North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt
Division Director

October 11, 2013

Pamela A. Scott
Poyner Spruill, LLP
Post Office Box 1801
Raleigh, North Carolina 27602-1801

No Review
Facility or Business: Carolina Breast Imaging, LLC (CBI)
Project Description: Acquisition of Diagnostic Equipment
County: Pitt

Dear Ms. Scott:

The Certificate of Need Section (CON Section) received your letter of September 30, 2013 regarding the above referenced proposal. According to the information that you provided, the cost of the proposal is $408,451.49 which includes the following medical equipment valued at $10,000 or more: mammography equipment (1 diagnostic and 1 screening) - $270,407.91; stereotactic biopsy accessory - $25,000.00; DEXA bone density device - $23,884.00; and ultrasound equipment - $56,213.00. 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.

Moreover, you need to contact the Acute and Home Care Licensure and Certification Section, Construction Section, and Radiation Protection Section of the Division of Health Service Regulation (DHSR) 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 by you. 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 the Certificate of Need Section. 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 the CON Section if you have any questions. Also, in all future correspondence you should reference the Facility I.D. # (FID) if the facility is licensed.

Sincerely,

Jane Rhoe-Jones, Project Analyst

Craig R. Smith, Chief
Certificate of Need Section

cc: Acute and Home Care Licensure and Certification Section, DHSR
Construction Section, DHSR
Radiation Protection Section, DHSR

Poyner Spruill LLP

September 30, 2013

Pamela A. Scott
Partner
D: 919.783.2954
F: 919.783.1075
pscott@poynerspruill.com

Via Hand Delivery

Craig R. Smith
Chief
CON Section
809 Ruggles Drive
Raleigh, NC 27603

Martha Frisone
Assistant Chief
CON Section
809 Ruggles Drive
Raleigh, NC 27603

RE: Request for No Review Determination – Acquisition of Diagnostic Equipment by Carolina Breast Imaging, LLC in Greenville

Dear Mr. Smith and Ms. Frisone:

I am writing on behalf of our firm's client, Carolina Breast Imaging, LLC (CBI), to correct an inadvertent omission from the no review determination request letter dated September 26, 2013 (No Review Determination Request) pertaining to CBI's proposed acquisition of diagnostic equipment. After further review of the No Review Determination Request this past weekend, CBI realized that the attached quote for a stereotactic biopsy accessory was inadvertently omitted.

Diagnostic Equipment. As explained in our September 26 letter, CBI plans to acquire medical and office equipment to be used in serving the patients of Carolina Breast Imaging Specialists, PLLC. Because the diagnostic equipment which CBI proposes to acquire will be refurbished or second-hand equipment, it is valued at significantly less than the original list price for new equipment. The cost estimates included in the quotes attached to the No Review Determination Request along with the quote attached to this clarification letter are the prices CBI was able to find on the secondary market, and therefore reasonably present the fair market value of this equipment.

The attached quote for the stereotactic biopsy accessory, estimated to cost $25,000.00, was inadvertently omitted from the No Review Determination Request, and should be deemed included in Appendix 4 to the Request. The stereotactic biopsy accessory will be used in conjunction with the diagnostic mammography unit. With the inclusion of the stereotactic biopsy accessory, the total capital costs of the diagnostic equipment CBI proposes to acquire is estimated at $408,451.49. *See* Diagnostic Equipment Capital Cost Table (Appendix 3), a corrected copy of which is attached hereto. Please note that the Capital Cost Table included with the No Review Determination Request inadvertently mislabeled the DEXA bone density device, with an estimated cost of $23,884.00, as a stereotactic biopsy system. A copy of the quote for the DEXA bone density device was included in Appendix 4 to the No Review Determination Request, and is included in the attached Capital Cost Table with the correct nomenclature.

The diagnostic equipment CBI proposes to acquire includes mammography equipment at $270,407.91, stereotactic biopsy accessory at $25,000.00, DEXA bone density device at $23,884.00, and ultrasound equipment at $56,213.00. *See* Diagnostic Equipment Vendor Quotes (Appendix 4) and Capital Cost Table. The cost of transporting and installing all of this diagnostic equipment is included in the purchase prices. Although the power injector for dual energy contrast enhanced spectral

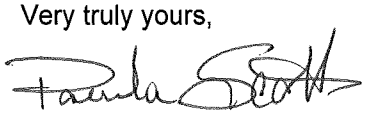
mammography costs less than $10,000, to be conservative, we have included it with the mammography equipment for purposes of determining the total diagnostic equipment capital costs. Thus, with the stereotactic biopsy accessory, the total cost of the diagnostic medical equipment which costs $10,000 or more which will be acquired by CBI remains well below the $500,000 level at which a diagnostic center would be deemed to be established pursuant to N.C. Gen. Stat. § 131E-176(7a); and please refer to our letter of September 26 for further discussion.

We regret the inadvertent omission of the stereotactic biopsy accessory quote and mislabeling of the DEXA bone density device, but with the corrections in this letter you have a comprehensive and supported description of the equipment costs that should be considered in conjunction with CBI's proposal. Based upon the information provided in the No Review Determination Request along with this letter of clarification, CBI respectfully requests that the CON Section confirm in writing that the activities described do not constitute a new institutional health service and that CBI does not need a certificate of need to proceed with its planned acquisition of the equipment described.

Thank you again for your attention to this matter, and please let us know if there is any additional information you may require.

With best regards, I am

Very truly yours,



Pamela A. Scott

cc: Jane Rhoe-Jones

Stereotactic Biopsy

GE Healthcare

QUOTATION

Quotation Number: PR1-C6094 V 2

Carolina Breast Imaging LLC
990 Johns Hopkins Dr
Greenville NC 27834-7224

Attn: Dr. Bruce Schroeder
Director
990 Johns Hopkins Dr
Greenville NC 27834

Date: 09-18-2013

This Agreement (as defined below) is by and between the Customer and the GE Healthcare business ("GE Healthcare"), each as identified herein. GE Healthcare agrees to provide and Customer agrees to pay for the Products listed in this GE Healthcare Quotation ("Quotation"). "Agreement" is defined as this Quotation and the terms and conditions set forth in either (i) the Governing Agreement identified below or (ii) if no Governing Agreement is identified, the following documents:

1) This Quotation that identifies the Product offerings purchased or licensed by Customer;

2) The following documents, as applicable, if attached to this Quotation: (i) GE Healthcare Warranty(ies); (ii) GE Healthcare Additional Terms and Conditions; (iii) GE Healthcare Product Terms and Conditions; and (iv) GE Healthcare General Terms and Conditions.

In the event of conflict among the foregoing items, the order of precedence is as listed above.

This Quotation is subject to withdrawal by GE Healthcare at any time before acceptance. Customer accepts by signing and returning this Quotation or by otherwise providing evidence of acceptance satisfactory to GE Healthcare. Upon acceptance, this Quotation and the related terms and conditions listed above (or the Governing Agreement, if any) shall constitute the complete and final agreement of the parties relating to the Products identified in this Quotation. The parties agree that they have not relied on any oral or written terms, conditions, representations or warranties outside those expressly stated or incorporated by reference in this Agreement in making their decisions to enter into this Agreement. No agreement or understanding, oral or written, in any way purporting to modify this Agreement, whether contained in Customer's purchase order or shipping release forms, or elsewhere, shall be binding unless hereafter agreed to in writing by authorized representatives of both parties. Each party objects to any terms inconsistent with this Agreement proposed by either party unless agreed to in writing and signed by authorized representatives of both parties, and neither the subsequent lack of objection to any such terms, nor the delivery of the Products, shall constitute an agreement by either party to any such terms.

By signing below, each party certifies that it has not made any handwritten modifications. Manual changes or mark-ups on this Agreement (except signatures in the signature blocks and an indication in the form of payment section below) will be void.

- Terms of Delivery: FOB Destination
- Quotation Expiration Date: 10-21-2013
- Billing Terms: 100% billing at Ship Completion (Fulfillment) / Delivery
- Payment Terms: UPON RECEIPT
- Governing Agreement: None

Each party has caused this agreement to be signed by an authorized representative on the date set forth below. Please submit purchase orders to GE Healthcare
3000 N. Grandview Blvd., Mail Code WT-897, Waukesha, WI 53188

GE HEALTHCARE

Kimberly Allen
09-18-2013
Vaso Healthcare - Authorized Manufacturer Rep

CUSTOMER

Authorized Customer Date

Print Name and Title

PO #

Desired Equipment First Use Date

GE Healthcare will use reasonable efforts to meet Customer's desired equipment first use date. The actual delivery date will be mutually agreed upon by the parties.

INDICATE FORM OF PAYMENT:
(If there is potential to finance with a lease transaction, GE HFS or otherwise, select lease.)
____ Cash * ____ Lease ____ HFS Loan
If financing please provide name of finance company below*:

*Selecting Cash or not identifying GE HFS as the finance company declines option for GE HFS financing.

Quotation Number: PR1-C6094 V 2

Item No.	Qty	Catalog No.	Description	Ext Sell Price
	1		**Senographe Essential IB Options**	
1	1	S30331FY	Senographe Essential Stereo Option	$25,000.00

Senographe Essential Stereotaxy The stereotaxy add-on simply slides onto the Senographe Essential for fine needle aspiration, core biopsy and vacuum assisted biopsy or hook wire placement in upright or recumbent positions.

It leverages GE Revolution TM detector for consistent image quality in screening, diagnostic and interventional applications.

Advanced ergonomics combined with the Senographe Essential detector enables streamlined stereotaxy for better patient care.

- Versitile add-on to Senographe Essential full-field digital mammography system
- Quick set-up
- Large image field of view for easy positioning and large accessible biopsy volume
- Vertical and lateral approach for easy access to breast lesions
- Ergonomic carbon cover designed for easy cleaning
- Dismountable paddles for easy cleaning
- Large working space
- Parking position for easy access
- to the breast Included in the Stereo Option are the following:
- Stereotaxy positioner and paddle (dismount able for cleaning purposes)
  - 3 removable guide holders and 3 bushing adapters
  - Stereo operator manuals (paper format) available in 28 languages
- Vertical approach kit
- Lateral approach kit and paddle (dismount able for cleaning purposes)
  - 6mm metal guides lateral approach (5 of each)
  - 8mm metal guides lateral approach (5 of each)
  - 3 fixing parts for Axis 8mm diameter
- Service publications

Quote Summary:

QUOTATION

Quotation Number: PR1-C6094 V 2

Item No.	Qty	Catalog No.	Description	Ext Sell Price
			Total Quote Net Selling Price	**$25,000.00**
			(Quoted prices do not reflect state and local taxes if applicable. Total Net Selling Price Includes Trade In allowance, if applicable.)	

Appendix 3

Proposed Carolina Breast Imaging Specialists Office

Diagnostic Equipment Capital Costs

Equipment	Cost
A. **Construction Upfitting**	
(1) Dedicated Power Circuits for Mammography Units	1,300.00
(2) Sub-Total Construction Upfitting Costs	**1,300.00**
B. Equipment	
(3) Screening Mammography Unit – GE Senographe Essential Madras	112,636.00
(4) Contrast Enhanced Spectral Mammography Upgrade	45,000.00
(5) Power Injector for Dual Energy Contrast Enhanced Spectral Mammography	6,700.00
(6) Diagnostic Mammography Unit – GE Senographe Essential IB	106,071.91
(7) DEXA Bone Density Device	23,884.00
(8) Stereotactic Biopsy Accessory – GE Senographe Essential IB Option	25,000.00
(9) Ultrasound 1 – GE Logiq S8	56,213.00
(10) Shipping and Installation	Included in purchase prices for all equipment
(11) Sales Tax	25,346.58
(12) Sub-Total Equipment Purchase and Installation	**400,851.49**
C. Miscellaneous	
(1) Mammography and DEXA – Shielding and Post-Installation Surveys by Physicist	3,600.00

Equipment	Cost
(2) Staff Training	2,700.00 (For Stereotactic Biopsy Only) Included in equipment purchase price of all other applicable equipment.
(3) **Sub-Total Miscellaneous Costs**	**6,300.00**
(4) TOTAL COSTS	**$408,451.49**

Poyner Spruill LLP

September 26, 2013

Pamela A. Scott
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Via Hand Delivery

Craig R. Smith
Chief
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809 Ruggles Drive
Raleigh, NC 27603

Martha Frisone
Assistant Chief
CON Section
809 Ruggles Drive
Raleigh, NC 27603

RE: Request for No Review Determination – Acquisition of Diagnostic Imaging Equipment by Carolina Breast Imaging, LLC in Greenville

Dear Mr. Smith and Ms. Frisone:

I am writing on behalf of our firm's client, Carolina Breast Imaging, LLC (CBI), which plans to acquire the medical equipment and associated items described in this letter in conjunction with a new radiology physician office at 990 Johns Hopkins Drive in Greenville, North Carolina. The proposed new radiology office will operate in physician office space leased by CBI from NC Med Holdings, LLC (NC Med). Carolina Breast Imaging Specialists, PLLC (CBS), owned by Dr. Bruce Schroeder, a board-certified radiologist, will provide the professional services at the new office. The proposed new radiology office which plans to open later this year, will offer mammography, bone density and ultrasound services. CBI will provide management and administrative support services to CBS when the new physician practice begins operations.

With this letter, CBI is requesting a no review determination regarding its acquisition of the medical equipment and associated items described below. CBI plans to make the equipment available to CBS for use in providing professional services to meet the needs of the practice's patients.

By letters dated July 25 and September 26, 2013, we provided written notice on behalf of NC Med regarding its plans to develop an exempt physician office building at this location pursuant to N.C. Gen. Stat. § 131E-184(a)(9). CBI plans to lease the physician office space in the building from NC Med in a fair market lease, and to establish the new radiology office on the first floor of the building. CBI will make this physician office space available to CBS for the provision of services to patients of the new radiology practice.

Based upon the information presented in this letter, we respectfully request that the CON Section confirm in writing that the activities described herein do not constitute a new institutional health service and that CBI does not need a certificate of need to proceed with its planned acquisition of the equipment described below.

Factual Background. CBI is a North Carolina limited liability company whose sole shareholder is Dr. Bruce Schroeder (Dr. Schroeder). Dr. Schroeder, a North Carolina licensed physician, has served radiology patients in Pitt County for many years. He is a nationally recognized thought leader in radiology.

CBS is a North Carolina professional limited liability company also owned by Dr. Schroeder. Dr. Schroeder formed CBI and CBS recently in anticipation of the new radiology practice he plans to open later this year. CBI does not yet, and never has, operated a radiology office or diagnostic imaging center. When the proposed new office opens and begins operations later this year, it will be located in the first floor space leased by CBI from the developer of the physician office building, NC Med. *See* Line Drawing for Carolina Breast Imaging office. (Appendix 1.) There are no current plans for use of the second floor of building, which will not contain any clinical space. While there is some commonality in ownership between NC Med and CBI, these are separate corporate entities which operate at arms' length.

As the architect has confirmed in his letter attached hereto, the up-fitting construction costs associated with making the diagnostic medical equipment operational in the planned radiology office space are limited to $1,300.00 for the dedicated electrical circuitry needed for the mammography equipment. With the exception of this dedicated circuitry, the remainder of the planned renovation construction is for general physician office space. *See* Cost Certification Letter from J. Michael Dunn. (Appendix 2.) Please note that although Mr. Dunn's letter addresses dedicated circuitry for a freestanding stereotactic unit in addition to two mammography units, CBI does not plan to acquire a freestanding stereotactic unit as part of its proposal. However, to be conservative, we have included the total $1,300.00 cost for this dedicated circuitry.

CBI will provide a variety of management and administrative services for the day-to-day operations of CBS, including billing and collections, payroll, accounts payable, information technology, managing computer networks and electronic records, and administrative staffing. CBI also will furnish the equipment and supplies necessary for CBS to serve patients.

Diagnostic Equipment. CBI plans to acquire medical and office equipment to be used in serving the patients of CBS. Because the diagnostic equipment which CBI proposes to acquire will be refurbished or second-hand equipment, it is valued at significantly less than the original list price for new equipment. The cost estimates included in the attached quotes are the prices CBI was able to find on the secondary market, and therefore reasonably present the fair market value of this equipment. The total capital costs of diagnostic equipment is estimated at $382,163.99. *See* Diagnostic Equipment Capital Cost Table. (Appendix 3.) This includes mammography equipment at $270,407.91, stereotactic biopsy accessory at $24,284.00 (including shipping), and ultrasound equipment at $56,213.00. *See* Diagnostic Equipment Vendor Quotes. (Appendix 4.) The cost of transporting and installing all of this diagnostic equipment will be included in the purchase prices. Although the power injector for dual energy contrast enhanced spectral mammography costs less than $10,000, to be conservative, we have included it with the mammography equipment for purposes of determining the total diagnostic equipment capital costs.

