2D Digital Mammography-
An update on vendor-recommended QC tests

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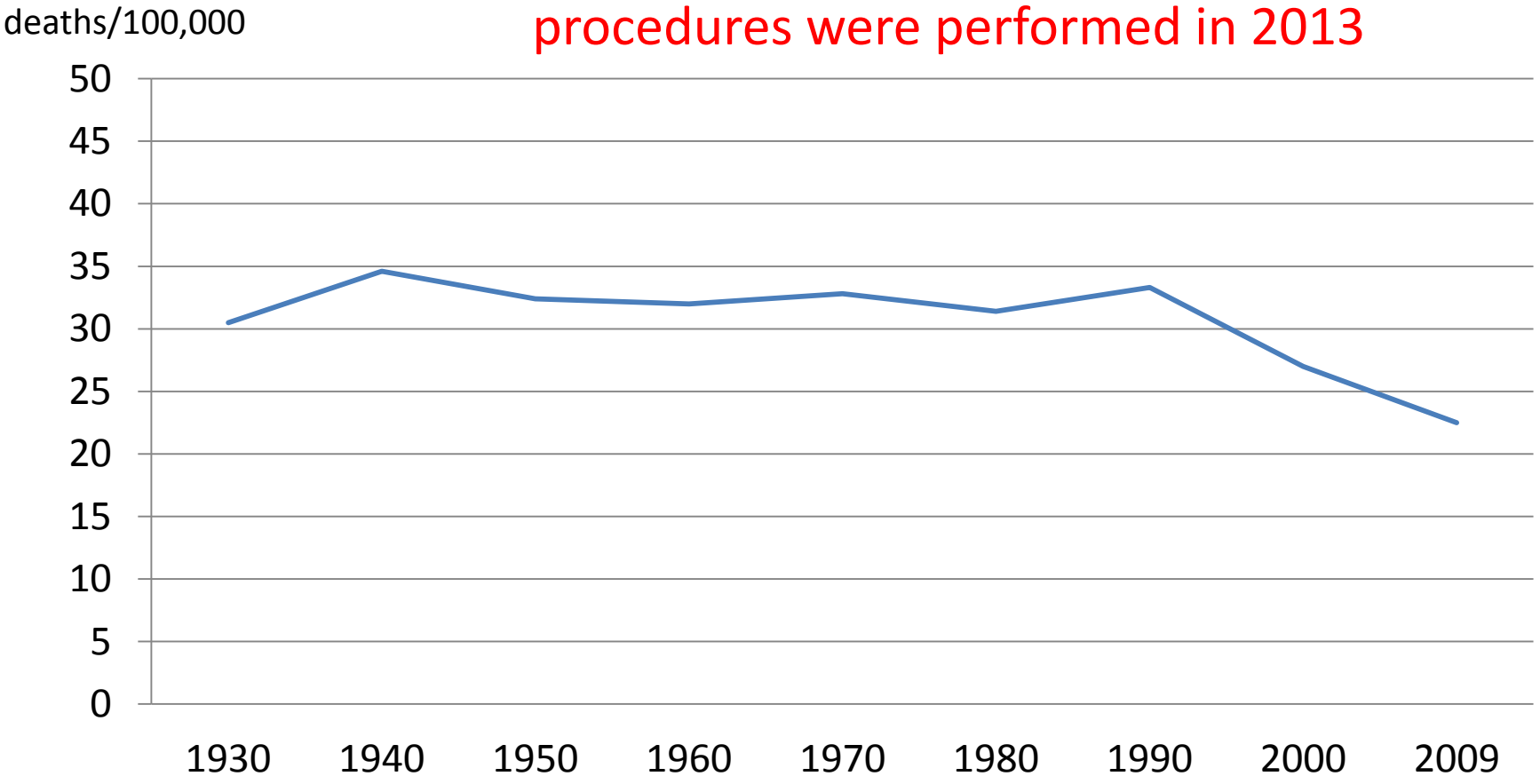
We will consider:

1. Benefit of screening mammography
2. Importance of good image quality in mammography
3. Value of QC in mammography
4. Current QC program requirements for FFDM
5. Potential changes for the future

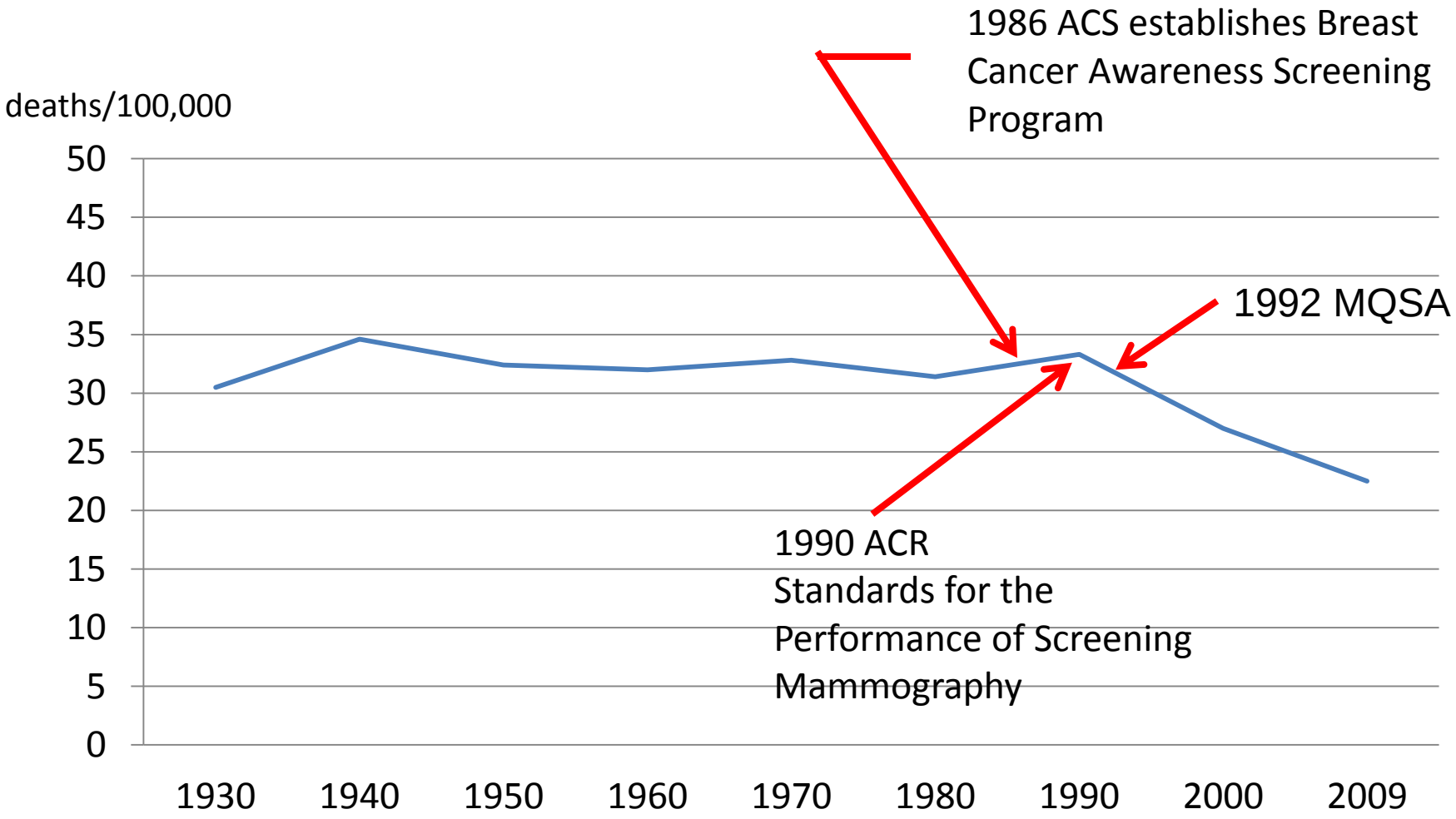
Age-adjusted Cancer Death Rates for Females in the US, 1930-2009

Approximately 38 million mammography procedures were performed in 2013



American Cancer Society. *Cancer Facts & Figures 2013*. Atlanta: American Cancer Society; 2013.

Age-adjusted Cancer Death Rates for Females in the US, 1930-2009



American Cancer Society. *Cancer Facts & Figures 2013*. Atlanta: American Cancer Society; 2013.

Survival is very good if the cancer is found early

5-year survival rates (%):

98 if cancer is local

84 if regional

24 if metastasized

American Cancer Society. *Cancer Facts & Figures 2013*. Atlanta: American Cancer Society; 2013.

Why do we do mammography?
What is the purpose of mammography?

early and accurate detection of breast cancer

with the minimum required radiation dose

What is mammography image quality?

How is breast cancer detected in a mammogram?

How is breast cancer detected in a mammogram?

What is mammography image quality?

What is the benefit of QC in mammography?

How does it assure good image quality?

How does it improve breast cancer detection?

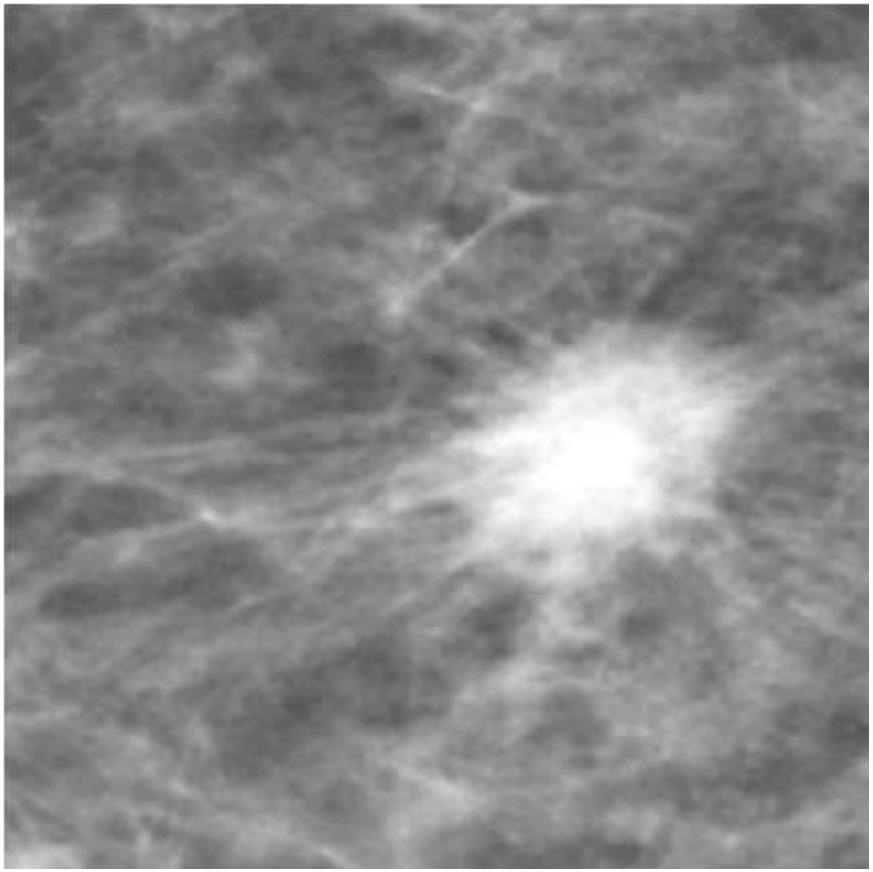
Quality control should not be thought of as an end in itself

What is mammography image quality?

Pathology to be seen:

high density mass

shape and margin are important

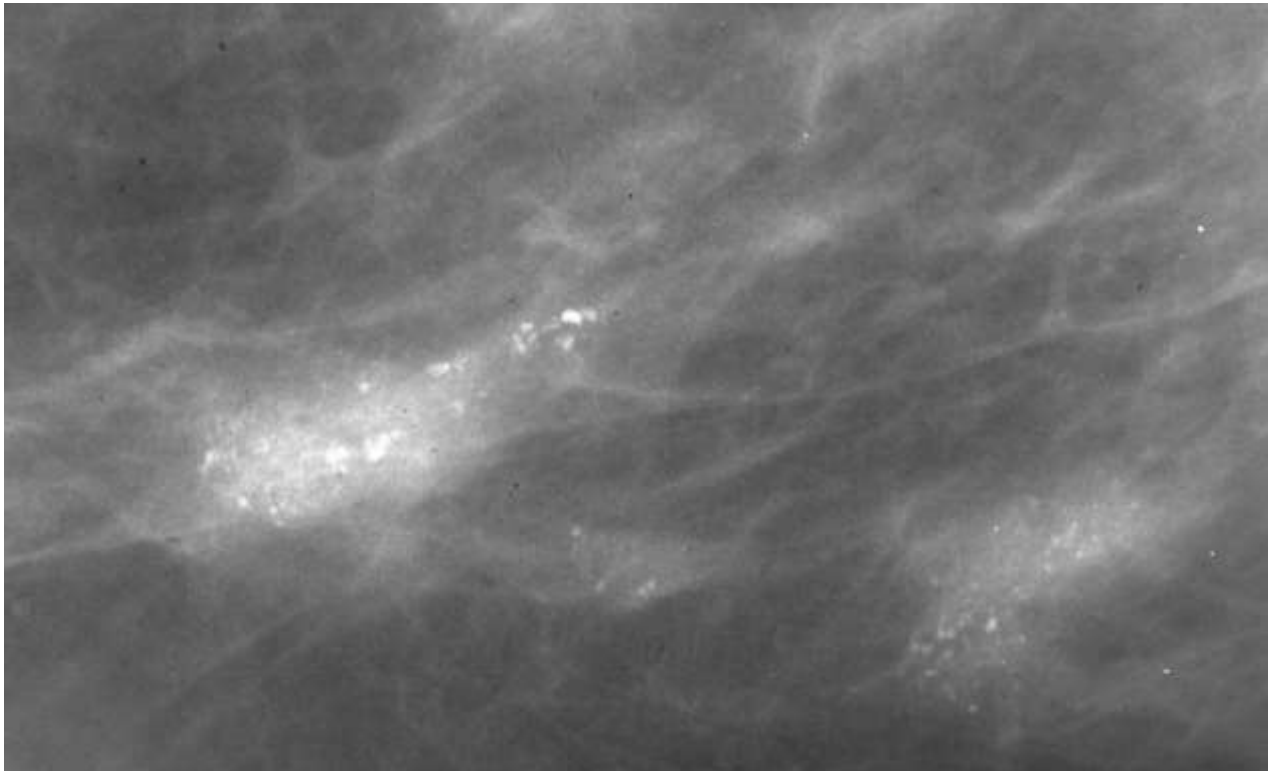


What is mammography image quality?

Pathology to be seen:

micro-calcifications

morphology and distribution are important



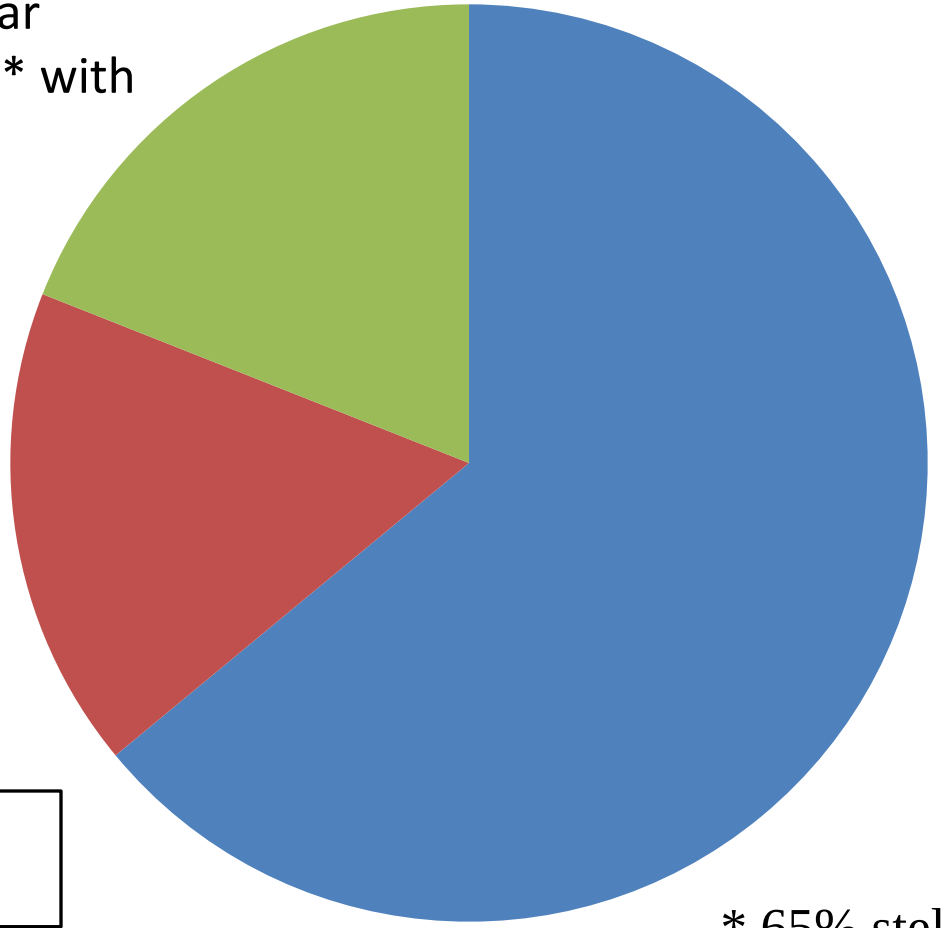
What is mammography image quality?

Pathology to be seen:

architectural distortion

deviation from normal parenchymal pattern

How is breast cancer detected in a mammogram?

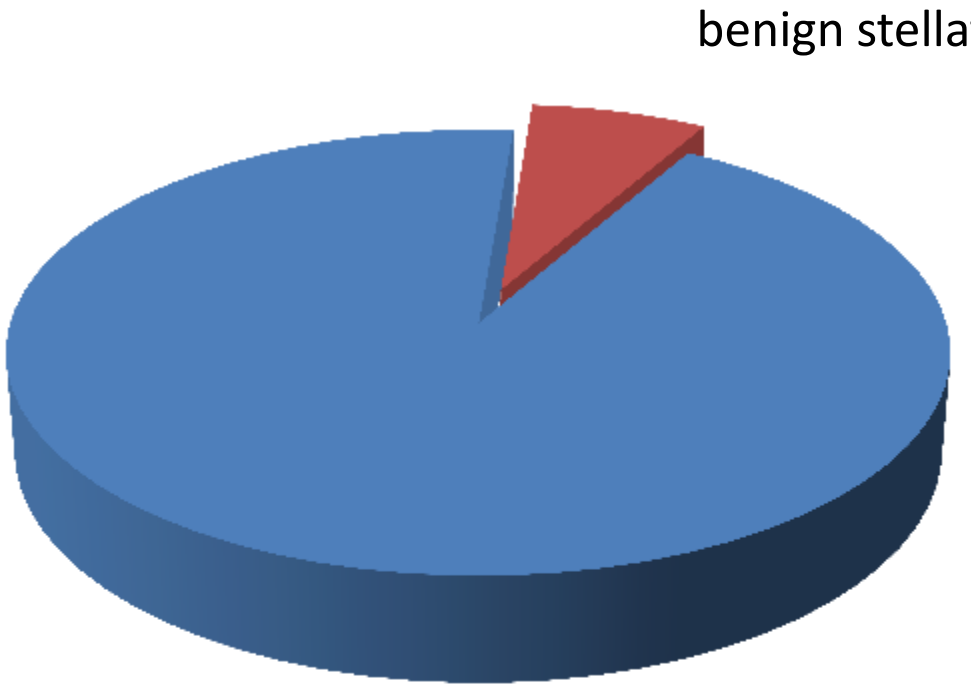


5 year retrospective study of 866 cancers

* 65% stellate, 35% circular

Tabar L, Tot T, Dean PB. Breast cancer: the art and science of early detection with mammography. Stuttgart, Germany, Thieme Verlag, 2005

How is breast cancer detected in a mammogram?



