



Chad M. Alford, M.D.
Danielle E. Bayer, M.D.
Noel W. Bedwell, M.D.

Cardiology Specialties:

Adult Cardiology • Interventional Cardiology
Electrophysiology • Echocardiography • Nuclear Cardiology

Christopher S. Brown, M.D.
Kevin B. DeAndrade, M.D.
Warren Dale Hardy, M.D.

December 7, 2023

VIA EMAIL (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 Mobile Heart Specialists, P.C.

Dear Ms. Marsal,

This response is being submitted by Mobile Heart Specialists, P.C. (referred to as MHS), 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).

Kindly regard this letter and the accompanying supporting documents as an official submission for an Initial Reviewability Determination ("**Request**") in accordance with SHDPA's Certificate of Need ("**CON**") program rules and regulations. The objective of this request is to secure approval for the procurement and operation of a Cardiac Positron Emission Tomography with Computed Tomography ("**PET/CT Scanner**") within Mobile County, designated as the "**Service Area**," and more specifically situated at 6701 Airport Blvd, Suite A107, Mobile, AL 36608, referred to as the ("**Location**.")

The planned initiative is designed to provide Cardiac PET/CT services, referred to as ("**Services**") to patients at the designated Location. These services are facilitated through an office that is both owned and operated by a Partnership. The Partnership is comprised of key stakeholders, including Kevin B. DeAndrade, M.D. (Partner and President), Warren Dale Hardy, M.D. (Partner and Medical Director), Chad M. Alford, M.D. (Partner and Vice President), Noel W. Bedwell, M.D. (Partner and Secretary), and Christopher S. Brown, M.D. (Partner, Treasurer, and the Authorized Agent of the Company). Notably, no other healthcare facility or entity holds any financial interest in this office, in accordance with the definition established by the relevant Alabama Supreme Court case. Hence, given this exemption, it is our belief that the facility should be exempt from the necessity of undergoing a Certificate of Need review, as it satisfies 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, encompassing equipment usage, will be exclusively performed, requested, and used by the Physician Partners and any physicians employed within the practice. Please see below listed providers who will be using the equipment.*
 - i. *Chad M. Alford, M.D.*
 - ii. *Christopher S. Brown, M.D.*
 - iii. *Noel W. Bedwell, M.D.*
 - iv. *Kevin B. DeAndrade, M.D.*
 - v. *Warren Dale Hardy, M.D.*
 - vi. *Danielle E. Bayer, M.D.*
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 related equipment will be exclusively available at the Private Physician's office, situated at 6701 Airport Blvd, Suite A107, Mobile, AL 36608, located within Mobile County.*
3. All patient billings related to such services are through, or expressly on behalf of, the physicians' practice;
 - a. *Billing for Cardiac PET/CT services will be exclusively managed by the practice itself, and it will be carried out on behalf of the practice.*
4. The equipment shall not be used for inpatient care, nor by or on behalf of a third-party health care facility.”
 - a. *The Cardiac PET/CT equipment will be used exclusively within the Outpatient setting, and no services will be rendered to patients in an Inpatient status. Additionally, no external facilities providing Inpatient services will have access to or the capability to request the use of the equipment.*

As a cardiology office the current services we provide are:

- a. *Nuclear Cardiology*
- b. *Echocardiogram Studies*
- c. *Vascular Studies*
- d. *EKG's*
- e. *Holter Monitoring*
- f. *Office Visits, etc.*

The new service we are requesting to add is:

- a. *Cardiac PET/CT Perfusion Imaging*

If a patient necessitates urgent acute care, we ensure that first aid kits and Crash Carts, equipped with AEDs, will be conveniently positioned within 20 feet of the PET/CT suite. Routine inspections by office

personnel guarantee their readiness. Our dedicated staff strictly follows the guidelines outlined by the American Heart Association to proficiently handle any emergencies that may arise. Furthermore, they are committed to promptly engaging Emergency Medical Services and facilitating transfers to USA Health Providence Hospital as directed by the supervising physician.

