

**FDA Required Breast Tomosynthesis Training**

On any new mammography technology, such as breast tomosynthesis, the Mammography Quality Standards Act (MQSA) ([http://fda.gov/Radiation-Emitting\\_Products/MammographyQualityStandardsActandProgram/FacilityCertificationandInspection/ucm114148.htm](http://fda.gov/Radiation-Emitting_Products/MammographyQualityStandardsActandProgram/FacilityCertificationandInspection/ucm114148.htm)) requires that all health care professionals obtain eight hours of training prior to using new mammography technology on patients.

PERSONNEL QUALIFICATIONS: RADIOLOGIC TECHNOLOGISTS WHO ARE QUALIFIED TO PERFORM DBT MAMMOGRAMS  
 List the current radiologic technologists who:  
 (1) meet all the requirements of 21 CFR 900.12(a)(3) "Mammography Quality Standards; Final Rule" that became effective on April 28, 1999; and  
 (2) have 8 hours of initial new-modality training in DBT, either including or supplemented by training in the unique features of the specific manufacturer's DBT system.

**Mammographer**

- 8 hours of training in using a mammographic modality (e.g., digital, tomosynthesis), before beginning to use that modality independently.
- **Continuing Experience : Perform 200 mammographic examinations over a 24-month period**
- **Continuing Education : 15 category 1 CEU's/ in mammography during 36 months.** Once certified in mammography, Registered Technologists (R.T.s) must complete 24 Category A or A+ continuing education (CE) credits each biennium — a two-year period that begins at the start of his or her birth month.

**New Mammographic Modality Training**

- Interpreting Physicians and Medical Physicist and Radiologic Technologists are required to have 8 hours of training in FFDM system(s) before providing services independently using the system
- Similar to a SFM requirement, the Quality Control (QC) technologist at a facility using an FFDM unit must be a qualified radiologic technologist who also meets the training requirement for performing FFDM examinations

**New Mammographic Modality Training**

- Medical physicists are required to have 8 hours training in surveying FFDM system(s) before conducting independent surveys and/or equipment evaluations
- Hands-on training is strongly recommended
- **Continuing Experience** – Survey 2 mammography facilities and 6 mammography units over a 24 – month period.
- **Continuing Education** – 15 CME/CEU's in mammography in a 36 – month period

**Qualified Radiologic Technologist**

- Certified by:
  - American Registry of Radiologic Technologists (ARRT), **or**
  - American Registry of Clinical Radiologic Technologists, **or**
  - Licensed to perform general radiographic procedures in a state
- **AND**
- 40 hours of training in mammography including:
  - Training in breast anatomy and physiology, positioning and compression, QA/QC techniques, and imaging of patients with breast implants, **and**
  - 25 mammography examinations under direct supervision of an appropriate MQSA-qualified individual

**Radiologic Technologists**

PERSONNEL QUALIFICATIONS: RADIOLOGIC TECHNOLOGISTS WHO ARE QUALIFIED TO PERFORM DBT MAMMOGRAMS

List the current radiologic technologists who:

(1) meet all the requirements of 21 CFR 900.12(a)(3) "Mammography Quality Standards; Final Rule" that became effective on April 28, 1999; and

(2) have 8 hours of initial new-modality training in DBT; training on any DBT system, or general DBT training, is sufficient to meet the MQSA new modality training requirement.\*

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\* Supporting documentation for these requirements will be checked during annual MQSA inspections.

## Tomosynthesis Training

- Radiologists - 8 hours of new modality training for tomosynthesis
- Physicists -8 hours of new modality training for tomosynthesis
- Technologists - 8 hours of new modality training for tomosynthesis

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Self-Assessment 2

02-001	<b>MAMMO</b> Negative      Recall R L Mass / Asym      Calcs Location _____ Comments:	<b>TOMO</b> Negative      Recall R L Mass / Asym      Calcs Slice # CC _____ MLO _____ Comments:
02-002	<b>MAMMO</b> Negative      Recall R L Mass / Asym      Calcs Location _____ Comments:	<b>TOMO</b> Negative      Recall R L Mass / Asym      Calcs Slice # CC _____ MLO _____ Comments:
02-003	<b>MAMMO</b> Negative      Recall R L Mass / Asym      Calcs Location _____ Comments:	<b>TOMO</b> Negative      Recall R L Mass / Asym      Calcs Slice # CC _____ MLO _____ Comments:

## Tomosynthesis Training for Radiologists:

- Radiologists must meet all MQSA requirements
- Radiologist will need 8 hours of training in the interpretation of breast tomosynthesis will be offered through non-CME courses.

