NC DEPARTMENT OF
HEALTH AND HUMAN SERVICES

ROY COOPER • Governor
MANDY COHEN, MD, MPH • Secretary
MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

April 9, 2021

Jeffery Shovelin
jshoveli@vidanthealth.com

No Review

Record #:	**3522**
Date of Request:	December 21, 2020
Facility Name:	The Vidant Healthplex-Wilson
FID #:	180206
Business Name:	Vidant Medical Group, LLC
Business #:	2813
Project Description:	Add a new 3D Mammography Unit
County:	Wilson

Dear Mr. Shovelin:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your correspondence on April 7, 2021 regarding the project described above. Based on the CON law **in effect on the date of this response to your request,** the project as described is not governed by, and therefore, does not currently require a certificate of need. 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.

This determination is binding only for the facts represented in your correspondence. If changes are made in the project or in the facts provided in the correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by this office.

Please do not hesitate to contact this office if you have any questions.

Sincerely,

Gregory F. Yakaboski
Project Analyst

Gloria C. Hale
Team Leader, Certificate of Need

cc: Construction Section, DHSR
Radiation Protection Section, DHSR

VIDANT HEALTH™

December 21, 2020

Ms. Martha Frisone, Chief
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
NC Department of Health and Human Services
2704 Mail Service Center
Raleigh, NC 27699-2704

RE: Request for "No Review" for a New 3D Mammography Unit

Dear Ms. Frisone:

Vidant Medical Group, LLC's (VMG) ambulatory physician practice in Wilson, NC d/b/a/ Vidant Healthplex – Wilson (Healthplex) is planning to purchase a GE Senographe Pristina full field digital 3D mammography system. This medical equipment is typically used to perform routine diagnostic mammography. Reference Appendix A for the manufacturer's materials describing the capabilities of the unit. The mammography unit will be operated in renovated space in the existing practice (Appendix B) and is expected to be operational by March 2021.

VMG believes the proposed project is not subject to review under North Carolina's Certificate of Need laws. Pursuant to N.C.G.S. 131E-176(14o), the proposed project does not meet the definition of "major medical equipment" as defined below.

> *"Major medical equipment" means a single unit or single system of components with related functions which is used to provide medical and other health services and which costs more than seven hundred fifty thousand dollars ($750,000). In determining whether the major medical equipment costs more than seven hundred fifty thousand dollars ($750,000), the costs of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the major medical equipment shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater. Major medical equipment does not include replacement equipment as defined in this section.*

Specifically, according to the manufacturer's itemized quote (Appendix C), the total capital cost of the equipment is $473,859. This includes the equipment and all options, accessories, on-site training, installation, delivery, insurance and fees. VMG believes the manufacturer's quoted price represents the fair market value for the equipment. The cost of the renovations and other activities essential to making the equipment operational is estimated at $197,165. Reference Appendix D for a certified cost estimate. In addition, pursuant to approved CON Project ID L-11498-18, the Healthplex is already designated as a diagnostic center (Appendix E), so those rules do not apply.

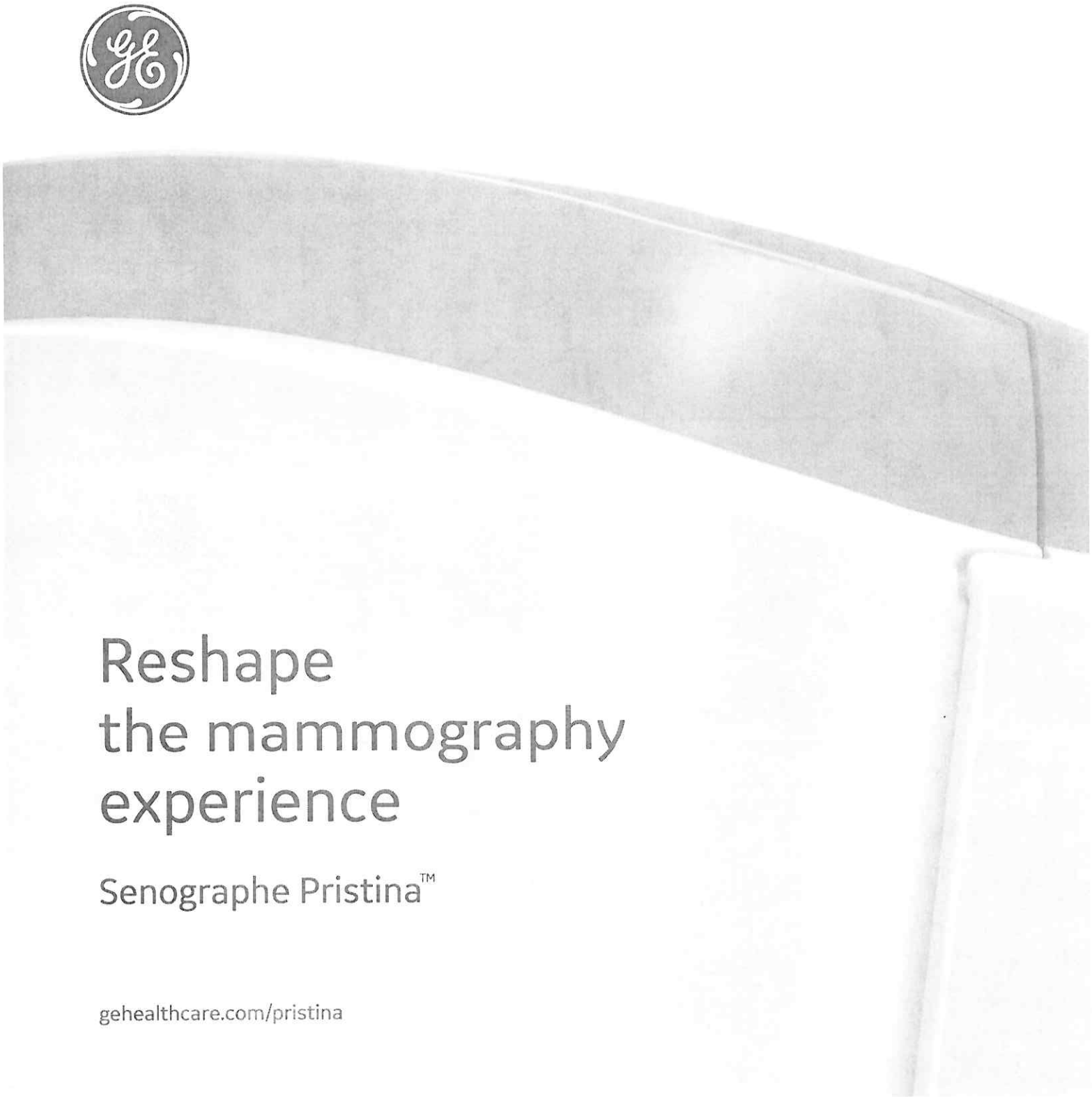
Since the proposed project is less than $750,000 and the existing practice is already an approved diagnostic center, the proposed project does not meet the definition of major medical equipment. Because

the proposed project does not meet the definition of major medical equipment, VMG requests a "no review" approval. If you need additional information or clarification, please do not hesitate to contact me at (252) 847-3631.

Sincerely,

Jeffrey Shovelin
Vice President, Business Development & Strategy
Vidant Health
PO Box 6028
Greenville, NC 27835-6028
Phone: (252)-714-5156
Email: jshoveli@vidanthealth.com

APPENDIX A: Equipment Brochure



Reshape the mammography experience

Senographe Pristina™

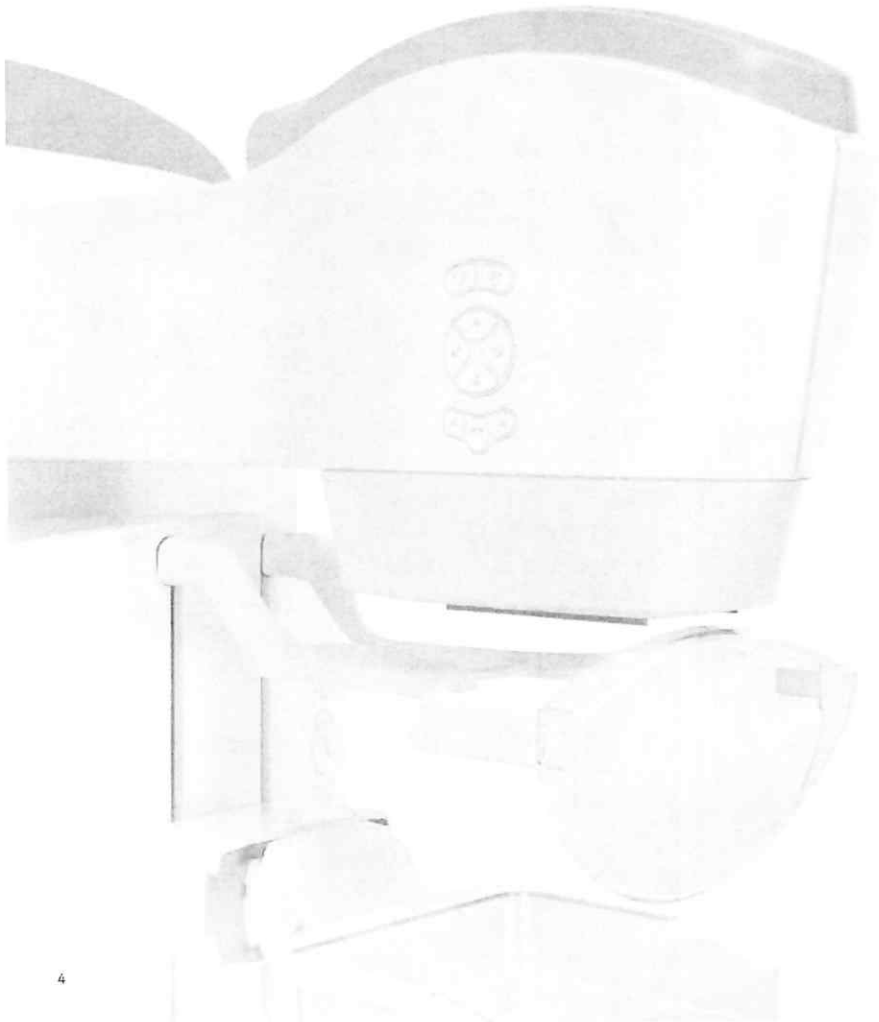
gehealthcare.com/pristina

Reshape the mammography experience with comfort, confidence and clarity

At GE Healthcare, we believe it's time to improve the entire mammography experience.

