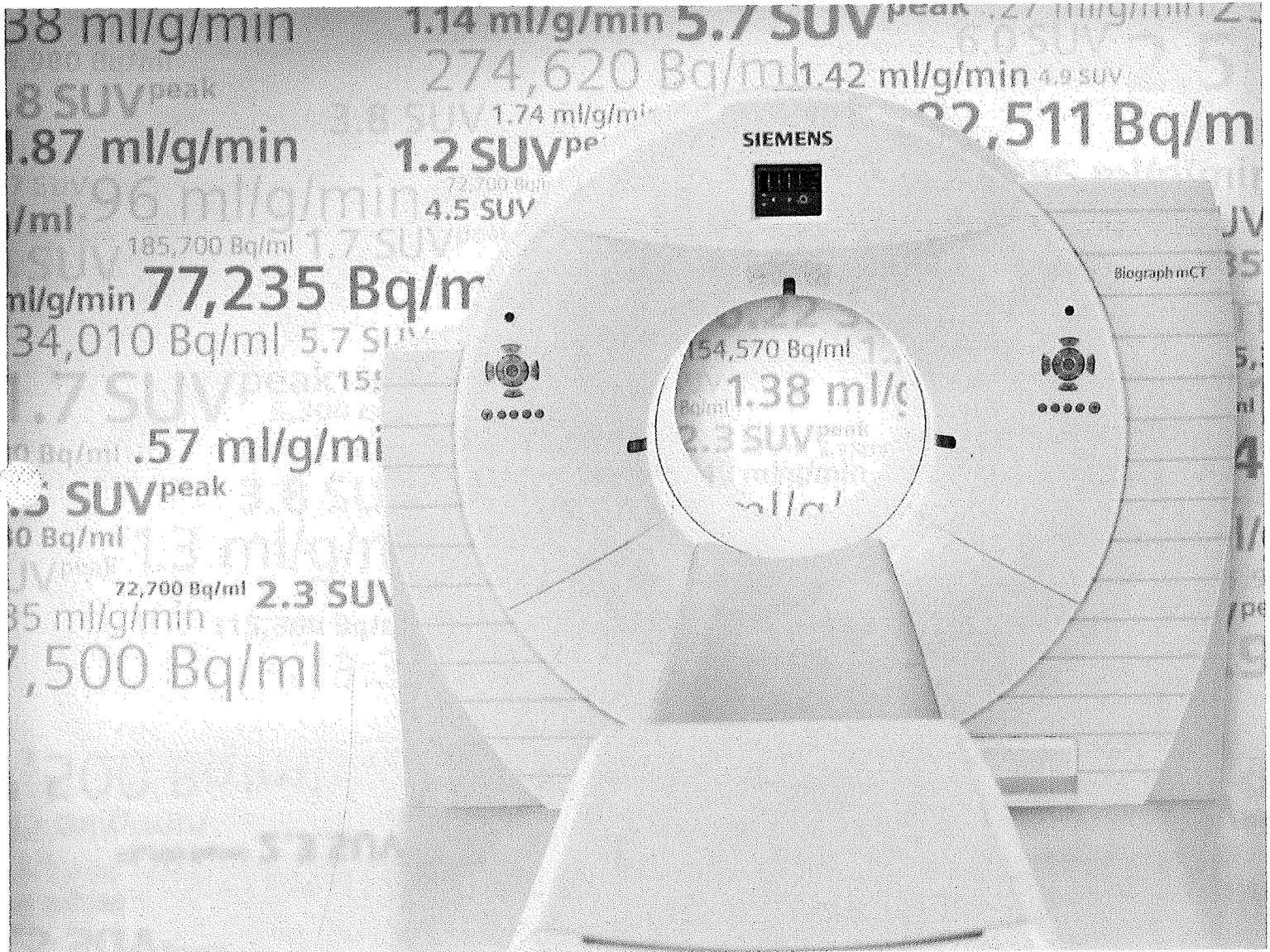


[www.siemens.com/mi](http://www.siemens.com/mi)

# Biograph mCT

molecular CT. quantification redefined.

Answers for life.



38 ml/g/min

8 SUV<sup>peak</sup>

1.87 ml/g/min

96 ml/g/min

185,700 Bq/ml

34,010 Bq/ml

1.7 SUV<sup>peak</sup>

0.57 ml/g/min

3 SUV<sup>peak</sup>

10 Bq/ml

72,700 Bq/ml

35 ml/g/min

7,500 Bq/ml

1.14 ml/g/min 5.7 SUV<sup>peak</sup> 27 ml/g/min 2.5

274,620 Bq/ml 1.42 ml/g/min 4.9 SUV

1.74 ml/g/min

1.2 SUV<sup>peak</sup> 22,511 Bq/ml

72,700 Bq/ml 4.5 SUV

1.7 SUV<sup>peak</sup>

155,000 Bq/ml

1.38 ml/g

2.3 SUV<sup>peak</sup>

ml/g

SIEMENS

Biograph mCT

54,570 Bq/ml

1.38 ml/g

2.3 SUV<sup>peak</sup>

ml/g

Biograph mCT –  
molecular CT.  
quantification redefined.



Quantificati



# Inno

## The Siemens Molecular Imaging Leadership

### Innovation Leadership

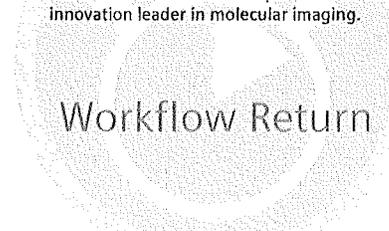
For more than 130 years, Siemens Healthcare has been a recognized leader in medical innovation. From the first electromedical devices in 1896 to the latest PET hybrid technologies, we have a long history of pioneering technological achievements that have helped make the impossible possible. We have always believed that even the farthest technical horizons were temporary and could be surpassed with consistent dedication to improved healthcare. This visionary approach, backed up by the largest R&D budgets in the medical imaging industry, has made Siemens an undisputed innovation leader in molecular imaging.

### A Focus on Return on Innovation

Driven by this passion to make a difference, the core of Siemens Molecular Imaging is based upon the assumption that achieving the highest technical performance is only important when it meets the needs of our customers and the patients they serve. To gain a deep understanding of our customers' needs and the environments they work in, we collaborate closely with leading medical experts from around the world. This cooperation is the driving force behind our innovative solutions and services. From the earliest stages of research, product development and design, we rely upon the advice and recommendations of our customers to determine our focus. As a result, our products are able to offer you the highest return on innovation possible.



Clinical Return



Workflow Return



Financial Return

# novation

From the beginning, one of the most frequent demands of our customers has been to improve diagnostic decision making to enable greater confidence. At the same time, healthcare is facing the dual mandates to improve patient safety and increase productivity, while ensuring the highest quality and cost-efficient patient care.

With a focus on fulfilling your clinical, workflow and financial needs, our mandate is to deliver innovations that consistently meet the following three criteria:

- Lead the way in technological and medical advancement
- Maximize workflow efficiency
- Make state-of-the-art molecular imaging affordable

## Introducing the new Biograph mCT

Our dedicated team of molecular imaging experts have helped shape the diagnostic imaging world with their inventions and ideas. And we are continuing this tradition of innovation by continuously pioneering new technologies. With the introduction of the new Biograph™ mCT, we offer our customers ever-increasing opportunities to benefit from their investments in innovation. No matter which way you look at it, Siemens Molecular Imaging is helping you to expand your Return on Innovation.

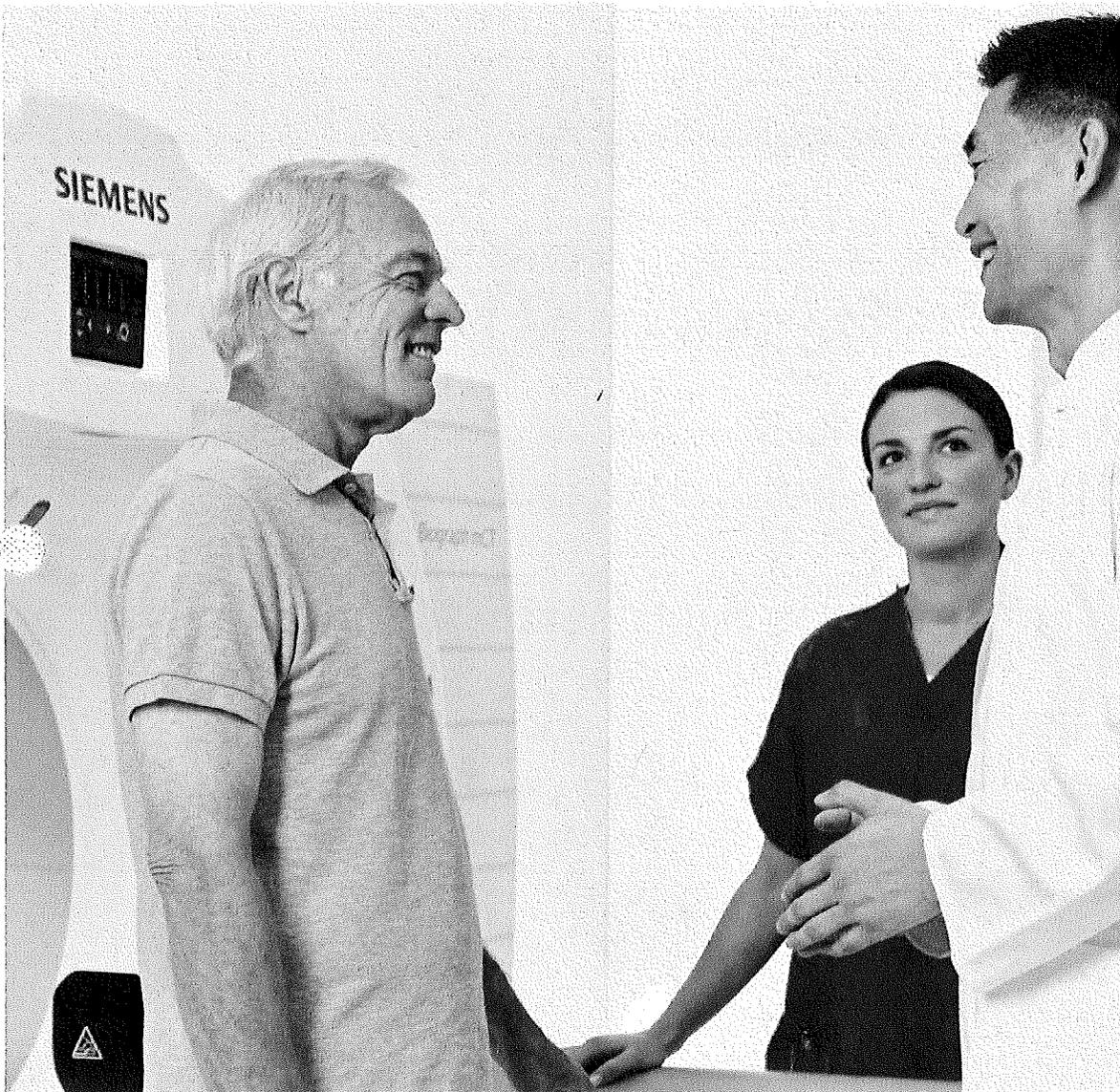
## Biograph mCT – molecular CT. quantification redefined.

With today's PET/CT, the smallest details can go unnoticed, lowering diagnostic confidence. Inaccurate quantification may mislead treatment response monitoring. Longer examination times lead to fewer patients per day, and unnecessary dose could compromise patient safety. Addressing these challenges requires a PET/CT designed from the ground up that improves diagnostic confidence by offering reproducible quantification, the highest image resolution\* and speed in both PET and CT, all while minimizing radiation dose.

The new Biograph mCT. Bringing accurate and reproducible quantification to PET/CT imaging by ensuring that each element of the measurement chain is optimized. Starting with the industry's highest volumetric image resolution\*, Biograph mCT features unique daily quality control, SMART registration technologies and intelligent software to bring accuracy and reproducibility to PET/CT imaging. In addition, innovative CARE technologies ensure the lowest possible dose is administered.

With the new Biograph mCT, now you can detect, characterize and monitor the finest cancer lesions with reproducible quantification, making cancer treatment more cost effective. Now you can quantify absolute myocardial blood flow, making more accurate treatment decisions, minimizing risk to your patients. Now you can potentially\*\* quantify amyloid deposits in the brain, making dementia diagnosis possible, slowing disease progression.

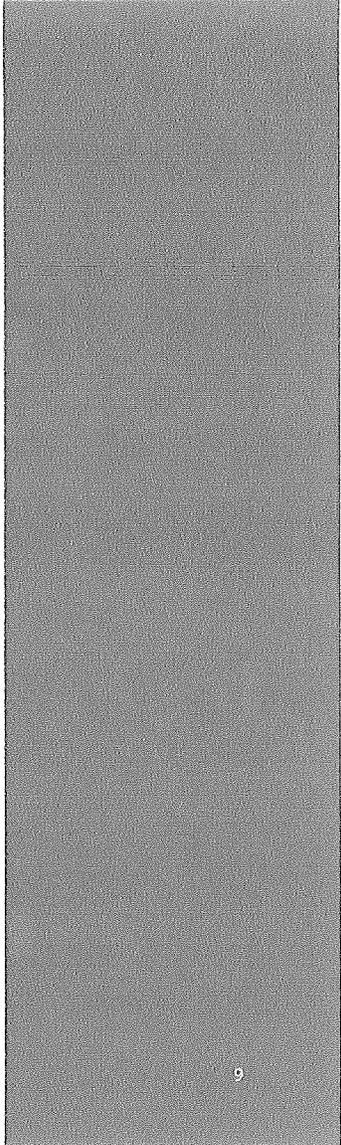
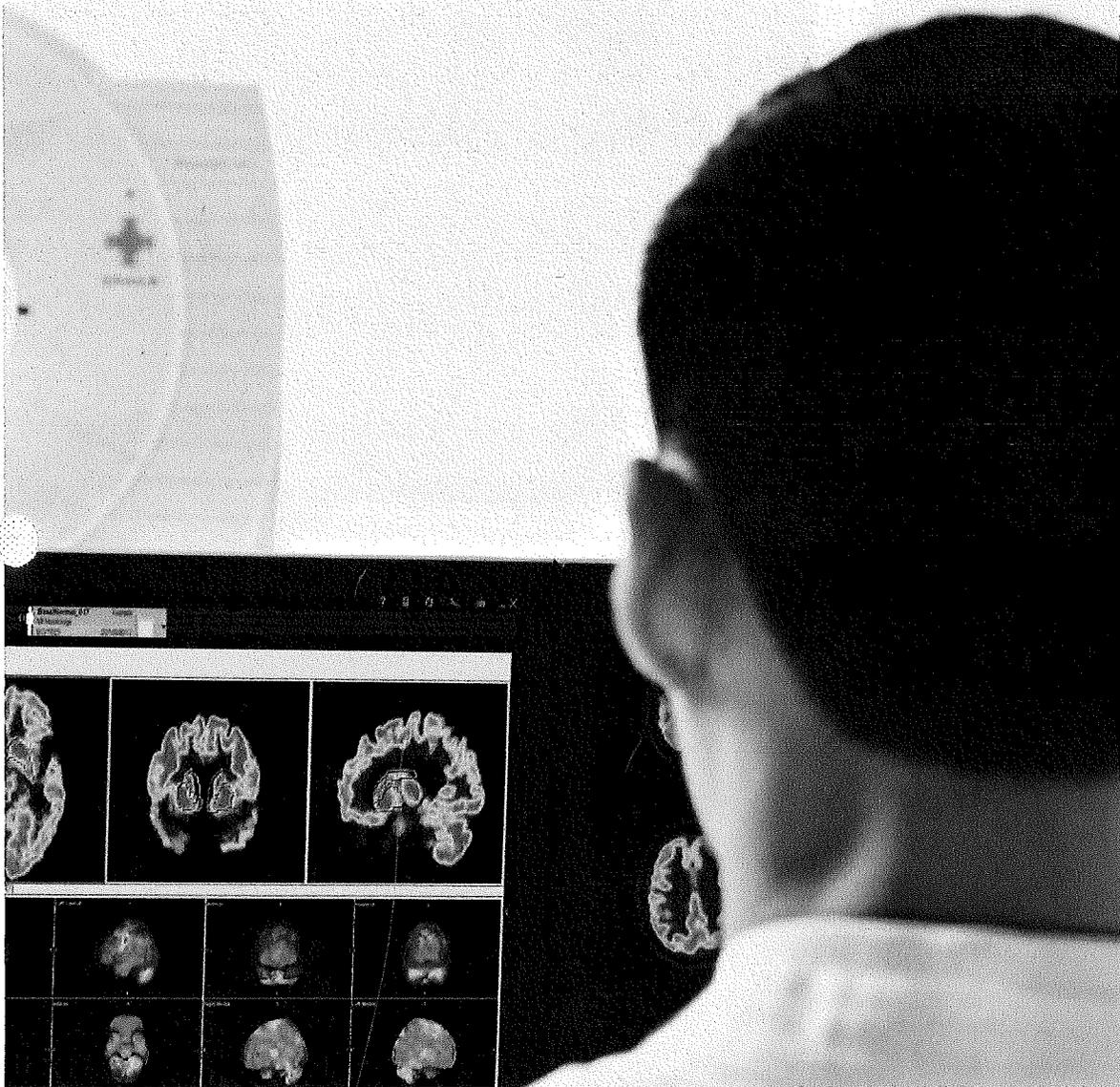
Now, more than ever, you are able to rely on molecular imaging with quantification that is accurate and reproducible. For results that will redefine clinical decision making. The confirmation you need for more diagnostic certainty and more informed treatment planning. Study after study. Scan after scan. Without question.



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# Intelligently Reproducible Quantification

In order to help physicians make sound decisions, imaging must not only be quantifiable – it must be accurate and consistent. With conventional technology, customers face the issue of variability in results due to both software and hardware challenges. Inherent scanner drift and inaccurate attenuation correction through misregistration of anatomical and functional images have a direct impact on reproducibility and accuracy of acquired quantitative data. In addition, standard measurement techniques and inter-user variability affect accurate diagnostic results.

Now, for the first time, Biograph mCT gives you quantifiable results that are precise. Reproducible. And consistent over time. With its unique combination of intelligent software, daily calibration and precise anatomical and functional co-registration Biograph mCT makes a quantifiable difference in diagnostic confidence, therapy planning and treatment monitoring.