For inquiries regarding this determination request, please feel free to contact Susan Bryan, RN, BSN, MHA, the Authorized Representative at the Location. You can reach her at the office phone number (251) 435-8567 or on her cell phone at (251) 458-5830. This request is being submitted on behalf of Christopher S. Brown, MD, who holds the position of Authorized Agent for the Company.

Approximated costs of the proposed Cardiac PET/CT project:

a) Equipment

- \$14,900.00 per month (paid in installments over 60 months)

b) First year annual operating costs

- Approximately \$622,888.16

c) Capital costs, to include:

i. Leases

- The Cardiac PET/CT equipment will be acquired through a lease agreement with CDL Nuclear Technologies, LLC. This lease is scheduled for a duration of 60 months, with a total lease amount of \$894,000.00 over 5 years (\$14,900 per month). This will also cover the first \$200,000 cost of the buildout outlined below.
 - The leased equipment will be a Siemens Horizon (16-slice) Cardiac PET/CT scanner. (Please see attached brochure)

- The office space designated for housing the Cardiac PET/CT equipment will be previously leased space at an estimated cost of \$174,075.30 for the remaining eight years of the lease term.

d) Land/Building costs

- Not Applicable

e) Construction costs

- We expect that the construction costs will total approximately \$200,000.00. Nonetheless, it is essential to acknowledge that unexpected challenges or savings during the construction process could potentially result in a revision to this estimated cost.

Moreover, given that the project aligns with the criteria for both capital costs and operational costs as mentioned earlier, we respectfully request that SHPDA grant a determination of non-reviewability. An attestation from the requesting party is enclosed for your reference. Furthermore, in compliance with SHPDA Rule 410-1-3-.09, the obligatory filing fee of \$1,000 has been duly submitted through the SHPDA electronic payment portal.

If you require any additional information, please feel free to contact me at the following email address:

sbryan@mobheart.com. You can also reach me at the office by calling (251) 435-8567, or you may

contact me on my cell phone at (251) 458-5830.


Kindest Regards,



Susan Bryan, RN, BSN, MHA
Practice Administrator
6701 Airport Blvd., Suite A107
Mobile, AL 36608
(251) 435-8567 Direct Line
(251) 458-5830 Cell Phone

Affirmation of Requesting Party:

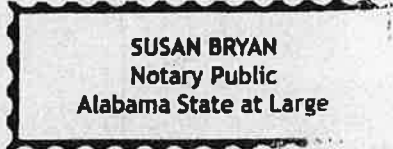
The undersigned, being first duly sworn, hereby make oath or affirm that he is the authorized agent of Mobile Heart Specialists, P.C., has knowledge of the facts in this request, and to the best of his information, knowledge and belief, such facts are true and correct.

Affiant 

(SEAL)

SUBSCRIBED AND SWORN to before me this 7 day of December 2023.