"…perception of the stellate lesion—while they are small [is] the number one task of mammography" L. Tabar

Tabar L, Tot T, Dean PB. Breast cancer: the art and science of early detection with mammography. Stuttgart, Germany, Thieme Verlag, 2005

Mammography QC- a little history:

- 1985 NEXT (FDA)
- 1986 Galkin et al

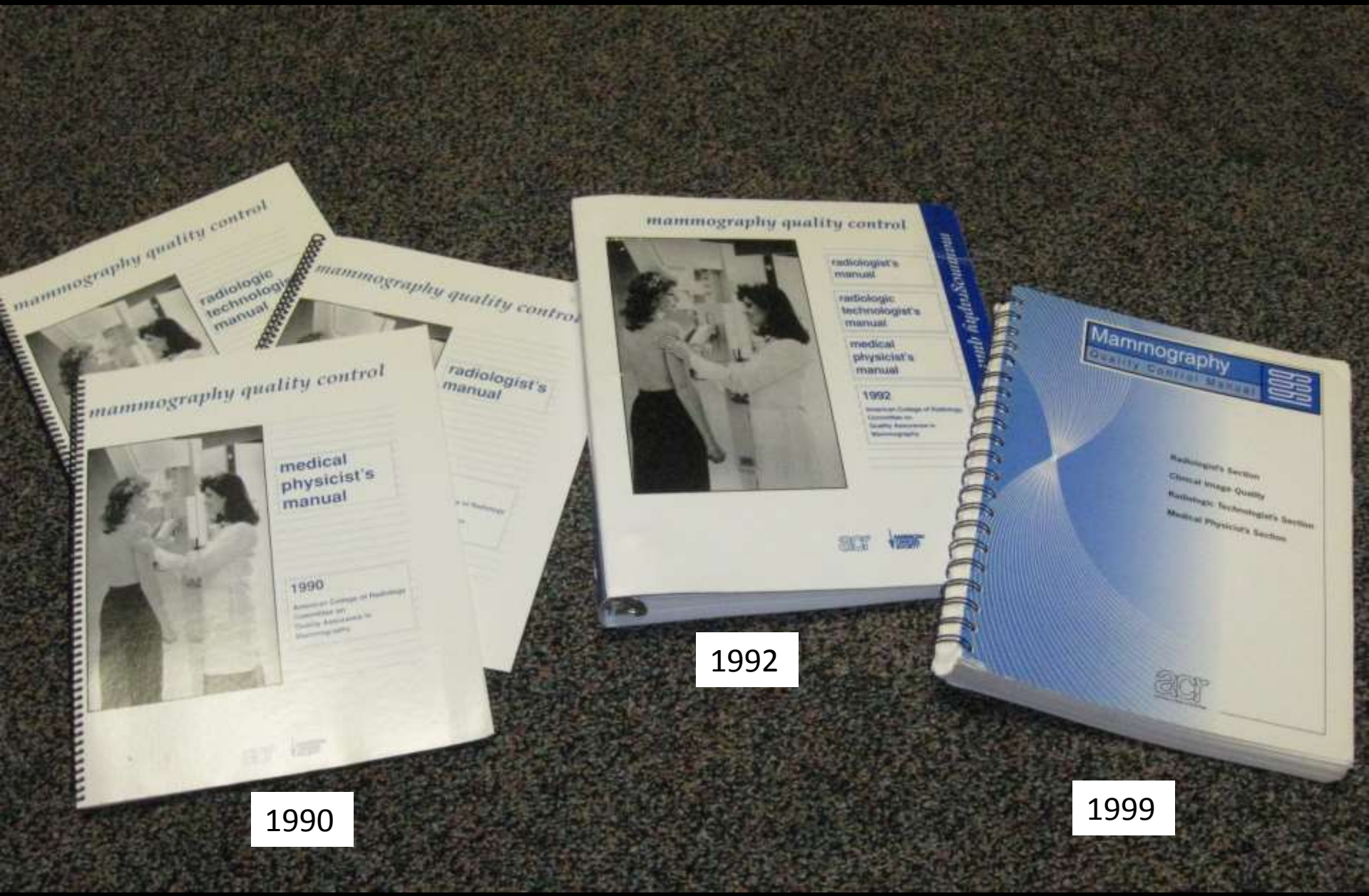
Wide variability in image quality and radiation dose in radiography

- 1986 ACS establishes Breast Cancer Awareness Screening Program
  ACS-ACR collaboration sets standard for quality mammography
- 1987- ACR launches voluntary accreditation program including mandatory QC testing

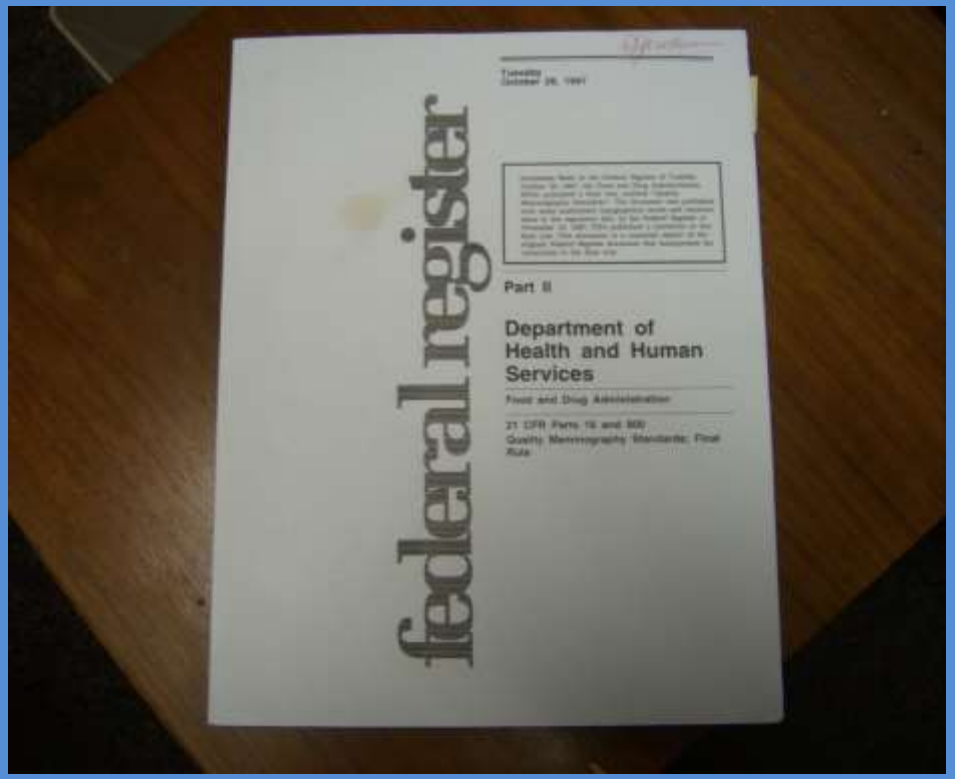
A little more history ….

1987: ACR initiates voluntary accreditation
1990: 1st ACR QC manuals
10/27/92: President Bush signs MQSA bill to take effect 10/1/94 (21CFR Part 900)
1992: 2nd ACR manual published
10/23/93: Interim MQSA regulations published
10/28/97: Final MQSA regulations published to take effect 4/28/99 (a few effective 10/28/02)
1999: New ACR manual to work with MQSA

The ACR QC program



- **FDA certification and ACR accreditation**
  Mammography Quality Standards Act, 1992



Sec. 900.11
Requirements for certification.

(a) *General*. After October 1, 1994, a **certificate** issued by FDA is required for lawful operation of all mammography facilities subject to the provisions of this subpart. To obtain a certificate from FDA, facilities are required to meet the quality standards in Sec. 900.12 and to be **accredited** by an approved accreditation body or other entity as designated by FDA.

21CRF 900.12(e)(6):

*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.

21CRF 900.12(e)(5)(vi):

Dosimetry.

The average glandular dose delivered during a single cranio-caudal view of an FDA-accepted phantom simulating a standard breast shall not exceed 3.0 milligray (mGy) (0.3 rad) per exposure. The dose shall be determined with technique factors and conditions used clinically for a standard breast.

Standard breast is defined as 4.2 cm compressed breast consisting of 50% glandular and 50% adipose tissue

Other modalities (as of August 2013) are:

- ***Full field digital mammography (FFDM)***
  - *General Electric 2000D was first – 01/28/00*
  - *Currently 26 different models are approved*

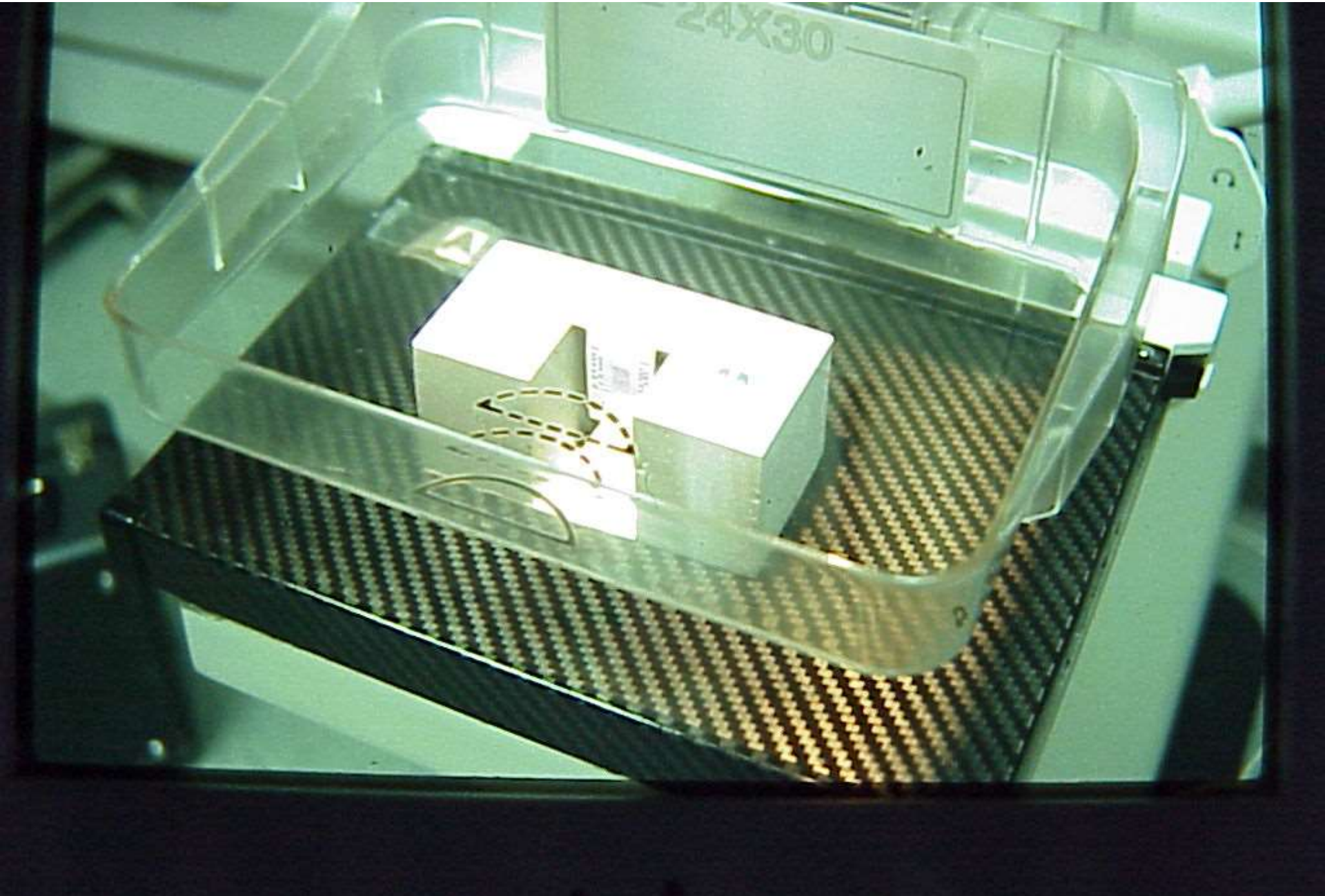
- ***Digital Breast Tomosynthesis (DBT)***
  - *Hologic Selenia Dimensions DBT – 02/11/11*

Generic description of selected mammographic QC tests

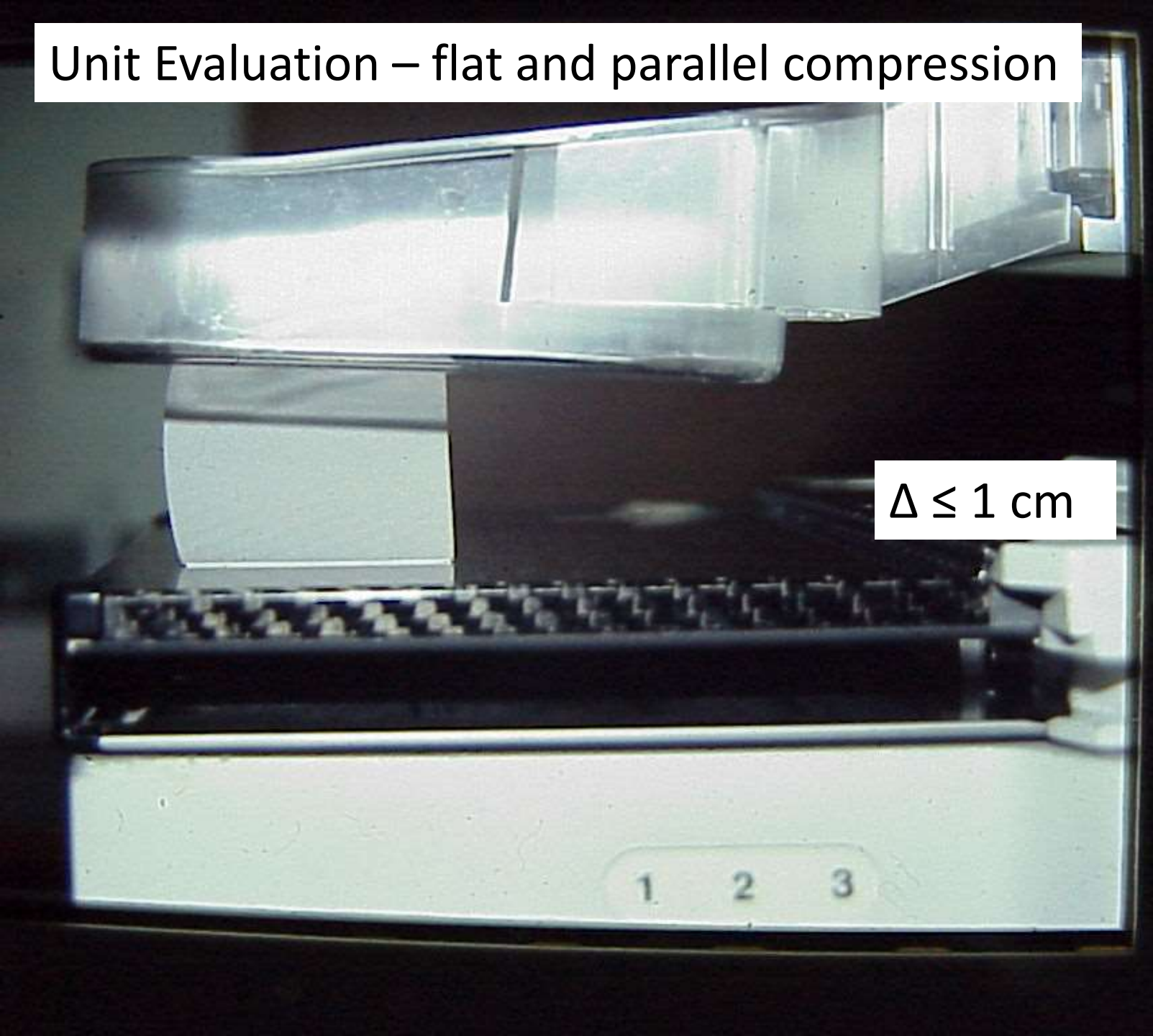
Medical physicist QC tests for Screen-Film Systems: ACR and MQSA

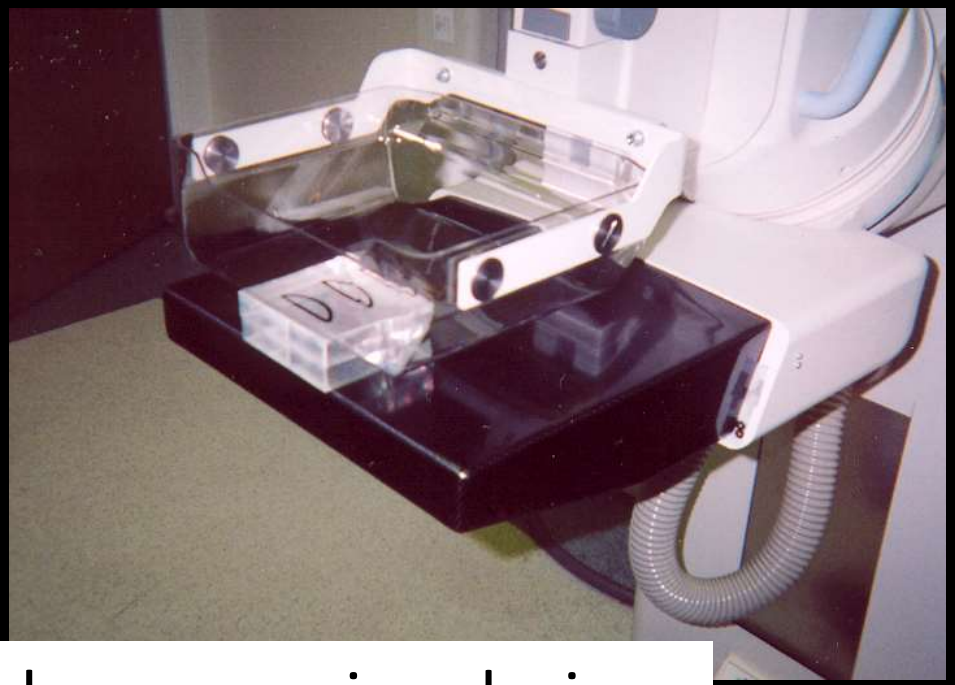
	PASS/FAIL ACR Guides	PASS/FAIL MQSA Regs
1. Mammographic Unit Assembly Evaluation		
2. Collimation Assessment		
Deviation between X-ray field and light field ≤2% of SID		
X-ray field does not extend beyond any side of the IR by more than 2% of SID		
Chest wall edge of compression paddle doesn't extend beyond IR by more than 1% of SID		
3. Evaluation of Focal Spot Performance		
Measured performance within acceptable limits for large focal spot		
Measured performance within acceptable limits for small focal spot		
4. Automatic Exposure Control (AEC) System Performance		
Exposure reproducibility is within acceptable limits		
AEC compensation for kVp, breast thickness and image mode is adequate		
AEC density control function is adequate		
5. Uniformity of Screen Speed		
Optical density range is ≤0.30		
6. Artifact Evaluation		
Artifacts were not apparent or not significant		
7. Phantom Image Quality Evaluation		
4 largest fibers, 3 largest speck groups and 3 largest masses are visible		
Phantom image quality scores: Fibers		
Specks		
Masses		
8. kVp Accuracy and Reproducibility		
Measured average kVp within ±5% of indicated kVp		
kVp coefficient of variation ≤0.02		
9. Beam Quality (Half-Value Layer) Assessment		
Half-value layer is within acceptable lower and upper limits at all kVp values tested		
10. Breast Entrance Exposure, Average Glandular Dose and Radiation Output Rate		
Average glandular dose for average breast is below 3 mGy (300 mrad)		
Average glandular dose to a 4.2-cm-thick breast on your unit is ____ mrad		
Radiation output rate is ≥800 mR/sec (7.0 mGy/sec) at 28 kVp with Mo/Mo ____ mR/sec		
11. Viewbox Luminance and Room Illuminance		
Mammographic viewbox is capable of a luminance of at least 3000 nit		
Room illuminance (viewbox surface & seen by observer) is 50 lux or less		

Unit Evaluation – flat and parallel compression



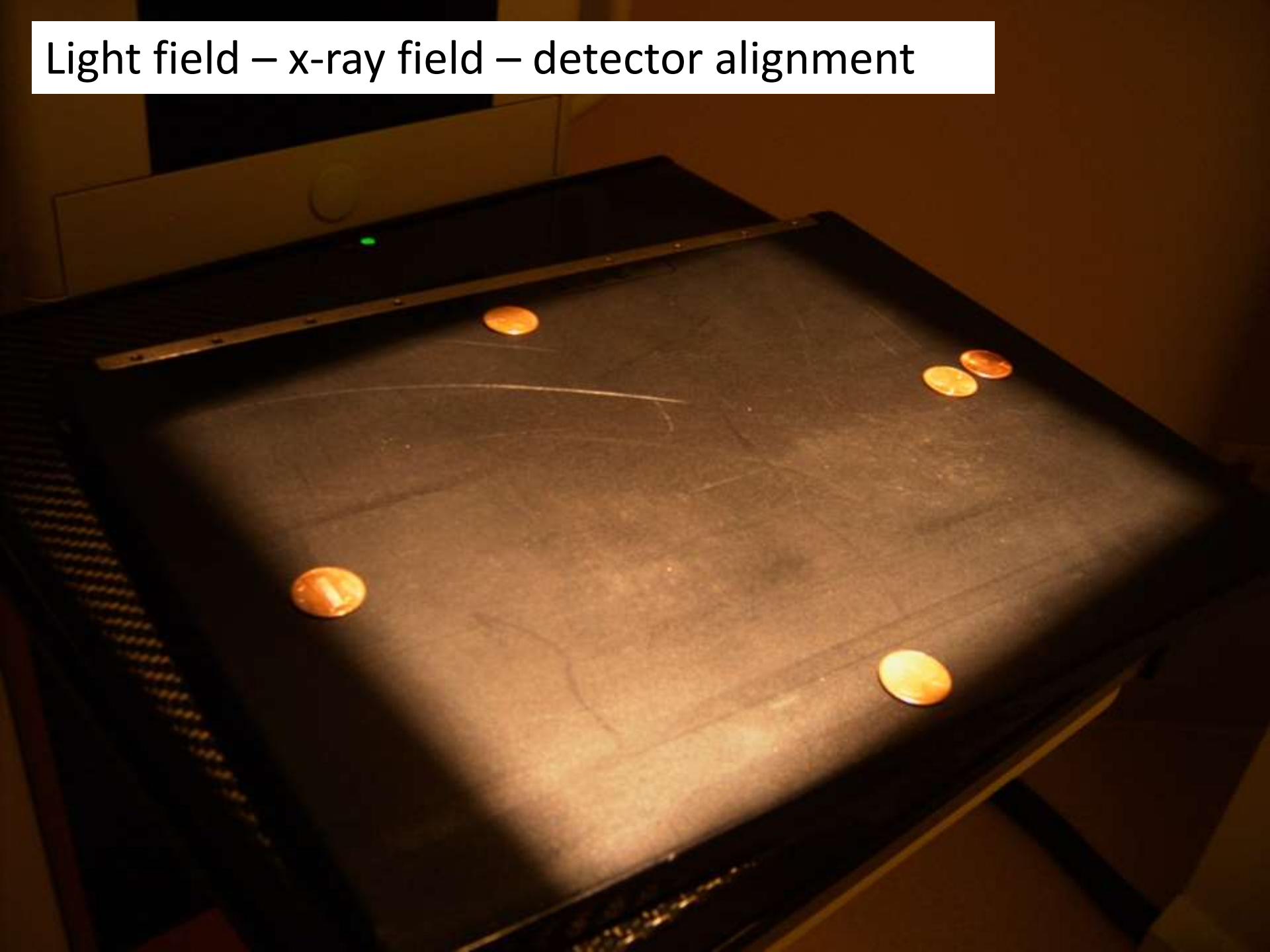
Unit Evaluation – flat and parallel compression



