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# ACR Digital Mammography QC Manual

Eric Berns, Ph.D.
University of Colorado Hospital
Denver Health Medical Center
Member, NMQAAC
Chair, ACR Subcommittee on Quality Assurance in Mammography
and lead author of the ACR Digital Mammography QC Manual

## Overview

- Welcome
- Introductions
- Phantom
- QC Program and Manual
- What's Next for the ACR

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# ACR DM QC Manual – Status

- February 17, 2016 - FDA approved ACR's alternative standard allowing facilities to use new manual under MQSA
  - Only applies to FFDM systems without advanced imaging capabilities (i.e., tomosynthesis, contrast enhancement, etc.)

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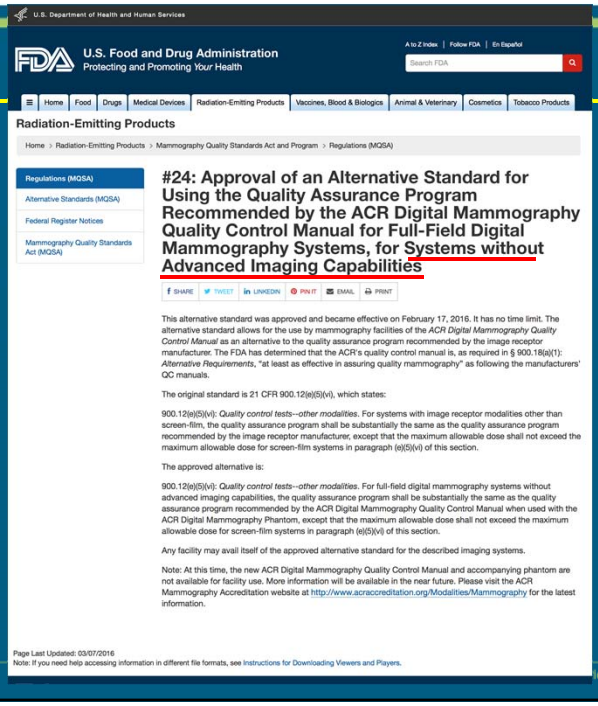

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Regulations (MQSA)
Alternative Standards (MQSA)
Federal Register Notices
Mammography Quality Standards Act (MQSA)

**#24: Approval of an Alternative Standard for Using the Quality Assurance Program Recommended by the ACR Digital Mammography Quality Control Manual for Full-Field Digital Mammography Systems, for Systems without Advanced Imaging Capabilities**

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This alternative standard was approved and became effective on February 17, 2016. It has no time limit. The alternative standard allows for the use by mammography facilities of the *ACR Digital Mammography Quality Control Manual* as an alternative to the quality assurance program recommended by the image receptor manufacturer. The FDA has determined that the ACR's quality control manual is, as required in § 900.18(a)(1): *Alternative Requirements*, "at least as effective in assuring quality mammography" as following the manufacturers' QC manuals.

The original standard is 21 CFR 900.12(e)(5)(vi), which states:

900.12(e)(5)(vi): *Quality control tests--other modalities*. For systems with image receptor modalities other than screen-film, the quality assurance program shall be substantially the same as the quality assurance program recommended by the image receptor manufacturer, except that the maximum allowable dose shall not exceed the maximum allowable dose for screen-film systems in paragraph (e)(5)(vi) of this section.

The approved alternative is:

900.12(e)(5)(vi): *Quality control tests--other modalities*. For full-field digital mammography systems without advanced imaging capabilities, the quality assurance program shall be substantially the same as the quality assurance program recommended by the ACR Digital Mammography Quality Control Manual when used with the ACR Digital Mammography Phantom, except that the maximum allowable dose shall not exceed the maximum allowable dose for screen-film systems in paragraph (e)(5)(vi) of this section.

Any facility may avail itself of the approved alternative standard for the described imaging systems.

Note: At this time, the new ACR Digital Mammography Quality Control Manual and accompanying phantom are not available for facility use. More information will be available in the near future. Please visit the ACR Mammography Accreditation website at http://www.acraccreditation.org/Modalities/Mammography for the latest information.

Page Last Updated: 03/07/2016
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

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## Strengths & Take Home Points

- QC Manual is comprehensive
- Phantom is of major importance
  - Most failures are artifacts
- Includes most “legacy” tests
- Includes most “current” Mfr Tests
- Accomodates Mfr specific test (where app)
- Accomodates growth of QC program
- Manual can realistically be implemented

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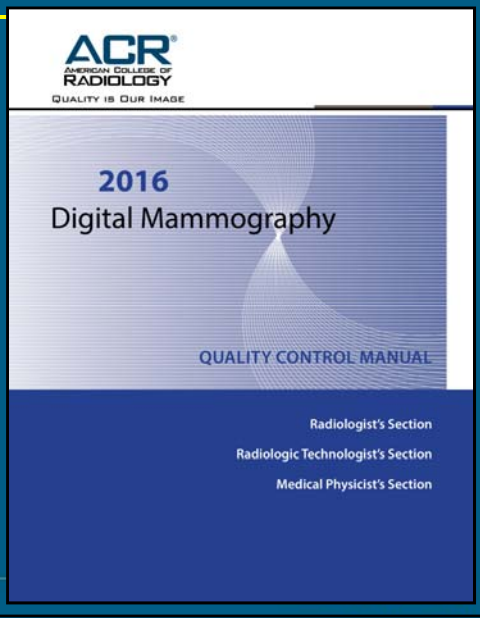
## ACR DM QC Manual

**Published**
**July 29, 2016**



# ACR DM QC Manual Project

**Subcommittee on Quality Assurance in Mammography**
**of the**
**Committee on Mammography Accreditation**

Eric Berns, PhD (chair)
Jay Baker, MD
Lora Barke, DO
Lawrence Bassett, MD, FACR
R. Edward Hendrick, PhD, FACR
Debra Monticciolo, MD, FACR
Doug Pfeiffer, MS, FACR
Margarita Zuley, MD
Christine Adent, RT(R)
Shelli Dixon, RT(R)
John Sandrick, PhD (MITA, retired)
Robert Uzenoff, BS (MITA)
Moustaffa Zerhouni (MITA)
Priscilla Butler, MS, FACR (ACR Staff Member)
Marion Boston, RT(R) (ACR Staff Member)
Pamela Platt, BSRT(R) (ACR Staff Member)

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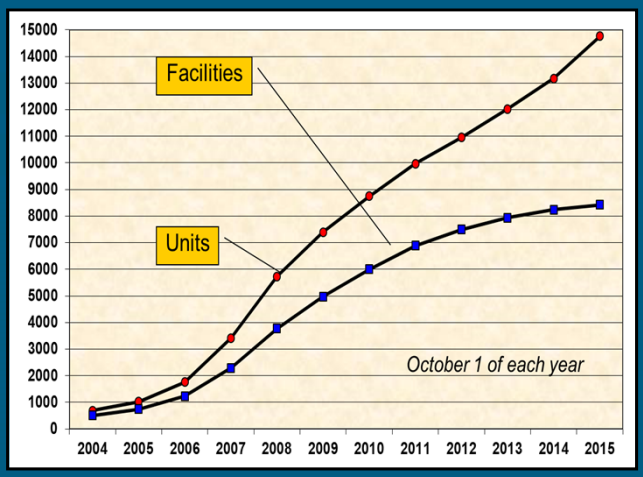
# Digital Mammography in the US *(as of 9/1/2016)*




- 16,560 units at 8,748 facilities
- 12,601 FFDM units
- 3,703 DBT units

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| Full Field Digital Mammography (FFDM) or Digital Breast Tomosynthesis (DBT) Unit | Accreditation Body Approval Date Effective Date | | | |
|---|---|---|---|---|
| | ACR | SAR | SIA | STX |
| GE Senographe 2000D | 12/18/02<br>02/15/03 | 08/15/06<br>08/15/06 | 08/28/03<br>10/01/03 | 05/21/04<br>05/21/04 |
| Fischer Imaging SenoScan | 07/24/03<br>08/15/03 | | | 05/21/04<br>05/21/04 |
| Lorad/Hologic Selenia (Molybdenum target) | 09/02/03<br>09/15/03 | 08/15/06<br>08/15/06 | 08/28/03<br>10/01/03 | 05/21/04<br>05/21/04 |
| GE Senographe DS | 08/12/04<br>09/15/04 | 08/15/06<br>08/15/06 | 01/12/06<br>01/17/06 | 08/12/04<br>09/15/04 |
| Siemens Mammomat Novation DR | 10/07/05<br>10/15/05 | 08/26/08<br>08/26/08 | 01/26/06<br>02/01/06 | 06/29/06<br>06/29/06 |
| GE Senographe Essential | 06/29/06<br>07/15/06 | 08/15/06<br>08/15/06 | 08/24/06<br>08/24/06 | 09/05/06<br>09/05/06 |
| Fuji Computed Radiography for Mammography | 11/13/06<br>11/15/06 | 10/12/06<br>10/12/06 | 11/13/06<br>11/13/06 | 11/13/06<br>11/13/06 |
| Hologic Selenia (Tungsten target) | 02/01/08<br>02/01/08 | 02/01/08<br>02/01/08 | 02/01/08<br>02/01/08 | 02/01/08<br>02/01/08 |
| Siemens Mammomat Novation S | 02/11/09<br>02/11/09 | 02/11/09<br>02/11/09 | 02/11/09<br>02/11/09 | 02/11/09<br>02/11/09 |
| Hologic Selenia S | 02/11/09<br>02/11/09 | 02/11/09<br>02/11/09 | 02/11/09<br>02/11/09 | 02/11/09<br>02/11/09 |
| Hologic Selenia Dimensions 2D | 02/11/09<br>02/11/09 | 02/11/09<br>02/11/09 | 02/11/09<br>02/11/09 | 02/11/09<br>02/11/09 |
| Carestream Directview Computed Radiography (CR) Mammography | 02/08/11<br>02/16/11 | 01/07/11<br>01/07/11 | 01/07/11<br>01/07/11 | 02/08/11<br>02/08/11 |
| Siemens Mammomat Inspiration | 02/11/11<br>02/11/11 | 02/11/11<br>02/11/11 | 02/11/11<br>02/11/11 | 02/11/11<br>02/11/11 |
| Hologic Selenia Encore | 06/15/11<br>06/15/11 | 06/15/11<br>06/15/11 | 06/15/11<br>06/15/11 | 06/15/11<br>06/15/11 |
| Philips (Sectra) MicroDose L30 | 10/20/11<br>10/21/11 | 07/18/11<br>07/18/11 | | 08/03/11<br>08/03/11 |
| Siemens Mammomat Inspiration Pure | 08/23/11<br>08/23/11 | 08/23/11<br>08/23/11 | 08/23/11<br>08/23/11 | 08/23/11<br>08/23/11 |
| GE Senographe Care | 10/07/11<br>10/07/11 | 10/07/11<br>10/07/11 | 10/07/11<br>10/07/11 | 10/07/11<br>10/07/11 |
| Planmed Nuance | 12/13/11<br>12/27/11 | 12/20/11<br>12/20/11 | | 01/20/12<br>01/20/12 |
| Planmed Nuance Excel | 12/13/11<br>12/27/11 | 12/20/11<br>12/20/11 | | 01/20/12<br>01/20/12 |
| Fuji Aspire Computed Radiography for Mammography | 01/20/12<br>01/20/12 | 01/20/12<br>01/20/12 | 01/20/12<br>01/20/12 | 01/20/12<br>01/20/12 |
| Giotto Image 3D/3DL | 11/02/12<br>11/02/12 | 7/24/12<br>7/24/12 | | 03/09/12<br>03/09/12 |
| Fuji Aspire HD | 03/28/12<br>04/10/12 | 7/24/12<br>7/24/12 | 05/25/12<br>05/25/12 | 03/28/12<br>04/10/12 |
| Konica Minolta Xpress Digital Mammography CR System | 04/19/12<br>04/27/12 | 7/24/12<br>7/24/12 | | 04/19/12<br>04/27/12 |
| Agfa CR Mammography System | 09/04/12<br>09/14/12 | 7/24/12<br>7/24/12 | | 06/08/12<br>06/08/12 |
| Fuji Aspire HD-s | 06/25/13<br>06/25/13 | 06/25/13<br>06/25/13 | 06/25/13<br>06/25/13 | 06/25/13<br>06/25/13 |
| Fuji Aspire HD Plus | 06/25/13<br>06/25/13 | 06/25/13<br>06/25/13 | 06/25/13<br>06/25/13 | 06/25/13<br>06/25/13 |
| Siemens Mammomat Inspiration Prime | 07/11/13<br>07/11/13 | 07/11/13<br>07/11/13 | 07/11/13<br>07/11/13 | 07/11/13<br>07/11/13 |
| Philips MicroDose SI L50 | 09/23/13<br>09/23/13 | 09/23/13<br>09/23/13 | 09/23/13<br>09/23/13 | 09/23/13<br>09/23/13 |
| Siemens Mammomat Inspiration ECO | 11/20/13<br>11/20/13 | 11/20/13<br>11/20/13 | 11/20/13<br>11/20/13 | 11/20/13<br>11/20/13 |
| Fuji Aspire Cristalle | 10/21/14<br>10/21/14 | 10/21/14<br>10/21/14 | 10/21/14<br>10/21/14 | 10/21/14<br>10/21/14 |
| iCRco 3600M Mammography CR System | 01/20/15<br>02/03/15 | | | |
| Siemens Mammomat Fusion | 09/21/15 | 09/21/15 | 09/21/15 | 09/21/15 |