## Intelligently Reproducible Quantification

Fast Volume Acquisition Accuracy

Minimum Scan and Acquisition Speed

Engineered Clinical Usability

Simple

Customer Care

Molecular Imaging Biomarker Research

# Return on Innovation

## Clinical Return

- Increased confidence in quantitative results with automatic daily quality control with normalization
- Enhanced precision in staging and follow-up with inter-user reproducibility of SUV values



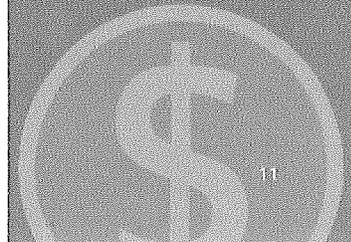
## Workflow Return

- Fast and consistent perfusion results with automatic cardiac registration
- Generate simultaneous PET and CT results with intelligent one-click segmentation



## Financial Return

- Accurate and reproducible quantification attracts more referring physicians and patients
- Grow beyond oncology with unique quantitative offerings in neurology and cardiology



# Intelligently Reproducible Quantification

## Intelligently Reproducible Quantification

Exact Volume in Image Accuracy

Maximum Dose and Maximum Speed

Engineered Electrical Flexibility

*syngo.via*

Customer Care

Molecular Imaging  
Simulator Research

## Daily calibration ensures consistent performance over time

Leaving nothing to chance, Biograph mCT's automatic quality check process was designed to provide confidence that performance is consistent and measurements are accurate, day after day. With Quanti•QC, you can begin each day knowing that overnight your scanner was calibrated and tuned to precisely the right specifications, using phantom data that allows for daily PET normalization and optimal performance. In addition the tightly regulated water-cooled gantry ensures system temperature stability for consistent performance.

## Better attenuation correction for more accurate, quantifiable data

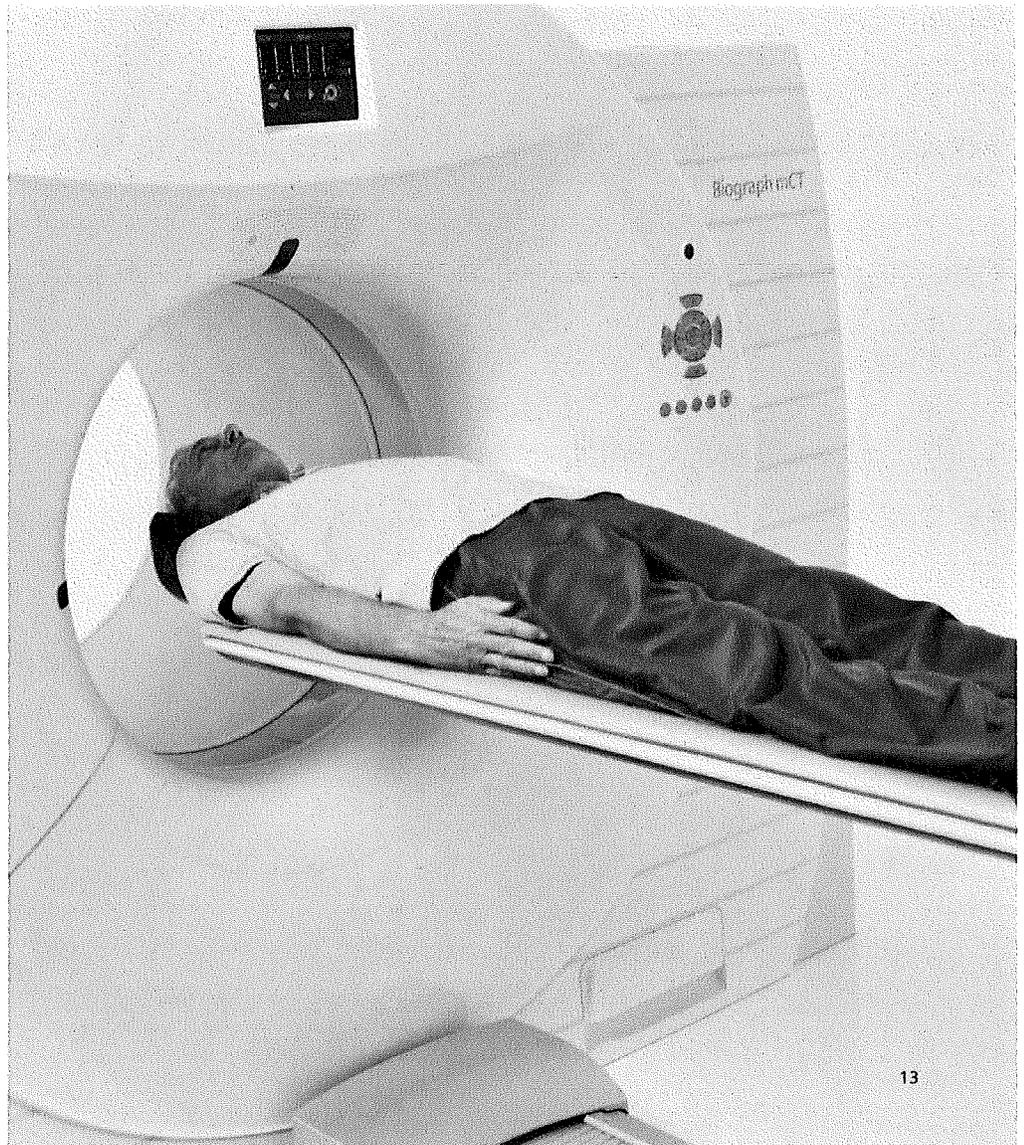
The desire for perfect attenuation correction lies at the heart of our SMART (Siemens Molecular & Anatomical Registration Technologies) research development philosophy. With SMART innovations, Siemens continues to pioneer new ways to address PET attenuation. From a unique patient handling system that eliminates differential deflection to Auto Cardiac Registration which automatically aligns CT and PET heart images and reduces variability between users. And Siemens novel SMART Neuro AC enables you to correct neurological PET data without a CT scan\*. The result in each case is accurate attenuation correction and reliable quantitative measurements.

## Quantitative assessments with *syngo.via*

Advanced *syngo* clinical applications provide essential tools to get more accurate and reproducible, quantifiable measurements in neurology, cardiology and oncology imaging. SUV<sub>peak</sub>, new in the *syngo.mCT* Oncology Engine, provides consistent and reproducible quantitative assessments of hot spots. Myocardial Blood Flow (MBF) can be used as an absolute quantification method to assess balanced disease in all areas of the heart. And an exciting quantitative tool in neurology, part of the *syngo.mCT* Neurology Engine\*, automatically registers brain data to a normals database to assist in the assessment of neurological disorders.

## Summary

In order to help physicians make sound decisions, imaging must not only be quantifiable – it must be accurate and reproducible. Siemens Biograph mCT has been intelligently engineered to meet this need. The new technologies incorporated in Biograph mCT are an exciting step forward in furthering the understanding of disease, its progression and response to treatment. From daily system normalization and precise PET and CT alignment with SMART innovations to intelligent software that assists with the interpretation of dementia, evaluation of balanced myocardial disease and accurate assessment of treatment response on oncology. Accuracy and reproducibility is the key to precisely assessing disease status.



How it works

# Intelligently Reproducible Quantification



## Intelligently Reproducible Quantification

Fastest Measurement  
Large Accuracy

Maximum Data and  
Maximum Speed

Experienced Clinical  
Flexibility

Systemic

Customer Care

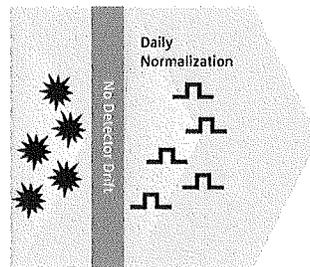
Molecular Imaging  
Biomarker Research

Biograph mCT gives you quantifiable results that are accurate and reproducible by overcoming inherent variabilities faced by conventional PET/CT systems. By incorporating daily system normalization,

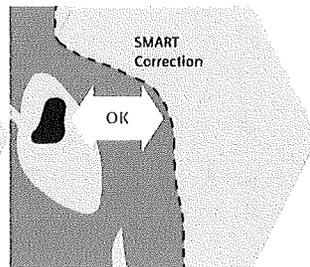
precise PET and CT alignment with SMART innovations and intelligent software, Biograph mCT brings accuracy and reproducibility to daily routine.

- Daily calibration ensures consistent performance over time
- Better attenuation correction for more accurate, quantifiable data
- Quantitative assessments with *syngo.via*

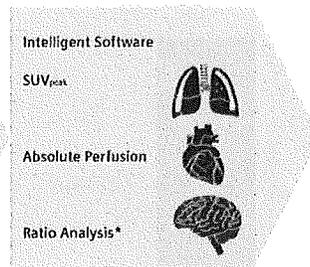
### Quality Control



### PET and CT Registration



### Quantification Software



\* This feature is under development and is not yet commercially available in the United States. Due to regulatory reasons its future availability cannot be guaranteed.

## How it works

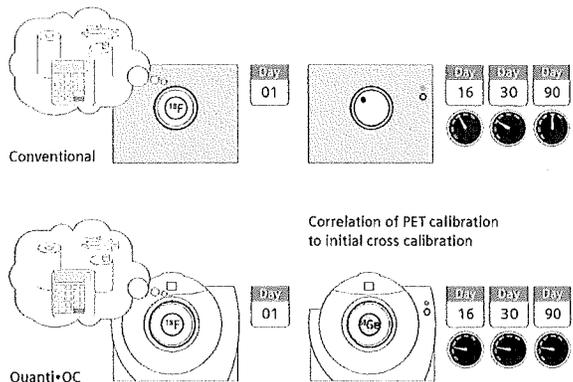
# Quanti•QC

Biograph mCT's Quanti•QC assures day-to-day consistency in your system response and quantitative reproducibility. The comprehensive daily quality check and calibration can be scheduled to run overnight so the scanner is ready to begin imaging before the first patient arrives.

Quanti•QC is performed with a 20 cm Germanium-68 uniformity phantom of known activity. This method allows for correlation with the dose calibrator via daily comparison to previously acquired cross calibration – bringing increased confidence in the quantification efficacy of the system. Once the phantom scan is completed, normalization results are reported, including a PET calibration factor check confirming correct computation of the absolute image calibration.

Environmental factors such as temperature fluctuations in the scan room have long been recognized as a potential source of system performance drift. Biograph mCT vastly reduces such influence with the tightly regulated integrated water-cooling system which ensures system temperature stability for consistent performance.

- Daily normalization is routine
- Can be scheduled to run overnight
- Allows for correlation with dose calibrator via daily comparison to previously acquired cross calibration for assurance of quantitative accuracy

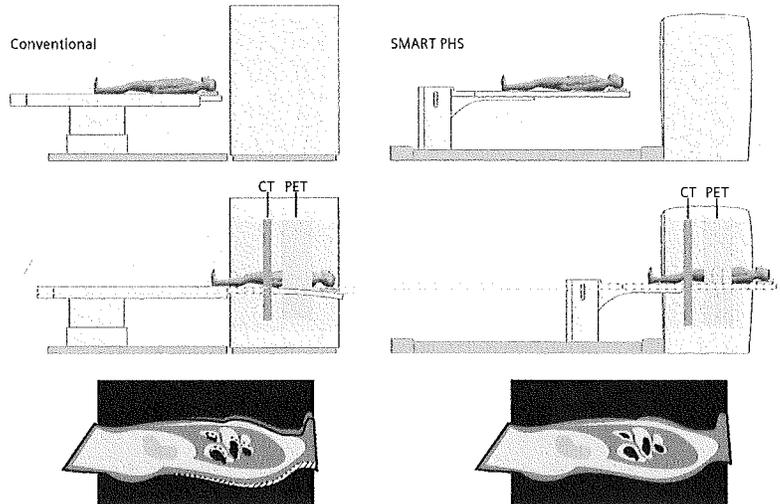


How it works

## SMART PHS

Biograph mCT employs a SMART patient handling system (PHS) that was specifically designed for use in PET/CT imaging. Its unique cantilever design, in which the pedestal and table move as one unit, supports a full 227 kg (500 lb) without any differential deflection between PET and CT acquisitions. This no-flex feature ensures accurate attenuation correction for more precise quantification.

- Unique cantilever design
- Full 227 kg (500 lb) table capacity
- No differential deflection



### Intelligently Reproducible Quantification

Precise Molecular  
Imaging Accuracy

Minimum Dose and  
Maximum Speed

Engineered Clinical  
Flexibility

syngeneo

Customer Care

Molecular Imaging  
Bioscience Research

How it works

## SMART Auto Cardiac Registration

SMART Auto Cardiac Registration quickly, automatically and precisely registers CT and PET scans during cardiac imaging. Using a proprietary algorithm, SMART Auto Cardiac Registration identifies the heart and aligns the molecular and anatomical images for optimal attenuation correction.

SMART Auto Cardiac Registration is integrated within the cardiac acquisition workflow. A rapid reconstruction of the non-attenuation corrected PET image is automatically registered to the CT for optimal registration confirmation. PET attenuation corrected images are reconstructed based on the confirmed optimal registration.

SMART Auto Cardiac Registration reduces the variability between users, providing consistently accurate and reproducible quantification.

- Automatic and fast PET and CT registration
- Reproducible between users
- Consistently accurate quantification

Conventional



SMART Auto Cardiac Registration



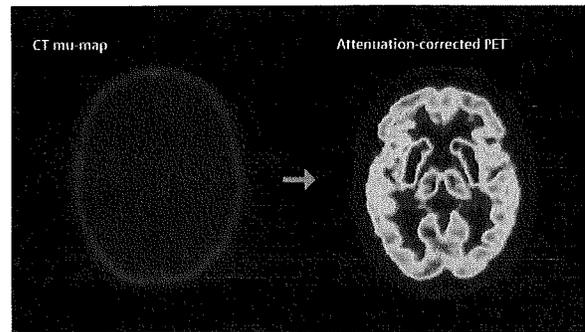
How it works

# SMART Neuro AC

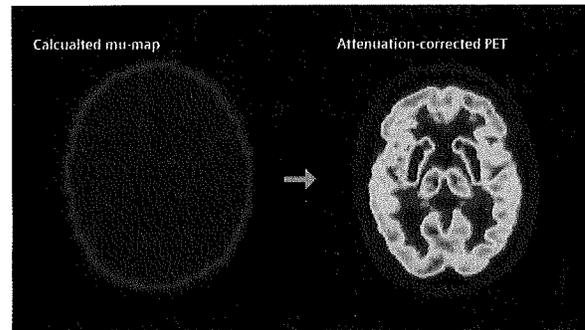
SMART Neuro AC\* enables quantification of PET data without requiring a CT scan for attenuation correction. The ability to perform attenuation correction without a CT scan avoids any co-registration problems that can occur due to patient motion. Siemens SMART Neuro AC assesses and applies an appropriate attenuation map to the PET data to make accurate corrections without requiring a CT scan, relieving the patient of further radiation exposure and eliminating the chance of registration inaccuracies.

- Calculated attenuation correction
- Quantitative PET data
- Minimize radiation dose

Conventional CT AC



SMART Neuro AC



\* SMART Neuro AC is pending 510k clearance, and is not yet commercially available in the United States.

## How it works

# SUV<sub>peak</sub>

SUV<sub>peak</sub> employs a 1 cm<sup>3</sup> sphere volume of interest (VOI) within a lesion for more robust evaluation of uptake. SUV<sub>peak</sub> automatically identifies the peak value within a VOI. Compared to the conventional single pixel SUV<sub>max</sub>, SUV<sub>peak</sub> can decrease the influences of noise and together with the pre-set 1 cm<sup>3</sup> volume and automatic peak algorithm, can potentially reduce reader variability. This method provides accurate and reproducible information for therapy response assessment.

- Automatic identification of 1 cm<sup>3</sup> SUV peak volume within VOI
- Fixed dimensions of peak volume reduces inter-operator variability
- Reduced susceptibility to noise



How it works

# Myocardial Blood Flow

## Intelligently Reproducible Quantification

Highest Volumetric  
Imaging Accuracy

Minimum Dose and  
Maximum Speed

Engineered Clinical  
Flexibility

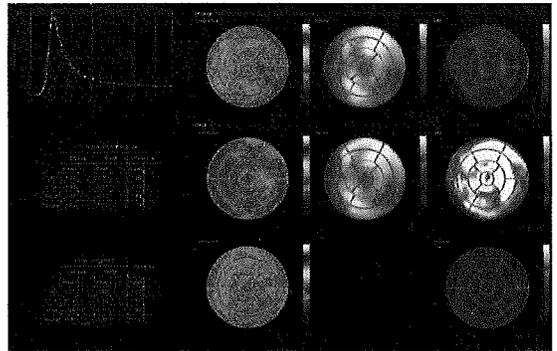
syngo

Customer Care

Molecular Imaging  
Biomarker Research

Conventional myocardial perfusion imaging assesses the blood's relative distribution, assuming that at least one section of the heart performs normally and can be used as a reference. The myocardial blood flow (MBF) application is an absolute quantification method that helps to confidently assess balanced disease in all areas of the myocardium. This technology now supports  $^{82}\text{Rb}$  Rubidium as well as  $^{13}\text{N}$  Ammonia imaging.

- Non-invasive quantitative assessment of myocardial blood flow and coronary flow reserve
- Supports  $^{82}\text{Rb}$  and  $^{13}\text{N}$  Ammonia biomarkers



How it works

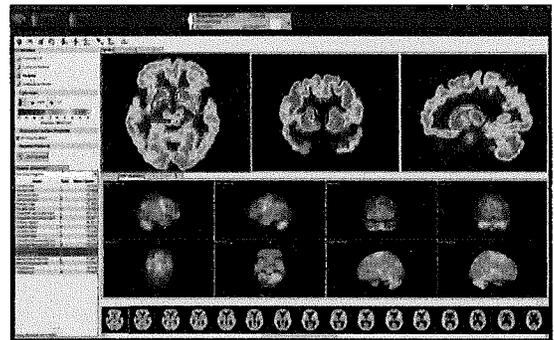
## PET Neurology Quantification

syngo.PET Neuro DB Comparison\* includes a PET FDG normals database which provides quantitative assessment of biomarker uptake in the brain to aid in the assessment of neurological disorders such as dementia. The application registers brain data to a normals database automatically, so regional volume of interest (VOI) generation and statistical analysis can be obtained. The comparison quickly reveals abnormalities if present.

As an innovation leader, Siemens is continually looking towards the future to find ways to answer tomorrow's challenges sooner. New biomarkers are steadily being researched and developed. Such biomarkers often benefit from different tools than

currently exist. Siemens is presently working to develop another quantitative tool in neurological imaging, which would assess the biomarker activity ratio\*\* between two regions of the brain (i.e. a region of interest compared to a reference region such as the cerebellum).

