

DBT Supplement to the ACR DM QC Manual

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DBT Accreditation

The FDA has approved the ACR to begin to accredit all previously FDA-approved DBT systems beginning April 9, 2018. Your facility has been identified as having a DBT unit(s) that received an extension of your MQSA certificate from the FDA to include this DBT unit(s). You must now accredit your DBT unit(s) with the ACR. You will begin the accreditation process of your FDA-approved DBT unit(s) based on your facility's MQSA certificate expiration date.

- **ACR-accredited facilities with MQSA certificates that expire within the next 8 months** will add the DBT unit(s) to your accreditation at the time of renewal. Your facility must renew the accreditation for all your existing mammography units, as well as accredit your DBT unit(s) at this time. Once approved, all your units will receive an ACR accreditation expiration date that is three years from your current expiration date.
- **ACR-accredited facilities that are currently in the reaccreditation process (renewal) with the ACR** must add the DBT unit(s) to your accreditation during this current reaccreditation (renewal) process. Once approved, all of your units will receive an ACR accreditation expiration date that is three years from your current expiration date.
- **ACR-accredited facilities with more than 13 months left on their MQSA certificate** will add the DBT unit(s) to their accreditation at the time of renewal.

When submitting your application for your FDA-approved DBT unit(s) you must upload the MQSA Certification Extension Approval Letter from the FDA that you received when your certificate was extended to include your DBT unit(s), as well as the Medical Physicist Equipment Evaluation.

Please call the ACR at (800) 227-6440 if you have questions. Thank you for continuing your support of quality mammography by accrediting with the ACR.

Background

- The Digital Mammography QC Manual took much longer to get approved than anticipated
- DBT came into being during the approval process
- Manufacturer DBT QC poses many of the same issues that were presented by manufacturer FFDM QC manual
- ACR desired to include DBT in the DM Manual
- ACR and the Committee on Quality Assurance in Mammography had a choice
 - Delay approval and include DBT
 - Proceed with approval and deal with DBT later

So here we are...

- Approval proceeded – and later is now



MQSA National Statistics

Certified facilities, as of October 1, 2017	8,726	• FFDM
Certification statistics, as April 1, 2018		
Total certified facilities / Total accredited units	8,683 / 18,640	□ 68%
Certified facilities with FFDM ² units / Accredited FFDM units	8,606 / 12,750	
Certified facilities with DBT ^{3,4} units / Accredited DBT units	4,142 / 5,791	• DBT
FY2018 inspection statistics, as of April 1, 2018		□ 31%
Facilities inspected	3,984	
Total units at inspected facilities	8,279	• F-S
Percent of inspections where the highest noncompliance was at:		□ 0.5%
Level 1 violation	.7%	
Level 2 violation ⁵	12.2%	
Level 3 violation	%	
Percent of inspections with no violation	87.2%	
Total annual mammography procedures reported, as of April 1, 2018 ¹	39,332,300	

Typo in the quiz! Answer D and move on!

Current Status

- Supplement has been drafted
- Supplement has been provided to MITA for comment
- ACR has responded to MITA comments and made changes as appropriate
- Supplement has been submitted to FDA as an application to be an alternative standard
- Supplement is currently under review by FDA
- There will probably be changes based on the FDA review and comment

EVERYTHING
I SAY FROM
NOW ON IS
SUBJECT TO
CHANGE!



ACR DBT Tests - Technologist

Fuji Aspire Cristalle	GE SenoClaire	GE Pristina	Hologic Selenia Dimensions	Siemens Inspiration
Weekly ACR MAP Phantom	Phantom IQ Test with MTD Phantom IQ 3D Test	Phantom IQ 3D Test	Phantom Image Quality	System Image Quality
Weekly Homogeneity	Flat Field 3D Test	Reconstructed Image Uniformity	Artifact Evaluation	
	CNR and MTF Measurement with MTD		SNR and CNR Measurements	
	Grid Texture Test			
	Visual Checklist		Visual Checklist	
	AOP 2D and SNR Check with MTD AOP 3D Check	AOP 3D Check		
			Geometry Calibration	