- 4 accrediting bodies
- ~32 FDA approved models and manufacturers

# Quality Control: What It and Why Is It Important?

## Primary Purpose

- Reduce exposure to patients and personnel
- Ensure adequate and consistent patient image quality
- Detect and correct for potential problems, before they impact patient image quality and care
- What it's not:
  - Not a detailed technical evaluation of a unit
  - Not a detailed measure of a limits of a unit
  - Not the optimization of a unit

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## ACR DM QC Manual Project

- Subcommittee Goals:
  - Standardize all QC tests for all digital Mfr's
  - Standardize test frequencies
  - Standardize performance criteria

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## ACR DM QC Manual Project

- QC Tests:
  - Tests come from a review of a variety of sources (MQSA, SFM, ACRIN DMIST, Manufacturer's QC programs, MITA, European and other Int'l QC programs, subcommittee clinical experience, etc.)
  - Clinically relevant
  - User/operator friendly
  - Eliminate non-productive testing
- *Just because you can test something, doesn't mean you should!*

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## ACR Digital QC Manual - Structure

- Radiologist's Section
- Radiologic Technologist's Section
- Medical Physicist's Section
- Appendices
- **Clinical Image Quality Section (w/Patient Positioning and Compression and Clinical Image Quality Evaluation) will be revised at a later date and posted on ACR website

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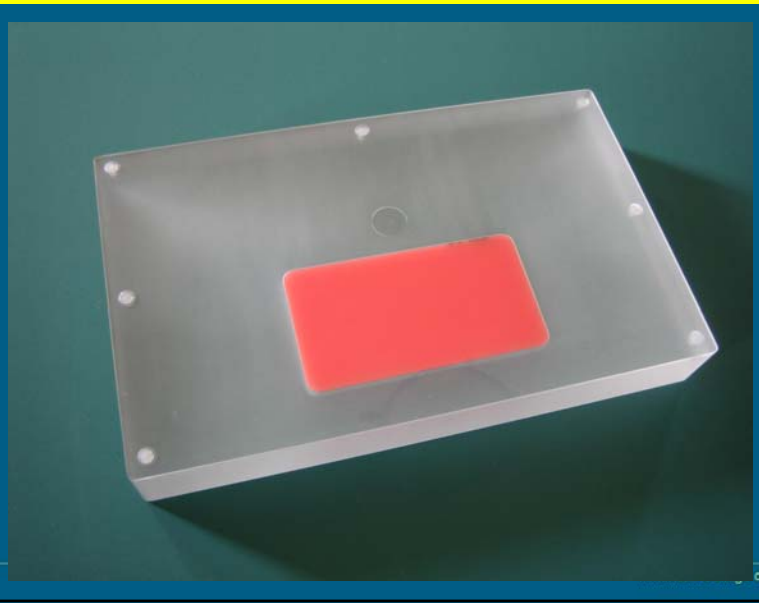
## The ACR DM Phantom Prototype



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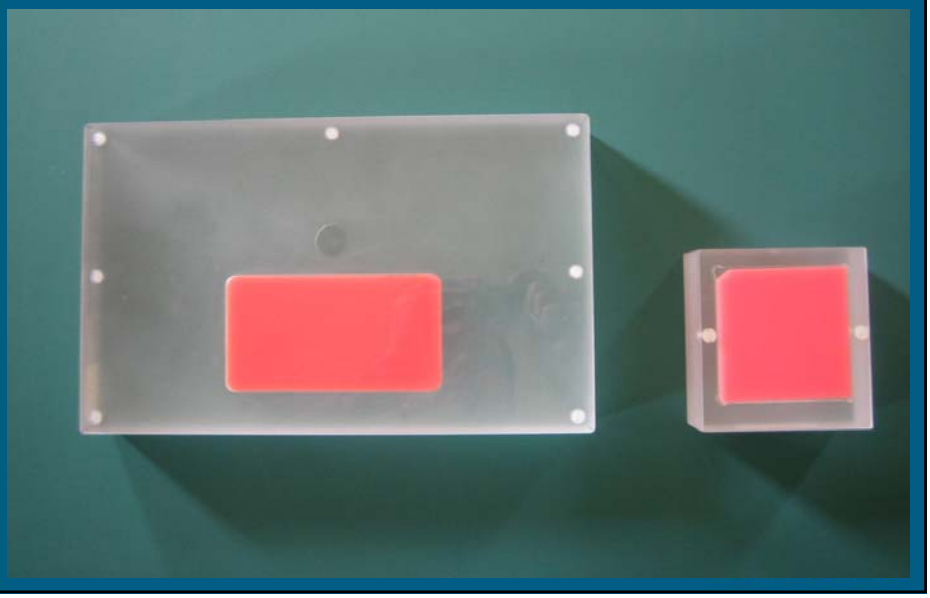
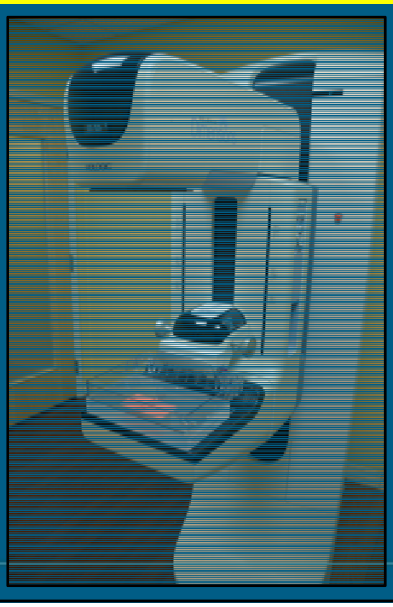
## Phantom Prototype Design Principles



## Phantom Prototype Design Principles



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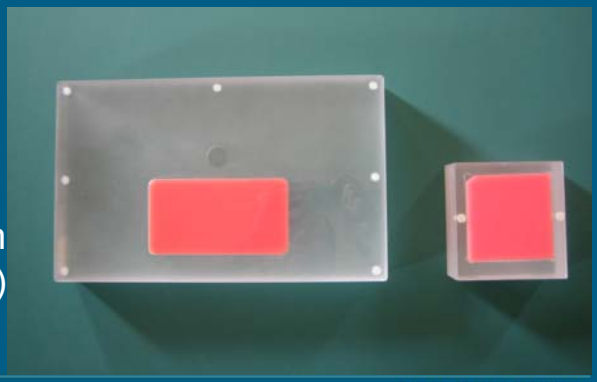
## Phantom Prototype Design Principles

- Based on existing ACR Accreditation Phantom
- Similar imaging and scoring to current phantom
- Build on experience of QC techs and physicists at ~8,700 US facilities who already know how to use and score the existing phantom (~25,000+ techs)



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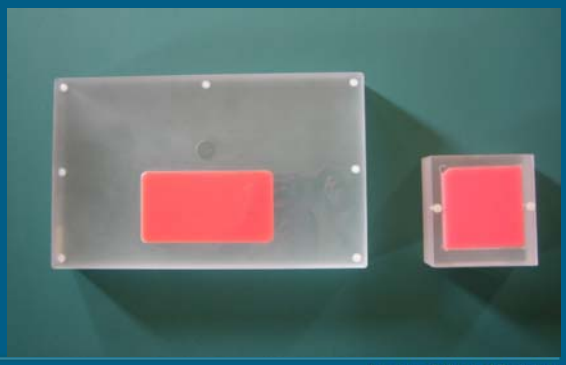
## Phantom Prototype Design Principles

- Can be used on both SFM & FFDM
- Total attenuation matched to current SFM phantom
  - Similar thickness
  - Similar total dose
- Permits testing of the MQSA 3.0 mGy dose limit (single CC view)



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## Proposed Scoring Changes

- Eliminate subtraction for artifacts
- Added a "Fail" for artifacts
- New pass/fail criteria
  - From: 4,3,3
  - To: 2,3,2
  - **But, objects are the same (effective) size as SFM Phantom

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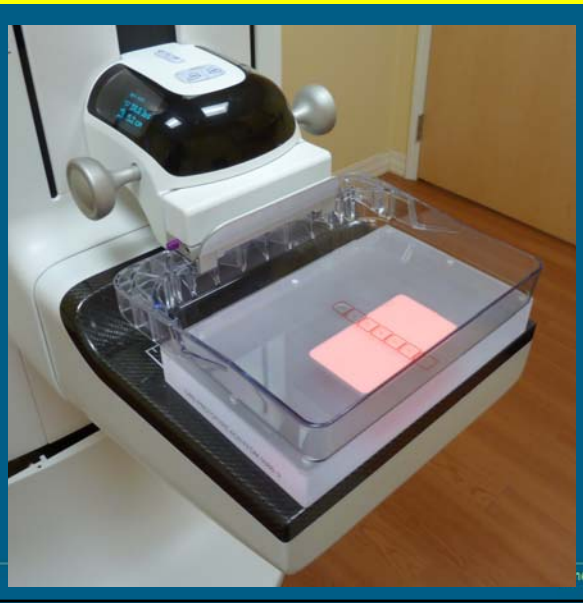
## The ACR DM Phantom Prototype



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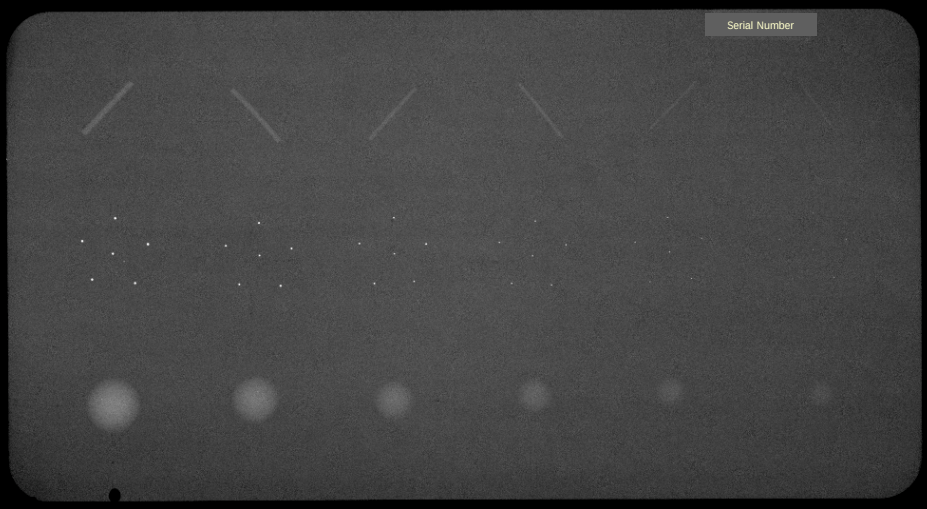
## Image of Entire Phantom

*Note: Gray dot in lower left corner of wax insert is an artifact due to a bubble in wax insert.

## Wax Insert

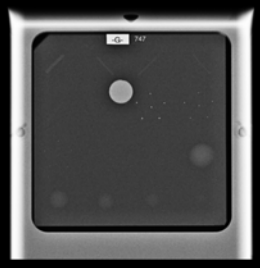


## Expanded View of Wax Insert

***Pass Criteria:*** ***2 Fibers, 3 Specks, 2 Masses***

***Equivalent to SFM Phantom:*** ***4 Fibers, 3 Specks, 3 Masses***

# Effects of Thickness Equalization

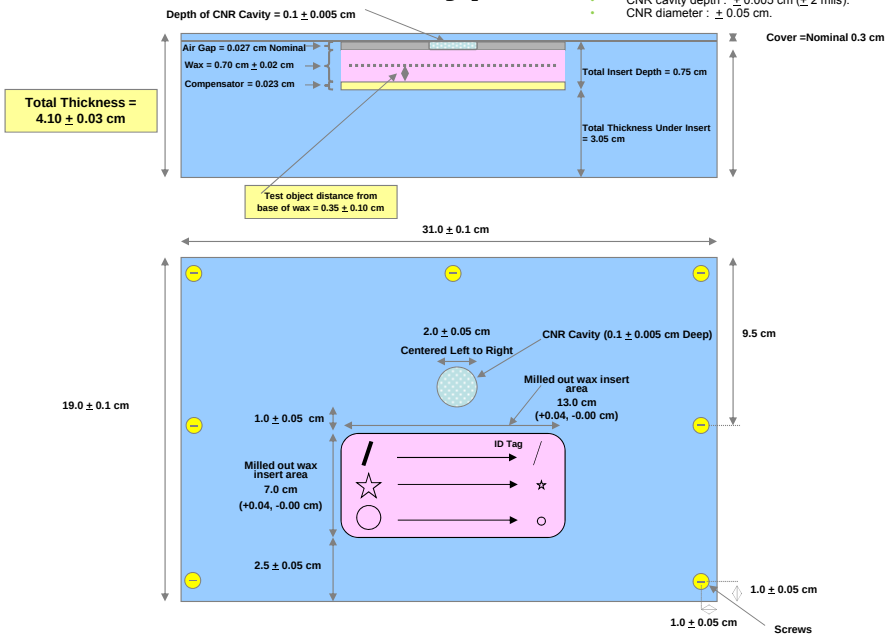


- New FFDM phantom equalizes attenuation inside and outside wax insert.
- This permits evaluation of artifacts over entire phantom area with same WW and WL used to score test objects.

