



NC DEPARTMENT OF  
**HEALTH AND  
HUMAN SERVICES**

ROY COOPER • Governor

MANDY COHEN, MD, MPH • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

September 7, 2018

Denise Gunter  
380 Knollwood Street  
Suite 530  
Winston-Salem, NC 27103

**No Review**

**Record #:** 2697  
**Facility Name:** Novant Health Imaging-The Breast Center at Langtree  
**Business Name:** Novant Health, Inc.  
**Business #:** 1341  
**Project Description:** Acquire one 3D Mammography Unit  
**County:** Iredell

Dear Ms. Gunter:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your letter of June 27, 2018 and your email of September 5, 2018 regarding the above referenced proposal. Based on the CON law **in effect on the date of this response to your request**, the proposal described in your correspondence is not governed by, and therefore, does not currently require a certificate of need. However, please note that if the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective.

However, you need to contact the Agency's Construction Section to determine if they have any requirements for development of the proposed project.

It should be noted that this determination is binding only for the facts represented in your correspondence. Consequently, if changes are made in the project or in the facts provided in your correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by this office. Changes in a project include, but are not limited to: (1) increases in the capital cost; (2) acquisition of medical equipment not included in the original cost estimate; (3) modifications in the design of the project; (4) change in location; and (5) any increase in the number of square feet to be constructed.

Please contact this office if you have any questions. Also, in all future correspondence you should reference the Facility ID # (FID) if the facility is licensed.

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION

HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

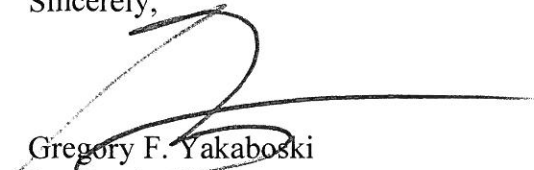
LOCATION: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603

MAILING ADDRESS: 2701 Mail Service Center, Raleigh, NC 27699-2701

www.ncdhhs.gov/dhstr/ • TEL: 919-855-3750 • FAX: 919-733-2757

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

Sincerely,



Gregory F. Yakaboski  
Project Analyst



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

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

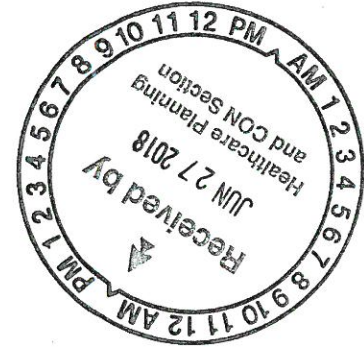
Denise M. Gunter  
T 336.774.3322 F 336.774.3372  
denise.gunter@nelsonmullins.com

380 Knollwood Street | Suite 530  
Winston-Salem, NC 27103  
T 336.774.3300 F 336.774.3299  
nelsonmullins.com

June 27, 2018

**Hand Delivered**

Martha J. Frisone, Chief  
North Carolina Department of Health and Human Services  
Division of Health Service Regulation  
Healthcare Planning and Certificate of Need Section  
809 Ruggles Drive  
Raleigh, North Carolina 27603



Re: Letter of No Review  
Novant Health Imaging – The Breast Center at Langtree  
Iredell County  
Health Service Area III

Dear Ms. Frisone:

Pursuant to N.C. Gen. Stat. §§ 131E-176(7a), (9b), (16)a. and 178(a), this letter requests a determination of non-reviewability under the CON Law.

Novant Health Imaging – The Breast Center at Langtree (“NHI-Langtree”) proposes to establish a breast imaging center located at 106 Langtree Village Drive, Suite 200, Mooresville, North Carolina (the “Project”). NHI-Langtree proposes to acquire one 3D mammography unit and install it in space leased from a third party developer. The space will be renovated to accommodate the mammography unit. The total capital cost, including the acquisition of the mammography unit, all construction and all electrical work needed to make the equipment operational, and the contingency, is \$430,507. A certified capital cost form is attached as **Exhibit A**, and the supporting documentation for the capital cost form is attached as **Exhibits A-1, A-2, and A-3**. A floor plan is attached as **Exhibit B**. NHI-Langtree does not propose to acquire any other imaging equipment.

N.C. Gen. Stat. § 131E-176(16)a. defines “new institutional health services” to include “[t]he construction, development, or other establishment of a new “health service facility.” A “diagnostic center” is a type of “health service facility.” See N.C. Gen. Stat. §§ 131E-176(7a) & (9b). A “diagnostic center” is defined as:

Martha J. Frisone  
June 27, 2018  
Page 2

. . . [A] freestanding facility, program, or provider, including but not limited to, physicians' offices, clinical laboratories, radiology centers, and mobile diagnostic programs, in which the total cost of all the medical diagnostic equipment utilized by the facility which cost ten thousand dollars (\$10,000) or more exceeds five hundred thousand dollars (\$500,000). In determining whether the medical diagnostic equipment in a diagnostic center costs more than five hundred thousand dollars (\$500,000), the costs of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the 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.

N.C. Gen. Stat. § 131E-176(7a).

Since the total capital cost of the Project is less than \$500,000, the Project is not a "diagnostic center" and therefore not regulated by the CON Law.

