



7/20/2023

VIA EMAIL ([SHPDA.ONLINE@SHPDA.ALABAMA.GOV](mailto:SHPDA.ONLINE@SHPDA.ALABAMA.GOV))

Hon. Emily T. Marsal, Executive Director  
State Health Planning and Development Agency  
RSA Union Building  
100 North Union Street, Suite 870  
Montgomery, Alabama 36104

Re: Non-Reviewability Determination Request – Acquisition and Operation of a Cardiac PET/CT scanner by North Alabama Cardiology Center

Dear Ms. Marsal,

This response is being submitted by North Alabama Cardiology Center, P.C. (referred to as NACC), a Private Physician's Office, in accordance with Section 410-1-7-.02 of the Alabama State Health Planning and Development Agency Rule, the Alabama Supreme Court case Ex parte Sacred Heart Health Sys., Inc., 155 So. 3d 980, 988 (Ala. 2012), and Ala. Admin. Code § 22-21-260(6).

Please consider this letter and the accompanying supporting documentation as a formal request for an Initial Reviewability Determination (“Request”) under the SHDPA's Certificate of Need (“CON”) program rules and regulations. The purpose of this request is to seek approval for the acquisition and operation of a Cardiac Positron Emission Tomography with Computed Tomography (“PET/CT Scanner”) within Etowah County (the “Service Area”), specifically at 503 South 5th St, Gadsden, AL 35901 (the “Location”).

The proposed project shall provide Cardiac PET/CT services to patients (the “Services”) at the Location. The office providing these services is solely owned and operated by Bankim J. Patel, MD, with no other healthcare facility or entity having any financial interest in the office, as per the definition provided in the relevant Alabama Supreme Court case. Therefore, based on this exemption, it is believed that the facility should be exempt from the requirement for a Certificate of Need review, as it meets the conditions outlined below:

- 1) The proposed services are to be provided, and related equipment used, exclusively by the physicians identified as owners or employees of the physicians’ practice for the care of their patients;
  - a. *All Cardiac PET/CT services, including the utilization of the equipment, will be conducted, requested, and solely utilized by the owner of the practice and any physicians employed within the practice.*
- 2) The proposed services are to be provided, and related equipment used, at an office of such physicians;
  - a. *All Cardiac PET/CT services and the associated equipment will be offered exclusively at the Private Physician's office located at 503 South 5th St, Gadsden, AL 35901, which is situated within Etowah County.*

- 3) All patient billings related to such services are through, or expressly on behalf of, the physicians' practice;
  - a. *All billing for Cardiac PET/CT services will be handled solely by the practice itself, and it will be conducted on behalf of the practice.*
- 4) The equipment shall not be used for inpatient care, nor by, through, or on behalf of a health care facility."
  - a. *The Cardiac PET/CT equipment will be exclusively used within the Outpatient setting, and no services will be provided to patients in an Inpatient status. Furthermore, no external facilities that offer Inpatient services will have access to or be able to request the use of the equipment.*

Larue S. Cline, RCS, RVS, the Authorized Representative at the Location, can be contacted regarding this determination request. She can be reached at the office phone number (256) 546-6200 Ext 103 or on her cell phone at (256) 312-7297. The request is being made on behalf of Bankim J. Patel, MD, who serves as the Authorized Agent of the Company and is the owner of the practice.

**Access to Care.** The project addresses the absence of dedicated Cardiac PET/CT systems within the Northeastern region of the state. Currently, there are approximately eight Private Physician's offices that conduct this specific test, but they are all located more than 50 miles away. Extensive documentation supports the notion that patients generally prefer seeking medical treatment within their local vicinity. For further details, please refer to the table provided below.

Name	Address	Address 2	City	State	Zip	Distance from Office
Birmingham Heart Clinic	100 Pilot Medical Drive	Suite 300	Birmingham	AL	35235	52.8
Brookwood Cardiology Diagnostic Center	3980 Colonnade Parkway		Birmingham	AL	35243	65.1
Cardiology, PC	801 Princeton Avenue SW	Suite 106	Birmingham	AL	35211	65.8
Heart South Cardiovascular Group, PC	1022 1st Street North	Suite 500	Alabaster	AL	35007	79.1
River Region Cardiology Associates, PC	185 Mitylene Park Lane		Montgomery	AL	36117	158
Cardiology Associates - Springhill	3715 Dauphin Street	Suite 1100	Mobile	AL	36608	314
Cardiology Associates - Fairhope	188 Hospital Drive	Suite 100	Fairhope	AL	36532	318
Rihner, Gupta and Grosz Cardiology, P.C.	600 Providence Park Drive		East Mobile	AL	36695	320

The limited availability of this modality in the area contributes to the increasing health disparities experienced by patients. This is particularly concerning considering the already scarce availability of advanced cardiac imaging options. In cases where the current standard of Cardiac SPECT produces inconclusive or non-diagnostic results, or when patients receive false positive results, they may be required to undergo unnecessary invasive procedures like cardiac catheterizations to confirm the presence of cardiac disease. These circumstances highlight the need for improved access to accurate and reliable cardiac imaging techniques, such as Cardiac PET/CT, to mitigate the risks and potential harm associated with unnecessary invasive procedures.