We partnered with radiologists, technologists and patients to create a mammography platform that is designed to each of their needs – easing patients' anxieties, making technologists' jobs easier and helping radiologists diagnose with greater confidence.

The result of our rigorous, collaborative design process is the Senographe Pristina.



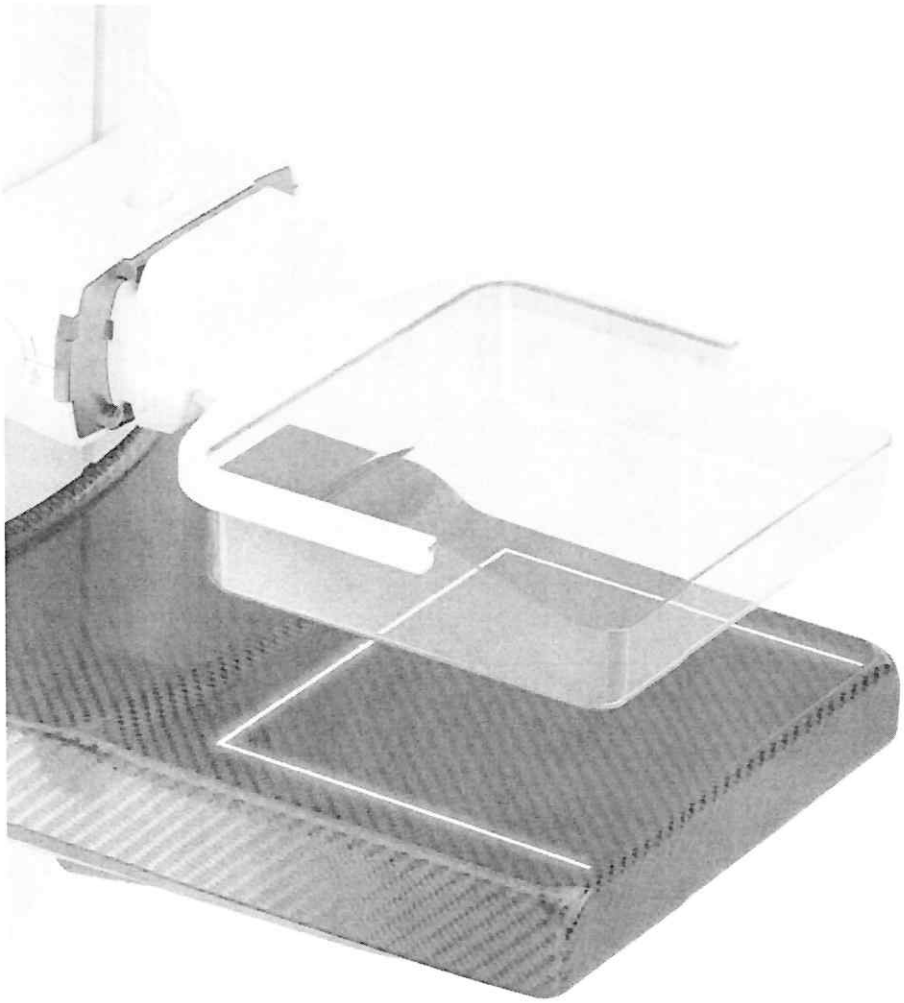
Comfort for patients

The gantry: attractive and well-designed like a beautiful piece of art

The new, inviting gantry promotes a sense of calm, with elegant lighting and gentle, rounded shapes. Senographe Pristina was built with one objective in mind: to ease patient anxiety when they enter the exam room.

A soft-curved surface invites patients into a space of comfort and support.

You'll need to experience it to truly realize what it can do for you.



Rethinking patient comfort

The new gentle, rounded edges of the detector can reduce discomfort and may also help reduce anxiety for patients. The soft armrests have replaced the typical hand grips. Patients can lean comfortably on the armrests relaxing their muscles to simplify compression and image acquisition.

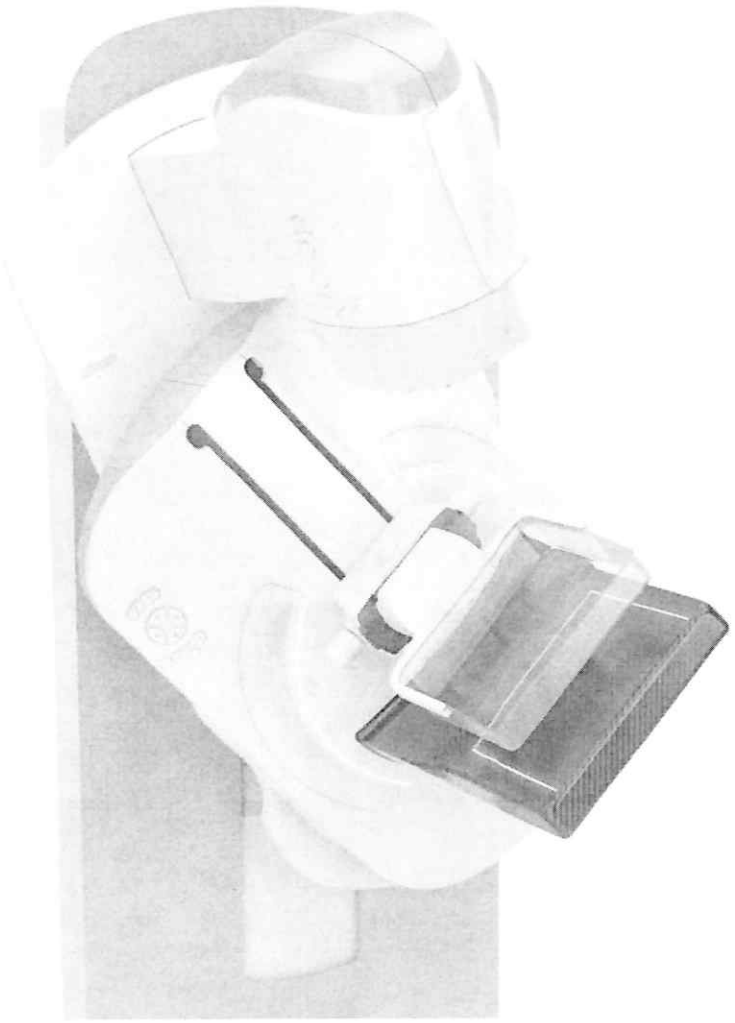
In addition, the Senographe Pristina includes specialized paddles such as the flex paddle that can tilt to adapt to women's varying morphology and the implant paddle specifically for breast implants as well as small breasts.

Confidence for technologists

Patient comfort easing positioning

Anxious patients are more prone to moving and contracting muscles, creating challenges for technologists to position them appropriately.

By making patients more comfortable during the exam, technologists can then focus on more suitable positioning, enabling a faster and smoother experience for both patient and technologist.



A new design to avoid physical strain

Making it easy for technologists to position patients is critical to improving the overall mammography experience for both patients and technologists.