Please confirm that the Project is not regulated by the CON Law. If you have any questions, please let me know.

Thank you for your time and consideration.

Sincerely,



Denise M. Gunter

Enclosures


PROPOSED CAPITAL COSTS

Project Name: Novant Health Imaging: The Breast Center at Langtree

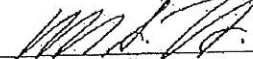
Proponent: Novant Health Imaging

A. <u>Site Costs</u>		
(1)	Full purchase price of land.....	\$ _____
(2)	Acres _____ Price per Acre \$ _____	\$ _____
(3)	Closing costs.....	\$ _____
(4)	Site Inspection and Survey.....	\$ _____
(5)	Legal fees and subsoil investigation.....	\$ _____
	<u>Site Preparation Costs</u>	
	Soil Borings.....	\$ _____
	Clearing-Earthwork.....	\$ _____
	Fine Grade For Slab.....	\$ _____
	Roads-Paving.....	\$ _____
	Concrete Sidewalks.....	\$ _____
	Water and Sewer.....	\$ _____
	Footing Excavation.....	\$ _____
	Footing Backfill.....	\$ _____
	Termite Treatment.....	\$ _____
	Other (Specify).....	\$ _____
	Sub-Total Site Preparation Costs.....	\$ _____
(6)	Other (Specify).....	\$ N/A
(7)	Sub-Total Site Costs.....	\$ N/A
(8)	<u>Construction Contract</u>	
(9)	<u>Cost of Materials</u>	
	General Requirements	
	Concrete/Masonry	
	Woods/Doors & Windows/Finishes	
	Thermal & Moisture Protection	
	Equipment/Specialty Items	
	Mechanical/Electrical	
	Other (Specify).....	\$ _____
	Sub-Total Cost of Materials.....	\$ _____
(10)	Cost of Labor.....	\$ N/A
(11)	Other (Specify).....	\$ _____
(12)	Sub-Total Construction Contract.....	\$ 38,597.68
B. <u>Miscellaneous Project Costs</u>		
(13)	Building Purchase.....	\$ _____
(14)	Fixed Equipment Purchase/Lease (MRI, Injector).....	\$ 378,050
(15)	Movable Equipment Purchase/Lease.....	\$ _____
(16)	Furniture.....	\$ _____
(17)	Landscaping.....	\$ _____
(18)	<u>Consultant Fees</u>	
	Architect and Engineering Fees.....	\$ 10,000
	Legal Fees.....	\$ _____
	Market Analysis.....	\$ _____
	Other (Specify).....	\$ _____
	Sub-Total Consultant Fees (All Inclusive).....	\$ 10,000
(19)	Financing Costs (e.g. Bond, Loan, etc.).....	\$ _____
(20)	Interest During Construction.....	\$ _____
(1)	Other (Contingency for Unforeseen Construction/ Shielding/ Professional Fees).....	\$ 3,859.77 (10%)
(21)	Sub-Total Miscellaneous.....	\$ _____
(22)	Total Capital Cost of Project (Sum A-C above).....	\$ 430,507.35

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

  
 (Signature of Licensed Architect or Engineer)

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

  
 (Proponent - signature of officer)

President & COO  
 (Title of officer)

**Ec,a**  
Architecture, PC



June 14, 2018

Novant Health  
3480 Preston Ridge Road, Suite 600  
Alpharetta, GA 30022  
Ms. Heidi Kirk, Project Manager

Re: Architectural and Engineering Fees for A& E Design Services  
Langtree Mammography Center, Mooresville, NC  
Ec,a Architect's Project Number 15418- LT Mammo

Dear Ms. Kirk:

Thank you for the opportunity to provide this proposal for architectural & engineering services for a 3D mammo room at the new Langtree Mammography Center in Mooresville, NC. The area of the work has been determined and ready to proceed into design documents. The scope of work is outlined by a sketch. The A&E services are outlined below. The architect and an engineer will field survey the building space prior to drawing. The architect and an engineer will assist the contractor over the phone during construction. We will provide signed and sealed plans for permit and respond to reviewer comments from the Building Department and other Regulatory Review Agencies. The drawings will include the following:

- Architectural Drawings – cover sheet w/ Appendix B, overall shield floor plan, floor plans, finish schedules and details, partition details and outline specifications on the drawings.
- Structural Review – We will review the drawings of the slab/structure and overhead structure to evaluate the adequacy of the existing structure for installation / support of medical equipment. No Structural drawings included.
- Engineering – The engineering will include Electrical, Plumbing plans, schedules, details and related notes and outline specifications on the drawings.
- Civil Engineering – not included
- Interior Design – not included

**The Architectural and Engineering fee for this project will be \$10,000.00 plus reimbursable expenses.** We will provide services and required drawings for various phases – DD, CD, B and C as outlined in our Master Agreement. Payment will be made per Master Agreement.

**Reimbursable Expenses** for travel, printing, meals and postage shall be invoiced at actual costs or fed approved guidelines for travel.

**Not Included in Scope of Work** is permit and other related building agencies' fees. Reports from testing agencies or the Physicist Report will be provided by the owner. All certifications and any inspections required will be by others and not included in our services. Any additional site visits will be done on an hourly basis as needed. These services do not include bidding of the project to various contractors. Networking design or engineering is not included. Design and engineering work is not included for any deficiencies in the existing building not defined as part of this scope now. These may include but are not limited to environmental conditions – asbestos, contaminations - building leaks, vibration, seismic, structural or equipment deficiencies or facility upgrades. Any changes in scope will be performed on an hourly basis at \$150.00 per hour.