- Clear and quick assessment of hyper- and hypo-metabolic brain regions
- Standard voxel-by-voxel reporting of statistics
- Predefined 3D anatomical brain regions



\* syngo.PET Neuro DB Comparison is pending 510k clearance, and is not yet commercial available in the United States.

\*\*This feature is under development and is not yet commercially available in the United States. Due to regulatory reasons its future availability cannot be guaranteed.

**Intelligently  
Reproducible  
Quantification**

Finest Volumetric  
Image Accuracy

Minimum Dose and  
Maximum Speed

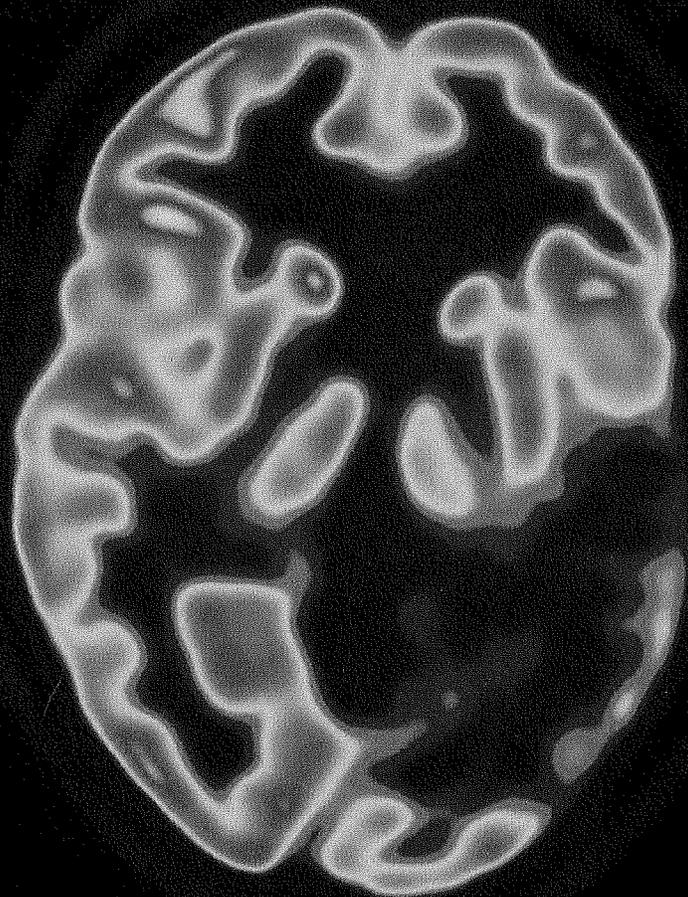
Engineered Clinical  
Flexibility

*synqo*.via

Customer Care

Molecular Imaging  
Biomarker Research

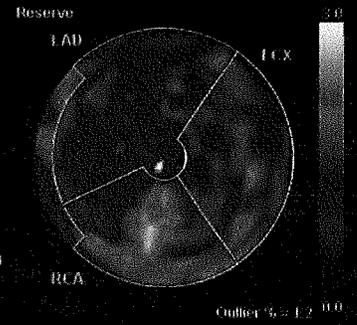
*synqo* PET/MR Neuro DB Comparison\*  
automatically registers brain data  
to a normaly database so VOI can  
be generated for quantitative  
assessment of biomarker uptake



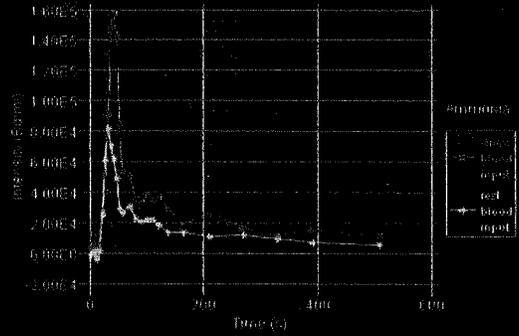
1  
 Max:8.81 SUV bw 90 HU  
 Max Diameter:2.7 cm  
 Volume:4.19 cm<sup>3</sup>  
 Peak:4.54 SUV bw  
 Peak Diameter:1.24 cm

Volume of sphere 1 with  
 SUV = provides  
 color and reproducible  
 quantification

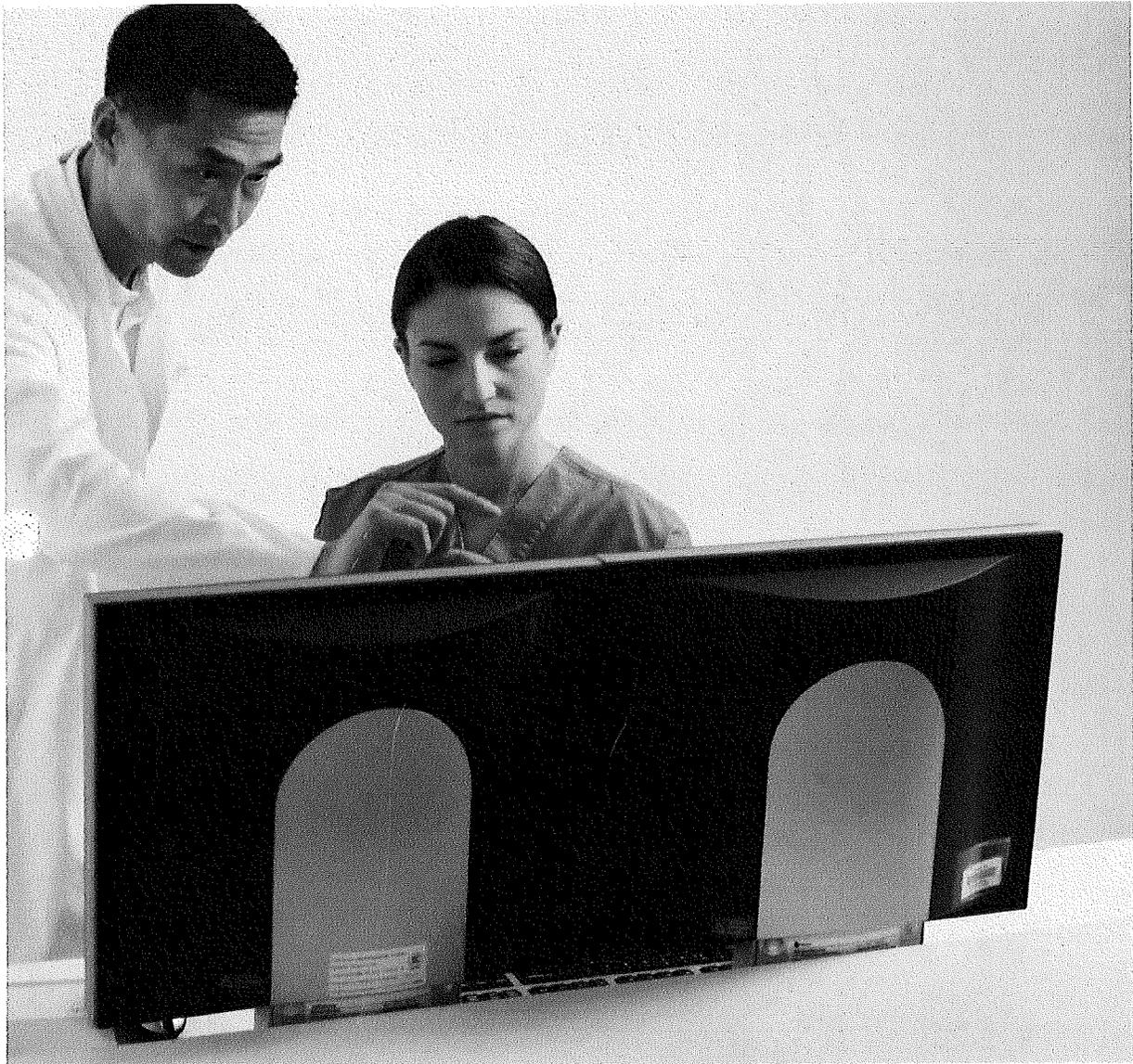
1 PT CT 3D



Myocardial blood flow  
 provides an absolute  
 quantification method  
 to assess balanced  
 disease in the  
 myocardium



# Finest Volumetric Image Accuracy\*



# Finest Volumetric Image Accuracy\*

improving  
Reproducible  
Quantification

## Finest Volumetric Image Accuracy

Maximum Data and  
Maximum Speed

Engineered Clinical  
Flexibility

Simple

Customer Care

Biological Imaging  
Oncology Research

An accurate diagnosis starts with an accurate image in all dimensions. With conventional technology, small or low-grade lesions can go undetected or lose definition towards the edge of the FOV and are subject to motion blurring thereby lowering diagnostic confidence. Siemens recognizes that at the core of a good image is an accurate detection system, which begins with optimized components. From the very beginning of Siemens PET-CT technology, image quality has been the first priority, this is still true today. Biograph mCT optimizes the components of the detection system into a superbly designed imaging chain. From the design and configuration of the isotropic LSO crystals to the high speed electronics to the industry's best 400 x 400 reconstruction matrix, all resulting in the finest volumetric image accuracy\*. Combined with high definition technologies that bring uniform resolution and images virtually free of motion, it's now possible to diagnose with the increased confidence that this exquisite molecular clarity provides.

# Return on Innovation

## Clinical Return

- Superb visualization, particularly of small tumors with industry-leading 87  $\mu\text{m}^3$  volumetric resolution\*
- Increased diagnostic confidence with the finest uniform resolution\* and a 4x increase in signal-to-noise



## Workflow Return

- Reduced time to image review enabled by fast and consistent reconstruction times
- One-click gating integrated in daily routine



## Financial Return

- Attract patients and referring physicians with high-definition image quality
- Reduction of false negatives associated with breathing artifacts



# Finest Volumetric Image Accuracy

## Patented OptisoHD Detection System delivers the industry's finest volumetric resolution\*

Siemens continues to deliver exquisite diagnostic image quality. The unique OptisoHD Detection System provides a robust foundation comprised of optimized components enabling peak performance throughout the scanner. Biograph mCT continues to set the standard for image quality by delivering the finest NEMA\* and volumetric resolution in the market.

## Excellence in Cardiac Imaging

Biograph mCT provides excellence in cardiac imaging through innovative PET and CT technologies. The patented Prompts Gamma Correction provides clarity in PET cardiac imaging with a reduction in noise while the

highly renowned and compact STRATON™ tube with z-Sharp™ delivers true temporal resolution of up to 150 ms for motion-artifact free CT imaging of the heart.

## Uniform resolution throughout the field of view

Siemens ultraHD-PET delivers increased image quality, easily outperforming conventional PET/CT technology. It combines two important innovations: HD-PET, which provides uniform resolution throughout the FOV; and Time of Flight (TOF), which doubles improvement in signal-to-noise. Combined with z-Sharp™ technology that provides an isotropic resolution of 0.33 mm at any position within the scan field, Biograph mCT continues to push the boundaries of spatial resolution.

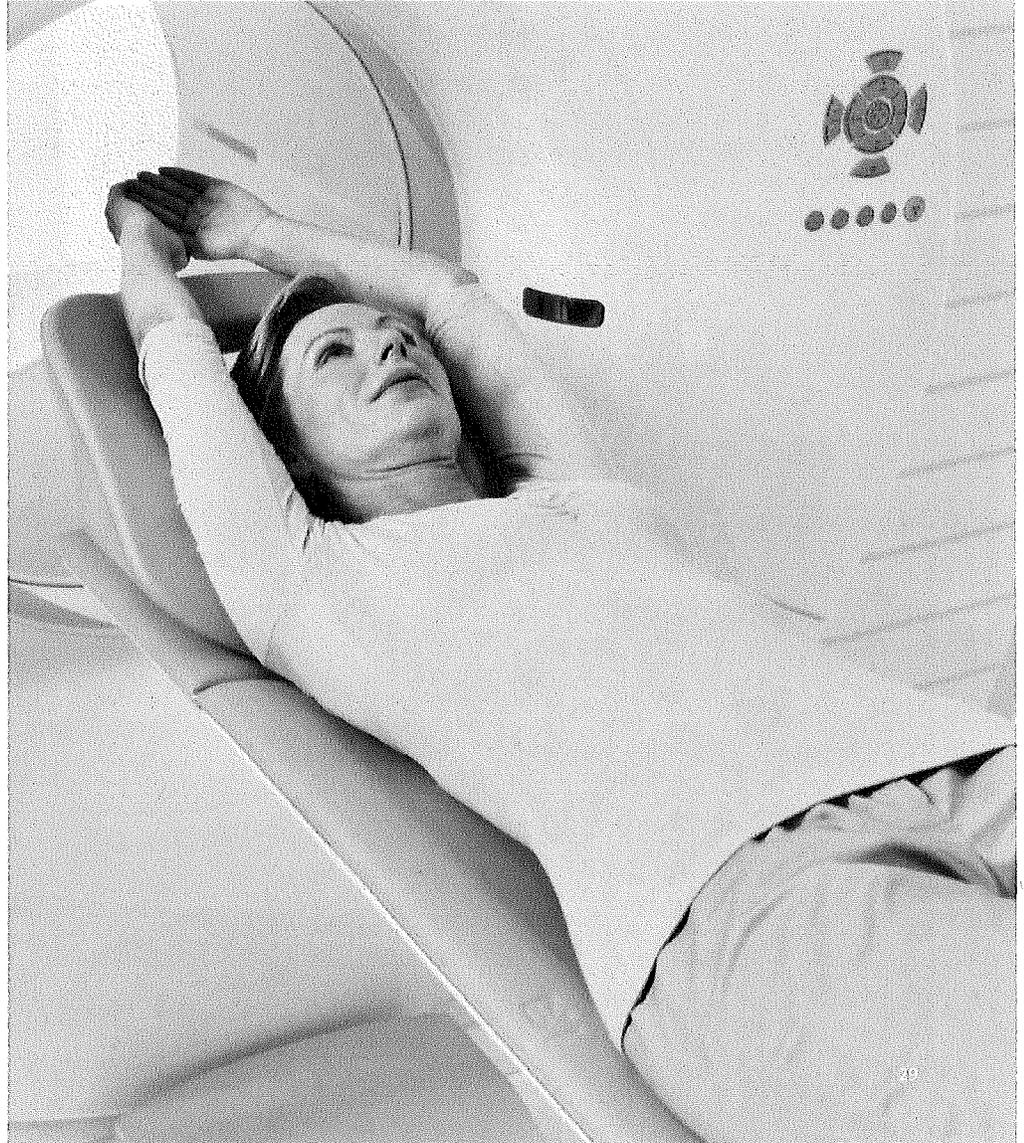
## No motion for full HD lesion detection, accurate SUV quantification

HD-Chest is a breakthrough technology from Siemens that eliminates the tradeoff between diagnostic confidence and examination time. An innovative combination of hardware and software, HD-Chest virtually freezes respiratory motion, enabling full HD lesion detection and accurate standard uptake value (SUV) quantification. Best of all, HD-Chest is designed to be as fast as a conventional PET examination, so you can have increased diagnostic confidence without affecting your patient schedule.

\* Based on competitive literature available at time of publication. Data on file.

## Summary

Image clarity and precise localization are key to disease detection, accurate staging and improved therapy planning. Biograph mCT's OptisoHD Detection System and innovative technologies like Prompts Gamma Correction, Time of Flight, z-Sharp and HD Chest work together to acquire and reconstruct images that accurately represent molecular processes with superb image quality in all dimensions. So cardiac studies are more exact. Tumors are more clearly defined. Brain lesions can be precisely mapped. Siemens new Biograph mCT is a quantum leap forward, refining images and setting another new standard in diagnostic imaging.



How it works

## OptisoHD Detection System

Imaging time  
Independent file  
Download

Finest Volumetric  
Image Accuracy

Minimum Dead and  
Maximum Speed

Engineered for total  
Flexibility

Simple to use

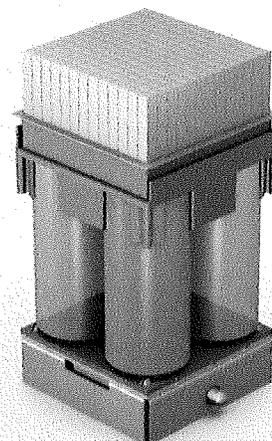
Fast image time

Molecular imaging  
Biomarker Research

Siemens OptisoHD Detection system is designed for optimum performance. The Lutetium Oxyorthosilicate (LSO) crystals – manufactured by Siemens and long recognized for their density, fast scintillation decay time (the fastest of all PET scintillators currently in use) and light output – are the foundation of the system. These isotropic LSO crystal elements are tightly packed and incorporate Siemens patented air reflector technology which optimizes the light output for even greater timing performance and energy resolution.

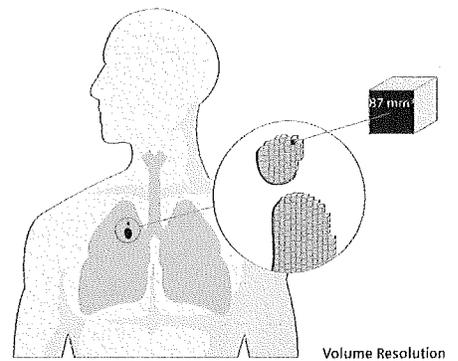
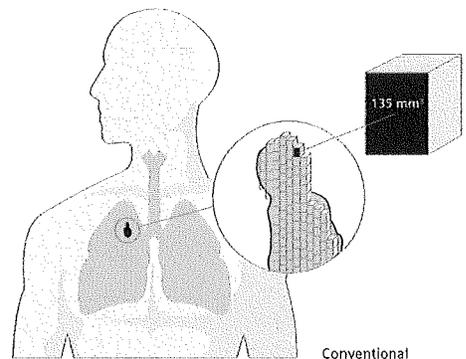
Ultrafast detector electronics, combined with the speed of LSO and the unique block design of OptisoHD Detection System, allow fast coincidence timing with efficient rejection of random events. This provides very high count rates that are essential to high-speed PET scanning. Ultimately, the result is superb clarity and better localization of events. These events are then reconstructed using the industry's highest matrix size of 400 x 400\*, delivering superb image quality with leading NEMA resolution\*.

- Patented air reflector technology
- High resolution –  
4 x 4 x 20 mm LSO crystals
- Industry's highest matrix size of  
400 x 400\*



In a three-dimensional world, decisions should be made with three-dimensional information. And a simple comparison of voxel size helps explain the volumetric resolution advantage of Biograph mCT. Conventional equipment uses larger, non-isotropic elements; Biograph mCT employs smaller isotropic elements. These smaller elements and fine axial sampling help to create extraordinary images in any dimension, resulting in the industry's finest volumetric resolution\* of only 87 mm<sup>3</sup>, up to 35% smaller than conventional systems. Sampling statistics reduce partial volume effects and achieve an increased quantitative accuracy for detection of smaller lesions.

