



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

ROY COOPER • Governor
KODY H. KINSLEY • Secretary
MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

September 7, 2022

Brian Yates
brian.yates@ashememorial.org

No Review

Record #: 1573
Date of Request: August 23, 2022
Facility Name: Ashe Memorial Hospital
FID #: 942944
Business Name: Ashe Memorial Hospital, Inc.
Business #: 94
Project Description: Acquire 3D mammography equipment
County: Ashe

Dear Mr. Yates:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your correspondence 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,

Ena Lightbourne
Project Analyst

Micheala Mitchell
Chief

cc: Acute and Home Care Licensure and Certification Section, DHSR

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: 809 Ruggles Drive, 2704 Mail Service Center, Raleigh, NC 27699-2704
<https://info.ncdhhs.gov/dhsr/> • TEL: 919-855-3873

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER



Ashe Memorial Hospital

August 19, 2022

Via Email

Ena Lightbourne, Project Analyst, Certificate of Need
N.C. Department of Health Service Regulation
809 Ruggles Drive
Raleigh, North Carolina 27603

Re: Ashe Memorial Hospital
Request for "No Review" Determination to Acquire 3-D Mammography Equipment
Jefferson, North Carolina (FID # 942944; Ashe County)

Dear Ms. Lightbourne:

Ashe Memorial Hospital intends to acquire a 3-D Mammography unit at its facility in Jefferson, North Carolina. This new mammography unit will be a Hologic Selenia Dimensions 3D Performance System. This mammography system will be located in existing space in the Radiology Department.

See **Attachment A** for the equipment quote of the new equipment. The proposed equipment and related construction costs will not exceed the cost threshold of \$2,000,000 for Major Medical Equipment acquisitions as defined in N.C.G.S. §131E-176(14o). See **Attachment B** for the Projected Capital Costs Summary.

Ashe Memorial Hospital is requesting a determination from the Certificate of Need Section that this proposed project with total costs, including equipment and all related capital costs of \$585,000 is not considered Major Medical Equipment and, as such, is not subject to CON review.

If you need additional information, please do not hesitate to contact me.

Sincerely,



Brian Yates
Chief Executive Officer

ATTACHMENT A



Purchase Quotation

PLEASE REFER TO THIS NUMBER ON ALL CORRESPONDENCES AND ORDERS

Quote #: Q-273562

Status: Approved

Quote Expiration Date: 9/30/2022

TO:

CUSTOMER NAME	CUSTOMER NUMBER
ASHE MEMORIAL HOSPITAL	88802
BILL TO ADDRESS	SHIP TO ADDRESS
200 HOSPITAL AVE JEFFERSON North Carolina US 28640	200 HOSPITAL AVE JEFFERSON North Carolina US 28640

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.

This Quotation is based on the information known by Hologic regarding your needs as of the date the Quotation is generated. This offer is subject to change or withdrawal by Hologic prior to acceptance. This Quotation and the governing terms as noted herein shall 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. In the event of a conflict between this Quotation and the governing terms, this Quotation shall prevail. 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
BSHSalesSupportUS@hologic.com

ATTN: Marty Haynes Phone: (336) 277-0260 Fax: Email: mhaynes@novanthealth.org

Quote Date	Hologic Representative	Estimated Delivery Date	Quote Currency
3/4/2022	Billy Markey william.markey@hologic.com	10/26/2022	U.S. Dollar

Summary of Governing Terms/Contracts	Contract Number	FOB	Payment Terms	Freight Terms
Hologic Std T&C*		DESTINATION	30 NET	NO CHARGE
NOVANT - MAMMO & BONE		DESTINATION	30 NET	NO CHARGE

*For the purpose of clarity, the Products as contained herein that are not subject to a governing terms / contract as listed above, shall be governed by the applicable Hologic Terms and Conditions available at: <https://www.hologic.com/hologic-sales-terms-conditions>