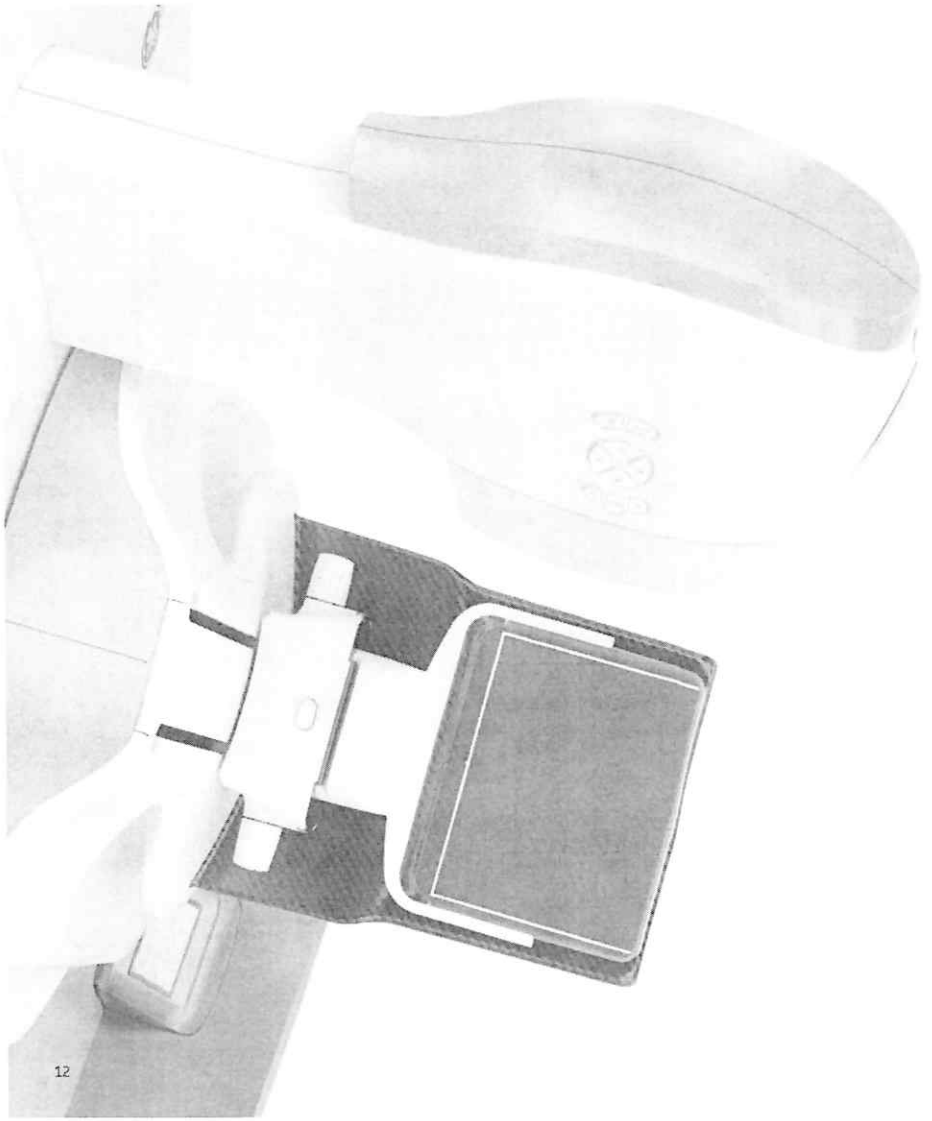
The upper space below the collimator is large, and the small tube design makes it easy for technologists to position patients.

The back space is also large enough to allow technologists to work without hitting their elbows when positioning the breast over the support.

Technologists can also position patients while facing them, allowing for better communication throughout the exam.

In addition, when positioning patients in mediolateral oblique (MLO), the tube head can be moved to a parked position away from the technologist's head.

This clears the upper space from obstruction so that the technologists can position the patient without physical strain.

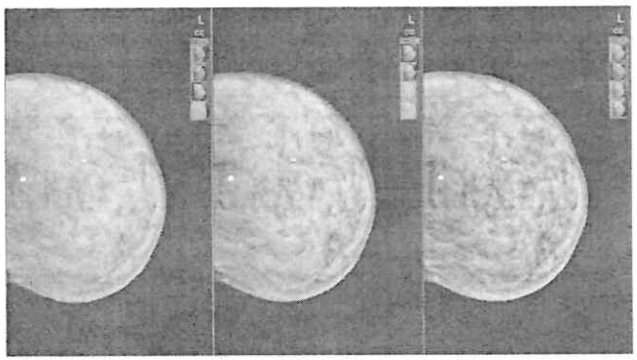


Reinventing the mammography experience to make the technologist's job easier

The console and gantry are ready to use within a few minutes after startup without requiring any calibration before starting the day.

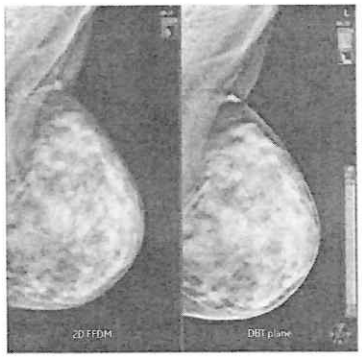
The image contrast can also be modified in real time, among six levels available, in order to accommodate user preferences.

The acquisition console is well-aligned with other GE Healthcare products, so that the learning curve is minimal for those familiar with other GE Healthcare equipment.

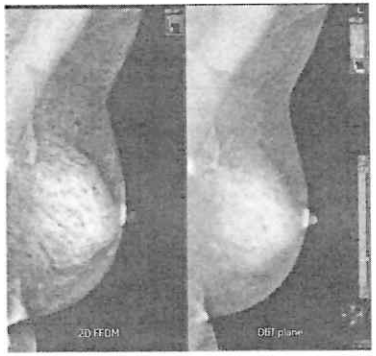


eContrast 5 options available to accommodate users preferences

Automated Optimization of Parameters with implants



Invasive ductal carcinoma



Surgical scar

Clarity for radiologists

Pristine images for accurate diagnosis

Pristina sets the bar for diagnostic confidence and performance, leveraging the Senographe family's widely recognized image quality.

GE Digital Breast Tomosynthesis delivers superior diagnostic accuracy at the same dose as 2D FFDM, the lowest patient dose of all FDA approved DBT systems[1].

1. GE screening protocol consists of 3D CC/MLO + V-Preview CC/MLO. V-Preview is the 2D synthesized image generated by GE Senoiris mammography software from GE DBT images. FDA PMA P130020/S001 http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm?id=P130020S001, Data on file. Average glandular dose in digital mammography and digital breast tomosynthesis: comparison of phantom and patient data. Bouwman, R. W. and al., et. 2015. Physics in Medicine & Biology, pp. 7893-7907.

Excellent Visualization of Microcalcifications

3D mammography platform allows for excellent visualization of breast lesions without increasing the dose compared to a 2D exam.
GE's 3D tomosynthesis uses ASIR[DR], an iterative reconstruction algorithm with a calcification artifact correction. ASIR[DR] delivers off-plane images, far superior to the traditional Filtered Back Projection (FBP) algorithm in terms of both in-plane and out-of-plane artifacts. Furthermore, a specific slabbing algorithm renders calcifications as if each were in its optimal plane, making the images easy to read.

Senographe Pristina™

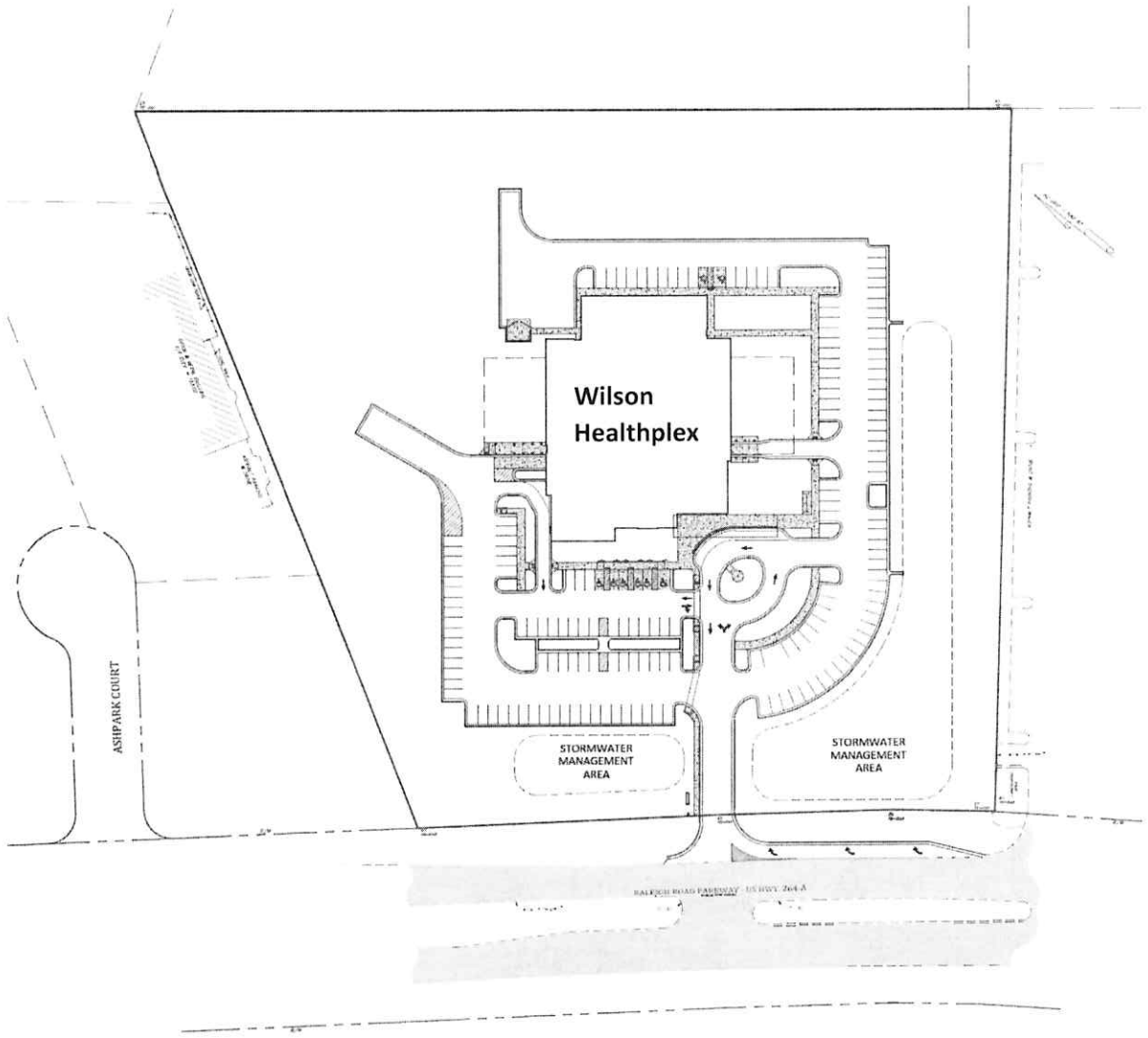
The Senographe Pristina platform is designed to support future functionalities, such as: Contrast Enhanced Spectral Mammography, biopsy and Senographe Pristina in a mobile environment.