***Ec,a Architecture, PC***

PO Box 30183 Charlotte, NC 28230 [ecebula@carolina.rr.com](mailto:ecebula@carolina.rr.com) 704.849.6748(tel) 704.906.675 (mob) 800.652.0689 (fax)

**Required Information** includes AutoCAD files or blueprints – as-built drawings of the existing building that includes the Architectural and Engineering areas of work. We will require AutoCAD files of the equipment drawings, which will be provided by owner. The owner will provide a soils report and test and balance reports of mechanical systems. Required information will be expected to be provided in a timely manner.

Please call to discuss this proposal should you have any questions. If the services herein are acceptable, please return a signed copy of this proposal as our contract. The above quoted fee is valid for the 60 days. I look forward to building our relationship and doing business together on this project. Thank you, once again.

Sincerely,



Eric Cebula, AIA

### **Contract Accepted**

Novant Health  
3480 Preston Ridge Road, Suite 600  
Alpharetta, GA 30022

Re: Architectural and Engineering Fees for A& E Design Services  
Langtree Mammography Center, Mooresville, NC  
**Ec,a Architect's Project Number 15418- LT Mammo**

The terms and conditions as set forth in this professional services contract are acceptable.

(Name, signature and date required)

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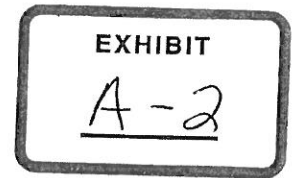
Printed Name

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Signature

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Date



June 22, 2018

Novant Health Imaging Langtree Mammography  
106 Langtree Village Drive  
 Mooresville, NC  
Attn: Chris Murphy

Proposal: Langtree 3D Mammography Room only

We appreciate the opportunity to give you our proposal on the above referenced project. The price for this work based on the below scope of work and E,cA Architect drawing (dependent on receipt of the final equipment and architectural drawings) includes the following:

- Convert Coaching Room 173 to 3D Mammography
  - Demo flooring as required
  - Install electrical as needed per Hologic drawing (once received)
  - Re-work/Repair existing lighting
  - Install new LVT flooring / Base in 3D Mammo and Carpet/Base in hallway
  - Repair drywall as necessary and paint
  - Install Paddle Racks / Equipment mounts

Notes/Exclusions:

- Femco to provide all supervision, tools and equipment. Portions of work to be performed after hours.
- Exclusions: Any additional support space up-fits, BAS system adjustments, Med Gas, Fire Sprinklers/Alarm, IT / Low voltage, leaded drywall, window film, Equipment Rigging or permits.

**Proposal Sum: \$38,597.68**

We appreciate the opportunity. Please let us know if you have any questions or items to discuss.

Respectfully,  
Scott Kittinger

7302 Cessna Drive, Greensboro NC 27409

O: 336.542.1490 [www.femcobuilds.com](http://www.femcobuilds.com)





**Quotation**

PLEASE REFER TO THIS NUMBER ON ALL CORRESPONDENCES AND ORDERS  
 Buying Group: NOVANT - MAMMO & BONE  
 Quote #: Q-57767  
 Status: Draft  
 Quote Expiration Date: 10/31/2018

**TO:**

<b>CUSTOMER NAME</b>	<b>CUSTOMER NUMBER</b>
NOVANT HEALTH INC	82397
<b>BILL TO ADDRESS</b>	<b>SHIP TO ADDRESS</b>
PO BOX 25686 WINSTON SALEM NC US 27114-5686	106 LANGTREE VILLAGE DR STE 200 MOORESVILLE NC US 28117

**TAX INFO:**

Hologic is required by law to collect all state and local taxes on all sales. If an exemption certificate is not provided by customer at time of order, final invoices will include these amounts. Many states require both specific operator qualifications and/or licensing and registration of x-ray devices. Hologic is not responsible for fulfilling customer's regulatory obligations.

We are pleased to offer you the products listed on the condition that this Quotation and Hologic's Sales Terms and Conditions comprise the complete and exclusive statement of the contract between us. This Quotation is based on the information known by Hologic regarding your needs as of the date the Quotation is generated. **This Quotation and the terms and conditions set forth in NOVANT - MAMMO & BONE supersede all other quotations, agreements, understandings, warranties and representations, whether written or oral, between us, and may be accepted only in accord with their terms.** This offer is subject to change or withdrawal by Hologic prior to acceptance. To accept, please sign below within the time period for acceptance. Signed quote and/or purchase order should be forwarded by mail, via e-mail or by fax to:

Breast Health:  
 HOLOGIC, INC.  
 250 Campus Drive  
 Marlborough, MA 01752  
 ATTN: Sales Administration  
 Fax: (203) 731-8463  
 capitalorders@hologic.com

ATTN: Charnaye Bosley Phone: (704) 975-8253 Fax: Email: cbosley@novanthealth.org

Quote Date	Hologic Representative	FOB	Payment Terms	Requested Delivery Date	Quote Currency
6/21/2018	Lynn Smith lynn.smith@hologic.com	DESTINATION PREPAY AND ADD	30 NET	9/21/2018	USD