Notary Public

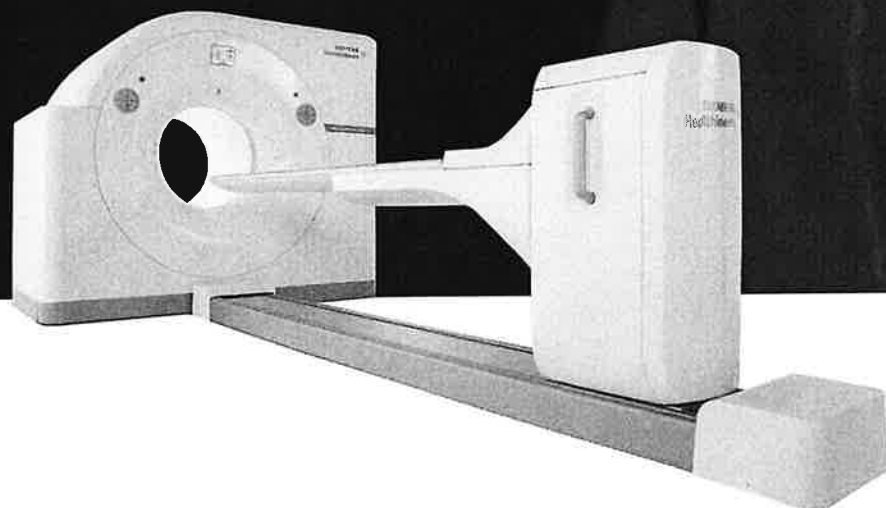


4/13/2024
My commission expires

Biograph Horizon PET/CT

**Ready
for more**

siemens-healthineers.com/biographhorizon

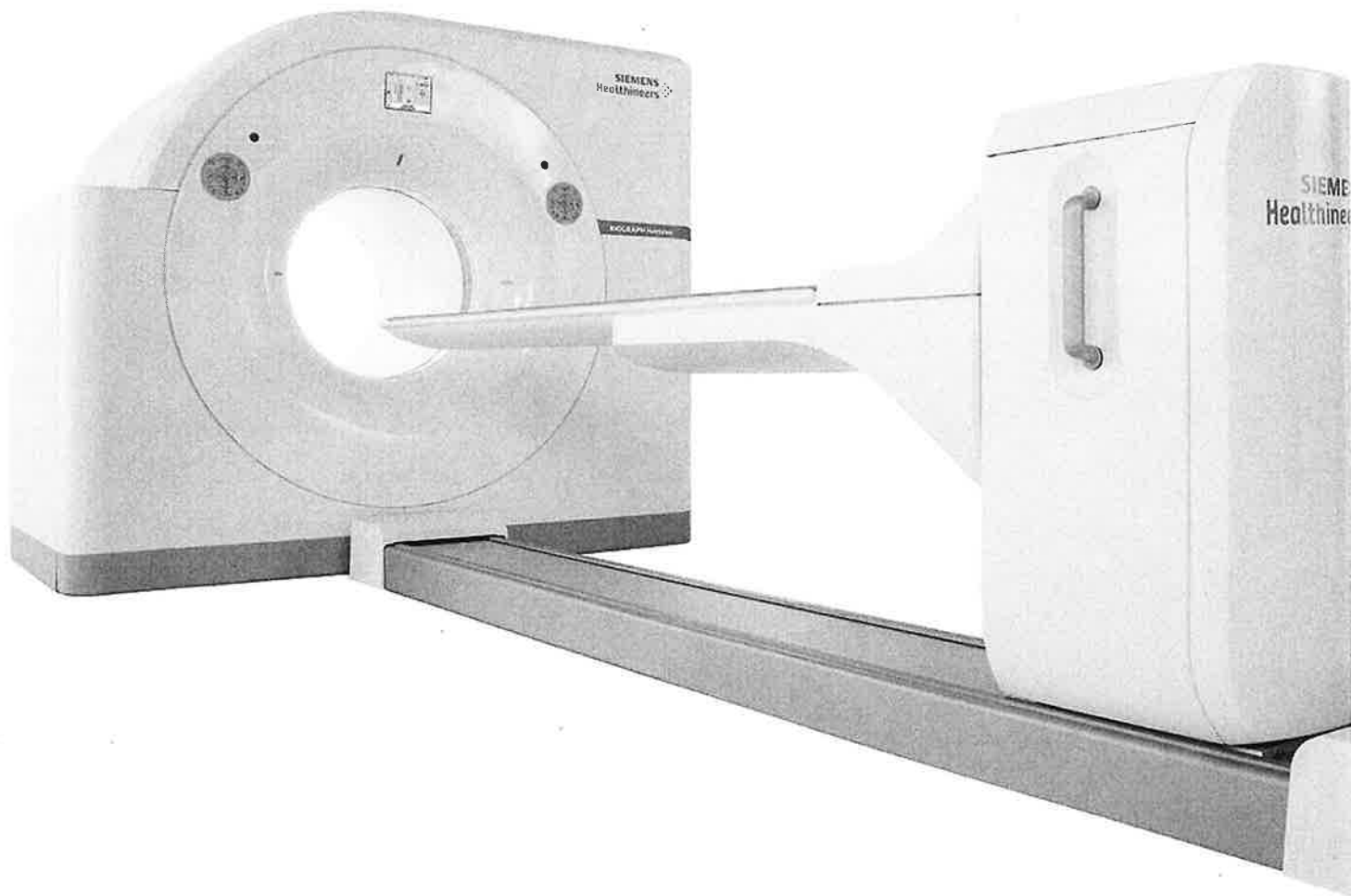


SIEMENS
Healthineers 

Innovative technology for better care

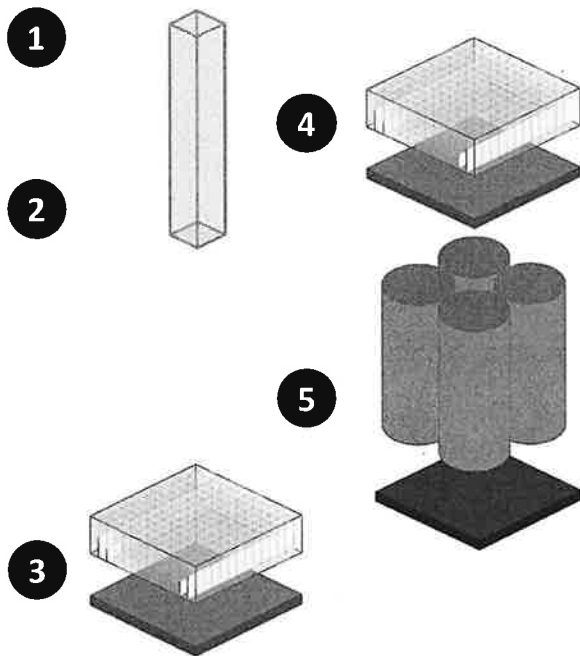
The demand for value-based care continues to grow. Technological advancements lead to greater potential for an earlier diagnosis and a more definitive treatment strategy, helping to improve patient outcomes. In response, healthcare providers are finding ways to reshape care pathways while driving down long-term asset costs.

Biograph™ Horizon helps you offset these expenses, expands your clinical capabilities, and simplifies your operations.



Technology that elevates performance

Biograph Horizon digital detectors give you PET/CT imaging with high 78-mm³ volumetric resolution¹ due to the small, 4 x 4-mm lutetium oxyorthosilicate (LSO) crystal elements, and the ability to offer true time of flight (TOF) for performance and clinical advantages. Dedicated CT solutions, previously available only on stand-alone systems, provide high-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-mm³ 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/kBq³ and an effective peak NEC rate of up to 366 kcps³.