Comparison of Manufacturer DBT Tests - Medical Physicist

Fuji Aspire Cristalle	GE SenoClaire	GE Pristina	Hologic Selenia Dimensions	Siemens Inspiration
	Phantom IQ Test with MTD	ACR phantom score 3D	Phantom Image Quality Evaluation	System Image Quality
	Phantom IQ 3D Test		SNR and CNR Measurements	Geometric Accuracy in X and Y direction
	Artifact Evaluation with Flat Field Uniformity with MTD	Reconstructed Image Uniformity tests	Artifact Evaluation	Artifact Detection
In-plane Resolution	CNR and MTF measurement with MTD		Evaluation of System Resolution	
REC Performance	AOP 2D and SNR Check with MTD AOP 3D Check	AOP 3D Check	Automatic Exposure Control Function Performance	
AGD	Breast Entrance Exposure and Average Glandular Dose with MTD, 3D mode	Breast Entrance Exposure and Average Glandular Dose in 3D mode	Breast Entrance Exposure, REC Reproducibility & AGD	Average Glandular Dose
Short-term Reproducibility			Phantom Unit Assembly Evaluation	
	Volume Coverage	Volume Coverage		
X-ray Field at Chest Wall				Radiation Field
Masked Test at Chest Wall Side	Compression Paddles to MTD Chest Wall Alignment Test			
Resolution	Grid Texture Test			Z-resolution

Required Tests

Test	Imaging Modes to Test					
	System Used for both 2D and DBT Acquisition			System Used for DBT Acquisition Only		
	2D	2D w/Add-on DBT Device	DBT	2D Syn	DBT	2D Syn
Technologist Tests						
1. ACR DM Phantom Image Quality	✓		✓	✓	✓	✓
2. Computed Radiography (CR) Cassette Erasure (if applicable)	✓					
3. Compression Thickness Indicator	✓	✓			✓	
4. Visual Checklist	✓		✓			
5. Acquisition Workstation (AW) Monitor QC	✓				✓	
6. Radiologist Workstation (RW) Monitor QC	✓				✓	
7. Film Printer QC (if applicable)	✓				✓	
8. Viewbox Cleanliness (if applicable)	✓				✓	
9. Facility QC Review	✓	✓	✓		✓	
10. Compression Force	✓	✓			✓	
11. Manufacturer Calibration (if applicable)	✓	✓	✓		✓	

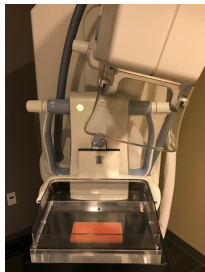
*Follow the 2D procedures outlined in the 2016 ACR Digital Mammography QC Manual
 **HVL and kVp tests must include kVp, target and filter combinations used for DBT

Test	Imaging Modes to Test					
	System Used for both 2D and DBT Acquisition			System Used for DBT Acquisition Only		
	2D	2D w/Add-on DBT Device	DBT	2D Syn	DBT	2D Syn
Medical Physicist Tests						
1. Mammography Equipment Evaluation (MEE)	✓				✓	
2. ACR DM Phantom Image Quality	✓		✓	✓	✓	✓
3. Spatial Resolution	✓	✓			✓	
4. Automatic Exposure Control System Performance	✓	✓	✓		✓	
5. Average Glandular Dose	✓	✓			✓	
6. Unit Checklist	✓	✓	✓		✓	
7. Computed Radiography (if applicable)	✓					
8. Acquisition Workstation (AW) Monitor QC	✓				✓	
9. Radiologist Workstation (RW) Monitor QC	✓				✓	
10. Film Printer QC (if applicable)	✓				✓	
11. Evaluation of Site's Technologist QC Program	✓	✓	✓		✓	
12. Evaluation of Display Device Technologist QC Program	✓				✓	
13. Manufacturer Calibration (if applicable)	✓	✓	✓		✓	
14. DBT Volume Coverage			✓		✓	
MEE or Troubleshooting - Beam Quality (Half-Value Layer) Assessment	✓**				✓**	
MEE or Troubleshooting - kVp Accuracy and Reproducibility	✓**				✓**	
MEE or Troubleshooting - Collimation Assessment	✓	✓			✓	

*Follow the 2D procedures outlined in the 2016 ACR Digital Mammography QC Manual
 **HVL and kVp tests must include kVp, target and filter combinations used for DBT