**Unmet Need.** The implementation of the Cardiac PET/CT program at NACC will effectively address an unmet need in healthcare delivery within the region. By offering advanced cardiac imaging services, this program will provide patients with crucial access to cutting-edge diagnostic capabilities. The utilization of this imaging modality will not only help overcome geographical barriers but also significantly reduce the need for extensive travel, associated costs, and inconvenience for patients. Ultimately, the availability of Cardiac PET/CT services will contribute to improved patient outcomes, enabling timely and accurate diagnoses for better management of cardiac conditions.

**Improved Patient Outcomes.** The Cardiac PET/CT program at NACC will fill an unmet need in the delivery of healthcare in the region by providing patients with access to advanced cardiac imaging

services. This imaging modality will help address geographic barriers access, reduce travel, costs, and improve patient outcomes.

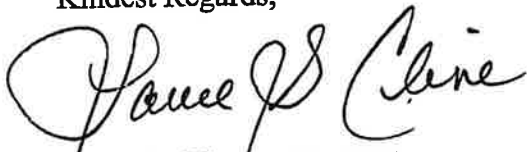
Approximated costs of the proposed Cardiac PET/CT project:

- a) Equipment
  - \$974,000.00
- b) First year annual operating costs
  - Approximately \$548,567.76
- c) Capital costs, to include:
  - i. Leases
    - The Cardiac PET/CT equipment will be obtained through a lease agreement with CDL Nuclear Technologies. The lease duration is set for 60 months, and the total lease amount is \$974,000.00.
    - The office area where the Cardiac PET/CT equipment will be housed will be leased at an estimated cost of \$125,749.00 for the duration of the 60-month lease term, aligning with the lease term of the scanner.
  - ii. Land/Building costs
    - Not Applicable
  - iii. Construction costs
    - We anticipate that the construction costs will amount to approximately \$150,000.00. However, it is important to note that unforeseen complications during the construction process may lead to the possibility of exceeding this estimated cost.

Furthermore, considering that the project falls within the parameters of both capital costs and operational costs mentioned previously, we kindly request that SHPDA grant a determination of non-reviewability. An attestation from the requesting party is also included for your reference. Additionally, as per SHPDA Rule 410-1-3-.09, the required filing fee of \$1,000 has been successfully submitted through the SHPDA electronic payment portal.

If you require any further information, please do not hesitate to contact me at the following email address: [northal.cardio@gmail.com](mailto:northal.cardio@gmail.com). You can also reach me at the office (256) 546-6200 ext. 103 or on my cell phone at (256) 312-7297.

Kindest Regards,

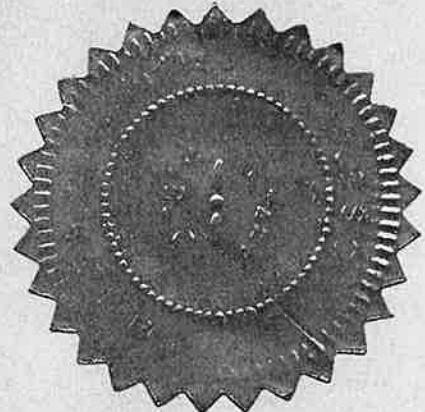


Larue S. Cline, RCS, RVS  
Office Manager  
North Alabama Cardiology Center  
503 S 5th St  
Gadsden AL 35901  
(256) 546-6200 Ext 103  
(256) 312-7297 Cell  
(256) 546-6250 Fax

Affirmation of Requesting Party:

The undersigned, being first duly sworn, hereby make oath or affirm that he is the authorized agent of North Alabama Cardiology Center P.C., has knowledge of the facts in this request, and to the best of his information, knowledge and belief, such facts are true and correct.

Affiant     *R. J. [unclear]*    



SUBSCRIBED AND SWORN to before me this 21<sup>st</sup> day of July 2023.

    *James S. [unclear]*      
Notary Public

    8-11-2025      
My commission expires



# North Alabama Cardiology Center

B.J. PATEL, M.D., F.A.C.C.  
VIRENJAN NARAYAN, M.D., F.R.C.P., F.A.C.P., F.A.C.C.

Full Invasive and Non-Invasive Services

RV 2023 025  
RECEIVED  
Aug 01 2023  
STATE HEALTH PLANNING AND  
DEVELOPMENT AGENCY

8/1/2023

VIA EMAIL ([SHPDA.ONLINE@SHPDA.ALABAMA.GOV](mailto:SHPDA.ONLINE@SHPDA.ALABAMA.GOV))

Hon. Emily T. Marsal, Executive Director  
State Health Planning and Development Agency  
RSA Union Building  
100 North Union Street, Suite 870  
Montgomery, Alabama 36104

Re: RV2023-025 North Alabama Cardiology Center, P.C.