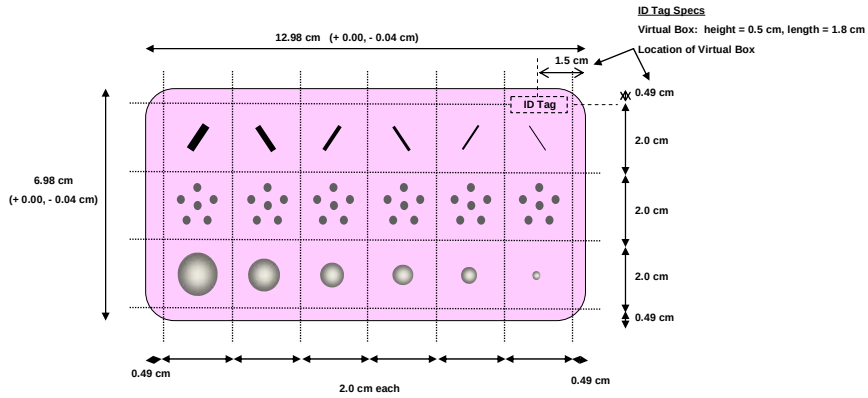
# ACR Phantom Prototype

**Tolerances (Insert Well & CNR Cavity)**

- Wax insert well depth : ± 0.005 cm (± 2 mils).
- Wax insert well width and length : + 0.04 / -0.00 cm.
- CNR cavity depth : ± 0.005 cm (± 2 mils).
- CNR diameter : ± 0.05 cm.



## Wax Insert Specifications with Virtual "Placement Grid"



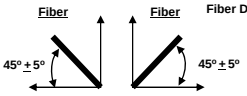

**Notes:**

Test objects to be centered on their respective "placement grid" locations.

0.49 cm perimeter around test object "placement grid".

0.635 cm (1/4 inch) radius on corners of wax insert.

**Fiber Placement specs**




**Fiber specifications**

Fiber Length = 1.0 cm ± 0.1 cm

Fiber Diameter = See Table

**Speck Placement & Specs**

1. Specks to be placed at points on star and middle of star
2. Speck Size (spherical) = See Table
3. Center speck placement to be within ± 0.1 cm of center of virtual grid
4. Distance from center speck to center of speck on perimeter = 0.5 cm ± 0.1 cm

**Mass Placement & Specs**

1. Mass pre-cut sphere diameter = 5/8 inch
2. Mass placement to be within ± 0.1 cm of center of virtual grid

## Wax Insert Test Object Specifications

| Test Object | Fiber Diameter | Speck Diameter (Glass Spheres) | Mass Thickness |
|---|---|---|---|
| | mm | mm | mm |
| 1 | 0.89 ± 0.05 | 0.33 ± 0.0100 | 1.00 ± 0.05 |
| 2 | 0.75 ± 0.03 | 0.28 ± 0.0083 | 0.75 ± 0.05 |
| 3 | 0.61 ± 0.03 | 0.23 ± 0.0069 | 0.50 ± 0.05 |
| 4 | 0.54 ± 0.03 | 0.20 ± 0.0059 | 0.38 ± 0.04 |
| 5 | 0.40 ± 0.03 | 0.17 ± 0.0084 | 0.25 ± 0.03 |
| 6 | 0.30 ± 0.03 | 0.14 ± 0.0070 | 0.20 ± 0.02 |

## Summary of Test Object "Visual Equivalency"

| Test Object | Fibers (mm) | | Specks (mm) | | Masses (mm) | |
|---|---|---|---|---|---|---|
| | ACR 156 | FFDM | ACR 156 | FFDM | ACR 156 | FFDM |
| | 1.56 | | | | | |
| | 1.12 | | 0.54 | | 2.00 | |
| | 0.89 | 0.89 | 0.40 | | 1.00 | 1.00 |
| | 0.75 | 0.75 | 0.32 | 0.33 | 0.75 | 0.75 |
| | | 0.61 | | 0.28 | 0.50 | 0.50 |
| | 0.54 | 0.54 | 0.24 | 0.23 | | 0.38 |
| | 0.40 | 0.40 | | 0.20 | 0.25 | 0.25 |
| | | 0.30 | 0.16 | 0.17 | | 0.20 |
| | | | | 0.14 | | |

## Pass/Fail Criteria

| Test Object | Fibers (mm) | | Specks (mm) | | Masses (mm) | |
|---|---|---|---|---|---|---|
| | ACR 156 | FFDM | ACR 156 | FFDM | ACR 156 | FFDM |
| | 1.56 | | | | | |
| | 1.12 | | 0.54 | | 2.00 | |
| Fail | 0.89 | 0.89 | 0.40 | | 1.00 | 1.00 |
| Pass | 0.75 4 | 0.75 2 | 0.32 3 | 0.33 | 0.75 3 | 0.75 2 |
| | | 0.61 | | 0.28 | 0.50 | 0.50 |
| | 0.54 | 0.54 | 0.24 | 0.23 3 | | 0.38 |
| | 0.40 | 0.40 | | 0.20 | 0.25 | 0.25 |
| | | 0.30 | 0.16 | 0.17 | | 0.20 |
| | | | | 0.14 | | |

## Benefits of Prototype Phantom Design

- Provides view of entire detector – artifact evaluation
- W/L optimized for test objects optimizes for artifact evaluation
- Finer gradations and smaller sizes of test objects
- AGD measurement & limit same as SFM – Meets MQSA
- Provides single image/exposure for evaluation(s)
- Minimal training
- Provides basis for monitor and printer QC
- ACR Physics Reviewers
  - Can see scores and artifacts on single submitted film (or image)
  - Do not need different WW/WL settings

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## ACR Digital Mammography Phantom Approval

- Open to all manufacturers – specifications, tolerances and performance criteria provided
- Approval process
  - Ensures uniformity of construction and performance
  - Mfr submits 2 samples to ACR
  - ACR medical physicist tests against tolerances and performance criteria
  - Approval or feedback for improvement
- Two manufacturers approved to date
  - CIRS
  - Gammex (Sun Nuclear)

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## Digital Mammography Quality Control Tests

### Radiologic Technologist's Tests

| Test* | Minimum Frequency** | Corrective Action Timeframe |
|---|---|---|
| 1. ACR Digital Mammography Phantom Image Quality | Weekly | Before clinical use |
| 2. CR Cassette Erasure *(if applicable)* | Weekly | Before clinical use |
| 3. Compression Thickness Indicator | Monthly | Within 30 days |
| 4. Visual Checklist | Monthly | Critical: before clinical use; less critical: w/in 30 days |
| 5. Acquisition Workstation (AW) Monitor QC | Monthly | W/in 30 days; before clinical use for severe defects |
| 6. Radiologist Workstation (RW) Monitor QC | Monthly | W/in 30 days; before clinical use for severe defects |
| 7. Film Printer QC *(if applicable)* | Monthly | Before clinical use |
| 8. Viewbox Cleanliness *(if applicable)* | Monthly | Before clinical use |
| 9. Facility QC Review | Quarterly | Not applicable |
| 10. Compression Force | Semiannual | Before clinical use |
| 11. Manufacturer Detector Calibration *(if applicable)* | Mfr. Recommendation | Before clinical use |
| Optional - Repeat Analysis | As Needed | Within 30 days after analysis |
| Optional - System QC for Radiologist | As Needed | W/in 30 days; before clinical use for severe artifacts |
| Optional - Radiologist Image Quality Feedback | As Needed | Not applicable |

** All required tests (except Facility QC Review) must be performed upon installation of new equipment and before clinical use.*

*** This is a minimum frequency; tests may be performed more often if problems are noted. Also, weekly tests do not need to be performed if mammography is not performed during that week. However, the test must be performed prior to examining patients once mammography resumes. In these cases, be sure to note in the QC charts that mammography was not performed during this time period.*

**Management Forms**

ACR Technique and Procedure Summaries
Corrective Action Log
Facility Offsite Display Locations
Digital Mammography Unit QC Summary Checklist
Facility Display Device QC Summary Checklist

**Mobile Systems**

In addition to meeting the minimum frequencies outlined in the table above, the following tests must be performed, evaluated, and pass after each move of the mobile system to a new location:

- ACR Digital Mammography Phantom Image Quality - after each move and prior to examining patients
- Radiologist Workstation (RW) Monitor QC (mobile RW only) - after each move and prior to interpretation
- Film Printer QC (mobile film printers only) - after each move and prior to printing patient images

**QC Equipment List - Technologist**

ACR Digital Mammography Phantom
Densitometer
Scale
Towels
Appropriate monitor cleaning materials

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## Digital Mammography Quality Control Tests

### Radiologic Technologist's Tests

| Test* | Minimum Frequency** | Corrective Action Timeframe |
|---|---|---|
| 1. ACR Digital Mammography Phantom Image Quality | Weekly | Before clinical use |
| 2. CR Cassette Erasure *(if applicable)* | Weekly | Before clinical use |
| 3. Compression Thickness Indicator | Monthly | Within 30 days |
| 4. Visual Checklist | Monthly | Critical: before clinical use; less critical: w/in 30 days |
| 5. Acquisition Workstation (AW) Monitor QC | Monthly | W/in 30 days; before clinical use for severe defects |
| 6. Radiologist Workstation (RW) Monitor QC | Monthly | W/in 30 days; before clinical use for severe defects |
| 7. Film Printer QC *(if applicable)* | Monthly | Before clinical use |
| 8. Viewbox Cleanliness *(if applicable)* | Monthly | Before clinical use |
| 9. Facility QC Review | Quarterly | Not applicable |
| 10. Compression Force | Semiannual | Before clinical use |
| 11. Manufacturer Detector Calibration *(if applicable)* | Mfr. Recommendation | Before clinical use |
| Optional - Repeat Analysis | As Needed | Within 30 days after analysis |
| Optional - System QC for Radiologist | As Needed | W/in 30 days; before clinical use for severe artifacts |
| Optional - Radiologist Image Quality Feedback | As Needed | Not applicable |

** All required tests (except Facility QC Review) must be performed upon installation of new equipment and before clinical use.*

*** This is a minimum frequency; tests may be performed more often if problems are noted. Also, weekly tests do not need to be performed if mammography is not performed during that week. However, the test must be performed prior to examining patients once mammography resumes. In these cases, be sure to note in the QC charts that mammography was not performed during this time period.*

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**Management Forms**

ACR Technique and Procedure Summaries

Corrective Action Log

Facility Offsite Display Locations

Digital Mammography Unit QC Summary Checklist

Facility Display Device QC Summary Checklist

**Mobile Systems**

In addition to meeting the minimum frequencies outlined in the table above, the following tests must be performed, evaluated, and pass after each move of the mobile system to a new location:

- ACR Digital Mammography Phantom Image Quality - after each move and prior to examining patients
- Radiologist Workstation (RW) Monitor QC (mobile RW only) - after each move and prior to interpretation
- Film Printer QC (mobile film printers only) - after each move and prior to printing patient images

**QC Equipment List - Technologist**

ACR Digital Mammography Phantom

Densitometer

Scale

Towels

Appropriate monitor cleaning materials

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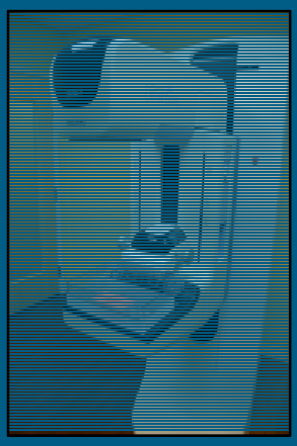

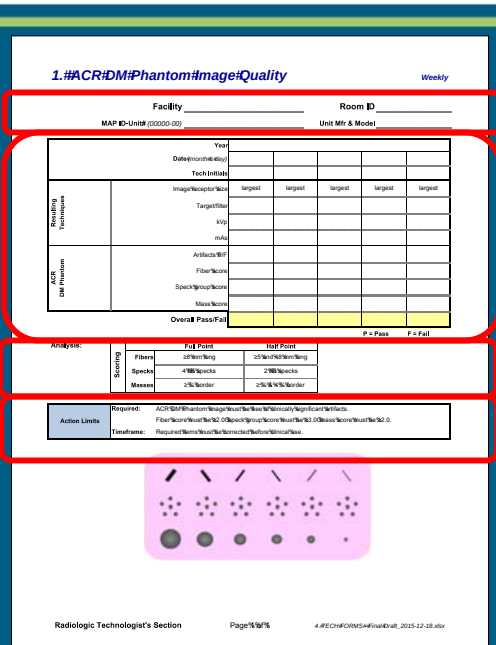

1.#ACR#DM#Phantom#Image#Quality

Weekly

Facility _____ Room ID _____

MAP ID-Unit# (00000-00) _____ Unit Mfr & Model _____

| | | | | | | |
|---|---|---|---|---|---|---|
| | Year | | | | | |
| | Date (month/day) | | | | | |
| | Tech Initials | | | | | |
| Resulting Techniques | Image/receptor/size | largest | largest | largest | largest | largest |
| | Target/filter | | | | | |
| | kVp | | | | | |
| | mAs | | | | | |
| ACR DM Phantom | Artifacts/IIF | | | | | |
| | Fiber/score | | | | | |
| | Speck/group/score | | | | | |
| | Mass/score | | | | | |
| | Overall Pass/Fail | | | | | |

P = Pass F = Fail

Analysis:

| Scoring | Full Point | Half Point |
|---|---|---|
| Fibers | ≥8/mm/long | ≥5/and/≤8/mm/long |
| Specks | 4/%/specks | 2/%/specks |
| Masses | ≥%/order | ≥%/%/%/order |

| Action Limits | |
|---|---|
| Required: | ACR/DM/Phantom/Image/must/be/free/of/clinically/significant/artifacts. Fiber/score/must/be/≥2.0/speck/group/score/must/be/≥3.0/mass/score/must/be/≥2.0. |
| Timeframe: | Required/items/must/be/corrected/before/clinical/use. |



Radiologic Technologist's Section Page%/%/% 4.#TECH#FORMS#Final#Draft_2015-12-18.xlsx