- Volume resolution 87 mm<sup>3</sup>
- Up to 35% finer volumetric resolution than conventional systems
- Decreased partial volume effect



How it works

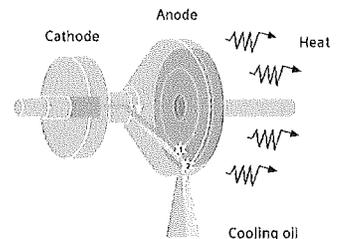
## Cardiac CT

High quality cardiac CT depends on a number of system performance features including high temporal resolution, fine spatial resolution and flexible acquisition techniques that adapt to different patients. Biograph mCT addresses all these requirements with 0.3 sec rotation speed, 0.33 mm isotropic resolution and up to 128 acquired slices per rotation.

The core technology that allows the new Biograph mCT to deliver clinical excellence in cardiac CT, is the highly renowned STRATON™ tube with z-Sharp™. Its revolutionary design based on a direct anode cooling eliminates the need for heat storage and results in an unmatched compact design thus allowing true temporal resolution of up to 150 ms. Instead of

decreasing the detector elements' size to improve spatial resolution, z-Sharp utilizes two overlapping X-ray beams, resulting in significantly increased spatial resolution without a corresponding increase in dose. This provides you with the industry's highest isotropic resolution of 0.33 mm at any scan and rotation speed, and at any position within the scan field. This for instance allows motion-artifact free imaging of the heart to perform accurate stenosis measurements or stent planning with outstanding precision.

- Compact tube design with 0.3 sec rotation speed
- 150 ms temporal resolution
- 0.33 mm isotropic resolution



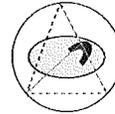
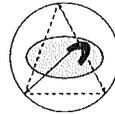
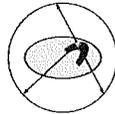
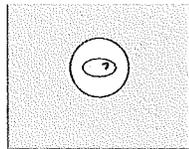
How it works

## Prompts Gamma Correction

Siemens patented Prompts Gamma Correction is the solution for cardiac imaging with rubidium-82 ( $^{82}\text{Rb}$ ), providing improved image accuracy through a reduction in image noise. The third gamma that  $^{82}\text{Rb}$  emits results in an additional and incorrect line of response to be calculated. Left uncompensated, this additional gamma leads to distortions with increased image noise and possible quantitative errors. Prompts Gamma Correction automatically addresses this anomaly in its scatter correction algorithms, resulting in more reliable, more accurate imaging.

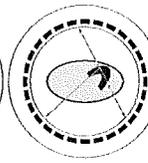
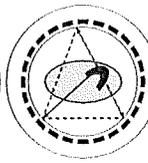
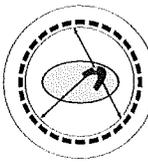
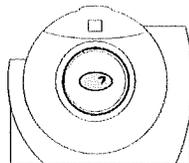
- Noise reduction for improved image contrast
- More quantitative accuracy
- Correction automatically incorporated in patented scatter correction algorithm

Conventional



More noise reduces image clarity

Prompts Gamma Correction

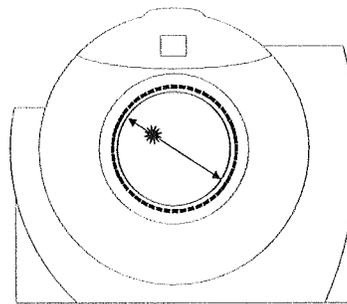


Less noise for greater image clarity

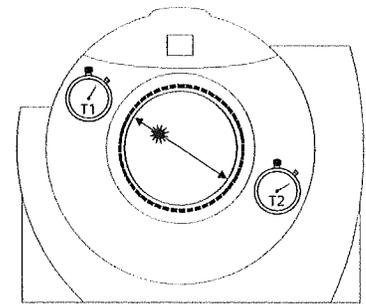
How it works

# Time of Flight

Conventional

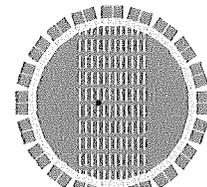
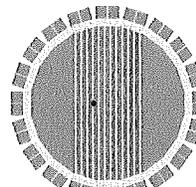


Time of Flight



Siemens TOF measures the actual time difference between the detection of each coincidence photon. This additional timing information is used to better localize the event within a small range along each line-of-response (LOR). The better localization of each event using TOF reduces noise in the reconstructed image.

- 2x improvement in signal-to-noise
- 2x improvement in contrast
- Signogram mode TOF with fixed and fast reconstruction times



Independently  
Reproducible  
Quantification

**Finest Volumetric  
Image Accuracy**

Minimum Dose and  
Maximum Speed

Engineered Clinical  
Flexibility

Simple via

Intuitive Care

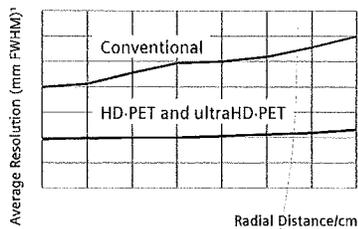
Advanced Imaging  
Breakthrough Research

## How it works

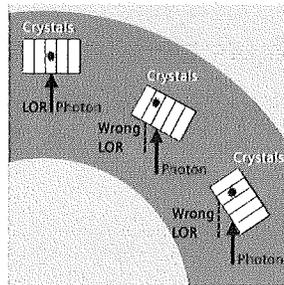
# HD-PET

HD uniformity · HD resolution · 2x HD contrast

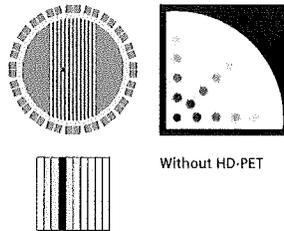
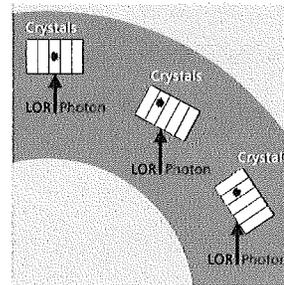
- HD-PET improves resolution
- Delivers uniform resolution throughout the FOV
- 2x improvement in signal-to-noise



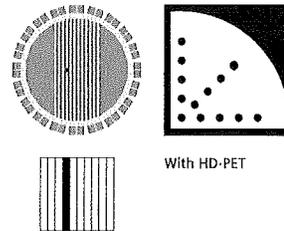
Conventional



HD-PET



Without HD-PET



With HD-PET

Conventional PET uses the same reconstruction principles across the entire FOV and does not take into account the detector geometry and mispositioning of the LORs. This results in fuzzy edges and increased distortion further from the center of the FOV.

HD-PET incorporates millions of accurately measured point spread functions (PSF) in the reconstruction algorithms. Using measured PSFs, HD-PET effectively positions the LORs in their actual geometric location, which dramatically reduces blurring and distortion in the final image.

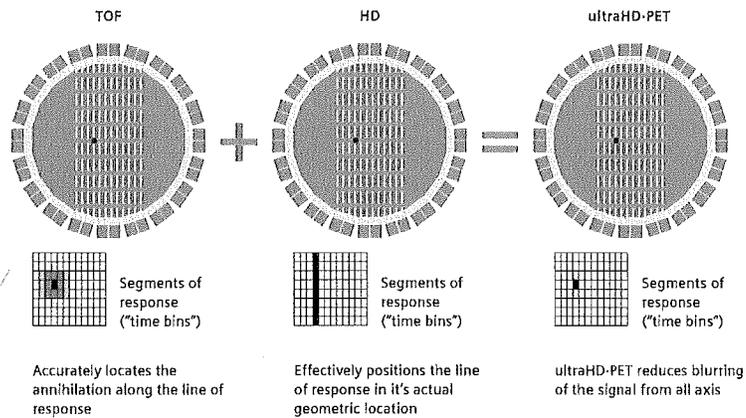
Measurements were taken with a line source suspended in air at radial positions from the center to 28 centimeters in 4 centimeter steps. The Biograph HD-REZ-FDP data were reconstructed with a standard filtered backprojection algorithm after FORE rebinning and the HD-PET data were reconstructed with the TrueX algorithm using six iterations and 14 subsets.

How it works

# ultraHD·PET

By combining Siemens HD-PET with TOF, the result is up to 4 times improvement in signal to noise for ultraHD contrast and uniform resolution throughout the FOV.

- Uniform resolution throughout the FOV
- 4x improvement in signal-to-noise
- Fast and consistent reconstruction time



Intelligence  
Reproducible  
Quantification

Finest Volumetric  
Image Accuracy

Minimum Data and  
Maximum Speed

Engineered Clinical  
Flexibility

Simple

Customer Care

Molecular Imaging  
Biomarker Research

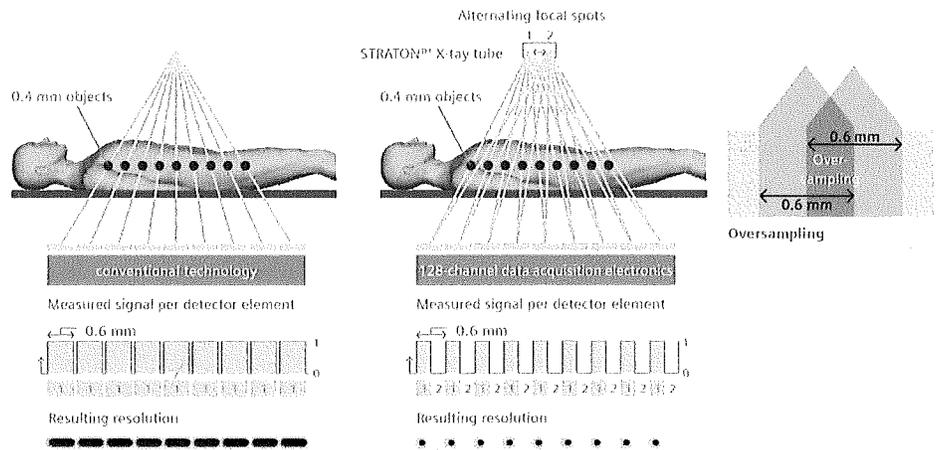
## How it works

# z-Sharp

Increased resolution without increased dose. z-Sharp uses two intersecting X-ray beams that produce isotropic resolution of 0.33 mm at any scan and rotation speed, and within any position in the scan field – all without an increase in dose.

For wrist, joint or inner ear studies, Siemens proprietary technology, z-UHR, adapts the system for ultra-high resolution bone imaging. In this case, providing 0.24 mm isotropic resolution.

- Increased resolution without dose penalty
- Isotropic 0.33 mm resolution throughout the FOV
- z-UHR provides 0.24 mm isotropic resolution

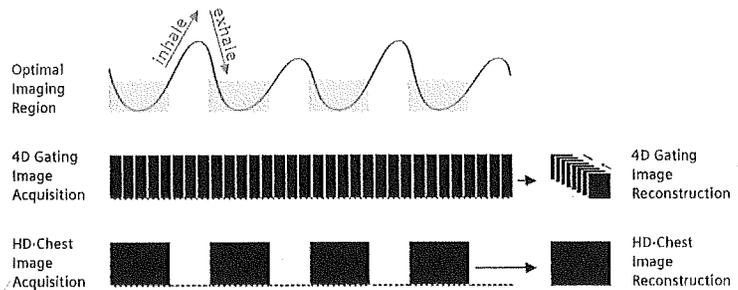


How it works

# HD·Chest

**Full HD lesion detection**  
**Accurate SUV quantification**  
**One-click routine**

- Amplitude based gating automatically analyzes each patient's individual breathing pattern
- Identifies portion of the respiratory cycle with the least motion and the most data – the optimum imaging area



HD-Chest applies an innovative algorithm to analyze each patient's individual breathing pattern and identify the portion of the respiratory cycle with the least motion. This area of the cycle is where most data can be collected, without motion, in the shortest amount of time.

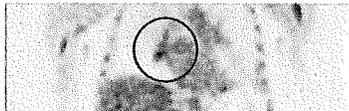
With HD-Chest, image data from the optimal portion of the breathing cycle goes to make up the image. The system then reconstructs a single, high resolution image with superior lesion conspicuity. The entire process is automated, which means it is operator independent, saving you valuable time.

**Conventional Examination**



In the conventional scan, respiratory motion causes the lesion to be obscured.

**HD-Chest**



With HD-Chest, the lesion is clearly visible.

**Full HD lesion detection**

With less noise and more data, small moving lesions are clearer and their edges are sharper.

**Conventional Examination SUV<sub>max</sub>4**



In this example, the conventional scan shows a single lesion blurred by respiratory motion.

**HD-Chest SUV<sub>max</sub>9**

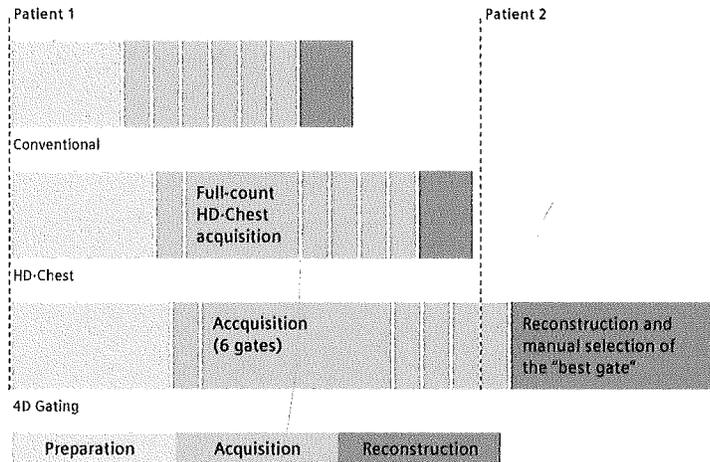


HD-Chest greatly improves quantification of lesions normally blurred by respiratory motion.

**Accurate SUV quantification**

HD-Chest's motion freeze also enables more accurate standard uptake value (SUV) measurement.

**Clinical Workflow**



**One-click routine**

HD-Chest enables automatic acquisition and reconstruction of virtually motion-free images in less time than conventional gating techniques.

Superb visualization  
of small tumors  
with industry leading  
volumetric resolution<sup>1</sup>

Intelligently  
Reproducible  
Quantification

Finest Volumetric  
Image Accuracy

Minimum Dose and  
Maximum Speed

Engineered Clinical  
Flexibility

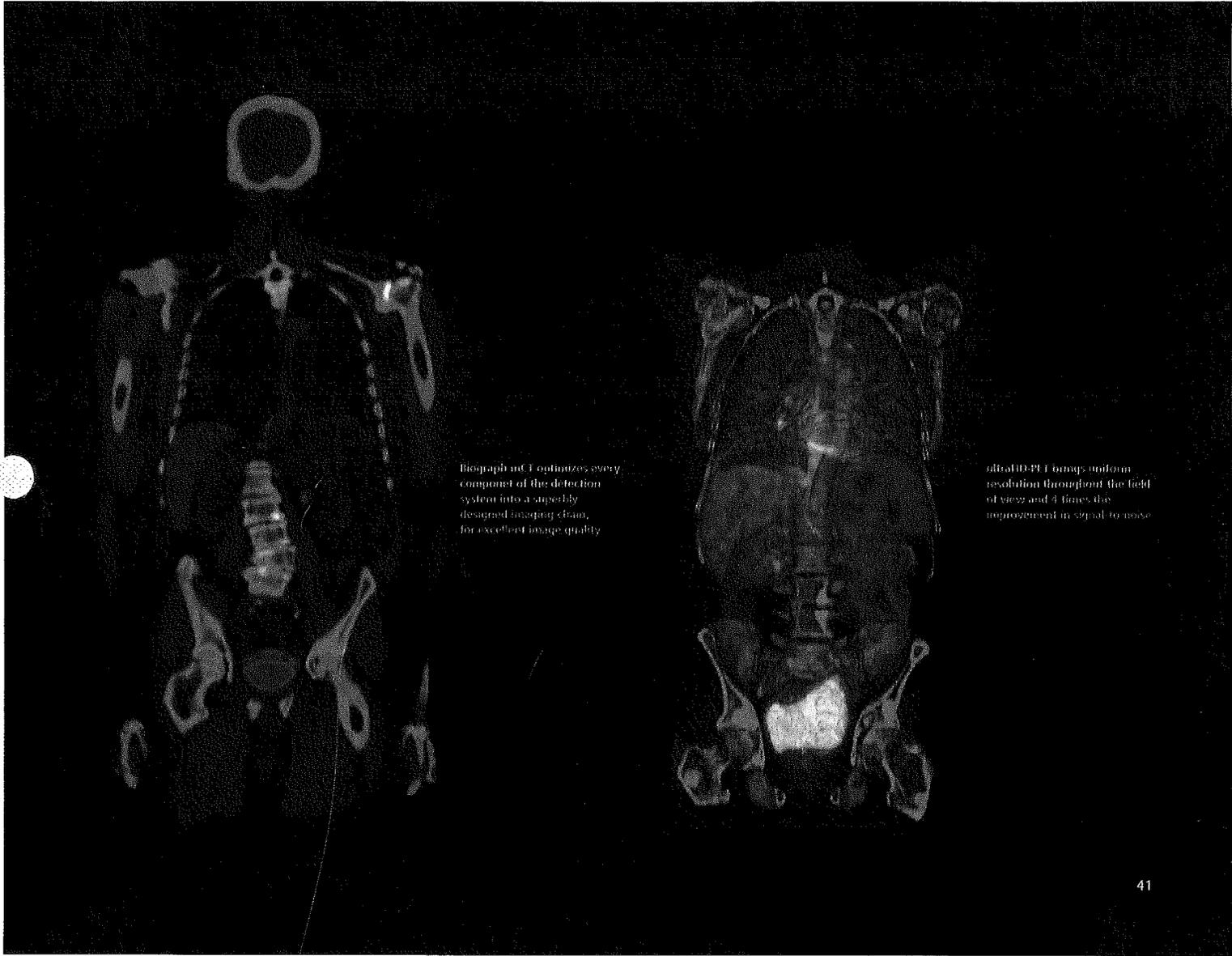
*synqo* via

Customer Care

Molecular Imaging  
Biomarker Research

40 <sup>1</sup> Based on competitor literature available  
at time of publication. Data on file.