Dear Ms. Marsal,

Thank you for your prompt response. Below, you will find the answers to the additional questions you requested information on.

1. Please provide information as to the full gamut of services currently offered at the existing medical practice and a listing of all new services the proposed Cardiac Positron Emission Tomography with Computed Tomography (PET/CT) scanner will provide to the patients of North Alabama Cardiology Center. If the Agency is unaware of the full scope of services being provided, it cannot be determined if a CON is currently required regardless of if additional or new services will be provided.
  - a. *Additional services provided at NACC are:*
    - i. *Nuclear SPECT Perfusion Imaging*
    - ii. *Nuclear Cardiac Blood Pool Imaging*
    - iii. *Echocardiography*
    - iv. *Vascular Ultrasound*
    - v. *Treadmill Stress Test*
    - vi. *EKGs*
    - vii. *Holter monitoring*
    - viii. *Office Visits, etc.*
  - b. *New Services will be:*
    - i. *Cardiac PET/CT Perfusion Imaging*
2. The request indicates North Alabama Cardiology Center is a private physician practice solely owned and operated by Bankim J. Patel, M.D. The request also states that all cardiac PET/CT services, including the utilization of the equipment, will be conducted, requested, and solely utilized by the owner of the practice and any physicians employed within the practice. Please provide a listing of the individual physicians who are currently practicing at the cardiology center.
  - a. *Physicians working at NACC are:*
    - i. *Bankim J. Patel, M.D.*
    - ii. *Virenjan K. Narayan, MD.*



# North Alabama Cardiology Center

B.J. PATEL, M.D., F.A.C.C.

VIREN JAN NARAYAN, M.D., F.R.C.P., F.A.C.P., F.A.C.C.

Full Invasive and Non-Invasive Services

3. Provide the Agency with planned emergency procedures in place on behalf of the proposed RV request.
  - a. *Emergency protocols within the PET CT suite will be as follows:*
    - i. *In the event that a patient requires immediate acute care, First Aid Kits and Crash Carts (including AED) will be conveniently positioned within 20 feet of the PET CT suite and subjected to regular checks by office personnel.*
    - ii. *Our staff will diligently adhere to the guidelines set forth by the American Heart Association to effectively manage any emergencies. Additionally, they will promptly contact Emergency Medical Services and initiate transfers to Riverview Regional Medical Center as directed by the supervising physician.*
4. Please furnish the manufacturer's literature pertaining to the proposed PET/CT scanner for the private physician practice in Etowah County, Alabama.
  - a. *Please see attachment SQ.IV. Siemens Biograph Horizon PETCT Brochure*

Should you need any additional information, please feel free to reach out to me at any time.

Kindest Regards,

Larue S. Cline, RCS, RVS

Office Manager

North Alabama Cardiology Center

503 S 5th St

Gadsden AL 35901

(256) 546-6200 Ext 103

(256) 312-7297 Cell

(256) 546-6250 Fax

RECEIVED

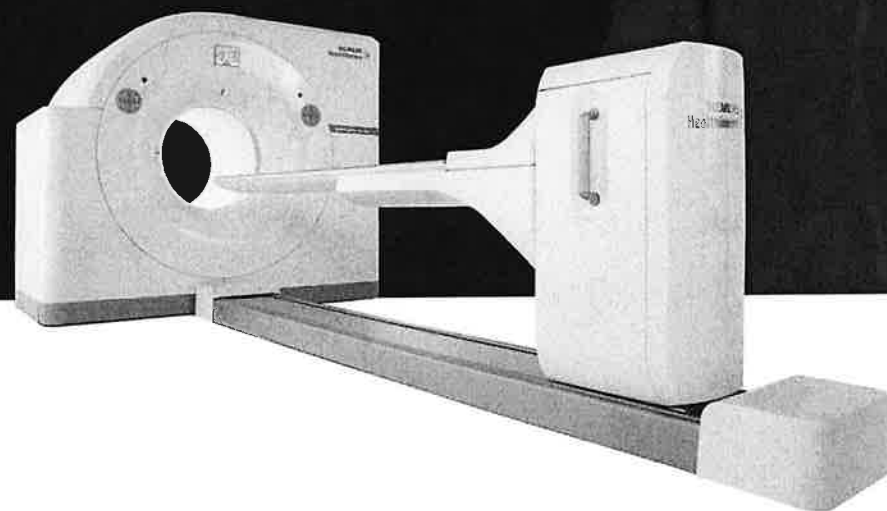
Aug 02 2023

STATE HEALTH PLANNING AND  
DEVELOPMENT AGENCY

# Biograph Horizon PET/CT

# Ready for more

[siemens-healthineers.com/biographhorizon](https://siemens-healthineers.com/biographhorizon)



**SIEMENS**  
Healthineers 

# ier care

based care continues to grow. Technological  
greater potential for an earlier diagnosis and  
ment strategy, helping to improve patient  
, healthcare providers are finding ways to  
while driving down long-term asset costs.