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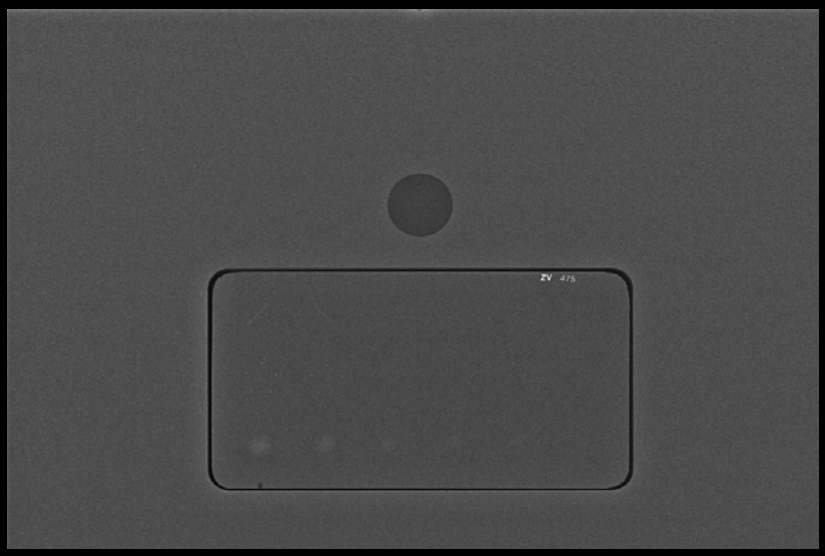
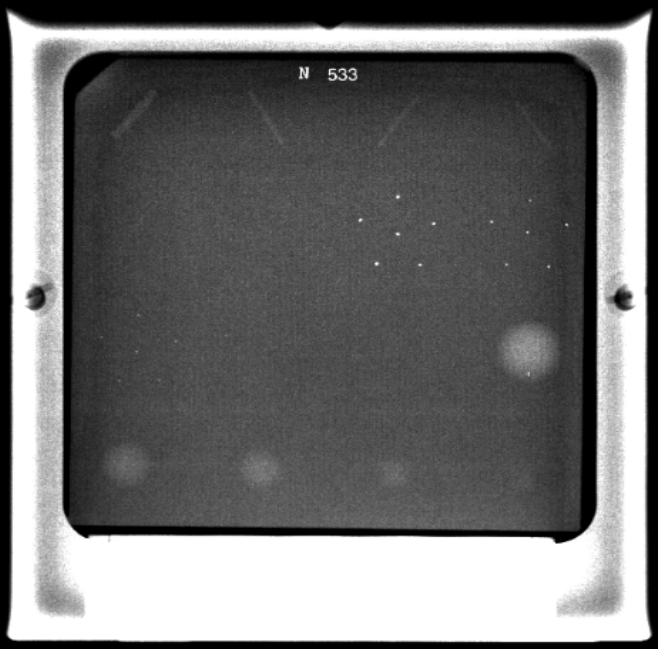
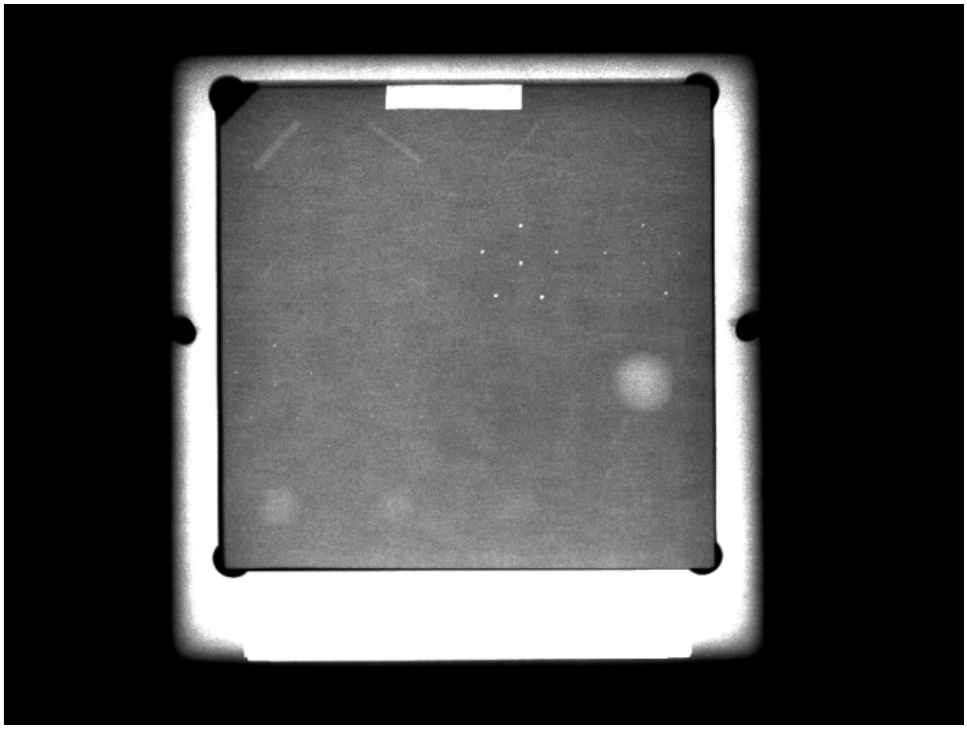
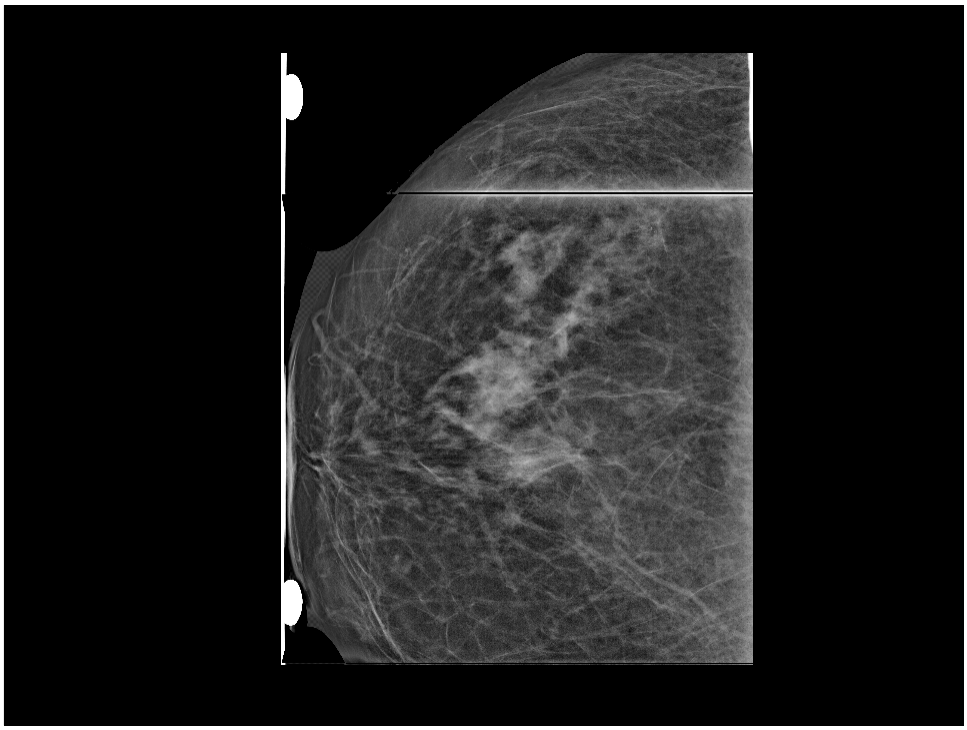
## Example