- PERSONNEL QUALIFICATIONS: INTERPRETING PHYSICIANS WHO ARE QUALIFIED TO INTERPRET DBT MAMMOGRAMS
- 
- List the current interpreting physicians who:
  - (1) meet all the requirements of 21 CFR 900.12(a)(1) "Mammography Quality Standards; Final Rule" that became effective on April 28, 1999; and
  - (2) have 8 hours of initial new-modality training in DBT, either including or supplemented by training in the unique features of the specific manufacturer's DBT system.

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Self-Assessment 1

01-001	<b>MAMMO</b> Negative      Recall R L Mass / Asym      Calcs Location _____ Comments:	<b>TOMO</b> Negative      Recall R L Mass / Asym      Calcs Slice # CC _____ MLO _____ Comments:
01-002	<b>MAMMO</b> Negative      Recall R L Mass / Asym      Calcs Location _____ Comments:	<b>TOMO</b> Negative      Recall R L Mass / Asym      Calcs Slice # CC _____ MLO _____ Comments:
01-003	<b>MAMMO</b> Negative      Recall R L Mass / Asym      Calcs Location _____ Comments:	<b>TOMO</b> Negative      Recall R L Mass / Asym      Calcs Slice # CC _____ MLO _____ Comments:
01-004	<b>MAMMO</b> Negative      Recall R L Mass / Asym      Calcs Location _____ Comments:	<b>TOMO</b> Negative      Recall R L Mass / Asym      Calcs Location _____ Comments:

## Tomosynthesis Training for Physicists

- Physicists must meet all MQSA requirements.
- 8 hours of new modality training for tomosynthesis will be offered. During installation, training will provide five hours of Quality Control training by a qualified field service engineer.
- Physicists will be able to obtain 3 hours of this training online or in a live setting prior to an install
- Additional 5 hours may be obtained with the FE during the install
- They could also spend 8 hours with the FE if they choose
- [www.MTMI.net](http://www.MTMI.net)

### Tomosynthesis Training for Technologists

- Technologists must be MQSA certified
- Technologists must have received 8 hours of training in FFDM before 8 hours of instruction for tomosynthesis
- PERSONNEL QUALIFICATIONS: MEDICAL PHYSICISTS WHO ARE QUALIFIED TO PERFORM DBT SURVEYS
- List the current medical physicists who:
  - (1) meet all the requirements of 21 CFR 900.12(a)(3) "Mammography Quality Standards; Final Rule" that became effective on April 28, 1999; and
  - (2) have 8 hours of initial new-modality training in DBT, either including or supplemented by training in the unique features of the specific manufacturer's DBT system.

February 2011

### Tomosynthesis Site Readiness

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### Once you have 8 hours Tomo Training Peer to peer

- peer to peer review, but must be specific topics

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### MQSA Accreditation as of April 9, 2018

Scenario 1. DBT - 2D Synthesized Images Available (whether or not 2D-Syn is used for interpretation)

Testing to be Submitted by Facility		
Type	2D FFDM Accreditation	DBT Accreditation
Clinical Testing (a clinical set = cc and mlo of 1 fatty and 1 dense case)	Whatever is primarily used clinically: 2D clinical set (cc and mlo), or 2D-Syn clinical set (cc and mlo), or 2D cc and 2D-Syn mlo clinical set, or 2D-Syn cc and 2D mlo clinical set	2D-Syn clinical set (cc and mlo), or 2D cc and 2D-Syn mlo clinical set, or 2D-Syn cc and 2D mlo clinical set
Phantom Testing	2D phantom image	3D best-slice phantom image*

Scenario 2. DBT - 2D Synthesized Images Not Available on System

Testing to be Submitted by Facility		
Type	2D FFDM Accreditation	DBT Accreditation
Clinical Testing (a clinical set = cc and mlo of 1 fatty and 1 dense case)	2D clinical set	2D clinical set
Phantom Testing	2D phantom image	3D best-slice phantom image*

### Lead Interpreting Physician Attestation to Staff Personnel Qualifications

- To the best of my knowledge and my belief, the information provided in this document is true and correct. I understand that FDA may request additional information to substantiate the statements made in the document. I understand that knowingly providing false information in a matter within the jurisdiction of an agency of the United States could result in criminal liability, punishable by up to \$10,000 fine and imprisonment of up to five years, or civil liability under MQSA, or both.
- Signature (Lead Interpreting Physician) \_\_\_\_\_
- Print Name \_\_\_\_\_
- Date \_\_\_\_\_

### Coordination of On-Site Tomosynthesis Training

Before applications can take place, radiologists must have completed their tomosynthesis 8 hour of interpretation training. Remember application specialist will not be allowed to train radiologist in DBT the way they could in 2D.

