

# Mammo 3D™ Performance Kit

## Comprehensive Quality Control for Digital Breast Tomosynthesis Systems

The Mammo 3D Performance Kit fulfills the tools needed for IEC 61223-3-6 (ED1) tests, and is a component of the Mammo 3D Quality Control Package – a complete solution for all your Tomosynthesis QC needs.



Criteria for acceptance testing of 3D Tomosynthesis Mammography systems has been internationally defined by the IEC, per protocol 61223-3-6. To fulfill these tests, a variety of tools are required, some of which are unique to Digital Breast Tomosynthesis (DBT).

The Mammo 3D Performance Kit includes several PMMA plates, spacers, aluminum plates and foils, steel plates, and a variety of customized test tools. It was designed to comply with:

- IEC Protocol 601223-3-6
- EUREF 1.03
- EUREF 4th Edition 2B
- German DIN 6868-14

## Specifications

Material	Quantity
<b>PMMA Plates, Spacers, &amp; Phantoms</b>	
Standard Test Plate (320 x 260 x 45 mm)	1
10 mm PMMA Plate (320 x 260 x 10 mm)	7
5 mm PMMA Plate (320 x 260 x 5 mm)	1
2 mm PMMA Plate (40 x 20 x 2 mm)	7
10 mm PMMA Spacers (180 x 15 x 10 mm)	2
30 mm PMMA Spacers (180 x 30 x 30 mm)	2
Geometric Distortion & Z-Resolution Phantom	1
<b>Aluminum Plates &amp; Foils</b>	
2 mm Aluminum Plate (100 x 100 x 2 mm)	1
0.2 mm Aluminum Foil Sheet (10 x 10 x 0.2 mm)	8
0.1 mm Aluminum Foil Sheets (100 x 100 x 2 mm)	8
<b>Steel Plates</b>	
3 mm Stainless Steel Plate (320 x 260 x 3 mm)	1
MTF Edge Tool (120 x 60 x 0.6 mm)	1
<b>Wire, Spacers, X-ray Rulers</b>	
25 micron Tungsten Wire (cm)	100
Foam Spacers (240 x 180 x 20 mm)	5
1mm scale X-ray Rulers (+2.5 to -2.5 cm)	4



## Perform 3D Acceptance Testing per IEC Requirement

Following is a list of IEC tests, and the applicable Mammo 3D Performance Kit equipment to support each test.

IEC Test	Test Frequency	Mode	Supporting Mammo 3D Performance Kit Equipment
7 - Visual inspection and functional check	Annual	-	-
8 - Alignment and collimation checks	Annual	Standard Tomosynthesis	<ul style="list-style-type: none"> <li>• 1 - Stainless Steel Plate</li> <li>• 1 - X-ray Ruler</li> </ul>
9.2 - AEC-system: Short term reproducibility	Annual	Standard Tomosynthesis	<ul style="list-style-type: none"> <li>• 1 - Standard Test Plate</li> </ul>
9.3 - AEC-system: Long term reproducibility	Weekly	Standard Tomosynthesis	<ul style="list-style-type: none"> <li>• 1 - Standard Test Plate</li> </ul>
9.4 - AEC performance	Annual	Zero Degree Angle Stationary mode, if applicable	<ul style="list-style-type: none"> <li>• 7- 10 mm PMMA Plates</li> <li>• 1 - 5 mm PMMA Plate</li> <li>• 1 - 0.2 mm Aluminum Foil Sheet</li> <li>• 1 - X-ray Ruler</li> <li>• 7 - 2 mm PMMA Plates</li> <li>• 2 - 30 mm PMMA Spacers</li> <li>• 2 - 10 mm PMMA Spacers</li> </ul>
10.1 - Image receptor: Response function	On Acceptance Only	Zero Degree Angle Stationary mode, if applicable	<ul style="list-style-type: none"> <li>• 1 - Standard Test Plate</li> <li>• 1 - 2 mm Aluminum Plate</li> </ul>
10.2 - Image receptor: element failure	Annual	-	-
10.3 - Image receptor: Uncorrected defective detector elements	Annual	Zero Degree Angle Stationary mode, if applicable	<ul style="list-style-type: none"> <li>• 1 - Standard Test Plate</li> </ul>
10.4 - System projection MTF	Annual	Standard Tomosynthesis	<ul style="list-style-type: none"> <li>• 1 - 2 mm Aluminum Plate</li> <li>• 1 - MTF Edge Tool</li> </ul>
11.1 - Image quality of the reconstructed image: Phantom testing	Daily	Standard Tomosynthesis	Mammo FFDM Phantom (sold separately)
11.2 - Image quality of the reconstructed image: Z-resolution	Annual	Standard Tomosynthesis	<ul style="list-style-type: none"> <li>• 6 - 10 mm PMMA Plates</li> <li>• 1 - Z-Resolution Phantom</li> </ul>
12.2 - Missed tissue at chest wall side in the reconstructed image	Annual	Standard Tomosynthesis	<ul style="list-style-type: none"> <li>• 1 - X-ray Ruler</li> </ul>
12.3 - Missed tissue at the top and bottom of the reconstructed tomosynthesis image	Annual	Standard Tomosynthesis	<p>For Flat Compression Paddles:</p> <ul style="list-style-type: none"> <li>• 1 - spool (100 cm) of 50 micron diameter Tungsten wire</li> <li>• 6 - 10 mm PMMA Plates</li> </ul> <p>For Curved Compression Paddles:</p> <ul style="list-style-type: none"> <li>• 1 - spool of 50 micron Tungsten wire</li> <li>• Polystyrene Foam Spacers</li> </ul>
13.2 - Artifacts in the reconstructed tomosynthesis image: Artifact evaluation	Weekly	Standard Tomosynthesis	<ul style="list-style-type: none"> <li>• 1 - Standard Test Plate</li> </ul>
13.3 - Artifacts in the reconstructed tomosynthesis image: Geometric distortion	On Acceptance Only	Standard Tomosynthesis	<ul style="list-style-type: none"> <li>• 6 - 10 mm PMMA Plates</li> <li>• 1 - Z-Resolution Phantom</li> </ul>
14 - Dosimetry for digital breast tomosynthesis	Annual	Zero Degree Angle Stationary mode, if applicable	<ul style="list-style-type: none"> <li>• 7 - 10 mm PMMA Plates</li> <li>• 1 - Standard Test Plate</li> <li>• 1 - X-ray Ruler</li> <li>• 7 - 2 mm PMMA Plates</li> <li>• 1 - Dosimeter (sold separately)</li> </ul>

To meet all your Tomosynthesis QC needs, Gammex also offers the Mammo 3D Quality Control Package, which includes:

- Mammo 3D Performance Kit
- Image Quality Phantom (Mammo FFDM™ Phantom)
- Dosimeter

**Interested in learning more?**

Contact your Gammex sales representative, or email [gammexsales@sunnuclear.com](mailto:gammexsales@sunnuclear.com)