Other Equipment and Software. CBI also plans to acquire other equipment which is not diagnostic equipment, and therefore should not be included in determining the total capital costs of its proposed diagnostic equipment acquisition. This equipment includes the following:

- Specimen system which is used to assess the adequacy of a sample after tissue is removed from the patient, with an estimated total cost of $20,400 (including shipping). (Appendix 5.) This specimen system is not used for any diagnostic purpose, but rather is used to simply determine the adequacy of a breast biopsy specimen. A dedicated specimen device can shorten the overall procedure time which benefits patients in terms of safety, comfort and convenience. It does not offer any capability or reimbursement over that of using the mammography unit. The device is only used on tissue that has already been removed from the patient.

- Picture Archive and Communication System (PACS), an imaging archive system used to sort and access medical images. The same types of images may be stored on removable media (CDs/DVDs) or printed on film. The system is not required for the function of any diagnostic equipment.

- Standard workstations used to view images. Images can be printed to film and viewed on a traditional light box or they can be viewed on any imaging workstation, on-site or off-site, that meets certain specifications.

- Printer.

None of this equipment is required for the operation of any of the diagnostic equipment which CBI proposes to acquire.

In addition, CBI plans to subscribe to a Computer Aided Detection (CAD) service provided by iCAD, with an estimated annual license fee of $6,900. (Appendix 6.) The CAD service will be provided through a computer server with licensed software that can analyze the images coming from a digital mammography device to show the physician areas that may require additional attention. It is essentially a workstation tool. It is not required or essential for the operation of the mammography units and is not used for any diagnostic purpose. The patient never interacts with the system which can be located in the facility or elsewhere over a wide area network. The CAD software creates an XML file (no image data, just text and numbers) that is used by the workstation to point out areas that may need additional attention. The CAD system does not create a diagnostic image. All diagnostic information comes from the image produced by the mammography unit. The *radiologist does not interpret* the CAD output, and the specific results of the tool are not included in the mammography report. The manufacturer's guide for the CAD system makes clear that it is *not a diagnostic tool*, but rather simply a workstation feature which indicates potential areas the radiologist may wish to review again. *See* CAD Operating Manual Excerpt, §§ 6.3 and 6.3.3.1. (Appendix 7.) The optional use of CAD is simply a safety check that may cause the radiologist to go back and re-interpret the images, but the radiologist's interpretation and diagnosis are not in any way made or assisted by CAD.

CAD is analogous to an image review workstation and the tools that are typically found on any workstation. These computers offer various tools to assist in the review of the images but the diagnosis is always made by the radiologist based upon the mammography images. The workstations include tools such as "zoom" which enlarges an area an image so the radiologist can look at the structures more carefully just as CAD may offer another mechanism to understand the image better so that the doctor can make a more accurate interpretation. Additional tools like contrast manipulation, image processing tools, multi-planar reconstruction, 3D reconstruction and quantitative analysis of particular regions of interest are all comparable tools available on commonplace workstations which do not serve a diagnostic purpose and therefore have been routinely excluded from CON oversight.

Finally, CBI's proposed CAD subscription involves a one-year software license, which would be renewed periodically, and this is, by its very nature an operational expense, not a capital expenditure. However, even with the annual cost of the CAD added to the other expenses, that does not change the result, as discussed below.

Analysis of Issues Under the CON Law. Based on the information provided in, and attached to, this letter, it is clear that the plans to acquire the diagnostic medical equipment described herein do not constitute a "diagnostic medical center" or any other "New Institutional Health Service," and therefore, no certificate of need is required. The information provided above comprehensively documents all of the costs associated with acquiring the equipment and making it operational.

The general physician office space which CBI will lease from the building developer is exempt from CON review pursuant to N.C. Gen. Stat. § 131E-184(a)(9). This provision exempts from CON review any activities or costs associated with the development or acquisition of a physician office building, regardless of cost, and so long as no new institutional health service (other than a capital expenditure exceeding $2,000,000) is to be offered or developed in the building. The capital cost for up-fitting construction necessary for the installation and operation of the diagnostic medical equipment is limited to $1,300.00 for the dedicated electrical circuits required to operate the mammography units.

No aspect of CBI's proposal can be interpreted as the establishment of a new "health service facility," as defined in N.C. Gen. Stat. § 131E-176(9b). The total cost of the diagnostic medical equipment which costs $10,000 or more which will be acquired by CBI is below the $500,000 level at which a diagnostic center would be deemed to be established pursuant to N.C. Gen. Stat. § 131E-176(7b):

> "Diagnostic center" means 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.

The acquisition of the diagnostic medical equipment described above will not result in the establishment of a diagnostic center. The resulting total capital cost is well below the $500,000 threshold that would constitute the establishment of a diagnostic center. Even if the costs of the biopsy specimen and CAD systems were to be included, despite the fact that they do not constitute diagnostic medical equipment, the total cost would still fall below the $500,000 threshold. Thus, it is clear that neither a diagnostic center nor any of the other types of health service facilities identified in the CON Law are involved in CBI's proposal.

CBI also is not proposing the acquisition by purchase, donation, lease, transfer, or comparable arrangement of major medical equipment, as defined in N.C.G.S. § 131E-176(14o). The total price for all of the aforementioned diagnostic medical equipment is $382,624.97, and therefore, no single unit or single system of components with related functions which is used to provide medical and other health services costs more than $750,000.

Finally, none of the proposed services or equipment in this letter are separately regulated by the CON Law by N.C.G.S. § 131E-176(16)(f) or § 131E-176(16)(f1).

CBI's proposal is consistent with the approach adopted in the Final Agency Decision in a case involving an Asheville oncology practice's proposal to install and operate a linear accelerator and CT scanner in a new physician office building. *See Mission Hosps., Inc. v. N.C. DHHS*, 205 N.C. App. 35, 696 S.E.2d 163 (2010). In the appeal stemming from that case, the Court of Appeals upheld the Division's approach of evaluating the applicable CON threshold dollar amounts based solely upon costs that were truly essential to acquiring and making operational the linear accelerator and CT scanner at issue in that case. Under the approach affirmed in this case, a developer's base costs to construct an exempt physician office building are disregarded and need not be included in determining whether a cost threshold in the CON Law has been exceeded. *Id.* at 50-55, 696 S.E2d at 174-77. In keeping with that approach, the only costs pertaining to development of the physician office building which would be included would be the up-fitting construction required to install the dedicated circuitry for the mammography units. The remainder of the building renovations are for general physician office space.

If, in the future, CBI decides to develop a new institutional health service as defined in N.C.G.S. § 131E-176(16) other than subsection 16b, it will apply for a certificate of need as required by N.C.G.S. § 131E-178.

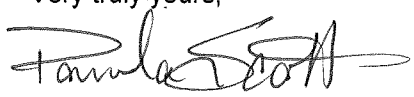
North Carolina courts have recognized that because the CON Law interferes with the normal right to do business, it must be narrowly construed. *See HCA Crossroads Residential Centers, Inc. v. N.C. Dep't of Human Resources*, 327 N.C. 573, 579, 398 S.E.2d 466, 470 (1990) ("When viewed in its entirety, Article 9 of Chapter 131E of the General Statutes, the Certificate of Need Law, reveals the legislature's intent that an applicant's fundamental right to engage in its otherwise lawful business be regulated but not be encumbered with unnecessary bureaucratic delay.") Failure to issue the requested no-review determination would delay and impede CBI in proceeding with a lawful business transaction.

Based upon the information provided in this letter, CBI respectfully requests your earliest possible attention to this request and looks forward to your written confirmation that the proposal described herein does not require a certificate of need. CBI and CBS wish to move forward with the opening of the planned new radiology office as soon as feasible, and accordingly, request a response from you on or before October 11, 2013, if possible.

Thank you for your attention to this matter, and please let us know if there is any additional information you may require.

With best regards, I am

Very truly yours,

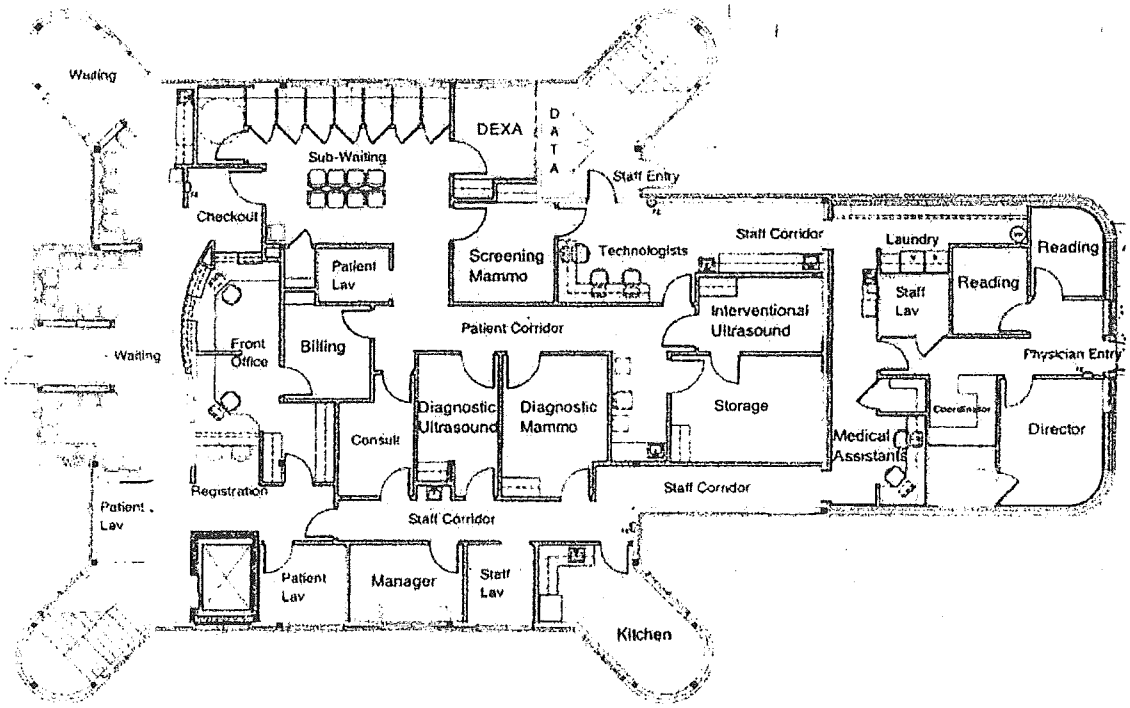


Pamela A. Scott

cc: Jane Rhoe-Jones

Index of Appendices

Appendix 1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Technologists
Staff Corridor
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Billing
Patient Corridor
Interventional Ultrasound
Waiting
Physician Entry
Diagnostic Ultrasound
Diagnostic Mammo
Storage
Consult
Medical Assistants
Director
Registration
Staff Corridor
Patient Lav
Staff Corridor
Patient Lav
Manager
Staff Lav
Kitchen

DUNN &
DALTON
ARCHITECTS

August 12, 2013

Dr. Bruce Schroeder

Re: **Cost Certification for Certificate of Need Verification**
Project: Medical Office, 990 Johns Hopkins Blvd., Greenville, NC

Dear Dr. Schroeder:

As requested, I have reviewed the drawings and construction to determine any difference in cost for the proposed medical facility in order to accommodate diagnostic procedures as compared to an identical medical office that would not offer diagnostic procedures.

The rooms in this facility that could be considered as being used for diagnostic procedures include two Ultra-Sound (LOGIQ 700) rooms, two Mammography (Senographe) rooms, a single Dexa (Lunar iDXA) room, and a single Stereotactic room. The size of the rooms is not specific to their use for this diagnostic equipment, and could be compared to standard exam rooms in a non-diagnostic medical practice. Other than the specific equipment itself, the only other cost attributable to the diagnostic procedures would be the special electrical costs associated with powering each piece of equipment.

The Dexa unit and two Ultra-Sound units connect to standard office grade receptacles, and would not contribute to any additional electrical costs. The two Mammography units and the Stereotactic unit each require 45 amp dedicated circuits, which is considered beyond the normal for an exam room, and would therefore be counted as an extra cost.

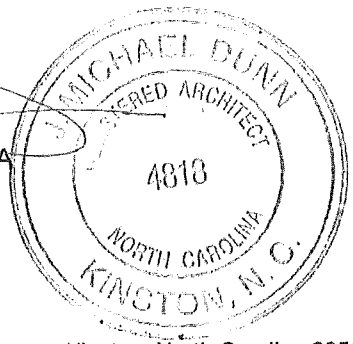
The three dedicated 45 amp circuits required are within the overall normal power requirements for a building of this size, and therefore would not require a larger electrical service. The construction cost to add the three dedicated circuits and the associated engineering design to facilitate the circuit sizing, therefore amounts to a total of $1,300.

As I mentioned, I am not aware of any other construction or design related costs specific with medical diagnostic procedures that would be applicable for this project.

Please let me know if you have any further questions.

Sincerely,

J. Michael Dunn, AIA



401 North Herritage Street Kinston, North Carolina 28501 252-527-1523 252-527-0049 Fax

Appendix 3

Proposed Carolina Breast Imaging Specialists Office

Diagnostic Equipment Capital Costs

Equipment	Cost
A. **Construction Upfitting**	
(1) Dedicated Power Circuits for Mammography Units	1,300.00
(2) Sub-Total Construction Upfitting Costs	**1,300.00**
B. Equipment	
(3) Screening Mammography Unit – GE Senographe Essential Madras	112,636.00
(4) Contrast Enhanced Spectral Mammography Upgrade	45,000.00
(5) Power Injector for Dual Energy Contrast Enhanced Spectral Mammography	6,700.00
(6) Diagnostic Mammography Unit – GE Senographe Essential IB	106,071.91
(7) Stereotactic Biopsy System	23,884.00
(8) Ultrasound 1 – GE Logiq S8	56,213.00
(9) Shipping and Installation	400.00 (Shipping for Faxitron Biopsy System) Included in purchase prices for all other equipment
(10) Sales Tax	23,659.08
(11) Sub-Total Equipment Purchase and Installation	**374,563.99**

Equipment	Cost
C. <u>Miscellaneous</u>	
(1) Mammography and DEXA – Shielding and Post-Installation Surveys by Physicist	3,600.00
(2) Staff Training	2,700.00 (For Stereotactic Biopsy System Only) Included in equipment purchase price of all other applicable equipment.
(3) **Sub-Total Miscellaneous Costs**	**6,300.00**
(4) **TOTAL COSTS**	**$382,163.99**

GE Healthcare

Appendix 4

QUOTATION

Quotation Number: PR10-C4112 V 4

Carolina Breast Imaging LLC
990 Johns Hopkins Dr
Greenville NC 27834-7224

Attn: Dr. Bruce Schroeder
Director
990 Johns Hopkins Dr
Greenville NC 27834

Date: 08-19-2013

This Agreement (as defined below) is by and between the Customer and the GE Healthcare business ("GE Healthcare"), each as identified herein. GE Healthcare agrees to provide and Customer agrees to pay for the Products listed in this GE Healthcare Quotation ("Quotation"). "Agreement" is defined as this Quotation and the terms and conditions set forth in either (i) the Governing Agreement identified below or (ii) if no Governing Agreement is identified, the following documents:

1) This Quotation that identifies the Product offerings purchased or licensed by Customer;

2) The following documents, as applicable, if attached to this Quotation: (i) GE Healthcare Warranty(ies); (ii) GE Healthcare Additional Terms and Conditions; (iii) GE Healthcare Product Terms and Conditions; and (iv) GE Healthcare General Terms and Conditions.

In the event of conflict among the foregoing items, the order of precedence is as listed above.

This Quotation is subject to withdrawal by GE Healthcare at any time before acceptance. Customer accepts by signing and returning this Quotation or by otherwise providing evidence of acceptance satisfactory to GE Healthcare. Upon acceptance, this Quotation and the related terms and conditions listed above (or the Governing Agreement, if any) shall constitute the complete and final agreement of the parties relating to the Products identified in this Quotation. The parties agree that they have not relied on any oral or written terms, conditions, representations or warranties outside those expressly stated or incorporated by reference in this Agreement in making their decisions to enter into this Agreement. No agreement or understanding, oral or written, in any way purporting to modify this Agreement, whether contained in Customer's purchase order or shipping release forms, or elsewhere, shall be binding unless hereafter agreed to in writing by authorized representatives of both parties. Each party objects to any terms inconsistent with this Agreement proposed by either party unless agreed to in writing and signed by authorized representatives of both parties, and neither the subsequent lack of objection to any such terms, nor the delivery of the Products, shall constitute an agreement by either party to any such terms.

By signing below, each party certifies that it has not made any handwritten modifications. Manual changes or mark-ups on this Agreement (except signatures in the signature blocks and an indication in the form of payment section below) will be void.