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### Certification Extension Program

Facilities must have either the provisional or final FFDM MQSA certification (site MAP I.D.) before applying for Tomosynthesis extension certification

Questions please contact:  
[Denise.Robinson@fda.hhs.gov](mailto:Denise.Robinson@fda.hhs.gov)  
 Certification Extension Program  
 Division of Mammography Quality and Radiation Program  
 FDA/CDRH/OCER  
 10903 New Hampshire Avenue WO66-4621  
 Silver Spring, MD 20903-0002  
 Phone: 301-796-5710 Fax: 301-847-8502

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### Questions??

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### 2D & Tomosynthesis Dimensions Unit Accreditation

Facilities must have either the provisional or final FFDM MQSA certification (site MAP I.D.) before applying for Tomosynthesis extension certification

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    graph TD
      Radiologist[Radiologist 8 hours training prior to interpreting images] --> Install[Install System]
      Physicist[Physicist 3 hours on-line training] --> Install
      Install --> Testing[Physicists testing for 2D & tomosynthesis /Receives 5 hrs tomosynthesis training credit]
      Testing --> ACR[2D paperwork submitted to ACR]
      Testing --> FDA[Tomosynthesis paperwork submitted to FDA]
      ACR --> ACR_Steps[Provisional MQSA accreditation received  
Applications training for 2D to satisfy 8 hours if needed  
2D imaging may begin]
      FDA --> FDA_Steps[14 days to receive tomosynthesis certification extension  
Applications training for tomosynthesis to satisfy 8 hours needed]
      ACR_Steps --> Final[Site has 45 days from provisional MQSA accreditation to apply for final accreditation]
      FDA_Steps --> Final
  
```

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Caring for her at every stage of life.

## Reimbursement

Hologic Confidential and Proprietary

### 2D Dimensions Upgraded to 3D Units

Facilities must have either the provisional or final FFDM MQSA certification (site MAP I.D.) before applying for Tomosynthesis extension certification

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    graph TD
      Radiologist[Radiologist 8 hours training prior to interpreting images] --> Install[Install System Tomosynthesis Option]
      Physicist[Physicist 3 hours on-line training] --> Install
      Install --> Testing[Physicists testing for Tomosynthesis /Receives 5 hrs Tomosynthesis training credit]
      Testing --> FDA[Tomosynthesis paperwork submitted to FDA]
      FDA --> Extension[14 days to receive tomosynthesis certification extension]
      Extension --> Training[Applications training for tomosynthesis to satisfy 8 hours needed]
  
```

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### Billing Options for Breast Tomosynthesis before 1/2015

"Breast tomosynthesis performed in conjunction with digital mammography is appropriately reported with the unlisted diagnostic procedure code 76499 to describe breast tomosynthesis and one of the HCPCS Level II "G" codes (G0202, G0204, or G0206) to describe the full-field digital mammography performed. If computer-aided detection (CAD) also is performed, it should be reported separately using one of the mammography CAD codes, 77051 (CAD performed in conjunction with diagnostic mammography) or 77052 (CAD performed in conjunction with screening mammography)."

June 2011 edition of Radiology Coding Source

### Billing Options for Breast Tomosynthesis

Reported with the unlisted diagnostic procedure code 76499 to describe breast tomosynthesis

AND

One of the HCPCS(Healthcare Common Procedure Coding System) Level II "G" codes (G0202, G0204, or G0206) to describe the full-field digital mammography performed.

AND

If computer-aided detection (CAD) also is performed, it should be reported separately using one of the mammography CAD codes, 77051 (CAD performed in conjunction with diagnostic mammography) or 77052 (CAD performed in conjunction with screening mammography)."