Comforting, empowering, enlightening

Never has a mammography system been so focused on patients, technologists and radiologists alike – putting everyone in a better position for a more relaxing experience, productive workflow and effective care.

APPENDIX B: Site and Floor Plans

Wilson Healthplex 3D Mammography Upfit

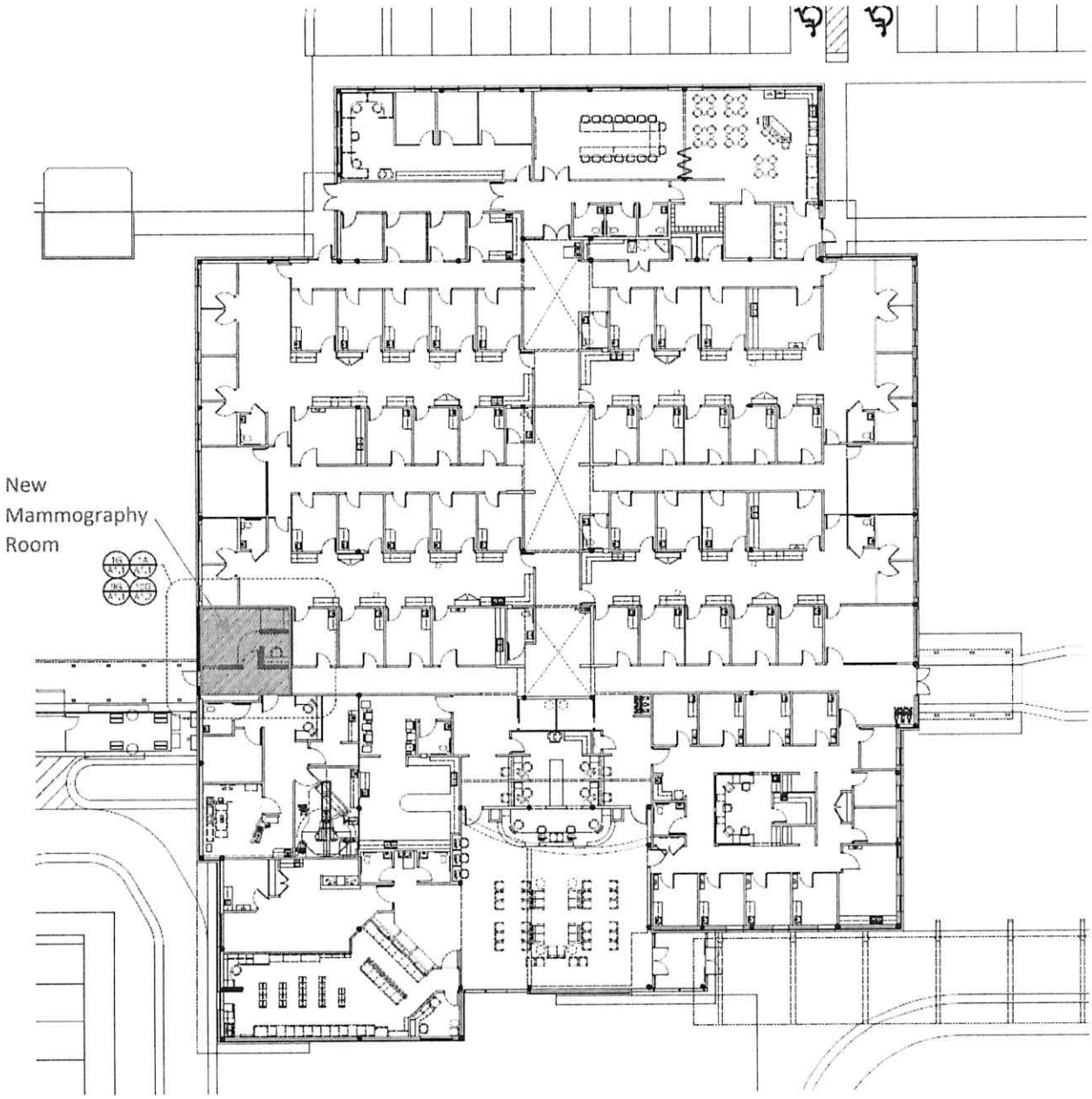


Location/Site Plan

3724 Raleigh Road Parkway

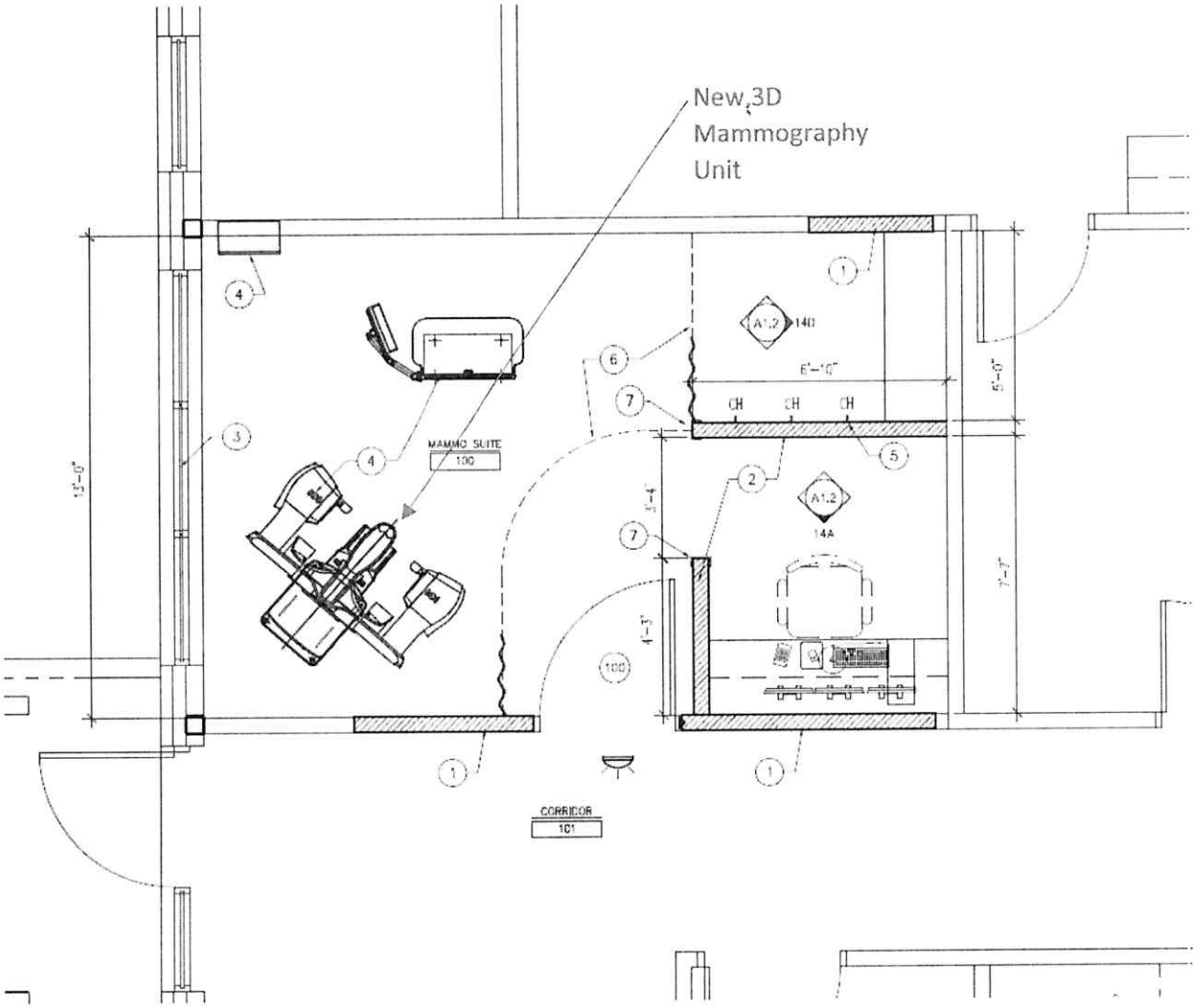
Wilson NC

Wilson Healthplex 3D Mammography Upfit



Overall Building Floor Plan

Wilson Healthplex 3D Mammography Upfit



Floor Plan of New Mammography Room

APPENDIX C: Detailed Equipment Quote and Specifications

GE Healthcare

August 28, 2020
Quote Number: **2005227763.3**
Customer ID: **U-6K9GBU**
Agreement Expiration Date: **11/26/2020**

Vidant Medical Group LLC dba Vidant Healthplex Wilson
3724 Raleigh Road Pkwy W
Wilson, NC 27896-9742

This Agreement (as defined below) is by and between the Customer and the GE Healthcare business ("GE Healthcare"), each as identified below for the sale and purchase of the Products and/or Services identified in this Quotation, together with any applicable schedules referred to herein ("Quotation"). "Agreement" is this Quotation and either: (i) the Governing Agreement identified below; or (ii) if no Governing Agreement is identified, the GE Healthcare Terms and Conditions and Warranties that apply to the Products and/or Services identified in this Quotation. In the event of conflict, the Quotation supersedes.