3D Performance

Qty	Product Name	Description	Unit Price	Extended Price
1	SDA-SYS-3000-3D	SELENIA® DIMENSIONS® 3D™ PERFORMANCE SYSTEM	\$299,595.00	\$299,595.00
1	ASY-10935	3D KIT MAMMOPAD ACCESSORY	Included	Included
1	PRD-04420	HIGH RESOLUTION READY DETECTOR	Included	Included
1	PRD-04749	KIT, NON-TOUCH SCREEN CONTROL MONITOR, UNIVERSAL ERGO AWS	Included	Included
1	DIM-DISP-2MP	SDM; 2MP DISPLAY OPTION	\$2,883.00	\$2,883.00
1	FAB-12469	SHIELD, UNIVERSAL AWS	Included	Included
1	SDM-LIC-0005	C-VIEW SOFTWARE LICENSE	\$18,000.00	\$18,000.00

Qty	Product Name	Description	Unit Price	Extended Price
3	ASY-04662	RACK, PADDLE STORAGE	\$300.00	\$900.00
1	ASY-04194	KIT, DIAGNOSTIC, PADDLES	\$2,886.00	\$2,886.00
1	SVC-SDM-OPT-BTO	SELENIA DIMENSIONS BTO ENABLED.	Included	Included
1	DIM-TRAIN-APPS-INIT	TECHNOLOGISTS, DIMENSIONS, INITIAL TRAINING, 2 DAYS, 1 SITE, MAX 5 TECHNOLOGISTS	Included	Included
1	SDM-TRAIN-INIT-03	MEDICAL PHYSICIST, DIMENSIONS, INITIAL TRAINING, 8 HRS (5 HRS LIVE - 3 HRS ONLINE TRAINING), 1 SITE, MAX 2 PHYSICISTS	Included	Included
1	SDM-TRAIN-INIT-04	RADIOLOGISTS, TOMOSYNTHESIS, INITIAL TRAINING, 8 HOURS VIRTUAL TRAINING, 14 RADIOLOGISTS	Included	Included
1	DIM-LIC-IC	IMAGECHECKER CAD 10.0 SOFTWARE LICENSE ON AWS	\$22,000.00	\$22,000.00
1	ASY-10994	KIT, FIXED MONITOR MOUNT, 2MP COLOR MONITOR, UNIVERSAL ERGO AWS	\$1,152.00	\$1,152.00
1	TRADE-HOLX_SEL	TRADE-IN OF HOLOGIC SELENIA SYSTEM (INSTALLED AND FUNCTIONING)	-\$40,000.00	-\$40,000.00
1	HLX-LOYALTY-DISCOUNT	HOLOGIC LOYALTY DISCOUNT	-\$15,000.00	-\$15,000.00
1	701740001	FFDM THERMAL OUTER BOX	Included	Included
3D Performance TOTAL:				\$292,416.00

Affirm

Qty	Product Name	Description	Unit Price	Extended Price
1	STLC-00004	AFFIRM BREAST BIOPSY GUIDANCE SYSTEM	\$48,000.00	\$48,000.00
1	ASY-06484	KIT, FMI, DIMENSIONS TOMO BIOPSY	\$22,000.00	\$22,000.00
1	SDM-TRAIN-INIT-05	AFFIRM 3D UPGRADE, INITIAL TRAINING, 1 DAY, 1 SITE, MAX 3 TECHNOLOGISTS AND 3 PHYSICIANS	Included	Included
1	ASY-09880	AFFIRM LATERAL ARM UPRIGHT BIOPSY ACCESSORY KIT	\$25,000.00	\$25,000.00
1	BI-FURN-0002	AKRUS STANDARD MAMMOGRAPHY CHAIR	\$13,600.00	\$13,600.00
1	ASY-04662	RACK, PADDLE STORAGE	\$300.00	\$300.00
1	SDM-TRAIN-INIT-02	AFFIRM, INITIAL TRAINING, 3 DAYS, 1 SITE, MAX 3 TECHNOLOGISTS & 3 PHYSICIANS	Included	Included
Affirm TOTAL:				\$108,900.00

Brevera

Qty	Product Name	Description	Unit Price	Extended Price
1	BREVSYS	BREVERA® BREAST BIOPSY SYSTEM WITH CORLUMINA™ IMAGING TECHNOLOGY FOR HOLOGIC SYSTEMS, US	\$83,684.00	\$83,684.00
1	BREV-TRAIN-INIT	BREVERA BREAST BIOPSY SYSTEM, INITIAL TRAINING, 2 DAYS, 1 SITE, UP TO 3 TECHS & 3 RADIOLOGISTS	Included	Included
Brevera TOTAL:				\$83,684.00