June 2011 edition of Radiology Coding Source

- Note:** Patients will not be responsible for any co-pays associated with the new screening DBT codes. The screening tomosynthesis add-on code, 77063, would be subject to the same co-insurance/deductible policies as other screening mammography services. Code G0279 relates to a diagnostic procedure; therefore, it would not follow the same policies as those established for the screening studies.

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### Billing Options for Breast Tomosynthesis

- Digital breast tomosynthesis (DBT) has been assigned new billing codes and reimbursement rate values in the final rule for the calendar year (CY) 2015 Medicare Physician Fee Schedule (MPFS).

In response to a request from the American College of Radiology (ACR), the Current Procedural Terminology (CPT) Editorial Panel created three new codes (77061, 77062, and 77063) for CY 2015 to describe the physician work and practice expense associated with screening and diagnostic DBT. However, the Centers for Medicare & Medicaid Services (CMS) recommends in the 2015 MPFS that only 77063, (screening digital breast tomosynthesis, bilateral) be used at this time in conjunction with the digital screening mammography code G0202. The recommendation is based on a Food & Drug Administration requirement that a 2-D mammogram accompany a DBT when used for screening purposes.

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### In A Nut Shell

- 77061 Digital breast tomosynthesis diagnostic; unilateral + 77062 bilateral breast diagnostic (Do not report 77061, 77062 in conjunction with 76376, 76377, 77057)  
77063 Screening digital breast tomosynthesis, bilateral (List separately in addition to code for primary procedure) (Do not report 77063 in conjunction with 76376, 76377, 77055, 77056) (Use 77063 in conjunction with 77057)
- Multiple radiology societies requested three new Category I codes to describe diagnostic (77061 and 77062) and screening (77063) digital breast tomosynthesis procedures. Current mammography codes do not include the added physician work or practice expense involved in digital breast tomosynthesis and, therefore, new codes were needed to describe these additional resources. Currently under the CMS FAQ issued in November 2013, tomosynthesis is not separately billable. The publication of Medicare's Final Rule for 2015 this November will, we hope, clarify billing for tomosynthesis.

### Billing Options for Breast Tomosynthesis

- In lieu of using the new diagnostic DBT CPT codes (77061, 77062), CMS created a new add-on G code (G0279) to be used with the existing digital diagnostic mammography codes (G0204, G0206) to reflect the work of tomosynthesis when provided with diagnostic digital mammography. Therefore, the stand-alone diagnostic DBT codes have been replaced by add-on codes, leaving no means to report diagnostic DBT when it is reported separately from a full-field digital mammogram (FFDM).

BEDFORD, Mass., Oct. 31, 2014 /PRNewswire/ -- Hologic, Inc. (NASDAQ: HOLX) announced today that the Centers for Medicare and Medicaid Services (CMS) has released reimbursement rates for screening and diagnostic 3D mammography. The action establishes national average payment rates for the Category I Current Procedural Terminology (CPT) code for 3D screening mammography and creates a new add-on Healthcare Common Procedure Coding System (HCPCS) code for 3D diagnostic mammography.

The Medicare payment rates will go into effect January 1, 2015 and will allow providers in the U.S. to file reimbursement claims specific to screening and diagnostic 3D mammography. The CMS Medicare Physician Fee Schedule Final Rule issued today not only sets reimbursement rates for 3D mammography, but also creates a pathway for private insurers to explore broader coverage and payment options. The rates are as follows:

- 3D screening mammography CPT code, 77063, assigned a payment rate of approximately \$57. This is an add-on to the existing 2D mammography screening code, G0202, with an assigned payment rate of approximately \$135.
- 3D diagnostic mammography HCPCS code, G0279, assigned a payment rate of approximately \$57 for either unilateral or bilateral images.
- This is an add-on to the existing 2D mammography unilateral diagnostic code, G0206, with an assigned payment rate of approximately \$130.
- This is an add-on to the existing 2D mammography bilateral diagnostic code, G0204, with an assigned

Screening Breast Tomosynthesis (Bilateral)						
Code	Global		Hospital			
	Total RVU	Total Rate	Professional Total RVU	Professional Total Rate	Technical Total RVU	Technical Total Rate
G0202 - Screening Digital Mammography	1.77	\$134.97	0.99	\$35.44	2.78	\$99.53
77063 - Screening Breast Tomosynthesis	1.58	\$56.57	0.86	\$30.79	0.72	\$25.78
	5.35	\$191.54	1.85	\$66.23	3.5	\$125.31

  