GE Healthcare can withdraw this Quotation at any time before Customer: (i) signs and returns this Quotation or (ii) provides evidence of Quotation acceptance satisfactory to GE Healthcare ("Quotation Acceptance"). On Quotation Acceptance, this Agreement is the complete and final agreement of the parties relating to the Products and/or Services identified in this Quotation. There is no reliance on any terms other than those expressly stated or incorporated by reference in this Agreement and, except as permitted in this Agreement, no attempt to modify will be binding unless agreed to in writing by the parties. Modifications may result in additional fees and cannot be made without GE Healthcare's prior written consent.

Handwritten or electronic modifications on this Agreement (except an indication of the form of payment, Customer purchase order number and signatures on the signature blocks below) are void.

Governing Agreement:	Premier
Terms of Delivery	FOB Destination
Billing Terms	80% on Delivery / 20% on Acceptance
Payment Terms	NET 45 DAYS
Sales and Use Tax Exemption	No Certificate on File
Logistics Surcharge %	1.75%
Logistics Surcharge Amount	$6,212.08
Total Amount with Logistics Surcharge	$361,188.31

IMPORTANT CUSTOMER ACTIONS:

Please select your planned source of funds. Source of funds is assumed to be cash unless you choose another option. Once equipment has been shipped, source of funds changes cannot be allowed.

___ Cash

___ GE HFS Loan ___ GE HFS Lease

___ Other Financing Loan ___ Other Financing Lease Provide Finance Company Name _____

The parties have caused this Agreement to be executed by their authorized representative as of the last signature date below. Participating Member acknowledges and agrees to pay the 1.75% logistical surcharge.

Vidant Medical Group LLC dba Vidant Healthplex Wilson

Signature: _____

Print Name: _____

Title: _____

Date: _____

_____
Purchase Order Number, if applicable

GE Precision Healthcare LLC, a GE Healthcare business

Signature: Nicholas Bengel

Title: Imaging Account Manager

Date: August 28, 2020

GE Healthcare

August 28, 2020
Quote Number: **2005227763.3**
Customer ID: **U-6K9GBU**
Agreement Expiration Date: **11/26/2020**

To Accept This Quotation

Please sign and return this quotation together with your Purchase Order to:

Name: Nicholas Bengel

Email nicholas.bengel@ge.com

Phone: 414-238-7008

Fax:

Name: Kimberly McCrary

Email: kim.mccrary@ge.com

Phone: (910) 547-7956

Fax: 877 644-2245

Payment Instructions

Please **remit** payment for invoices associated with this quotation to:

GE Precision Healthcare LLC
P.O. Box 96483
Chicago, IL 60693

FEIN: 83-0849145

Vidant Medical Group LLC dba Vidant Healthplex Wilson

Addresses:

Bill To:	Vidant Medical Group LLC dba Vidant Healthplex Wilson	3724 Raleigh Road Pkwy W, Wilson, NC, US, 27896-9742
Ship To:	Vidant Medical Group LLC dba Vidant Healthplex Wilson	3724 Raleigh Road Pkwy W, Wilson, NC, US, 27896-9742

To Accept This Quotation

- Please sign the quote and any included attachments (where requested).
- If requested, please indicate your form of payment.
- If you include a purchase order, please make sure it references the following information:
  - The correct Quote number and Version number above
  - The correct Remit To information as indicated in **"Payment Instructions"** above
  - Your correct SHIP TO and BILL TO site name and address
  - The correct Total Price as indicated above

Upon submission of a purchase order in response to this quotation, GE Healthcare requests the following to evidence agreement to contract terms: Signature page on quote filled out with signature and P.O. number **** OR**** Verbiage on the purchase order must state one of the following:

(i)Per the terms of Quotation # _____, (ii) Per the terms of GPO #_____; (iii) Per the terms of MPA# _____: or (iv) Per the terms of SAA # _____.

Include applicable quote/agreement number with the reference on the purchase order. In addition, Source of Funds (choice of Cash/Third Party Load or GE HFS Lease Loan or Third Party Lease through _____), must be indicated, which may be done on the Quote Signature Page (for signed quotes), or the Purchase Order (where quotes are not signed) or via a separate written source of funds statement (if provided by GE Healthcare)."

Catalog Item Details

Line	Qty.	Catalog	
1	1.00	M85101LD	**DoseWatch IT and Professional Services**

A dedicated GEHC Project Manager will be assigned to provide and oversee the configuration and installation of purchased DoseWatch Enterprise software on a server of defined specification (hardware) and configuration of device software licenses on eligible imaging systems.

Customer will provide a (Customer) Project Manager to work directly with the GE DoseWatch project manager in the installation and setup of DoseWatch. The Customer Project Manager will be responsible for the ongoing maintenance of the hardware that houses the DoseWatch software.

Professional Services will be defined by the specific Statement of Work (SOW) and may include the following:
Understanding of the project architecture and the best workflow
Installation and configuration of purchased DoseWatch software components
Setup of the licensed systems in DoseWatch
Configure network communication between DoseWatch and GE Imaging devices. Work with customer to develop a comprehensive list of equipment to be connected to DoseWatch. This may include equipment not currently covered by GE service contract
For non GE equipment and/or equipment not currently covered by GE contract, the Project Manager will support the Customer Project Manager to determine technical details such as software rev, MPPS/DICOM capability, etc. in order to determine compatibility with DoseWatch. Please note, MPPS/DICOM capability is sometimes a "for purchase" option. The Customer may need to purchase such options if they wish to connect those systems to DoseWatch.
Set up initial web interface administrative access and configure user-defined thresholds and alerts.
Excludes:
Data migration services (unless specifically detailed in SOW)
Configuration of RIS and/or interface
Setup of Systems covered by an OEM or third party service agreement
Providing for and configuring the hardware/software platform for DoseWatch
Customer provided software, such as network administration, backup and antivirus solutions
Customer network and/or firewall configurations to ensure connections and bandwidth

Line	Qty.	Catalog	
2	1.00	M85101LL	**DoseWatch Device Connections - Others**

DoseWatch device license permits the acquisition of radiation dose data from devices other than CT or Interventional (i.e. radiography device, mammography systems) within the DoseWatch application. It is also used to connect a DICOM system (i.e. PACS system) so DoseWatch can receive or retrieve data from that system. In such case, a license is needed for each device generating the data and each DICOM system connected to DoseWatch.

This license includes, if applicable to X-ray or Mammography, the following:
The implementation of the connection of the device to DoseWatch. Only the DoseWatch side of the interface is covered by this license. Any additional software and/or services required on the device must be purchased by the customer. Depending on device capabilities, the connection may require sending DICOM MPPS, DICOM Radiation Dose SR, DICOM Images or specific device logs from the device. The actual solution implemented shall be specified by the DoseWatch team.
Configuration of DoseWatch to process the received data and store radiation dose and acquisition-related data into the DoseWatch database.

Modalities supported: X-ray and Mammography. Includes 90 Day Warranty

The final quotation is subject to GE Healthcare General Terms and Conditions, GE Healthcare Additional Terms and Conditions-DoseWatch, and the completed DoseWatch Statement of Work.

Line	Qty.	Catalog	
3	1.00	S30371AF	**Senographe Pristina digital full field mammography system**

Senographe Pristina digital full field mammography system provides a comprehensive breast care solution which includes screening and diagnostic capabilities with patient focused design and enhanced ergonomics for the technologist.

Senographe Pristina works with an GE-manufactured 24 x 29 cm active area detector, designed to offer different breast imaging capabilities in a fast and efficient workflow. Smaller breasts are also easily managed with the different paddles available that can slide to both sides of the detector.

With excellent enhanced detector performance, at low dose, the Senographe Pristina offers a remarkable image quality for diagnostic confidence.

Ergonomic design for technologists
- Intuitive user interface
- Park Positioning during patient positioning
- One touch access to preset rotation for positioning
- Single speed motorized gantry movements
- Sliding compression paddles that can move to the side of the detector for compression

Ergonomics and design for patient comfort

- LED lighted hand rests
- Wheelchair access, MITA compliant
- Thinner Bucky than previous platform
- Rounded edges of detector for patient comfort

Image quality

- Automatic Optimization of Parameters (AOP), selects all exposure parameters based on breast radiological properties
- Three AOP modes + 1 Automatic mode for implants
- eContrast image processing for making automatic adjustments of brightness and contrast
- DQE at IEC 62220-2-3 equivalent spectrum, at 75µGy: 70% (+/-3) at 0.5lp/mm and 64% (+/-3) at 2lp/mm

Smooth digital workflow connectivity
- Automated Quality Control
- Integrated Repeat and Reject Analysis

Technical Specifications
Detector

- Detector ready to use immediately after system start-up
- Detector size: 24 x 29 cm
- Pixel size (pitch): 100 µm
- Acquisition dynamic range: 14 bits
- Bucky front cover thickness: 40mm
- Optimized room for positioning due to the bucky depth: 470mm
- Image size:
  - LFOV image size - approx. 13 MB per image
  - Regular image size - approx. 9 MB per image
- Patented needle structure CsI scintillator, single piece construction
- Breast support with rounded edge
- Air cooling