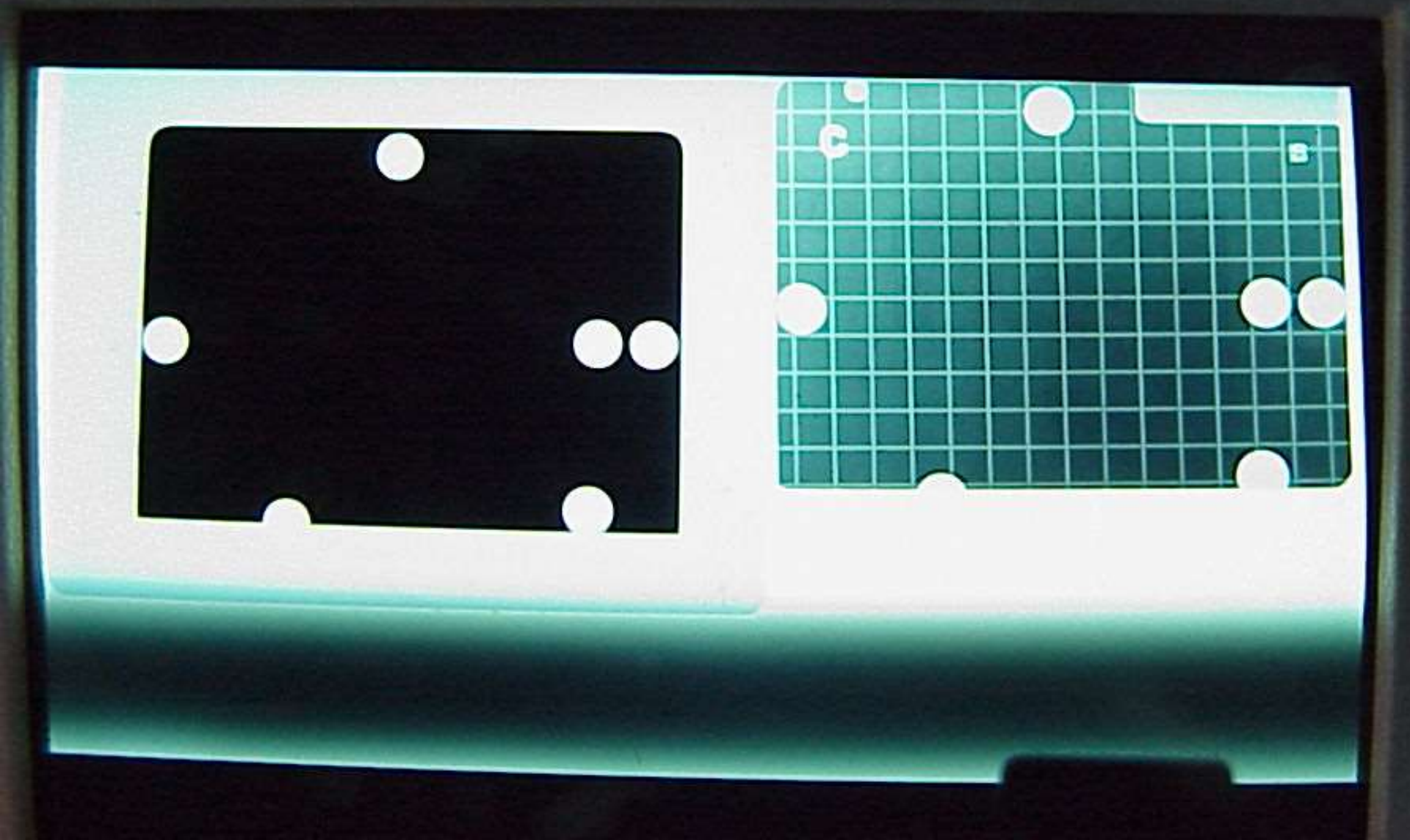


Non-flat and non-parallel compression designs

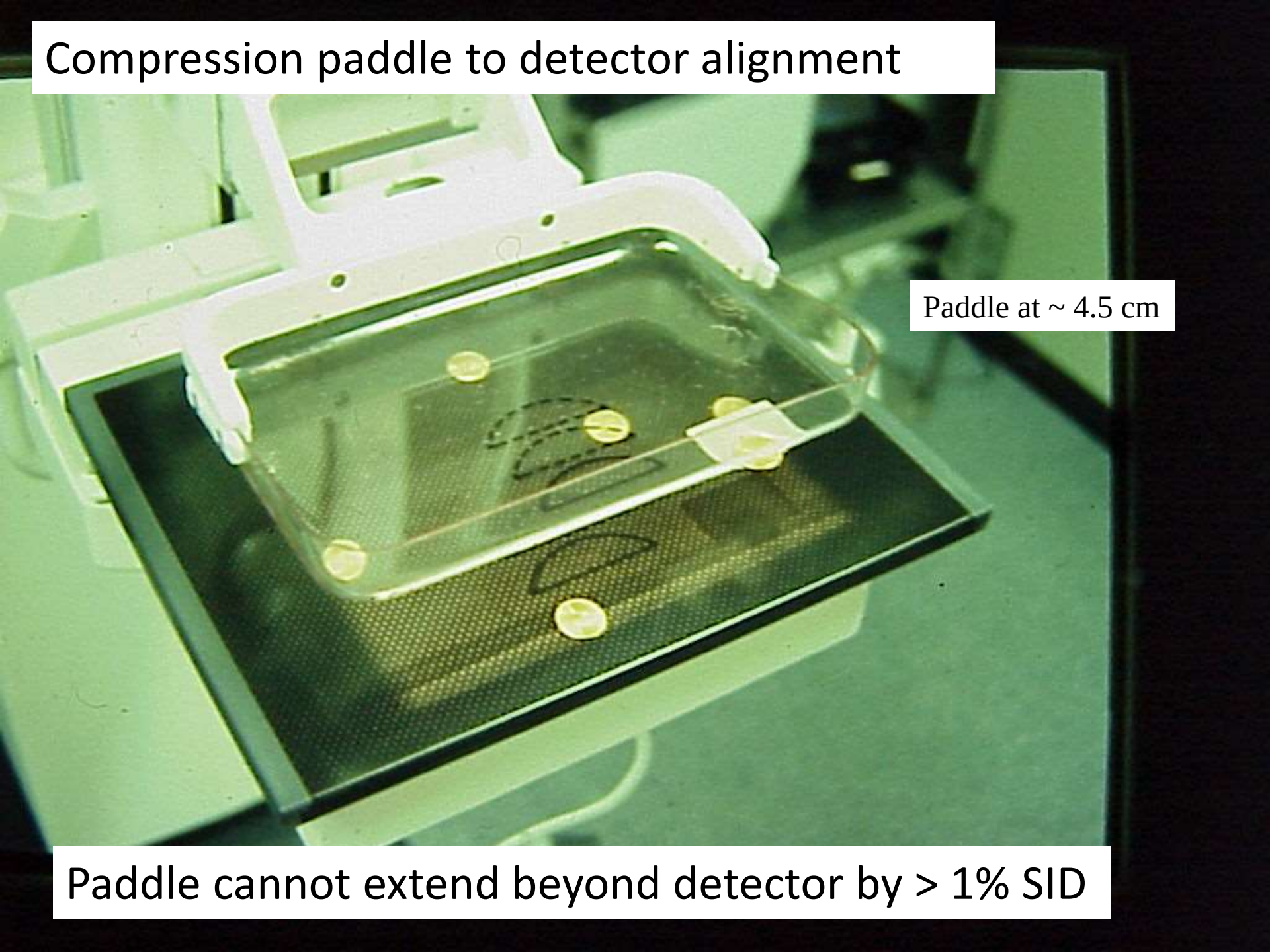
Light field – x-ray field – detector alignment



light to x-ray: X and Y sum Δ ≤ 2% SID
X-ray to detector: Δ ≤ 2% along any side

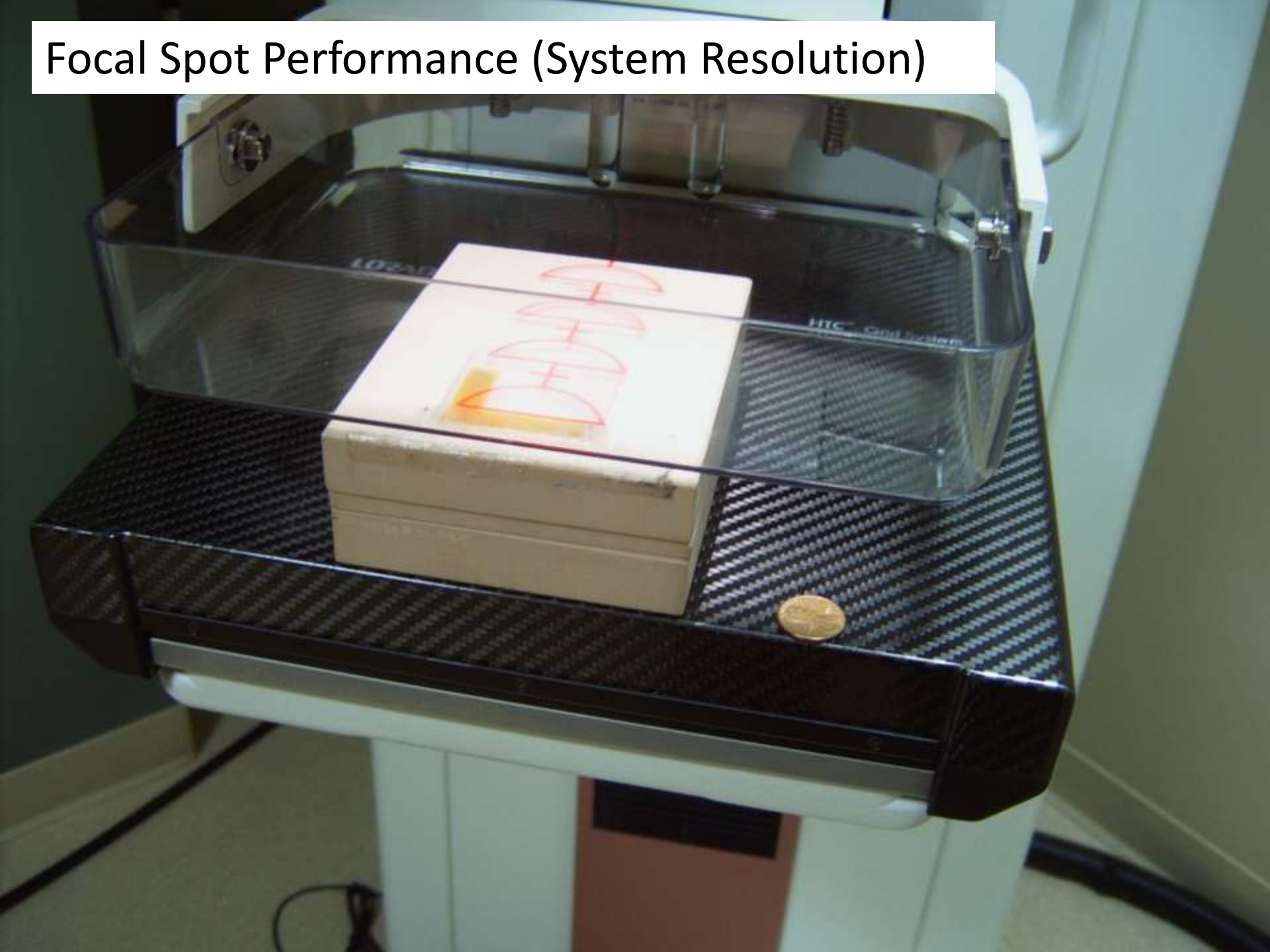


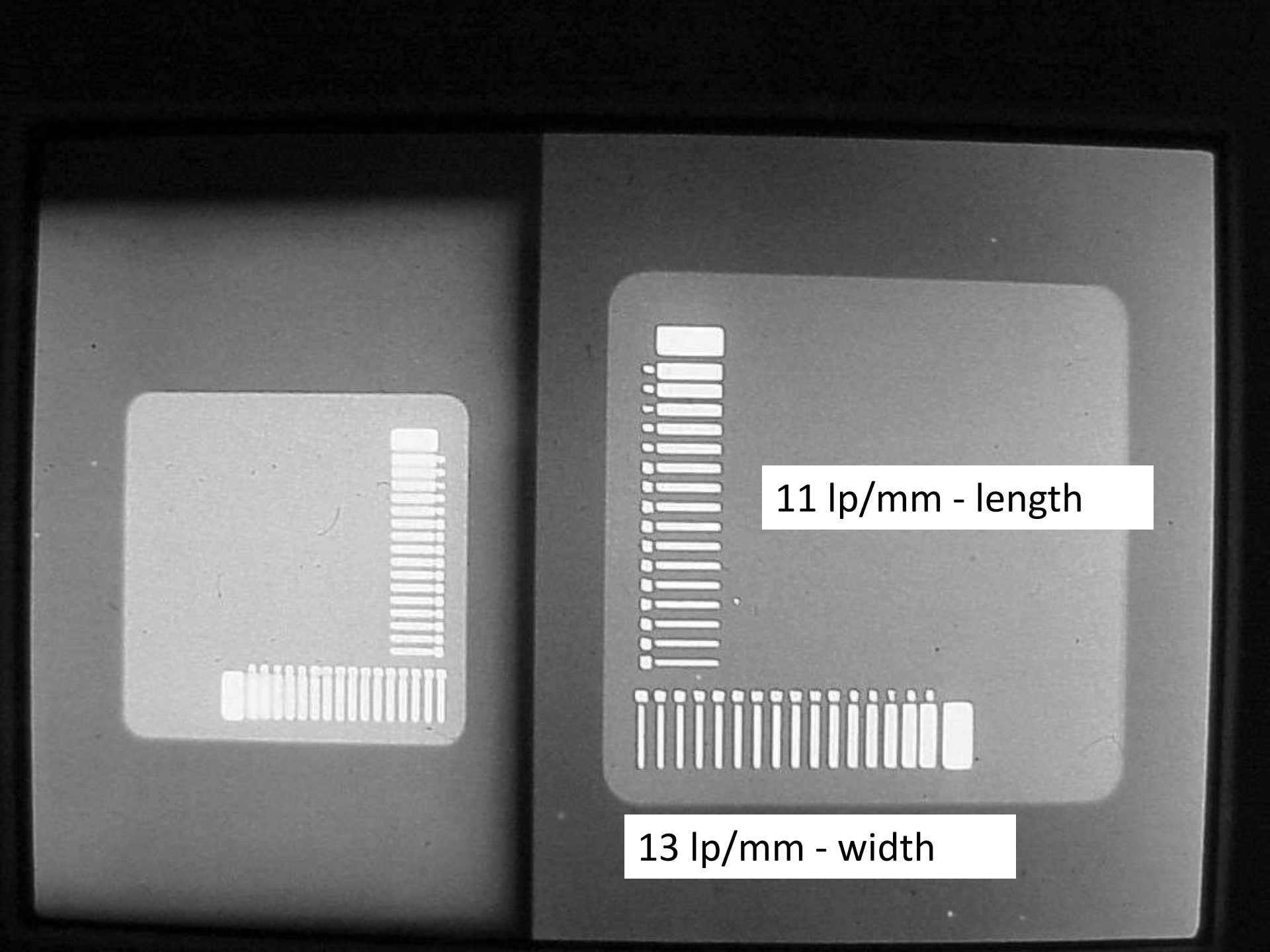
Compression paddle to detector alignment



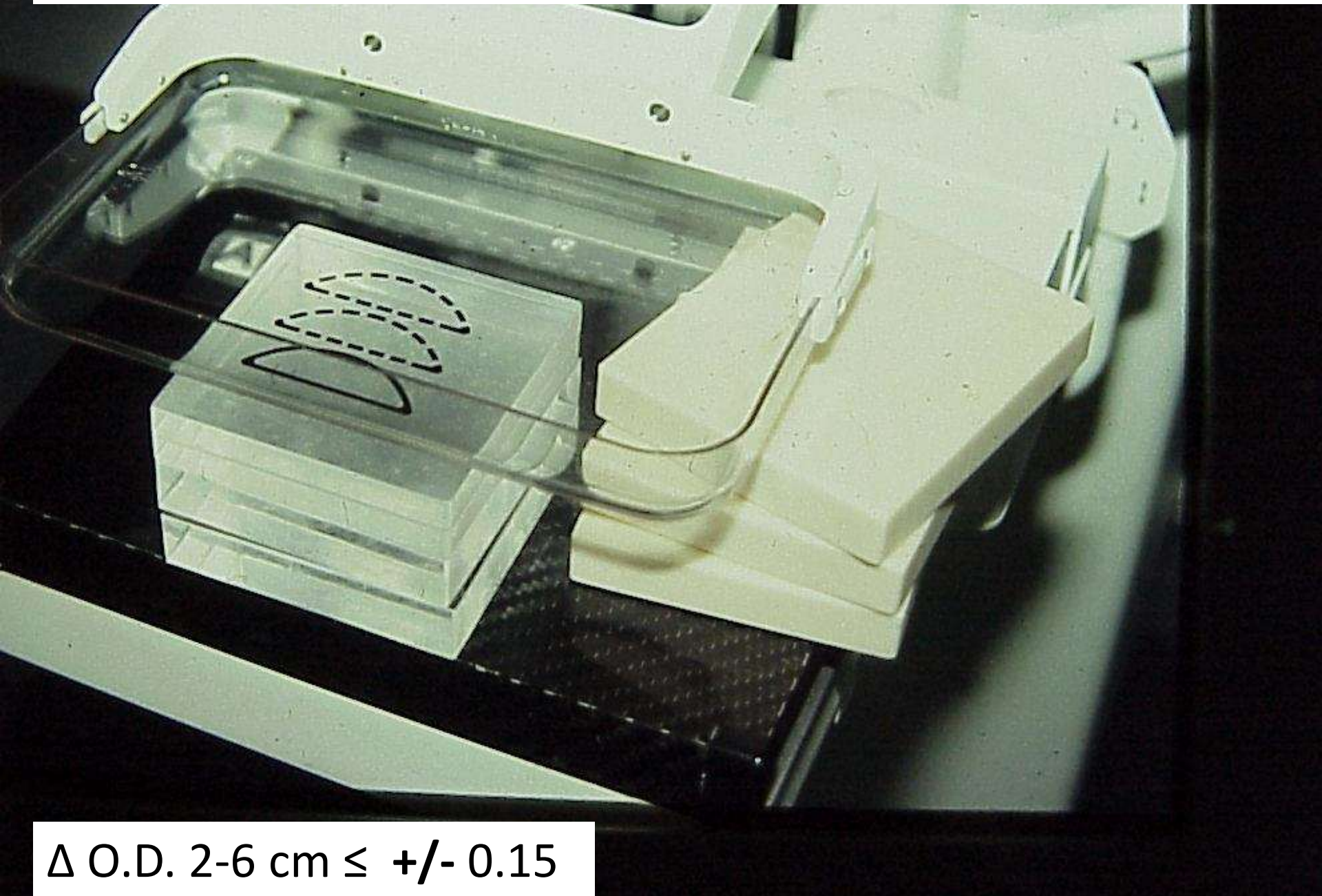
Paddle cannot extend beyond detector by > 1% SID

Focal Spot Performance (System Resolution)