- Terms of Delivery: FOB Destination
- Quotation Expiration Date: 09-29-2013
- Billing Terms: 80% delivery / 20% Installation
- Payment Terms: UPON RECEIPT
- Governing Agreement: None

Each party has caused this agreement to be signed by an authorized representative on the date set forth below. Please submit purchase orders to GE Healthcare
3200 N. Grandview Blvd., Mail Code WT-897, Waukesha, WI 53188

GE HEALTHCARE
Scott McCloskey
Product Sales Specialist

CUSTOMER
Bruce Schroeder 8/28/13
Authorized Customer Date
Bruce Schroeder, President
Print Name and Title

PO #

Desired Equipment First Use Date

GE Healthcare will use reasonable efforts to meet Customer's desired equipment first use date. The actual delivery date will be mutually agreed upon by the parties.

INDICATE FORM OF PAYMENT:
(If there is potential to finance with a lease transaction, GE HFS or otherwise, select lease.)
____ Cash * ____ Lease ____ HFS Loan
If financing please provide name of finance company below*:

*Selecting Cash or not identifying GE HFS as the finance company declines option for GE HFS financing.

TBD

Quotation Number: PR10-C4112 V 4

Item No.	Qty	Catalog No.	Description	Ext Sell Price
	1		**Goldseal Senographe Essential Madras**	
1	1	L3034AM	GS ESSENTIAL MADRAS	$106,071.91
			GoldSeal Senographe Essential The GE Senographe Essential FFDM units eliminate the need for film cassettes, and take advantage of digital technology advances including fast image acquisition, quick on-screen image display, networking flexibility, auto or manual filming, and efficient exam archiving. In addition, the Senographe Essential's streamlined ergonomics help allow technologists to focus on patients and the outstanding image quality helps provide healthcare professionals with greater diagnostic confidence. The Senographe Essential's digital workflow and connectivity helps enable speed and efficiency, along with reliability of accurate information and improved patient care. The system includes: The GE Senographe Detector Platform A Single Amorphous Silicon, Cesium Iodide-Based Detector with an independently optimized component matrix, CsI needle structure and an Active Area of 24 x 30.7 cm. A wide Dynamic range of 14 bits provides outstanding contrast resolution. The 100Hm pixel size provides an excellent balance of high spatial resolution, low image noise, processing speed, networking and storage efficiency. The GE Senographe Apollon X-ray Tube: This small, lightweight high performance tube contains a Molybdenum and Rhodium Bi-metal grounded anode, and is thus capable of producing excellent energy spectrum for imaging all breast types. The X-Ray Tube has 4 focal spots, with true 0.1 and 0.3 IEC on each target. The target Angle of 0 degree enables the tube to produce 40mA on a fine 0.1 focal spot. The GE Senographe Automatic Optimization of parameters (AOP) Exposure Control The fully automatic exposure system is capable of selecting each exposure parameter (kVp, mAs, anode and filter material), according to the radiological thickness of the breast tissue being examined. The AOP technique offers consistent repeatability and superior image quality of all breast tissue densities and all breast sizes, as	

Item No.	Qty	Catalog No.	Description	Ext Sell Price

the actual detector replaced an AEC cell The Three AOP modes (standard, contrast, or dose reduction mode) enable more flexibility in dose management

Sharp image acquisition and image processing

GE's image processing algorithms, Tissue Equalization and Premium View, are designed to improve both diagnostic image quality as well as reading speed.Both algorithms help reduce windowing manipulation, improve visualization of dense breast tissue, and maintain peripheral contrast at the skin line and pectoral muscle. And by reducing the needed number of image manipulations (WW/WL), these essential imaging capabilities can help increase reader productivity. Essential's standard Fine View feature further enhances image acquisition by optimizing local contrast in breast structures and sharpening visibility of lesions.

The Senographe Essential Ergonomics

The streamlined ergonomics of the gantry and the acquisition workstation operations enable faster, more efficient exams and help technologists focus on patient care rather than system operation. GE Essential platform enables either a standard 19x23cm field of view or a 24x31 cm Large Field of View. For this reason, flexible, off-centered ergonomic paddles are available as an option to allow excellent compression of smaller breasts and refined chest compression capabilities to improve both patient comfort and image accuracy. The systems are also designed with automatic collimation and paddle auto-detection The system provides Parameters Display, including Tube arm support angulation, Compressed breast thickness (in mm), compression force (in daN), and provides information on system status The operator console automates many of the typical technologist workflow steps. For example, once the laterality of the breast is indicated, the digital system identifies all other parameters and places a digital marker permanently on the image (AutoMark). This helps enable the technologist to focus on the patient rather than the system. The system has a patient friendly design, with secondary handles, for forearm support, and rounded bucky edges. The system helps enable easy wheelchair access due to the extensive vertical travel range from 650 to 1500 mm. The system also comes with an Acquisition Workstation that will immediately display the acquired

Item No.	Qty	Catalog No.	Description	Ext Sell Price

digital images in the room on a monitor. It provides a 'quick check' for technologists of image quality prior to image transmission to the Review Workstation.

Networking and Archiving

Senographe FFDM systems seamlessly integrate for digital workflow and connectivity. The Senographe Essential helps enable speed and efficiency, along with reliability of accurate information and improved patient care. Patient images can be sent automatically from Senographe FFDM systems to any DICOM compliant device, for example: PACS, printer CAS and review workstations.

Essential service and support. GE is a reliable partner there at all phases, from initial room design to ultimate online equipment monitoring and support. And it's all backed by the reliability and stability of GEs enduring commitment to healthcare.

Senographe Essential Specifications

DETECTOR: Optimized needle structure CsI scintillator Detector Size: 24 x 30.7 cm

TUBE TECHNOLOGY: X Ray Tube Type: Apollon Anode Target Materials: Dual Track, Molybdenum enriched with Vanadium and Rhodium Focal spots: 4 focal spots, 0.1 and 0.3 IEC on each target

GRID/BREAST SUPPORT

New ergonomic breast support for exceptional patient comfort and clean ability. Low attenuation carbon fiber composite Motorized mechanism and removal for optimized grid alignment. Grid Ratio 5:1 Detector to Breast Support front edge to edge distance < 4 mm; Breast Support: low attenuation carbon fiber composite Optimized Grid Motion ensuring no grid structure in the images Removable Potter-Bucky device including breast support and grid

AUTOMATIC EXPOSURE

Automatic Optimization of Parameters (AOP) AOP is a fully automatic exposure system selecting all exposure parameters based on radiological density of the breast for superior and consistent image quality, ensuring a total reproducibility of the exposure

Parameters optimized are: Track (Mo or Rh) Filter (Mo or Rh) KV mAs

Quotation Number: PR10-C4112 V 4

Item No.	Qty	Catalog No.	Description	Ext Sell Price

Three AOP modes are available for more flexibility: Contrast: priority to image quality with dose to patient comparable to screen/film mammography Dose: priority to dose reduction Standard: balances low image noise and dose reduction Manual mode: Manual selection of all parameters: track, filter, kVp and mAs

COLLIMATOR

Filter: molybdenum: 0.030 mm; rhodium: 0.025 mm Field of view (in detector plane): 24x31 cm2 in contact mode or 19x23 cm2 regular FOV (centered, off-centered left and right) based on the paddle inserted. Automatic selection based on bucky or magnification platform installed. Manual modification possible using the switch on tube head. Light centering device: light automatically switched on when a preset

position is reached or during compression. Can be turned on with a switch located on the tube head Improved Lamp Lifetime

COMPRESSION

Compression Modes: Motor driven compression up to 20 daN Manual Compression possible up to 27 daN Dual foot-pedals for column height and compression adjustments User defined compression force limit: 4-20 daN Min force for AOP: 3 daN Compression speed: 2 speed levels User can select automatic decompression after exposure to minimize patient time under compression User-defined maximum decompression height

MAGNIFICATION

1.5 and 1.8 magnification platforms, dedicated magnification paddles

POSITIONER

Isocentric arm with motorized rotation and vertical movement SID: 660 mm Distance floor to image receptor: from 650 to 1500 mm Rotation angle: -165/+185 degrees Ergonomic handles with additional handles at the detector level

User Interface 4 sets of dual speed switches for rotation and lift movements 4 sets of preset positions buttons for quick and easy positioning in CC and MLO Automatic Stop at +/- 90 degrees for lateral positions Parameters Display Tube arm support angulation: Compressed breast thickness (in mm) Compression force (in daN)

Quotation Number: PR10-C4112 V 4

Item No.	Qty	Catalog No.	Description	Ext Sell Price
			Ergonomic Control Console Controls exposure Provides information on system status Gives access to advanced parameters for System set up Patented automatic view names marking ACQUISITION WORKSTATION Small footprint Dose calculated and displayed on the image after every exposure (Entrance Skin Dose and Average Glandular Dose) Dual core Sun Ultra 20 M2 Image Presentation: Fine View provides sharp images based on detector physics. 2 options for primary image processing: Thickness Equalization which provides a "film-like" aspect with improved visibility of the skin line, and Premium View which optimizes the contrast locally and offers the possibility to reduce the reading time displaying all breast information at once. Automatic windowing (window level and window width) Other features: zoom, roaming, inversion, flip, rotation of images, window width and level setting, annotations and measurements. STANDARD CONFIGURATION Motorized Isocentric Gantry Apollon X-Ray Tube with Rotating Mo/Rh anode Flat Panel Detector Acquisition Workstation with UPS: Pair of dual foot-pedals High-frequency generator and conditioner Face shield 24x31 Bucky with Grid 19 x 23 Standard sliding paddle 24x31 Standard paddle Square spot sliding compression paddle Round spot sliding compression paddle 1.5 magnification stand with dedicated paddles 1.8 magnification stand with dedicated paddles InSite Modem Quality control toolkit - dependant on country Operating Manual in English Quality check manual in English AVAILABILITY Since Gold Seal Pre-owned Equipment may be Offered Simultaneously to Several Customers, Its Sale to You is Subject to Availability and Subject to Prior Sale at the Time You Offer to Purchase it. If the Equipment is no Longer Available, (1) We Will Attempt to Identify Other Gold Seal Pre-owned Equipment in Our Inventory That Meets Your Needs, and (2) If Substitute Equipment is Not Acceptable to You, We Will Cancel Your Order and Refund Any Deposit You Have Paid Us for the Canceled Order.	
2	1	S30331CA	Flexible and Ergonomic 24 x 31cm Compression Paddle	$1,959.06

Quotation Number: PR10-C4112 V 4

Item No.	Qty	Catalog No.	Description	Ext Sell Price
			Flexible and Ergonomic compression paddle 24 x 31cm for Senographe Essential The optional ergonomic 24x31 cm sliding paddle provides tilting and flexibility for better compression uniformity from chest wall to nipple. Positioning is made easier especially in MLO position for large pectoral muscle and in CC when chest wall and nipple side show large thickness variation. Patient comfort is improved by requiring less compression on pectoral muscle or chest wall to achieve proper compression on the whole breast.	
3	1	S30331CC	Sliding Flexible and Ergonomic 19 x 23 cm Compression Paddle Sliding Flexible and Ergonomic compression paddle 19 x 23 cm for Senographe Essential The optional ergonomic 19x23 cm sliding paddle provides tilting and flexibility for better compression uniformity from chest wall to nipple. It is used in combination with the 19x23 field of view. Positioning is made easier especially in MLO position for large pectoral muscle and in CC when chest wall and nipple side show large thickness variation. Patient comfort is improved by requiring less compression on pectoral muscle or chest wall to achieve proper compression on the whole breast.	$1,306.04
4	1	S30331B	2d Biopsy Optical Localiser 2D Biopsy Optical Localizer Includes: • 2D Cross-hair • 2D Large localization paddle • 2D Spot localization paddle	$2,098.99
5	1	E6315T	Mammography Accessories Cabinet GE Mammography Accessories Cabinet FEATURES/BENEFITS • Holds 9 Paddles, Mag Stand, QC Phantoms and more	$1,200.00

Quotation Number: PR10-C4112 V 4

Item No.	Qty	Catalog No.	Description	Ext Sell Price
			• Can be wall mounted or floor standing SPECIFICATIONS • Dimensions (L x W x H): 30.5" x 15.5" x 40.5" • Weight: 48 lbs.	

Quote Summary:

Total Quote Net Selling Price **$112,636.00**

(Quoted prices do not reflect state and local taxes if applicable. Total Net Selling Price Includes Trade In allowance, if applicable.)

GE Healthcare

QUOTATION

Quotation Number: PR1-C6097 V 1

Carolina Breast Imaging LLC
990 Johns Hopkins Dr
Greenville NC 27834-7224

Attn: Dr. Bruce Schroeder
Director
990 Johns Hopkins Dr
Greenville NC 27834

Date: 08-16-2013

This Agreement (as defined below) is by and between the Customer and the GE Healthcare business ("GE Healthcare"), each as identified herein. GE Healthcare agrees to provide and Customer agrees to pay for the Products listed in this GE Healthcare Quotation ("Quotation"). "Agreement" is defined as this Quotation and the terms and conditions set forth in either (i) the Governing Agreement identified below or (ii) if no Governing Agreement is identified, the following documents:

1) This Quotation that identifies the Product offerings purchased or licensed by Customer;

2) The following documents, as applicable, if attached to this Quotation: (i) GE Healthcare Warranty/ies; (ii) GE Healthcare Additional Terms and Conditions; (iii) GE Healthcare Product Terms and Conditions; and (iv) GE Healthcare General Terms and Conditions.

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This Quotation is subject to withdrawal by GE Healthcare at any time before acceptance. Customer accepts by signing and returning this Quotation or by otherwise providing evidence of acceptance satisfactory to GE Healthcare. Upon acceptance, this Quotation and the related terms and conditions listed above (or the Governing Agreement, if any) shall constitute the complete and final agreement of the parties relating to the Products identified in this Quotation. The parties agree that they have not relied on any oral or written terms, conditions, representations or warranties outside those expressly stated or incorporated by reference in this Agreement in making their decisions to enter into this Agreement. No agreement or understanding, oral or written, in any way purporting to modify this Agreement, whether contained in Customer's purchase order or shipping release forms, or elsewhere, shall be binding unless hereafter agreed to in writing by authorized representatives of both parties. Each party objects to any terms inconsistent with this Agreement proposed by either party unless agreed to in writing and signed by authorized representatives of both parties, and neither the subsequent lack of objection to any such terms, nor the delivery of the Products, shall constitute an agreement by either party to any such terms.

By signing below, each party certifies that it has not made any handwritten modifications. Manual changes or mark-ups on this Agreement (except signatures in the signature blocks and an indication in the form of payment section below) will be void.

- Terms of Delivery: FOB Destination
- Quotation Expiration Date: 10-21-2013
- Billing Terms: 100% billing at Ship Completion (Fulfillment) / Delivery
- Payment Terms: UPON RECEIPT
- Governing Agreement: None

Each party has caused this agreement to be signed by an authorized representative on the date set forth below. Please submit purchase orders to GE Healthcare
3200 N. Grandview Blvd., Mail Code WT-897, Waukesha, WI 53188

GE HEALTHCARE _____
Scott McCloskey Date
Product Sales Specialist

CUSTOMER

Bruce Schroeder 8/20/13
Authorized Customer Date

Bruce Schroeder, President
Print Name and Title

PO # TBD

10/20/13
Desired Equipment First Use Date

GE Healthcare will use reasonable efforts to meet Customer's desired equipment first use date. The actual delivery date will be mutually agreed upon by the parties.

INDICATE FORM OF PAYMENT:

(If there is potential to finance with a lease transaction, GE HFS or otherwise, select lease.)

____ Cash * ____ Lease ____ HFS Loan

If financing please provide name of finance company below*:

_____

*Selecting Cash or not identifying GE HFS as the finance company declines option for GE HFS financing.

Quotation Number: PR1-C6097 V 1

Item No.	Qty	Catalog No.	Description
	1		**Senographe Essential IB Options**
1	1	S30331CM	CESM OPTION WITH LICENSE

SenoBright Contrast Enhanced Spectral Mammography

SenoBright is an exciting innovation to help doctors in the diagnosis of breast diseases. Two images are provided for each of the standard CC and MLO views. The first image of each view represents a standard mammography view, while the second is a recombined iodine contrast-enhanced image.

A variety of technologies are combined to add this option to standard Senographe DS or Senographe Essential mammography systems. SenoBright performs data acquisition at multiple KV levels, spectrally filters the resulting x-rays to take advantage of typical attenuation curves of iodinated contrast agents, performs the data collection of these multiple energies of the x-ray profile and finally uses a patented recombination of the data to provide the resulting contrast-enhanced image.

Intended Use

Contrast Enhanced Spectral Mammography (CESM) is an extension of the existing indication for diagnostic mammography with the Senographe Essential or Senographe DS. The CESM application shall enable contrast enhanced breast imaging using a dual energy technique. This imaging technique can be used as an adjunct following mammography and ultrasound exams to localize a known or suspected lesion.