Tube Technology

- X-Ray tube type: Artemis
- Anode target materials - Dual track: Molybdenum (Mo)
- Enriched with Vanadium, and Rhodium (Rh)
- Four focal spots: 0.1 and 0.3 IEC on each target
- Target angle: 0 degree
- Maximal high voltage: 49 kV
- Tube current:

o Molybdenum target:
- 100 mA from 25 to 30 kV on large focal spot
- 40 mA from 25 to 30 kV on small focal spot

o Rhodium target:
- 62 mA from 25 to 30 kV on large focal spot
- 35 mA from 25 to 30 kV on small focal spot

- Anode size (tracks diameter): 100 mm
- Anode heat storage capacity: 250kJ (340 kHU)
- Anode maximum dissipation: 500 W (40 kHU/min)
- Max casing continuous dissipation:
- 150 W (12 kHU/min) at 40 °C
- Permanent filtration: 0.69 mm Beryllium
- Weight: 7 kg
- X-ray tube assembly: self-encased X-ray tube, oil-free,
- lead-free, air-cooled head
- Tube protection: software monitoring of tube load

Grid/breast support
- Universal grid compatible with 2D Conventional Mammography and DBT
- Ergonomic breast support designed for patient comfort and cleanability
- Motorized lock of the grid and breast support
- Breast support material: carbon fiber composite
- Optimized grid motion ensuring no grid structure visible in the image
- Detector to breast support edge-to-edge distance ≤ 5 mm

Automatic Exposure
Automatic Optimization of Parameters (AOP)

Fully automatic mode

- AOP is an automatic exposure system that selects all exposure parameters based on radiological density of the breast:

o track (Mo or Rh)
o filter (Mo or Ag)
o kV
o mAs

The system identifies the densest part of the breast to select the appropriate exposure parameters
- Three AOP modes are available:

o Standard + ": dose to patient comparable to screen/film Mammography
o "Dose -": priority is given to dose reduction
o "Standard": balances low noise and dose reduction
o Automatic acquisition mode for implants

Manual mode
- Manual selection of all parameters: track, filter, kV and mAs

Collimator
- Filters: Molybdenum: 0.030 mm; Silver: 0.030 mm
- Field of View (FOV) in detector plane, in cm:

for standard contact views: 24 x 29 maximum FOV or 19 x 23 regular FOV, automatic adjustment depending on paddle used, breast support and gantry rotation angle
- Field of View (FOV) selection: automatic and manual

• FOV size: selected automatically based on the paddle or geometric magnification platform used, can be modified manually by using the collimation size switch on the tube head
• FOV location (left, right, center): selected automatically based on the tube arm angle, can be modified manually by using the collimation position switch on the tube head
• Compression and exposure are prevented if the FOV and compression paddle sizes or locations are not consistent
• Light centering device: a light automatically switches on when a preset position is reached, at compression start or at paddle insertion; can be turned on with the collimation switches buttons located on the tube head or on the acquisition console

Compression
Compression modes:
• Motor driven compression up to 20 daN
• Manual compression up to 27 daN
• Dual foot-pedals for column height and compression adjustments
• User defined motorized compression force limit: 4 to 20 daN
• Min force for AOP: 3 daN
• Compression speed: 3 speed levels
• Selectable automatic decompression after exposure, to minimize patient time under compression

Positioner
• Isocentric arm with motorized rotation and vertical movement
• Source to image receptor distance: 660 mm
• Floor to image receptor distance: from 65 cm to 150 cm
• Rotation angle: -180/+180 degrees
• Ergonomic hand-rest: one at each side of the tube arm and two additional behind

User interface
• Four sets of single speed switches for rotation, angulation and lift movements, with an accelerating speed profile
• Four sets of preset position switches for positioning in CC and MLO
• Automatic stop at +/- 90 degrees for lateral positions
• Collimation buttons on the tube head for field of view size and location
• Parameters display
o Tube arm support rotation angle
o Compressed breast thickness (in mm)
o Compression force (in daN)
• Ergonomic control console
o Controls exposure
o Provides information on system status
o Gives access to advanced parameters for system set-up
• Patented automatic view names marking based on breast laterality
• View name can be edited while the exam is performed

Acquisition workstation
• Time to display processed image (average): 10 seconds
• Time between exposures (typical): 12 seconds
• Dose calculated and displayed on the image after every exposure (Entrance Skin Dose and Average Glandular Dose)
• Quad core Intel i5 workstation:
– Memory: 32GB
– Hard disk: 1 internal 250GB disk for the system
– Hard disk: 1TB for image storage
– Ports: 4 Gigabit Ethernet port
– DVI Display and port connector
– 3MP monitor display:
High performance color IPS 3MP monitor
54cm (21.2")
2048 x 1536 pixels (landscape)
Brightness: 1000 Cd/m2
Contrast ratio: 1400:1

Viewing angle: 170 degrees
Mounted on a rotating arm for in-room access

Image Presentation

eContrast allows you to choose among 6 levels to better adapt to breast morphology and radiologist display preferences:
– eContrast 1 provides a "film-like" aspect with improved visibility of the skin line
– eContrast 2 to 4 provide increasing steps of image sharpness and contrast
– eContrast 5 provides a high level of sharpness and contrast, with a very high level of tissue penetration
– eContrast 6 is adapted to very dense breast or implants
– Automatic windowing (window level and window width)
– Other features: zoom, roaming, inversion, flip, rotation of images, window width and level setting, annotations and measurements

Connectivity

DICOM** 3.0 platform:
– Modality Worklist User
– Storage Provider
– Storage Commitment User
– Query/Retrieve User
– Basic Grayscale Print User
– Verification Provider
– DICOM-compliant CD, DVD-R/-RW and USB Data Interchange
Connectivity features: customizable Autopush to multiple DICOM databases, Autoprint, Autodelete based on Storage Commitment
Modality Perform Procedure Step User
Connectivity to GE Service for remote diagnostic capability
IHE Profiles: Scheduled workflow, Mammography image, Tomosynthesis profile, Portable data for imaging, Consistent time integration

Quality assurance
• Complete quality control program
• Automation of quality control tests: Flat Field, MTF, AOP, SNR
• Test history and results can be reviewed
• Data can be exported for data tracking
• Automated Repeat and Reject Analysis

Radiation shield
• Choice between two radiation shields:
o Integrated to the control console
o Standalone

High voltage generator
• Generator Integrated into the gantry for room saving
• Generator type: high frequency single-phase power supply
• Ripple: < 4% from peak to peak
• Power: 5 kW max
• Generator max rating:
• 2 to 600 mAs (depending on track, filter and kV)
• 22 to 49 kV, in 1 kV steps depending on track
Generator protection: software monitoring tube load

Standard configuration
• Motorized isocentric gantry
• X-ray tube with rotating Mo/Rh anode
• 24 x 29 cm flat panel detector
• Software M3-3 UP2

• Acquisition workstation
– CD, DVD-R/-RW
– 1MP or 3MP display
– Control console
– UPS
• Pair of dual foot-pedals
• Standard Face shield
• 24 x 29 cm bucky with grid
• 24 x 29 cm paddle
• Quality control toolkit
• User manual and technical documentation

Options

• Additional 24 x 29 cm paddle
• 24 x 29 cm Flexible compression paddle
• 19 x 23 cm Flexible & sliding compression paddle
• 10x23 Sliding Implant/Small breast compression paddle
• Square spot sliding compression paddle
• Round spot sliding paddle
• 2D Localization 19x23 Swiss Cheese sliding compression paddle
• 2D Localization 19x23 sliding standard compression paddle
• 2D crosshair device
• X-Ray protective shield
• Bar code reader
• Printers compatibility: AGFA DRYSTAR AXYS
• Upgradable to Senographe Pristina 3D

System Power supply
• Input frequency: 50Hz/60Hz
• Input voltage: single-phase 200-240 V~
• EATON UPS 5P650 650VA

System Weight
• Gantry: 420 kg
• Control Station without monitors: 160 kg

Environmental conditions
• Temperature range: 15° to 30°C
• Humidity range: 10% to 80%
• Atmospheric pressure range: 70 kPa to 106kPa
(0 to 3000m altitude)

Line	Qty.	Catalog	
4	1.00	S30371BA	**Senographe Pristina Control Station Front Cover**

Senographe Pristina Control Station Front Cover

Line	Qty.	Catalog	
5	1.00	S30371BW	**Barco 3MP Monitor 21" Color LCD**

Barco 3MP Monitor 21" Color LCD

Line	Qty.	Catalog	
6	1.00	S30371CA	English Keyboard

English Keyboard

Line	Qty.	Catalog	
7	1.00	S30331BR	Standard Radiation Shield

Additional Stand-alone Radiation Shield (MAVIG) This radiation screen is a stand-alone shield validated for fixed configurations only.

Line	Qty.	Catalog	
8	1.00	S30311CW	Radiation Screen Extension

Additional Extension Radiation Protective Shield

Extension shield that widens the X-ray protective shield. This is an extension for the lead protection screen and can be fitted either right or left side. The radiation shield extension kit requires the standard radiation shield.

Line	Qty.	Catalog	
9	1.00	S30321MS	Bar Code Reader for Aquisition Workstation

Bar Code Reader for mammography AWS This is a bar code reader for the acquisition workstation.