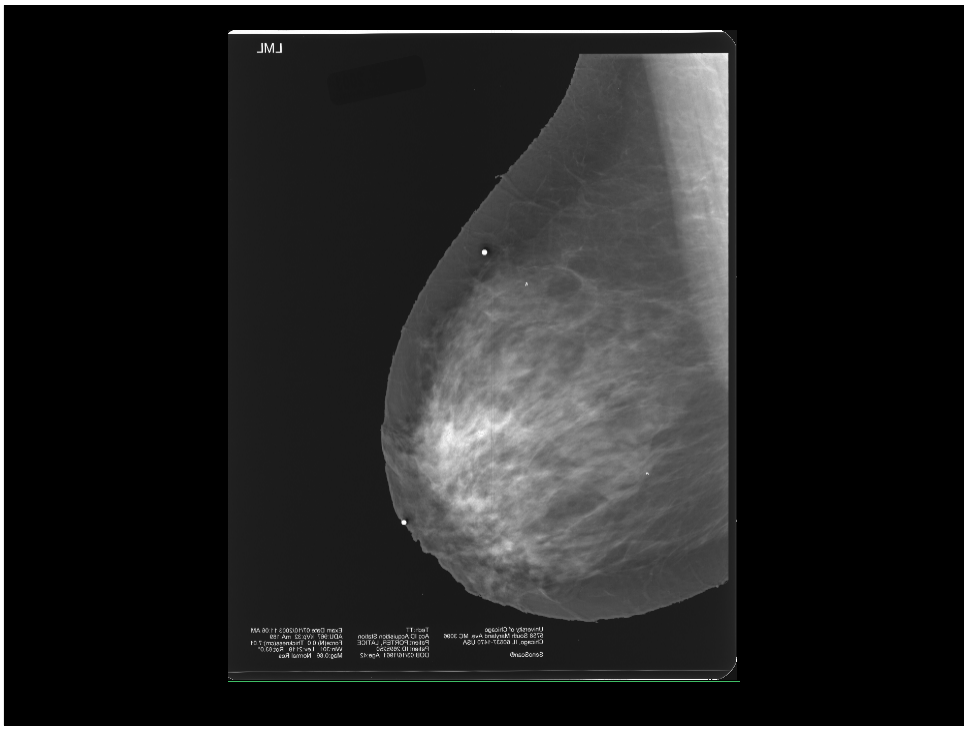






R M.L.O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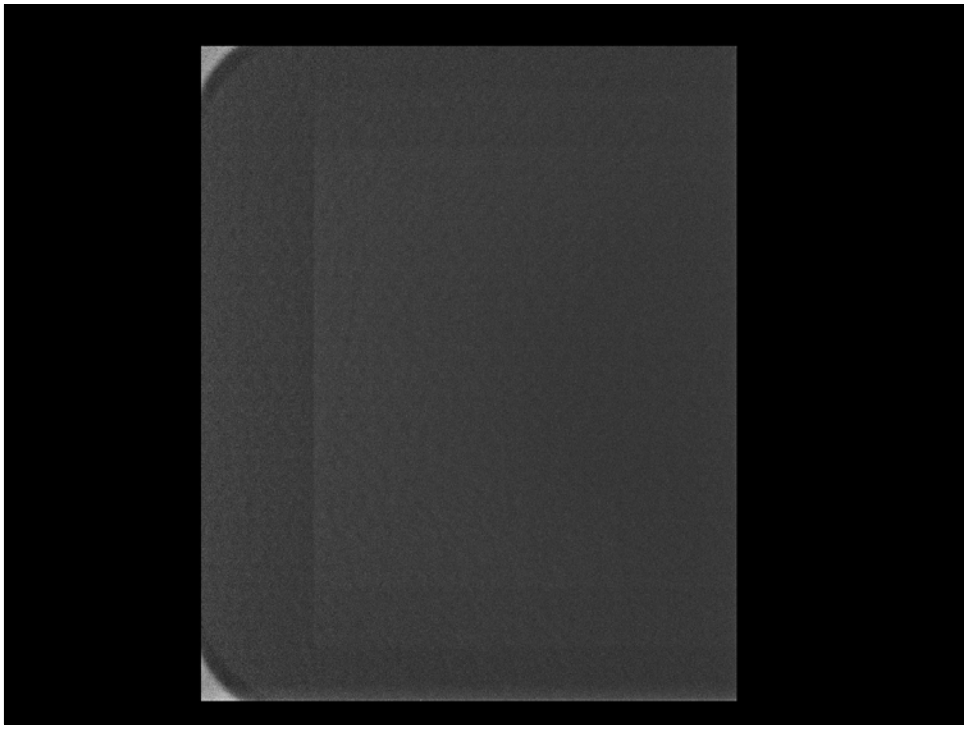
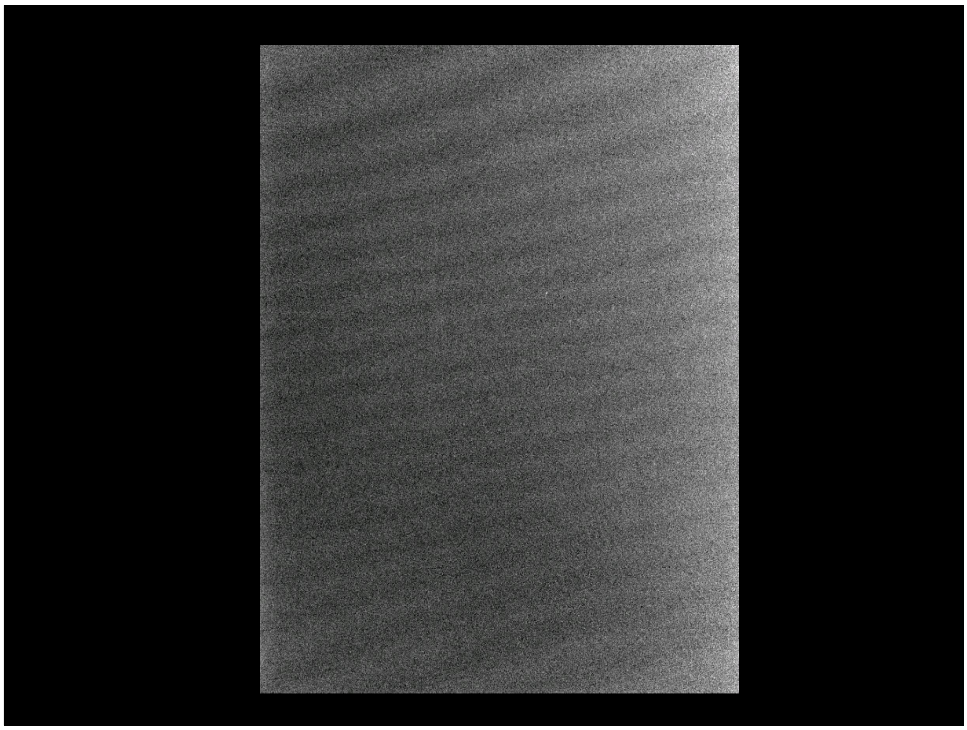
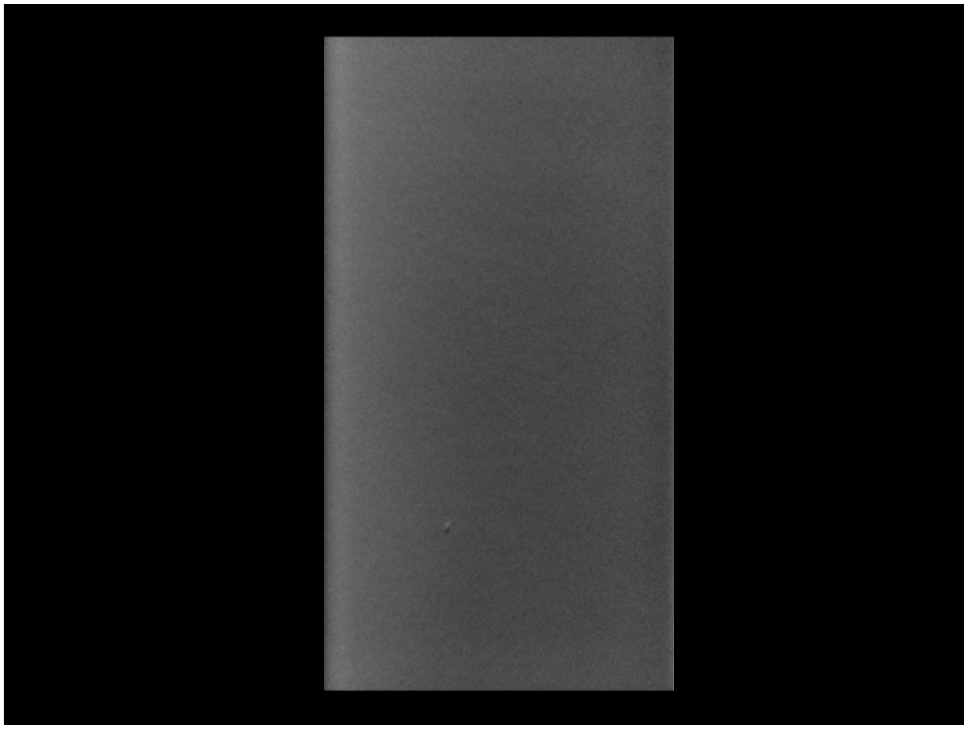
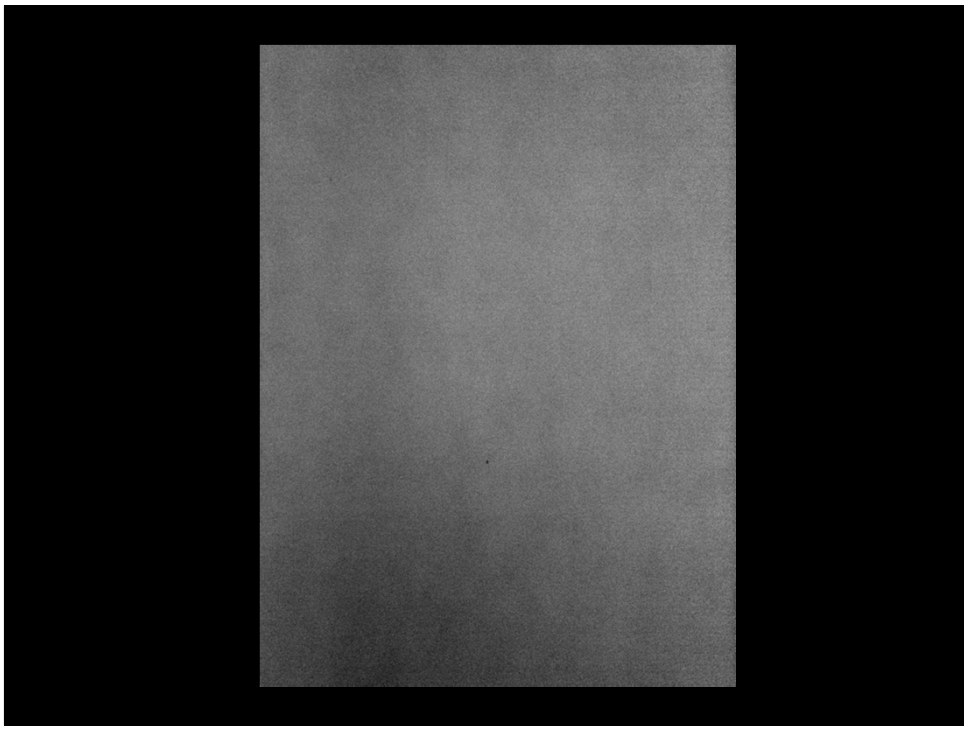
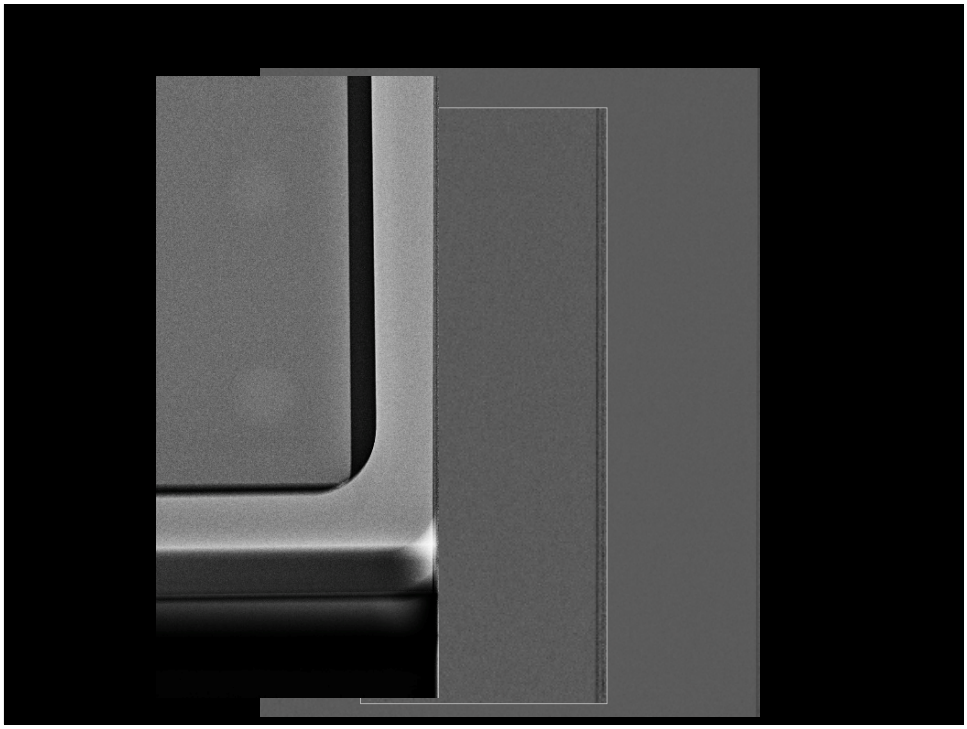
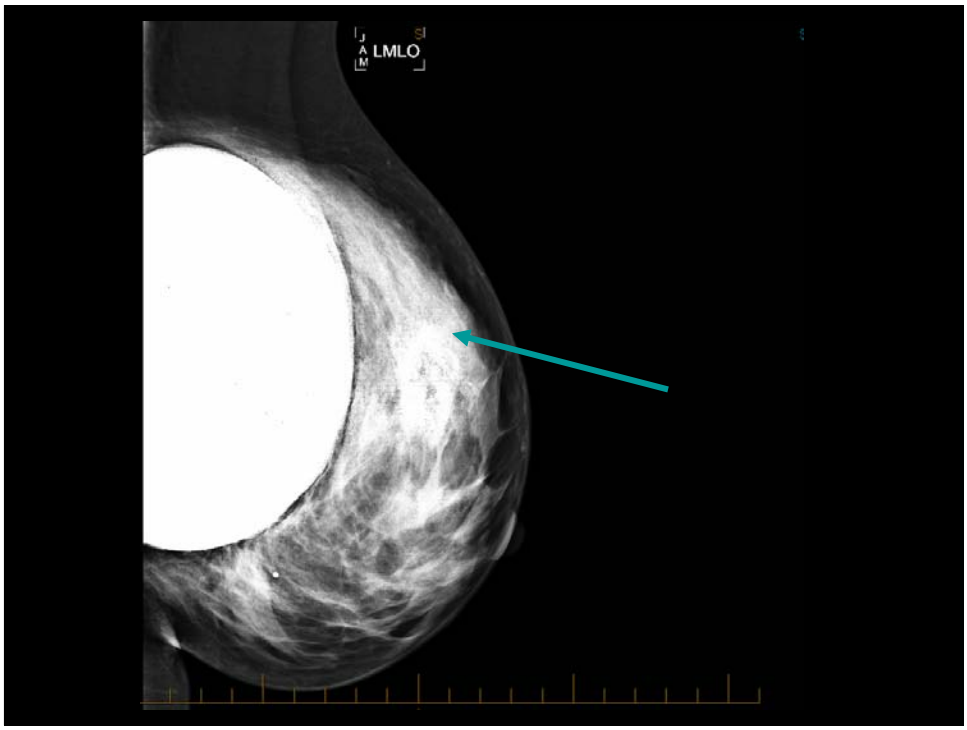