*To the extent this Quotation contains any Professional Services for Equipment relocation or clinical training, such Professional Services shall be governed by the Hologic Professional Services Terms and Conditions (US Customers), available at <https://www.hologic.com/hologic-master-sales-terms-conditions>. To the extent this Quotation contains any Products with Product Name UA-SUB-SW-0001, UA-SW-002, UEQ-SUB, DIM-LIC-QT-SUB (collectively "Subscription Products"), such Subscription Products shall be governed by the Hologic Subscription Terms and Conditions US, available at [available at https://www.hologic.com/hologic-master-sales-terms-conditions](https://www.hologic.com/hologic-master-sales-terms-conditions), and the Effective Term for said Subscription Products shall be a twelve (12) month period beginning on the date of designated Equipment for such Subscription

Software. Otherwise, any Products with Governing Terms listed as "Hologic Std T&C" shall be governed by the Hologic Sales Terms and Conditions US, available at <https://www.hologic.com/hologic-master-sales-terms-conditions>.

**Final Quote
Price:** USD 485,000.00

Affirm

Upgrade	Serial Number
ASY-06484	

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.

Product Name	Long Description
SDA-SYS-3000-3D	<p>Hologic Selenia® Dimensions® 3000 system for Genius® 3D Mammography™ screening and diagnostic imaging. Upgradable to interventional or mobile imaging. INCLUDES:</p> <p>X-ray Gantry:</p> <ul style="list-style-type: none"> • Generator: Fully integrated constant potential, high frequency, inverter type. • Detector: High-resolution ready detector. • X-ray Tube: Tungsten, bi-angular, high speed, high heat capacity. • X-ray Filters: Rhodium, silver, aluminum. • Anti-scatter Grid: Auto-retracting linear grid. <p>Fixed-height Acquisition Workstation:</p> <ul style="list-style-type: none"> • CPU: Standard computer, multi-core Intel-based CPU, minimum 16 GB RAM, minimum 2 TB disk, Windows 10/64, NVIDIA GPU. • Includes DVD +/- R/W. • User Interface: 1.2 MP color LCD control monitor. Full X-ray shield, pull-out keyboard drawer, keyboard and mouse. <p>Selenia Dimensions Software:</p> <ul style="list-style-type: none"> • User access control, patient and study selection, imaging procedure selection and definition, X-ray parameter control, image review and acceptance/rejection, quality control. • Licenses: Tomosynthesis imaging, Diagnostic Imaging, Dynamic Tube Head Motion. <p>Connectivity:</p> <ul style="list-style-type: none"> • DICOM: Modality work list, storage, storage commitment, query/retrieve, print. • IHE Profiles: Scheduled workflow, patient information reconciliation, mammography image. • Advanced Connectivity: Ability for the system to participate in DICOM Modality Performed Procedure Step (MPPS) transactions and to output DICOM Radiation Dose Structured Report (RDSR) objects to third-party dose aggregation and reporting systems. The MPPS and RDSR capabilities can be enabled and disabled independently. <p>Accessories:</p> <ul style="list-style-type: none"> • Screening Paddles (3): 24 x 29 cm, 18 x 24 cm, small breast. • Other Paddles (3): 10 cm contact, 10 cm magnification, 7.5 cm spot contact for use during QC testing only. • Other: Magnification stand with imag platform, flat field phantom and case, ACR tomosynthesis geometry calibration phantom, Dimensions interconnect cable kit, 2D fixed face shield, retractable 3DMammography™ face shield, User, service, maintenance, and QC manuals. MammoPad® Breast Cushion trial box. <p style="text-align: center;">Page 8 of 15</p> <p>Hologic Platinum Marketplace: Co-operative marketing program focused on business growth through patient and referring physician education. Complete initiation form at hologicmarketplace.com/user/register. Estimated</p> <p style="text-align: right;">Quote #: Q-273562-1</p>