Line	Qty.	Catalog	
10	1.00	S30371BP	Mag Stand 1.8

Mag Stand 1.8

Line	Qty.	Catalog	
11	1.00	S30371BN	Mag Stand 1.5

Mag Stand 1.5

Line	Qty.	Catalog	
12	1.00	S30371BC	2D Crosshair

2D Crosshair

Line	Qty.	Catalog

13	**1.00**	**S30371FB**	**19X23CM SLIDING COMPRESSION PADDLE**

19X23CM SLIDING COMPRESSION PADDLE

Line	Qty.	Catalog	
14	**1.00**	**S30371FC**	**24X29cm Flexible Compression Paddle**

The optional flexible and ergonomic 24x29.8cm sliding paddle provides tilting and flexibility for compression uniformity from chest wall to nipple. It is designed for easier positioning especially in the MLO position for large pectoral muscles and in the CC position when the chest wall and nipple-side show large thickness variation. Patient comfort is improved by requiring less compression on the pectoral muscle or chest wall to achieve proper compression on the whole breast.

Line	Qty.	Catalog	
15	**1.00**	**S30371FD**	**19X23CM Flexible Sliding Paddle**

19X23CM Flexible Sliding Paddle

Line	Qty.	Catalog	
16	**1.00**	**S30371FE**	**Round Spot Compression Paddle**

Round Spot Compression Paddle

Line	Qty.	Catalog	
17	**1.00**	**S30371FF**	**Sliding Square Spot Compression Paddle**

Sliding Square Spot Compression Paddle

Line	Qty.	Catalog	
18	**1.00**	**S30371FJ**	**10X23 Sliding Small Breast Paddle**

10X23 Sliding Small Breast Paddle

Line	Qty.	Catalog	
19	**1.00**	**S30371HK**	**Senographe Pristina 3D**

Senographe Pristina 3D Senographe Pristina 3D

Line	Qty.	Catalog	
20	**1.00**	**S30371HF**	**Senographe Pristina 3D Standard Plus**

For competitive sites looking for a different image look.

Senographe Pristina 3D Standard Plus

For competitive sites looking for a different image look. Senographe Pristina 3D Standard Plus

For competitive sites looking for a different image look.

Line	Qty.	Catalog	
21	1.00	S30371BJ	**Senographe Pristina 3D - Clinical and Non-Clinical Information**

Senographe Pristina 3D - Clinical and Non-Clinical Information

Line	Qty.	Catalog	
22	1.00	S30331VP	**USA ICAD Powerlook AMP**

USA PowerLook AMP iCAD 7.2

PowerLook Advanced Mammography Platform (AMP) is iCAD digital mammography CAD platform offering radiologists the flexibility to choose the products and functions that best fit their reading environment. A wide range of tools for disease detection and analysis provide users with workflow enhancements that improve overall efficiency.

Multi-vendor CAD server allows for easy practice expansion. PowerLook AMP includes a multi-vendor CAD server that provides consistency across all digital mammography systems. PowerLook AMP allows hospitals and imaging facilities to:

- Process cases using a single server
- Connect up to 4 connections from any combination of supported mammography acquisition devices
- Eliminate the need to purchase a separate server for each digital mammography system
- Reduce hardware and service costs

In the U.S., supported vendors are GE, Siemens, Fujifilm Im, or Hologic (Selenia). Outside of the U.S., additional vendors are available, including Philips Microdose, IMS Giotto, Philips CR and DR, Planmed, and Agfa.

PowerLook promoted by GE is offering CAD 7.2 CAD 7.2 algorithms analyze mammography images using methodologies that are complementary to the radiologist. Potential cancers are identified using patented artificial intelligence and pattern recognition technology to analyze images and identify patterns. Sophisticated mathematical analysis identifies and marks suspicious areas without obscuring the underlying image, enabling fast and accurate reading.

Clinical Performance:
- Detects up to 72% of actionable missed cancers in an average of 15 months earlier than screening mammography alone*
- 90-96% sensitivity with 2.0 or 2.9 false positives per 4-view study * Brem RF, Baum J, Lechner, M Kaplan, S Souders, S Naul L. Gill, Hoffmeister, J. Improvement in Sensitivity of Screening Mammography with Computer-Aided Detection: A Multi-institutional Study. AJR 2003; 181: 687-693

CAD markers:
- CAD marks highlight suspicious lesions with out obscuring underlying structures
- Marks densities with ellipses and microcalcifications with rectangles that surround the region of interest

Seamless DICOM integration enhances clinical workflow. PowerLook Digital platform provides powerful and flexible DICOM connectivity

solutions - for optimal digital workflow and enabling seamless integration with acquisition systems, review workstations, and PACS from leading vendors. Flexible integration options enable CAD results to be viewed on workstations or sent to a printer.
- Analyses unlimited views per studies
- Processes CAD on up to 30 four-views studies per hour
- CAD server supports up to four FFDM system

Flexible DICOM Connectivity
- Supports multiple DICOM outputs including:
- Mammography CAD Structured Reporting
- DICOM 6000 Overlay
- Secondary Image Capture
- RTSS
- Grayscale Presentation State
- Encapsulated PDF

- Sends CAD results to multiple destinations in different formats simultaneously
- Automatic send/receive or manual push of CAD results
- 10/100/1000 Base T Ethernet connectivity
- Remotely accessible

CAD server Processor: Intel i3 Chassis: Desktop with pedestal to convert to tower configuration Hard Drive: 250 GB Network Adaptor: Up to 1000 base T Operating System: Windows 7 Embedded 64 bit

Line	Qty.	Catalog	
23	**1.00**	**S30351TN**	**SenoIris CONNECT with PC**

SenoIris CONNECT software is a tool for fast transmission of medical image data. It connects DICOM enabled devices in different locations over a given - preferably secure - connection. SenoIris CONNECT enables fast teleradiology transparent to connected DICOM devices leveraging JPEG2000 image compression. SenoIris CONNECT also manages centrally the review workflow of multi-workstation installation. Interfaces with information systems must be clarified and quoted with a IDI Sales Specialist. SenoIris CONNECT comes on HPZ2G4 PC with 1TB SSD, and an English keyboard.

Line	Qty.	Catalog	
24	**1.00**	**S30351AR**	**Power Cord Kit 1 Set**

One set of power cords for UK/USA/JAPAN/CHINA

Line	Qty.	Catalog	
25	**1.00**	**E6322DJ**	**ACR Breast Phantom - RMI 156**

Mammography Breast Phantom - ACR Gammex 156

The Mammographic Accreditation Phantom is designed to test the performance of a mammographic system by a quantitative evaluation of the system's ability to image small structures similar to those found clinically.

Objects within the phantom simulate calcifications, fibrous calcifications in ducts, and tumor masses.
The phantom is also designed to determine if a mammographic system can detect small structures that are important in the early detection of breast cancer.

Test objects within the phantom range in size from those that should be visible on any system, to objects that will be difficult to see

even on the best mammographic system.

Breast phantom is compatible with analog and digital equipments.

Approved by ACR for Mammography.

SPECIFICATIONS
- Height: 1.75 in. (4.5 cm)
- Width: 4 in. (10.2 cm)
- Depth: 4.25 in. (10.8 cm)

Line	Qty.	Catalog	
26	1.00	E6315TA	**Pristina Accessories Storage Cabinet**

Cabinet to hold additional paddles and other mammography accessories

Line	Qty.	Catalog	
27	1.00	W0301MM	**TIP MM System Training Program**

This TIP MM System Training Program ("MM System Training Program") is designed for customers purchasing a GEHC Mammography System. GEHC will work with the designated Customer contact to agree upon a reasonable training schedule for a pre-defined group of core technologists (generally up to 5 technologists) that will leverage blended content delivery and may include a combination of onsite days and virtual offerings, to include the GEHC Answerline, and available on-demand courses ("Virtual Inclusions"). This blended curriculum with multiple delivery platforms promotes learner retention and allows for efficient and effective skill development.

This MM System Training Program may contain:

- Onsite training, the length of which is as agreed to between GEHC and Customer, but generally not to exceed 6 days, which days are defined as an 8-hour day Monday through Friday and shall be provided in a manner that does not require GEHC personnel to make more than 2 visits to Customer's facility. Onsite training will be at a mutually agreeable time set by Customer and the applications team within the 6-month time frame. Onsite training must be completed within 6 months from Acceptance. Following 6 months from Acceptance, additional onsite days may be available for purchase separately.

- Virtual Inclusions may include: (Unlimited for 6 months from Acceptance)
- Remote instructor-led training: Instructor leads a remote training session one-on-one or in a group, typically for 1 hour
- Answerline Support: Access to GEHC experts for clinical, non-emergency applications assistance via phone or by using the iLinq button on the imaging console
- On Demand courses: Provided through GE Healthcare's learning system website. Self-paced courses and webinars (CE and non-CE).

All GEHC Training terms and conditions apply. Given the unique nature of the MMS System Training Program, if this Program is purchased under a Governing Agreement, including any Master Purchase Agreement, Group Purchasing Organization Agreement, or Strategic Alliance Agreement, the terms of the MM System Training Program shall take precedence over any conflicting training deliverables set forth therein.