Qty	Product Name
1	SDM-SYS-6000-3D
1	PRD-01702
1	ASY-08062
1	CMP-01270
1	FAB-12469
1	PRD-04096
1	SVC-INSTALL
1	SDM-SVC-CAD_CVIEW
1	SVC-SDM-OPT-BTO
1	DIM-TRAIN-APPS-INIT
1	SDM-TRAIN-INIT-03
1	SDM-TRAIN-INIT-04



Qty	Product Name
1	MP301-D
1	FAB-14680
1	SDM-LIC-0005
3	ASY-04662
1	R2LIC-2111
1	R2SYS-2200
1	R2-TRAIN-INIT-01
1	ASY-10994
1	ASY-01940
1	BSH-VOLUME-DISCOUNT

**Final Quote Price:** USD 378,050.00

Upgrade	Serial Number
SDM-LIC-0005	
R2LIC-2111	

Digital imaging mammography x ray tubes warranted for 24 months.

Customer agrees to keep the discount price provided to them in this quote or agreement confidential and not disclose it to anyone other than as required by law or court order.

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***Hologic may request new customers and established customers to complete our credit application to create or update current credit files. This requirement will be contingent on order amount and prior history with Hologic.***

The parties acknowledge that they intend for purchases under this Quote to be reported to the identified group purchasing organization ("identified GPO") for payment of administrative fees in accordance with the applicable group purchasing organization contract between the identified GPO and Hologic. This Quote is not entered into, pursuant to, or in connection with any other group purchasing or IDN/System, arrangement of which Customer or Hologic is a party, and is not intended to result in the reporting of sales or the payment of administrative fees to any such organization other than the identified GPO.

The Customer agrees to treat all quoted and sales information as confidential and not to disclose it to any third party other than the identified GPO or as required by law.

In no event will Hologic be obligated to pay administrative fees to a group purchasing organization ("GPO"), integrated delivery network, or other entity other than the identified GPO with respect to any single purchase order by Customer, and whose Equipment and purchase options are not included in the separate GPO agreement between the identified GPO and Hologic.

Customer acknowledges that the pricing guaranteed under this Quote is strictly provided to Customer only because the pricing is based on the Customer's commitment related to quantity and commitment to Hologic products, and in no event shall Hologic be required to offer such pricing to any other customer who is in anyway affiliated with or is a member of the identified GPO.

If purchasing under a buying group with existing terms and conditions, those conditions would supersede Hologic's standard terms and conditions. If a buying group does not have their own terms and conditions, Hologic's would apply.

**Buyer Acceptance**

NOVANT HEALTH INC

By: \_\_\_\_\_ (signature)

Name: \_\_\_\_\_ Title: \_\_\_\_\_ (print/type)

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

**Additional Buyer Acceptance (if applicable)**

By: \_\_\_\_\_ (signature)

Name and Title: \_\_\_\_\_ (print/type)

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

Please provide the Shipping and Billing address here if different from the quote address above  
(If this section is left blank, the product will ship and bill to the addresses printed at the top)