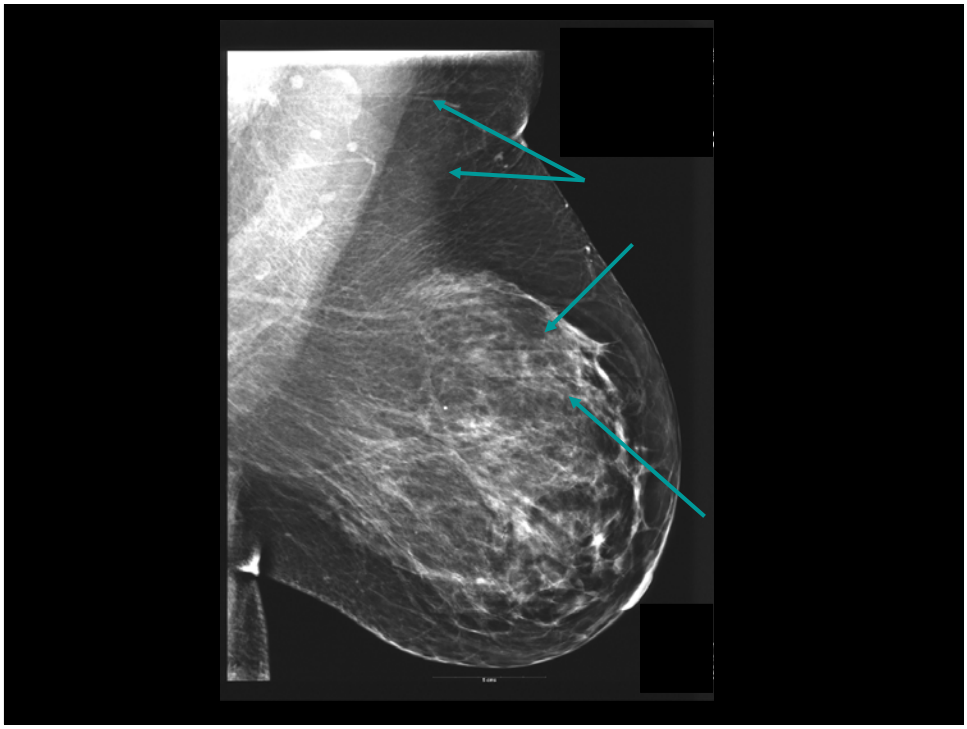


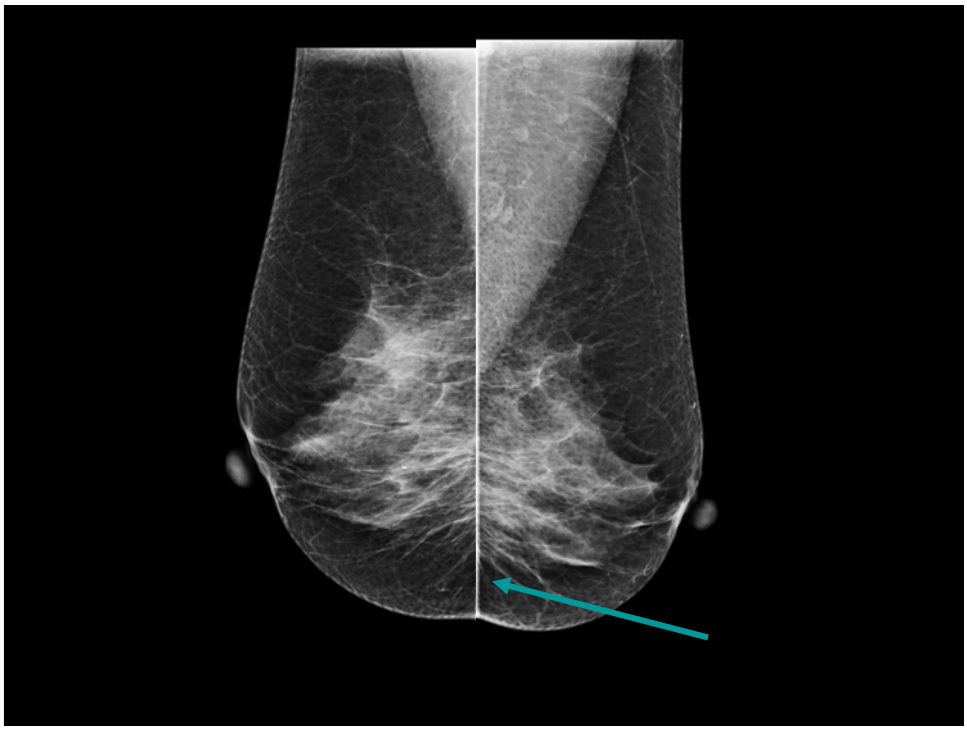


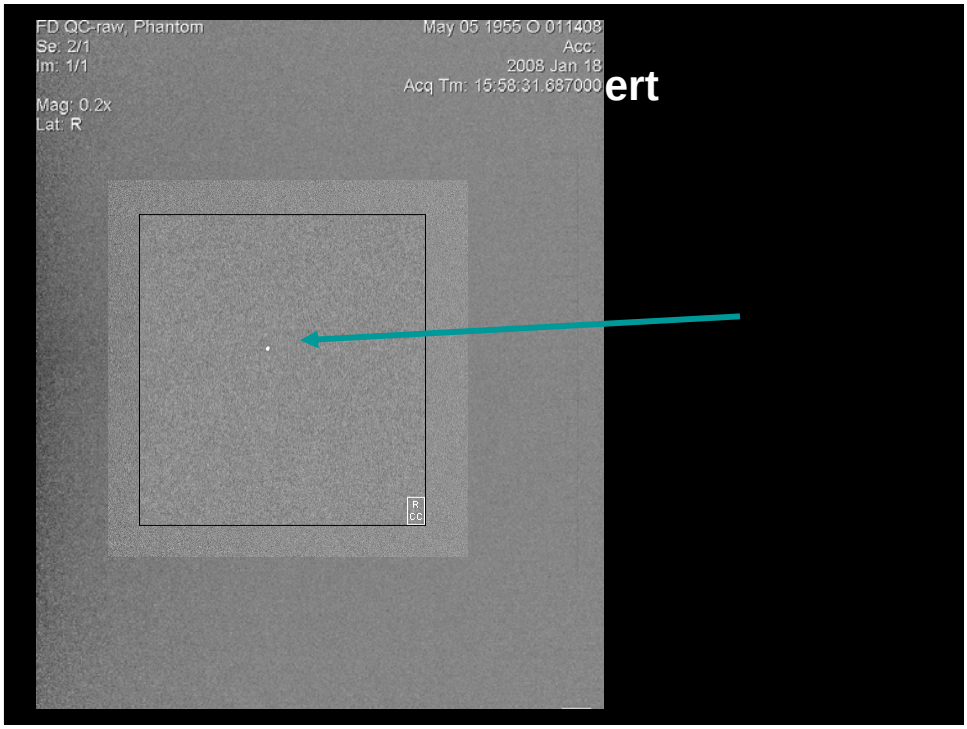


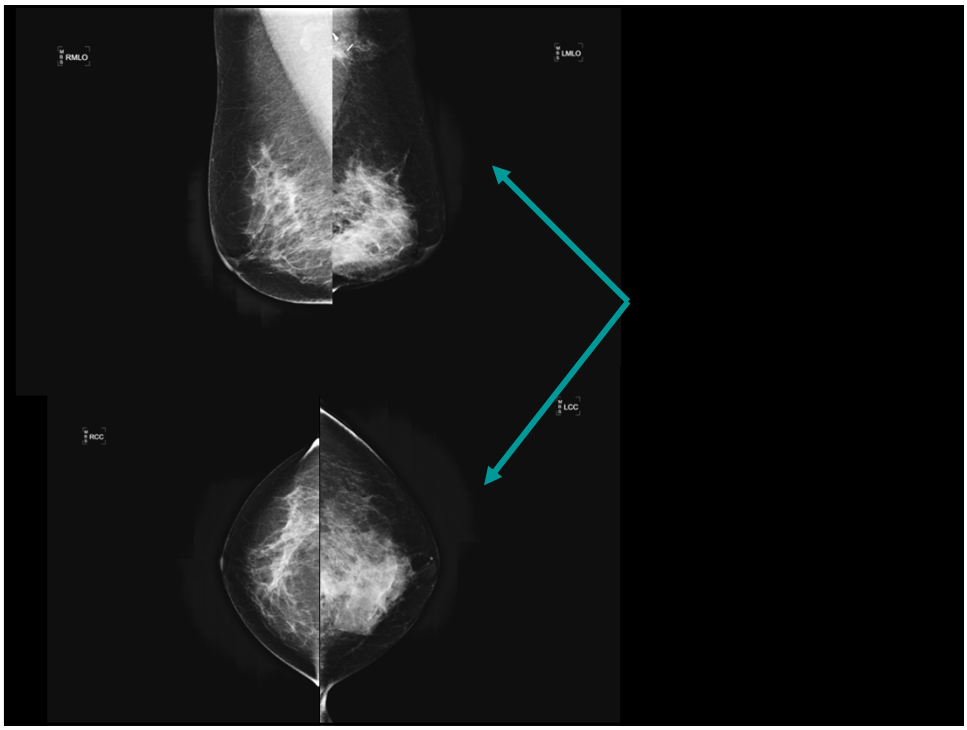



LMLO






FD QC-raw, Phantom
Se: 2/1
Im: 1/1
Mag: 0.2x
Lat: R
May 05 1955 O 011408
Acc:
2008 Jan 18
Acq Tm: 15:58:31.687000
R
CC
ert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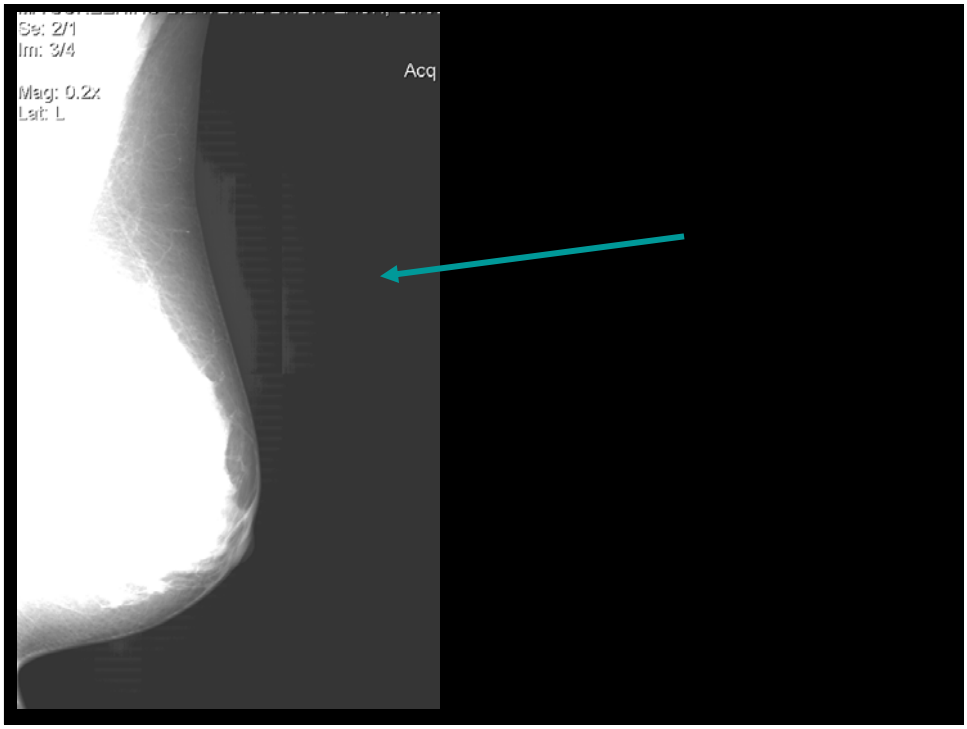
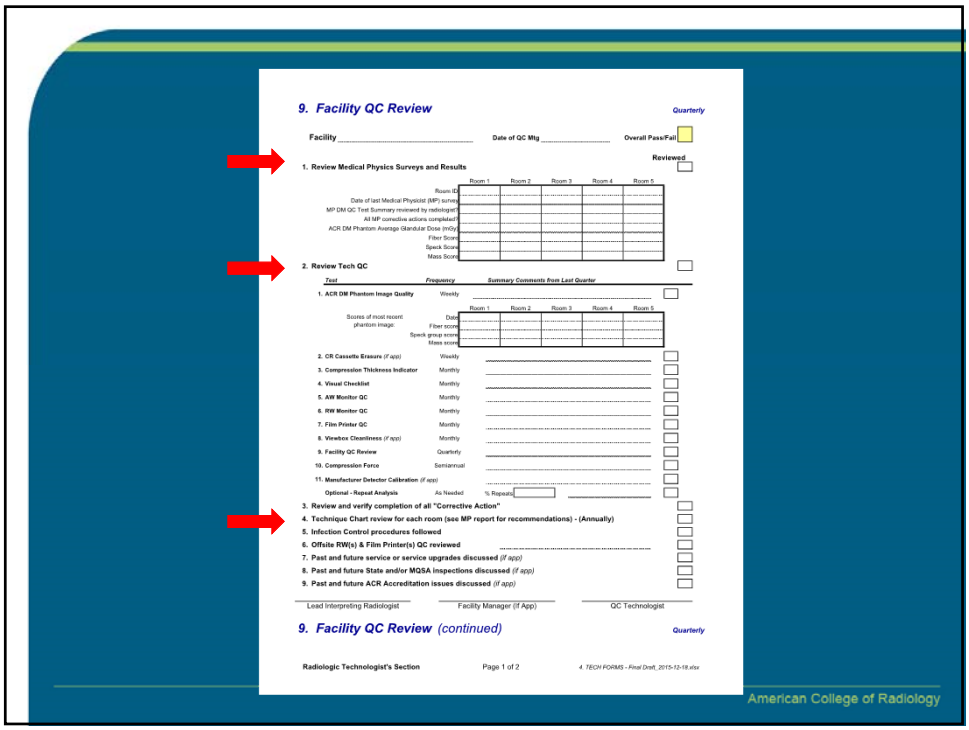
LMLO
RCC
LCC



**9. Facility QC Review** *Quarterly*

**Facility** _____ **Date of QC Mtg** _____ **Overall Pass/Fail** ☐

**Reviewed** ☐

**1. Review Medical Physics Surveys and Results**

| | Room 1 | Room 2 | Room 3 | Room 4 | Room 5 |
|---|---|---|---|---|---|
| Room ID | | | | | |
| Date of last Medical Physicist (MP) survey | | | | | |
| MP DM QC Test Summary reviewed by radiologist? | | | | | |
| All MP corrective actions completed? | | | | | |
| ACR DM Phantom Average Glandular Dose (mGy) | | | | | |
| Fiber Score | | | | | |
| Speck Score | | | | | |
| Mass Score | | | | | |

**2. Review Tech QC** ☐

| *Test* | *Frequency* | *Summary Comments from Last Quarter* |
|---|---|---|
| **1. ACR DM Phantom Image Quality** | Weekly | _____ ☐ |

| Scores of most recent phantom image: | Room 1 | Room 2 | Room 3 | Room 4 | Room 5 |
|---|---|---|---|---|---|
| Date | | | | | |
| Fiber score | | | | | |
| Speck group score | | | | | |
| Mass score | | | | | |

| | | | |
|---|---|---|---|
| **2. CR Cassette Erasure** *(if app)* | Weekly | _____ | ☐ |
| **3. Compression Thickness Indicator** | Monthly | _____ | ☐ |
| **4. Visual Checklist** | Monthly | _____ | ☐ |
| **5. AW Monitor QC** | Monthly | _____ | ☐ |
| **6. RW Monitor QC** | Monthly | _____ | ☐ |
| **7. Film Printer QC** | Monthly | _____ | ☐ |
| **8. Viewbox Cleanliness** *(if app)* | Monthly | _____ | ☐ |
| **9. Facility QC Review** | Quarterly | _____ | ☐ |
| **10. Compression Force** | Semiannual | _____ | ☐ |
| **11. Manufacturer Detector Calibration** *(if app)* | | _____ | ☐ |
| **Optional - Repeat Analysis** | As Needed | % Repeat: ____ _____ | ☐ |

**3. Review and verify completion of all "Corrective Action"** ☐

**4. Technique Chart review for each room (see MP report for recommendations) - (Annually)** ☐

**5. Infection Control procedures followed** ☐

**6. Offsite RW(s) & Film Printer(s) QC reviewed** _____ ☐

**7. Past and future service or service upgrades discussed** *(if app)* ☐

**8. Past and future State and/or MQSA inspections discussed** *(if app)* ☐

**9. Past and future ACR Accreditation issues discussed** *(if app)* ☐

Lead Interpreting Radiologist _____ Facility Manager (if App) _____ QC Technologist _____

**9. Facility QC Review** *(continued)* *Quarterly*

**Radiologic Technologist's Section** Page 1 of 2 *4. TECH FORMS - Final Draft, 2015-12-18.xlsx*

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## 7. Facility QC Review (continued)

Quarterly

Facility _____ Date of QC Mtg _____

Follow-up Completed (if Appl.)