Diagnostic Breast Tomosynthesis Unilateral						
Code	Global		Hospital			
	Total RVU	Total Rate	Professional Total RVU	Professional Total Rate	Technical Total RVU	Technical Total Rate
G0206 - Digital Diagnostic Mammography, Unilateral	3.62	\$129.60	0.99	\$35.44	2.63	\$94.16
G0279 - Diagnostic Breast Tomosynthesis	1.58	\$56.57	0.86	\$30.79	0.72	\$25.78
	5.2	\$186.17	1.85	\$66.23	3.35	\$119.94

  

Diagnostic Breast Tomosynthesis Bilateral						
Code	Global		Hospital			
	Total RVU	Total Rate	Professional Total RVU	Professional Total Rate	Technical Total RVU	Technical Total Rate
G0204 - Digital Diagnostic Mammography, Bilateral	4.6	\$164.69	1.24	\$44.39	3.36	\$120.29
G0279 - Diagnostic Breast Tomosynthesis	1.58	\$56.57	0.86	\$30.79	0.72	\$25.78
	6.18	\$221.26	2.1	\$75.18	4.08	\$146.07

### Prices for manufactures machines

- **Pricing for Full-Field Digital Mammography:**
  - Low: \$175,000
  - High: \$435,000
  - Average Price: \$273,940
- **System Service Support Prices**
  - Low: \$29,500
  - High: \$59,575
  - Average Price: \$43,290
- **Pricing for Digital Breast Tomosynthesis:**
  - Low: \$399,400
  - High: \$551,900
  - Average Price: \$462,010
- **System Service Support Prices**
  - Low: \$42,000
  - High: \$78,910
  - Average Price: \$53,990

- The ACR argued before the RUC that surveying mammography along with DBT would preclude an accurate valuation of DBT. DBT and mammography involve different technologies, different work, different practice expenses and often different patients. Because DBT is a new technology, the data regarding utilization, site of service and specialty remain to be seen. To include DBT as simply part of the mammography code family is premature and may eventually prove to be inaccurate. The ACR plan is to re-review the DBT family in three years per the conventional Relativity Assessment Workgroup schedule for the re-review of new technologies.

### Will the trend continue in more states?

- **Illinois Adds Breast Tomosynthesis to Insurance Coverage**

Breast tomosynthesis will be covered by insurance in Illinois next year. Gov. Bruce Rauner has signed SB 54, which amends the insurance code by adding tomosynthesis to the list of definitions of low-dose mammograms. As a result, the insurance mandate will cover breast tomosynthesis, as well as traditional 2D mammograms. The bill was sponsored by Sen. John Mulroe (D-Chicago). The law will go into effect on July 1, 2016.

**DEPARTMENT USE ONLY**  
**Cancer Imaging Exam Report**  
 Facility: RMI Menz City

Exam: Digital Mamm Screen BI MA w tomo  
 Exam Status: Completed  
 Transcription: Pending-UNKNOWN, PERSONNEL  
 Report Status: Final  
 Transcribed Date/Time: 8/6/2013 10:09

Reason for Exam: SCREENING

**Digital Mamm Screen BI MA w tomo**  
 -DIGITAL MAMMO SCREEN BI MA W TOMO  
 BILATERAL DIGITAL SCREENING MAMMOGRAM 3D/2D WITH CAD: 8/3/2012  
 CLINICAL: Screening/Routine.

2D digital mammographic images and 3D digital tomosynthesis images were obtained in the CC and MLO projections. Current study was evaluated with a Computer Aided Detection (CAD) system. Comparison is made to exams dated: 10/27/2010 mammogram - Memorial Hermann Memorial City and 4/29/2008 mammogram - RIVER OAKS IMAGING. There are scattered fibroglandular elements in both breasts that could obscure a lesion on mammography. Tomosynthesis imaging was also performed which did not show any suspicious finding. There are benign scattered calcifications in both breasts. No significant masses, calcifications, or other findings are seen in either breast. There has been no significant interval change.

**IMPRESSION: BENIGN**  
 There is no mammographic evidence of malignancy. A screening mammogram in one year is recommended.

### PENN GOV MANDATES INSURANCE COV>

- October 14, 2015 -- Gov. Tom Wolf of Pennsylvania has announced that digital breast tomosynthesis (DBT), or 3D mammography, will be covered by insurance under existing state law and must be provided to Pennsylvania women at no cost.