**Shipping Address**

**Billing Address:**

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Hologic Approval:**

\_\_\_\_\_

**Date:**

\_\_\_\_\_

HOLOGIC, INC. 250 CAMPUS DRIVE. MARLBOROUGH MA 01752

Product Name	Long Description
SDM-SYS-6000-3D	<p>Hologic Selenia Dimensions 6000 package for 3D™ screening and diagnostic mammography. Upgradable to interventional or mobile. Includes: •X-Ray Gantry: •Generator: Fully integrated Constant Potential, High Frequency, Inverter Type •X-Ray Tube: Tungsten, Bi-Angular, High Speed, High Heat Capacity •X-Ray Filters: Rhodium, Silver •Anti-Scatter Grid: Auto-retracting linear grid •Adjustable-Height Acquisition Workstation: •Motorized, adjustable-height flat work surface; X-ray exposure footswitch; pull-out keyboard drawer •CPU: Multi-Core Intel-based CPU, 16 GB RAM min., 2 TB disk min., DVD +/- R/W, Win 7/64 •Uninterruptible Power Supply •User Interface Display – 1.2 MP Color LCD Display •Selenia Dimensions Software, including: •User Access Control •Patient and Study Selection •Imaging Procedure Selection and Definition •X-Ray Parameter Control •Image Review and Acceptance/Rejection •Quality Control •Connectivity: •DICOM: Modality Worklist; Storage; Storage Commitment; Query/Retrieve; Print •IHE Profiles: Scheduled Workflow, Patient Information Reconciliation, Mammography Image •Selenia Dimensions Software Licenses, including: •Selenia Dimensions System License •Diagnostic Imaging License •Dynamic Tube Head Motion Licenses •Tomosynthesis Imaging License •Keyboard •Mouse •Genius™ 3D™ Platinum Program: Access to a comprehensive co-operative marketing program focused on business growth through patient and referring physician education on the benefits of the Genius™ 3D Mammography™ exam. Online entry into the program will be provided once order is placed and online initiation form completed at <a href="http://genius3dplatinum.com/invitation">genius3dplatinum.com/invitation</a>. Estimated value included per system: \$5,000.00 Training Requirements (US): •FFDM accreditation is required: apply to the ACR or your State for FFDM certification. •Once FFDM accredited, contact the MSQA FFDM Certification Extension Program for Tomosynthesis at 301-796-5710. •Sites must obtain ACR or State FFDM accreditation before using the Tomosynthesis Modality. Necessary Training (Worldwide): •Hologic strongly recommends that radiologists attend the ICPME (<a href="http://www.icpme.us">www.icpme.us</a>) webinar entitled "State of the Art Mammography: The Role of full Field Digital Imaging, Generated 2D images, and Digital Breast Tomosynthesis" prior to reading C-View. This one-hour, on demand webinar is available 24/7 at no charge. Physicians (US) can earn 1 CME. Existing Hologic C-View customers as well as new users are encouraged to attend this training. SecurView Recommendations: •If using SecurView, please contact your Hologic representative to confirm your SecurView workstations meet the minimum software and hardware requirements to support this Dimensions configuration. Warranty: •Standard One-Year Parts and Labor Warranty; Two-Year Prorated Manufacturer's Warranty on X-Ray Tube Hologic® Platinum Marketplace: Access to a comprehensive co-operative marketing program focused on business growth through patient and referring physician education on the benefits of the digital mammography. Online entry into the program will be provided once order is placed and online initiation form completed at <a href="http://hologicmarketplace.com/user/register">hologicmarketplace.com/user/register</a>. Estimated value included per system: \$5,000.00</p>
PRD-01702	<p>Hologic 3D MAMMOGRAPHY™ Digital Image Receptor for Selenia Dimensions 2D/3D™ imaging systems. Includes: • Digital Image Receptor • Amorphous Selenium, TFT • Structure – Single 24 cm x 29 cm Plate • Image Matrix Sizes – 2560 x 3328 (18 cm x 24 cm); 3328 x 4096 (24 cm x 29 cm) • Pixel Size – 0.070 mm • Limiting Spatial Resolution – 7.1 lp/mm</p>
ASY-08062	<p>Hologic accessory kit for Selenia Dimensions system 6000 package for 3D™ screening and diagnostic mammography. . Includes: • Standard Compression Paddles: • 24 cm x 29 cm Screening Paddle • 18 cm x 24 cm Screening Paddle • Standard Diagnostic Paddles: • 10 cm Contact Paddle • 10 cm Contact Paddle, Magnification • X-Ray Shield and Mounting Kit • Other Accessories: • 7.5 cm Spot Contact Paddle -- for use during Quality Control testing only • Face Shields: Fixed, for 2D Mammography; Sliding, for 3D MAMMOGRAPHY™ • Magnification Platform • Flat-field Block Phantom and Case • Tomosynthesis Geometry Calibration Phantom • Dual-Function Gantry Footswitches (2) • Dimensions Interconnect Cable Kit • Documentation package: • User Manual • Service and Maintenance Manual • Quality Control Manual</p>
CMP-01270	BARCO, 21.3 INCH, 2MP LED MONITOR
FAB-12469	None
PRD-04096	A 17" flat panel color monitor available on the Selenia Dimensions Avia 3000 and 6000 packages (1280X1024 viewing area, 56-76HZ).

