

# Mammo 3D™ Performance Kits

## Comprehensive Quality Control for Digital Breast Tomosynthesis Systems

Sun Nuclear's Mammo 3D Performance Kits fulfill the tools needed for IEC 61223-3-6 (ED1) and EUREF/EFOMP tests. These kits are part 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/EFOMP 1.03 (Tomosynthesis)
- German DIN 6868-14

### Standard Kit – Specifications

PMMA Plates, Spacers, & Phantoms	Quantity
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 (320 x 260 x 5 mm)	1
Aluminum Plates & Foils	Quantity
2 mm Aluminum Plate (100 x 100 x 2 mm)	1
0.2 mm Aluminum Foil Sheet (10 x 10 x 0.2 mm)	1
0.1 mm Aluminum Foil Sheets (100 x 100 x 0.1 mm)	8

Steel Plates	Quantity
3 mm Stainless Steel Plate (320 x 260 x 3 mm)	1
MTF Edge Tool (120 x 60 x 0.6 mm)	1
Wire, Spacers, X-ray Rulers	Quantity
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

### Supplemental Kit – Specifications

PMMA Plates & Spacers	Quantity
2.5 mm PMMA Plate (320 x 260 x 2.5 mm)	1
1 mm PMMA Spacer (180 x 15 x 1 mm)	2
2 mm PMMA Spacer (180 x 15 x 2 mm)	2
5 mm PMMA Spacer (180 x 15 x 5 mm)	8
8 mm PMMA Spacer (180 x 15 x 8 mm)	2
10 mm PMMA Spacer (180 x 15 x 10 mm)	2
15 mm PMMA Spacer (180 x 15 x 15 mm)	2
20 mm PMMA Spacer (180 x 15 x 20 mm)	2
30 mm PMMA Spacer (180 x 15 x 30 mm)	2
PE Plates	Quantity
10 mm HDPE Plate (320 x 260 x 10 mm)	5
5 mm HDPE Plate (320 x 260 x 5 mm)	1
2.5 mm HDPE Plate (320 x 260 x 2.5 mm)	1

## 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	Modular DBT 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, Sun Nuclear also offers the Mammo 3D Quality Control Package, which includes:

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



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