11 lp/mm - length
13 lp/mm - width

AEC performance – thickness compensation – density control

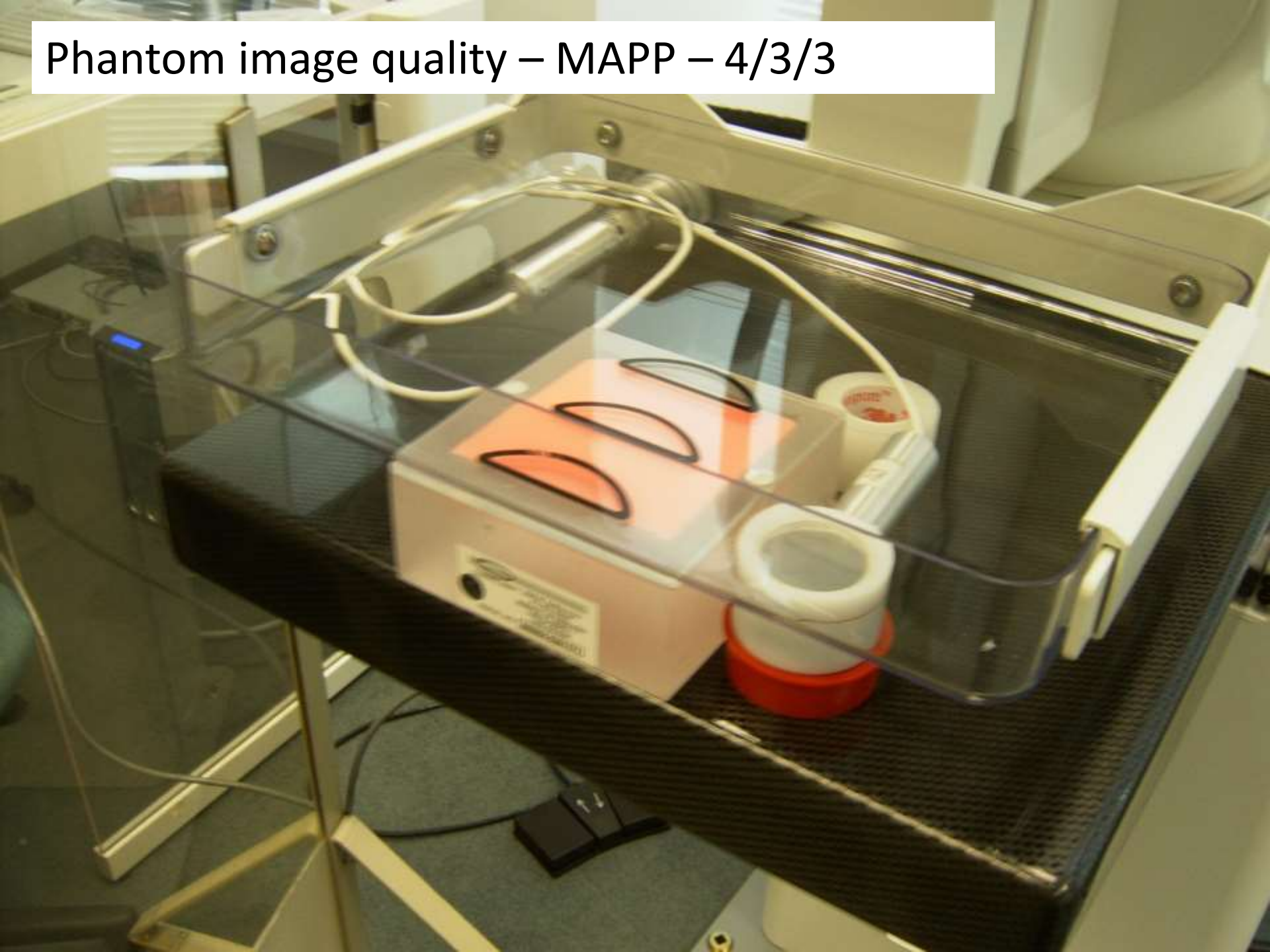


Δ O.D. 2-6 cm ≤ **+/-** 0.15

Screen uniformity and artifacts

Artifacts are not apparent or significant

Phantom image quality – MAPP – 4/3/3



kVp accuracy and repeatability

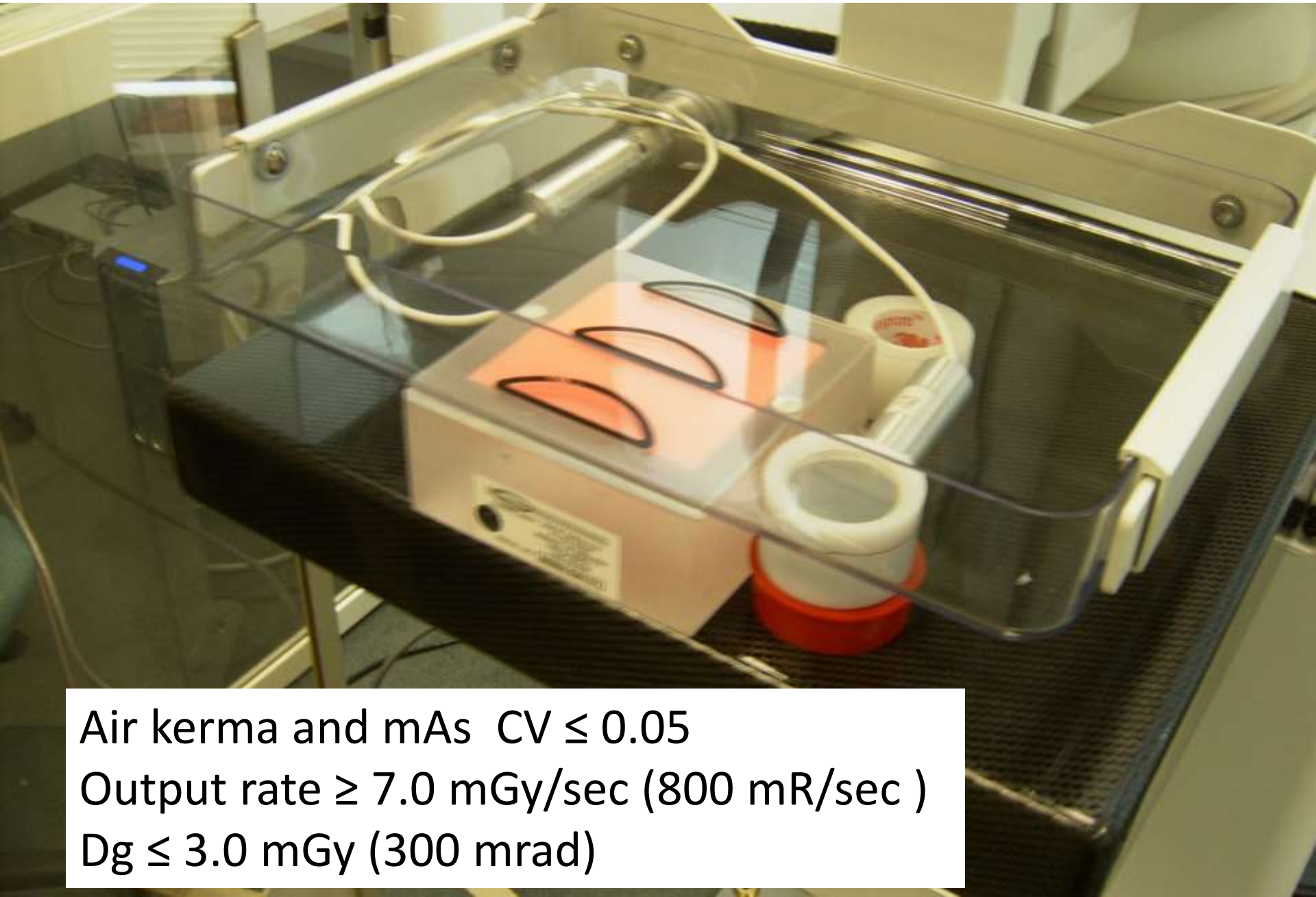
accuracy 5%

CV ≤ 0.02

Beam quality (HVL)

HVL ≥ kVp/100

Entrance exposure, average glandular dose, radiation output rate

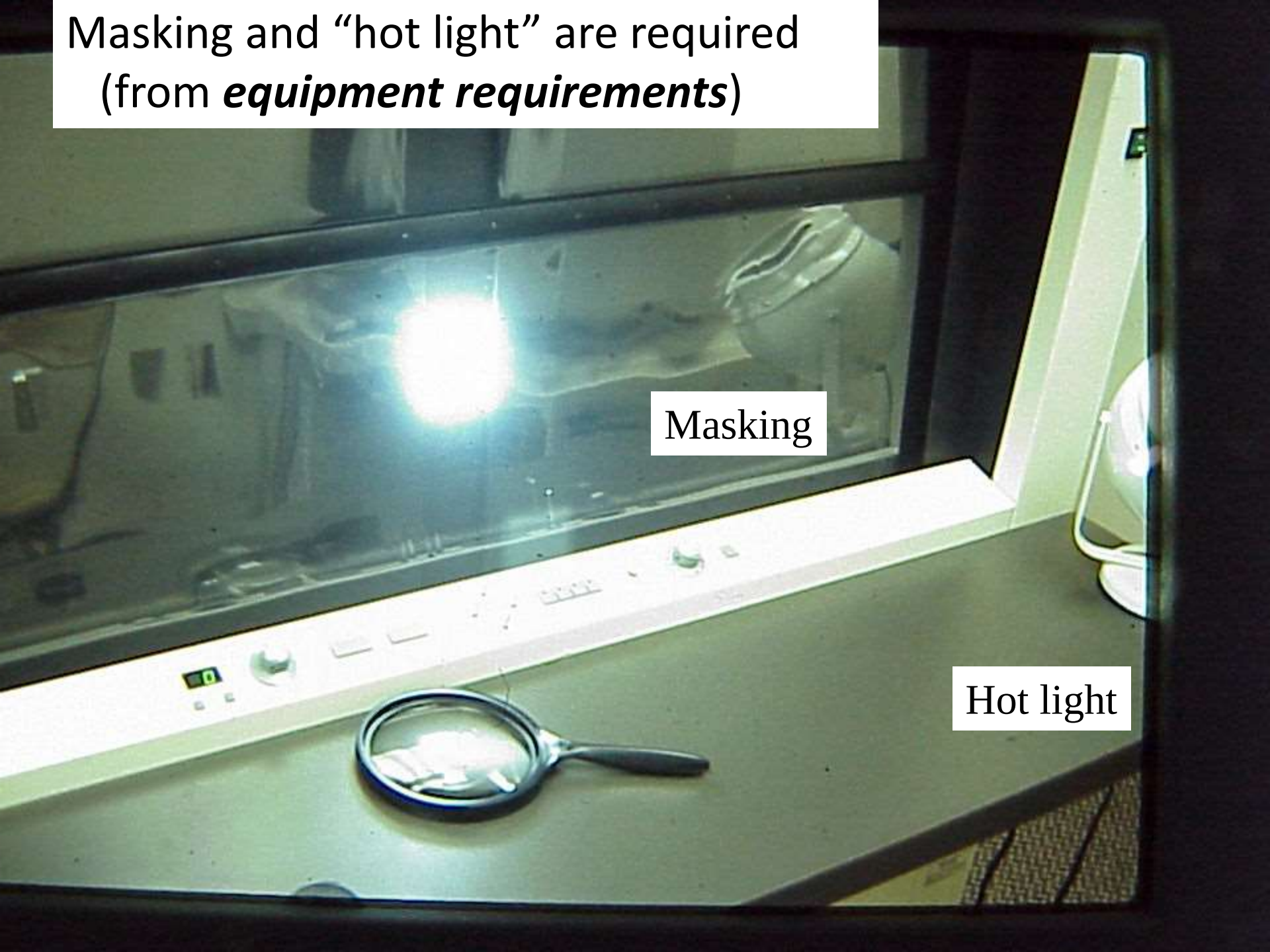


Air kerma and mAs CV ≤ 0.05
Output rate ≥ 7.0 mGy/sec (800 mR/sec)
Dg ≤ 3.0 mGy (300 mrad)

Viewbox luminance and viewing conditions (optional under MQSA)

Viewbox luminance ≥ 3000 cd/m^2
Luminance ≤ 50 lux

Masking and “hot light” are required
(from ***equipment requirements***)



Currently approved FFDM systems

FFDM and DBT Systems

FDA approved, cleared, or accepted the following FFDM and DBT units for use as indicated by date:

Konica-Minolta	Siemens Mammomat Inspiration Prime Edition cleared on 6/27/13
	Konica Minolta Xpress Digital Mammography Computed Radiography (CR) System on 12/23/11
Agfa	Agfa Computed Radiography (CR) Mammography System on 12/22/11
	Fuji Aspire Computed Radiography for Mammography (CRM) System on 12/8/11
Giotto	Giotto Image 3D-3DL Full-Field Digital Mammography (FFDM) System on 10/27/11
Fuji-DR	Fuji Aspire HD Full-Field Digital Mammography (FFDM) System on 9/1/11
	GE Senographe Care Full-Field Digital Mammography (FFDM) System on 10/7/11
Planmed	Planmed Nuance Excel Full-Field Digital Mammography (FFDM) System on 9/23/11
	Planmed Nuance Full-Field Digital Mammography (FFDM) System on 9/23/11
	Siemens Mammomat Inspiration Pure Full-Field Digital Mammography (FFDM) System on 8/16/11
Philips	Hologic Selenia Encore Full-Field Digital Mammography (FFDM) System on 6/15/11
	Philips (Sectra) MicroDose L30 Full-Field Digital Mammography (FFDM) System on 4/28/11
	Hologic Selenia Dimensions Digital Breast Tomosynthesis (DBT) System on 2/11/11
Carestream	Siemens Mammomat Inspiration Full Field Digital Mammography (FFDM) System on 2/11/11
	Carestream Directview Computed Radiography (CR) Mammography System on 11/3/10
	Hologic Selenia Dimensions 2D Full Field Digital Mammography (FFDM) System on 2/11/09
	Hologic Selenia S Full Field Digital Mammography (FFDM) System on 2/11/09
	Siemens Mammomat Novation S Full Field Digital Mammography (FFDM) System on 2/11/09
Fuji-CR	Hologic Selenia Full Field Digital Mammography (FFDM) System with a Tungsten target in 11/2007
	Fuji Computed Radiography Mammography Suite (FCRMS) on 07/10/06
	GE Senographe Essential Full Field Digital Mammography (FFDM) System on 04/11/06
Siemens	Siemens Mammomat Novation DR Full Field Digital Mammography (FFDM) System on 08/20/04
	GE Senographe DS Full Field Digital Mammography (FFDM) System on 02/19/04
Lorad	Lorad/Hologic Selenia Full Field Digital Mammography (FFDM) System on 10/2/02
	Lorad Digital Breast Imager Full Field Digital Mammography (FFDM) System on 03/15/02
Fischer	Fischer Imaging SenoScan Full Field Digital Mammography (FFDM) System on 09/25/01
GE	GE Senographe 2000D Full Field Digital Mammography (FFDM) System on 01/28/00

Common QC tests for FFDM

Mechanical/safety checks
Acquisition monitor checks
X-ray beam collimation and alignment (dead space)
Compression paddle position, flat and parallel
Spatial resolution (detector and system: GE)
AEC: thickness response, exposure compensation
Artifacts/uniformity (flat-field uniformity)
Image quality: 4/3/3 or 5/4/4
kVp accuracy and repeatability
HVL
Radiation dose
Radiation output rate
SNR/CNR

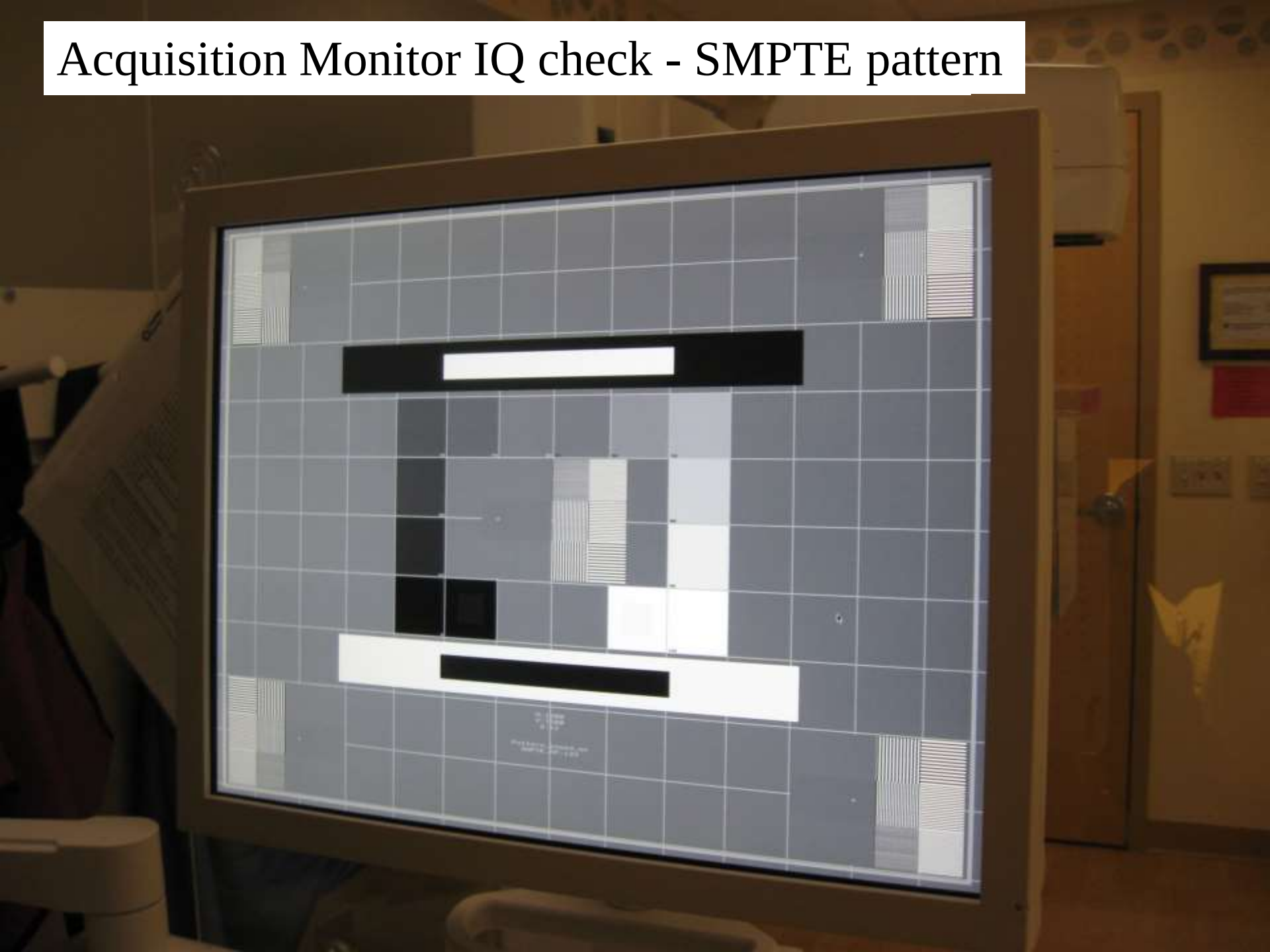
Reading workstation
Film printer

Common QC tests for FFDM – same as S/F

Mechanical/safety checks
Acquisition monitor checks
X-ray beam collimation and alignment (dead space)
Compression paddle position, flat and parallel
Spatial resolution (detector and system: GE)
AEC: thickness response, exposure compensation
Artifacts/uniformity (flat-field uniformity)
Image quality: 4/3/3 or 5/4/4
kVp accuracy and repeatability
HVL
Radiation dose
Radiation output rate
SNR/CNR