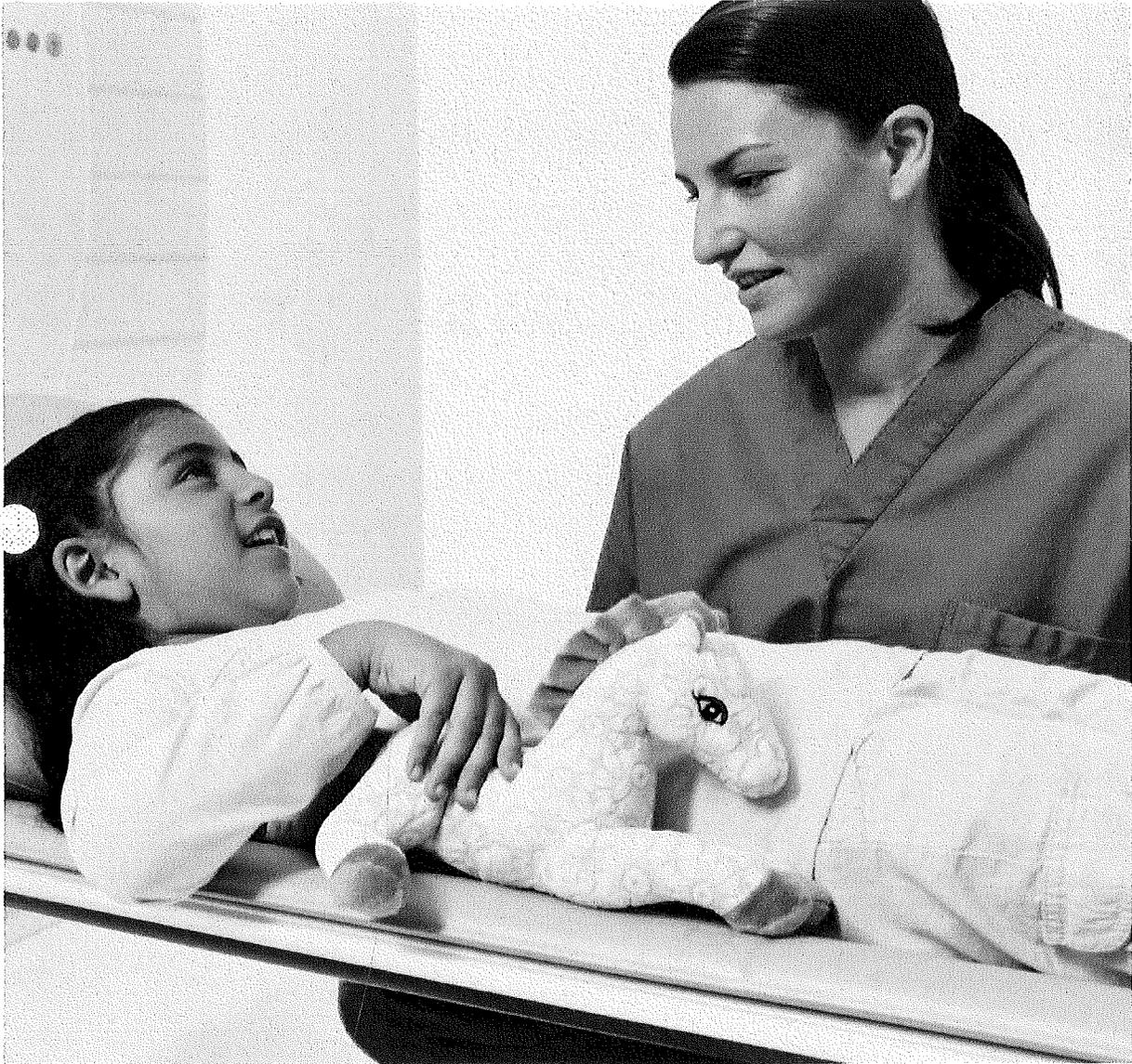


Biograph mCT optimizes every component of the detection system into a superbly designed imaging chain, for excellent image quality.

ultraHD-PET brings uniform resolution throughout the field of view and 4 times the improvement in signal to noise.

# Minimum Dose and Maximum Speed





# Minimum Dose and Maximum Speed

Two of the most challenging issues facing healthcare today are the dual mandates to improve patient safety and increase productivity. From a patient care and economic perspective, each is critically important. With conventional systems, clinicians have to choose between protecting patients with minimum dose, or greater productivity with faster scanning. The new Biograph mCT offers innovative imaging solutions where the lowest dose can be used, while still scanning patients faster than ever before. Now, clinicians can have it all – scans with half dose and double speed. By reducing dose and increasing speed, patient safety is improved, costs are dramatically reduced, while increased utilization can also be achieved.

Imaging with  
Appropriate  
Quantification

Finest Performance,  
Image Accuracy

**Minimum Dose and  
Maximum Speed**

Engineered Clinical  
Flexibility

Scalable

Customer Care

Molecular Imaging  
Biomarker Research

# Return on Innovation

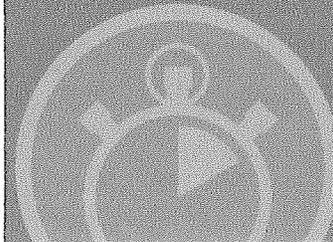
## Clinical Return

- Half the dose and the acquisition time while maintaining highest image quality
- Minimum dose, especially to critical patients (children and patients with frequent follow-up exams)



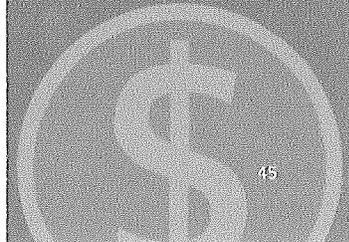
## Workflow Return

- Whole-body PET scans in only 5 minutes
- Lowest possible dose and high-speed workflow enabled by FAST CARE technologies



## Financial Return

- Reduce imaging radioisotope costs by reducing injected dose
- Attract more referrals by increasing patient comfort with shorter exam times



# Minimum Dose and Maximum Speed

Intelligently  
reproducible  
quantification

First Molecular  
Biography

Minimum Dose and  
Maximum Speed

Unprecedented Clinical  
Flexibility

Scapigo

Customer Care

Molecular Imaging  
Biomarker Research

## CARE

Achieving the highest technical performance is only important when it meets the needs of the patient and our customers. In molecular imaging, patient safety translates primarily into dose reduction.

Principles such as "As Low as Reasonably Achievable" (ALARA) have developed as a guideline to reduce all radiation exposure to the lowest possible level. With CARE (Combined Applications to Reduce Exposure), Siemens has been highly successful in integrating many innovations into the Siemens scanners that significantly reduce radiation dose in comparison to other systems available on the market.

## FAST

An increasingly competitive and rapidly changing healthcare market requires improvements in quality and throughput. Utilizing FAST (Fully Assisting Scanner Technologies) innovations, typically time consuming and complex procedures during the scan process are extremely simplified and automated, not only improving workflow efficiency and scanner utilization, but optimizing the overall clinical outcome by creating reproducible results, making diagnosis more reliable and reducing patient burden through streamlined examinations. In addition, faster scans result in less patient motion, so image quality and the overall patient experience can be optimized.

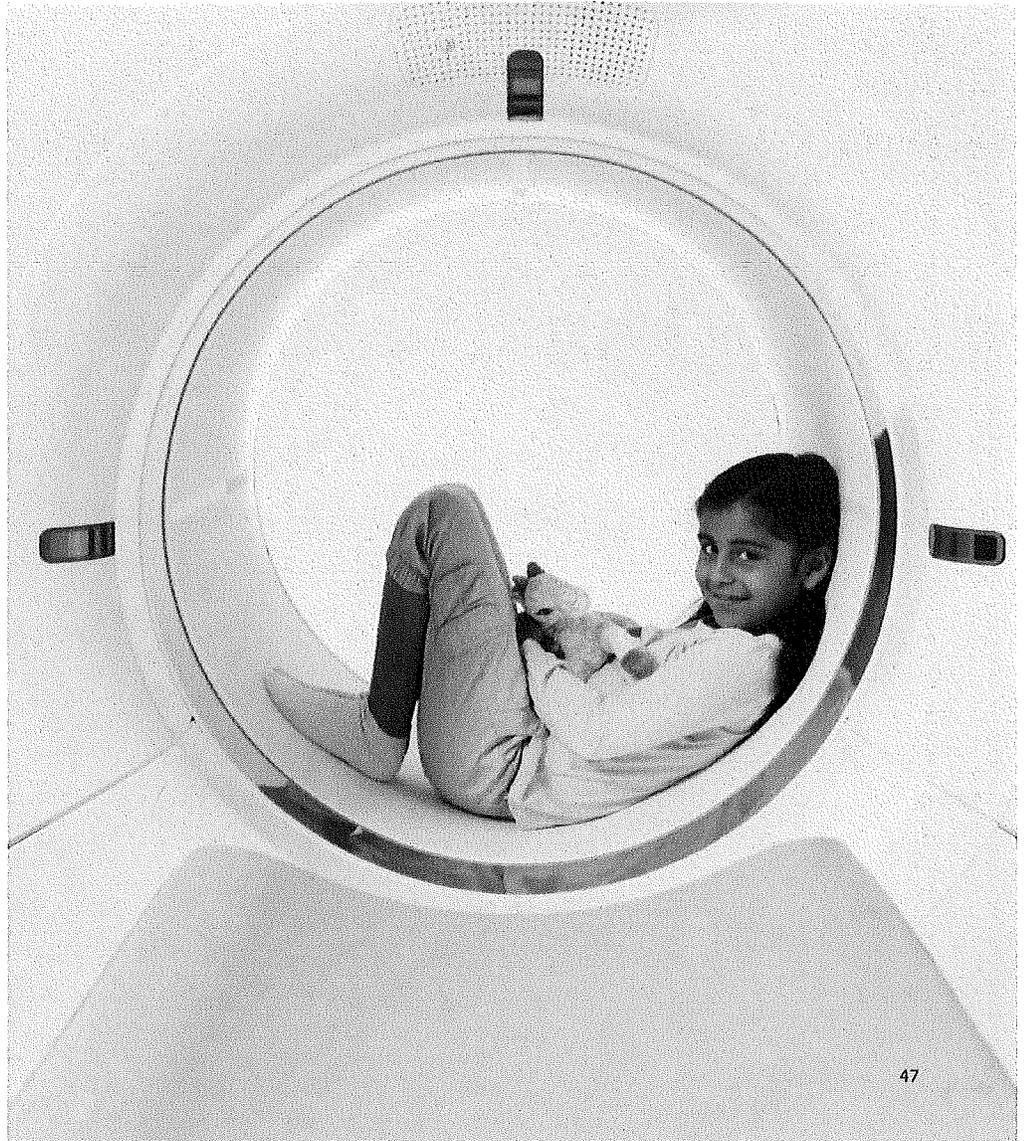
## Half the dose, twice the speed

Biograph mCT is meeting both of the core needs of improving patient safety and increasing productivity, at the same time, through our commitment: "Minimum Dose and Maximum Speed." By combining FAST and CARE technologies, Biograph mCT offers innovative imaging solutions enabling half the dose to be used while doubling the scan speed. By reducing dose and increasing speed, costs are dramatically reduced, while increased utilization can also be achieved.

## Summary

In order to address two of the most important concerns in healthcare today, improving patient safety and increasing productivity, Siemens lives by the philosophy of minimum dose and maximum speed, which benefits both the patient and provider. At the core of this philosophy are the innovative FAST and CARE technologies which improve the patient experience through increased scan speeds, while using as little exposure as possible, all without sacrificing image quality. For the provider, increased speed improves throughput for more efficient operation.

Siemens is moving the technology forward – to create faster and safer imaging while maintaining the highest of standards for image quality.



How it works

# Minimum Dose and Maximum Speed

Application  
to provide the  
Quantitative  
Image

Fast Volume  
Imaging  
Imaging

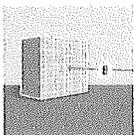
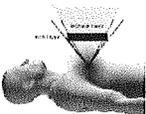
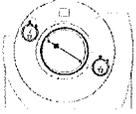
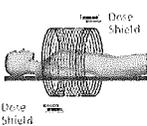
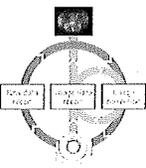
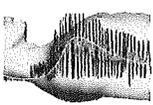
**Minimum Dose and  
Maximum Speed**

Engineered Clinical  
Flexibility

programmable

Customer Care

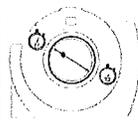
Molecular Imaging  
Biomarker Research

 <p><b>LSO</b></p> <ul style="list-style-type: none"><li>• Cornerstone of low-dose imaging</li><li>• 8x faster crystal</li></ul>	 <p><b>True V</b></p> <ul style="list-style-type: none"><li>• 2x lower dose</li><li>or</li><li>• 2x faster scan speed</li></ul>	 <p><b>ultraHD-PET</b></p> <ul style="list-style-type: none"><li>• 2x lower dose</li><li>• 2x faster scan speed</li></ul>
 <p><b>Adaptive Dose Shield</b></p> <ul style="list-style-type: none"><li>• Up to 25% lower dose</li><li>• Fully automated</li></ul>	 <p><b>SAFIRE**</b></p> <ul style="list-style-type: none"><li>• Iterative reconstruction software</li><li>• Fast recon in image and raw data space</li></ul>	 <p><b>CARE Dose4D</b></p> <ul style="list-style-type: none"><li>• Up to 68% lower dose</li><li>• Fully automated</li></ul>



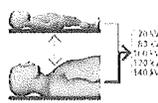
### FAST Planning\*

- Improves workflow efficiency
- Minimizes wait times for patients



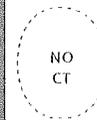
### Time of Flight

- 2x lower dose
- 2x faster scan speed



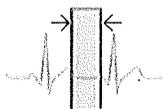
### CARE KV\*

- Up to 60% lower dose
- Optimize contrast-to-noise-ratio



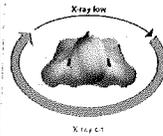
### SMART Neuro AC\*

- No CT dose
- PET attenuation correction without CT



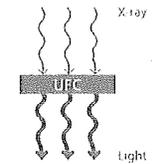
### Adaptive Cardio Sequence

- 1 – 3 mSv Cardio
- Fully automated



### X-CARE\*

- Up to 60% lower dose
- Reduce exposure in sensitive areas



### UFC

- Up to 30% lower dose
- Fast acquisition



### FAST Cardio wizard\*

- Intuitive step-by-step guidance
- Higher reliability and reproducibility in cardiac CT

## How it works

# TrueV

Intelligently  
to provide the  
Quantification

Fastest Volume  
Imaging Accuracy

Minimum Dose and  
Maximum Speed

Engineered Clinical  
Flexibility

Acquire via

Customized Care

Molecular Imaging  
Research and Research

TrueV high-speed technology widens the axial FOV and features 30% fewer bed positions when compared to a standard FOV. With an increased count rate performance of more than 70%, you can lower dose rates of scan time. For example, a scan time reduced to 10 minutes or a 50% less injected dose to the patient.

TrueV = ½ injected dose or 2x speed due to 70% increase in NEC performance.

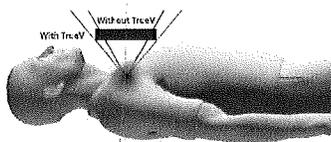
ultraHD-PET and TrueV as combined technologies make a 5-minute PET scan possible – unprecedented for a routine clinical.

ultraHD-PET + TrueV = ½ injected dose AND 2x speed due to 70% increase in NEC performance and 4x improved signal to noise.

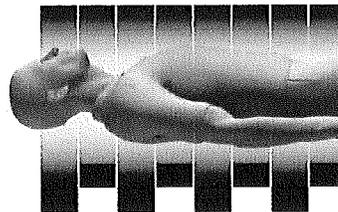
Minimum Dose and Maximum Speed benefits:

- Provides 2x lower dose
- Offers 2x faster scan speed

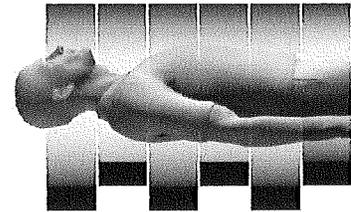
TrueV widens the axial field of view by 33%



Conventional field of view



Biograph with TrueV



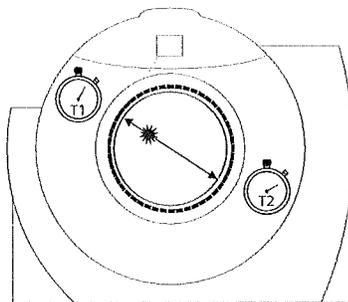
How it works

# ultraHD·PET = HD·PET + Time of Flight

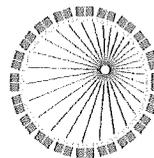
By combining Siemens HD·PET with Time of Flight (TOF), the result is up to 4 times improvement in signal to noise for ultraHD contrast.

Minimum Dose and Maximum Speed benefits:

- Provides 2x lower dose
- Offers 2x faster scan speed
- Enables a five-minute, whole-body scan with TrueV

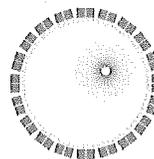


Conventional PET



Conventional PET detects coincidence photons and records individual LORs between the crystals. The actual location where the annihilation occurred along the LOR is not measured, which inherently generates blurring in the reconstructed image.

ultraHD·PET



Siemens ultraHD·PET with TOF measures the actual time difference between the detection of each coincidence photon. This additional timing information is used to better localize the event within a small range along each LOR. The better localization of each event using TOF reduces blurring in the reconstructed image.

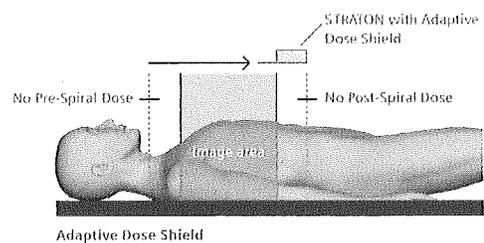
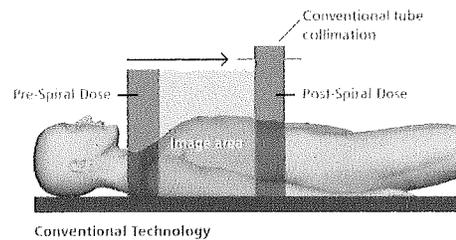
How it works

## Adaptive Dose Shield

As part of the STRATON X-ray tube, the unique Adaptive Dose Shield moves collimators on the X-ray tube to block unnecessary radiation dose. The shield dynamically opens at the onset of a spiral range and dynamically closes at the end, eliminating all clinically irrelevant dose. The result can be up to 25% lower CT doses.