Product Name	Long Description
SDM-SVC-CAD_CVIEW	This item indicates a customer request to enable CAD for C-View processing at this facility. For the Hologic products included in the CAD for C-View processing (Selenia Dimensions 3D™ imaging, C-View, Cenova, ImageChecker CAD, Advanced Workflow Manager), those products must conform to the requirements listed below. Requirements: • Selenia Dimensions must be configured with the tomosynthesis option • Selenia Dimensions must be configured with the C-View option • Selenia Dimensions must be running Dimensions software version 1.8.2 or later • Cenova must be running Cenova software version 2.4 or later • Cenova must be running ImageChecker CAD software version 10.0 or later • Advanced Workflow Manager must be running AWM software version 1.8.2 or later Conditions: • Required but independently sold software features are not included gratis under Hologic Warranty, or Hologic Service Contracts that include software upgrades, and must be ordered separately • Required system software updates that are included under Hologic Warranty, or Hologic Service Contracts that include software upgrades, will be provided at no charge
SVC-SDM-OPT-BTO	This configuration enables output of tomosynthesis slices in DICOM Breast Tomosynthesis Image Object form. Use of this configuration will first require an integrated planning team, including your IT department, Hologic and other vendors, to work together to ensure that your enterprise is ready for use of the tomosynthesis data in DICOM Breast Tomosynthesis Image Object form. The completion of critical feasibility questions included in Hologic's Enterprise Survey will guide the team through understanding any infrastructure requirements and changes necessary. Note: While a preliminary check by your Hologic representatives may have allowed the ability to quote this output configuration, completion of the Enterprise Survey is required before Dimensions Tomosynthesis system or option is enabled. Software and hardware upgrades may be required. Hologic makes no guarantees of software and hardware performance for products not associated to Hologic. By signing this quote, the customer agrees that the completion of purchase of the accompanying Hologic products shall not be contingent on the implementation of this no-charge configuration. Requires: - Completion of Hologic Enterprise Survey by site personnel in conjunction with Hologic representatives - PACS system including Deep Archive capable of storing / retrieving DICOM Breast Tomosynthesis Image Objects and with suitable storage capacity - Softcopy review workstation capable of displaying DICOM Breast Tomosynthesis Image Objects
DIM-TRAIN-APPS-INIT	Included in the purchase price of your 3Dimensions™ or Selenia® Dimensions® system(s); Initial applications added value of \$5,100. Technologists: Onsite applications training or other clinical support at one site, maximum of 5 technologists. •Online CEU courses required prior to onsite applications training •Video training available during and post applications training •Onsite portion of purchased applications training or other clinical support must be completed within 24 months of equipment installation. Required FDA training: •FFDM accreditation is required: Apply to the ACR or your State for FFDM certification. •Once FFDM accredited, contact the MQSA FFDM Certification Extension Program for Tomosynthesis at 301-796-5710. •Sites must obtain ACR or State FFDM accreditation before using the tomosynthesis modality Note: Cancellation must be made 6 business days prior to the confirmed and scheduled applications training start date. Fee for cancellation within 6 business days of confirmed training is \$2,000.
SDM-TRAIN-INIT-03	Included in the price are (8) hours of Hologic tomosynthesis educational training for up to (2) physicists. This consists of (3) hours of Online training; (5) hours of QC training with a Hologic Field Engineer. Education must be completed within 12 months of equipment shipment. Visit <a href="http://www.hologic.com/medical-professionals">www.hologic.com/medical-professionals</a> for a list of Hologic educational opportunities. Initial Added Value: \$1,500.00
SDM-TRAIN-INIT-04	Tomo Modality – Radiologist Included in the price of your Selenia® Dimensions® system(s) are 8 hours of Hologic tomosynthesis educational training for up to 7 radiologists. Radiologists can either participate in Essentials of 3DTM Breast Tomosynthesis Interpretation (virtual course) or a live Hologic hosted course when available (Regionals). The virtual course is streamed through the internet on a standard computer with 24/7 access for 30 days. Education must be completed within 12 months of equipment shipment. Excludes travel and expenses. Visit <a href="http://www.hologic.com/training">www.hologic.com/training</a> for a list of Hologic educational opportunities. Initial Added Value: \$5,250.00
MP301-D	Starter supply of 29 x 30 cm MammoPad Breast Cushions.
SDM-LIC-0005	Enables creation of C-View™ generated 2D images on Selenia® Dimensions® systems or 3Dimensions™ systems configured with Hologic standard resolution 3D™ imaging. The C-View software license adds the ability to create low dose tomosynthesis studies in Tomo HD (standard tomo + C-View) and Combo HD (standard tomo + FFDM + C-View) imaging modes. Includes: •C-View Generated 2D Imaging software license

Product Name	Long Description