Advanced PET and CT in one platform

Biograph Horizon is built on technology that all together adds up to more. Our wide range of features expands your clinical capabilities and delivers excellent lesion detectability, spatial resolution, and quantification accuracy—letting you bring a higher standard of care to more patients.

Biograph Horizon offers a scalable and flexible range of PET and CT technologies available on a single platform. All advanced PET and CT features are field upgradable, which helps to keep your system up to date for many years.

Experience more CT technologies²

16-/32-slice CT

Evaluate the smallest structures with optional 32-slice reconstruction featuring IVR (Interleaved Volume Reconstruction).

SAFIRE

Enhance patient outcomes by delivering excellent image quality at very low doses.

iMAR

Yield images with a reduced level of metal artifacts compared to conventional reconstruction.

Dual energy

Combine tissue information with morphology using different kV levels.

FAST CARE CT technologies

Optimize dose, image quality, and streamline workflow. Innovations include CARE Dose4D™, CARE kV, and more.

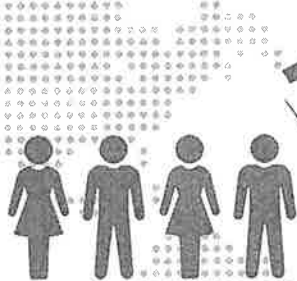
Radiation therapy (RT) planning

Support RT workflow, including motion management solutions for precise therapy planning.