**is you offset these expenses, expands your  
d simplifies your operations.**

Increase your options with the advances and efficacy of Biograph Horizon. With technologies that set the standard in PET/CT, Biograph Horizon offers you premium flexibility at an attractive level of investment. Increased flexibility you bring high-quality care to more patients and a wide variety of clinical indications. Intelligent imaging capabilities streamline scans, saving you time while increasing reproducibility and standardization for advanced imaging.

**Technology that elevates performance.**

**Performance that creates opportunities.**

**Opportunity that advances your practice.**





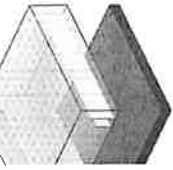
# Performance

LSO detectors give you PET/CT imaging with excellent resolution<sup>1</sup> due to the small, 4 x 4-mm (LSO) crystal elements, and the ability to use TOF for performance and clinical advantages. TOF is previously available only on stand-alone PET systems, providing quality imaging at low doses.

1

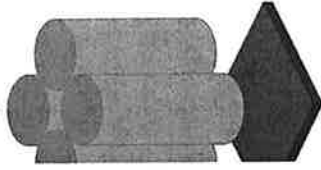
**A fast, efficient scintillator, LSO** is grown and cut in-house through a vertically integrated manufacturing process, ensuring the highest product quality.

2



**4 x 4 x 20-mm crystal elements** are individually selected and deliver high 78-mm<sup>3</sup> isotropic volumetric resolution; higher image resolution may result in improved lesion detectability.

3



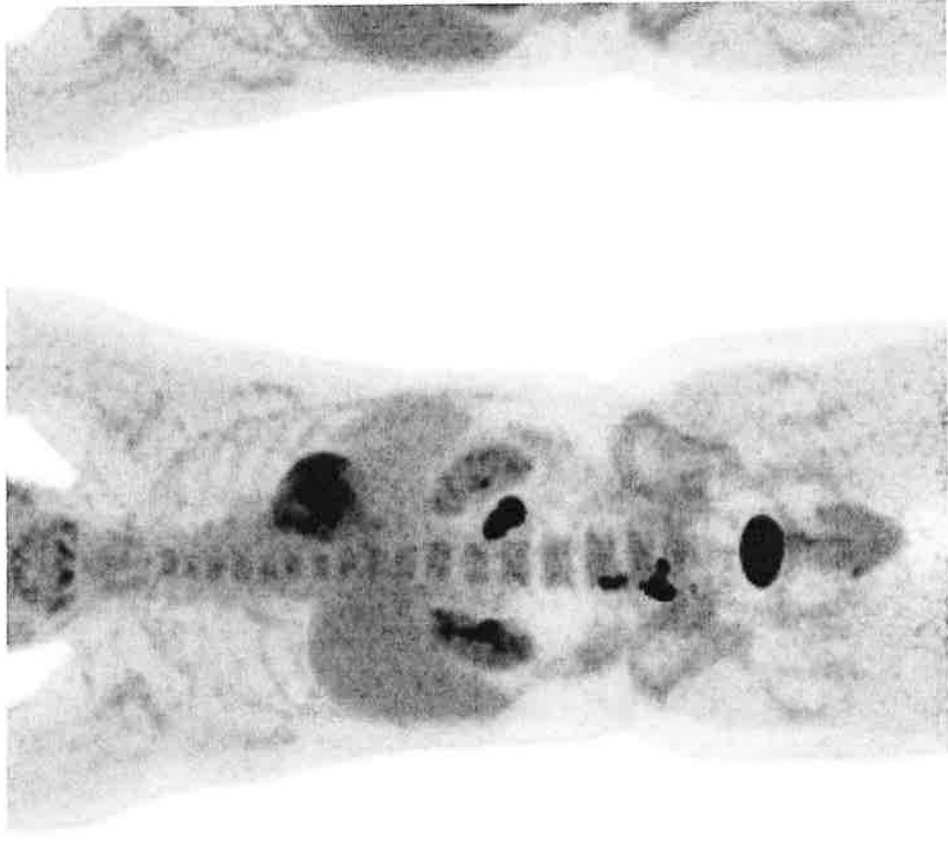
**Small, 4 x 4-mm crystals** with integrated light guidance arranged in a 13 x 13 matrix create a block that is combined with a light guide without partitions to spread light to photomultiplier tube (PMT) photosensors.

4

**Biograph Horizon's digital LSO-based detectors** and high-speed electronics support true TOF for improved signal-to-noise ratio. This enables faster scans, lower injected dose, and better image quality.