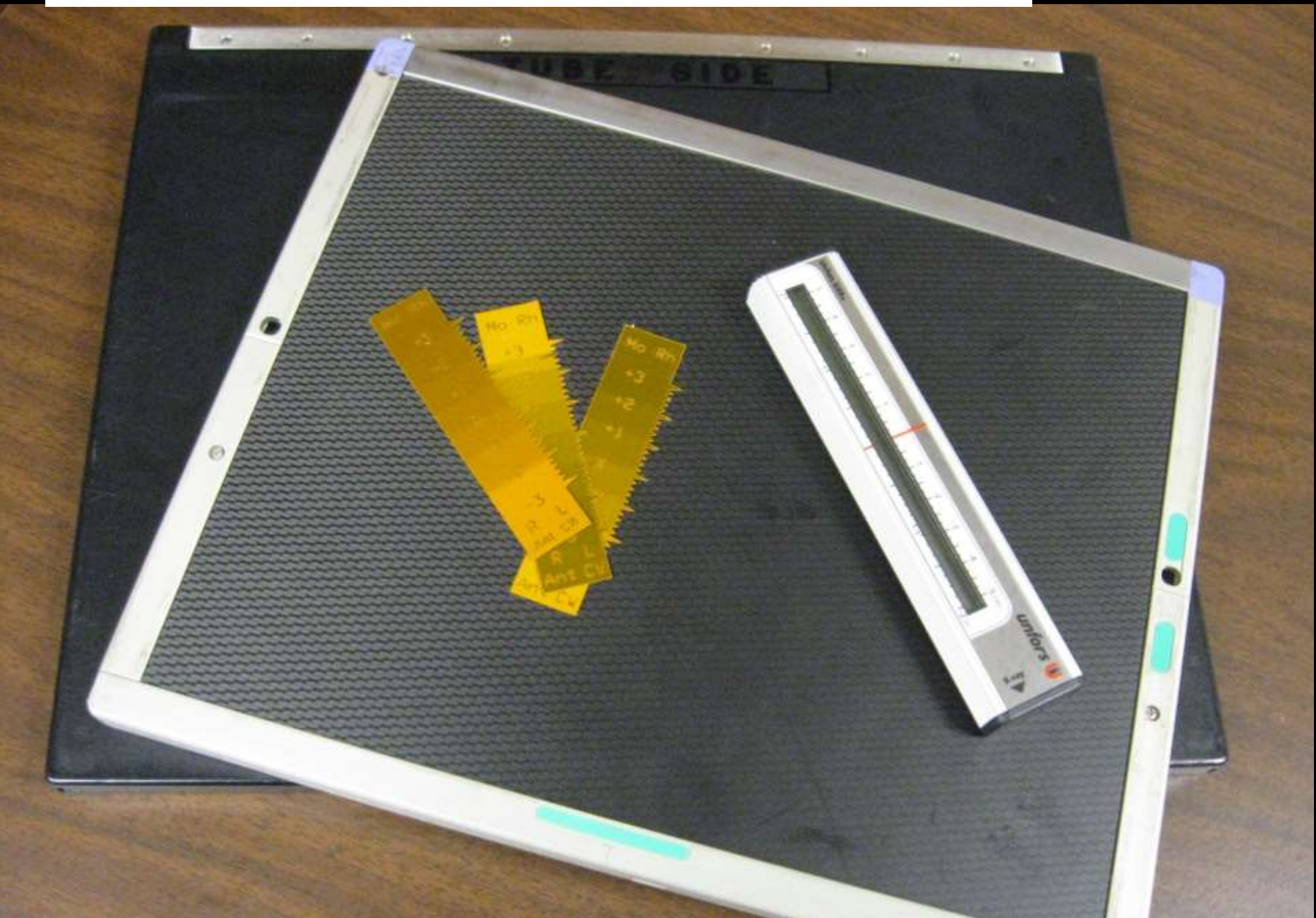
Reading workstation
Film printer

Acquisition Monitor IQ check - SMPTE pattern

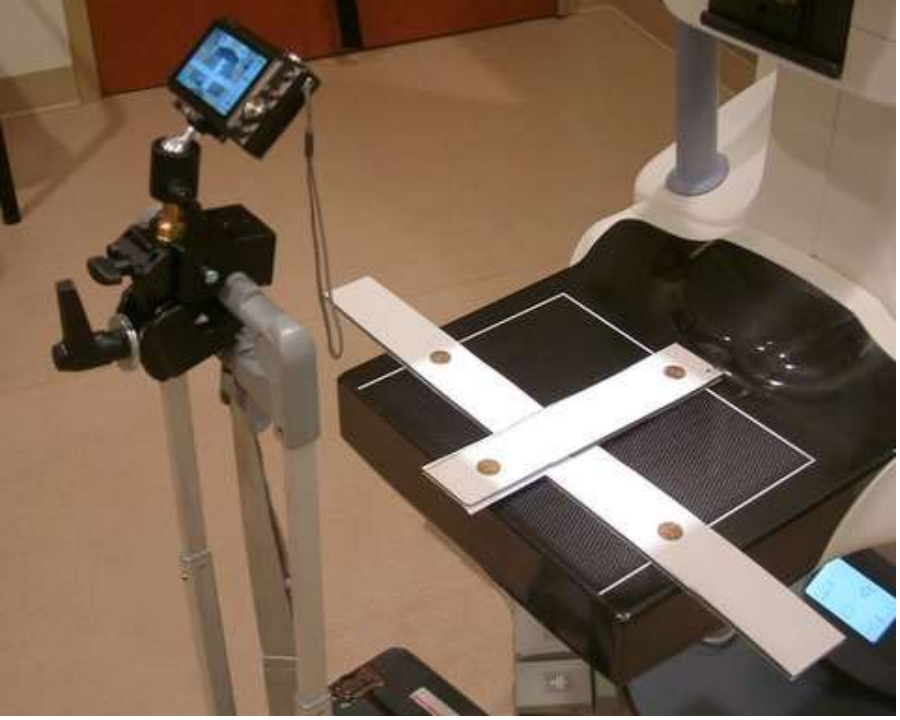


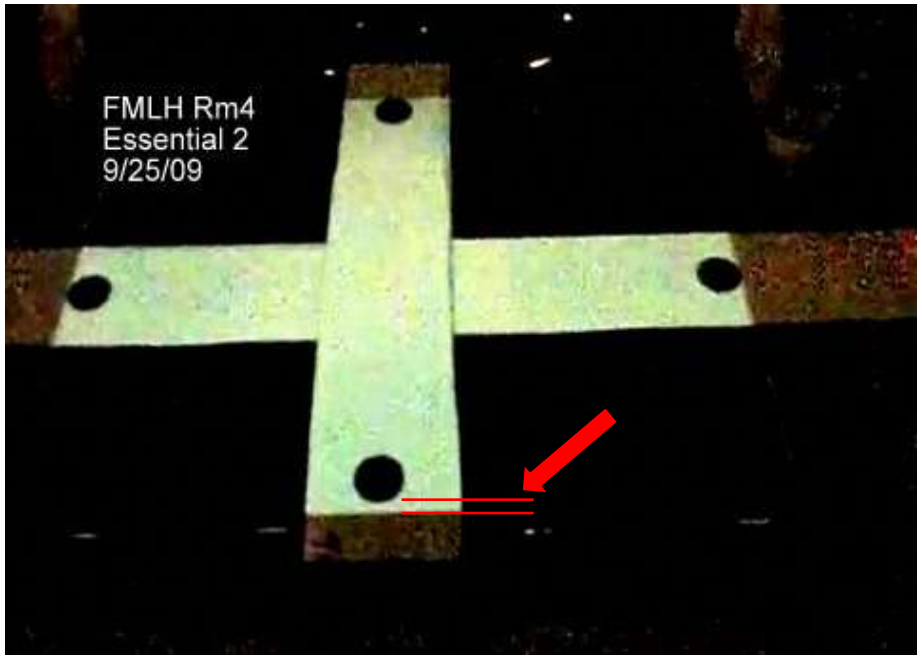
Flat field calibration and test

Collimation testing without film is a challenge



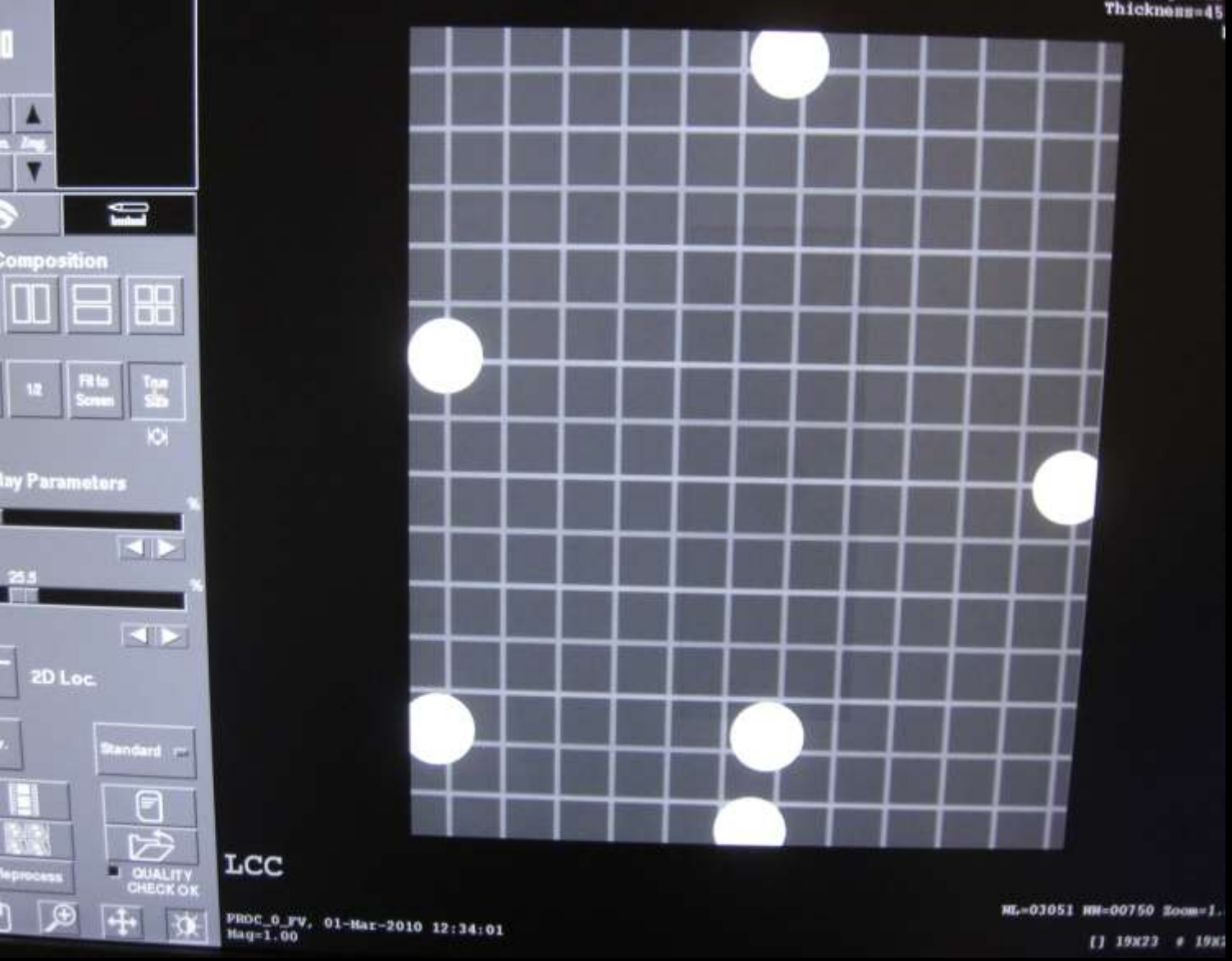

Gammac
Gammac

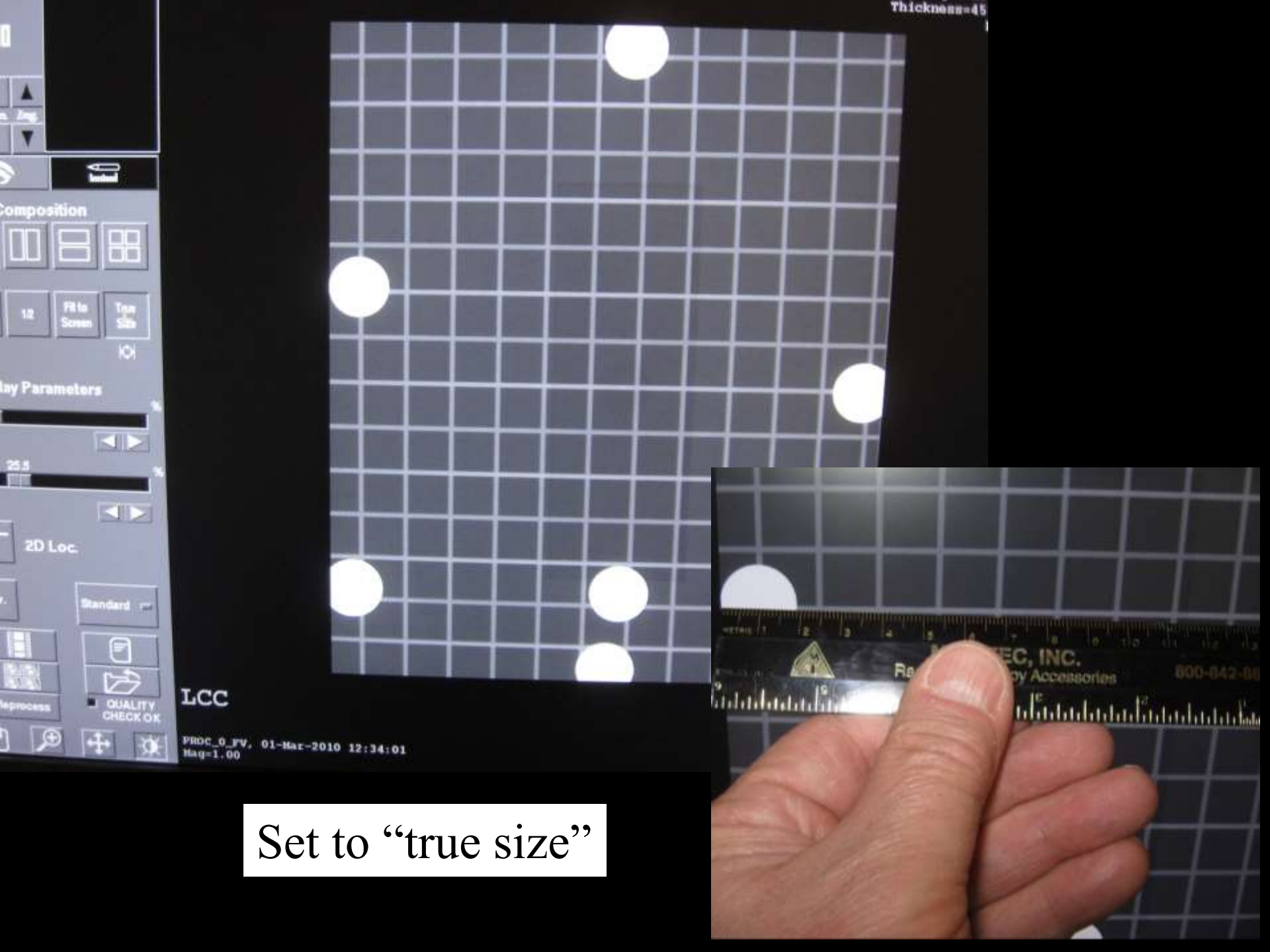




video ~ 1 sec

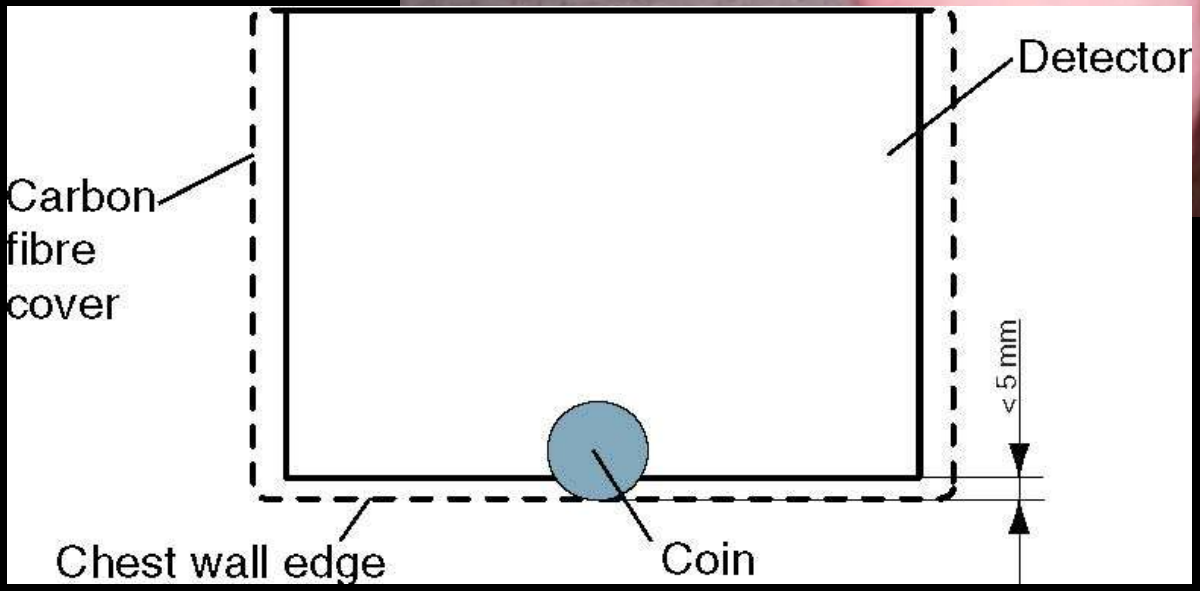
take snap-
shot from video


Thickness=45
Composition
1:2
Fit to Screen
True Size
lay Parameters
25.5
2D Loc
Standard
QUALITY CHECK OK
LCC
PROC_0_FV, 01-Mar-2010 12:34:01
Mag=1.00
ML=03051 MH=00750 Zoom=1.
[] 19X23 # 19X



Set to “true size”

Dead space



Collimation – sliding paddle

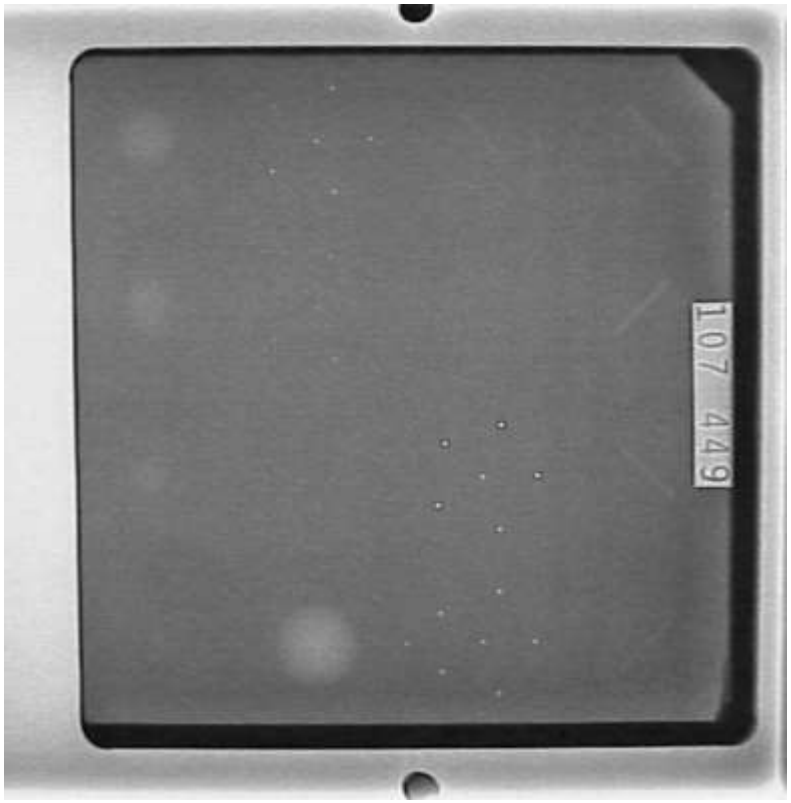
System Spatial Resolution

Image quality is still assessed with the MAP phantom

Fibers = 4, 5

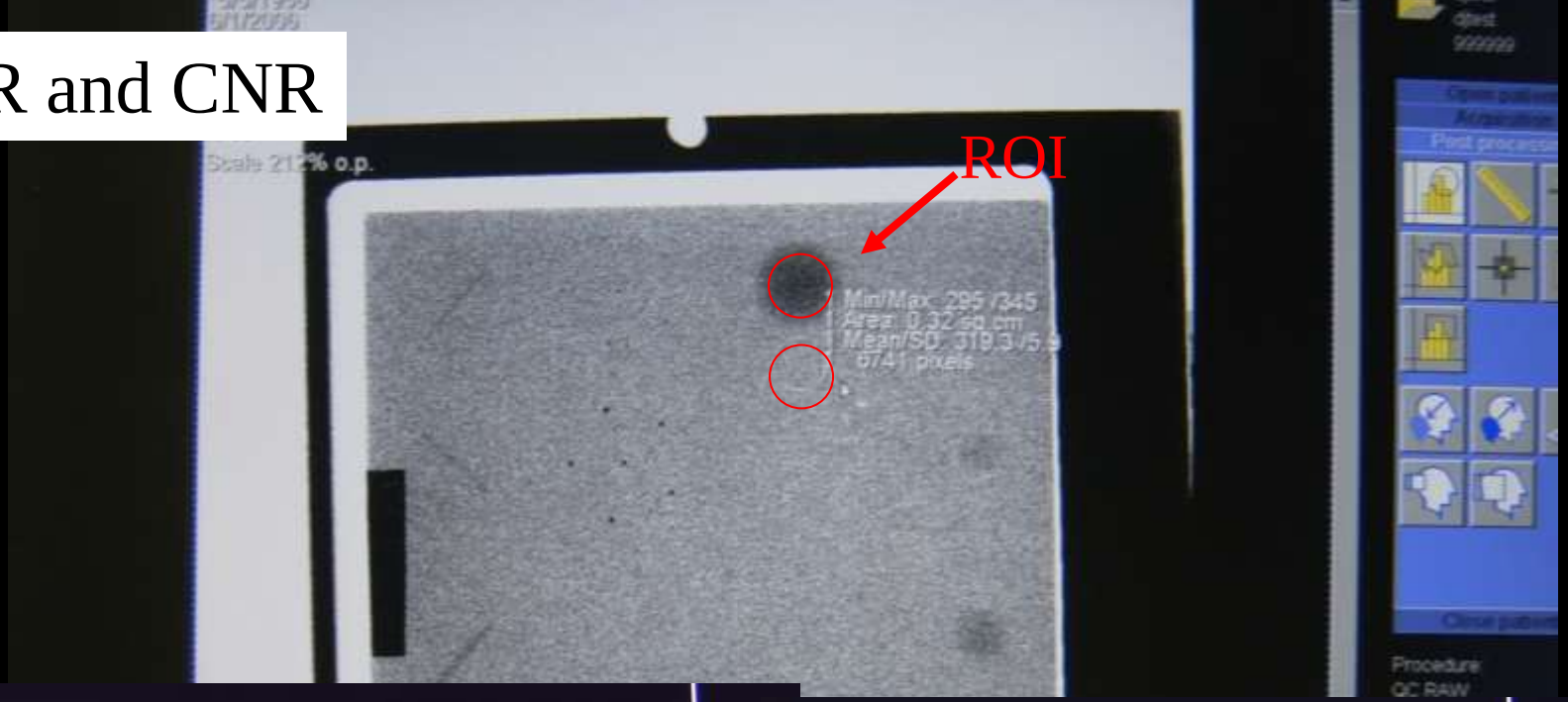
Specks = 3, 4

Masses = 3, 4



Radiation dose must be < 300 mrad (3 mGy)