Performance that creates opportunity

Address a broader range of oncology, neurology, and cardiac indications using all commercially available PET tracers and unique features that elevate image quality, standardization, and clinical insights. From fast, low-dose PET/CT imaging to whole-body dynamic studies, Biograph Horizon is designed to support your clinical needs and research interests. Plus, the opportunity to incorporate advanced CT technology allows you to expand your diagnostic capabilities.



More than
3,900
Biograph Horizon
studies per day⁶

Clinical versatility for unlimited opportunities

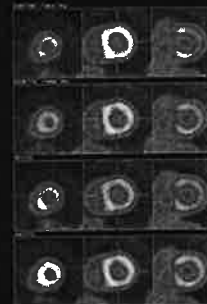
Oncology

Biograph Horizon's ability to support low-dose, fast imaging enables a comprehensive oncology imaging workflow. Additionally, oncology-dedicated technologies like deviceless gating, whole-body dynamic imaging, and RT planning packages help to expand capabilities beyond traditional PET/CT imaging.



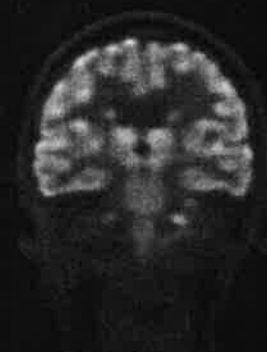
Cardiology

Biograph Horizon's digital LSO-based detectors enable routine use of short-lived isotopes for cardiac imaging. Additionally, cardiac-dedicated features deliver automated PET and CT data registration and rapid reconstruction of dynamic datasets simultaneously with acquisition for a quick and reproducible workflow.



Neurology

Biograph Horizon demonstrates precise delineation of cerebral anatomy with small elements, including 78-mm³ volumetric resolution and a large 360 x 360 acquisition matrix.



Opportunity that advances your results

Better support clinical routines with an enhanced patient and user experience. On top of its patient-friendly design, Biograph Horizon offers AIDAN—our intelligent imaging platform for Biograph PET/CT. With AIDAN, you can leverage the demanding processing power of AI-based solutions to perform PET/CT exams with more efficiency. Optimize clinical operations and the patient experience with just a click of a button.

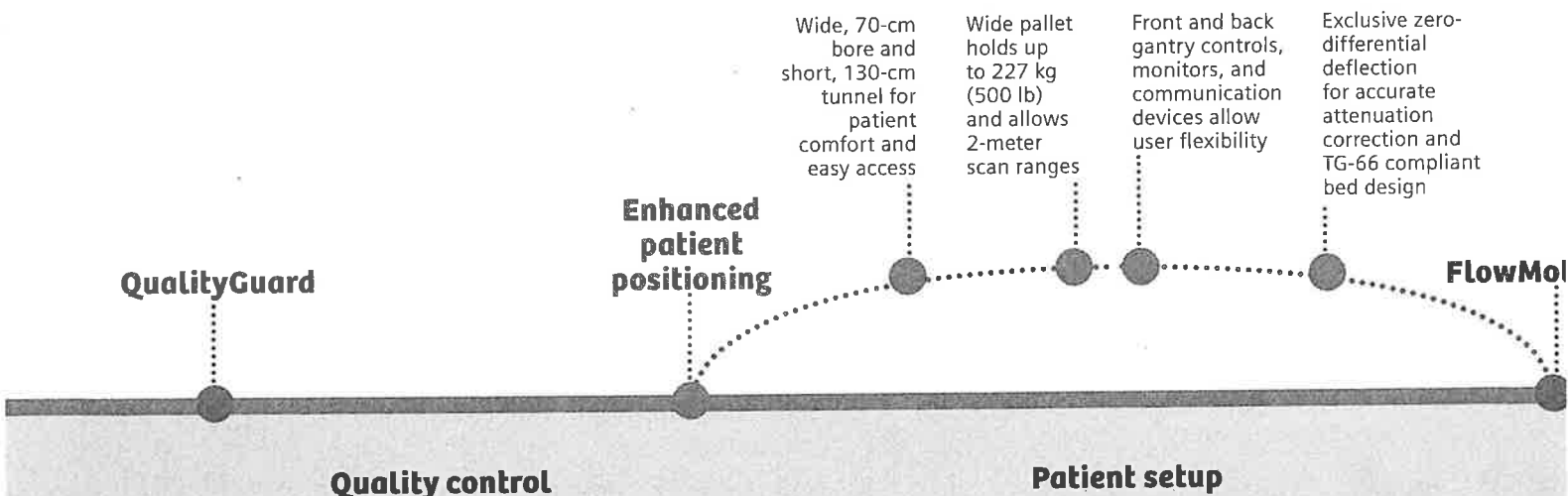
Short, 130-c
Reduced patient claustrophobia and more room for patient preparation