Compatibility

SenoBright is compatible with the following new GE Digital Mammography systems:

- Senographe Essential
- Senographe DS. In addition, all of the existing Senographe Essential and Senographe DS can be field upgraded to run SenoBright. Contact your GE Sales Representative with questions about compatibility.

SenoBright is DICOM compatible. Refer to the appropriate Senographe Essential or Senographe DS DICOM Conformance Statement for details.

SenoBright is compatible with the following workstations:

- IDI version 4.6 or higher (recommended)

Ergonomic design for technologists

- Simple user switching between standard mammography and Spectral Mammography mode

Quotation Number: PR1-C6097 V 1

Item No.	Qty	Catalog No.	Description

- Contrast media information can be stored with the images
- SenoBright provides a timer function to both monitor and record time after injection which is displayed as an annotated field in the images
- SenoBright offers both automated and manual exposure modes for the dual-energy exam
- SenoBright will automatically acquire the Spectral Mammography images for each view with a single action of the x-ray exposure control
- Dose information is provided, both for skin entrance and average glandular dose for each image of the Spectral Mammography acquisition

Simple review Workflow

- Automatic display and storage of "Low Energy" conventional images
- Automatic calculation, display and storage of the recombined iodine image

Patient Comfort

- Compression time for each view is designed to be a maximum of 15 seconds
- Depending on the patient and technologist, the entire imaging procedure can be completed in as little as 4 minutes following the contrast media injection
- As with our standard mammography systems, patients lying in a recumbent position can be examined with SenoBright

Filter

SenoBright chooses filtering materials depending on the operating mode and the exposure levels necessary. For the high-energy acquisition, a proprietary multi-layer filter is used to shape the resulting energies of the x-ray spectrum to those required to best highlight iodine.

Energy Levels

The energy levels will vary depending on the patient, specifically on the breast thickness within the range:

- 26-30 KVp for lower energy acquisition
- 45-49 KVp for higher energy acquisition

Quality Control

A dedicated quality control protocol is used for SenoBright, with the same phantoms used for Senographe DS and Senographe Essential

Quote Summary:

Total Quote Net Selling Price **$45,000.00**

GE Healthcare

QUOTATION

Quotation Number: PR1-C6097 V 1

Item No.	Qty	Catalog No.	Description
			(Quoted prices do not reflect state and local taxes if applicable. Total Net Selling Price Includes Trade In allowance, if applicable.)

GE Healthcare

QUOTATION

Quotation Number: PR9-C9578 V 1

Carolina Breast Imaging LLC
990 Johns Hopkins Dr
Greenville NC 27834-7224

Attn: Dr. Bruce Schroeder
Director
990 Johns Hopkins Dr
Greenville NC 27834

Date: 09-23-2013

This Agreement (as defined below) is by and between the Customer and the GE Healthcare business ("GE Healthcare"), each as identified herein. GE Healthcare agrees to provide and Customer agrees to pay for the Products listed in this GE Healthcare Quotation ("Quotation"). "Agreement" is defined as this Quotation and the terms and conditions set forth in either (i) the Governing Agreement identified below or (ii) if no Governing Agreement is identified, the following documents:

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2) The following documents, as applicable, if attached to this Quotation: (i) GE Healthcare Warranty(ies); (ii) GE Healthcare Additional Terms and Conditions; (iii) GE Healthcare Product Terms and Conditions; and (iv) GE Healthcare General Terms and Conditions.

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By signing below, each party certifies that it has not made any handwritten modifications. Manual changes or mark-ups on this Agreement (except signatures in the signature blocks and an indication in the form of payment section below) will be void.

- Terms of Delivery: FOB Destination
- Quotation Expiration Date: 12-22-2013
- Billing Terms: 100% billing at Ship Completion (Fulfillment) / Delivery
- Payment Terms: UPON RECEIPT
- Governing Agreement: None

Each party has caused this agreement to be signed by an authorized representative on the date set forth below. Please submit purchase orders to GE Healthcare
3000 N. Grandview Blvd., Mail Code WT-897, Waukesha, WI 53188

GE HEALTHCARE

Kimberly Allen
09-23-2013
Vaso Healthcare - Authorized Manufacturer Rep

CUSTOMER

Authorized Customer Date

Print Name and Title

PO #

Desired Equipment First Use Date

GE Healthcare will use reasonable efforts to meet Customer's desired equipment first use date. The actual delivery date will be mutually agreed upon by the parties.

INDICATE FORM OF PAYMENT:
(If there is potential to finance with a lease transaction, GE HFS or otherwise, select lease.)
____ Cash * ____ Lease ____ HFS Loan
If financing please provide name of finance company below*:

*Selecting Cash or not identifying GE HFS as the finance company declines option for GE HFS financing.

GE Healthcare

QUOTATION

Quotation Number: PR9-C9578 V 1

Item No.	Qty	Catalog No.	Description	Ext Sell Price
	1		**Senographe Essential IB Options**	
1	1	W0001MM	1 Day MM TiP Onsite Training	$2,750.00
			1 Day MM TiP Onsite Training One Day MM Onsite Training provided from 8AM to 5PM, Monday through Friday. Includes T&L expenses. This training program must be scheduled and completed within 12 months after the date of product delivery.	

Quote Summary:

Total Quote Net Selling Price **$2,750.00**

(Quoted prices do not reflect state and local taxes if applicable. Total Net Selling Price Includes Trade In allowance, if applicable.)

EXPERT X-RAY
A Sales and Service Company

INVOICE

P.O. BOX 2556
HENDERSON, NC 27536
Phone 252-432-0884 Fax 252-431-0886

INVOICE #2140
DATE: JULY 23, 2013

TO:
DR. BRUCE SCHROEDER
CAROLINA BREAST IMAGING LLC
990 JOHNS HOPKINS DRIVE
GREENVILLE, NC 27834
Phone 252-414-9348

SHIP TO:
DR. BRUCE SCHROEDER
CAROLINA BREAST IMAGING LLC
990 JOHNS HOPKINS DRIVE
GREENVILLE, NC 27834
Phone 252-414-9348

COMMENTS OR SPECIAL INSTRUCTIONS:

TOTAL COST INCLUDES DELIVERY AND INSTALLATION

SALESPERSON	P.O. NUMBER	PURCHASER	SHIPPED VIA	F.O.B. POINT	TERMS
L NOEL		SCHROEDER	BEST WAY		NET 30

QUANTITY	DESCRIPTION	UNIT PRICE	TOTAL
1	CERTIFIED PRE-OWNED MEDRAD ENVISION CT INJECTOR	$6,700.00	$6,700.00

SUBTOTAL	$6,700.00
SALES TAX	452.25
SUBTOTAL	$7,152.25
PAYMENTS	$7,152.25
TOTAL DUE	$0.00

Make all checks payable to **EXPERT X-RAY**
If you have any questions concerning this invoice, contact LORELEI WINCKLER 252-425-4948

THANK YOU FOR YOUR BUSINESS!

GE Healthcare

QUOTATION

Quotation Number: PR10-C4115 V 4

Carolina Breast Imaging LLC
990 Johns Hopkins Dr
Greenville NC 27834-7224

Attn: Dr. Bruce Schroeder
Director
990 Johns Hopkins Dr
Greenville NC 27834

Date: 09-18-2013

This Agreement (as defined below) is by and between the Customer and the GE Healthcare business ("GE Healthcare"), each as identified herein. GE Healthcare agrees to provide and Customer agrees to pay for the Products listed in this GE Healthcare Quotation ("Quotation"). "Agreement" is defined as this Quotation and the terms and conditions set forth in either (i) the Governing Agreement identified below or (ii) if no Governing Agreement is identified, the following documents:

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- Terms of Delivery: FOB Destination
- Quotation Expiration Date: 09-27-2013
- Billing Terms: 80% delivery / 20% Installation
- Payment Terms: UPON RECEIPT
- Governing Agreement: None

Each party has caused this agreement to be signed by an authorized representative on the date set forth below. Please submit purchase orders to GE Healthcare
3000 N. Grandview Blvd., Mail Code WT-897, Waukesha, WI 53188

GE HEALTHCARE

Kimberly Allen
09-18-2013
Vaso Healthcare - Authorized Manufacturer Rep

CUSTOMER

Authorized Customer Date

Print Name and Title

PO #

Desired Equipment First Use Date

GE Healthcare will use reasonable efforts to meet Customer's desired equipment first use date. The actual delivery date will be mutually agreed upon by the parties.

INDICATE FORM OF PAYMENT:
(If there is potential to finance with a lease transaction, GE HFS or otherwise, select lease.)
____ Cash * ____ Lease ____ HFS Loan
If financing please provide name of finance company below*:

*Selecting Cash or not identifying GE HFS as the finance company declines option for GE HFS financing.

Quotation Number: PR10-C4115 V 4

Item No.	Qty	Catalog No.	Description	Ext Sell Price
	1		**Goldseal Senographe Essential Madras**	
1	1	L3034AM	GS ESSENTIAL MADRAS	$106,071.91
			GoldSeal Senographe Essential	
			The GE Senographe Essential FFDM units eliminate the need for film cassettes, and take advantage of digital technology advances including fast image acquisition, quick on-screen image display, networking flexibility, auto or manual filming, and efficient exam archiving. In addition, the Senographe Essential's streamlined ergonomics help allow technologists to focus on patients and the outstanding image quality helps provide healthcare professionals with greater diagnostic confidence. The Senographe Essential's digital workflow and connectivity helps enable speed and efficiency, along with reliability of accurate information and improved patient care.	
			The system includes:	
			The GE Senographe Detector Platform	
			A Single Amorphous Silicon, Cesium Iodide-Based Detector with an independently optimized component matrix, CsI needle structure and an Active Area of 24 x 30.7 cm. A wide Dynamic range of 14 bits provides outstanding contrast resolution. The 100Hm pixel size provides an excellent balance of high spatial resolution, low image noise, processing speed, networking and storage efficiency.	
			The GE Senographe Apollon X-ray Tube:	
			This small, lightweight high performance tube contains a Molybdenum and Rhodium Bi-metal grounded anode, and is thus capable of producing excellent energy spectrum for imaging all breast types. The X-Ray Tube has 4 focal spots, with true 0.1 and 0.3 IEC on each target. The target Angle of 0 degree enables the tube to produce 40mA on a fine 0.1 focal spot.	
			The GE Senographe Automatic Optimization of parameters (AOP) Exposure Control	
			The fully automatic exposure system is capable of selecting each exposure parameter (kVp, mAs, anode and filter material), according to the radiological thickness of the breast tissue being examined. The AOP technique offers consistent repeatability and superior image quality of all breast tissue densities and all breast sizes, as	

Item No.	Qty	Catalog No.	Description	Ext Sell Price

the actual detector replaced an AEC cell The Three AOP modes (standard, contrast, or dose reduction mode) enable more flexibility in dose management

Sharp image acquisition and image processing

GE's image processing algorithms, Tissue Equalization and Premium View, are designed to improve both diagnostic image quality as well as reading speed.Both algorithms help reduce windowing manipulation, improve visualization of dense breast tissue, and maintain peripheral contrast at the skin line and pectoral muscle. And by reducing the needed number of image manipulations (WW/WL), these essential imaging capabilities can help increase reader productivity. Essential's standard Fine View feature further enhances image acquisition by optimizing local contrast in breast structures and sharpening visibility of lesions.

The Senographe Essential Ergonomics

The streamlined ergonomics of the gantry and the acquisition workstation operations enable faster, more efficient exams and help technologists focus on patient care rather than system operation. GE Essential platform enables either a standard 19x23cm field of view or a 24x31 cm Large Field of View. For this reason, flexible, off-centered ergonomic paddles are available as an option to allow excellent compression of smaller breasts and refined chest compression capabilities to improve both patient comfort and image accuracy. The systems are also designed with automatic collimation and paddle auto-detection The system provides Parameters Display, including Tube arm support angulation, Compressed breast thickness (in mm), compression force (in daN), and provides information on system status The operator console automates many of the typical technologist workflow steps. For example, once the laterality of the breast is indicated, the digital system identifies all other parameters and places a digital marker permanently on the image (AutoMark). This helps enable the technologist to focus on the patient rather than the system. The system has a patient friendly design, with secondary handles, for forearm support, and rounded bucky edges. The system helps enable easy wheelchair access due to the extensive vertical travel range from 650 to 1500 mm. The system also comes with an Acquisition Workstation that will immediately display the acquired

Item No.	Qty	Catalog No.	Description	Ext Sell Price

digital images in the room on a monitor. It provides a 'quick check' for technologists of image quality prior to image transmission to the Review Workstation.

Networking and Archiving

Senographe FFDM systems seamlessly integrate for digital workflow and connectivity. The Senographe Essential helps enable speed and efficiency, along with reliability of accurate information and improved patient care. Patient images can be sent automatically from Senographe FFDM systems to any DICOM compliant device, for example: PACS, printer CAS and review workstations.

Essential service and support. GE is a reliable partner there at all phases, from initial room design to ultimate online equipment monitoring and support. And it's all backed by the reliability and stability of GEs enduring commitment to healthcare.

Senographe Essential Specifications

DETECTOR: Optimized needle structure CsI scintillator Detector Size: 24 x 30.7 cm

TUBE TECHNOLOGY: X Ray Tube Type: Apollon Anode Target Materials: Dual Track, Molybdenum enriched with Vanadium and Rhodium Focal spots: 4 focal spots, 0.1 and 0.3 IEC on each target

GRID/BREAST SUPPORT

New ergonomic breast support for exceptional patient comfort and clean ability. Low attenuation carbon fiber composite Motorized mechanism and removal for optimized grid alignment. Grid Ratio 5:1 Detector to Breast Support front edge to edge distance < 4 mm; Breast Support: low attenuation carbon fiber composite Optimized Grid Motion ensuring no grid structure in the images Removable Potter-Bucky device including breast support and grid

AUTOMATIC EXPOSURE

Automatic Optimization of Parameters (AOP) AOP is a fully automatic exposure system selecting all exposure parameters based on radiological density of the breast for superior and consistent image quality, ensuring a total reproducibility of the exposure

Parameters optimized are: Track (Mo or Rh) Filter (Mo or Rh) KV mAs

Item No.	Qty	Catalog No.	Description	Ext Sell Price

Three AOP modes are available for more flexibility: Contrast: priority to image quality with dose to patient comparable to screen/film mammography Dose: priority to dose reduction Standard: balances low image noise and dose reduction Manual mode: Manual selection of all parameters: track, filter, kVp and mAs

COLLIMATOR

Filter: molybdenum: 0.030 mm; rhodium: 0.025 mm Field of view (in detector plane): 24x31 cm2 in contact mode or 19x23 cm2 regular FOV (centered, off-centered left and right) based on the paddle inserted. Automatic selection based on bucky or magnification platform installed. Manual modification possible using the switch on tube head. Light centering device: light automatically switched on when a preset

position is reached or during compression. Can be turned on with a switch located on the tube head Improved Lamp Lifetime

COMPRESSION

Compression Modes: Motor driven compression up to 20 daN Manual Compression possible up to 27 daN Dual foot-pedals for column height and compression adjustments User defined compression force limit: 4-20 daN Min force for AOP: 3 daN Compression speed: 2 speed levels User can select automatic decompression after exposure to minimize patient time under compression User-defined maximum decompression height

MAGNIFICATION

1.5 and 1.8 magnification platforms, dedicated magnification paddles

POSITIONER

Isocentric arm with motorized rotation and vertical movement SID: 660 mm Distance floor to image receptor: from 650 to 1500 mm Rotation angle: -165/+185 degrees Ergonomic handles with additional handles at the detector level

User Interface 4 sets of dual speed switches for rotation and lift movements 4 sets of preset positions buttons for quick and easy positioning in CC and MLO Automatic Stop at +/- 90 degrees for lateral positions Parameters Display Tube arm support angulation: Compressed breast thickness (in mm) Compression force (in daN)

Quotation Number: PR10-C4115 V 4

Item No.	Qty	Catalog No.	Description	Ext Sell Price

Ergonomic Control Console Controls exposure Provides information on system status Gives access to advanced parameters for System set up Patented automatic view names marking

ACQUISITION WORKSTATION

Small footprint

Dose calculated and displayed on the image after every exposure (Entrance Skin Dose and Average Glandular Dose) Dual core Sun Ultra 20 M2 Image Presentation: Fine View provides sharp images based on detector physics. 2 options for primary image processing: Thickness Equalization which provides a "film-like" aspect with improved visibility of the skin line, and Premium View which optimizes the contrast locally and offers the possibility to reduce the reading time displaying all breast information at once. Automatic windowing (window level and window width) Other features: zoom, roaming, inversion, flip, rotation of images, window width and level setting, annotations and measurements.