ASY-04662	Wall-mounted, felt-lined rack for storing system compression paddles. Each rack, sold separately, provides enough storage room for 3-4 compression paddles. Includes: •Paddle storage rack with felt lining •Wall-mounting bracket (installation not included) •Graphic paddle labels Dimensions: •W x H x D: 36 1/4" x 7" x 4" (from the wall) •Minimum Vertical Pitch: 12" to 14" when multiple racks are installed one above another Recommended: •Selenia® Dimension® Avia systems: min. 1 rack •Selenia Dimensions 2D systems: min. 2 racks •Selenia Dimensions 3D™ systems: min. 3 racks •3Dimensions™ systems: min. 3 racks Requirements: •Must be securely attached to the wall •Must be installed by a professional installer
R2LIC-2111	The ImageChecker® Digital computer-aided detection (CAD) and Citra™ advanced CAD display software adds one port license to a Cenova™ image analytics server to process images from a single digital mammography system. Includes: •One ImageChecker CAD software license to support: •Hologic software generated 2D images •Hologic and other manufacturers 2D FFDM systems •Citra advanced CAD display license to provide additional information about why ImageChecker CAD marked specific regions: •RightOn™ CAD marks placed right on the region-of-interest to unambiguously flag the location •Malc™ CAD marks placed where the algorithm sees signs of both density and calcifications •PeerView Digital to show exactly the tissue that caused CAD to mark the region •EmphaSize™ variable size CAD marks differentiate CAD marks that have more prominent features •LesionMetrics™ ancillary CAD information to display additional information about the finding Requirements: •A Cenova server at Cenova software version 2.4.3 or later •Specify serial number, manufacturer and model of FFDM system at time of order •For CAD on C-View generated 2D images, a Dimensions@ tomosynthesis system with software version 1.8.3 or higher •Please refer to SecurView® DX diagnostic workstation description for minimum requirements Notes: •Advanced Citra CAD features require workstations that conform to proper display of those features. They can be disabled for use with other non-conformant workstations. The customer needs to check with their workstation vendor •This item is for use with 2D Images only. •Verify with the technical team that the number of licenses on a server can be adequately supported. •Order additional licenses for each additional FFDM system. •With respect to the future development path of our products, during the warranty period and during the term of any Hologic Service Agreement, Hologic will provide, at no cost to the Customer, any commercially released software update that (i) improves the ability of any Equipment purchased under the Agreement or software purchased as part of the Equipment to function in accordance with its published specifications and (ii) does not require any new hardware or other hardware modifications. Hardware is not part of Hologic service agreements; if Hardware needs to be replaced, there will be an additional charge. This offer is entirely contingent on whether Hologic receives applicable regulatory approval for the software update, and the software update is subsequently commercially released. There are no guarantees that this will be the case, and, therefore, Hologic makes no commitment and assumes no obligation to the contrary.
R2SYS-2200	The Cenova™ digital mammography processing system hosts image analytics software applications. Image analytics licenses are sold separately. Includes: •Cenova processing unit server (6U) •Windows 7 operating system •Dynamic resource management and case control •Output transmission re-try mechanism •Flexible output routing to multiple output destinations •License dongle •Hologic Connect™ remote system diagnostics software for post-installation service and applications support; conforms with Verisign security Requirements: •Specify manufacturer and model of FFDM system at time of order •Verify with the technical team that the number of licenses on a server can be adequately supported. Notes: •This server can be used horizontally and rack-mounted by ordering R2ACC-2001. (R2SYS-2200-1U is a thinner server, ships with a rack mount and is preferred for rack mounting.) •The system is designed to process 2D images only
R2-TRAIN-INIT-01	* One (1) day of Applications Training. Training for up to 10 Rads * Applications must be completed within 24 months of equipment installed. * This training cannot be performed until FFDM certification extension is received for Tomosynthesis. * Please note: Cancellation must be made 6 business days prior to the confirmed and scheduled applications training start date. * Fee for cancellation \$2,000.00 * Initial Application Added Value: \$2,500.00
ASY-10994	Provides all mounting hardware and cabling necessary for mounting a 2MP Color Monitor onto a fixed pole on the Selenia Dimensions system Avia 3000, 6000 and 9000 packages. Monitor sold separately.
ASY-01940	Dimensions 8x24 cm small breast screening paddle.
BSH-VOLUME-DISCOUNT	1) Additional discount applied to customer purchasing multiple modalities (ex. Dimensions and Horizon products) across Hologic portfolio 2) Products being bundled must have line item value on quote 3) If bundled products are NOT on the same quote, the correlating quote or contract number must be referenced in the customer notes