5

**Arranged with no gaps between detector blocks**, Biograph Horizon delivers an effective sensitivity of up to 26.5 cps/kBq<sup>3</sup> and an effective peak NEC rate of up to 366 kcps<sup>3</sup>.



non-TOF

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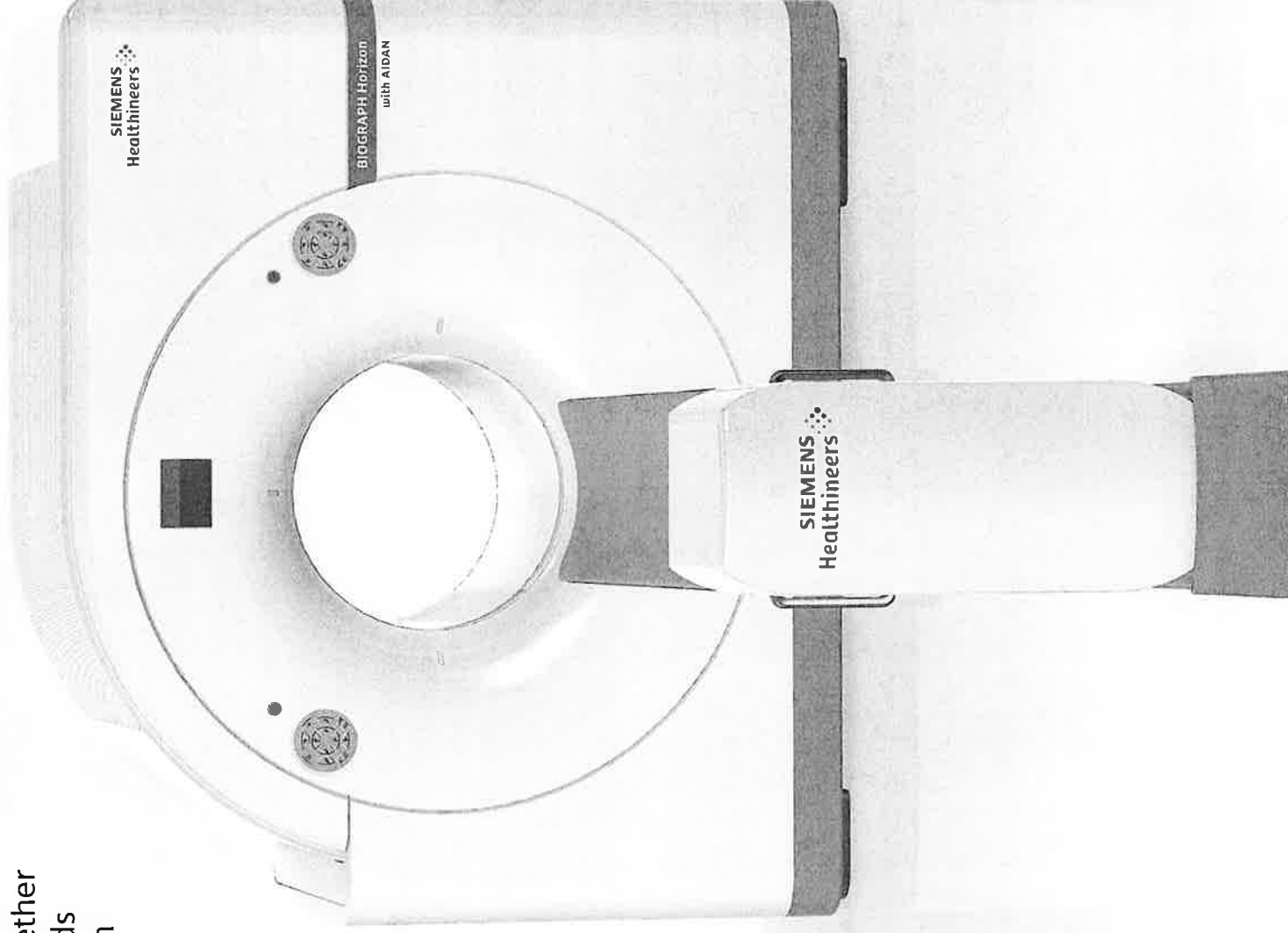
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)<sup>TM</sup>, CARE kV, and more.

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## Experience more PET techn

### TrueV

Extend the PET axial field of view fi  
33% more detector elements, which  
rate performance<sup>1</sup>.

### ultraHD • PET

Improve image signal-to-noise by u  
the resolution recovery of HD • PET.  
reduce patient acquisition time.

### FlowMotion™/FlowMotion AI

Create standardized imaging workf  
personalized results with disease-b  
patient's anatomy.

### Whole-body dynamic imaging

Simplify workflow for whole-body  
enables new clinical PET applicati

### Multiparametric PET AI

Expand the available parameters a  
facilitate more reproducible image  
quantification.

### OncoFreeze™ AI

Locate and correct anatomy impac  
and increase clinical confidence wi  
patient interaction.