Product Name	Long Description
PRD-04420	<p>Hologic 3D Mammography™ high-resolution ready digital image receptor for 3Dimensions™ mammography systems or Selenia® Dimensions® systems.</p> <p>INCLUDES:</p> <p>Digital Image Receptor</p> <ul style="list-style-type: none"> •Amorphous selenium, TFT •Structure: Single 24 x 29 cm plate •Image Matrix Sizes: 2560 x 3328 (18 x 24 cm); 3328 x 4096 (24 x 29 cm) •Pixel Size: 0.070 mm •Limiting Spatial Resolution: 7,1 lp/mm. <p>(Hologic Clarity HD license purchase required to enable Clarity HD high-resolution imaging on 3D Performance and Dimensions 6000 and 9000 systems. This license is included with a 3Dimensions system.)</p>
PRD-04749	<p>A 17" flat panel color monitor available on the Selenia Dimensions Avia 3000 and 6000 packages (1280X1024 viewing area, 56-76HZ).</p>
DIM-DISP-2MP	<p>Selenia Dimensions 2MP Display Option.</p> <p>Includes:</p> <ul style="list-style-type: none"> • 21.3" clinical display monitor for hospital wide-viewing of clinical data and images, with 1600x1200 maximum resolution tft am color, active display 432hx324mm(17x12.8), lcd 2mp, 100/240v, 5a 50/60
FAB-12469	<p>Shield, Universal AWS</p>
SDM-LIC-0005	<p>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.</p> <p>Includes:</p> <ul style="list-style-type: none"> • C-View Generated 2D Imaging software license

Product Name	Long Description
ASY-04662	<p>Wall-mounted, felt-lined rack for storing system compression paddles. Each rack, sold separately, provides enough storage room for 3-4 compression paddles.</p> <p>Includes:</p> <ul style="list-style-type: none"> • Paddle storage rack with felt lining • Wall-mounting bracket (installation not included) • Graphic paddle labels <p>Dimensions:</p> <ul style="list-style-type: none"> • 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 <p>Recommended:</p> <ul style="list-style-type: none"> • 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 <p>Requirements:</p> <ul style="list-style-type: none"> • Must be securely attached to the wall • Must be installed by a professional installer
ASY-04194	<p>The diagnostic paddle kit for Selenia® Dimensions®. Includes: frameless spot contact paddle (ASY-01950), 7.5cm spot contact paddle (ASY-01986), 7.5cm spot magnification paddle (ASY-02162).</p>
SVC-SDM-OPT-BTO	<p>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.</p> <p>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.</p> <p>Requires:</p> <ul style="list-style-type: none"> • 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

Product Name	Long Description
DIM-TRAIN-APPS-INIT	<p>Technologist training for a new 3Dimensions™ or Selenia® Dimensions® system. Initial training is included in the purchase price of your system and is valued at \$5,100 (unused training cannot be deducted from your purchase price). Training duration to be determined by customer needs up to 2 days.</p> <ul style="list-style-type: none"> • One session of technologist onsite applications training or other clinical support for maximum of 5 technologists based on training effectiveness and space limitations. • Additional sessions may be needed. For additional groups of up to 5 technologists add purchasable DIM-TRAIN-APPS-ADDL. • Online CEU courses required prior to onsite training. • Video training available during and post training. • Onsite portion of training or other clinical support must be completed within 24 months of equipment installation. <p>Required FDA training:</p> <ul style="list-style-type: none"> • 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. • Sites must obtain ACR or State FFDM accreditation before using the tomosynthesis modality. <p>Please note: Cancellation must be made 6 business days prior to the confirmed and scheduled training start date. Fee for cancellation within 6 business days of confirmed training is \$2,000.</p>
SDM-TRAIN-INIT-03	<p>Medical physicists training for a new mammography system. Included in the purchase price of your system are (8) hours of Hologic tomosynthesis educational training for up to (2) physicists. Initial training is included in the purchase price of your system/license and is valued at \$1,500 (unused training cannot be deducted from your purchase price). Five (5) hours of live tomosynthesis training for up to 2 medical physicists with a Hologic Field Service Engineer during the installation of the system and access to Hologic's 3-hour online tomosynthesis training course for medical physicists to fulfill the 8-hour FDA requirement. See course description for more details and requirements. Visit www.hologic.com/training for a complete list of Hologic educational opportunities.</p> <p>Please note: Cancellation must be made 6 business days prior to the confirmed and scheduled training start date. Fee for cancellation within 6 business days of confirmed training is \$2,000.</p>
SDM-TRAIN-INIT-04	<p>Radiologist training for 3Dimensions™ or Selenia® Dimensions® system(s). Initial training is included in the purchase price of your system and is valued at \$5,250 (unused training cannot be deducted from your purchase price). Access to Hologic's virtual tomosynthesis training course for up to 14 radiologists. This program will fulfill the 8-hour FDA training requirement. See course description for more details and requirements. Visit www.hologic.com/training for a complete list of Hologic educational opportunities.</p>