RT Tests - ACR Digital Mammography (DM) Phantom Image Quality

- Performed weekly
- Must use ACR DM Phantom
- Align to chest wall
- Compress
 - Approximately 5 daN
 - Engage AEC
 - Be consistent
- Use clinical DBT factors for 4.2 cm 50/50 breast
 - Use AEC
- Use combo mode if used clinically
- If synthesized 2D used, create that image



Depth of CNR Cavity = 9.11 ± 0.05 cm

Top View Dimensions:

- Overall Width: 31.0 ± 0.1 cm
- Overall Height: 10.0 ± 0.1 cm
- Distance from top edge to top of CNR cavity: 1.0 ± 0.05 cm
- Distance from left edge to left of CNR cavity: 1.0 ± 0.05 cm
- Distance from bottom edge to bottom of CNR cavity: 2.0 ± 0.05 cm
- Distance from right edge to right of CNR cavity: 1.0 ± 0.05 cm
- CNR Cavity Width: 2.0 ± 0.05 cm
- CNR Cavity Depth: $(9.11 \pm 0.05 \text{ cm Deep})$
- Centered Left to Right
- Milled out wax insert area: 7.0 cm ($+0.04, -0.05$ cm)
- ID Tap
- Screws

Side View Dimensions:

- Overall Height: 9.5 cm
- Distance from top edge to top of CNR cavity: 1.0 ± 0.05 cm
- Distance from bottom edge to bottom of CNR cavity: 2.0 ± 0.05 cm
- Distance from left edge to left of CNR cavity: 1.0 ± 0.05 cm
- Distance from right edge to right of CNR cavity: 1.0 ± 0.05 cm
- CNR Cavity Depth: 7.5 cm
- Distance from top edge to top of milled out wax insert area: 1.0 ± 0.05 cm
- Distance from bottom edge to bottom of milled out wax insert area: 2.0 ± 0.05 cm
- Distance from left edge to left of milled out wax insert area: 1.0 ± 0.05 cm
- Distance from right edge to right of milled out wax insert area: 1.0 ± 0.05 cm
- Milled out wax insert area: 7.0 cm ($+0.04, -0.05$ cm)
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- Screws

Top View Details:

- Star symbol
- Circle symbol
- Rectangle symbol
- Triangle symbol
- Circle symbol
- Star symbol
- Circle symbol

Side View Details:

- Star symbol
- Circle symbol
- Rectangle symbol
- Triangle symbol
- Circle symbol
- Star symbol
- Circle symbol

Top View Tolerances (Insert, Wall & CNR):

- Wax insert gill depth: $\pm 0.05 \text{ cm}$ ($\pm 2 \text{ mils}$)
- Wax insert gill width and length: $\pm 0.04 / -0.00 \text{ cm}$
- CNR cavity depth: $\pm 0.005 \text{ cm}$ ($\pm 2 \text{ mils}$)
- CNR diameter: $\pm 0.05 \text{ cm}$

Side View Tolerances (Insert, Wall & CNR):

- Wax insert gill depth: $\pm 0.05 \text{ cm}$ ($\pm 2 \text{ mils}$)
- Wax insert gill width and length: $\pm 0.04 / -0.00 \text{ cm}$
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Side View Details:

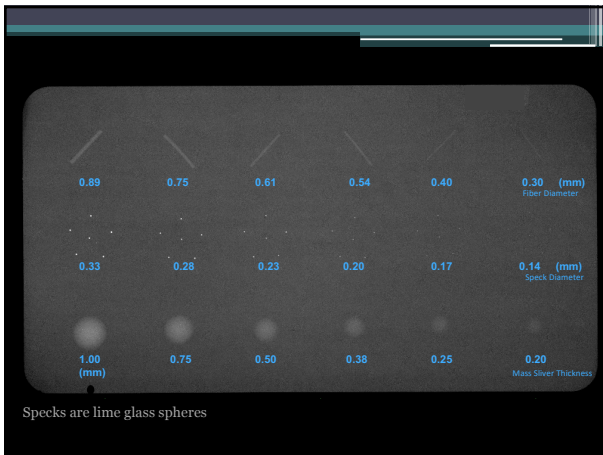
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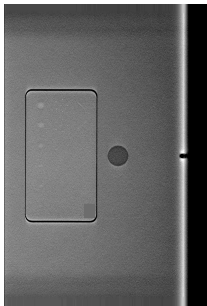