### Cardiac imaging

Complete myocardial blood flow  
automated PET and CT data registr  
dynamic datasets, simultaneously

### QualityGuard™

Use intrinsic radioactive properties  
calibrate the scanner—eliminating  
source for daily and weekly PET qu  
technologist time.

# opportunity

of oncology, neurology, and cardiac  
merically available PET tracers and unique  
age quality, standardization, and clinical  
-dose PET/CT imaging to whole-body  
pgraph Horizon is designed to support your  
rch interests. Plus, the opportunity to  
T technology allows you to expand your

neuroendocrine imaging since 2018.<sup>4</sup>

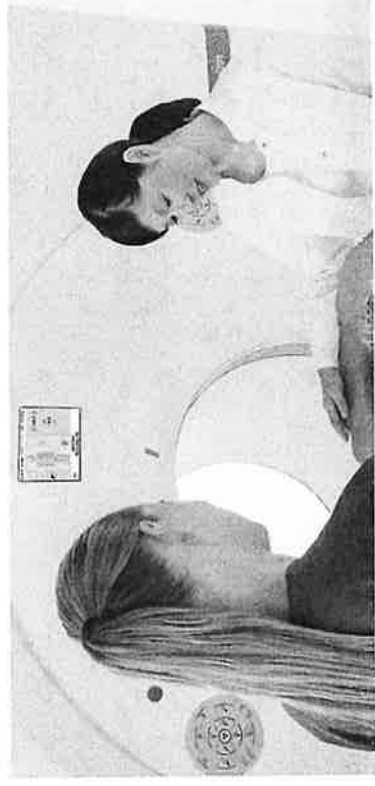
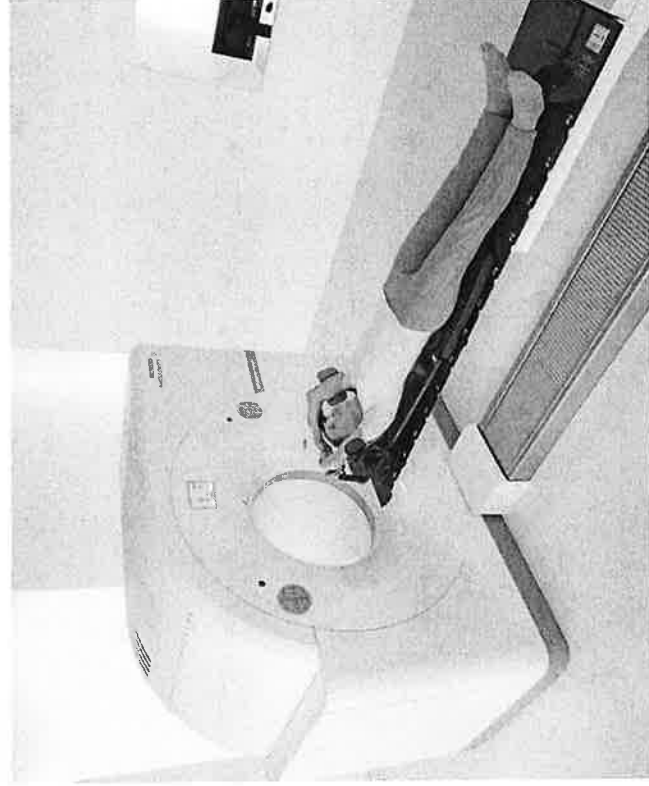
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 **5X** increase

in the use of prostate-specific  
tracers since 2018.<sup>4</sup>

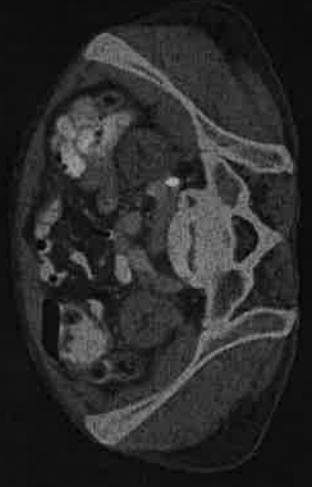
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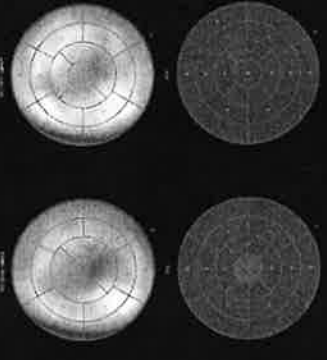
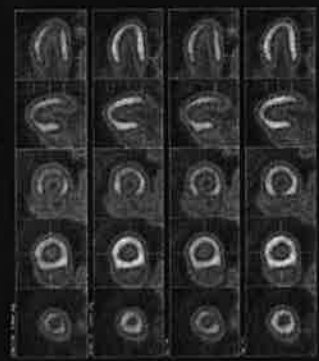


