Hologic 3D MAMMOGRAPHY™ Site Readiness & Initial Training Programs

Hologic 3D MAMMOGRAPHY™ Site Readiness

If Your Site Is Already MQSA Certified In Digital Mammography:
If you are adding breast tomosynthesis, the unit will be accredited under your facility’s existing digital mammography certification through the MQSA’s FFDM Certification Extension Program. To become breast tomosynthesis certified, your site must apply to the MQSA for a 3D extension certification. Once an application is sent for breast tomosynthesis certification, it will take approximately 14 days for the MQSA to process and approve/deny the request. At this time, only the MQSA will need to certify breast tomosynthesis imaging at your site. Neither the state nor ACR is involved in the certification process. Please note that phantom images are required to be sent to MQSA along with the application.

If Your Site Is Not Yet MQSA Certified Or Requires Renewal In Digital Mammography:
If your site has not yet been accredited or requires FFDM renewal, you will need to apply to the ACR or state for FFDM certification. Either the 2D FFDM or the 2D images generated (C-View™ Software) from the tomosynthesis image set should be submitted to your accrediting body for the 2D component of your unit. Once 2D image accreditation is received, you may contact the MSQA for the FFDM certification extension program for tomosynthesis. Please note that phantom images are required to be sent to MQSA along with the application.

The addition or replacement of 2D FFDM images by 2D images generated (C-View Software) from the tomosynthesis image set at any time does not require re-certification.

FFDM and DBT Certification Extension Program
Division of Mammography Quality Standards
FDA/CDRH/OIR
10903 New Hampshire Ave., WO66-4528 (Attn: Denise Robinson)
Silver Spring, MD 20993-0002
Phone: 301-796-5919
Fax: 301-847-8502
Contact: Denise Robinson, denise.robinson@fda.hhs.gov
Website: http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/FacilityCertificationandInspection/ucm127739.htm.
Hologic 3D MAMMOGRAPHY™ Initial FDA Required Training

The Mammography Quality Standards Act (MQSA) requires that all health care professionals obtain eight hours of training prior to using new mammography technology on patients. Hologic understands the challenges of staying current in the ever-changing practice of medicine. We strive to improve diagnostic skills by addressing educational needs through diverse impactful programs and informative resources. We are committed to providing you with the knowledge and confidence to deliver the best care for patients.

If You Are A Radiologist, Technologist, Or Medical Physicist Not Yet Trained In Digital Mammography:

- The FDA requires you to complete eight hours of digital mammography training. Under MQSA, 21 CFR 900.12(a), personnel must receive 8 hours of initial new-modality training prior to using any new mammographic modality. Therefore, each manufacturer’s DBT unit is treated as a new mammographic modality, due to the technological differences between units. These courses below meet the requirement for Hologic 3D MAMMOGRAPHY™ only.

If You Are Already Trained In Digital Mammography:

- Radiologists - Hologic offers eight hours of training in the interpretation of our 3D MAMMOGRAPHY™ technology. All training options meet the 8-hour FDA requirement intended for radiologists who have acquired a Hologic breast tomosynthesis system. For more information, dates, and registration please visit www.hologic.com/training
  - Hologic Essentials of Breast Tomosynthesis Interpretation – Virtual training providing didactic instructional modules which prepare the participant for two interactive self-guided study-sets. Course can be accessed on demand 24/7 via the internet. Non-accredited
  - Hologic 3D MAMMOGRAPHY™ Workshops – Live hands-on training on a dedicated workstation in various U.S. locations. Non-accredited
  - WCCME WebEx 3D MAMMOGRAPHY™ Training – Live web-based hands-on training limited to sites that have a dedicated SecurView® workstation. Availability is based on a maximum of 2 radiologists per SecurView® workstations at the facility. 8.0 AMA PRA Category 1 Credit

Hologic recommends participation in the ICPME State of the Art Mammography webinar for existing and new C-View users for optimal implementation of our generated 2D imaging. www.icpme.us

- Technologists - Six hours of applications training is offered through Clinical Services. For the remaining hours, two online CE programs are available, providing two CAT A CEU upon successful completion. Please note that this training should not be performed until the MQSA FFDM certification extension is received for tomosynthesis.
  - A scheduling coordinator will contact your site once tomosynthesis installation is planned in order to determine training needs and to schedule training dates at your location.