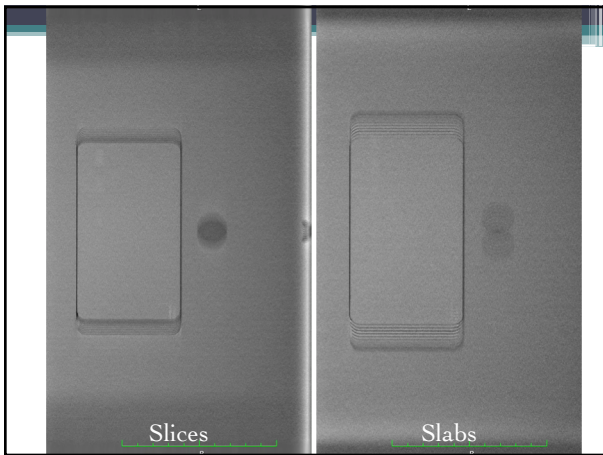
Phantom Scoring

Test Object	Full Point	Half Point
Fibers (6)	<ul style="list-style-type: none"> Full length visible (≥ 8 mm long) Correct location Correct orientation 1 break allowed (must be \leq width of fiber) 	<ul style="list-style-type: none"> At least half of length visible (≥ 5 and < 8 mm long) Correct location Correct orientation 1 break allowed (must be \leq width of fiber)
Speck Groups (6)	<ul style="list-style-type: none"> 4 - 6 specks visible Correct locations 	<ul style="list-style-type: none"> 2 - 3 specks visible Correct locations
Masses (6)	<ul style="list-style-type: none"> Density difference visible Border is continuous and generally circular ($\geq \frac{1}{2}$ border visible) Correct location 	<ul style="list-style-type: none"> Density difference visible Border is not continuous or generally circular ($\geq \frac{1}{4}$ and $< \frac{1}{2}$ border visible) Correct location

RT Tests - Phantom

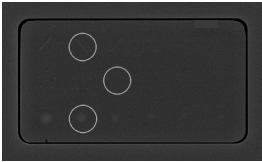
- Score at AWS, or at RWS if necessary
- In DBT stack, find the slice that best demonstrates the test objects
 - Can use slabs if slices not available
- Optimize WW/WL to visualize test objects
- Observe the image for artifacts





RT Tests - Phantom

- Must be able to see
 - 2 fibers
 - 3 speck groups
 - 2 masses
- No clinically significant artifacts
 - Artifacts are as prominent as (or more prominent than) the visible test objects in the phantom image
 - Artifacts obscure test objects in the phantom
 - Artifacts could affect clinical interpretation
 - Pass/Fail
- Corrective action prior to clinical use
- Repeat scoring for synthesized 2D, if applicable



1. ACR DM Phantom Image Quality

Facility: _____ Image Mode: _____ Patient ID: _____
MAP ID: _____ Unit ID: _____

Test	Pass/Fail			
	1	2	3	4
Image Quality	Date (month & day)			
	Resolution			
	View or selected target			
	ROI (mm)			
	Target/ROI			
Artifacts	Noise			
	Artifacts			
	Fiber noise			
	Speck group noise			
	Other noise			
Overall Pass/Fail				

Analysis: _____

Test	Pass/Fail	Pass/Fail
Fiber	4.0 mm long	1.0 and 4.0 mm long
Speck	4.0 mm long	1.0 mm long
Masses	4.0 mm long	4.0 x 4.0 mm

Notes: _____

Reidinger Technology's Section

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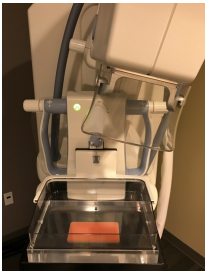
RT Tests - Manufacturer Calibrations

- Must be performed at the frequency specified by the manufacturer
- Must follow manufacturers procedures and recommendations
- Document performance of the calibration

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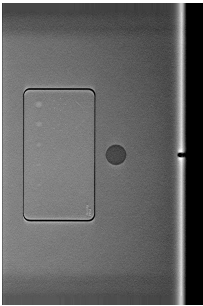
MP Tests - ACR Digital Mammography (DM) Phantom Image Quality