# Applications

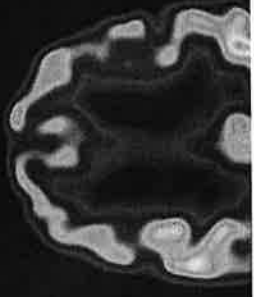
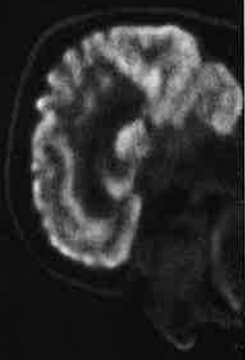
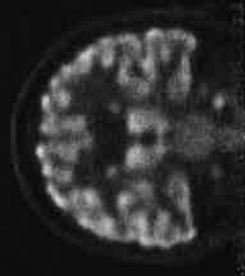
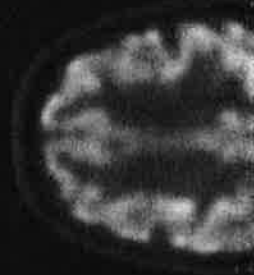
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# es your results

routines with an user experience. On lly design, Biograph our intelligent ograph PET/CT. With e the demanding based solutions to with more efficiency. ions and the patient lick of a button.

**Short, 130-cm tunnel**  
Reduced patient claustrophobia and more room for patient positioning

**70-cm bore size**  
Easy patient access and positioning of external accessories

**Large patient imaging**  
Wide pallet holds up to 227 kg (500 lb) and allows 2-meter scan ranges

**Exclusive bed design**  
Zero-differential deflection for accurate attenuation correction

## Intelligent imaging

Wide, 70-cm bore and short, 130-cm tunnel for patient comfort and easy access

Wide pallet holds up to 227 kg (500 lb) and allows 2-meter scan ranges

Front and back gantry controls, monitors, and communication devices allow user flexibility

Exclusive zero-differential deflection for accurate attenuation and TG-66 compliant bed design

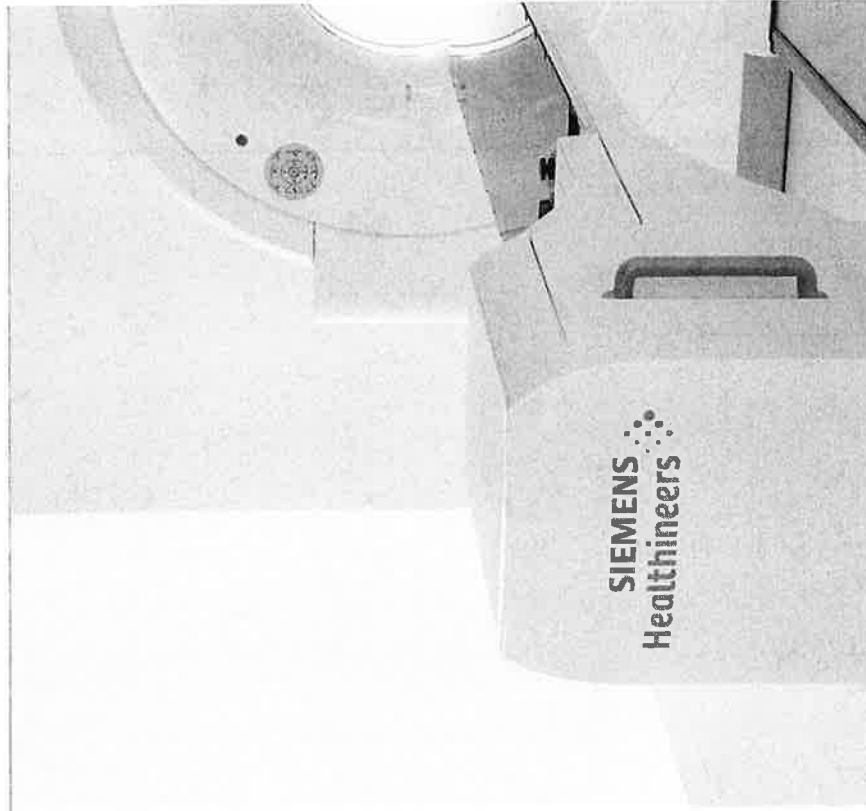
## Enhanced patient positioning

### FlowMotion AI

### OncoFreeze AI

### ultraHD•PET

### FAST PET WorkI



...with Biograph Horizon  
indicate good image quality and good  
lesion detection, even in difficult-to-image  
patients.”

Professor Nagara Tamaki  
Kyoto Prefectural University of Medicine (KPUM)  
Kyoto, Japan

“Not only did Biograph Horizon answer all  
our needs in terms of cost effectiveness and  
quality control, it also improved our daily  
practice with high-resolution images and  
great sensitivity.”