PROPOSED FLOOR PLAN

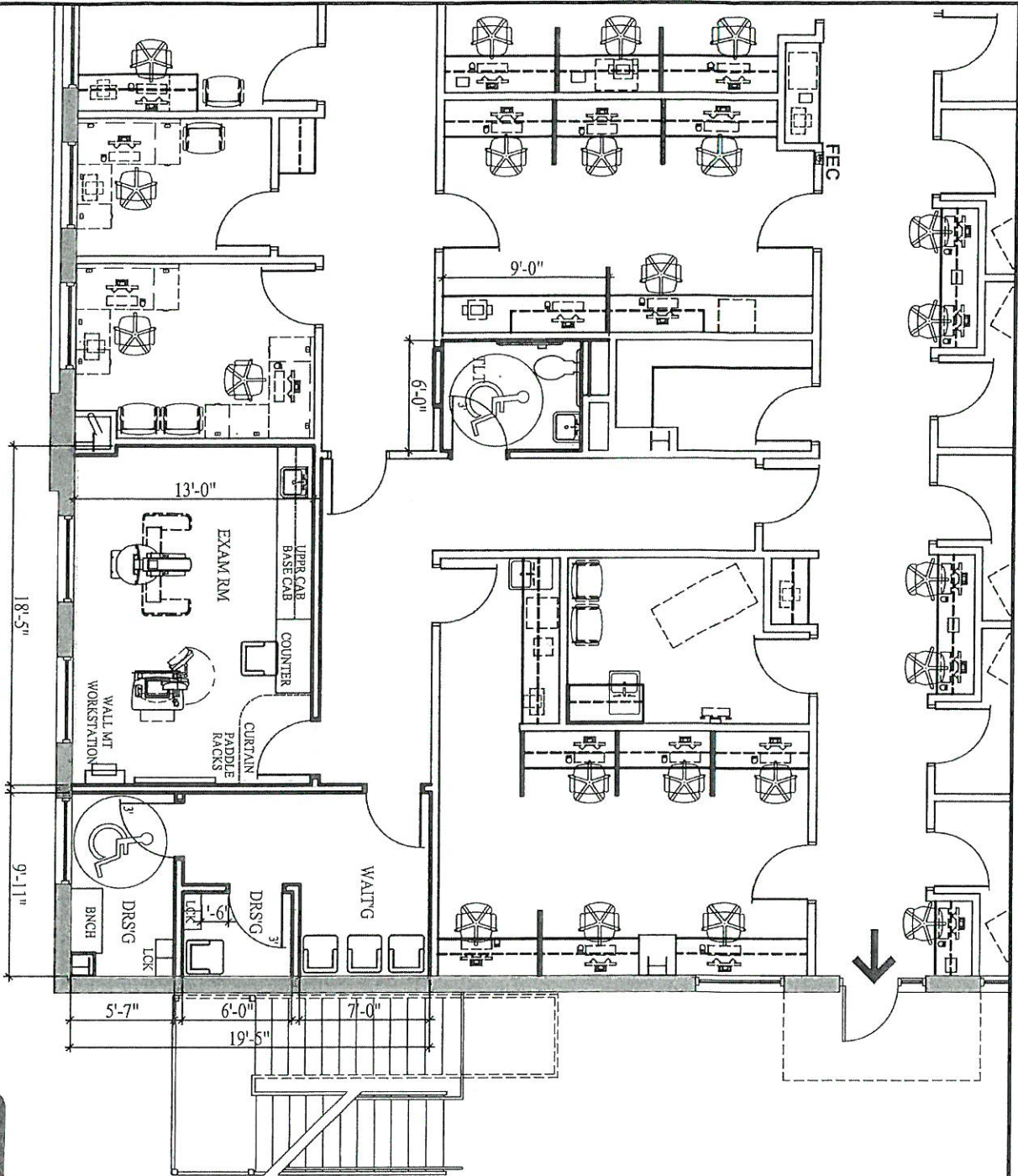


EXHIBIT  
B

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Architecture, PC

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**NOVANT HEALTH**  
**LANGTREE MAMMOGRAPHY**  
106 LANGTREE VILLAGE DR MOORESVILLE, NC  
RENOVATIONS for MAMMO & SUPPORT SPACES

ADDENDUM - REVISION

061418  
SKA 1

DATE - PHASE - ARCH.

## Yakaboski, Greg

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**From:** Denise Gunter <denise.gunter@nelsonmullins.com>  
**Sent:** Tuesday, September 04, 2018 11:02 AM  
**To:** Yakaboski, Greg  
**Subject:** RE: [External] No review letter for Iredell County

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Greg, it's my understanding from previous discussions with Martha about similar types of projects that we are only required to include costs specific to mammography, i.e., what is essential to make that equipment operational. Thus, we have not included costs for other support space.

Please advise if the Agency's position has changed on this. If it's more efficient to talk by phone, my direct line is 336-774-3322.

Thanks.

**From:** Yakaboski, Greg [mailto:greg.yakaboski@dhhs.nc.gov]  
**Sent:** Tuesday, September 4, 2018 10:52 AM  
**To:** Denise Gunter <denise.gunter@nelsonmullins.com>  
**Subject:** RE: [External] No review letter for Iredell County

Good Morning Denise,

Thank you for confirming that the projected capital costs identified in your letter of 6/27 were for the one room. In Exhibit B of the 6/27/18 letter there is a proposed floor plan for Langtree Mammography "for Mammo and support spaces".

Please identify the capital costs for the rest of the proposed suite of rooms outside of the one room where the mammography equipment will be placed.

Thank you,  
Greg

Gregory F. Yakaboski  
Project Analyst  
Division Health Service Regulation, Healthcare Planning and Certificate of Need Section  
North Carolina Department of Health and Human Services

919-855-3873 office  
[Greg.yakaboski@dhhs.nc.gov](mailto:Greg.yakaboski@dhhs.nc.gov)

809 Ruggles Drive  
2704 Mail Service Center  
Raleigh, NC 27699-2704





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**From:** Denise Gunter [<mailto:denise.gunter@nelsonmullins.com>]  
**Sent:** Tuesday, September 04, 2018 10:11 AM  
**To:** Yakaboski, Greg <[greg.yakaboski@dhhs.nc.gov](mailto:greg.yakaboski@dhhs.nc.gov)>  
**Subject:** RE: [External] No review letter for Iredell County

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Hi, Greg,

Below is my response from July 23. Please let me know if you need anything else. Thanks.

Hi, Greg,

I am out of town right now on vacation, but my assistant said you reached out with a question. The costs are for one 3-D mammo room. Please let me know if you have any questions or need anything else.

Thanks.

**From:** Yakaboski, Greg [<mailto:greg.yakaboski@dhhs.nc.gov>]  
**Sent:** Tuesday, September 4, 2018 10:08 AM  
**To:** Denise Gunter <[denise.gunter@nelsonmullins.com](mailto:denise.gunter@nelsonmullins.com)>  
**Subject:** FW: [External] No review letter for Iredell County

Good Morning Denise,

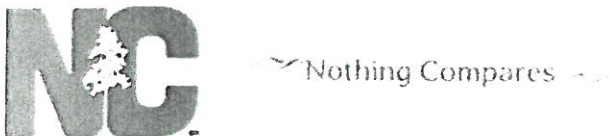
From your email below that Gloria forwarded to me I realize that it is your understanding that your team has already responded to my request for additional information. However, I cannot locate any such response. Would you mind sending me your response again?

Thanks,  
Greg

Gregory F. Yakaboski  
Project Analyst  
Division Health Service Regulation, Healthcare Planning and Certificate of Need Section  
North Carolina Department of Health and Human Services

919-855-3873 office  
[Greg.yakaboski@dhhs.nc.gov](mailto:Greg.yakaboski@dhhs.nc.gov)

809 Ruggles Drive  
2704 Mail Service Center  
Raleigh, NC 27699-2704



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**From:** Hale, Gloria  
**Sent:** Monday, August 20, 2018 3:29 PM  
**To:** Yakaboski, Greg <[greg.yakaboski@dhhs.nc.gov](mailto:greg.yakaboski@dhhs.nc.gov)>  
**Subject:** FW: [External] No review letter for Iredell County

Greg, here is the note from Denise regarding her request for a No Review. Thanks.

**Gloria C. Hale, MPH**  
Team Leader, Certificate of Need