- Performed weekly
- Must use ACR DM Phantom
- Align to chest wall
- Compress
 - Approximately 5 daN
 - Engage AEC
 - Be consistent
- Use clinical DBT factors for 4.2 cm 50/50 breast
 - Use AEC
- Use combo mode if used clinically
- If synthesized 2D used, create that image

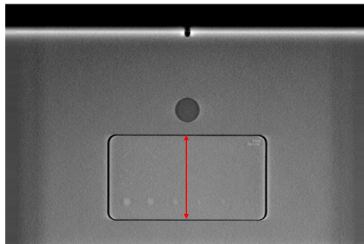


MP Tests - Phantom

- Score at AWS, or at RWS if necessary
- In DBT stack, find the slice that best demonstrates the test objects
 - Can use slabs if slices not available
- Optimize WW/WL to visualize test objects
- Observe the image for artifacts



- Distance measurement



- Must be able to see
 - 2 fibers
 - 3 speck groups
 - 2 masses
- No clinically significant artifacts
 - Artifacts are as prominent as (or more prominent than) the visible test objects in the phantom image
 - Artifacts obscure test objects in the phantom
 - Artifacts could affect clinical interpretation
 - Pass/Fail
- Measured distance must be $70 \text{ mm} \pm 14 \text{ mm}$
- Corrective action prior to clinical use
- Repeat scoring for synthesized 2D, if applicable

2. ACR DM Phantom Image Quality

Facility Name _____ MR Unit _____ ACR DM Phantom MR and SW _____		MR ID-Number (XXXX-XX) _____ Room # _____ Survey Date _____	
---	--	--	--

		Phantom Type		Phantom Size	
Phantom Type		General-purpose for Technological ACR Techniques & Procedures Summaries Use manual technique for signal averaging, repeat of 4 or 8 SRs (SR) and repeat of 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 91, 92, 93, 94, 95, 96, 97, 98, 99, 100, 101, 102, 103, 104, 105, 106, 107, 108, 109, 110, 111, 112, 113, 114, 115, 116, 117, 118, 119, 120, 121, 122, 123, 124, 125, 126, 127, 128, 129, 130, 131, 132, 133, 134, 135, 136, 137, 138, 139, 140, 141, 142, 143, 144, 145, 146, 147, 148, 149, 150, 151, 152, 153, 154, 155, 156, 157, 158, 159, 160, 161, 162, 163, 164, 165, 166, 167, 168, 169, 170, 171, 172, 173, 174, 175, 176, 177, 178, 179, 180, 181, 182, 183, 184, 185, 186, 187, 188, 189, 190, 191, 192, 193, 194, 195, 196, 197, 198, 199, 200, 201, 202, 203, 204, 205, 206, 207, 208, 209, 210, 211, 212, 213, 214, 215, 216, 217, 218, 219, 220, 221, 222, 223, 224, 225, 226, 227, 228, 229, 230, 231, 232, 233, 234, 235, 236, 237, 238, 239, 240, 241, 242, 243, 244, 245, 246, 247, 248, 249, 250, 251, 252, 253, 254, 255, 256, 257, 258, 259, 260, 261, 262, 263, 264, 265, 266, 267, 268, 269, 270, 271, 272, 273, 274, 275, 276, 277, 278, 279, 280, 281, 282, 283, 284, 285, 286, 287, 288, 289, 290, 291, 292, 293, 294, 295, 296, 297, 298, 299, 300, 301, 302, 303, 304, 305, 306, 307, 308, 309, 310, 311, 312, 313, 314, 315, 316, 317, 318, 319, 320, 321, 322, 323, 324, 325, 326, 327, 328, 329, 330, 331, 332, 333, 334, 335, 336, 337, 338, 339, 340, 341, 342, 343, 344, 345, 346, 347, 348, 349, 350, 351, 352, 353, 354, 355, 356, 357, 358, 359, 360, 361, 362, 363, 364, 365, 366, 367, 368, 369, 370, 371, 372, 373, 374, 375, 376, 377, 378, 379, 380, 381, 382, 383, 384, 385, 386, 387, 388, 389, 390, 391, 392, 393, 394, 395, 396, 397, 398, 399, 400, 401, 402, 403, 404, 405, 406, 407, 408, 409, 410, 411, 412, 413, 414, 415, 416, 417, 418, 419, 420, 421, 422, 423, 424, 425, 426, 427, 428, 429, 430, 431, 432, 433, 434, 435, 436, 437, 438, 439, 440, 441, 442, 443, 444, 445, 446, 447, 448, 449, 450, 451, 452, 453, 454, 455, 456, 457, 458, 459, 460, 461, 462, 463, 464, 465, 466, 467, 468, 469, 470, 471, 472, 473, 474, 475, 476, 477, 478, 479, 480, 481, 482, 483, 484, 485, 486, 487, 488, 489, 490, 491, 492, 493, 494, 495, 496, 497, 498, 499, 500, 501, 502, 503, 504, 505, 506, 507, 508, 509, 510, 511, 512, 513, 514, 515, 516, 517, 518, 519, 520, 521, 522, 523, 524, 525, 526, 527, 528, 529, 530, 531, 532, 533, 534, 535, 536, 537, 538, 539, 540, 541, 542, 543, 544, 545, 546, 547, 548, 549, 550, 551, 552, 553, 554, 555, 556, 557, 558, 559, 560, 561, 562, 563, 564, 565, 566, 567, 568, 569, 570, 571, 572, 573, 574, 575, 576, 577, 578, 579, 580, 581, 582, 583, 584, 585, 586, 587, 588, 589, 590, 591, 592, 593, 594, 595, 596, 597, 598, 599, 600, 601, 602, 603, 604, 605, 606, 607, 608, 609, 610, 611, 612, 613, 614, 615, 616, 617, 618, 619, 620, 621, 622, 623, 624, 625, 626, 627, 628, 629, 630, 631, 632, 633, 634, 635, 636, 637, 638, 639, 640, 641, 642, 643, 644, 645, 646, 647, 648, 649, 650, 651, 652, 653, 654, 655, 656, 657, 658, 659, 660, 661, 662, 663, 664, 665, 666, 667, 668, 669, 670, 671, 672, 673, 674, 675, 676, 677, 678, 679, 680, 681, 682, 683, 684, 685, 686, 687, 688, 689, 690, 691, 692, 693, 694, 695, 696, 697, 698, 699, 700, 701, 702, 703, 704, 705, 706, 707, 708, 709, 710, 711, 712, 713, 714, 715, 716, 717, 718, 719, 720, 721, 722, 723, 724, 725, 726, 727, 728, 729, 730, 731, 732, 733, 734, 735, 736, 737, 738, 739, 740, 741, 742, 743, 744, 745, 746, 747, 748, 749, 750, 751, 752, 753, 754, 755, 756, 757, 758, 759, 760, 761,			