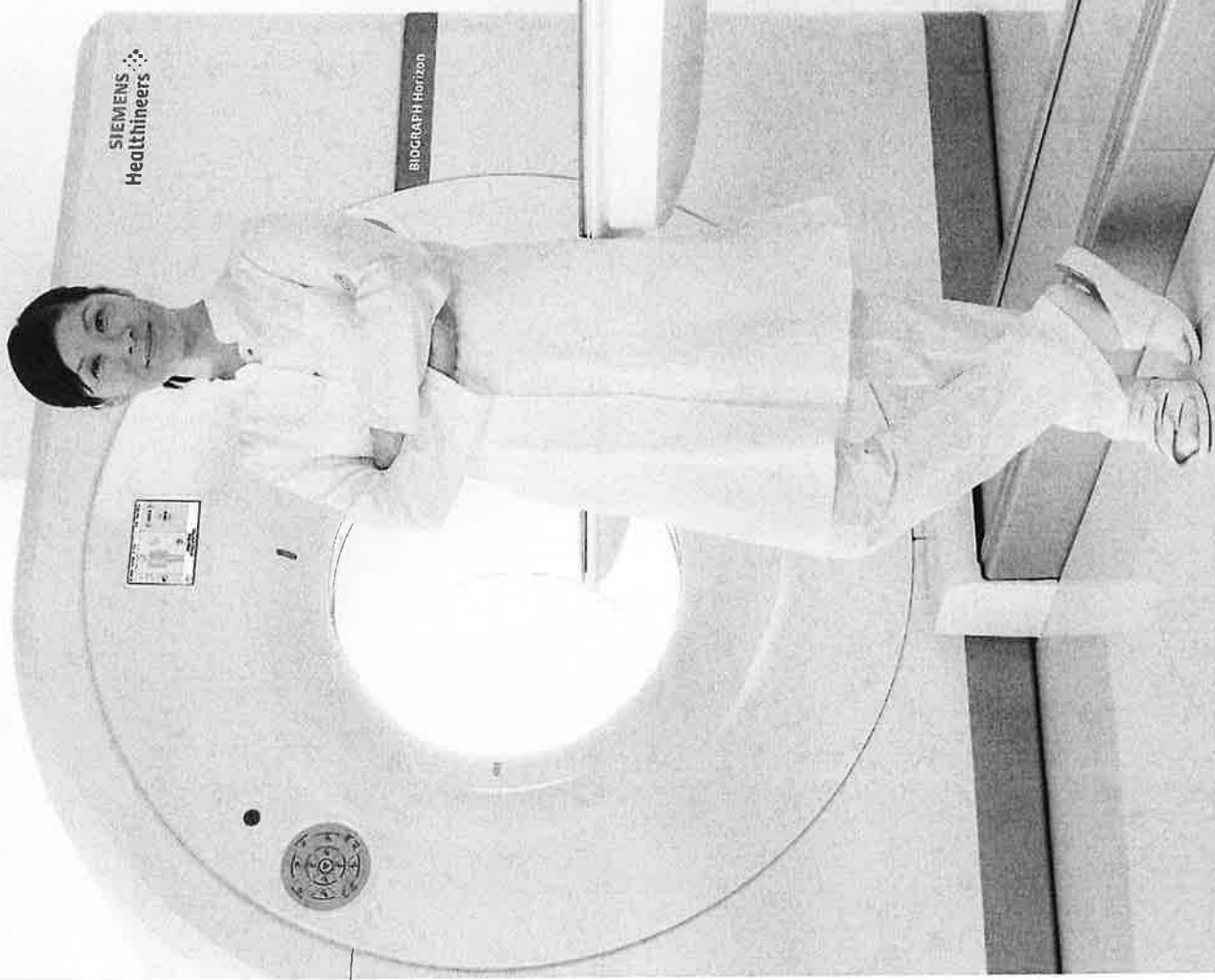
Andre Luiz Alberti Leitao  
Medical Physicist  
Núcleoos  
Brasília, Brazil

“The AI features allow us to focus on a  
specific task, which usually is the patient.  
You want to spend time with them to make  
sure they’re OK and that they are getting  
the best solution they need for treatment.”

Katie Morris  
Deputy Service Lead for Nuclear Medicine and PET/CT



**in PET/CT  
orizon**



**SIEMENS  
Healthineers**

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Clinical image featured on page 9: data courtesy of Praxis für Fusionierte Bildgebung, Halle (Saale), Germany.

<sup>1</sup> Based on internal measurements available at time of publication. Data on file.

<sup>2</sup> Optional.

<sup>3</sup> With TrueV and time of flight option.

<sup>4</sup> IMV 2022 PET Imaging Market Summary Report.

<sup>5</sup> IMV 2020 Radiation Therapy Market Summary Report.

<sup>6</sup> Worldwide data on file.

The statements by Siemens Healthineers customers described herein are based on results that were achieved in the customer’s unique setting. Because there is no “typical” hospital or laboratory and many variables exist (eg, hospital size, samples mix, case mix, level of IT, and/or automation adoption) there can be no guarantee that other customers will achieve the same results.

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