Product Name	Long Description
DIM-LIC-IC	<p>The ImageChecker® computer-aided detection (CAD) and Citra™ advanced CAD display software adds one license to the AWS to process 2D images from a single mammography system.</p> <p>INCLUDES:</p> <ul style="list-style-type: none"> • One ImageChecker CAD software license to support: <ul style="list-style-type: none"> • Hologic software generated 2D For Processing synthesized images • Hologic For Processing 2D FFDM images • Citra advanced CAD display license provides additional information about why ImageChecker CAD marked specific regions: <ul style="list-style-type: none"> • RightOn™ CAD marks placed right on the potential region-of-interest to unambiguously flag the location • Malc™ CAD marks placed where the algorithm detects signs of both density and calcifications • PeerView™ CAD marks provide anatomic outline of tissues • EmphaSize™ markers are scaled according to the prominence of features • Training provided via Video-On-Demand from Hologic.com. Training may be accessed at any time for unlimited staff for an unlimited period. <p>REQUIREMENTS:</p> <ul style="list-style-type: none"> • AWS software minimum 1.10/2.1 • Specify serial number at time of order • Please refer to Hologic's diagnostic workstation description for minimum requirements <p>NOTES:</p> <ul style="list-style-type: none"> • 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.
ASY-10994	<p>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.</p>
HLX-LOYALTY-DISCOUNT	<p>Customers who trade in their existing Hologic mammography gantry for a new Hologic 3D™ capable system, are eligible for an additional "Loyalty Discount" in conjunction with their trade-in credit. Please see notes section for additional eligibility requirements.</p>

Product Name	Long Description
STLC-00004	<p>The Affirm® upright breast biopsy guidance system for a 3Dimensions™ system or Selenia® Dimensions® system supports stereotactic 2D biopsy and wire localization. Supports fast positioning through motorized X and Y axis guidance with manual Z direction positioning. The Affirm upright does more than deliver superior imaging performance to 2D biopsy. It is designed to integrate with the Selenia Dimensions system from the ground up to streamline workflow and accelerate the journey from screening to breast biopsy.</p> <p>INCLUDES:</p> <ul style="list-style-type: none"> • Affirm breast biopsy guidance module • Biopsy control module with touchscreen display • One (1) Stereotactic 2D Biopsy software license for one gantry; additional licenses may be purchased • Biopsy compression paddles (3): Standard biopsy compression paddle (biopsy window: 5.4 x 5.2 cm); axillary biopsy compression paddle (biopsy window: 5.4 x 5.2 cm); wide biopsy compression paddle (biopsy window: 7.4 x 6.2 cm) • Quality assurance needle and needle guide holder • Geometry calibration and targeting phantoms • Affirm tabletop stand • User and service manuals • 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 Affirm breast biopsy guidance system. Online entry into the program will be provided once order is placed and online initiation form completed at hologicmarketplace.com/user/register. Estimated value included per system: \$5,000. <p>TRAINING:</p> <ul style="list-style-type: none"> • Three days onsite training for 3 technologists and 3 radiologists <p>REQUIREMENTS:</p> <ul style="list-style-type: none"> • 2MP medical grade LCD display • Dimensions software minimum v. 1.9 • 3Dimensions or Selenia Dimensions system with both diagnostic and dynamic tube head motion for 2D Biopsy license installed • 3Dimensions or Selenia Dimensions system serial number at time of order <p>RECOMMENDATIONS:</p> <ul style="list-style-type: none"> • 3MP medical grade DICOM monitor
ASY-06484	<p>Affirm® Tomosynthesis Biopsy software license provides the ability to easily and accurately target lesions with tomosynthesis imaging including lesions that may only be found under tomosynthesis.</p> <p>INCLUDES:</p> <ul style="list-style-type: none"> • 3D biopsy license • 3D QAS target • Tomosynthesis biopsy QAS needle <p>REQUIREMENTS:</p> <ul style="list-style-type: none"> • Affirm breast biopsy guidance system and license. • Dimensions system with minimum software version 1.9 and tomosynthesis imaging license <p>RECOMMENDATIONS:</p> <ul style="list-style-type: none"> • 3MP medical grade DICOM monitor • Two (2) dual-function gantry footswitches