Minimum Dose and Maximum Speed benefits:

- Reduces CT dose exposure by up to 25%
- Significantly reduces the possibility of over-radiation
- Shields the patient from pre- and post-helical radiation



Intelligent  
Reproducible  
Optimization

Energy Modulation  
Image Quality

Minimum Dose and  
Maximum Speed

Engineered Clinical  
Flexibility

Synthetic

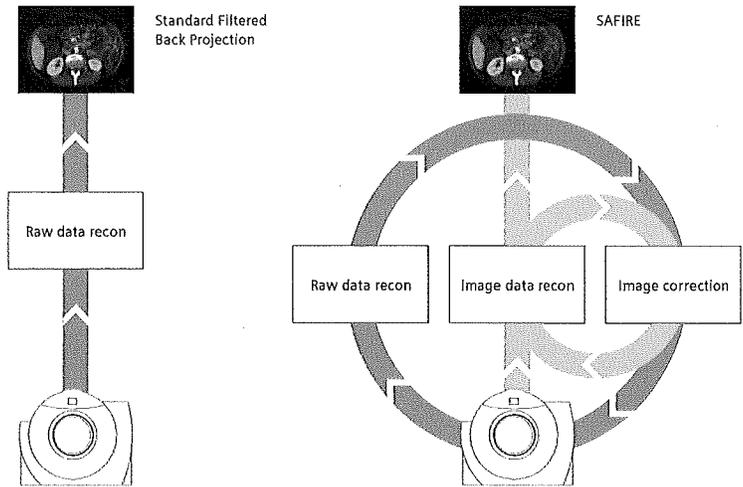
Automatic Care

Molecular Imaging  
Biomedical Research

## How it works

# SAFIRE

SAFIRE\* – Sinogram Affirmed Iterative Reconstruction – should allow you to utilize raw-data information (which is visualized in the so-called sinogram) in the iterative image reconstruction process.



\* SAFIRE is pending 510k clearance, and is not yet commercially available in the United States.

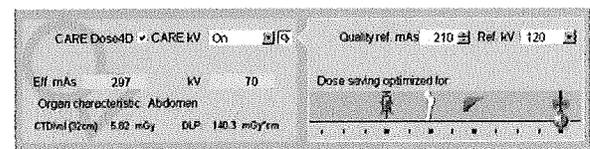
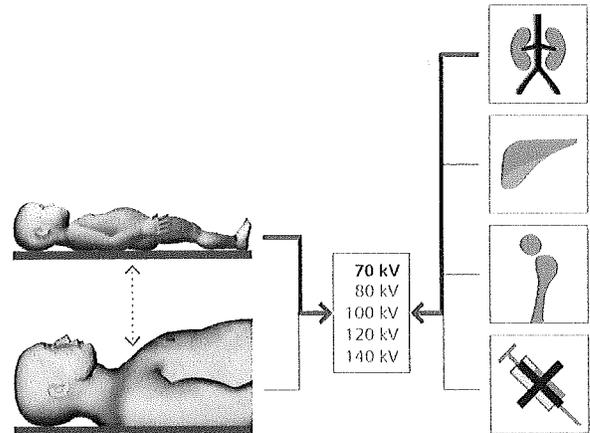
## How it works

# CARE kV

Siemens has introduced the first automated voltage setting to optimize contrast-to-noise-ratio and reduce dose by up to 60%. The automated selection is based on patient habitus and specific exam. CARE kV\* is especially useful in pediatric imaging, sparing smaller patients from unnecessary exposure.

Minimum Dose and Maximum Speed benefits:

- Optimize contrast-to-noise-ratio
- Up to 60% dose reduction



Example: For a contrast media enhanced vessel examination of a small patient, CARE kV proposes to scan with 70 kV and sets the other values accordingly.

How it works

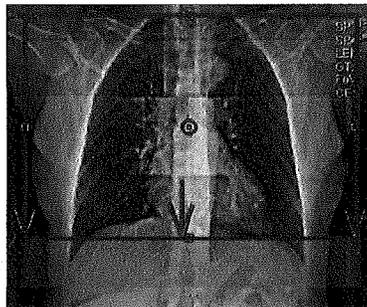
## FAST Planning

Siemens' Fully Assisting Scanner Technologies (FAST) features help radiologists and technicians plan and prepare for examinations and minimize the wait time for patients.

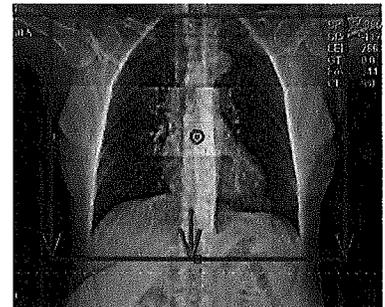
FAST Planning\* performs an immediate, organ-based setting of the scan and reconstruction ranges. The goal is a safer and faster experience for the patient and more predictable workflow at the scanner.

Minimum Dose and Maximum Speed benefits:

- Minimizes wait times for patients
- Automatic detection of scan field based on organ characteristics

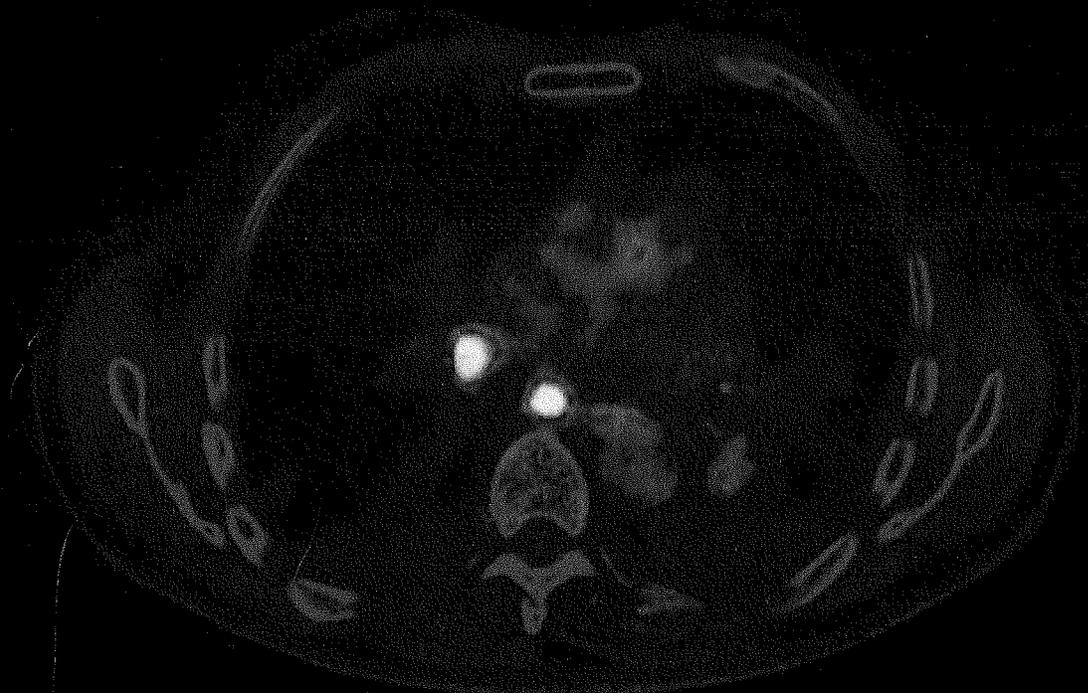


Conventional



FAST Planning

Superb image quality  
with 1/2 injected dose  
using TOF technology



Intelligently  
Reproducible  
Quantification

Finest Volumetric  
Image Accuracy

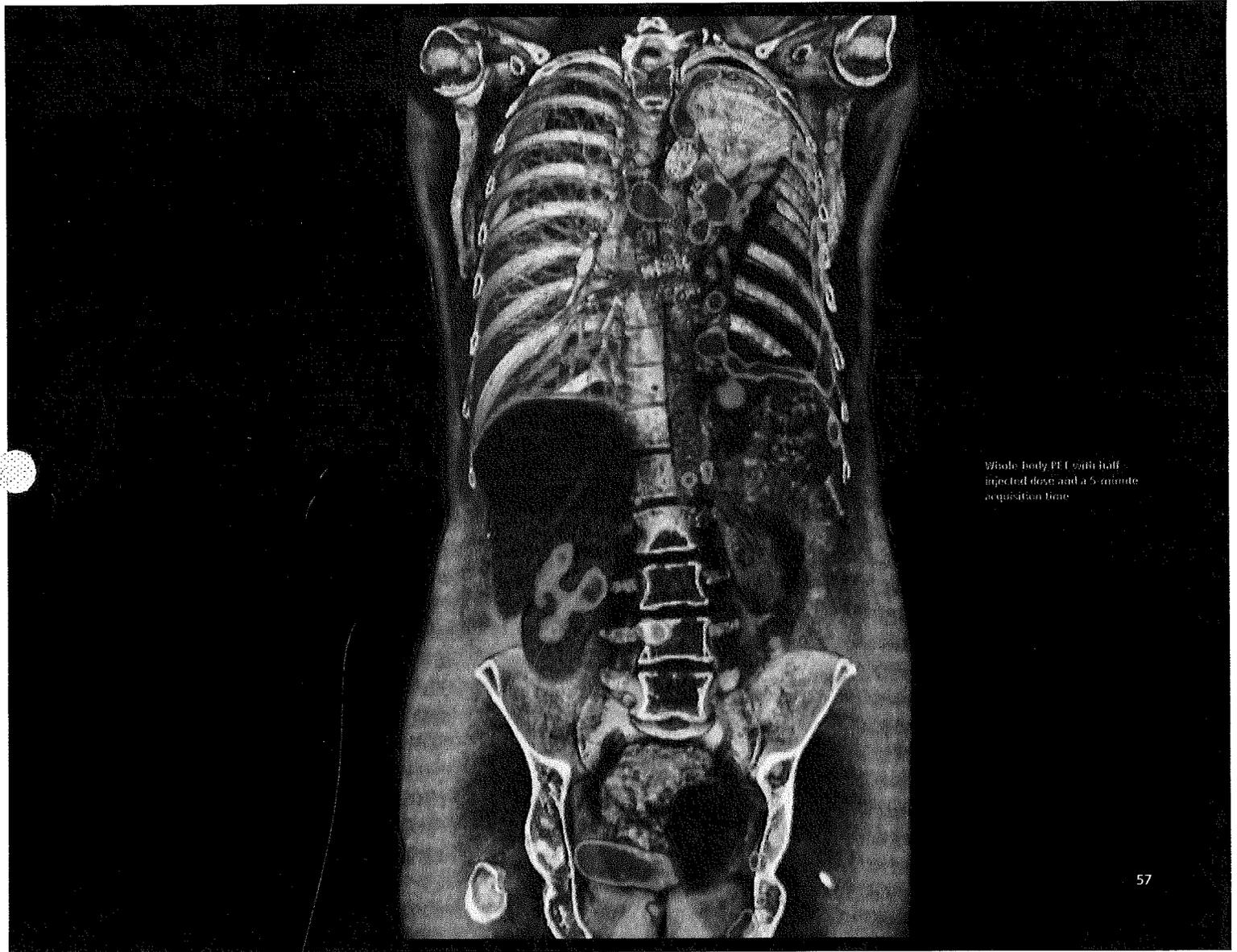
Minimum Dose and  
Maximum Speed

Engineered Clinical  
Flexibility

[syngo.via](http://syngo.via)

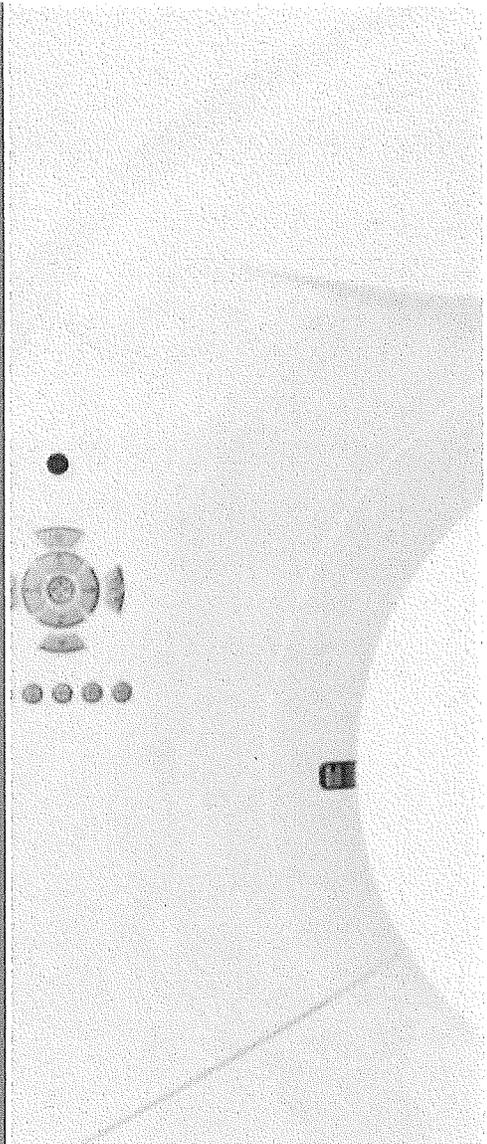
Customer Care

Molecular Imaging  
Biomarker Research



Whole body PET scan half injected dose and a 5 minute acquisition time

# Engineered Clinical Flexibility



SIEMENS



Biograph mCT

SIE

# Engineered Clinical Flexibility

Integrating  
PET and CT  
Capabilities

Expand Volume with  
Single Accessory

Minimize Downtime and  
Maximize Speed

## Engineered Clinical Flexibility

Imaging

Customer Care

Molecular Imaging  
Biomarker Research

In order to grow your business, you need a system that is flexible to accommodate all patients\* and procedures in PET and CT, today and in the future. With a conventional PET/CT system a standard bore size does not allow access to all patients, nor does it integrate high-end CT. The new Biograph mCT is engineered as a true dual-use solution to help customers multiply studies and increase business growth. Biograph mCT provides the clinical flexibility to use high resolution CT in conjunction with high definition PET imaging, or as a standalone CT. And with the industry's only 78 cm bore, Biograph mCT can accommodate a wide range of patients, including bariatric for both PET and CT studies. The engineered flexibility and scalability allows customers to configure a system which best meets their needs, and of course their patient needs today and tomorrow.

# Return on Innovation

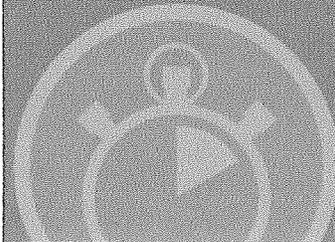
## Clinical Return

- Improve diagnostic accuracy with less patient movement enabled by large bore and fast scan times
- Expand clinical capabilities on both PET and CT with a complete portfolio of advanced applications



## Workflow Return

- Image bariatric PET and CT patients without impacting schedule
- Streamline dual modality workflow with engineered integration of state-of-the-art PET and premium CT



## Financial Return

- Increase revenue with a 78 cm bore for imaging a wider variety of patients and procedures
- Reduce operating cost by uniting stand-alone PET and CT services into a single integrated offering



# Engineered Clinical Flexibility



Intelligently  
Responding to  
Quantitative

Fluorimetry  
Imaging Accuracy

Minimally Dose and  
Maximum Speed

**Engineered Clinical  
Flexibility**

Scalability

Customer Care

Molecular Imaging  
Biomarker Research

## Maximizing patients base

Today's conventional technology often falls short for a simple reason – it fails to accommodate a wide patient demographic and therefore inhibits the growth a wider referral base can generate. Siemens has engineered Biograph mCT for clinical flexibility and growth, with a large 78 cm bore, short tunnel and a 227 kg (500 lb) table capacity which improves patient comfort and accessibility. Additionally, with features such as a powerful 100 kW CT generator – which provides ample X-ray power reserves for high quality imaging and HD FoV\* (field of view) which improves image quality beyond the standard CT diagnostic FoV, Siemens is making bariatric PET imaging more accurate with excellent image quality.

## Maximize modality performance

Biograph mCT is engineered as a true dual-modality scanner which integrates the best performance of both PET and CT modalities into a single compact system. Available in CT configurations of up to 128 acquired slices per rotation, it offers the capability of entire-body CT scans in just 10 seconds, and whole-body PET scans in as little as 5 minutes. Biograph mCT transforms a single room into a fast, dual-modality scanning facility. Now customers can offer advanced CT and PET imaging with one room; one team; one integrated system; one schedule; and if required, one comprehensive exam. Such clinical flexibility saves precious space, time and cost while maximizing dual-modality utilization and enabling business growth.

## Flexible scalability and upgradeability

Biograph mCT is designed as a remarkably scalable PET-CT platform and is designed to grow as business and clinical needs change. Biograph mCT offers a variety of in-field upgrades, from increasing the number of CT slices up to 128 to expanding the PET field of view up to 21.6 cm. With such flexible scalability and upgradeability Biograph mCT provides returns and referrals now and well into the future.