70-cm
Easy patient access and preparation of external accessories

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

Exclusive beam
Zero-differential deflection for accurate attenuation correction and TG-66 compliant bed design

Streamlined workflow with intelligent imaging





“Oncology scans 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
Núcleos
Brasília, Brazil

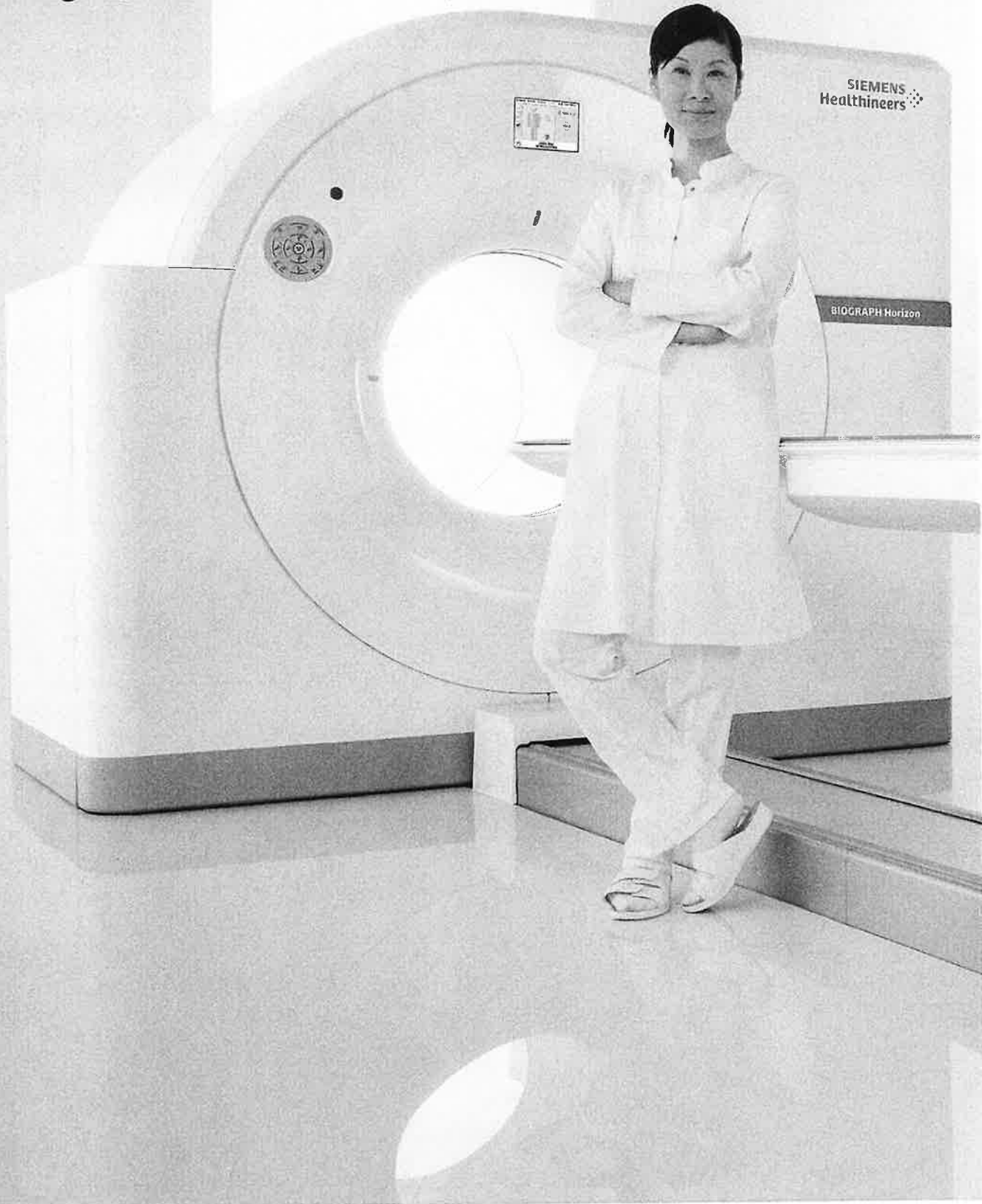


“The AI features allow us to focus on a specific task, which usually is the patient. You want to spend time with them to make sure they’re OK and that they are getting the best solution they need for treatment.”

Katie Morris
Deputy Service Lead for Nuclear Medicine and PET/CT
The Royal Marsden NHS Foundation Trust
London, United Kingdom

Ready for more

**Set the standard in PET/CT
with Biograph Horizon**



Trademarks and service marks used in this material are property of Siemens Healthcare GmbH. All other company, brand, product, and service names may be trademarks or registered trademarks of their respective holders. Please contact your local Siemens Healthineers sales representative for the most current information or contact one of the addresses listed below.

Note: Original images always lose a certain amount of detail when reproduced.

“Siemens Healthineers” is considered a brand name. Its use is not intended to represent the legal entity to which this product is registered.

All photographs © 2023 Siemens Healthcare GmbH. All rights reserved.

Clinical image featured on cover: data courtesy of Hakodate Goryoukaku Hospital, Hakodate, Japan.

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

¹ Based on internal measurements available at time of publication. Data on file.