STANDARD CONFIGURATION

Motorized Isocentric Gantry Apollon X-Ray Tube with Rotating Mo/Rh anode Flat Panel Detector Acquisition Workstation with UPS: Pair of dual foot-pedals High-frequency generator and conditioner Face shield 24x31 Bucky with Grid 19 x 23 Standard sliding paddle 24x31 Standard paddle Square spot sliding compression paddle Round spot sliding compression paddle 1.5 magnification stand with dedicated paddles 1.8 magnification stand with dedicated paddles InSite Modem Quality control toolkit - dependant on country Operating Manual in English Quality check manual in English

AVAILABILITY

Since Gold Seal Pre-owned Equipment may be Offered Simultaneously to Several Customers, Its Sale to You is Subject to Availability and Subject to Prior Sale at the Time You Offer to Purchase it. If the Equipment is no Longer Available, (1) We Will Attempt to Identify Other Gold Seal Pre-owned Equipment in Our Inventory That Meets Your Needs, and (2) If Substitute Equipment is Not Acceptable to You, We Will Cancel Your Order and Refund Any Deposit You Have Paid Us for the Canceled Order.

Quotation Number: PR10-C4115 V 4

Item No.	Qty	Catalog No.	Description	Ext Sell Price

Quote Summary:

Total Quote Net Selling Price **$106,071.91**

(Quoted prices do not reflect state and local taxes if applicable. Total Net Selling Price Includes Trade In allowance, if applicable.)

GE Healthcare

QUOTATION

Quotation Number: PR9-C4125 Version 3

Carolina Breast Imaging LLC
990 Johns Hopkins Dr
Greenville NC 27834-7224

Attn: Dr. Bruce Schroeder
Director
990 Johns Hopkins Dr
Greenville NC 27834

Date: 08-28-2013

This Agreement (as defined below) is by and between the Customer and the GE Healthcare business ("GE Healthcare"), each as identified herein. GE Healthcare agrees to provide and Customer agrees to pay for the Products listed in this GE Healthcare Quotation ("Quotation"). "Agreement" is defined as this Quotation and the terms and conditions set forth in either (i) the Governing Agreement identified below or (ii) if no Governing Agreement is identified, the following documents:

1) This Quotation that identifies the Product offerings purchased or licensed by Customer;

2) The following documents, as applicable, if attached to this Quotation: (i) GE Healthcare Warranty(ies); (ii) GE Healthcare Additional Terms and Conditions; (iii) GE Healthcare Product Terms and Conditions; and (iv) GE Healthcare General Terms and Conditions.

In the event of conflict among the foregoing items, the order of precedence is as listed above.

This Quotation is subject to withdrawal by GE Healthcare at any time before acceptance. Customer accepts by signing and returning this Quotation or by otherwise providing evidence of acceptance satisfactory to GE Healthcare. Upon acceptance, this Quotation and the related terms and conditions listed above (or the Governing Agreement, if any) shall constitute the complete and final agreement of the parties relating to the Products identified in this Quotation. The parties agree that they have not relied on any oral or written terms, conditions, representations or warranties outside those expressly stated or incorporated by reference in this Agreement in making their decisions to enter into this Agreement. No agreement or understanding, oral or written, in any way purporting to modify this Agreement, whether contained in Customer's purchase order or shipping release forms, or elsewhere, shall be binding unless hereafter agreed to in writing by authorized representatives of both parties. Each party objects to any terms inconsistent with this Agreement proposed by either party unless agreed to in writing and signed by authorized representatives of both parties, and neither the subsequent lack of objection to any such terms, nor the delivery of the Products, shall constitute an agreement by either party to any such terms.

By signing below, each party certifies that it has not made any handwritten modifications. Manual changes or mark-ups on this Agreement (except signatures in the signature blocks and an indication in the form of payment section below) will be void.

- Terms of Delivery: FOB Shipping Point
- Quotation Expiration Date: 09-19-2013
- Billing Terms: 100% billing at delivery
- Payment Terms: 30 DAYS NET
- Governing Agreement: None: Standard GEHC Quote Terms Apply

RETURN TO: GE Healthcare LUNAR, 3030 Ohmeda Drive, Madison, WI 53718, Fax: 608-237-2537
Each party has caused this Agreement to be signed by an authorized representative on the date set forth below.
www.gehealthcare.com

GE HEALTHCARE
Scott McCloskey
Product Sales Specialist

CUSTOMER
Authorized Customer — Date: 8/29/13
Bruce Schroeder
Print or Type Name
President
Title

INDICATE FORM OF PAYMENT:
(If there is potential to finance with a lease transaction, GE HFS or otherwise, select lease.)
____ Cash * ____ Lease ____ HFS Loan
If financing please provide name of finance company below*:

*Selecting Cash or not identifying GE HFS as the finance company declines option for GE HFS financing.

Quotation Number: PR9-C4125 Version 3

Item No.	QTY	CATALOG	DESCRIPTION
	1		**PRODIGY PRO FULL USA REFURB**
1	1	L9377PF	Certified Pre-Owned Prodigy Full Size Certified Pre-Owned Prodigy Full Size. Standard options include: Windows platform featuring enCORE with FRAX (WHO Fracture Risk Assessment Tool), AP Spine, Single Femur, Total Body BMD, Body Composition, and OneVision. The "Certified Pre-Owned" program allows the ownership of a world-class BMD system at an affordable price. The units are fully tested by highly qualified and well trained technicians. A certified pre-owned system is service contract ready (system does not need to be inspected prior to purchase of a service contract) and a world-class service support team is ready to serve the level of support purchased. 1-Year Warranty Included.
2	1	H8604WP	Prodigy-DPX Business Desktop PC, Windows 7, SFF HP Compaq 6000 Pro Business PC, Small Form Factor - Operating System: Windows 7 Professional - Processor: Intel Pentium E6800 Processor - Chipset: Q43 Express - RAM: 2GB PC3-10600 Memory (1x2GB) - Hard Drive: 160GB SATA 3.5 Gb/s - External Hard Drive: USB, 320GB - CD/DVD: SATA DVD Writer Drive - Graphics: Integrated Intel Graphics Media Accelerator 4500 - Networking: Integrated Intel 82567LM Gigabit Network Connection - I/O Ports: 10 USB 2.0 (4 front, 6 rear), 1 serial, 1 optional serial, 1 optional parallel, 2 PS/2, 1 RJ-45, 1 VGA, 1 DVI-D, 4 audio ports (line in, line out, microphone, headphone) - USB Keyboard and Mouse
3	1	H8625LB	17" LCD Monitor 17" Flat Panel LCD Monitor
4	1	H8625SD	Lunar Premium Printer HP OfficeJet Pro 8000 - Color Ink Jet Printer
5	1	H8699SD	Workstation Cart Computer Table, Mobile, 2 Tier, 64 cm W x 74 cm D x 72 cm T.
6	1	H8650DF	DualFemur Software

Quotation Number: PR9-C4125 Version 3

Item No.	QTY	CATALOG	DESCRIPTION
			Automated acquisition and analysis of bi-lateral femurs for better patient monitoring and additional diagnostic confidence.
7	1	H8650FA	Forearm Positioner and Software Potential third exam site with easy patient potitioning at the edge of the table top. Forearm software allows the measurement of the forearm BMD (UD 1/3 and Total ROI) at the radius and the ulna. Provided with forearm positioner.
8	1	H8650TB	Total Body BMD Software Provides overall skeletal assessment at a fraction of the dose of other scan sites
9	1	H8650BC	SW, Body Comp enCORE Body Composition Assessment Software
10	1	H8650NS	SW, oneVision one Vision Report + Protocols Software
11	1	H8650DA	DVA: Dual-energy Vertebral Assessment enCORE Dual Vertebral Assessment Software Kit provides both dual- &/or single-energy views of lumbar & thoracic vertebrae in one fast acquisition. The automated analysis reports the type and severity of deformities based on patient height. Both AP and lateral imaging included.
12	1	H8650BR	SW, Practice Management Tools enCORE Practice Management Tools
13	1	H8650SC	OneScan Software Simplified exam process & improved precision. Both AP Spine & DualFemur exams in a single acquisition, eliminating patient repositioning.
14	1	H8650CD	ScanCheck ScanCheck, formerly known as Computer-Assisted Densitometry (CAD), assists the user in detecting Spine, Femur, Forearm and Total Body abnormalities. ScanCheck provides guidelines to minimize operator error through automatic identification of potential measurement and/or analysis errors. ScanCheck assesses consistency of the current scan to the previous scan. When potential anomalies are identified, helpful instructions are displayed as well as multimedia help. A checklist of measurement and analysis tasks is available to ensure correct analysis, facilitate interpretation by doctor, and make an integrated assessment.

Quotation Number: PR9-C4125 Version 3

Item No.	QTY	CATALOG	DESCRIPTION
15	1	H8650PD	SW PEDIATRIC ENABLED Pediatric Software Specialized Spine and Total Body Analysis Software for Patients 5-19 Years Old
16	1	H8650PF	SW PED FEMUR, ENCORE Allows measurement of femur BMD for pediatric. The ROI are adjusted to the Patient's height.
17	1	H8650CM	Composer Physician's Reporting Software Quickly create printed or electronic reports customized for the patient or physician. Includes 10-year Fracture Risk probability calculator. Eliminates dictation for the reading physician. Easily integrates with your EMR system via HL7 or into your PACS via color or black & white DICOM reports.
18	1	H8650DC	DICOM Complete DICOM package with store, worklist, and printing capabilities. Send customized DICOM patient and physician reports, or separate bone images. Color reports standard. IHE compliant.
19	1	H8650HL	SW, Ambassador HL7 enCORE Ambassador HL7 Worklist Interface
20	1	H8650PS	UPS (110v) Uninterruptable Power Supply (110v)
21	1	H8601AM	PRDGY DST FULL USA Destination Kit - Manuals, Decals, Voltages to Meet Local Requirements, USA
22	2	H8680DA	Standard 1-day On-Site Applications Training Standard 1-day On-Site Applications Training: Initial 1 day of Training Consecutive to Installation: Comprehensive on-site education and training for up to 6 hours of Continuing Education Units (CEUs).

Quote Summary:

Total Quote Net Selling Price **$23,884.00**

(Quoted prices do not reflect state and local taxes if applicable.)

Quotation Number: PR9-C4125 Version 3

Item No.	QTY	CATALOG	DESCRIPTION

If the Terms of Delivery as set forth on Page 1 of this Quotation are FOB Shipping Point, freight charges of $950 will be added to the order for all Lunar DXA Bone Mineral Densitometer tables, $150 will be added for Achilles Insight or Express Ultrasonometers, and $200 will be added for InBody 230-720 products. If purchasing Lunar DXA table(s) in combination with Achilles Ultrasonometer or InBody 230-720, freight charges apply to Lunar DXA table(s) only. GE Healthcare shall contract with and pay the freight carrier and shall arrange for or provide insurance on behalf of the Customer against property damage or loss until delivery to Customer's site, subject to payment of above-stated freight charges by Customer to GE Healthcare, if applicable. Title and risk of ownership passes to Customer at FOB point. Further, freight charges will not apply to orders under any pre-existing contracts stating different delivery/freight payment terms for Enterprise Accounts, Corporate Accounts, Buying Groups, or Government Customers.

GE Healthcare

QUOTATION

Quotation Number: PR6-C4528 Version 4

Carolina Breast Imaging LLC
990 Johns Hopkins Dr
Greenville NC 27834-7224

Attn: Dr. Bruce Schroeder
Director
990 Johns Hopkins Dr
Greenville NC 27834

Date: 08-30-2013

This Agreement (as defined below) is by and between the Customer and the GE Healthcare business ("GE Healthcare"), each as identified herein. GE Healthcare agrees to provide and Customer agrees to pay for the Products listed in this GE Healthcare Quotation ("Quotation"). "Agreement" is defined as this Quotation and the terms and conditions set forth in either (i) the Governing Agreement identified below or (ii) if no Governing Agreement is identified, the following documents:

1) This Quotation that identifies the Product offerings purchased or licensed by Customer;

2) The following documents, as applicable, if attached to this Quotation: (i) GE Healthcare Warranty(ies); (ii) GE Healthcare Additional Terms and Conditions; (iii) GE Healthcare Product Terms and Conditions; and (iv) GE Healthcare General Terms and Conditions.

In the event of conflict among the foregoing items, the order of precedence is as listed above.

This Quotation is subject to withdrawal by GE Healthcare at any time before acceptance. Customer accepts by signing and returning this Quotation or by otherwise providing evidence of acceptance satisfactory to GE Healthcare. Upon acceptance, this Quotation and the related terms and conditions listed above (or the Governing Agreement, if any) shall constitute the complete and final agreement of the parties relating to the Products identified in this Quotation. The parties agree that they have not relied on any oral or written terms, conditions, representations or warranties outside those expressly stated or incorporated by reference in this Agreement in making their decisions to enter into this Agreement. No agreement or understanding, oral or written, in any way purporting to modify this Agreement, whether contained in Customer's purchase order or shipping release forms, or elsewhere, shall be binding unless hereafter agreed to in writing by authorized representatives of both parties. Each party objects to any terms inconsistent with this Agreement proposed by either party unless agreed to in writing and signed by authorized representatives of both parties, and neither the subsequent lack of objection to any such terms, nor the delivery of the Products, shall constitute an agreement by either party to any such terms.

By signing below, each party certifies that it has not made any handwritten modifications. Manual changes or mark-ups on this Agreement (except signatures in the signature blocks and an indication in the form of payment section below) will be void.

- Terms of Delivery: FOB Destination
- Quotation Expiration Date: 09-20-2013
- Billing Terms: 100% billing at delivery
- Payment Terms: 30 DAYS NET
- Governing Agreement: None: Standard GEHC Quote Terms Apply

RETURN TO: GE Ultrasound OTR, 9900 Innovation Dr, Wauwatosa, WI 53226.
Each party has caused this Agreement to be signed by an authorized representative on the date set forth below.
www.gehealthcare.com

GE HEALTHCARE

Scott Turner
Sales Specialist - GI Ultrasound
US
Phone: (704) 517-2657
FAX: (704) 973-0170
Scott.S.Turner@ge.com

CUSTOMER

Customer Authorized Representative / Date

Bruce Schroeder
Print Name

President
Title

INDICATE FORM OF PAYMENT:
(If there is potential to finance with a lease transaction, GE HFS or otherwise, select lease.)
____ Cash * ____ Lease ____ HFS Loan
If financing please provide name of finance company below*:

*Selecting Cash or not identifying GE HFS as the finance company declines option for GE HFS financing.

GE Healthcare

QUOTATION

Quotation Number: PR6-C4528 Version 4

QTY	CATALOG	DESCRIPTION	Ext Sell Price
1		**LOGIQ S8 BT11 DEMO**	
1	H45362LJ	LOGIQ S8 BT 11 USA Standard LOGIQ S8 general imaging ultrasound system provides superb image quality, simplified workflow and can be suited to your needs. Built upon Agile Acoustic Architecture technology, the LOGIQ S8 helps you achieve superb images even on your most difficult patients using innovative tools including CrossXBeam (Spatial Compounding), SRI HD (Speckle Reduction Imaging in High Definition), and Coded Harmonics. Productivity increases through many features such as Raw Data for post-processing of images, Automatic Optimization, Advanced 3D (w/ multiplanar displays) and Virtual Convex. Advanced ergonomics include a 19 inch color flat panel monitor (1280x1024) with fully articulating arm, fully adjustable console, 9.0 inch wide color LCD touch screen, four active transducer ports plus one parking port and an integrated gel warmer. Scanning modes include B-Mode, M-Mode, Color Flow, Pulsed Wave, and Power Doppler. Other system features include: 384MB cine memory, approximately160 GB internal hard drive, footrest, user programmable presets and digital copy of user documentation (eDocs). A DICOM software package providing provides Verify, Print, Store, Multiframe, Modality Worklist, MPPS (Modality Performed Procedure Step), Storage Commitment, and Media Exchange. Additionally, the LOGIQ S8 supports Multi-Modality Query Retrieve and Structured Reporting. Does not include network hardware, which may be required. Initial installation includes connection to customer network, a one-year warranty and three days of On-site Applications Training. Additional On-site Applications Training days are available for purchase. Attendance to advanced technology training at the GE Healthcare Education Center in Metro Milwaukee can be purchased separately.	$51,172.98
1	H40452LG	ML6-15-D Matrix Linear Array Transducer Matrix array broad-spectrum linear transducer. Applications include: small parts, vascular, pediatrics, neonatal, breast, thyroid, scrotal. Biopsy kit available.	$5,040.02
1	H4110JA	Demo Equipment This document describes an offer to sell demo ultrasound equipment. Pricing set forth in this quote is not valid for new equipment. Subject to availability.	Incl.
		Quote Summary:	
		Total List Price:	**$200,760.00**

GE Healthcare

QUOTATION

Quotation Number: PR6-C4528 Version 4

QTY	CATALOG	DESCRIPTION	Ext Sell Price
		Total Discount	**($144,547.00)**
		Total Quote Net Selling Price	**$56,213.00**
		(Quoted prices do not reflect state and local taxes if applicable.)	