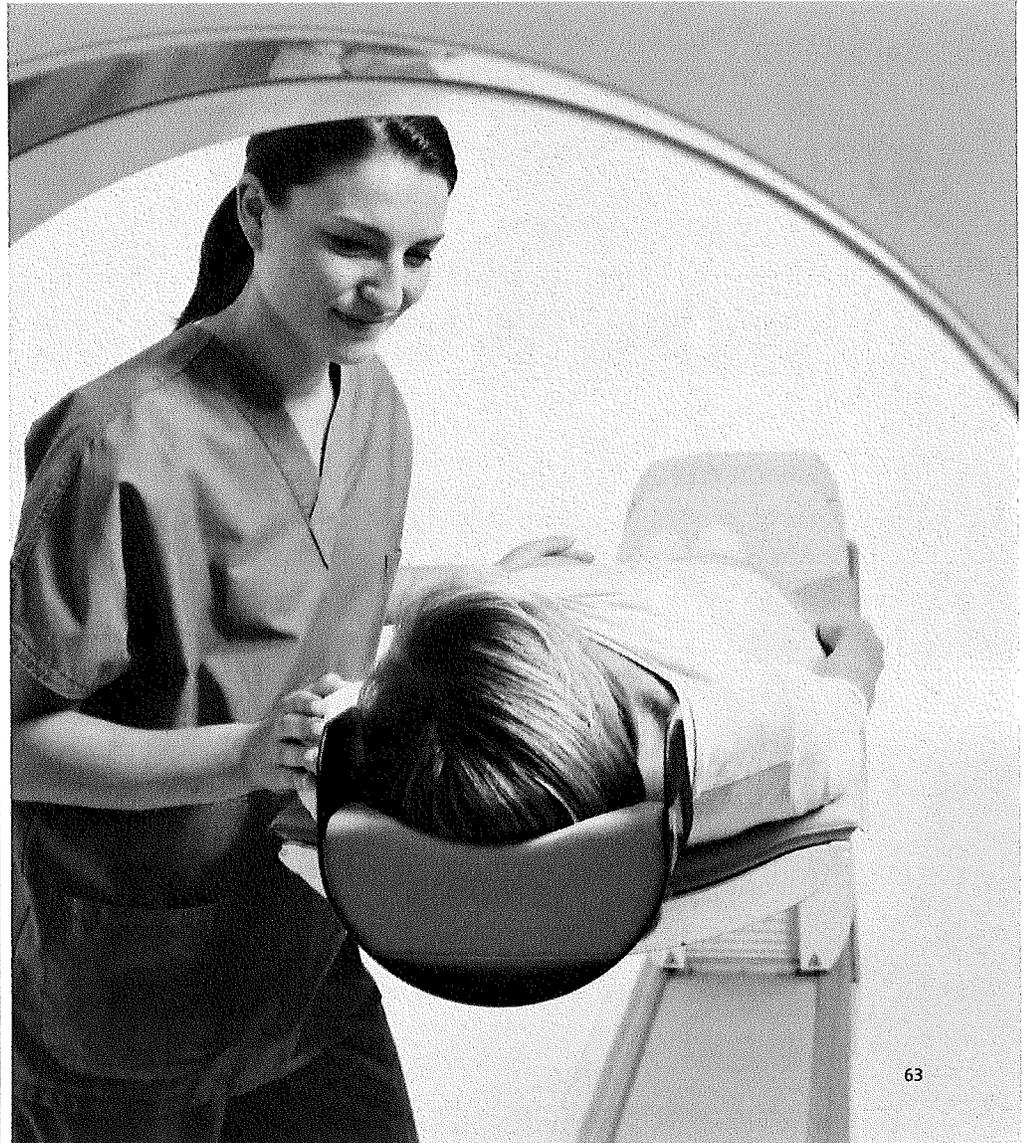
\* HD FoV is pending 510k clearance, and is not yet commercially available in the United States.

## Summary

To enable growth a PET/CT system must be able to accommodate even the most challenging patient situations, such as bariatric imaging, while providing high-end imaging applications in both modalities.

The new Biograph mCT has been engineered with the clinical flexibility to meet these needs now and in the future. Its large 78 cm bore and shorter tunnel accommodate even the largest patient\*, so your referral base is greatly expanded. And its multi-functionality (CT, PET and PET/CT) delivers savings in space, staffing and scheduling so clinical workflow is more efficient. The bottom line however, remains performance. Biograph mCT produces superb image quality, precise quantification and patient comfort and safety while delivering clinical flexibility that benefits everyone.

\* up to 227 kg (500 lb)



How it works

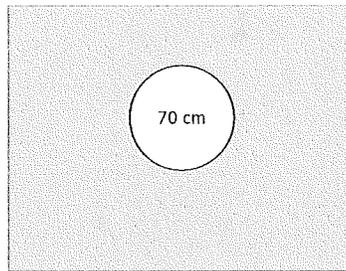
## Large Bore and Short Tunnel

The 78 cm bore of Biograph mCT can comfortably accommodate a greater range of patients in both PET and CT. Unlike conventional systems, whose narrow bore and long tunnel can make patients feel claustrophobic, Biograph mCT features a wider bore – 78 cm wide – and a shorter tunnel for a more open scanning experience. The large bore also allows better positioning of RTP devices, such as breast boards.

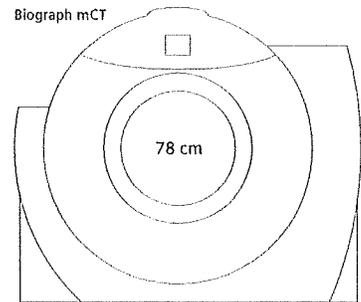
- Wide 78 cm bore
- Short tunnel
- 227 kg (500 lb) table capacity

The wider bed provides comfortable support even for obese patients and has a capacity of up to 227 kg (500 lb). And the design of the bed eliminates the CT and PET registration artifacts that can occur in bariatric imaging with a conventional system.

Conventional



Biograph mCT



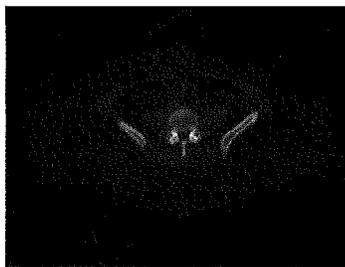
## How it works

# HD FoV

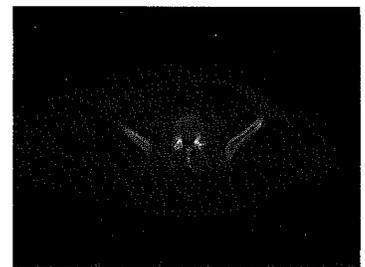
Conventional FOV for CT is 50 cm, but in some cases (e.g., with bariatric patients) CT measurements are truncated and image artifacts in PET attenuation-corrected (AC) images may result. Until now this problem was addressed using the extended field of view method (EFoV), but Siemens recently introduced an improved way to process truncated data sets in CT scans. This innovative new method, HD FoV\*, provides better image quality and improved Hounsfield Unit (HU) stability between 50 and 65 cm resulting in more quantitative PET images. This allows for more precise radiation therapy planning for bariatric patients and patients positioned outside the Biograph mCT isocenter.

- Improved CT image quality and HU > 50 cm
- Enhanced PET image quality > 50 cm
- Advanced PET quantification

Conventional



HD FoV



\* HD FoV is pending 510k clearance, and is not yet commercially available in the United States.

How it works

## High End CT

Intelligent  
Exposure  
Quantification

Range Motion  
Image Accuracy

Minimum Dose and  
Maximum Speed

Engineered Clinical  
Flexibility

Compact

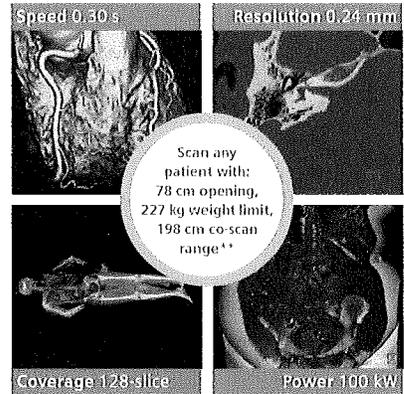
Customize Scan

Molecular Imaging  
Quantitative Research

The premium CT integrated into Biograph mCT is based on Siemens SOMATOM® Definition AS platform, offering full CT functionality with up to 128 acquired slices per rotation, into a compact dual modality design.

The revolutionary design of the STRATON X-ray tube features a direct anode cooling which eliminates the need for heat storage and results in a compact design thus allowing true temporal resolution of up to 150 ms. z-Sharp technology delivers the industry's highest isotropic resolution of 0.33 mm\* at any scan and rotation speed, and at any position within the scan field. Engineered to deliver such high performance and clinical flexibility, Biograph mCT opens doors to growth in all areas of PET and CT imaging.

- Isotropic 0.33 mm resolution anywhere in the scan field
- High temporal resolution of 150 ms
- 128 slices per rotation



\* Based on Competitive Literature available at time of publication. Data on file.

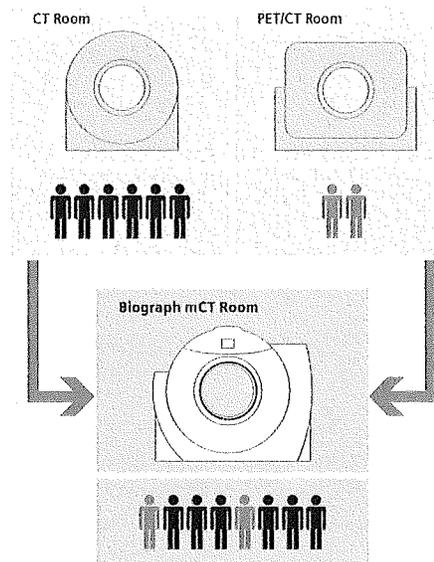
\*\*With TrueV and utilizing pallet extensions.

How it works

## Dual Use – Room

By seamlessly integrating high end PET and premium CT, Biograph mCT provides the power of two high-end modalities in a single solution, thereby offering efficiencies in square footage, utilities, service and staffing. Now you can offer high quality PET and CT in one room. With one schedule. One team. One user interface that has been engineered for simplicity and speed. And with Biograph mCT's new FAST CARE technologies, every step of the examination process has been streamlined, from scan preparation to image review.

- Single room
- High-end PET
- Premium CT

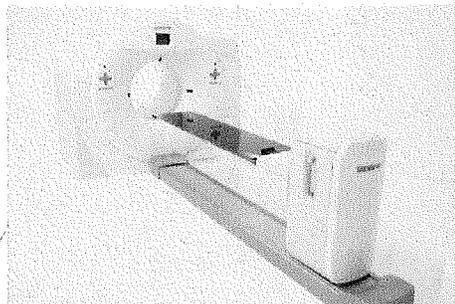


How it works

## Acculine RT

Biograph mCT offers a comprehensive solution for Radiation Oncology, from the wide 78 cm bore for ease of positioning and patient access, motion management with PET and CT respiratory gating to the unique canti-lever designed SMART PHS (patient handling system) with radiation therapy planning pallet and conforming to TG-66 requirements.

Biograph mCT extends beyond these offerings with Acculine RT – accurate multi-component alignment for high precision radiation therapy planning. Acculine RT ensures accurate alignment between gantry components, RTP room lasers, SMART PHS and RTP pallet as well as virtual image alignment and alignment to simulation system and treatment room.



- Comprehensive radiation oncology solution
- Accurate multi-component alignment for high precision radiation therapy planning
- Accuracy phantom for alignment measurements

Intelligently  
Reproducible  
Quantification

Fines, Volumetric  
Image Accuracy

Eliminating Dead and  
Motion Time Spent

**Engineered Clinical  
Flexibility**

• Virtual mCT

• Outpatient Care

• Molecular Imaging  
• Biomarker Research

How it works

# Flexible Scalability and Upgradeability

Biograph mCT offers a scaleable and flexible range of CT and PET features, giving customers the assurance that they will have access to features which enable business growth as their needs change. All advanced CT and PET features can be configured at system purchase or are available as an in-field upgrade. These flexible upgrade opportunities provide the best possible investment protection to keep the system clinically relevant for years to come.

Scaleable range of features:

- In-field upgrades for high end CT features
- In-field upgrades for high end PET features



**Biograph mCT**  
128-slice configuration



**Biograph mCT**  
64-slice configuration

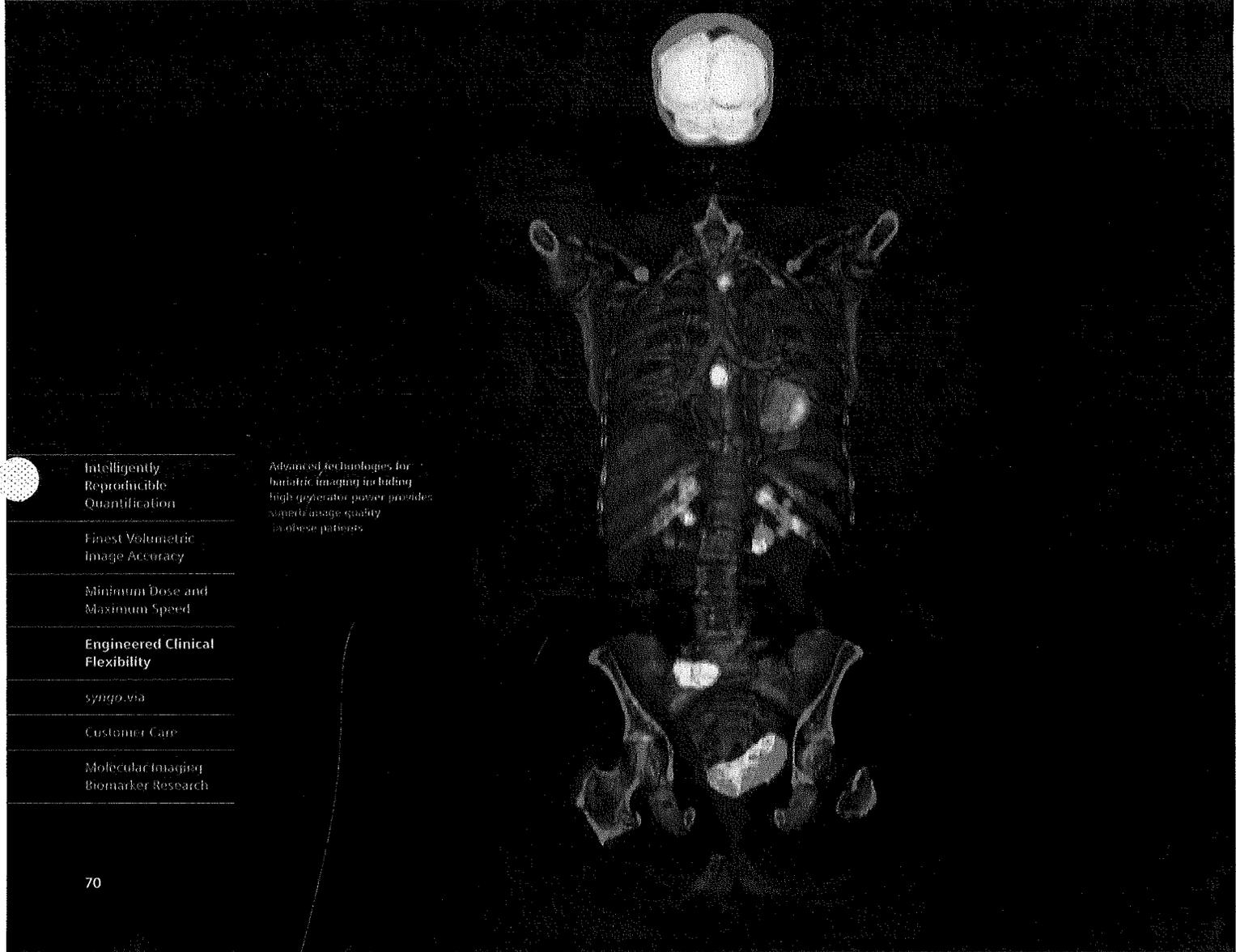


**Biograph mCT**  
40-slice configuration

## Available Options

- ultraHD-PET
- HD-PET
- TrueV
- HD-Chest
- Advanced Cardio Sequence
- SAFIRE\*\*
- Adaptive 4D Spiral
- SMART Auto Cardiac Registration
- SMART Neuro AC\*
- FAST Planning\*
- FAST Spine\*
- X-Care\*

\* SMART Neuro AC, FAST Planning, FAST Spine, CARE KV, X-CARE SAFIRE and FAST Cardio Wizard are pending 510k clearance, and are not yet commercially available in the United States.



Intelligently  
Reproducible  
Quantification

Finest Volumetric  
Image Accuracy

Minimum Dose and  
Maximum Speed

Engineered Clinical  
Flexibility

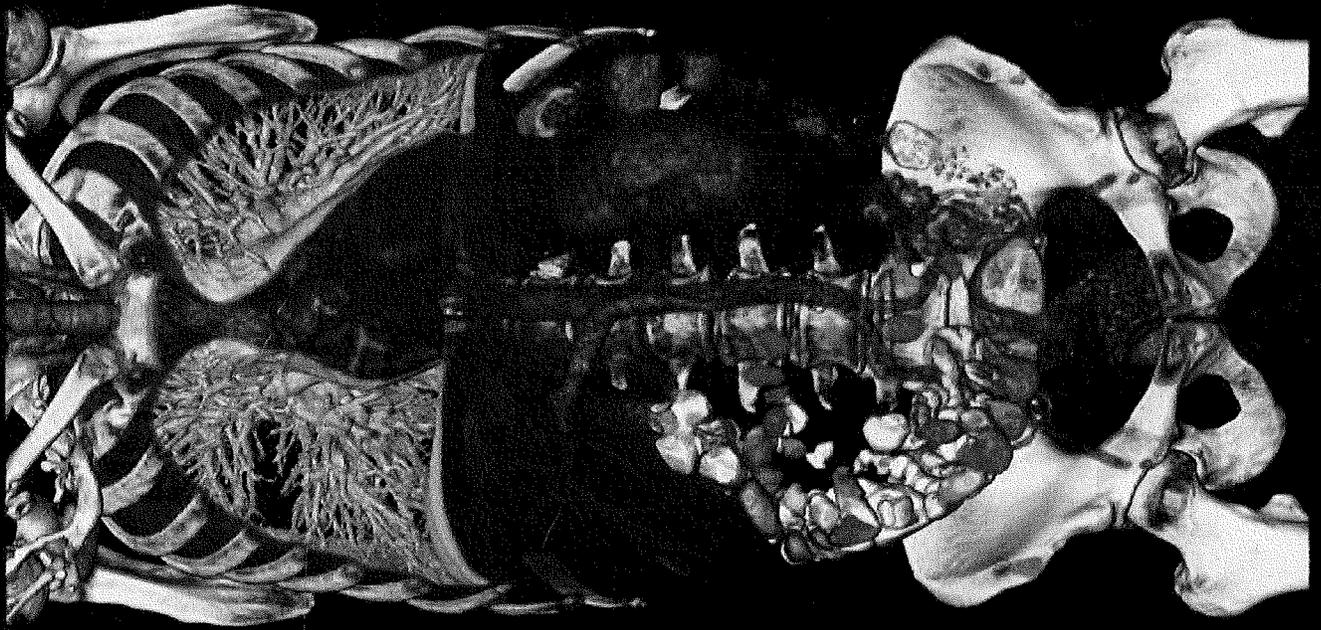
*syngo.via*

Customer Care

Molecular Imaging  
Biomarker Research

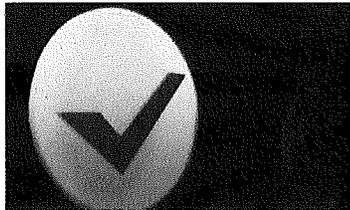
Advanced technologies for  
bariatric imaging include  
high generator power provides  
superb image quality  
in obese patients.

Expand clinical flexibility with  
premium CT and advanced  
applications.



*syngo.via*  
Images, my way

# Anywhere, Anytime Access to Integrated PET·CT Reading with Revolutionary Ease-of-Use



*syngo.via* is a multimodality reading solution that supports PET and CT on a unified platform, even on unified applications, which results in an effective and integrated workflow.