Product Name	Long Description
SDM-TRAIN-INIT-05	<p>Training for customers upgrading from 2D to 3D imaging on the Affirm® upright biopsy system. Initial training is included in the purchase price of your license and is valued at \$2,500 (unused training cannot be deducted from your purchase price).</p> <ul style="list-style-type: none"> • One 1-day session of onsite applications training or other clinical support for maximum of 3 technologists and 3 physicians based on training effectiveness and space limitations. • For additional groups of up to 3 technologists and 3 physicians add purchasable SDM-TRAIN-ADDL-05. • Training must be completed within 24 months of equipment installation. <p>Please note: Cancellation must be made 6 business days prior to the confirmed and scheduled training start date. Fee for cancellation within 6 business days of confirmed training is \$2,000.</p>
ASY-09880	<p>Provides secure mounting of biopsy hand pieces onto the Affirm® breast biopsy guidance system. The Affirm lateral arm upright biopsy accessory adds the capability to perform 2D or tomosynthesis-guided biopsies using a right or left lateral needle approach.</p> <p>INCLUDES:</p> <ul style="list-style-type: none"> • Lateral arm hardware and stand enables technicians to elevate the breast off the detector to maximize access and minimize the potential for needle-to-platform collision • 15 cm lateral biopsy paddle • Lateral QAS phantom • License and software for the lateral arm upright biopsy accessory • User and service manuals <p>REQUIREMENTS:</p> <ul style="list-style-type: none"> • Affirm breast biopsy guidance system • Dimensions® software version 1.8.3 or later • The Dimensions and Affirm breast biopsy guidance system serial numbers at time of order - last four digits of Affirm serial number must be greater than or equal to: 0913
BI-FURN-0002	<p>AKRUS mammography positioning and biopsy chair. Supports seated, decubitus and Trendelenburg positioning. Includes: • Adjustable backrest (0 to 90 degrees) • Adjustable backrest segments • Adjustable arm supports • Adjustable headrest • Lateral back support • Electronic lift • Three position braking system • Max pt weight 330 lb Warranty: • Standard one-year parts and labor warranty</p>
ASY-04662	<p>Wall-mounted, felt-lined rack for storing system compression paddles. Each rack, sold separately; provides enough storage room for 3-4 compression paddles.</p> <p>Includes:</p> <ul style="list-style-type: none"> • Paddle storage rack with felt lining • Wall-mounting bracket (installation not included) • Graphic paddle labels <p>Dimensions:</p> <ul style="list-style-type: none"> • 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 <p>Recommended:</p> <ul style="list-style-type: none"> • 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 <p>Requirements:</p> <ul style="list-style-type: none"> • Must be securely attached to the wall • Must be installed by a professional installer

ATTACHMENT B

Projected Capital Cost Form

Ashe Memorial Hospital - 3D Mammography Project

Building Purchase Price		NA
Purchase Price of Land		NA
Closing Costs		NA
Site Preparation		NA
Landscaping		NA
Construction/Renovation	\$	60,295
Architect / Engineering / DHSR	\$	22,675
Medical Equipment	\$	485,000
Non-Medical Equipment		NA
Furniture		NA
DPS/IT Systems		NA
Financing Costs		NA
Other: (Identify)		NA
Other: Contingency	\$	17,030
Total Capital Cost	\$	585,000

CERTIFICATION BY A LICENSED ARCHITECT OR ENGINEER

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

DocuSigned by:
Cullen Pitts
88888F004E88110...

Date Signed: 08/02/2022 | 4:49:28 EDT

Signature of Licensed Architect or Engineer – Cullen Pitts, McMillan Pazdan Smith

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 is our intent to carry out the proposed project as described.

DocuSigned by:
Brian Yates
2B6AE59109BC4CC...

Date Signed: 08/03/2022 | 9:50:01 CDT

Signature of Officer/Agent

Chief Executive Officer

Title of Officer/Agent