Questions? Call Scott Turner at (704) 517-2657.

Appendix 5

faxitron®

3440 E Britannia Drive, Suite 150
Tucson, AZ, 85706
faxitron.com

CONFIDENTIAL

Carolina Breast Imaging LLC.
990 Johns Hopkins Dr.
Greenville, NC 27834
252.565.8670

DATE:	20 August 2013
Quote #:	130820-JD1
Customer RFQ #:	N/A
Quotation valid until:	04 October 2013
Sales Manager:	Jason Dyer
FOB:	Tucson, AZ
Freight:	Prepay & Add
Terms:	20 % Down/80% Net 15
Estimated Ship Date:	**30 Days ARO**

Qty	Product - Description	Price Each	Total Price
1	**CoreVision - 5x10 Demo Unit** Digital Core Biopsy Radiography system 50mm x 100mm FOV Compact and self contained One-button operation with automatic exposure control DICOM Compliant with store, print and modality work list features High resolution 2.3 MP flat-panel LCD monitor Note: Taxes and Freight not included in price.	**$ 59,900**	**$ 59,900**
	Demo Purchase Price		**$ (39,900)**
	System Purchase Price		**$ 20,000**

Quotation Summary		Total Price
This is a quotation on the goods named, subject to company's standard terms and conditions which can be reviewed at www.faxitron.com	System Price	$ 59,900
	Preferred Discount	$ (39,900)
Customer Signature:	**Total**	$ 20,000

Notes

Any questions please contact :
Jason Dyer
E: jdyer@faxitron.com
T: 520.399.8180
F: 520.399.8182
C: 919.906.3452

THANK YOU FOR CHOOSING FAXITRON

Appendix 6

iCAD, Inc.
iCAD RSM Name: Kerry Schofield
98 Spit Brook Road, Suite 100
Nashua, NH03062
Phone: (603) 882-5200Fax: (603) 880-3843
www.icadmed.com

Facility:	Carolina Breast Imaging Specialists, PLLC	**Date:**	9/18/2013
Contact Name:	Bruce Schroeder	**Quote #:**	2657_v9
Title/Department:	Radiologist	**iCAD Sales Manager**	Kerry Schofield
Billing Address:	990 John Hopkins Drive Greenville, NC 27834	**Installation Address:**	990 John Hopkins Drive Greenville, NC 27834
Telephone #:	(252) 414-9348	**License Term Start Date:**	
Email Address:	schroeder@cbispecialists.com	**Serial Number:**	

iCAD, Inc. is pleased to submit the following quotation and offers to sell the products described at the prices below, subject to iCAD's Platinum Service and License Agreement Terms and Conditions of Sale. (Quote valid for 30 days). This Quote shall, once signed by the parties, be deemed a Product Order Form as defined in the Platinum Service and License Agreement Terms and Conditions of Sale.

Part Number	Description	Qty	Term	List Price	Sale Price	Extended Price
DSC010-01-US-A	**GE Platinum PowerLook AMP** 1 Year Platinum Initial License Agreement Includes license of CAD system for the early detection of breast cancer. Includes annual license of computer, initial port, installation and applications training. Unlimited telephone technical support, Remote internet support, On-site labor during standard business hours, Software updates and upgrades, Hardware refreshes, as determined by iCAD, Replacement parts; Installation and training, as deemed necessary by iCAD. Review exhibit A for service hours of operation. *Requires VPN Access Bill license annually unless otherwise specified in the special instructions $5,900.00 -	1	1	$11,500.00	$5,900.00	$5,900.00
D70079	**Additional Port License Kit** 1 Year Platinum Initial License Agreement Annual Service and License Agreement Add up to three additional ports per CAD server $1,000.00 -	1	1	$2,000.00	$1,000.00	$1,000.00
					Grand Total:	**$6,900.00**

iCAD, Inc.
iCAD RSM Name: Kerry Schofield
98 Spit Brook Road, Suite 100
Nashua, NH03062
Phone: (603) 882-5200Fax: (603) 880-3843
www.icadmed.com

Terms and Conditions of Purchase:

1. Net 30 (with approved credit terms)
2. FOB Origin
3. Freight – prepaid and add
4. In order to purchase the Volpara Breast Density Solution, Customer shall be obligated to purchase no less than (a) a three year annual service and license term for such Volpara Breast Density Solution and (b) no less than a three year Platinum Annual Service and License term for Platinum PowerLook AMP
5. Refunds are not available on purchases cancelled part way through the committed term

Please Note:

This price does not include any applicable state or local sales, use or excise taxes, which are customer's responsibility. Invoice will be broken down by line-item to meet Federal Auditing Standards.

Installation and Training are expected to be performed at the same time. If your staff is not available for training at the time of installation, and successive Training sessions are required, then a Purchase Order for the Training Session must be submitted to schedule the session.

Unit must be in working order and pass system verification to be eligible for upgrade

iCAD, Inc.
iCAD RSM Name: Kerry Schofield
98 Spit Brook Road, Suite 100
Nashua, NH03062
Phone: (603) 882-5200Fax: (603) 880-3843
www.icadmed.com

iCAD Platinum Service and License Agreement Term and Conditions

This iCAD Platinum Service and License Agreement Terms and Conditions (the "Agreement"), effective as the date below (the "Effective Date"), is entered into by and between iCAD, Inc., a Delaware corporation, with a principal place of business at 98 Spit Brook Road, Suite 100, Nashua, NH 03062 ("iCAD"), Carolina Breast Imaging Specialists, PLLC , a NC corporation with a principal place of business at 990 John Hopkins Drive, Greenville,NC,27834 ("Customer"). Customer agrees to be bound by the following terms and conditions in connection with its purchase and use of iCAD Products and Services

1. DEFINITIONS

1.1 "Designated Site" means a specific Customer location(s) set forth on the Product Order Form where Customer may install and use the Products.
1.2 "Documentation" means the published and generally available user manuals and written materials iCAD delivers or makes available with the Products.

1.3 "License Term" means the period of time in which Customer may use the Product. The Initial License Term shall be one (1) year from the date specified on the Product Order Form or shipment date for new customers.

1.4 "Product" means the iCAD product listed on a Product Order Form. Products consist of (i) Software or (ii) hardware along with Software embedded thereon.
1.5 "Product Order Form" means each iCAD ordering document signed by the duly authorized representatives of Customer and iCAD which identifies the Products and Services ordered by Customer from iCAD, sets forth the price to be paid for such Products and Services and contains additional terms and conditions regarding Customer's use of such Products and Services including the applicable License Term.
1.6 "Services" means iCAD's services as described on Exhibit A hereto.
1.7 "Software" means the software products provided by iCAD to Customer and which are listed on a Product Order Form and all updates, enhancements, bug fixes and new releases thereto that iCAD provides to Customer. Software is licensed to Customer either on a stand-alone basis or as embedded on a hardware Product.

2. PRODUCT LICENSE

2.1. *License*. Subject to the terms and conditions of this Agreement, iCAD hereby grants to Customer a non-exclusive, non-transferable license to use the Products solely at the Designated Site, solely during the applicable License Term and solely for Customer's internal use in accordance with the applicable Documentation. The Product is licensed to Customer solely for the specific and limited use by medical personnel during the interpretation of mammography images.. The Product may not be used for interpretation or diagnostic purposes, and such misuse may result in serious harm or death to subjects and patients. Limitations and precautions set forth in applicable Documentation apply.

2.2. *Delivery*. All shipments are FOB iCAD's designated shipping facility and delivery shall be deemed to have been made upon the transfer of the Product by iCAD to its shipping agent.

2.3. *Ownership/Restrictions*. The Products are owned by iCAD or its licensors and are licensed (and not sold) to Customer. Title to the Products and all intellectual property rights in and to the Products and all updates, modifications and derivative works thereto are retained by iCAD or its licensors. Customer shall not allow any lien, security interest or other encumbrance to attach to the Products. Customer will not and will not allow a third party to: (i) decompile, reverse engineer, disassemble or otherwise attempt to derive, analyze or use any source code or underlying ideas or algorithms related to the Products by any means whatsoever, except and only to the minimal extent the provisions of this Section are expressly prohibited by applicable statutory law; (ii) remove any product identification, copyright or other notices on any Product, or (iii) provide, lease, lend, use for timesharing or service bureau purposes or otherwise use or allow others to use the Software or Product to or for the benefit of third parties. Customer agrees to hold in confidence, not disclose, and not use the Software, the Product or related technology, ideas, algorithms or information except as expressly permitted herein. Customer further agrees that it shall not use the Product for the purposes of conducting comparative analysis, evaluations or product benchmarks without iCAD's prior written approval. Customer recognizes and agrees that there is no adequate remedy at law for a breach of this Section 2.3 and that such breach would irreparably harm iCAD for which monetary damages would not be an adequate remedy and that iCAD is entitled to equitable relief in addition to any other remedies.

2.4. *Return of Products.* Customer shall take all reasonable efforts to protect the Products from damage and theft and upon termination or expiration of this Agreement or the applicable License Term shall return the Products to iCAD, at Customer's sole cost and expense, in good working condition (reasonable wear and tear excepted). Customer shall immediately notify iCAD in the event any Products have been stolen, lost or damaged and shall be responsible to pay iCAD the full replacement cost thereof.

2.5. *Equipment Previously Delivered*. Customer acknowledges and agrees that iCAD has previously delivered Product to Customer prior to the date of this Agreement. Customer and iCAD hereby agree that Customer's use of the Product shall now be governed by and subject to the terms and conditions of this Agreement. Accordingly, this Agreement hereby supersedes and replaces any prior agreement between Customer and iCAD with respect to the Product and Customer's use thereof.

2.6. *Return of Former Equipment*. In connection with the Services, iCAD may, from time to time, deliver to Customer new replacement or upgraded Products. In the event that iCAD delivers to Customer any such replacement or upgraded Products, Customer agrees to promptly relinquish all rights to the Product being replaced and to return to iCAD in good working condition (reasonable wear and tear excepted) such replaced Product at Customer's expense.

3. FEES AND PAYMENT TERMS; SERVICES

Customer shall pay iCAD the fees, charges and other amounts specified on the Product Order Form in accordance with the payment terms set forth on the Product Order Form. If Customer fails to pay any amount when due, iCAD may suspend all Services provided under this Agreement. Customer shall also pay all reasonable travel and out-of-pocket expenses incurred by iCAD in connection with any services rendered. Customer shall be responsible for all shipping costs and taxes levied on any transaction under this Agreement, including, without limitation, all federal, state, and local sales taxes, levies and assessments, excluding, however, any taxes based on iCAD's income (unless Customer is tax-exempt and provides proper supporting documentation to iCAD of such tax exempt status). *Overdue balances may be subject to a service charge of one and one-half percent (1½ %) per month, but not more than that allowed by law.*

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4. CONFIDENTIALITY

4.1. *Confidential Information*. During the term of this Agreement, each party will regard any information provided to it by the other party and designated in writing as proprietary or confidential to be confidential ("Confidential Information"). Confidential Information shall also include information which, to a reasonable person familiar with the disclosing party's business and the industry in which it operates, is of a confidential or proprietary nature. A party will not disclose the other party's Confidential Information to any third party without the prior written consent of the other party, nor make use of any of the other party's Confidential Information except in its performance under this Agreement. Each party accepts responsibility for the actions of its agents or employees and shall protect the other party's Confidential Information in the same manner as it protects its own valuable confidential information, but in no event shall less than reasonable care be used. The parties expressly agree that the Software and the terms and pricing of this Agreement are the Confidential Information of iCAD. The receiving party shall promptly notify the disclosing party upon becoming aware of a breach or threatened breach hereunder, and shall cooperate with any reasonable request of the disclosing party in enforcing its rights.

4.2. *Exclusions*. Information will not be deemed Confidential Information hereunder if such information: (i) is known prior to receipt from the disclosing party, without any obligation of confidentiality; (ii) becomes known to the receiving party directly or indirectly from a source other than one having an obligation of confidentiality to the disclosing party; (iii) becomes publicly known or otherwise publicly available, except through a breach of this Agreement; or (iv) is independently developed by the receiving party. The receiving party may disclose Confidential Information pursuant to the requirements of applicable law, legal process or government regulation, provided that it gives the disclosing party reasonable prior written notice to permit the disclosing party to contest such disclosure, and such disclosure is otherwise limited to the required disclosure.

5. LIMITED WARRANTY

5.1. *Warranty*. iCAD warrants that (a) during the applicable License Term the Products will perform in conformity with its Documentation, in all material respects, and (b) all Services will be provided with reasonable skill and care conforming to generally accepted industry standards. Such warranty does not apply to Products that have been damaged, mishandled, mistreated, altered or used or maintained or stored other than in conformity with this Agreement and the Documentation.

5.2. *No Other Warranty*. THE ABOVE WARRANTIES ARE IN LIEU OF ALL OTHER WARRANTIES EXPRESS, IMPLIED, OR STATUTORY, INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY, NONINFRINGEMENT, TITLE, QUALITY, OR FITNESS FOR A PARTICULAR PURPOSE.

5.3. *Remedy*. If the above warranties are breached, iCAD will, at its option and at no cost to Customer, (a) provide remedial services necessary to enable the Products or Services to conform to the warranty, or (b) replace any defective Products, or (c) terminate Customer's license to the Product and refund any prepaid unused amounts paid by Customer and received by iCAD in respect of the defective Products or Services for the unexpired portion of the License Term. Customer will provide iCAD with a reasonable opportunity to remedy any breach and reasonable assistance in remedying any defects. Customer will notify iCAD in writing of any breach of warranty promptly after becoming aware of the same, but in any event, within the warranty period set forth in Section 5.1. The remedies set out in this subsection are Customer's sole and exclusive remedies for breach of the above warranties.

5.4. *Exclusions.* All Services and Customer's license to use the Product is contingent upon proper use of the Product by Customer and Customer's observance of all operational instructions set forth in the Documentation and does not cover, among other things, labor and replacement parts required because of accidents, acts of God, fire, flood, war, embargoes, labor disputes, acts of sabotage, terrorism, riots, delay of carriers, voluntary or mandatory compliance with any government act, regulation or request, shortage of labor, materials or manufacturing facilities, neglect, misuse, failure of electrical power, air-conditioning, humidity control, transportation and unusual physical or electrical stress, relocation of the Product unless such relocation is done by iCAD or its authorized representative or any other cause or causes beyond iCAD's control. The iCAD warranty and Services specifically exclude: (1) operating supplies or accessories not furnished by iCAD, painting or refinishing of the Product , or furnishing of materials for this purpose; (2) electrical work external to the Product or maintenance of accessories, alterations, attachments, or other devices furnished or not furnished by iCAD, unless specifically noted; (3) Products which have been modified, altered, added to, improperly repaired, serviced, installed or reinstalled (moved) by other than iCAD authorized personnel (or Customer's own service personnel certified by iCAD) without iCAD's prior written approval; (4) Products used in violation of iCAD's instructions or causes resulting from other than ordinary use. Parts coverage under this Agreement excludes consumables (e.g., bar code labels, tack sheets, QA Target, swabs, etc.). Special refurbishment, overhaul, or reconditioning of Product due to age, use, or condition is not covered under this Agreement.

6. LIMITATION OF LIABILITY.

6.1. *Consequential Damage Waiver*. Except as may arise out of either party's breach of Section 4 or Customer's breach of Section 2.3 above, neither party nor any of iCAD's suppliers, licensors and/or its or their officers, directors, employees or agents will be liable to the other or any third party for loss of profits, or special, indirect, incidental, consequential or exemplary damages, including costs, in connection with the supply, use or performance of the Products or Services, or the performance of its other obligations under this Agreement, even if it is aware of the possibility of the occurrence of such damages.

6.2. *Limitation of Liability* In any event, the total cumulative liability of iCAD (including any of its suppliers, licensors and/or its or their officers, directors, employees or agents) to Customer and/or any third party for any and all claims and damages under this Agreement, whether arising by statute, contract or otherwise, will not exceed the amounts paid by (and not otherwise refunded to) Customer to iCAD under this Agreement for the Products or Services which form the subject of the claim. The provisions of this Agreement allocate risks between the parties. The pricing set forth herein reflects this allocation of risk and the limitation of liability specified herein.

7. USAGE VERIFICATION

7.1 *Usage Verification*. At iCAD's written request, and no more than every six (6) months, Customer shall provide iCAD with a signed certification verifying that the Products are being used pursuant to the provisions of this Agreement. In addition to the foregoing, at iCAD's written request, and no more than annually, Customer will permit iCAD to review and verify Customer's records, deployment and use of the Products for compliance with the terms and conditions of this Agreement, at iCAD's expense. Any such review shall be scheduled at least ten (10) days in advance, shall be conducted during normal business hours at Customer's facilities, and shall not unreasonably interfere with Customer's business activities.