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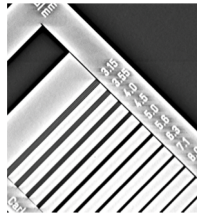
MP Tests - Spatial Resolution

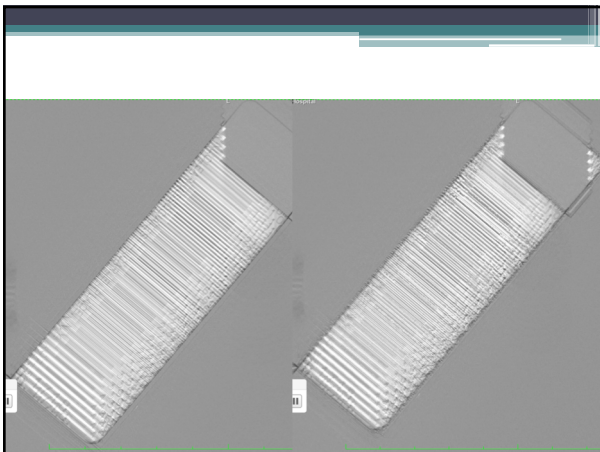
- Use
 - ACR DM Phantom
 - Line pair pattern up to 10 lp/mm
- Place phantom reversed from normal
- Place pattern on phantom at 45° to A-C axis
- Compress lightly
- Make DBT exposure using manual techniques as close as possible to phantom techniques
- Repeat for all targets used clinically for DBT

