

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 recertification.

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.

Trained in Digital Mammography:

Each manufacturer's tomosynthesis 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. For more information, dates, and registration please visit www.hologic.com/training.

- **Radiologists** - Hologic offers eight hours of training in the interpretation of our 3D MAMMOGRAPHY™ technology to meet the FDA requirement.
 - **Hologic Essentials of Breast Tomosynthesis Interpretation** - Virtual training provides didactic modules with two hands on self-guided case sets. This course is accessible for 30 days from the date of activation.
Non-CME accredited
- **Medical Physicists** - Eight hours of training in breast tomosynthesis is offered through Hologic. During installation, a Field Service Engineer will provide five hours of training. For the remaining three hours, Hologic offers online training. In addition, you may find training courses to meet this requirement through another qualified provider.
 - **Tomosynthesis Training for Medical Physicists** - This three hours training can be used towards the FDA requirement.
- **Technologists** - Six hours of applications training is offered through Clinical Services. For the remaining hours, two Hologic online CE programs are available, providing two CAT A CEU upon successful completion. Please note on-site 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.
 - **Hologic Online Technologist Training** - These courses are approved by ASRT for 1 CE credit each:
 - **Introduction to Breast Tomosynthesis for Technologists**
 - **Advancements in 3D MAMMOGRAPHY™ Technology for Technologists**

Trained in Breast Tomosynthesis (Non-Hologic Equipment):

If you have already completed eight hours of tomosynthesis training on another manufacturer's system you will need training on Hologic equipment to meet the FDA requirement for vendor unique feature training. These courses below meet this FDA requirement. In addition, you may find training courses to meet this requirement through another qualified provider.

- **Radiologists** - (Three hour non-CME hands on training)
 - **3D MAMMOGRAPHY™ Interpretation - Hologic's Unique Features**
- **Medical Physicists** - (Three hour online training)
 - **Tomosynthesis Training for Medical Physicists**
- **Technologist** - (ASRT approved 1 CE credit each)
 - **Introduction to Breast Tomosynthesis for Technologists**
 - **Advancements in 3D MAMMOGRAPHY™ Technology for Technologists**

hologic.com | MedEd-BSH@hologic.com | +1.781.999.7300