7.2 *Audit*. iCAD agrees until the expiration of four (4) years after the furnishing of Services under this Agreement, to make available upon written request, to the Secretary of Health and Human Services or upon request, to Comptroller General of the United States of America or any of their duly authorized representatives such contract(s) and books, documents and records as are necessary to certify the nature and extent of reimbursable costs under the Medicare law.

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8. TERMINATION

8.1 This Agreement will commence on the Effective Date as set forth above and will continue in effect until otherwise terminated in accordance with Section 8.2 below. Upon the expiration of the initial License Term set forth on the Product Order Form or any renewal term, unless either party provides the other with written notice of its election not to renew such License Term at least thirty (30) days prior to such renewal date, the Product Order Form (and the applicable License Term) will thereafter automatically renew for additional periods of one year each at iCAD's then current rates. iCAD reserves the right to change the rates, applicable charges and usage policies and to introduce new charges, upon providing Customer written notice thereof (which notice may be provided by e-mail) at least 60 days prior to end of the then current License Term.

8.2 This Agreement or an individual license granted hereunder may be terminated (a) by mutual agreement of iCAD and Customer, (b) by either party if the other party is adjudicated as bankrupt, or if a petition in bankruptcy is filed against the other party and such petition is not discharged within sixty (60) days of such filing, or (c) by either party if the other party materially breaches this Agreement and fails to cure such breach to such party's reasonable satisfaction within thirty (30) days following receipt of written notice thereof. Customer's license to use the Product shall also terminate upon the expiration of the applicable License Term. Upon any termination of this Agreement or a license granted hereunder by iCAD, all applicable licenses are revoked and Customer shall immediately cease use of the applicable Product and certify in writing to iCAD within thirty (30) days after termination that Customer has returned to iCAD such Product in accordance with Section 2.4. Termination of this Agreement or a license granted hereunder shall not limit either party from pursuing any remedies available to it, including injunctive relief, or relieve Customer of its obligation to pay all fees that have accrued, have been paid, or have become payable by Customer hereunder. All provisions of this Agreement which by their nature are intended to survive the termination of this Agreement shall survive such termination.

9. INDEMNIFICATION

9.1 *Indemnification*. iCAD will defend and indemnify, at its own expense, any third party claim against Customer that arises due to a claim that the Product infringes any valid United States patent, copyright or involves the misappropriation of a trade secret. iCAD will pay such damages or costs as are finally awarded against Customer or agreed to in settlement for such claim provided that Customer gives iCAD: (a) written notice of any such claim or threatened claim within ten (10) days of Customer being made aware of the claim or threat; (b) sole control of the defense, negotiations and settlement of such claim; and (c) full cooperation in any defense or settlement of the claim (at iCAD's cost). iCAD will not be liable for the settlement of a claim made without iCAD's prior written consent.

If Customer's use of the Product results in or, in iCAD's opinion, is likely to become subject to a claim of infringement or misappropriation, then iCAD will, at its sole option and expense, either: (i) obtain for the Customer the right to continue using the Product; (ii) replace or modify the Product so that it is non-infringing and substantially equivalent in function to, and interchangeable with, the enjoined Product; or (iii) if options (i) and (ii) above cannot be accomplished despite the reasonable efforts of iCAD, then iCAD may terminate Customer's rights and iCAD's obligations under this Agreement. When option (iii) is elected, iCAD will refund any prepaid unused fees for the unexpired portion of the License Term. THE RIGHTS GRANTED TO CUSTOMER UNDER THIS SECTION 9 SHALL BE CUSTOMER'S SOLE AND EXCLUSIVE REMEDY FOR ANY ALLEGED INFRINGEMENT BY THE PRODUCT OF ANY PATENT, COPYRIGHT OR OTHER PROPRIETARY RIGHT.

9.2 *Exclusions*. iCAD shall have no obligation under this Section 9 with respect to any claim of infringement or misappropriation based upon: (i) combination of the Product with products, programs or data not furnished by iCAD where, but for the combination, the claim would have been avoided; (ii) any modification of the Product not performed by iCAD, if such claim would have been avoided by use of the unmodified Product; (iii) compliance by iCAD with Customer's custom requirements or specifications if and to the extent such compliance with Customer's custom requirements or specifications resulted in the infringement of a third party's patent(s); or (iv) failure of Customer to use a replacement Product provided by iCAD to Customer in a timely manner to avoid such claim of infringement or misappropriation.

10. GENERAL PROVISIONS

10.1. Miscellaneous. (a) This Agreement shall be construed in accordance with and governed for all purposes by the laws of the Commonwealth of Massachusetts and the parties hereto agree that only the Massachusetts courts, either federal or state, shall have exclusive jurisdiction over this Agreement and any controversies arising out of this Agreement; (b) this Agreement, along with the accompanying Product Order Forms constitutes the entire agreement and understanding of the parties hereto with respect to the subject matter hereof and supersedes all prior agreements and undertakings, both written and oral. No terms and conditions of any Customer purchase order shall modify the terms and conditions of this Agreement, or add any additional or inconsistent terms for any reason or purpose whatsoever, regardless of any statement in a purchase order to the contrary; (c) this Agreement may not be modified except by a writing signed by each of the parties; (d) in case any one or more of the provisions contained in this Agreement shall for any reason be held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions of this Agreement but this Agreement shall be construed as if such invalid, illegal or other unenforceable provision had never been contained herein; (e) Customer shall not assign its rights or obligations hereunder without iCAD's advance written consent.; (f) subject to the foregoing subsection (e), this Agreement shall be binding upon the and shall inure to the benefit of the parties hereto and their successors and permitted assigns; (g) no waiver of any right or remedy hereunder with respect to any occurrence or event on one occasion shall be deemed a waiver of such right or remedy with respect to such occurrence or event on any other occasion; and (h) the headings to the sections of this Agreement are for ease of reference only and shall not affect the interpretation or construction of this Agreement..

10.2. *Export.* Customer acknowledges that the export of any Product is subject to export or import control and Customer agrees that any Product or the direct or indirect product thereof will not be exported (or re-exported from a country of installation) directly or indirectly, unless Customer obtains all necessary licenses from the U.S. Department of Commerce or other agency as required by law.

10.3. *Government Restricted Rights*. This Section 10.3 applies to all acquisitions of the Software by or for the federal government, or by any prime contractor or subcontractor (at any tier) under any contract, grant, cooperative agreement or other activity with the federal government. The Software was developed at private expense and is Commercial Computer Software, as defined in Section 12.212 of the Federal Acquisition Regulation (48 CFR 12.212 (October 1995)) and Sections 227.7202-1 and 227.7202-3 of the Defense Federal Acquisition Regulation Supplement (48 CFR 227.7202-1, 227.7202-3 (June 1995)). Accordingly, any use, duplication or disclosure by the Government or any of its authorized users is subject to restrictions as set forth in this standard license agreement for the Software. If for any reason, Sections 12.212, 227.7202-1 or 227.7202-3 are deemed not applicable, then the Government's rights to use, duplicate or disclose the Software are limited to "Restricted Rights" as defined in 48 CFR Section 52.227-19(c)(1) and (2) (June 1987), or DFARS 252.227-7014(a)(14) (June 1995), as applicable. If this Agreement fails to meet the government's needs or is inconsistent in any respect with Federal law, the government agrees to return the Software, unused, to iCAD. Manufacturer is iCAD, Inc. 98 Spit Brook Road, Suite 100, Nashua, NH 03062.

10.4. *Relationship of the Parties*. iCAD and Customer are independent contractors, and nothing in this Agreement shall be construed as making them partners or creating the relationships of employer and employee, master and servant, or principal and agent between them, for any purpose whatsoever. Neither party shall make any contracts, warranties or representations or assume or create any obligations, express or implied, in the other party's name or on its behalf.

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10.5. *Force Majeure*. Except for the obligation to make payments, nonperformance of either party shall be excused to the extent that performance is rendered impossible by strike, fire, flood, governmental acts or orders or restrictions, failure of suppliers, or any other reason where failure to perform is beyond the reasonable control of the non-performing party.

10.6. *Third Party Products*. Customer acknowledges that the Software may contain or be accompanied by certain third party hardware and software products ("Third-Party Products"). These Third Party Products, if any, are identified in, and subject to, special license notices, terms and/or conditions as set forth in the Product Order Form, the Third Party Product packaging and/or in a text file, installation file or similar file or folder accompanying the Software ("Third-Party Notices"). The Third-Party Notices may include important licensing and warranty information and disclaimers. In the event of conflict between the Third-Party Notices and the other portions of this Agreement, the Third-Party Notices will take precedence (but solely with respect to the Third-Party Products to which the Third-Party Notices relate). Customer acknowledges that the Third-Party Products are licensed for use solely with the Software and may not be used on a stand-alone basis or with any other third party products and that Sections 5.1 and Section 9 of this Agreement shall not be applicable to the Third-Party Products.

10.7. *HIPAA*. If any information obtained or created by iCAD in performing Services for Customer constitutes Protected Health Information for the purposes of the Health Insurance Portability and Accountability Act of 1996 and the Standards for Privacy of Individually Identifiable Health Information promulgated there under (collectively, as amended from time to time, "HIPAA"), this Agreement shall be deemed to incorporate all terms that HIPAA requires to be included in a Business Associate Agreement with respect to such Protected Health Information, as if set forth in full herein, and iCAD and Customer shall comply with such terms.

10.8. *Volpara Software*. Customer acknowledges that the Products may contain certain software licensed by iCAD from Matakina International Limited ("Matakina"). In such case, Customer also agrees to the following additional terms and conditions (in addition to the other terms and conditions set forth in this Agreement) as they pertain to such software: (a) Matakina or its licensors shall own all intellectual property rights in such software, including all modifications, adaptations, developments or customizations of such software; (b) use of such software is for Customer's internal and lawful business purposes only; (c) Customer shall not disclose any proprietary information of Matakina, its products, operations or personnel or modify, translate, emulate, vary, decompile, disassemble, reassemble or reverse engineer the software or extract any ideas, algorithms, procedures, workflows or hierarchies from the software or Documentation; (d) Customer shall not merge or integrate the software with any other software; and (e) Matakina shall not be liable to Customer or any other person under or in connection with this Agreement or otherwise, in contract, tort (including negligence), equity or otherwise

10.9. *Notices*. Any demand, notice, consent, or other communication required by this Agreement must be given in writing and shall be deemed delivered upon receipt when delivered personally or upon confirmation of receipt following delivery by a nationally recognized overnight courier service, in each case addressed to the receiving party at its address set forth on the applicable Product Order Form. Either party may change its address by giving written notice of such change to the other party.

10.10. Counterparts. This Agreement may be executed in multiple counterparts, each of which shall be deemed to be an original and all of which shall be deemed to be an original instrument.

IN WITNESS WHEREOF, iCAD and Customer have caused this Agreement to be executed by their duly authorized representatives.

Carolina Breast Imaging Specialists, PLLC	iCAD Inc.
By:_____	By:_____
Name:_____	Name: _____
Title:_____	Title: iCAD Representative_____
Date:_____	Date: _____

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EXHIBIT A
SERVICES

SERVICES PROVIDED:Services include the following:

- Unlimited telephone technical support from 7:00 AM – 8:00 PM Eastern Standard Time, Monday – Friday (excluding iCAD holidays);
- Remote internet support on Products that Customer provides remote access to iCAD;
- On-site labor during standard business hours, 8:00 AM – 5:00 PM; Monday – Friday (excluding iCAD holidays) if required; After hours will be billable charged at the then prevailing billable call rates in effect, inclusive of travel time and expenses;
- Software updates and upgrades, as deemed necessary by iCAD in its sole discretion to ensure the unit is at the latest approved version of the SecondLook CAD software
- Hardware refreshes, as determined by iCAD in its sole discretion;
- Replacement parts;
- iCAD pays for shipping replacement parts out to the Customer;
- Installation and training, as deemed necessary by iCAD in its sole discretion.

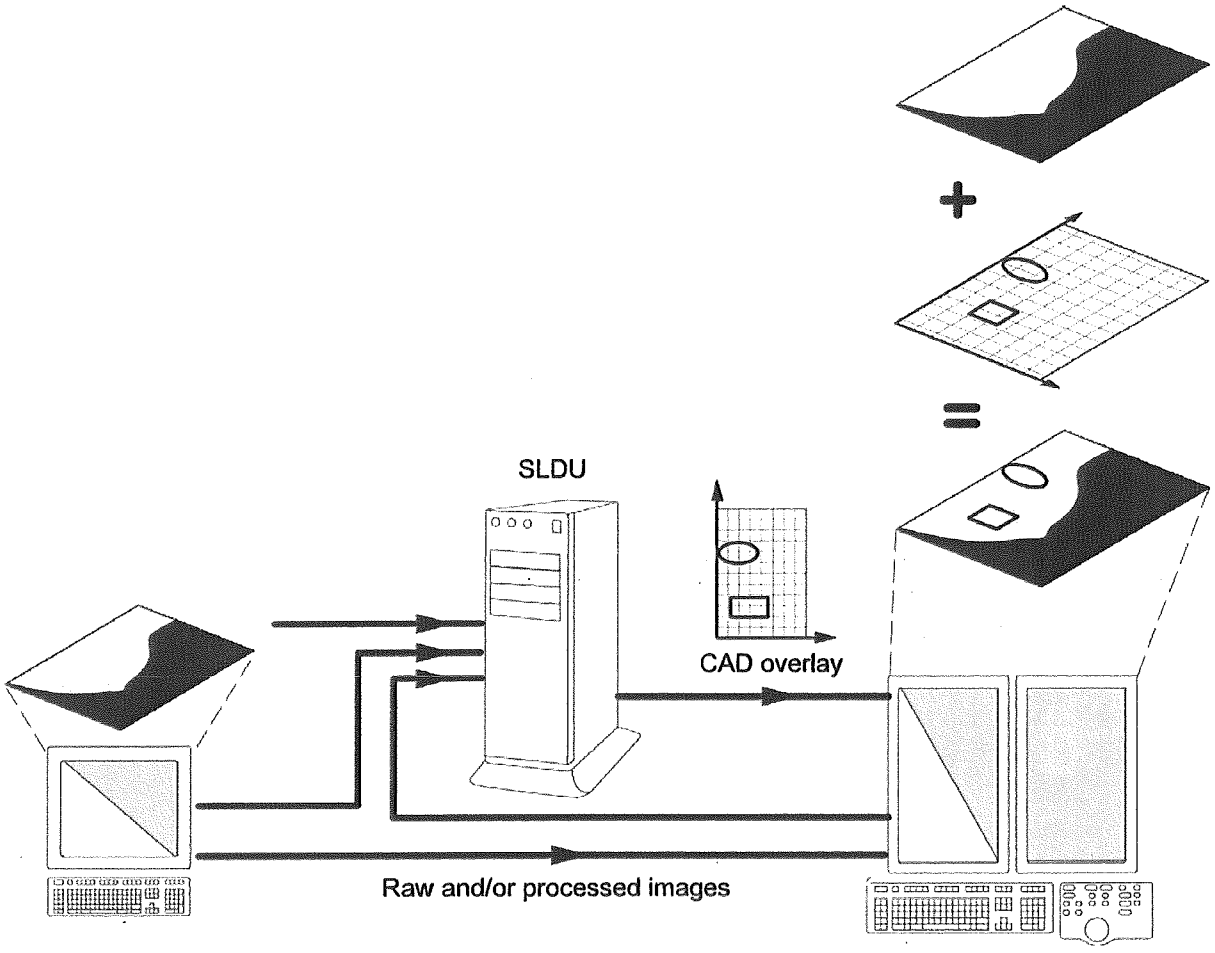
SERVICE EXCLUSIONS: When responding to a request for on-site or return-to-factory service and no service is required, or performance of requested service is not possible due to non-accessibility of the Product or related software, or for any reason beyond the control of iCAD the same shall become billable at the then prevailing rates, inclusive of travel time, shipping, and any other related expenses.
ACCESS TO PRODUCT: Customer will provide full, free and safe access to the Product on each scheduled inspection or emergency service visit. iCAD will also have access to and use of any machine, service, attachments, features or other equipment necessary to perform the necessary service contemplated herein at no charge to iCAD.
DETERMINATION CALL: If a service call is determined to be caused by a Customer peripheral (iCAD excluded) product, said service call shall become billable to the Customer inclusive of site time, travel time and expenses.
REPLACEMENT PARTS AND COMPONENTS. iCAD may, at its sole discretion, utilize reconditioned parts or components or utilize quality substitute parts or components from sources other than the original vendors. When Customer accepts delivery of a replacement part or component, Customer accepts the responsibility of returning a comparable item (Return Part) to iCAD. The Return Part must be (i) of the same type and for the same Covered Product as the replacement part, and must be identified for return by the assigned iCAD RMA number; (ii) in a repairable form, with no signs of physical abuse or mishandling and properly packaged for shipping. If an item is returned in a non-repairable condition as determined by iCAD, Customer will be invoiced and responsible for the entire current list price of the replacement part; (iii) received by iCAD within thirty (30) days from the date of shipment from iCAD of the replacement part. If the replacement part is not received within such time period Customer will be invoiced and responsible for the entire current list price of the replacement part; (iv) delivered in a proper and protective shipping container so as to avoid damage to the Return Part during shipment to iCAD. Defective parts that are replaced become the property of iCAD.
ADDITIONAL CHARGES. Additional charges will apply for the following:
(i) If remote access is not available and lack of such results in increased costs to iCAD a supplemental charge to cover those costs will be assessed.
(ii) In the event a Product is out of initial warranty at the time an Extended Service Program is purchased, iCAD may charge for an assessment service, to confirm the condition and operation of a Covered Product prior to the commencement of an Extended Service Program.
(iii) A charge may be assessed in the event a service call or replacement of parts is required as a result of an excluded condition or event, or in the event no malfunction is found or determined.