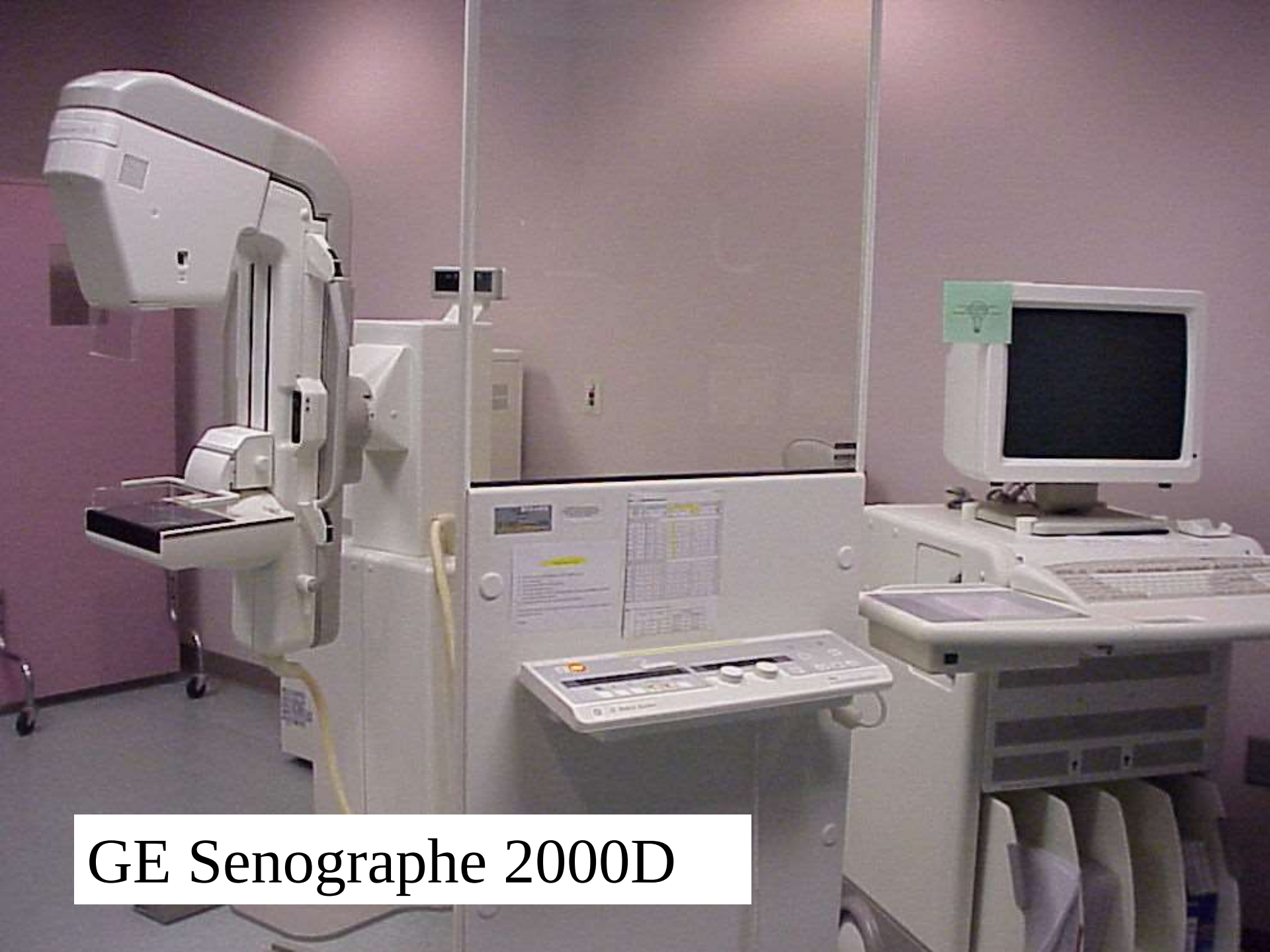
SNR and CNR


ROI
Min/Max 295 /345
Mean/SD 319.3 /5.9
Procedure
QC RAW


(Left,Top,Width,Height) = (1356, 1942, 64, 64)
Min/Max Pixel = (307, 359)
Mean, Std, SNR = (334.3, 7.4, 44.7)
OK


(Left,Top,Width,Height) = (1520, 1933, 64, 64)
Min/Max Pixel = (396, 453)
Mean, Std, SNR = (422.2, 8.1, 51.8)
OK

Current Manufacturer-required QC tests for FFDM



GE Senographe 2000D

GE Senographe 2000DS

GE
Senographe Essential

General Electric

1. **Flat Field**
2. **Phantom Image Quality**

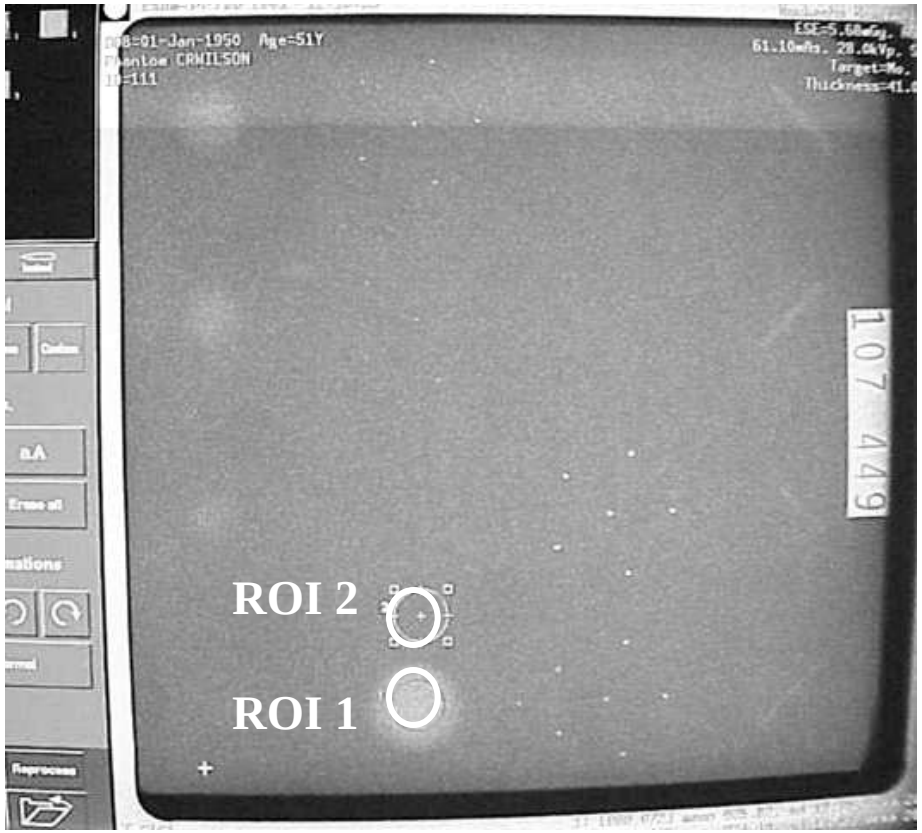
	Fibers	Specks	Masses
Phantom IQ Test on AWS			
Phantom IQ Test on Printer			

3. **CNR Measurement** *(NA for **DS, Essential or Care** if Sub-System MTF test done)*
   CNR [ ] *(Required for both new unit Mammography Equipment Evaluations and Annual Surveys)*
   Change in CNR ≤0.2 *(NA for Mammography Equipment Evaluations)*
4. **MTF Measurement** *(NA for **2000D, DS, Essential or Care** if Sub-System MTF test done)*
5. **AOP Mode and SNR**
6. **Collimation Assessment**

	Mammo Equipment Evaluation			Annual Survey		
	Ess/Care	DS	2000D	Ess/Care	DS	2000D
24 cm x 30.7 cm						
19 cm x 23 cm tests						

7. **Evaluation of Focal Spot Performance** *(NA for **2000D, DS, Essential or Care** if Sub-System MTF test done)*
8. **Sub-System MTF** *(NA for **2000D** if MTF and Focal Spot Performance tests done;*
   *NA for **DS, Essential or Care** if CNR, MTF and Focal Spot Performance tests done)*
9. **Breast Entrance Exposure, Average Glandular Dose and Reproducibility**
   Average glandular dose for average breast is ≤3 mGy (300 mrad) [ ] mrad
   Exposure reproducibility (CV) for air kerma (R) and mAs is ≤0.05
10. **Artifact Evaluation and Flat Field Uniformity**
11. **kVp Accuracy and Reproducibility**
12. **Beam Quality Assessment (Half-Value Layer Measurement)**
13. **Radiation Output**
    Radiation output is ≥800 mR/s [ ] mR/s
14. **Mammographic Unit Assembly Evaluation**
    Meets requirements for motion of tube-image receptor assembly
    Meets requirements for compression paddle decompression
15. **Review Workstation (RWS) Tests** *(for all RWS, even if located offsite; NA if only hardcopy read)*

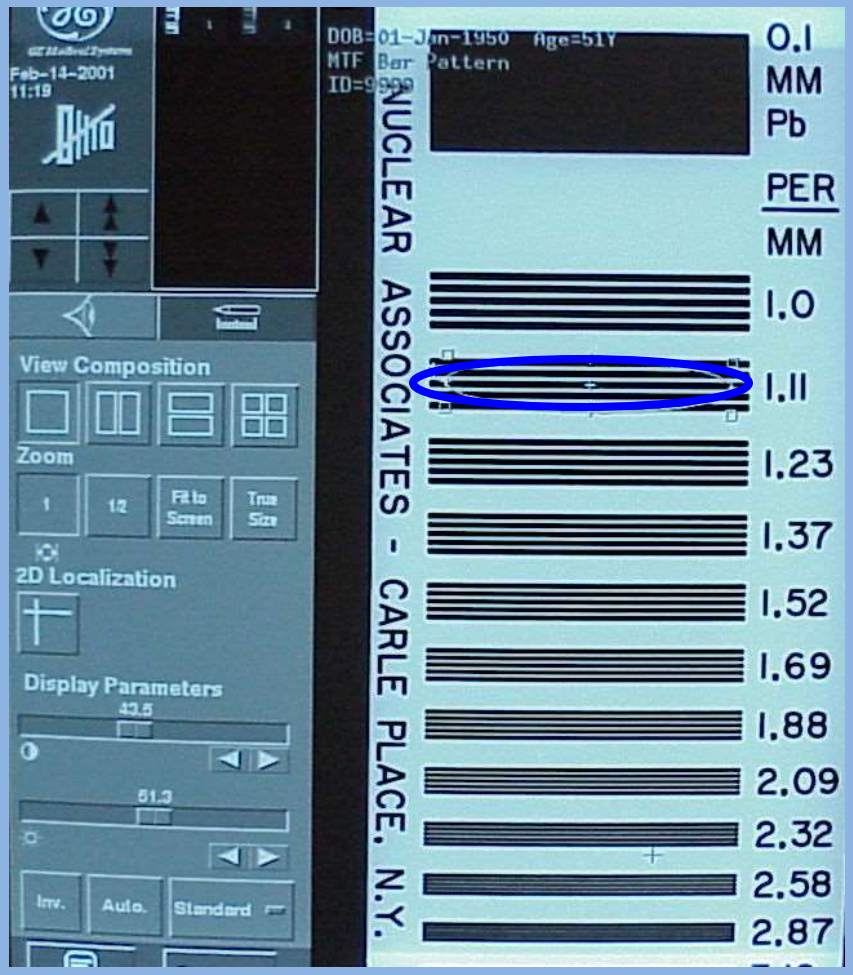
Contrast to Noise Ratio

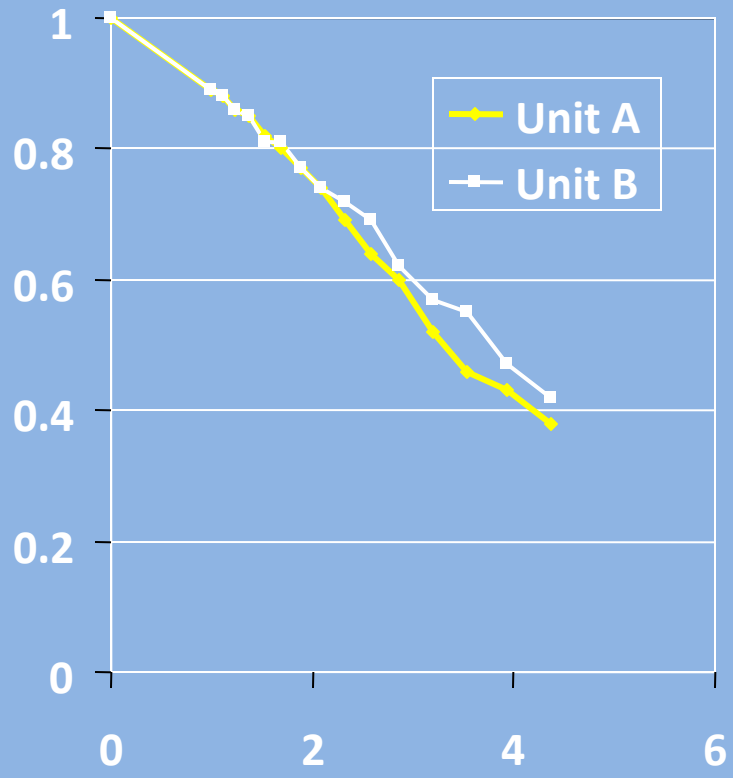


- Contrast is difference between means of ROI 1 and 2.
- Noise is the SD of the ROI 2 (background)
- Contrast is measured between background and largest mass

GE

MTF Measurement

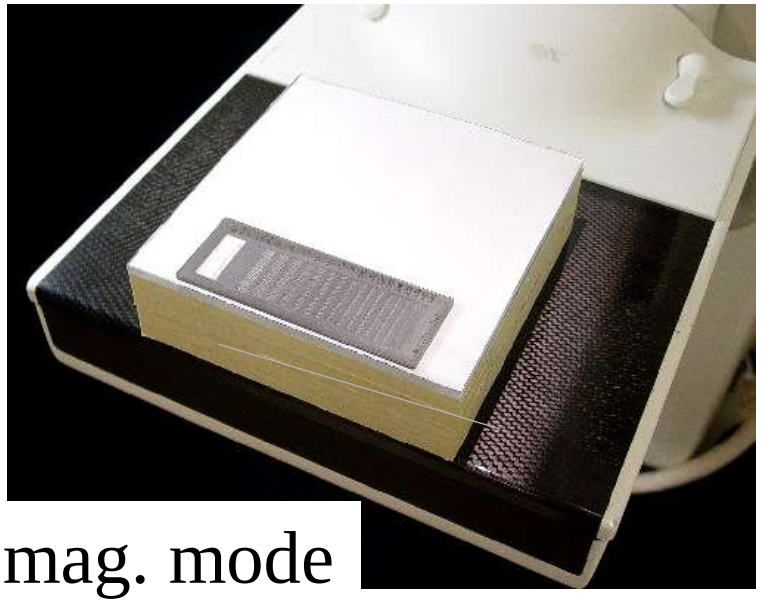




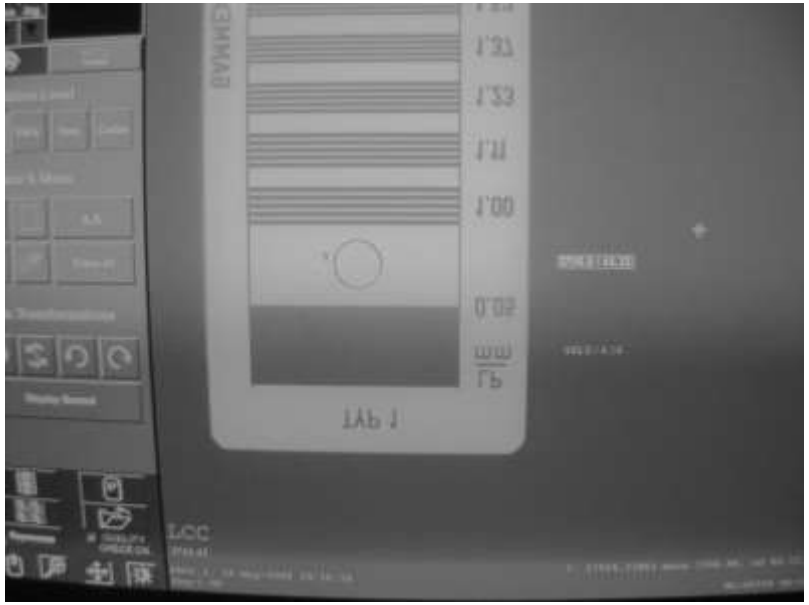
MTF @ 2 lp/mm > 0.58

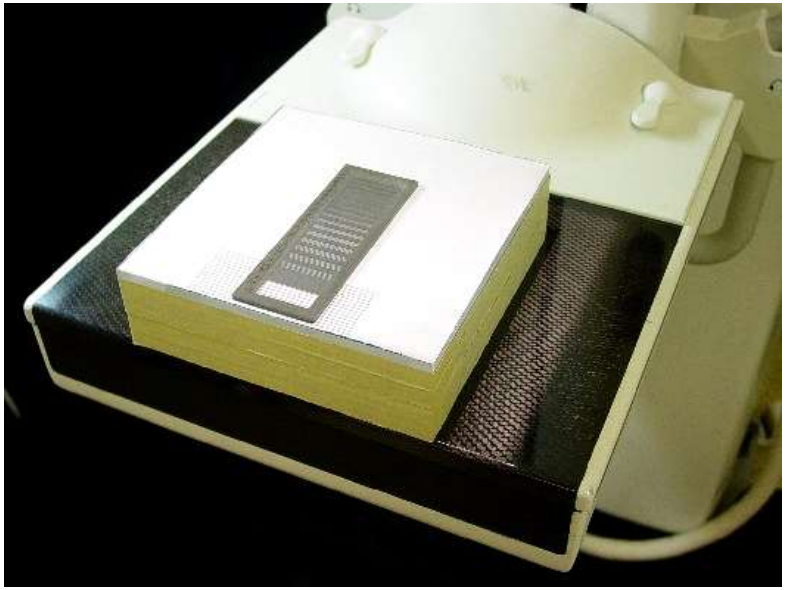
MTF @ 4 lp/mm > 0.25

Sub-system MTF



Contact and mag. mode



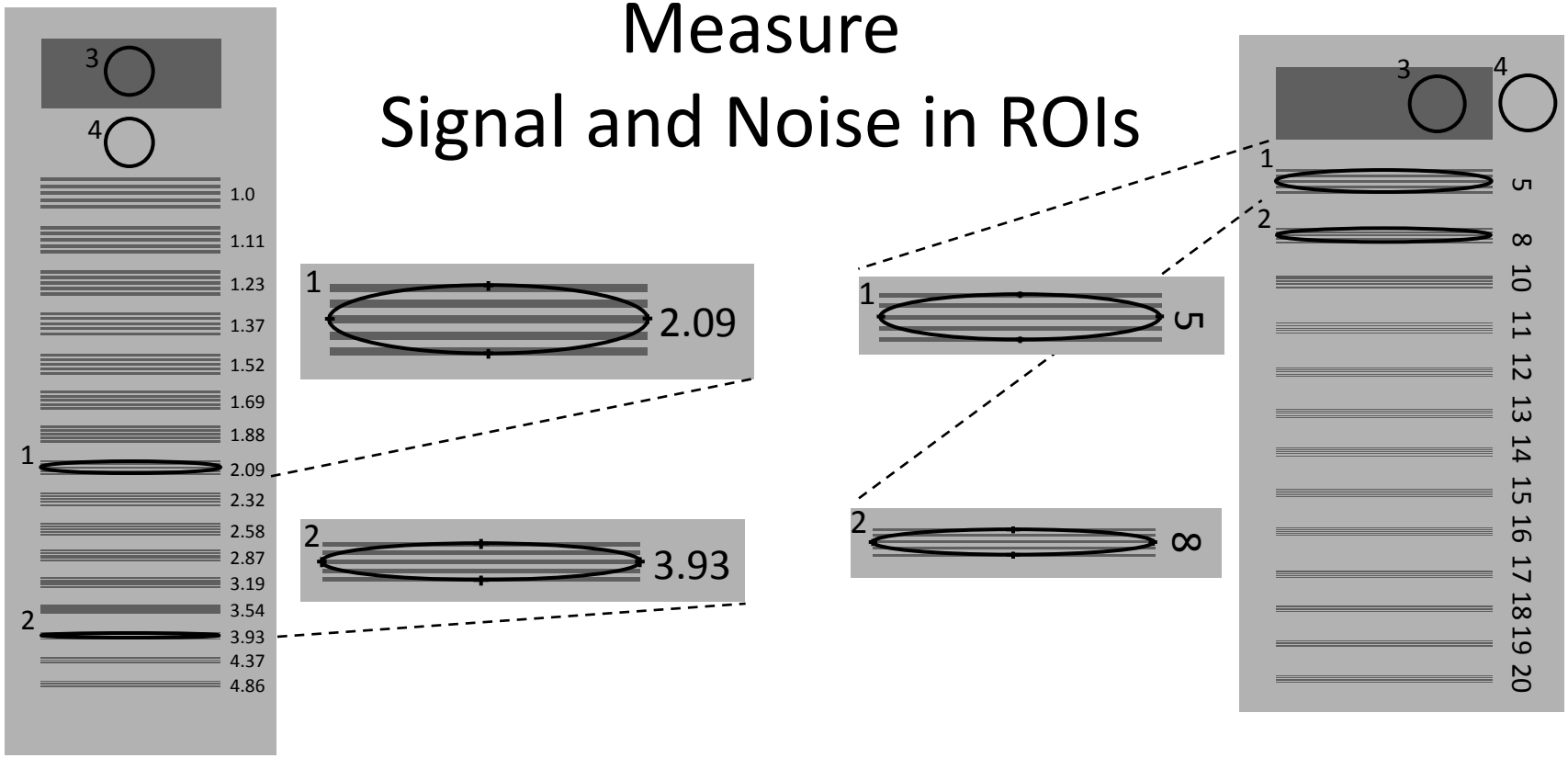


Sub-System MTF Test

Contact

Magnification

Measure
Signal and Noise in ROIs



2.09 and 3.93 lp/mm

5 and 8 lp/mm

Fisher Senoscan

Generator

Gantry

Acquisition Station/
Technologist Shield

Review Station

Fischer

1. **X-Ray Field, Chest Wall Missed Tissue and Light Field Checks**
2. **Compression Paddle Alignment**
3. **kVp Accuracy Test**
4. **Linearity, Reproducibility and Accuracy**
5. **Half-Value Layer and Output**
6. **Dosimetry – Average Glandular Dose and Output**
   - Average glandular dose for average breast is ≤3 mGy (300 mrad) _____ mrad
7. **Phantom Image Acquisition Test** *(values required for all tests)*
   - No obvious artifacts
   - Background StDev _____ within +50/-0 ADU counts of baseline *(NA for Equipment Evaluations)*
   - Background mean _____ within ±100 ADU counts of baseline *(NA for Equipment Evaluations)*
   - ADU level difference _____ within ±300 ADU counts of baseline *(NA for Equipment Evaluations)*
8. **Image Quality**
   - Largest 4 fibers, 3 speck groups and 3 masses

Fibers	Specks	Masses

   - Phantom IQ Test on Review Work Station
9. **System Resolution/Scan Speed Uniformity**
10. **Flat Field Test**
11. **Geometric Distortion and Resolution Uniformity**
12. **Automatic Decompression Control**
13. **System Artifacts**
14. **Image Viewing Room Illuminance Test** *(≤50 lux)*
15. **Review Workstation (RWS) Tests** *(for all RWS, even if located offsite; NA if only hardcopy read)*