As a client-server-based platform, *syngo.via* provides collaboration and automation features that enable the full diagnostic and productive potential of hybrid scanners.

My cases – ready

My images – networked

My needs – anticipated

Integrating  
Reproducible  
Quantification

Direct Volume via  
Image-to-Image

Submillimeter Dose and  
Maximum Speed

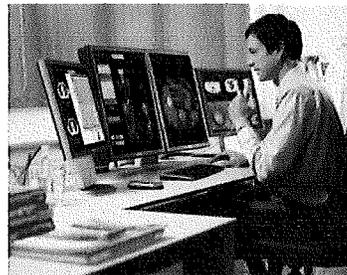
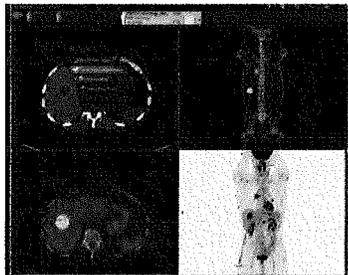
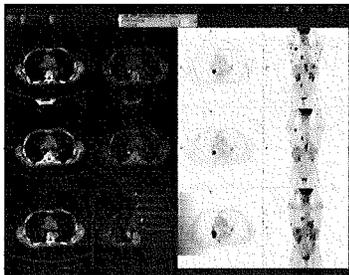
Engineered Clinical  
Flexibility

**syngo.via**

Customer Care

Molecular Imaging  
Biomarker Research

## syngo.via provides a multimodality platform for hybrid applications in molecular imaging



### Advanced automation for high-volume hybrid studies

Hybrid exams consist of two data sets, which already double the available diagnostic information. In addition, oncology studies are often whole-body exams, further increasing the volume. And many patients have a history of prior studies for comparison. *syngo.via* automates all necessary preparation steps so your workflow starts where it should – with reading. When selecting a patient, *syngo.via*:

- Provides pre-fetched prior exams and displays up to eight time points
- Fuses hybrid studies and registers them across time points
- Starts the appropriate reading environment: for example, the *syngo.mCT* Oncology Engine
- Displays prior findings

### Reproducible results with integrated, quantitative tools

To maximize the benefit from PET's quantitative capabilities and the reproducibility of follow-up assessments, *syngo.via* provides state-of-the-art quantification tools for PET and CT in unified applications for the most intuitive anatomical and functional assessment. You can take  $SUV_{peak}$  and  $SUV_{max}$  as well as RECIST and WHO measurements with a single stroke of the mouse – all without changing tools or taking your eyes off the image.

### End-to-end workflow support from case preparation to results sharing

*syngo.via* is more than a diagnostic tool: it supports your workflow all the way to the tumor board presentation. From processing to diagnosis and sharing, *syngo.via* provides a single common platform. Working on the same data set preserves results and eliminates redundancies. First, the technologist can prepare the case. Next, the reading physician creates findings and documents the diagnosis. Finally, the case and its results can be elegantly presented in the tumor board meeting.

## syngo.via

*syngo.via* can be used as a standalone device or together with a variety of *syngo.via* based software options, which are medical devices in their own rights. These products are pending regulatory clearance in some countries and therefore not yet commercially available in all countries. Usage of *syngo.via* in an operating room or for an emergency case requires that the customer provides respective emergency measure in case of non-availability of the system or network.

*syngo.via* can be used anywhere if the following prerequisites are given: Internet connection to clinical network, DICOM compliance, meeting of Siemens minimum hardware requirements, and adherence to local data security regulations.

# Siemens Guardian Program Including TubeGuard

Biograph mCT comes with the dependability of TubeGuard, a unique remote service that provides real-time condition reports of the scanner's STRATON X-ray tube. TubeGuard employs more than 10 proactive sensors to monitor the performance of the tube and assess its longevity. Based on real-time data from sensors and other complex algorithms, TubeGuard estimates how long the tube will last and when it is due for replacement. This helps schedule service and maintenance appointments and virtually eliminates the possibility of a sudden tube failure.

Quantitative  
Dependable  
Quantification

Exact Measurement  
Image Accuracy

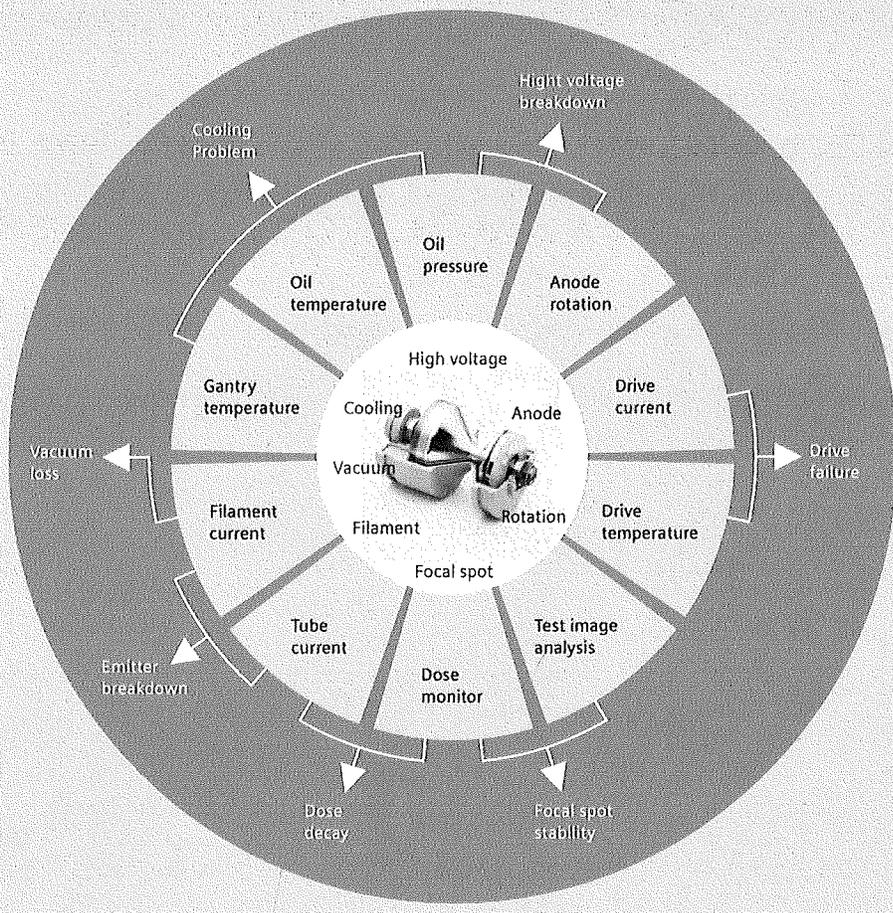
Minimum Dose and  
Maximum Speed

Engineered Clinical  
Flexibility

Synapse

Customer Care

Molecular Imaging  
Biomarker Research



- Predictable failures
- Tube functions
- TubeGuard sensors

## Customer Care

# Dedicated to Your Success

Remain one step ahead and tap the full potential of your Biograph mCT system from Siemens with our customer care program.

As a worldwide innovation leader in medical imaging, Siemens has gained remarkable knowledge in molecular imaging. You can profit from excellent PET-CT systems and innovative, flexible and comprehensive service solutions that enable you to concentrate on what is most important for you: patient care. The customer care program, is a unique solution from Siemens that helps you maximize return on innovation throughout the entire life cycle of your system.

## Software Updates and Hardware Upgrades

### Stay competitive with up-to-date systems

Due to increasing healthcare demands, you have to stay on the cutting edge to be competitive. We will help you to keep your solutions up-to-date and to stay abreast of the latest technological advancements. With our technology portfolio, you can be sure that workflow improvements, clinical applications and diagnostic functions are all embedded into advanced technologies for equipment and IT. With our *syngo* Evolve program we offer you certainty in budget planning, feature enhancements for your PET-CT, access to new applications and lower cost upgrades for your PET-CT system.

## Information and Communication

### Be informed – get connected

To ensure you are always up-to-date on what is happening in the PET-CT world, we offer you a variety of information services including easily accessible information portals, monthly newsletters, our customer magazine *Imaging Life* and the Biograph World Summit, our global PET-CT users forum on clinical trends and best practices. Customer communities help you explore new technologies and share clinical cases with your peers and global experts.

Highly Accurate  
Quantification

Fast Medication  
Image Accuracy

Minimum Dose and  
Maximum Speed

Engineered Clinical  
Flexibility

*syngo*

Customer Care

Molecular Imaging  
Biomarker Research

## Education and Training

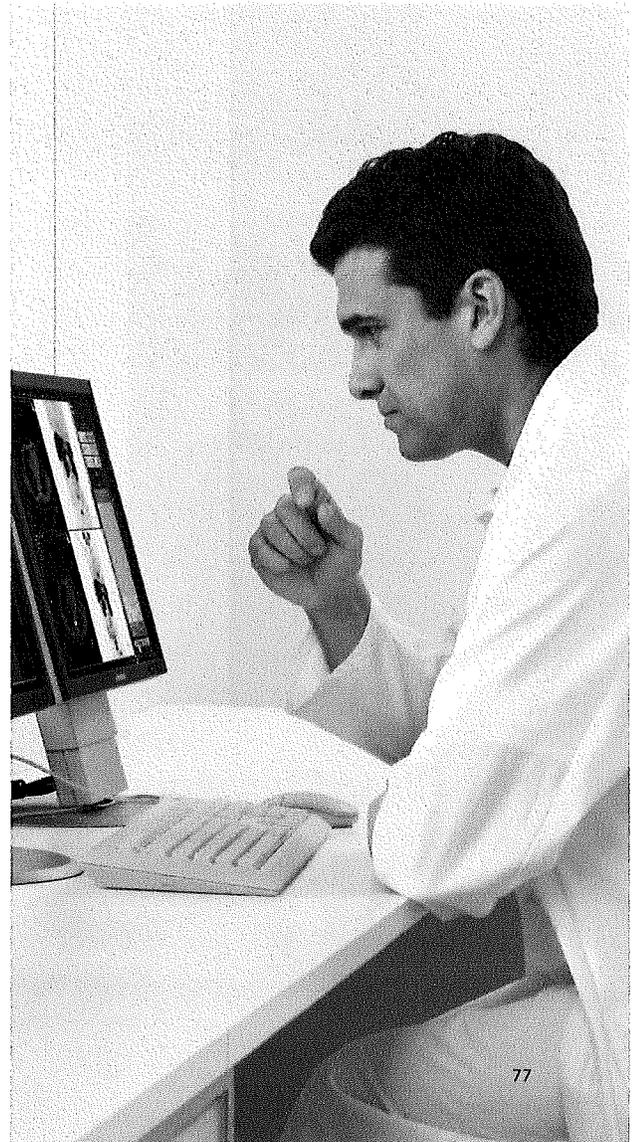
### **Broaden your knowledge and expertise**

Know-how is the key to success. With our extensive portfolio of education and training programs you can deepen your knowledge and clinical expertise. We show you how to maximize the benefits that can be achieved with our advanced technology. Classroom trainings, workshops and seminars are only a few examples of our broad portfolio. Valuable knowledge transfer through hands-on workshops with renowned clinical experts will also help you to optimize your workflows so you can offer an even higher quality of care for your patients.

## Services and Support

### **Feel confident with our proactive service solutions**

High system availability, diagnostic confidence and optimized workflow are crucial for the success of your PET-CT service. To meet your performance expectations, we systematically focus on being proactive. Based on real-time system monitoring we detect system errors and alert you before problems occur. The Siemens Guardian Program helps to make unplanned downtime a thing of the past.



The Era of Personalized Medicine Starts Today

# Molecular Imaging Biomarker Research

Highly sensitive  
quantification  
Fast 20-minute  
image recovery  
Minimum Dose and  
Maximum Speed  
Engineered Clinical  
Flexibility

synopsi

Customer Care

Molecular Imaging  
Biomarker Research

## Siemens Molecular Imaging Biomarker Research

Siemens Molecular Imaging Biomarker Research is a leader in the discovery and development of new imaging biomarkers for applications in oncology, cardiology and neurology. These novel imaging biomarkers, when approved for clinical use, will advance molecular imaging to a completely new level by enabling targeted therapies via more personalized clinical assessment of disease and improving therapy management.

## Biograph mCT

Siemens maximizes your return on innovation by incorporating from the earliest stages of product development and design of the Biograph mCT the technology to support the use of future imaging biomarkers in oncology, cardiology and neurology, to ensure the best patient care throughout the life of the system. This obsolescence protection is made possible through the collaboration between Siemens MIBR scientists and engineers to make sure that Biograph and our imaging biomarkers are designed to work together.

# Personalized

#### Oncology

Siemens is investigating new imaging biomarkers that address the fundamental hallmarks of cancer beyond metabolism. Among the areas being explored are cell proliferation biomarkers to help oncologists assess the replicative potential of tumors, an imaging biomarker to identify hypoxic (oxygen deprived) areas of tumors to assess the insensitivity to anti-growth signals and an imaging biomarker to better understand angiogenesis, which details how blood is supplied to tumors.

#### Cardiology

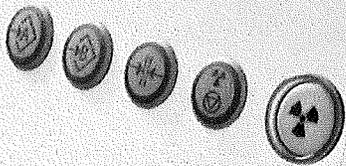
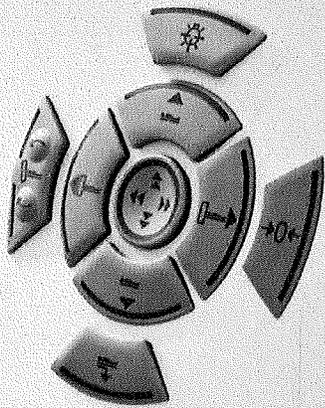
Cardiology-related procedures represent the highest potential of growth for molecular imaging. New imaging biomarkers are being investigated to improve patient risk stratification in CAD with perfusion, enhance viability, and support vulnerable plaque studies providing the clinician with all necessary information in a single imaging device to personalize treatment for each specific patient.

#### Neurology

Neurological-related procedures are expected to grow due to the rise of dementia cases resulting from the increase in the global aging population. The development of new imaging biomarkers designed for neurological studies will provide a non-invasive imaging test to help in the assessment of dementia in patients. Siemens is investigating the development of imaging biomarkers with the goal to quantify the degree of beta amyloid and tau proteins certain regions of the brain thought to be a precursor to certain types of dementia such as Alzheimer's disease.

medicine

# Biograph mCT



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Northern California PET Imaging Center, Sacramento, CA, USA - Page 23, 41 (middle)  
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**Global Siemens Headquarters**  
Siemens AG  
Wittelsbacherplatz 2  
80333 Munich  
Germany

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**Global Siemens Healthcare Headquarters**  
Siemens AG  
Healthcare Sector  
Henkestrasse 127  
91052 Erlangen  
Germany  
Telephone: +49 9131 84-0  
[www.siemens.com/healthcare](http://www.siemens.com/healthcare)

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**Global Business Unit**  
Siemens Medical Solutions USA, Inc.  
Molecular Imaging  
2501 N. Barrington Road  
Hoffman Estates, IL 60192-5203  
USA  
Telephone: +1 847 304 7700  
[www.siemens.com/mi](http://www.siemens.com/mi)

**Legal Manufacturer**  
Siemens Medical Solutions USA, Inc.  
Molecular Imaging  
810 Innovation Drive  
Knoxville, TN 37932-2751  
USA  
Telephone: +1 865 218 2000  
[www.siemens.com/mi](http://www.siemens.com/mi)

Attachment 1 - EQUIPMENT COMPARISON

	Existing Equipment	Replacement Equipment
Type of Equipment (List each component)	PET/CT	PET/CT
Manufacturer of Equipment	Siemens	Siemens
Tesla Rating for MRIs	n/a	n/a
Model Number	Biograph Duo	Biograph mCT S 64
Serial Number	0301010 / 0301029	unknown
Provider's Method of Identifying Equipment	Biograph Duo	Biograph mCT S 64
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	11/10/2003	unknown
Does Provider Hold Title to Equipment or Have a Capital Lease?	yes	n/a
Specify if Equipment Was/Is New or Used When Acquired	New when acquired	New when acquired
Total Capital Cost of Project (Including Construction, etc.) <Use Attached Form>		
Total Cost of Equipment		\$1,704,325
Fair Market Value of Equipment		
Net Purchase Price of Equipment		
Locations Where Operated	Morehead Imaging Center	Morehead Imaging Center
Number Days in Use/To Be Used in N.C. per Year	257	257
Percent of Change in Patient Charges (by procedure)	0%	0%
Percent of Change in Per Procedure Operating Expenses (by procedure)	0%	0%
Type of Procedures Currently Performed on Existing Equipment	PET/CT -Oncology (limited diagnosis) -Brain	
Type of Procedures New Equipment is Capable of Performing		PET/CT -Oncology (inc. Head & Neck) -Brain Diagnostic CT



## Wilson, Fatimah

---

**From:** Kirkman, Elizabeth [Elizabeth.Kirkman@carolinashealthcare.org]

**Sent:** Thursday, March 13, 2014 3:17 PM

**To:** Wilson, Fatimah

**Subject:** Request for documentation

Fatimah,

In response to your request that we provide documentation that administrative and financial control of CMC is exercised at the site where the equipment proposed to be replaced is currently located, we submit the following:

### CMC Linac Replacement

The proposed replacement equipment will be located in the Levine Cancer Institute building on the main campus of Carolinas Medical Center (496 feet from the main hospital building). The main hospital building from which Carolinas Medical Center exercises financial and administrative control over Carolinas Medical Center services is located at 1000 Blythe Boulevard, Charlotte, NC 28203 (see Attachment A of the December 11<sup>th</sup> request for a site plan). Carolinas Medical Center's President's office is located on the second floor of the main hospital building.

### CMC PET/CT Replacement

The proposed replacement equipment will be located in the Morehead Medical Plaza building on the main campus of Carolinas Medical Center (327 feet from the main hospital building). The main hospital building from which Carolinas Medical Center exercises financial and administrative control over Carolinas Medical Center services is located at 1000 Blythe Boulevard, Charlotte, NC 28203 (see Exhibit 8 of the February 5<sup>th</sup> request for a site plan). Carolinas Medical Center's President's office is located on the second floor of the main hospital building.

If you need any further information, please let me know.

Thanks,  
Elizabeth

**Elizabeth V. Kirkman**  
Assistant Vice President

*CHS Management Company*

**Carolinas HealthCare System**

704-446-8475 Office

704-780-6503 Cell

[Elizabeth.kirkman@carolinashealthcare.org](mailto:Elizabeth.kirkman@carolinashealthcare.org)

2709 Water Ridge Parkway, Charlotte, NC 28217

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3/13/2014