² Optional.

³ With TrueV and time of flight option.

⁴ IMV 2022 PET Imaging Market Summary Report.

⁵ IMV 2020 Radiation Therapy Market Summary Report.

⁶ 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.

Siemens Healthineers Headquarters

Siemens Healthcare GmbH
Henkestr. 127
91052 Erlangen, Germany
Phone: +49 9131 84-0
siemens-healthineers.com

Published by

Siemens Medical Solutions USA, Inc.
Molecular Imaging
2501 North Barrington Road
Hoffman Estates, IL 60192
USA
Phone: +1 847 304-7700
siemens-healthineers.com/mi

Legal Manufacturer

Siemens Medical Solutions USA, Inc.
Molecular Imaging
2501 North Barrington Road
Hoffman Estates, IL 60192
USA
Phone: +1 847 304-7700
siemens-healthineers.com/mi



Mobile Heart SPECIALISTS, P.C.

RV2024-003

Chad M. Alford, M.D.
Danielle E. Bayer, M.D.
Noel W. Bedwell, M.D.

Cardiology Specialties:

Adult Cardiology • Interventional Cardiology
Electrophysiology • Echocardiography • Nuclear Cardiology

Christopher S. Brown, M.D.
Kevin B. DeAndrade, M.D.
Warren Dale Hardy, M.D.

December 20, 2023

VIA EMAIL (SHFDA.ONLINE@SHFDA.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 (RV2024-003)- (Response to 12.13.23 Information Request)

Dear Ms. Marsal,

This is being submitted by Mobile Heart Specialists, P.C. (referred to as MHS), in response to letter dated 12.13.23 requesting additional information.

- The address for the physical location of the office space where the PET/CT equipment will be located is 6701 Airport Blvd, Suite A107, Mobile, AL 36608.

Kindest Regards,

Susan Bryan, RN, BSN, MHA
Practice Administrator
6701 Airport Blvd., Suite A107
Mobile, AL 36608
(251) 435-8567 Direct Line
(251) 458-5830 Cell Phon