- Medical Physicists - Eight hours of training in breast tomosynthesis is offered through Hologic. Three hours of this training may be completed online or in a live setting. In addition, you may find training courses to meet this requirement through another qualified provider.
  - Contact tomoMPtraining@hologic.com to set up live FE training and/or the 3-hour online tomosynthesis course.
Other Training Opportunities

Radiologist Live Programs

ACR CME Breast Imaging Boot Camp with Tomosynthesis
• For more information and to register, visit www.acr.org

WCCME Breast Tomosynthesis Workshops
8.0 AMA PRA Category 1 Credit
• For more information and to register, visit www.worldclasscme.com

For a complete list of all live 3D MAMMOGRAPHY™ training opportunities, please visit www.hologic.com/training/facilitated

Radiologist On-Demand Webinars

*Qualifies as supplemental/unique feature tomosynthesis training for Hologic 3D MAMMOGRAPHY™ equipment.

3D MAMMOGRAPHY™ Programs (Refreshers)

ICPME – 1.0 AMA PRA Category 1 Credit www.icpme.us
• Case Studies in Digital Breast Tomosynthesis* – Dr. Kara L. Carlson
• Case Studies in Digital Breast Tomosynthesis* – Dr. Linda R.N. Greer
• Digital Breast Tomosynthesis: Clinical Perspectives on a New Breast Cancer Screening Modality* – Dr. Sarah M. Friedewald

C-View™ - Generated 2D Imaging

Hologic recommends participation in these webinars for existing and new C-View users for optimal implementation.

ICPME – 1.0 AMA PRA Category 1 Credit www.icpme.us
• State-of-the-Art Mammography: The Role of Full Field Digital Imaging, Generated 2D Images and Digital Breast Tomosynthesis* – Dr. Linda R.N. Greer

Applied Radiology – 1.0 AMA PRA Category 1 Credit www.appliedradiology.org/tomo
• Tomosynthesis & Generated 2D Part 1: Evolution of Mammography – Dr. Elizabeth A. Rafferty & Dr. Aron J. Belfer
• Tomosynthesis & Generated 2D Part 2: Evolution of Mammography – Dr. Elizabeth A. Rafferty & Dr. Aron J. Belfer

Implementation Strategies

ICPME – 1.0 AMA PRA Category 1 Credit www.icpme.us
• The Practical and Clinical Experience One Year Out – Dr. Gary Levine, Dr. Kara Carlson & Dr. Donna Plecha
• Real World Tomo – Lessons Learned: Digital Breast Tomosynthesis Implementation in a Community-based Breast Imaging Practice – Dr. Stamatia Destounis
• Digital Breast Tomosynthesis: Tips for Smooth Implementation – Dr. Linda R.N. Greer

All CME accredited programs are supported by Hologic, Inc. through an unrestricted education grant.
Technologists – Live Programs

Hologic Live Technologist Courses – David Ellenbogen Center, Bedford, MA

- For more information & to register, please visit www.gotrainingcenter.com

ASRT Power Hour Presentations – 1 hour local presentations offered to individual sites, local societies, etc. For more information, contact your sales representatives or email trainingcenter@hologic.com for scheduling and availability. Offered to individual sites, local societies, etc.

On-Site Mammography Positioning Course

A full day course awarded 4 hours of ARRT CAT A credit by the ASRT. For registration information, email appschedule@hologic.com or contact your Hologic Clinical Applications Specialist

Technologists – On-Demand Webinars

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Hologic – Free Online CE Programs 1 CE credit www.hologic.com/training/self-guided

- I-View Software for Contrast Enhanced 2D Imaging 1 hour – ASRT approved program
- Introduction to Breast Tomosynthesis for Technologists* 1 hour – ASRT approved program
- Advancements in Digital Breast Tomosynthesis* 1 hour – ASRT approved program

Applied Radiology – 1.0 ARRT Category A Credit www.appliedradiology.org/tomo

- Tomosynthesis & Generated 2D Part 1: Evolution of Mammography – Dr. Elizabeth A. Rafferty & Dr. Aron J. Belfer
- Tomosynthesis & Generated 2D Part 2: Evolution of Mammography – Dr. Elizabeth A. Rafferty & Dr. Aron J. Belfer

ICPME – 1.0 ARRT Category A Credit www.icpme.us

- A Practical & Clinical Approach One Year Out – Dr. Gary Levine, Dr. Kara Carlson & Dr. Donna Plecha

AHRA – 1.0 ARRT Category A Credit www.ahraonline.org

- The Changing Landscape of Breast Imaging: From Volume to Value with 3D MAMMOGRAPHY™ – Sherri Lewman, CNM, BA
- The Value of Implementing 3D MAMMOGRAPHY™: A Best Practice Example – Rosemary Fisher, RT(R)(CT)(MR)