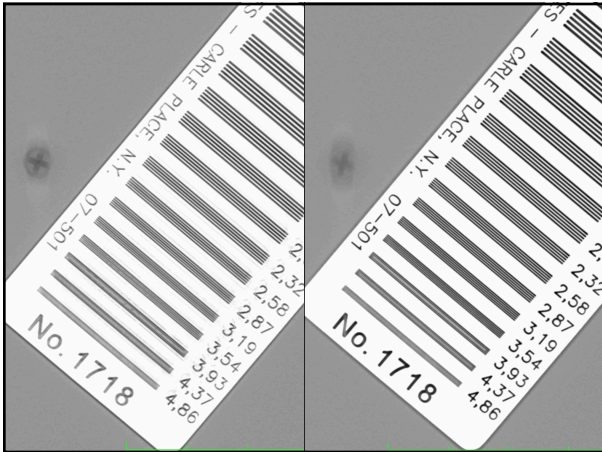


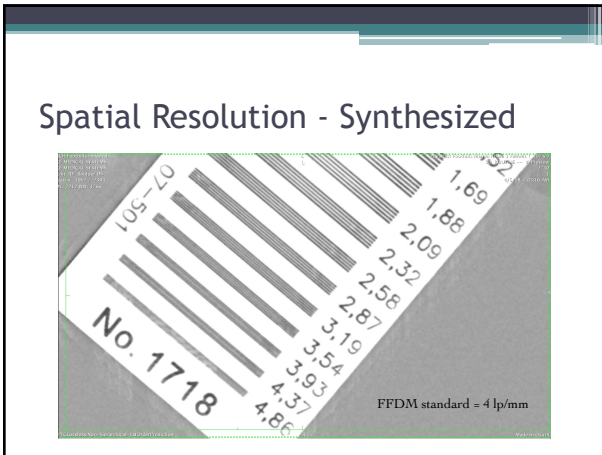
MP Tests - Spatial Resolution

- Record the highest frequency for which at least half the length of the lines can be continuously resolved in each image
- Ensure that the polarity of the lines does not reverse
- Must visualize ≥ 3.0 lp/mm
- Corrective action within 30 days









3. Spatial Resolution

Facility Name: _____ MAP ID: MAP-000000-000 _____
 MR & MRC: _____ Review ID: _____
 Survey Date: _____

Procedure: Position: _____
 1. Place the chart on the top of the patient and center it. Position: _____
 2. Press the patient on top of the patient and center it. Position: _____
 3. Press the patient on top of the patient and center it. Position: _____
 4. Press the patient on top of the patient and center it. Position: _____

Target	Image	Image	Image	Image
Target	Image	Image	Image	Image
Target	Image	Image	Image	Image
Target	Image	Image	Image	Image
Target	Image	Image	Image	Image
Target	Image	Image	Image	Image

Action Items: For 3D: spatial resolution must be 4.0 lp/mm for contact mode and 4.0 lp/mm for image capture mode.
 For 2D: spatial resolution must be 4.0 lp/mm for contact mode.
 For 3D: spatial resolution must be 4.0 lp/mm for contact mode.

Chart Edge

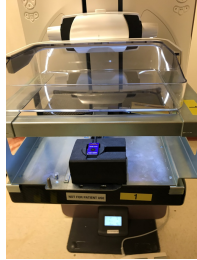
SNR = $\frac{(\text{Mean Bkgd Signal} - \text{DC offset})}{\text{Std Dev of Bkgd}}$

1863.9 / 29.3 = 63.6

[illegible]

MP Tests - Average Glandular Dose

- Protect the detector
- Dosimeter is placed
 - 4.2 cm above breast support
 - Or inverse square correction to 4.2 cm
 - 4 cm in from chest wall edge
 - Centered laterally
- Select target, filter, kVp as used for phantom imaging
- Select mAs as close as possible to phantom value
- Perform manual DBT exposure
 - Tube parked at center position, if possible
- Repeat for combo mode technical factors, if applicable



MP Tests - Average Glandular Dose

- Calculate average glandular dose using Dance method

$$D = K g c s$$

D = Average Glandular Dose (mGy)
 K = Entrance Exposure (mR)
 g = g-factor for breast simulated with acrylic or BR-12
 c = c-factor for breasts simulated with acrylic or BR-12
 s = s-factor for clinically used spectra

g is the incident air kerma to mean glandular dose conversion factor
 c corrects for any difference in breast composition for 50% glandularity