10. Notable findings during QC meeting

11. Items for quality improvement from QC Meeting

12. Other QC Notes:

| Action Limit: | | |
|---|---|---|
| | Required: | Supervising radiologist and facility manager must review QC quarterly. The test passes if meeting held. |
| | Recommended: | Technologist and supervising radiologist should review technique charts at least annually for each DM system. |
| | Timeframe: | Not applicable. |

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## Facility Offsite Display Locations

Facility _____ MAP ID# (00000) _____

Address _____

**Offsite Locations or Facilities Where Images are Interpreted for this Facility**
*(list facility name, address, and MAP ID)*

| Location or Facility Name | Address | MAP ID |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

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## Facility Display Device QC Summary Checklist

Facility _____ MAP ID# (99000) _____

Address _____

Address _____

**QC Summary information for display devices at this MAP ID**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Physical Location at Facility/ ID Designation | | | | | | | | | |
| Device (RW, film printer, viewbox) | | | | | | | | | |
| Manufacturer | | | | | | | | | |
| Model | | | | | | | | | |
| Jan | Date | | | | | | | | |
| | Tech Initials | | | | | | | | |
| Feb | Date | | | | | | | | |
| | Tech Initials | | | | | | | | |
| Mar | Date | | | | | | | | |
| | Tech Initials | | | | | | | | |
| Apr | Date | | | | | | | | |
| | Tech Initials | | | | | | | | |
| May | Date | | | | | | | | |
| | Tech Initials | | | | | | | | |
| Jun | Date | | | | | | | | |
| | Tech Initials | | | | | | | | |
| Jul | Date | | | | | | | | |
| | Tech Initials | | | | | | | | |
| Aug | Date | | | | | | | | |
| | Tech Initials | | | | | | | | |
| Sep | Date | | | | | | | | |
| | Tech Initials | | | | | | | | |
| Oct | Date | | | | | | | | |
| | Tech Initials | | | | | | | | |
| Nov | Date | | | | | | | | |
| | Tech Initials | | | | | | | | |
| Dec | Date | | | | | | | | |
| | Tech Initials | | | | | | | | |
| Medical Physicist Survey Date | | | | | | | | | |
| Medical Physicist Name(s) | | | | | | | | | |

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## Digital Mammography Quality Control Tests
## Medical Physicist's Tests

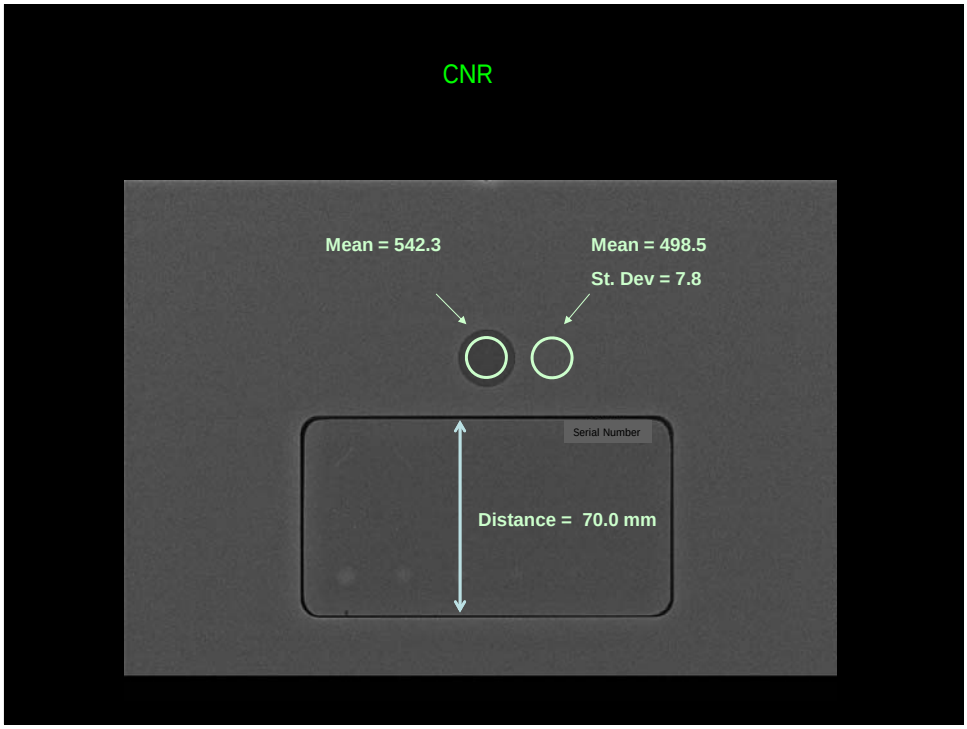
| Test | Minimum Frequency | Corrective Action Timeframe |
|---|---|---|
| 1. Mammography Equipment Evaluation - MQSA Requirements | MEE | Before clinical use |
| 2. ACR DM Phantom Image Quality | MEE and Annual | Before clinical use |
| 3. Spatial Resolution | MEE and Annual | Within 30 days |
| 4. Automatic Exposure Control System Performance | MEE and Annual | Within 30 days |
| 5. Average Glandular Dose | MEE and Annual | Before clinical use |
| 6. Unit Checklist | MEE and Annual | Critical: before clinical use; less critical: w/in 30 days |
| 7. Computed Radiography *(if applicable)* | MEE and Annual | Before clinical use |
| 8. Acquisition Workstation (AW) Monitor QC | MEE and Annual | W/in 30 days; before clinical use for severe defects |
| 9. Radiologist Workstation (RW) Monitor QC | MEE and Annual | W/in 30 days; before clinical use for severe defects |
| 10. Film Printer QC | MEE and Annual | Before clinical use |
| 11. Evaluation of Site's Technologist QC Program | MEE and Annual | Within 30 days |
| 12. Evaluation of Display Device Technologist QC Program | MEE and Annual | Within 30 days |
| MEE or Troubleshooting - Beam Quality (Half-Value Layer) Assessment | MEE or Troubleshooting | MEE - before clinical use; troubleshooting - w/in 30 days |
| MEE or Troubleshooting - kVp Accuracy and Reproducibility | MEE or Troubleshooting | MEE - before clinical use; troubleshooting - w/in 30 days |
| MEE or Troubleshooting - Collimation Assessment | MEE or Troubleshooting | MEE - before clinical use; troubleshooting - w/in 30 days |
| Troubleshooting - Ghost Image Evaluation | Troubleshooting | Before clinical use |
| Troubleshooting - Viewbox Luminance | Troubleshooting | NA |

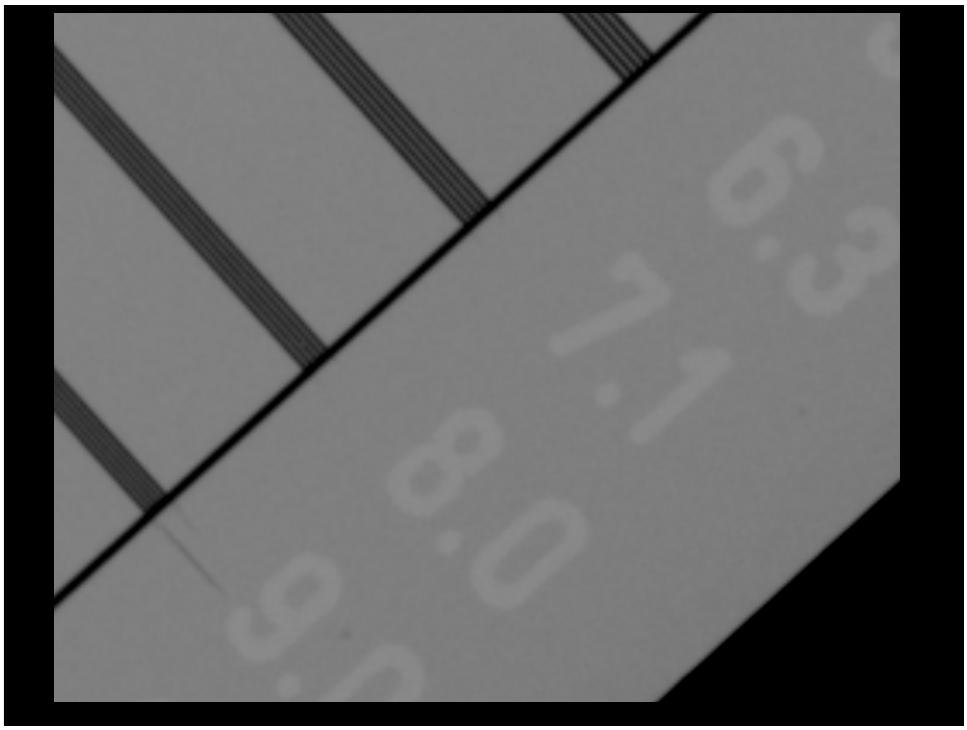
**Summary Report Forms**

Medical Physicist's DM QC Test Summary

Mammography Technique Chart

Medical Physicist QC Letter for the Radiologist


CNR
Mean = 542.3
Mean = 498.5
St. Dev = 7.8
Serial Number
Distance = 70.0 mm



# *D = Kgcs*

**D** = Mean Glandular Dose

**K** = Entrance surface air kerma

**g** = glandularity of 50%

**c** = corrects for difference in composition (age dependent)

**s** = X-ray spectrum correction (Target/Filter)

**Note:** g and c depend on thickness, glandularity, and HVL.

***Primary Ref*:** D.R. Dance, et al. Additional for the Estimation of Mean Glandualar Breast Dose Using the UK Mammography Dosimetry Protocol. Physics in Medicine and Biology 45, 3225-3240, 2000.

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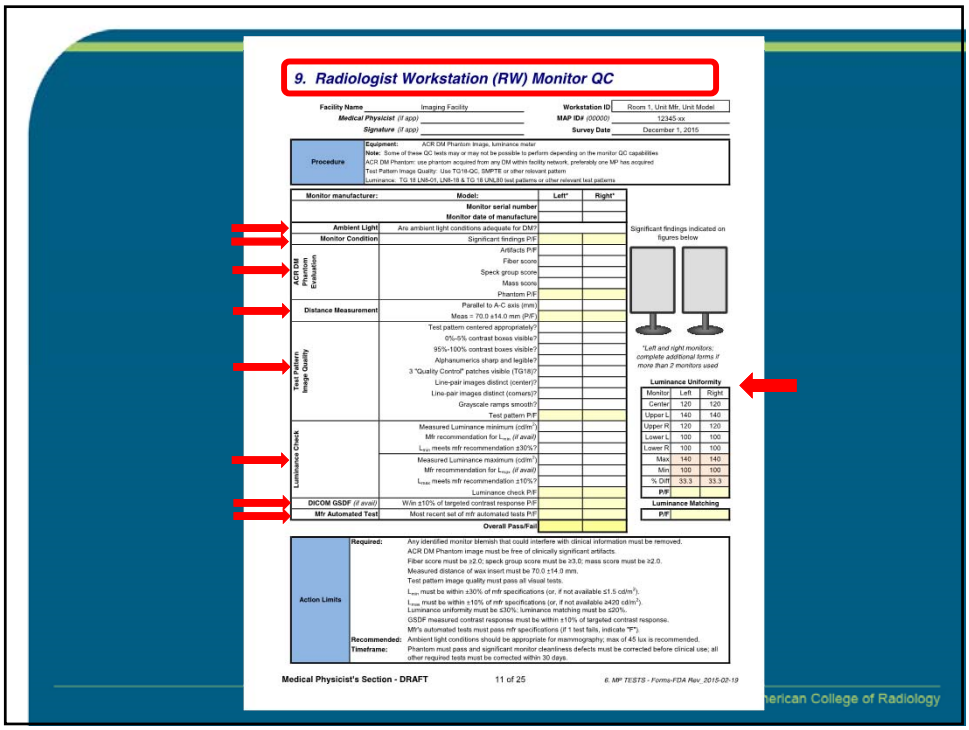

**9. Radiologist Workstation (RW) Monitor QC**

Facility Name: Imaging Facility
Medical Physicist (if app):
Signature (if app):
Workstation ID: Room 1, Unit Mfr, Unit Model
MAP ID# (00000): 12345-xx
Survey Date: December 1, 2015

| Procedure | |
|---|---|
| Equipment: | ACR DM Phantom Image, luminance meter |
| Note: | Some of these QC tests may or may not be possible to perform depending on the monitor QC capabilities<br>ACR DM Phantom: use phantom acquired from any DM within facility network, preferably one MP has acquired<br>Test Pattern Image Quality: Use TG18-QC, SMPTE or other relevant pattern<br>Luminance: TG 18 LN8-01, LN8-18 & TG 18 UNL80 test patterns or other relevant test patterns |

| | | Left* | Right* |
|---|---|---|---|
| Monitor manufacturer: | Model: | | |
| | Monitor serial number | | |
| | Monitor date of manufacture | | |
| Ambient Light | Are ambient light conditions adequate for DM? | | |
| Monitor Condition | Significant findings P/F | | |
| ACR DM Phantom Evaluation | Artifacts P/F | | |
| | Fiber score | | |
| | Speck group score | | |
| | Mass score | | |
| | Phantom P/F | | |
| Distance Measurement | Parallel to A-C axis (mm) | | |
| | Meas = 70.0 ±14.0 mm (P/F) | | |
| Test Pattern Image Quality | Test pattern centered appropriately? | | |
| | 0%-5% contrast boxes visible? | | |
| | 95%-100% contrast boxes visible? | | |
| | Alphanumerics sharp and legible? | | |
| | 3 "Quality Control" patches visible (TG18)? | | |
| | Line-pair images distinct (center)? | | |
| | Line-pair images distinct (corners)? | | |
| | Grayscale ramps smooth? | | |
| | Test pattern P/F | | |
| Luminance Check | Measured Luminance minimum (cd/m²) | | |
| | Mfr recommendation for $L_{min}$ (if avail) | | |
| | $L_{min}$ meets mfr recommendation ±30%? | | |
| | Measured Luminance maximum (cd/m²) | | |
| | Mfr recommendation for $L_{max}$ (if avail) | | |
| | $L_{max}$ meets mfr recommendation ±10%? | | |
| | Luminance check P/F | | |
| DICOM GSDF (if avail) | W/in ±10% of targeted contrast response P/F | | |
| Mfr Automated Test | Most recent set of mfr automated tests P/F | | |
| | Overall Pass/Fail | | |