Total Quote Net Selling Price:	***$354,976.23***
Logistics Surcharge: %	***1.75%***
Logistics Surcharge Amount:	***$6,212.08***

Total Amount with Logistics Surcharge: ***$361,188.31***

Optional Items

Please initial the Catalogs you wish to purchase

Catalog Number	Qty.	Description	Net Price	Initial
S30371GA	**1.00**	**Pristina Dueta**	**$35,490.00**	____

The Pristina Dueta feature is an option that enables the patient to take an active part in the examination. It consists of a remote control to be held in the patient's hand. Once the technologist has carefully positioned and stabilized the breast with initial compression, the patient is invited to continue the compression movement using a dedicated remote control, under the technologist's continuous supervision. The technologist will follow the same compression guidelines regardless of whether this operation is performed by the technologist or by the patient. The technologist always has control of the compression for each patient, and will guide the patient to achieve the appropriate compression level needed. In case of emergency, the technologist can use any gantry motion user interface to stop the patient-assisted compression motion, as well as push an emergency stop button.

Catalog Number	Qty.	Description	Net Price	Initial
S30371FH	**1.00**	**2D LOCALIZATION 19X23 COMPRESSION PADDLE**	**$2,491.13**	____

2D LOCALIZATION 19X23 COMPRESSION PADDLE

Catalog Number	Qty.	Description	Net Price	Initial
S30371FG	**1.00**	**2D localization (swiss cheese) paddle**	**$3,708.25**	____

2D localization (swiss cheese) paddle

Catalog Number	Qty.	Description	Net Price	Initial
S30371JB	**1.00**	**SenoBright HD**	**$70,980.00**	____

SenoBright HD -
CESM SW License
CESM OM extract in all required languages
CESM User publication CD
CESM Clinical/ Non Clinical information manual
CESM Service Publication CD in English

GE Healthcare

August 28, 2020
Quote Number: **2005227763.3**
Customer ID: **U-6K9GBU**
Agreement Expiration Date: 11/26/2020

GPO Agreement Reference Information

Customer:	Vidant Medical Group LLC dba Vidant Healthplex Wilson
Contract Number:	Premier
Billing Terms:	80% on Delivery / 20% on Acceptance
Payment Terms:	NET 45 DAYS
Shipping Terms	FOB DESTINATION

Offer subject to the Terms and Conditions of the applicable Group Purchasing Agreements currently in effect between GE Healthcare and Premier

Please consult the following to access the applicable Agreements and Contract Summaries for the following Group Purchasing Organizations:

This product offering is made per the terms and conditions of Premier /GE Healthcare GPO Agreements as follows:

Imaging: Bone Densitometry:PP-IM-263, Cardiovascular Imaging:PP-IM-264, CT:PP-IM-265, General Radiography:PP-IM-266, Mammography:PP-IM-267, Molecular Imaging (Nuc/Pet):PP-IM-269, MRI:PP-IM-270, (Invasive Cardiology:PP-CA-320.

Ultrasound: PP-IM-271

Premier: Access the login page at https://premierconnect.premierinc.com. If a copy of the contract is not available, please consult your GPO Client Manager.

APPENDIX D: Certified Cost Estimate

New Mammography Unit for the Wilson Healthplex

Projected Capital Cost Sheet

Building Purchase Price	
Purchase Price of Land	
Closing Costs	
Site Preparation	
Construction/Renovation Contract(s)	$167,000
Landscaping	
Architect / Engineering Fees	$15,165
Medical Equipment	$473,859
Non Medical Equipment	
Furniture	
Consultant Fees (specify)	
Financing Costs	
Interest during Construction	
Other (Info Sys. & Security)	$15,000
Total Capital Cost	**$671,024**

CERTIFICATION BY A LICENSED ARCHITECT OR ENGINEER

I certify that, to the best of my knowledge, the projected capital cost for the proposed project is complete and correct.

[signature], N.C. Lic. # 5977
Signature of Licensed Architect or Engineer

Date Signed: 12-15-20

CERTIFICATION BY AN OFFICER OR AGENT FOR THE PROPONENT

I certify that, to the best of my knowledge, the projected total capital cost for the proposed project is complete and correct and that it is our intent to carry out the proposed project as described.

[signature]
Signature of Officer/Agent

Date Signed: 12-15-20

Vice President, Vidant Health Facilities & Properties
Title of Officer/Agent

APPENDIX E: Diagnostic Center CON Documentation

NC DEPARTMENT OF
HEALTH AND HUMAN SERVICES

ROY COOPER • Governor
MANDY COHEN, MD, MPH • Secretary
MARK PAYNE • Director, Division of Health Service Regulation

November 6, 2018

Jeffrey Shovelin
P.O. Box 6028
Greenville, NC 27835

Transmittal of Certificate of Need

Project ID #:	L-11498-18
Facility:	The Vidant Healthplex - Wilson
Project Description:	Develop a new diagnostic center
County:	Wilson
FID #:	180206

Dear Mr. Shovelin:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) is happy to transmit your certificate of need for the above referenced project. This office will notify the appropriate Sections that the certificate of need has been issued. However, please note that it is the responsibility of the holder of the certificate of need to contact these Sections concerning the next steps to follow in the development of the approved project.

Please be aware that pursuant to N.C. Gen. Stat. §131E-181(b), you are required to materially comply with the representations made in your application for a certificate of need, or with any conditions the Agency placed on the certificate of need. **If you subsequently propose to develop the project on a site different from that named on this certificate, you must first seek and obtain approval from the Agency.** If you operate a service which materially differs from the representations made in your application for a certificate of need, or with any conditions the Agency placed on the certificate of need, including any increase in per diem reimbursement rates/charges, the Agency may bring remedial action against the holder of the certificate of need pursuant to N.C. Gen. Stat. §131E-189 and 131E-190.

The holder of a certificate of need is obligated to submit progress reports to this office as required by 10A NCAC 14C .0209. The applicant shall notify this office of any variations from the schedule or the projected capital cost of the project. During the development of the project, this office may request any additional information pertinent to the project, including additional progress reports, to determine:

1) If the timetable specified on the certificate is being met;
2) If the amount of the capital expenditure for the development of the project is expected to exceed the maximum amount under the certificate;

3) If the terms and conditions of the approval are being met; and
4) If the project is progressing as proposed in the application.

The first progress report on this project is due March 1, 2019. Forms for the submittal of these reports are enclosed. Failure to submit any scheduled or requested progress report in a timely manner may result in the Agency withdrawing the certificate pursuant to N.C. Gen. Stat. §131E-189. If after reviewing the status of the project, the Agency determines that the holder of the certificate is not meeting the timetable and is not making a good faith effort to meet it, the Agency may withdraw the certificate in accordance with N.C. Gen. Stat. §131E-189.

Moreover, please be advised that this Agency may assess a civil penalty not to exceed $20,000 against any person who violates the terms of a certificate of need which has been issued each time the service provided is in violation of this provision (N.C. Gen. Stat. §131E-190(f)). If for some reason, the holder of a certificate of need determines it necessary to request an increase in a per diem charge or reimbursement rate over that which was stated in the application for the certificate of need, then the holder must first contact the Agency to obtain proper instructions for initiating such a request. The request for the increase will be considered by the Agency pursuant to N.C. Gen. Stat. §131E-181(b).

Please keep us informed of the progress in the development of this project. Please refer to the Project ID # and Facility ID # (FID) in all correspondence.

Sincerely,

Michael J. McKillip
Project Analyst

Martha J. Frisone
Chief, Healthcare Planning and
Certificate of Need Section

Enclosures

cc: Melinda Boyette, Administrative Assistant, Healthcare Planning, DHSR

STATE OF NORTH CAROLINA

Department of Health and Human Services
Division of Health Service Regulation

CERTIFICATE OF NEED

for

Project ID #: L-11498-18
FID #: 180206

ISSUED TO: Vidant Medical Group, LLC

Pursuant to N.C. Gen. Stat. § 131E-177(6), 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 described below. The certificate holder shall develop the project in a manner consistent with the representations in the application and with the conditions contained herein and shall make good faith efforts to meet the timetable contained herein, as documented by the periodic progress reports required by 10A NCAC 14C .0209. 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 section.

SCOPE: Develop a new diagnostic center/ Wilson County

CONDITIONS: See Reverse Side

PHYSICAL LOCATION: The Vidant Healthplex-Wilson
3724 Raleigh Road Parkway West
Wilson, NC 27896

MAXIMUM CAPITAL EXPENDITURE: $917,801

TIMETABLE: See Reverse Side

FIRST PROGRESS REPORT DUE: March 1, 2019

This certificate is effective as of the 30th Day of October, 2018.

Martha J. Frisone

Martha J. Frisone, Chief

CONDITIONS:

1. **Vidant Medical Group, LLC shall materially comply with all representations made in the certificate of need application.**

2. **Vidant Medical Group, LLC shall develop a new diagnostic center at The Vidant Healthplex-Wilson in a medical office building being constructed at 3724 Raleigh Road Parkway West in Wilson.**

3. **Vidant Medical Group, LLC, as part of this project, shall not acquire any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**

4. **No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, Vidant Medical Group, LLC shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**

   a. **Payor mix for the services authorized in this certificate of need.**
   b. **Utilization of the services authorized in this certificate of need.**
   c. **Revenues and operating costs for the services authorized in this certificate of need.**
   d. **Average gross revenue per unit of service.**
   e. **Average net revenue per unit of service.**
   f. **Average operating cost per unit of service.**

5. **Vidant Medical Group, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to insurance of the certificate of need.**

A letter acknowledging acceptance of and agreeing to comply with all conditions stated in the conditional approval letter was received by the Agency on October 12, 2018.

TIMETABLE:

1. Equipment Installed _____ **January 15, 2019**
2. Services Offered _____ **February 1, 2019**
3. Final Annual Report Due _____ **May 1, 2022**