Breast Thickness (cm)	g-factor * c-factor * 0.76 mGyR for Acrylic						
	0.3	0.35	0.4	0.45	0.5	0.55	0.6
4.2	1.668	1.628	2.037	2.261	2.499	2.736	2.972

s-factors for Acrylic and BR-12	
Target/Filter	s-factor
Mo/Mo	1.000
Mo/Rh	1.017
Ru/Ru	1.051
Ru/Au	1.044
Ru/Ag	1.087
W/Rh	1.042
W/Au (0.5 mm)	1.134
W/Au (0.7 mm)	1.082
W/Ag	1.042

MP Tests - Average Glandular Dose

- AGD ≤ 3.0 mGy
 - Single DBT view
 - Combined 2D, DBT view ("combo")
 - Correction prior to clinical use
- Compare measured dose to system-reported dose
 - Must agree $\pm 25\%$
 - Correction within 30 days

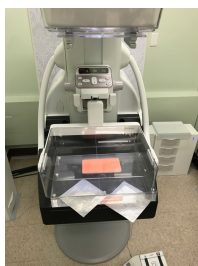
MP Tests - Manufacturer Calibrations

- Must be performed at the frequency specified by the manufacturer
- Must follow manufacturers procedures and recommendations
- Document performance of the calibration

13. Manufacturer Calibrations (if applicable)											
Facility Name _____		MAM ID Number (XXXX-XX) _____									
MAM Model _____		Receptor ID _____									
		Exposure Date _____									
<div> <div>Procedure</div> <div>Enter Manufacturer's Instructions</div> </div>											
<table border="1"> <thead> <tr> <th>Name of Calibration</th> <th>Operator</th> </tr> </thead> <tbody> <tr> <td>101 mAs/Min on DBT System</td> <td></td> </tr> <tr> <td>102</td> <td></td> </tr> <tr> <td>Overall Pass/Fail</td> <td></td> </tr> </tbody> </table>				Name of Calibration	Operator	101 mAs/Min on DBT System		102		Overall Pass/Fail	
Name of Calibration	Operator										
101 mAs/Min on DBT System											
102											
Overall Pass/Fail											
<div> <div>Notes/Comments</div> <div> Response: _____ Troubleshooting: _____ </div> </div>											

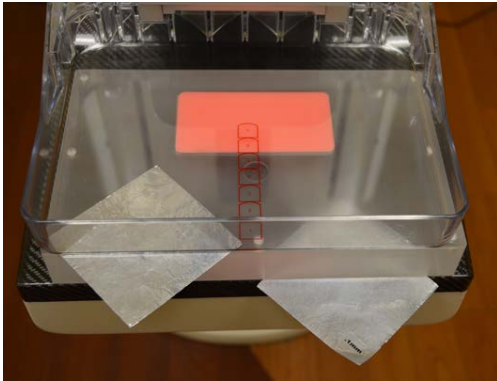
MP Tests - DBT Volume Coverage

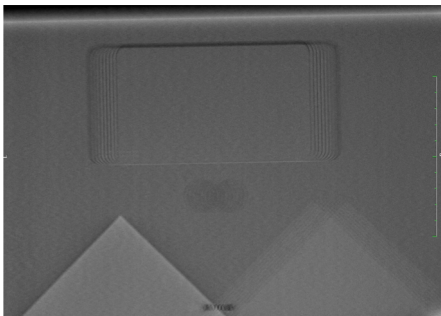
- Use
 - ACR Digital Mammography Phantom
 - Two 0.1 mm thick sheets of Al
- Select the largest receptor size and paddle
- Position phantom rotated 180°
 - Place 1 sheet Al under phantom
 - Place 1 sheet Al on top of phantom
- Perform DBT exposure



MP Tests - DBT Volume Coverage

- Intent is to ensure that the depth of the breast is fully images
- Criterion
 - Must verify that both the top and bottom Al sheets appear well defined in a slice





[illegible]

Other Questions

- **Timing?**
 - Hard to say. FDA review continues.
 - Once approved by FDA, ACR will integrate supplement into 2016 manual and reissue a new publication that covers both DM and DBT... hopefully before Penny Butler retires this summer
- **Who can use it**
 - After approval by FDA and implementation by ACR, any facility doing FFDM or DBT can use the new manual
 - Per MQSA Hotline: CESM "is an interventional procedure and therefore, [sic] not subject to the MQSA regulations"

Thank you!