Significant findings indicated on figures below

**Left and right monitors; complete additional forms if more than 2 monitors used*

**Luminance Uniformity**

| Monitor | Left | Right |
|---|---|---|
| Center | 120 | 120 |
| Upper L | 140 | 140 |
| Upper R | 120 | 120 |
| Lower L | 100 | 100 |
| Lower R | 100 | 100 |
| Max | 140 | 140 |
| Min | 100 | 100 |
| % Diff | 33.3 | 33.3 |
| P/F | | |

**Luminance Matching**

| P/F | |
|---|---|

| Action Limits | |
|---|---|
| Required: | Any identified monitor blemish that could interfere with clinical information must be removed.<br>ACR DM Phantom image must be free of clinically significant artifacts.<br>Fiber score must be ≥2.0; speck group score must be ≥3.0; mass score must be ≥2.0.<br>Measured distance of wax insert must be 70.0 ±14.0 mm.<br>Test pattern image quality must pass all visual tests.<br>$L_{min}$ must be within ±30% of mfr specifications (or, if not available ≤1.5 cd/m²).<br>$L_{max}$ must be within ±10% of mfr specifications (or, if not available ≥420 cd/m²).<br>Luminance uniformity must be ≤30%; luminance matching must be ≤20%.<br>GSDF measured contrast response must be within ±10% of targeted contrast response.<br>Mfr's automated tests must pass mfr specifications (if 1 test fails, indicate "F"). |
| Recommended: | Ambient light conditions should be appropriate for mammography; max of 45 lux is recommended. |
| Timeframe: | Phantom must pass and significant monitor cleanliness defects must be corrected before clinical use; all other required tests must be corrected within 30 days. |

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## 11. Evaluation of Site's Technologist QC Program

Facility Name: Imaging Facility

Room ID, Mfr & Model: Room 1, Unit Mfr Unit Model

MAP ID-Unit# (00000-00): 12345-xx

Survey Date: December 1, 2015

| Radiologic Technologist's Quality Control Tests | Frequency | Test Performed, Analyzed & Documented | Missing Data | Incorrect Scoring or Calculations | Missing Corrective Action Documentation | Other | Comments |
|---|---|---|---|---|---|---|---|
| 1. ACR DM Phantom Image Quality | Weekly | | | | | | |
| Scores of latest phantom image: Lateral QC Tech Score / Med Phys Score | | | | | | | |
| Fiber | | | | | | | |
| Speck group | | | | | | | |
| Mass | | | | | | | |
| 2. CR Cassette Erasure (if app) | Weekly | | | | | | |
| 3. Comp Thickness Indicator | Monthly | | | | | | |
| 4. Visual Checklist | Monthly | | | | | | |
| 5. AW Monitor QC | Monthly | | | | | | |
| 9. Facility QC Review | Quarterly | | | | | | |
| 10. Compression Force | Semiannual | | | | | | |
| 11. Mfr Detector Calibration (if app) | | | | | | | |
| Optional - Repeat Analysis | As Needed | | | | | | |
| Optional - System QC for Radiologist | NA | | | | | | |
| Optional - Radiologist IQ Feedback | NA | | | | | | |
| Corrective Action Log documentation adequate | | | | | | | |

Overall Pass/Fail for Performance of Technologist QC Program

Additional Comments:

**Action Limits**

**Required:** MQSA regulations [FDA Rule 900.12(d)(1)(ii)] specify that "each facility shall have the services of a medical physicist available to survey mammography equipment and oversee the equipment-related quality assurance practices of the facility." Completion of this "Evaluation of Site's Technologist QC Program" form documents that this oversight has been conducted. In order for the overall evaluation to pass, there must be a) no significant missing data, b) the tests must be analyzed without gross errors, and c) appropriate corrective action for failures must be taken (and documented). See test procedures for more information.

**Timeframe:** Failures must be corrected within 30 days.

Medical Physicist's Section

1 of 1

6. MP FORMS - Final Draft_2015-12-18.xlsx

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## 12. Evaluation of Display Device Technologist QC Program

**Facility Name** Imaging Facility

**MAP ID-Unit#** *(00000-00)* 12345-xx

**Medical Physicist** (if app)

**Location of Display Devices** Frederick, MD office

**Signature** (if app)

**Survey Date**

| Display Device ID & Room | Display Device Description (RW, Printer, Viewbox) | Test Performed, Analyzed & Documented Incorrectly | Missing Data | Incorrect Scoring or Calculations | Missing Corrective Action Documentation | Mfr Automated Tests (if Applicable) | Other | Comments |
|---|---|---|---|---|---|---|---|---|
| Example: Mammography reading room | RW | ✓ | ✓ | ✓ | ✓ | | | Discussed with manager |
| | | | | | | | | |
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| | | | | | | | | |
| Corrective Action Log documentation adequate? | | | | | | | | |

Overall Pass/Fail for Performance of Display Device Technologist QC Program

Additional Comments:

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## *Medical Physicist QC Letter for the Radiologist*

December 2, 2015

John Doe, MD
Imaging Facility
1891 Preston White Dr
Reston, VA 20191

| | Room & Unit Mfr/Model | Survey Date |
|---|---|---|
| **Re: Medical Physicist Survey:** | Room 1, Unit Mfr Unit Model | 12/1/2015 |

Dear Lead Interpreting Radiologist,

The above mammography unit at your facility recently underwent an Annual Medical Physics Survey. Below is the relevant summary information as a result of this survey. Please note that your facility must follow-up on the Action Items below and obtain relevant documentation from the service engineer. Please evaluate the ACR Digital Mammography Phantom image acquired during the medical physicist testing (Image ID information listed below) and see my comments. If you have any questions please don't hesitate to call.

- ***Image Quality***

**Patient ID (Phantom):** _____

**Date:** 12/1/2015

**ACR Digital Mammography Phantom Scores**

| | Your Unit Room 1 | Passing Criteria | Pass /Fail |
|---|---|---|---|
| **Fiber score** | | ≥2.0 | |
| **Speck group score** | | ≥3.0 | |
| **Mass score** | | ≥2.0 | |
| **Artifacts** | | No Clinically Significant Artifacts | |

**Comments on phantom image:** _____

- **Radiation Dose**

**ACR Digital Mammography Phantom Radiation Dose Values**

| | Your Unit | Passing Criteria | Pass /Fail |
|---|---|---|---|
| **ACR Phantom Dose (mGy)** | | ≥3.0 | |

**Note:** The above dose is an estimate determined with a phantom representing the FDA-defined 4.2 cm thick, 50% glandular/50% adipose standard breast. Doses will vary with patient size and density. Specific patient doses can be estimated by your medical physicist.

**Comments on radiation dose:** _____

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## *Medical Physicist QC Summary Letter for the Radiologist, Cont'd*

- ***Required Action Items***

| Time Frame | Description |
|---|---|
| | |

- ***Recommended Action Items***

| Time Frame | Description |
|---|---|
| | |

- ***Comments on Monitors, Monitor QC, & Viewing Conditions***

| Time Frame | Description |
|---|---|
| | |

- ***Comments on Tech QC***

| Time Frame | Description |
|---|---|
| | |

If you have any questions, please do not hesitate to call.

Sincerely,

Mary Smith, PhD

Phone 000-000-0000
Email physicist@xxx.com

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The following combination of testing must be performed:

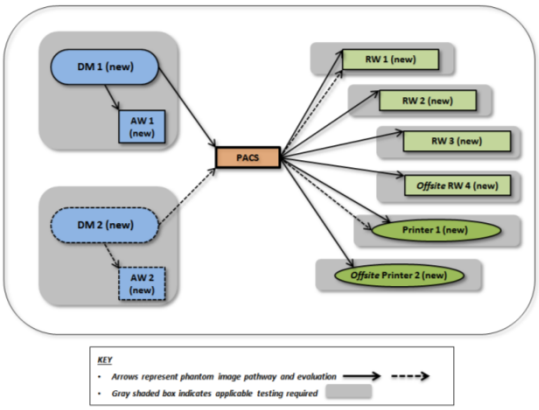


**Figure x – MEE – All New Digital Mammography Units and Display Devices.**

## 2. Mammography Equipment Evaluation (MEE) – New Digital Mammography Units (with Existing Display Devices)

In this scenario, only the digital mammography unit 1 is new (including the acquisition workstation). The display devices (review workstations and film printers) are pre-existing as is digital mammography unit 2. The new digital mammography unit may be new, previously owned or relocated from another facility under the same ownership.

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The following combination of testing must be performed:

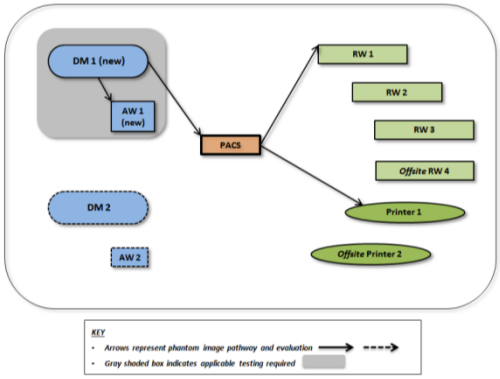


**Figure x – MEE – New Digital Mammography Units (with Existing Display Devices).**

## 3. Mammography Equipment Evaluation (MEE) – New Display Devices (with Existing Digital Mammography Units)

In this scenario, only display devices (an acquisition workstation 2, review workstation 1 and 4 and film printer 2) are new. The digital mammography unit 2 is pre-existing. Digital mammography unit 1 and also AW 1 are also pre-existing. The display devices may be new, previously owned or relocated from another facility under the same ownership. The phantom images used for evaluation should have been acquired from any of the facility's digital mammography units within the past month.

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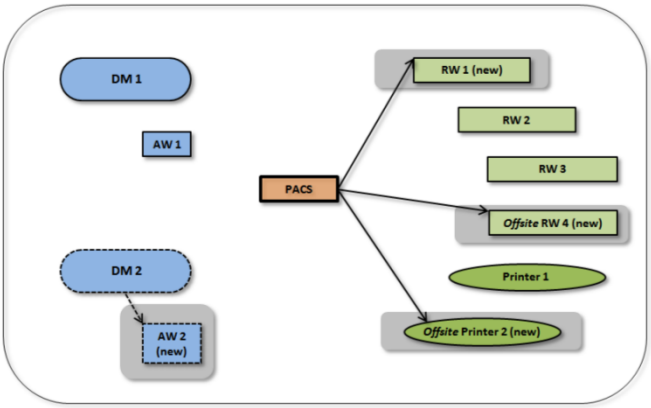
The following combination of testing must be performed:




KEY
- Arrows represent phantom image pathway and evaluation
- Gray shaded box indicates applicable testing required

**Figure x – MEE – New Display Devices (with Existing Digital Mammography Units).**

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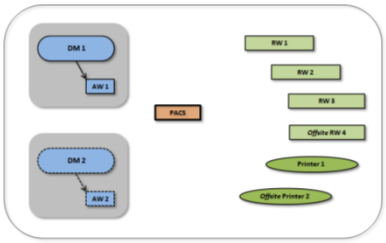
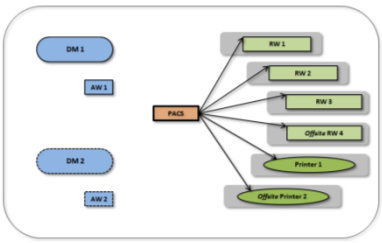
The following combination of testing must be performed:




A




B

KEY
- Arrows represent phantom image pathway and evaluation
- Gray shaded box indicates applicable testing required

**Figure – Annual Surveys a. Digital Mammography Units. b. Display Devices.**

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## ACR DM QC Manual – What's Next

- ACR developing training for techs, physicists, reviewers, inspectors and manufacturers
  - Webinars
  - In-person
- ACR revising accreditation process and software to incorporate new manual and phantom

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## ACR Website & FAQs – Updated 8/22/16

(www.acraccreditation.org/Modalities/Mammography)

**Our facility would like to begin using the new ACR Digital Mammography QC Manual. Can we do so as soon as we receive our new manual?**

Before the facility QC technologist may start using the new DMQC Manual on a particular unit, the medical physicist must first conduct an ***annual survey*** of the digital mammography unit and display devices using the new manual and phantom. This is important to provide testing techniques and procedures for the QC technologist to use during routine QC. After this is done, the QC technologist may start performing routine QC using the new manual.

**May I use our old ACR phantom to perform the tests in the new ACR Digital Mammography QC Manual instead of obtaining the new ACR Digital Mammography Phantom?**

No. The new ACR Digital Mammography QC Manual procedures were designed around the new ACR Digital Mammography Phantom. The old ACR phantom cannot be used to conduct the tests in the new manual.

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## End of Presentation

## Questions?

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