GE Healthcare

Senographe SecondLook Digital CAD System

Operator Manual

CE



Manufactured by iCAD

DTM103
Revision B

2 CAD in mammography

2-1 What CAD can do

Detecting and diagnosing breast cancer is a complex clinical problem. The combination of viewing a large number of cases (99.5% of which are expected to be non-cancerous in a screening population), radiologist fatigue (and the resulting observational oversights), the complex image structure of the breast on a mammogram, and the subtle nature of certain observational characteristics of the disease, may result in false negative mammographic readings.

The SecondLook Digital Computer-Aided Detection system developed for use with GE' s Full Field Digital Mammography system is designed to minimize observational oversights made by the radiologist.

Intended to be an aid for a radiologist reading routine screening and diagnostic mammograms, SecondLook Digital identifies areas, or "regions of interest" (ROIs), on the digital image which show features that may be associated with cancer, and may warrant a second review. These ROIs are brought to the attention of the radiologist after he or she has completed normal interpretation of the digital mammogram.

2-2 What CAD cannot do

It is important to note that CAD is not meant to be used for primary diagnosis. CAD is not meant to replace the expertise of the radiologist. It is meant to be used as an aid to *detection*, and not as an *interpretive* aid. CAD should be used only after the initial reading by the radiologist. Only the mammogram images provided directly by the GE Senographe may be used for interpretation by the radiologist. By design, the Senographe Review Workstations only allows the display of ROI markers after the images are presented, free of markers, to the radiologist for his/her primary diagnostic interpretation.

CAD is a highly sophisticated system, but it cannot identify all abnormalities. You should base your interpretation upon the original mammogram images and use CAD only as an aid to detection.

Individual practice patterns may influence the results obtained when using this system. Therefore, each facility and radiologist should carefully monitor the results that this device has on their practice of mammography in order to optimize its effectiveness.

3 CAD Principles

The CAD system includes three sub-systems: the SecondLook Digital Unit (SLDU), the Review Workstation (RWS or Seno Advantage), and the Acquisition Workstation (AWS).

CAD processing functions are provided by the SLDU, a dedicated computer which runs the CAD processing algorithms and generates the CAD results as an overlay. The review workstation displays the overlay with the associated image.

The CAD image workflow, illustrated below, includes three main steps:

1. *RAW images are pushed to the SecondLook Digital Unit (SLDU)* from the AWS or the review workstation, or from an image storage system if present. Each image must have been produced by a licensed workstation, declared in the CAD configuration. Images may be pushed individually or in groups. Corresponding images (RAW or PROCESSED) from the AWS must also be pushed to the review workstation before results can be viewed.
2. *The SLDU performs its analysis on each image* and delivers the results of the analysis to the review workstation in the form of a CAD overlay.

   CAD processing of an image is not instantaneous. The SLDU takes an average of 30 seconds (maximum 120 seconds) to process a 19 x 23 cm RAW image and generate a CAD overlay, or 2 minutes for a group of four images. Additional time may be required if there are multiple processing requests.
3. *The* CAD *overlay is displayed with the associated images* in the form of markers and labels.

6 Radiologist Training and SLD CAD Algorithm Descriptions

6-1 Overview

This section is intended to describe the SecondLook Digital Computer-Aided Detection algorithms and provide training to radiologists using the SecondLook Digital system in breast cancer detection.

- Section 6-2 *SecondLook Digital in Breast Cancer Detection* gives an overview of the role of SecondLook Digital in breast cancer detection.
- The SecondLook Digital Device Labeling is included in section 6-3 *SecondLook Digital Device Labeling*, which provides a brief description of the system, indications for use, contraindications, warnings and precautions, adverse effects, summary of clinical studies, a description of the principles of operation for the Computer-Aided Detection (CAD) algorithms, a list of conformance to standards, and how the system is supplied.
- The procedures for a radiologist using the SecondLook Digital CAD marks are described in Section 6-4 *Radiologist Use of SecondLook Digital.*
- Sample cases are provided in Section 6-5 *Radiologist Training with Sample Cases* to familiarize the radiologist with the SecondLook Digital system prior to clinical use.
- Section 6-6 *Summary of Radiologist use of SecondLook Digital* summarizes a radiologist' s use of SecondLook Digital.

6-2 SecondLook Digital in Breast Cancer Detection

6-2-1 Background

SecondLook, a Computer-Aided Detection (CAD) system for mammography, has been developed by iCAD, Inc. to identify and mark regions of interest on screening and diagnostic mammograms to bring them to the attention of radiologists after the initial reading has been completed. Thus, the system assists the radiologist in minimizing observational oversights by identifying areas on the original mammogram that may warrant a second review. The SecondLook system was first developed for use with screen-film mammography (SFM).

For SecondLook to process full-field digital mammography (FFDM) from the General Electric Medical Systems (GEMS) Senographe, a new optional system component has been developed, SecondLook Digital. SecondLook Digital can be configured as a stand-alone system that only processes FFDM.

In the U.S. in 2002, invasive breast cancer is expected to be newly diagnosed in 203,500 women, and an additional 54,300 women will be diagnosed with in situ breast cancer. Therefore, breast cancer will be the cause of death in 39,600 women in 2002, making it the second highest cause of cancer death in U.S. women. The lifetime risk of a woman in the U.S. developing breast cancer has been estimated to be one in nine.[1.]

Although recent analysis of the 8 randomized breast cancer screening trials has questioned the reduction in mortality from screening with mammography [2.] and the PDQ (Physician Data Query) panel sponsored by the NCI (National Cancer Institute) concurred with this uncertainty [3.], other U.S. and international organizations still affirm that screening with mammography and/or clinical breast examination is effective in reducing breast cancer mortality. The USPSTF (U.S. Preventive Services Task Force), sponsored by HHS (Health & Human Services), commissioned an evaluation of the 8 mammography screening trials and concluded that mammography reduces breast cancer mortality by 16%.[4.] The IARC (International Agency for Research on Cancer), which is part of the WHO (World Health Organization), concluded that these randomized trials show that mammography reduces breast cancer mortality by 25-35% in women aged 50-69 years.[5.]

The sensitivity of mammography ranges from 70% to 90%.[6,7,8,9,10,11,12,13]. Thus, for a woman with breast cancer, there is about a 70% to 90% probability that her cancer will be detected by screening mammography and a 10% to 30% probability it will not. Therefore, even though mammography is an effective tool to detect breast cancer and reduce mortality, there is need for further improvement in mammographic sensitivity.

Studies have shown that the accuracy of mammographic interpretation increases when a mammogram is evaluated by 2 radiologists (double reading). Double reading improves breast cancer detection by 5% to 15%.[14,15,16,17,18,19,20,21,22,23,24,25] However, double reading is not currently advocated as a standard of care and requires substantial additional resources, which are often not available.[25] A cancer can be missed because it is not mammographically visible or because of an oversight or misinterpretation. Clinical studies have shown that 30% to 70% of breast cancers diagnosed at screening mammography are visible in retrospect on prior examinations, and that detection errors are responsible for approximately half of missed breast cancers, with interpretation errors accounting for the other half.[9,26,27,28,29,30,31,32,33].

In view of the frequency of missed cancers and of the lack of general support for double reading as a standard of care, CAD of breast lesions on mammograms is a method to increase the sensitivity of mammography and possibly further reduce breast cancer mortality. CAD in combination with review by a single radiologist is an alternative to double reading for reducing the number of detection errors that lead to missed breast cancers.

6-2-2 Description of SecondLook Digital

SecondLook Digital is a mammographic CAD system that identifies and highlights potential areas of concern to assist radiologists in breast cancer detection. The CAD algorithms used in the SecondLook Digital computer system include image processing, feature computations, and pattern recognition technology to detect mammographic features indicative of malignancies. Areas of concern marked include suspicious clusters of microcalcifications, spiculated and non-spiculated masses, architectural distortions, and focal asymmetric densities. SecondLook Digital does not distinguish between benign and malignant processes and may highlight technical artifacts.

SecondLook Digital integrates with the GEMS Senographe FFDM system to process FFDM images. The resulting CAD marks are typically displayed overlying the appropriate locations of the mammogram on the review workstation used by the radiologist for softcopy reading. When the CAD marks are displayed within the review workstation, the radiologist can turn on or off the display of CAD marks overlying the mammogram. Although the remainder of this manual is written with the assumption that the CAD marks are viewed on a review workstation, a paper printout of the CAD marks is another possible option. The radiologist using a paper printout follows similar procedures.

Typical screening mammography includes four mammographic views: left and right craniocaudal projections (L-CC and R-CC) and left and right mediolateral oblique projections (L-MLO and R-MLO). SecondLook Digital assists radiologists with these mammographic views and full-breast diagnostic views. On occasion, other views are obtained for screening or diagnostic purposes, such as left and right exaggerated craniocaudal projections rotated laterally (L-XCCL and R-XCCL) and left and right straight mediolateral projections (L-ML and R-ML). When additional screening or diagnostic views are taken, SecondLook Digital may process more than 4 views for each patient. SecondLook Digital is not used to assist the radiologist in evaluating magnification/compression views or specimen radiography. For patients with breast implants, SecondLook Digital is used with implant-displaced views only. When SecondLook Digital processes magnification/compression views, specimen radiography, or non-displaced implant views, any resulting CAD marks should not be used by the radiologist in evaluating the patient.

SecondLook Digital is intended to be used by a radiologist as follows: The radiologist must first review the mammogram in the normal manner and only afterward consult the CAD marks to determine if SecondLook Digital has marked any areas of concern that were not observed on the initial review. To view the CAD marks prior to the initial unassisted review of the mammogram risks the so-called satisfaction-of-search error, in which the radiologist' s vigilance for other areas on the mammogram may be lowered by virtue of seeing one or more areas highlighted by SecondLook Digital. The absence of a CAD mark at a lesion initially detected without the assistance of SecondLook Digital should not be used by the radiologist to override the decision to further evaluate the lesion.

SecondLook Digital is designed to mark areas with the mammographic appearance of cancer; however, many of the marked areas will not contain a malignancy, and it is up to the radiologist to decide, using conventional clinical judgment and reviewing the mammogram itself, if the area is suspicious enough to warrant further work-up. SecondLook Digital is not a diagnostic device, as the CAD marks are intended to be used to assist only in detection and not in interpretation. Therefore, SecondLook Digital can assist a radiologist in detecting areas of concern that would have been missed without its use, but used properly it cannot cause a radiologist to miss areas of concern that would have been detected without SecondLook Digital.

SecondLook Digital was developed by leaders in the fields of image processing and artificial intelligence. Below is a description of how SecondLook Digital' s Computer-Aided Detection (CAD) works.

1. The GEMS Senographe full-field digital mammograms are processed by the system. Image processing is used to identify all the potential cancerous locations in the image.
2. These locations are analyzed using radiologic and proprietary measures as well as a feature selection process to determine the most likely locations to be cancer.
3. The most likely locations are evaluated in the context of the patient, and highlighted with CAD marks displayed overlying the mammograms on the review workstation used by the radiologist for softcopy reading.

It is important to remember that SecondLook Digital will not necessarily mark what a radiologist would work-up. This is an important consideration as every radiologist works-up different areas based on her or his own criteria.

SecondLook Digital does not function on its own, but always with a radiologist. Therefore, if SecondLook Digital highlights a mass or microcalcifications in one view only, the radiologist can look for it in the other view to determine if there is a lesion that warrants work-up.

6-3 SecondLook Digital Device Labeling

6-3-1 Indications for Use

The SecondLook Computer-Aided Detection (CAD) system for mammography is intended to identify and mark regions of interest on screening and diagnostic mammograms from GE full-field digital mammography (FFDM) systems to bring them to the attention of the radiologist after an initial reading has been completed. Thus the system prompts the radiologist to areas on GE mammograms for second review only.

6-3-2 Brief Device Description

SecondLook is a mammographic CAD system that prompts radiologists to areas on GE mammograms for a second review only. The CAD algorithm version 7.2 includes image processing feature computations, and pattern recognition technology to detect regions of interest. The algorithm was originally trained on digitized film-screen mammograms and intended to more specifically identify potential breast lesions appearing as clusters of microcalcifications and/or masses. The CAD system was adapted to run on GE images, but the CAD algorithm design remained unchanged, and was not otherwise retrained on the GE mammograms.

For hardcopy reading, the SecondLook output can be presented on a paper printout showing the CAD marks within the mammogram.

How to Use the CAD:

SecondLook with the GE FFDM system is intended to be used by a radiologist as follows: The radiologist must always first perform a full conventional read of the mammogram, and only after completing the conventional read, the radiologist may choose to display the CAD marks which may prompt to areas that were or were not examined during the first read. It is crucial to understand that 99.6% of all CAD marks will be placed over areas that are normal breast tissue or benign findings. Be aware that the SecondLook is not a diagnostic device, as the CAD marks are intended to be used to assist only in detection and not to assist with interpretation.

6-3-3 Warnings

6-3-3-1 Warnings: Radiological Interpretation

- The radiologist must always first perform a full conventional read of the mammogram, and only after completing the conventional read, the radiologist may choose to display the CAD marks which may prompt to areas that were or were not examined during the first read.
- The presence or absence of a CAD mark should not in any manner influence your diagnostic decision as to the nature of a mammographic finding, i.e. normal vs. benign vs. malignant, or the clinical action to be taken (e.g. additional imaging or biopsy).
- Do not rely on the size (or shape) of the CAD mark as it may not be representative of the actual extent (or shape) of the breast lesion.
- Upon re-evaluation for the original mammogram at the locations indicated by SecondLook, the radiologist must use their interpretative skills to determine if the area should be worked-up based on its mammographic appearance.
- SecondLook is neither designed nor intended to prompt to:
  - interval change(s) between mammographic exams
  - asymmetry between the left and right breast
  - tubular density/solitary dilated duct
  - skin thickening, or
  - nipple retraction

6-4 Radiologist Use of SecondLook Digital

6-4-1 Radiologist Review Prior to Viewing CAD Marks

The radiologist first reviews the GE mammograms without viewing the SecondLook Digital CAD marks, following her or his existing procedures of clinical practice. The radiologist will make an initial determination if a work-up is indicated for the patient prior to turning on and viewing the CAD marks with the softcopy review workstation.

6-4-2 Radiologist Review with CAD Marks

The radiologist turns on and views the SecondLook ® Digital CAD marks with the softcopy review workstation after determining whether or not a work-up is indicated from her or his initial review of the patient mammograms. The radiologist will take a "SecondLook" at the mammograms corresponding to any CAD marks. From this re-evaluation of the mammograms, the radiologist determines if any additional work-up is required. If there are no CAD marks, no re-evaluation of the mammograms is necessary. Work-up decisions are not based solely upon the CAD marks. All work-up decisions are based upon review of the mammograms, supporting clinical information, and CAD marks by the radiologist.

Areas of concern marked by SecondLook Digital include suspicious clusters of microcalcifications, spiculated and non-spiculated masses, architectural distortions, and focal asymmetric densities.

Below is the recommended case review process with SecondLook Digital:

1. Review patient history and evaluate GE mammograms prior to turning on and viewing CAD marks with softcopy review workstation
2. Make initial interpretation
3. Turn on and view CAD marks with softcopy review workstation and identify potential areas of concern
4. Review mammograms, re-evaluating areas of concern highlighted by CAD marks with softcopy review workstation
5. Render decision

It is very important to remember that it is the radiologist who makes the final decision about a case. When a radiologist decides to work-up a case, the CAD marks must not change the decision; however, the CAD marks can identify locations for further work-up that were initially undetected by the radiologist.