Hologic/Lorad Selenia

Hologic Selenia Dimensions 2D (3D)

Hologic/Lorad

EE- MP performs RT tests

1. **Mammographic Unit Assembly Evaluation**
2. **Collimation Assessment**
3. **Artifact Evaluation**
4. **kVp Accuracy and Reproducibility**
5. **Beam Quality Assessment - HVL Measurement**
6. **Evaluation of System Resolution**
7. **Automatic Exposure Control (AEC) Function Performance** *(NA for systems without AEC)*
8. **Breast Entrance Exposure, AEC Reproducibility and Average Glandular Dose**
   Average glandular dose for average breast is ≤3 mGy (300 mrad) _____ mrad
9. **Radiation Output Rate**
10. **Phantom Image Quality Evaluation**
    Phantom image scores: Fibers _____ Specks _____ Masses _____
11. **Signal-To-Noise Ratio and Contrast-To-Noise Ratio Measurements** *(values required for all tests)*
    SNR *(value)* _____
    CNR *(value)* _____ *(Required for both new unit Mammography Equipment Evaluations and Annual Surveys)*
    CNR should not vary by more than ±15% *(NA for Equipment Evaluation)*
12. **Diagnostic Review Workstation (RWS) QC** *(for all RWS, even if located offsite; NA if only hardcopy read)*
13. **DICOM Printer QC** *(Mammography Equipment Evaluations only)*
14. **Detector Flat Field Calibration** *(Mammography Equipment Evaluations only)*
15. **Compression Thickness Indicator** *(Mammography Equipment Evaluations only)*
16. **Compression** *(Mammography Equipment Evaluations only)*

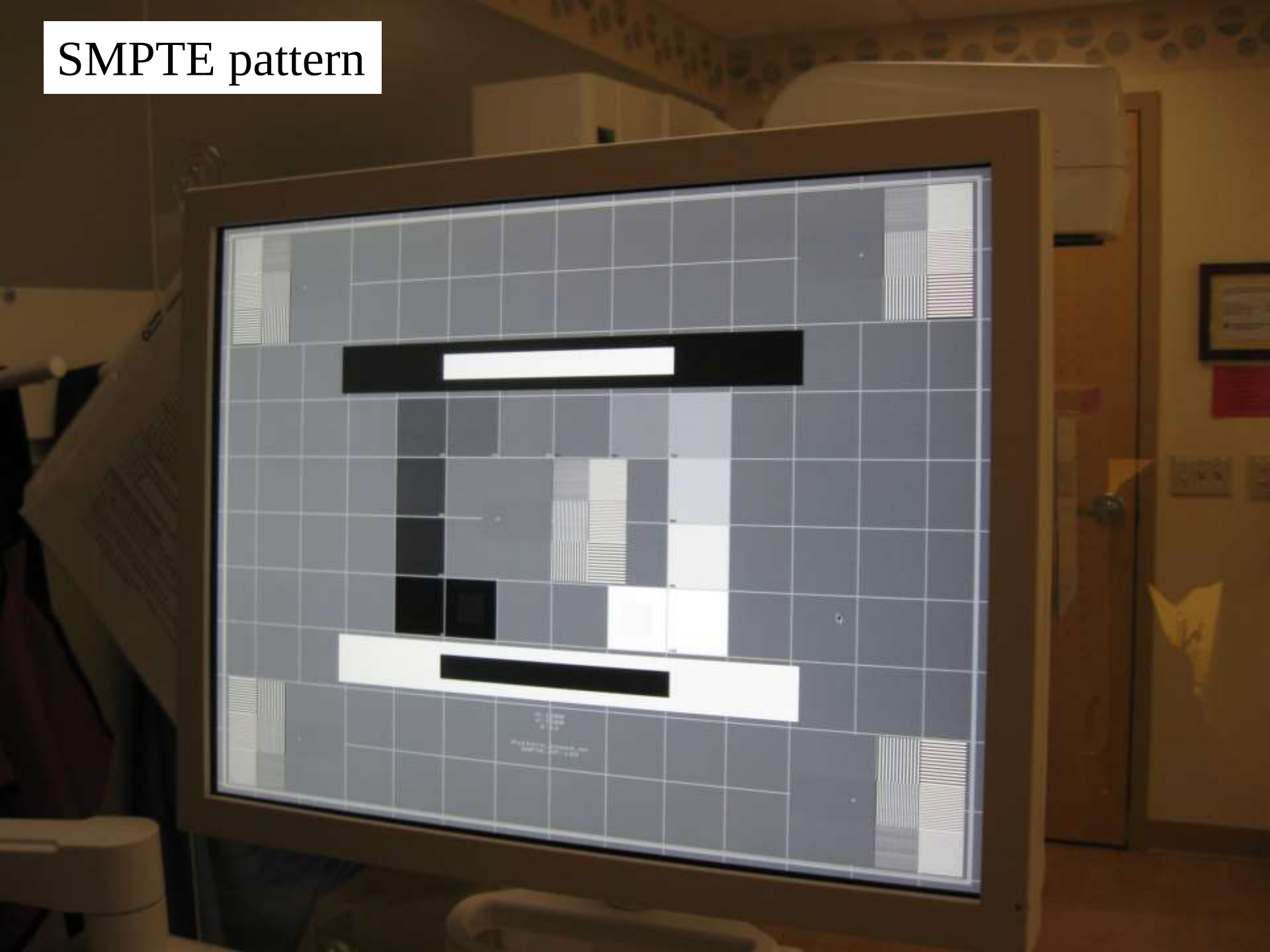
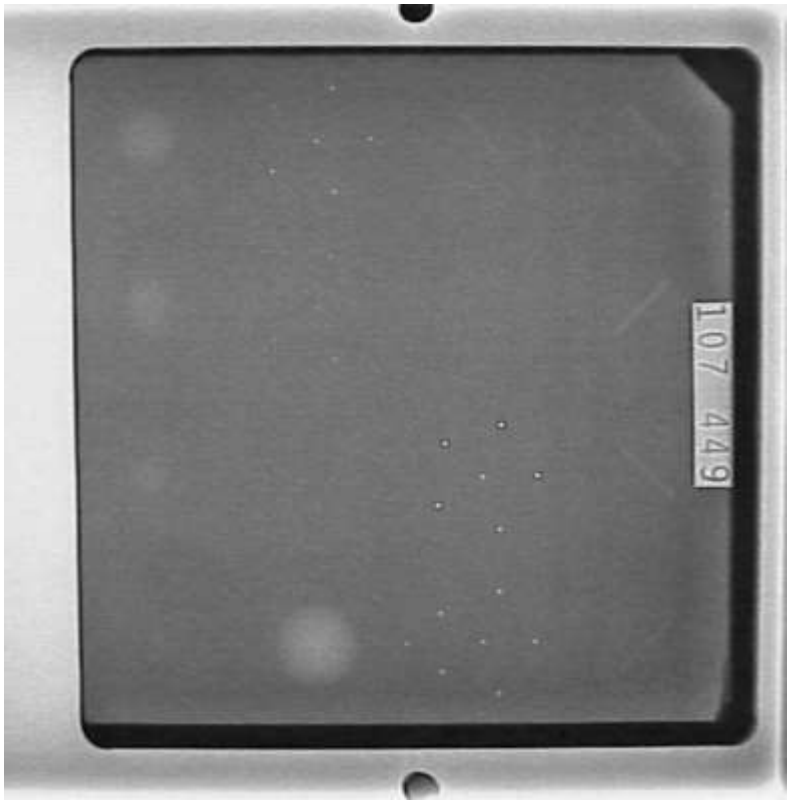

SMPTE pattern

Image quality is still assessed with the MAP phantom

Fibers = 5

Specks = 4

Masses = 4



Siemens
Mammomat
Novation

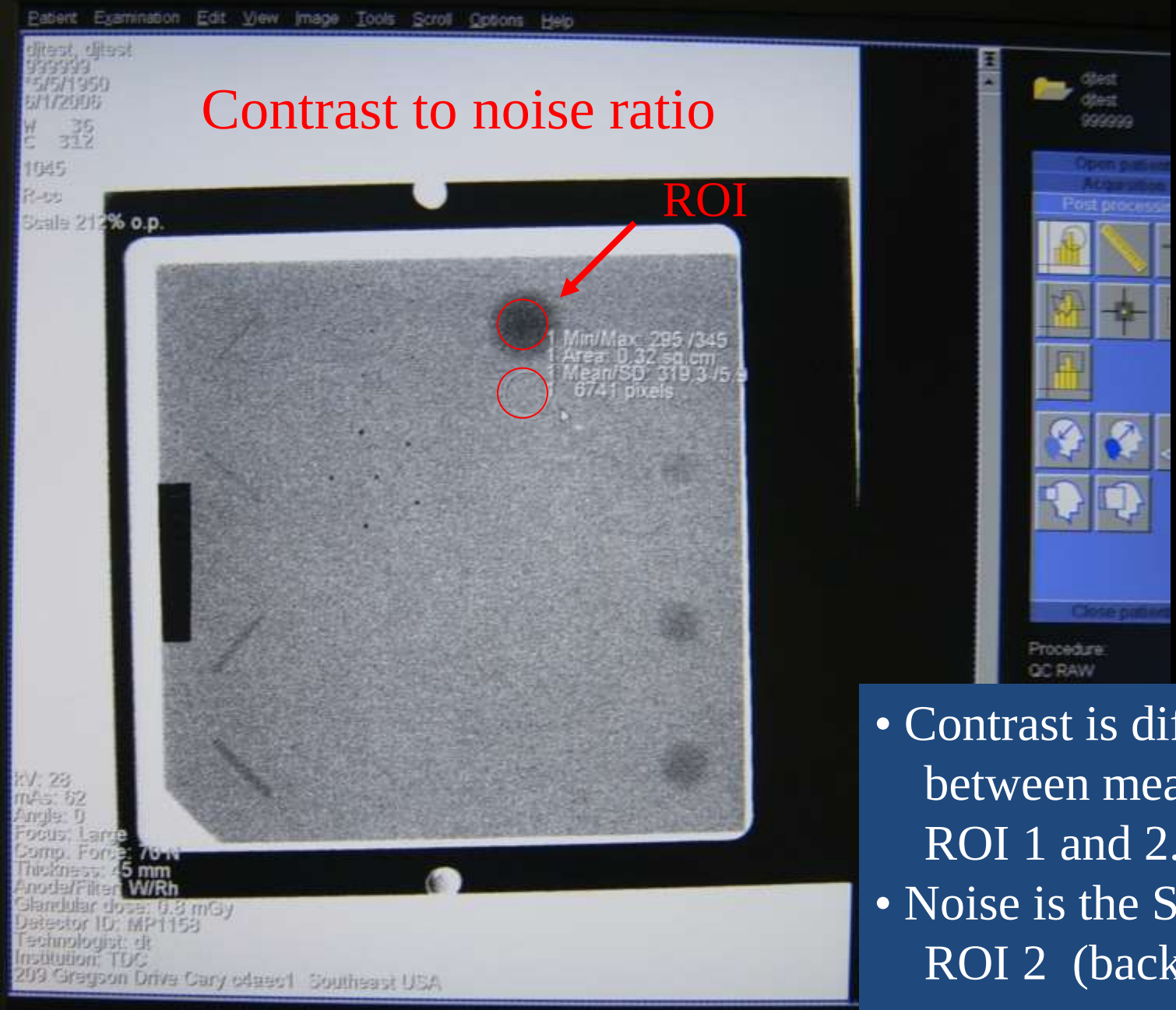
Siemens
Inspiration

Siemens

1. **Site Audit/Evaluation of Technologist QC Program**
2. **Mechanical Inspection**
3. **Acquisition Workstation Monitor Check**
4. **Detector Uniformity**
5. **Artifact Detection**
6. **Collimation, Dead Space & Compression Paddle Position**
7. **AEC Thickness Tracking**
8. **Spatial Resolution**
9. **SNR, CNR and AEC Repeatability**
   - Measured values: SNR [ ] CNR [ ]
   - CV for mAs and entrance air kerma ≤5%
   - Max deviation of mean pixel values and SNR within ±15% of mean for measurements
10. **Image Quality**
    - Largest 5 fibers, 4 speck groups and 4 masses visible*
    - *(*largest 4 fibers, 3 speck groups and 3 masses acceptable if spatial resolution and CNR pass)*
    - Phantom image scores: Fibers [ ] Specks [ ] Masses [ ]
11. **Radiation Dose**
    - Average glandular dose for average breast is ≤3 mGy (300 mrad) [ ] mrad
12. **HVL and Radiation Output**
13. **Tube Voltage Measurement & Reproducibility**
14. **Film Printer Check**
15. **Review Workstation (RWS) Tests** *(for all RWS, even if located offsite; NA if only hardcopy read)*

Siemens

Contrast to noise ratio



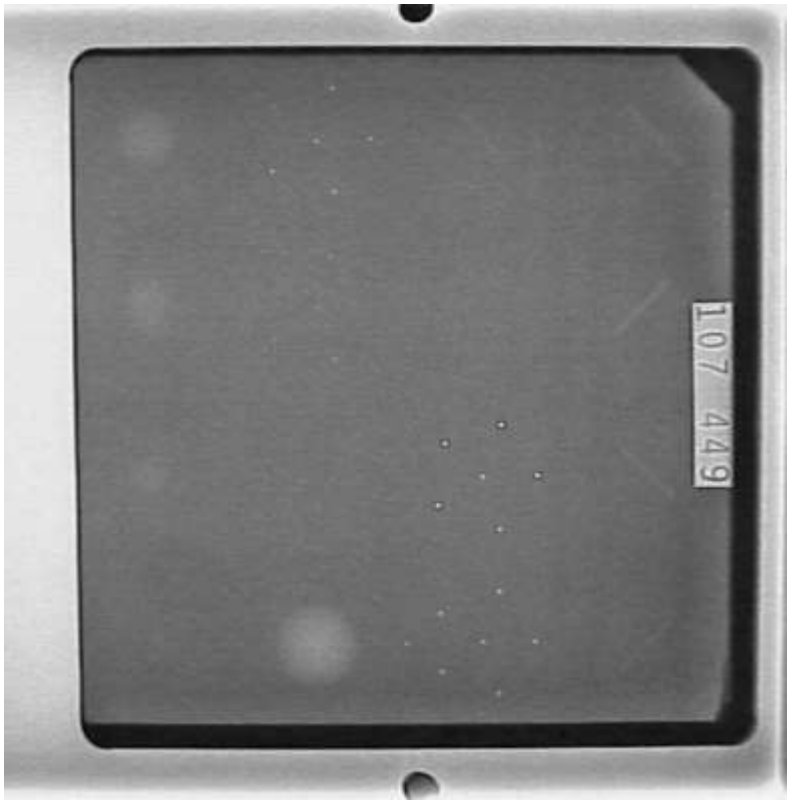
- Contrast is difference between means of ROI 1 and 2.
- Noise is the SD of the ROI 2 (background)

Image quality is still assessed with the MAP phantom

Fibers = 5

Specks = 4

Masses = 4




Radiation dose **must not** exceed 3 mGy
Radiation dose **should not** exceed 2 mGy

Pre-requisites to calculate the mean glandular dose

Use formulae:

D=Kgcs [Dance et al 2000]

D Mean glandular dose

K Entrance air kerma

g g-factor for breasts simulated with PMMA

c c-factor for breasts simulated with PMMA

s s-factor for clinically used spectra

Where ***K*** is the incident air kerma (without backscatter) calculated at the upper surface of the PMMA. The factor ***g***, corresponds to a glandularity of 50%, and is derived from the values calculated by Dance et al 2000 and is shown below for a range of HVL. The ***c***-factor corrects for the difference in composition of typical breasts from 50% glandularity [Dance et al 2000] and is given here for typical breasts in the age range 50 to 64. Note that the ***c*** and ***g***-factors applied are those for the corresponding thickness of typical breast rather than the thickness of PMMA block used. Where necessary interpolation may be made for different values of HVL. The factor ***s*** shown in the second table corrects for any difference due to the choice of X-ray spectrum (Dance et al 2000).

	PMMA thickness (mm)	Equivalent breast thickness (mm)	HVL (mm Al)							
			0.25	0.30	0.35	0.40	0.45	0.50	0.55	0.60
g-factor	45	53	0.130	0.155	0.177	0.198	0,220	0.245	0,272	0,295
c-factor	45	53	-	1.109	1.105	1.102	1.099	1.096	1.091	1.088
g-factor	50	60	0.112	0.135	0.154	0.172	0.192	0.214	0.236	0.261
c-factor	50	60	-	1.164	1.160	1.151	1.150	1.144	1.139	1.134

	Mo/Mo	Mo/Rh	W/Rh
s-factor	1.000	1.017	1.042

Fuji ClearView CR*m*

Fuji CR

1. **S Value Confirmation** *(≤120 ±20% [96 ≤ corrected S value ≤ 144])*
2. **System Resolution** *(8 lp/mm ±2 lp/mm in both directions)*
3. **CR Reader Scanner Performance**
4. **Mammography Unit Assembly Evaluation**
5. **Collimation Assessment** *Test date if different from above:*
   - Chest wall edge of X-ray field extends to edge of IR
   - Deviation between X-ray field and light field ≤2% of SID
   - X-ray field does not extend beyond any side of the IR by more than 2% of SID
   - Paddle chest wall edge not beyond IR by more than 1% of SID or appear on the image
6. **Automatic Exposure Control (AEC) System Performance Assessment**
   - AEC density control function meets Fuji performance criteria
   - Reproducibility (CV) for either exposure or mAs is ≤0.05
   - Image mode tracking meets Fuji performance criteria
   - CNR per object thickness meets Fuji performance criteria
7. **System Artifact Evaluation**
8. **Phantom Image Quality Evaluation** *(at least 4 fibers, 3 speck groups & 3 masses)*

	Fibers	Specks	Masses
Phantom IQ (printed images)			
Phantom IQ (softcopy)			

   - Other tests meet Fuji performance criteria *(mAs, OD & DD for hardcopy, S value for soft copy)*
9. **Dynamic Range**
10. **Primary Erasure (Additive and Multiplicative Lag Effects)**
11. **Inter-Plate Consistency** *(variation of mAs within ±10%; SNR within ±15%)*
12. **kVp Accuracy and Reproducibility** *Test date if different from above:*
    - Measured average kVp within ±5% of indicated kVp
    - kVp coefficient of variation ≤0.02
13. **Dose** *(average glandular dose for average breast is ≤3 mGy [300 mrad])* mrad
14. **Beam Quality Assessment & HVL Measurement** *Test date if different from above:*
    - HVL ≥kVp/100 mm Al
15. **Radiation Output** *Test date if different from above:*
    - Radiation output rate is ≥800 mR/sec (7.0 mGy/sec) at 28 kVp with Mo/Mo
16. **Viewing and Viewing Conditions** *Test date if different from above:*
    - Room illuminance ≤20 lux or as recommended by the monitor manufacturer
17. **Review Workstation (RWS) Tests** *(for all RWS, even if located offsite; NA if only hardcopy read)*
18. **Film Printer Tests** *(for all printers used for mammography, even if located offsite)*

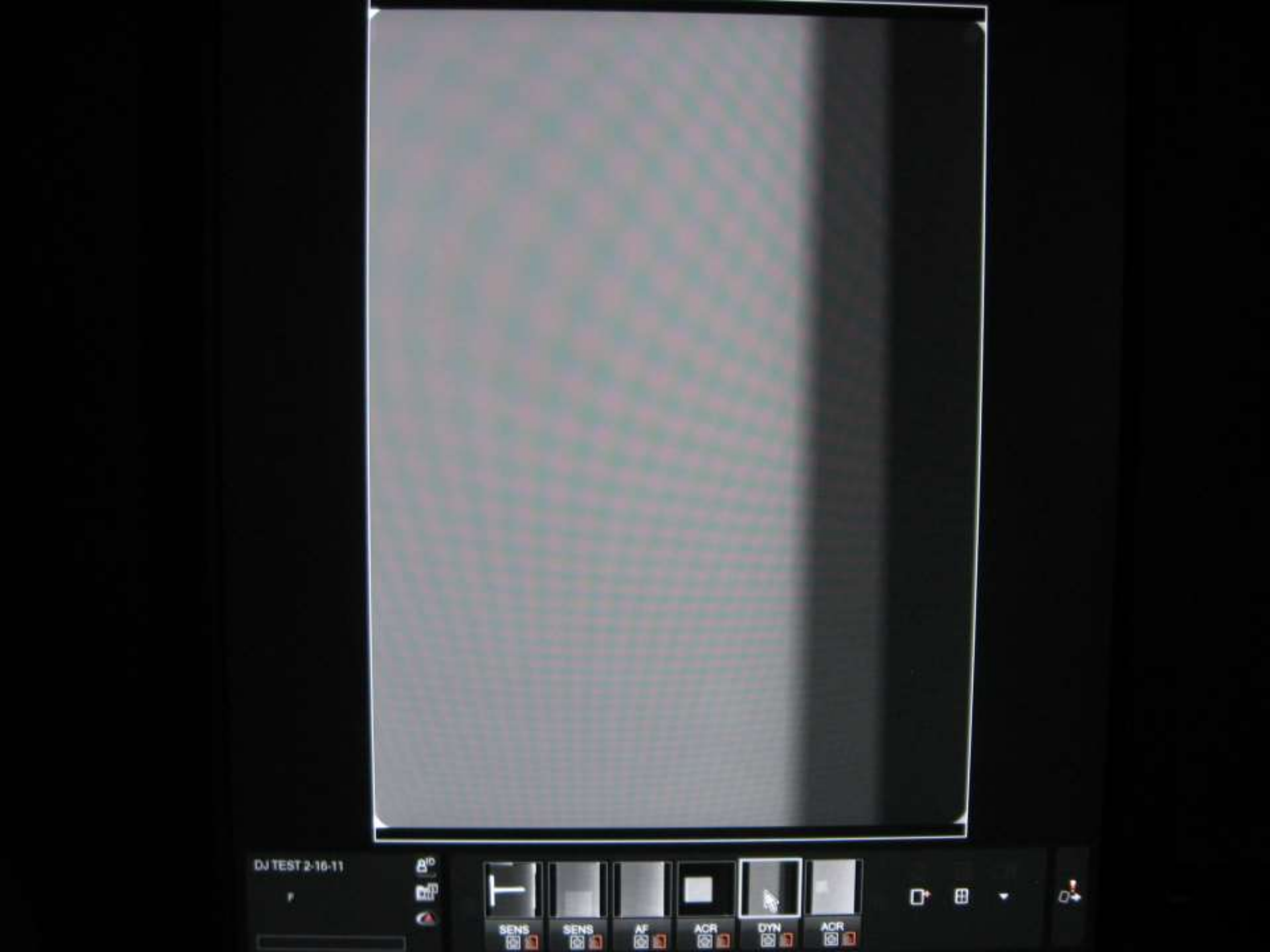
At 20 mR, for 25 kVp and Mo/Mo:

S= 120 +/- 20% (96-144)

Expose – read should be 5-10 minutes


DJ Test Annual Survey2
F
PHYSICS SENSITIVITY
AP
PHYSICS SENSITIVITY
AP
QA


Westcott


DJ TEST 2-16-11
SENS
SENS
AF
ACR
DYN
ACR

Carestream DirectView

Carestream

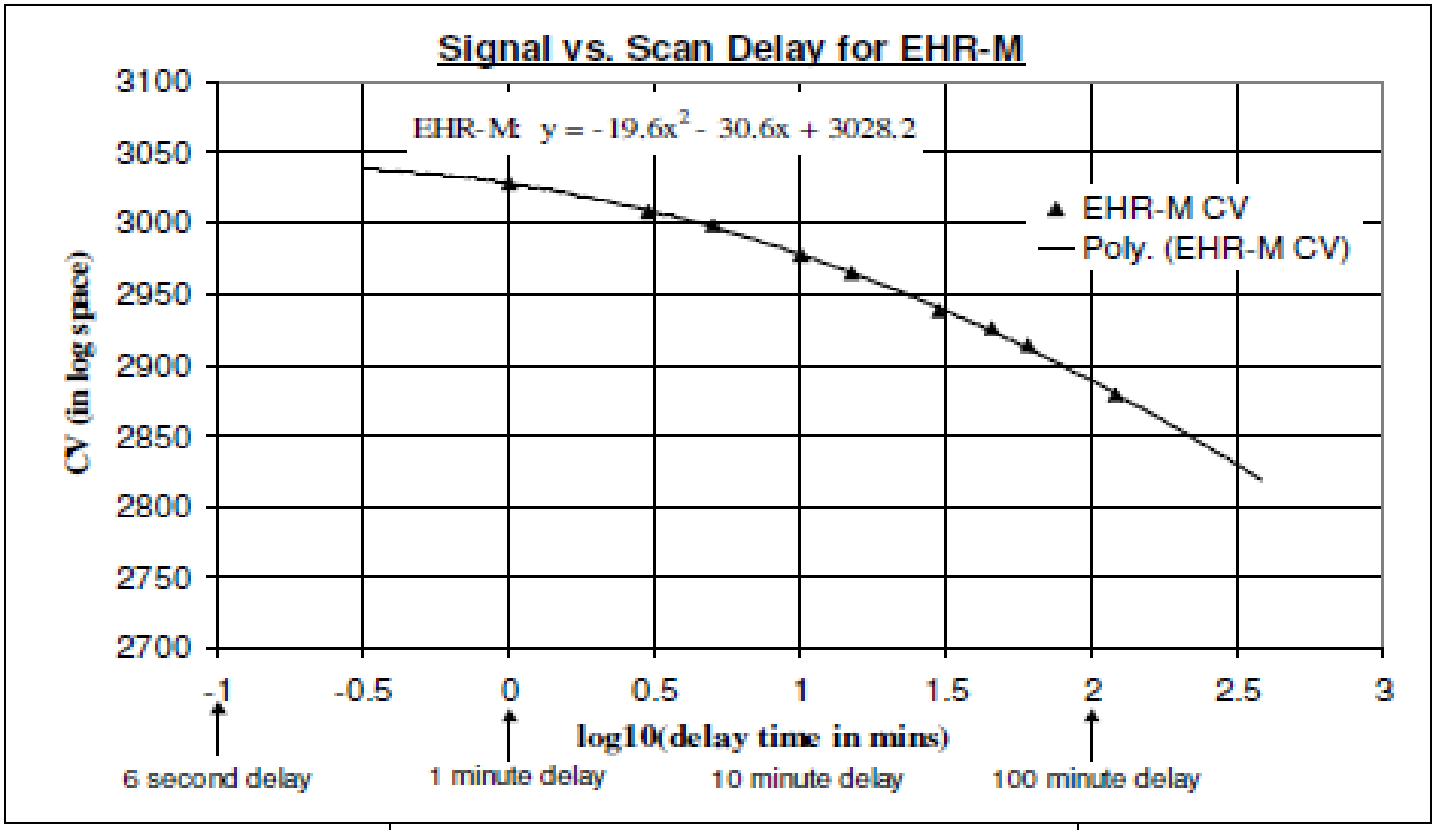
ROI target = 1000 x $\log_{10}$(mR) + 1000

1. **Cassette Exposure Response Test**
2. **Cassette/Phosphor Screen Artifact Test**
3. **Erased Screen Test**
4. **Scanner Uniformity Test**
5. **Scanner Response Linearity Test**
6. **Spatial Frequency Response Test**
7. **Geometric Accuracy Test**
8. **Image Plate Fog Test**
9. **AEC System Performance/Constancy Test**
   - AEC Function with Breast Thickness
   - AEC Density Control Function
   - CNR Tracking with Breast Thickness
10. **Mammography Unit Assembly Evaluation**
11. **Mammographic Unit Collimation Assessment** *Test date if different from above:* ____
    - X-ray Field to Light Field Alignment
    - X-ray Field to Image Plate Alignment
    - Alignment of Chest Wall Edge of Compression Paddle to Image Plate
12. **Beam Quality and Half-Value Layer** *Test date if different from above:* ____
13. **kVp Accuracy and Reproducibility** *Test date if different from above:* ____
    - Measured average kVp within ±5% of indicated kVp
    - kVp coefficient of variation ≤0.02
14. **Breast Entrance Exposure, Dose and Radiation Output**
    - Average glandular dose for average breast is below 3 mGy (300 mrad)
    - Average glandular dose to a 4.2-cm-thick breast on your unit is ____
    - Radiation output rate is ≥800 mR/sec (7.0 mGy/sec) at 28 kVp with Mo/Mo
15. **Phantom Image Quality Evaluation** *(at least 4 fibers, 3 speck groups & 3 masses)*

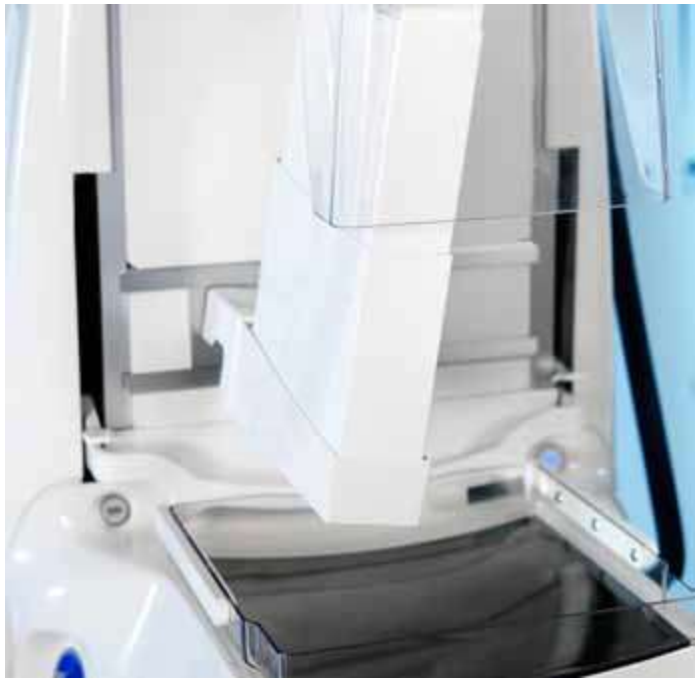
	Fibers	Specks	Masses
Phantom IQ (printed images)			
Phantom IQ (softcopy)			

16. **Review Workstation (RWS) Tests** (for all RWS, even if located offsite; NA if only hardcopy read)
17. **Film Printer Test** *(for all printers, even if located offsite)*

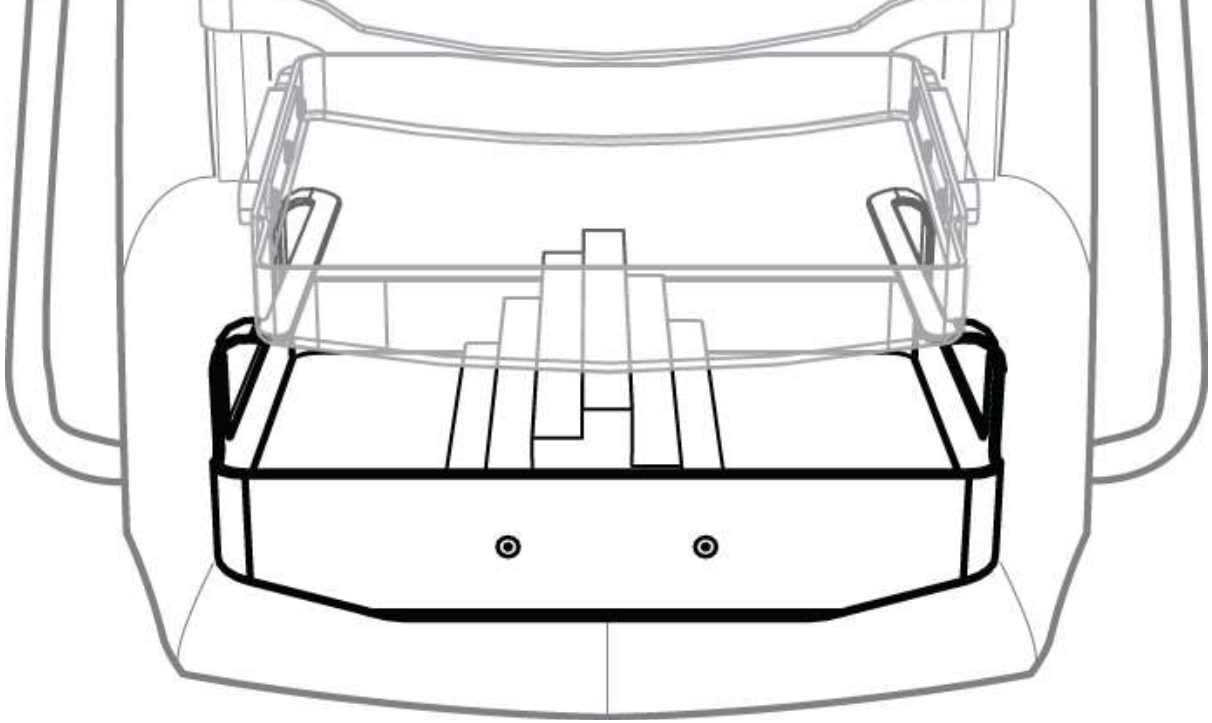
QC Manual – Important Points



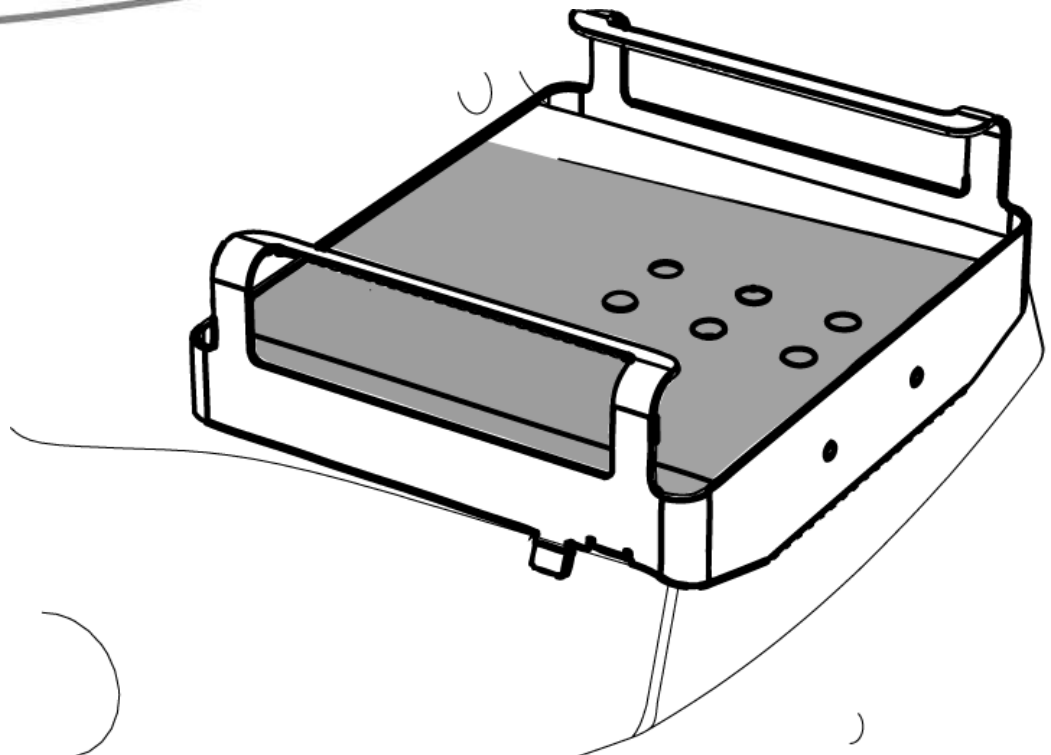
Calibration = 5 minutes
TQT = 5 minutes
QC testing = 5 minutes



Sectra
MicroDose
Mammography



Calibration phantom



Daily QC phantom

System uses scanning multi-slot geometry

X-ray exposure is pulsed:

10-50 msec, 5-30 pulses/sec.

mAs ≈ 1% conventional mAs

Assure that exposure and kVp meters will work with this system

Place Pb aperture on paddle for HVL

Philips (Sectra)

1. **X-ray Tube Output (air kerma)**
2. **Air Kerma Reproducibility**
3. **Half Value Layer**
4. **AEC System: Breast Thickness and Exposure**
5. **AEC System: Density Compensation**
6. **Image Quality Evaluation**
   - Phantom image scores: Fibers [ ] Specks [ ] Masses [ ]
   - Average glandular dose for average breast is ≤1 mGy (100 mrad) [ ]
7. **Contrast-to-Noise Ratio Reference Level**
   - CNR *(value)* [ ]
8. **Tube Voltage**
9. **Image Field and X-Ray Field Agreement**
10. **Missed Tissue at Chest Wall**
11. **Viewing Conditions**

The average glandular dose (AGD) is calculated by

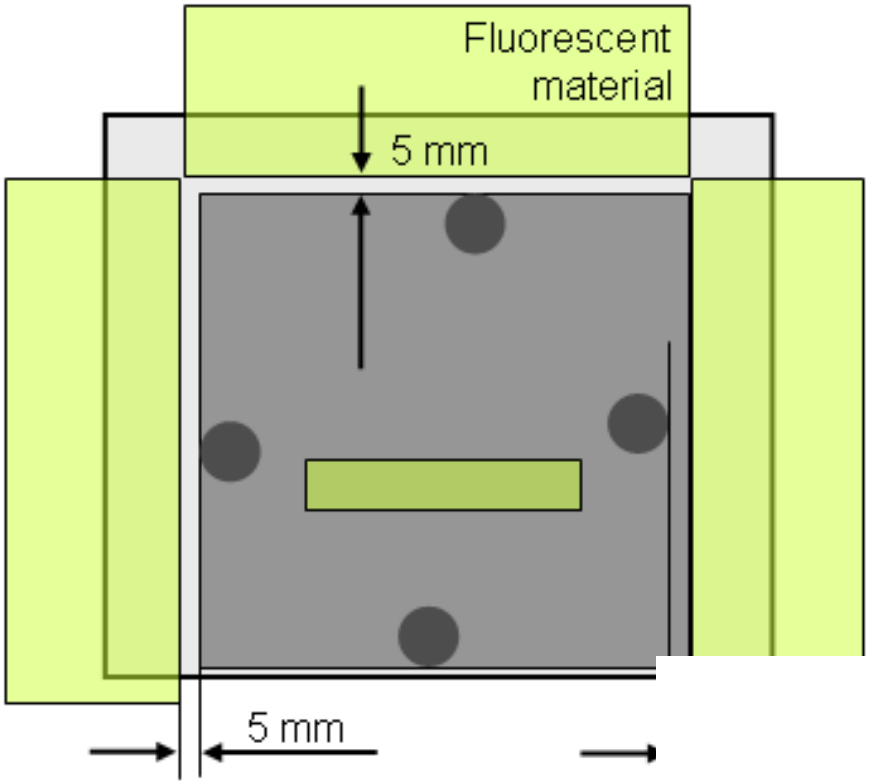
$$AGD = ESAK \cdot g \cdot c \cdot s ,$$

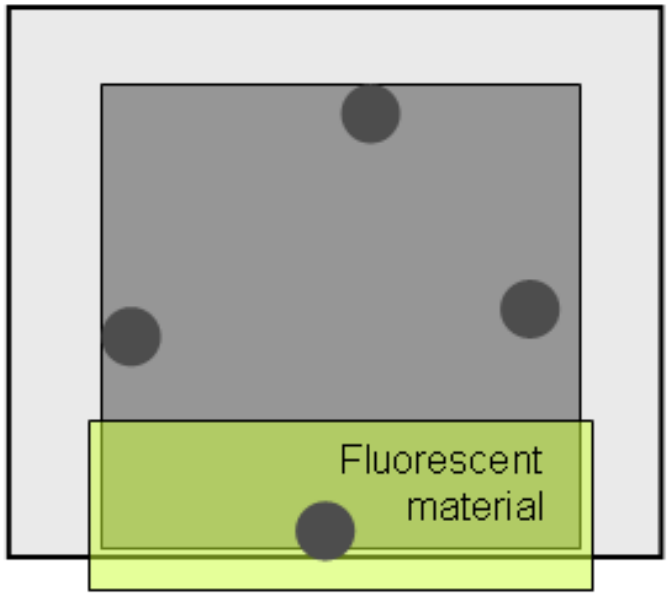
where *g* and *c* are functions of the breast thickness and HVL and *s* is a function of breast or PMMA thickness. The *g*-, *c*- and *s*-tables can be interpolated. The entrance surface air kerma (ESAK) should be calculated at the entrance surface of the breast.

Table 11 g-factor as a function of breast thickness and HVL [10].
Table 12 c-factors for average breasts for women 50 to 64 [10].
Table 13 s-factors

$$Dg \leq 1 \text{ mGy (100mrad)}$$

Contrast-to-noise ratio measured using the Daily QC Phantom


Fluorescent
material
5 mm
5 mm


Fluorescent
material

Planmed
Nuance

Planmed

1. **Monitor Cleaning (AWS and RWS)** *(Mammography Equipment Evaluation only)*
2. **Monitor Quality (AWS) - TG-18 QC test phantom** *(Mammography Equipment Evaluation only)*
3. **Phantom Image Quality (AWS and RWS)** *(Mammography Equipment Evaluation only)*

	Fibers	Specks	Masses
Phantom IQ Test on AWS			
Phantom IQ Test on RWS			

4. **Viewbox and Viewing Conditions** *(Mammography Equipment Evaluation only)*
5. **Signal Homogeneity** *(Mammography Equipment Evaluation only)*
6. **Uncorrected Defective Elements (DEL)** *(Mammography Equipment Evaluation only)*
7. **Large Focus Calibration** *(Mammography Equipment Evaluation only)*
8. **Small Focus Calibration (for mags only)** *(Mammography Equipment Evaluation only)*
9. **Signal-to-Noise (SNR)** *(Mammography Equipment Evaluation only)*
10. **Contrast-to-Noise Ratio (CNR)** *(Mammography Equipment Evaluation only)*
11. **Visual Checklist** *(Mammography Equipment Evaluation only)*
12. **Repeat Analysis** *(Mammography Equipment Evaluation only)*
13. **Defect Acceptance Test** *(Mammography Equipment Evaluation only)*
14. **System Fault Report** *(Mammography Equipment Evaluation only)*
15. **Review Workstation QC-Overall** *(Mammography Equipment Evaluation only)*
16. **Film Printer QC** *(Mammography Equipment Evaluation only)*
17. **Ghosting**
18. **Modulation Transfer Function (MTF)**
19. **Linearity/Noise Linearity**
20. **AEC**
21. **Compression Force**
22. **Mammographic Unit Assembly**
23. **Beam Quality Assessment - HVL Measurement**
24. **Breast Entrance Exposure and Average Glandular Dose**

Average glandular dose for average breast is ≤3 mGy (300 mrad) _____ mrad

FUJI Aspire

Fuji Aspire HD

1. **1Shot PhantomM**
   - Missed Tissue on Chest Wall Edge
   - CNR *(Mammography Equipment Evaluation only)*
   - 1 Shot Phantom Sensitivity Constancy *(Mammography Equipment Evaluation only)*
   - Geometric Distortion *(Mammography Equipment Evaluation only)*
   - System Artifact Evaluation *(Mammography Equipment Evaluation only)*
   - Uniformity *(Mammography Equipment Evaluation only)*
   - Dynamic Range *(Mammography Equipment Evaluation only)*
   - Spatial Resolution (SR) *(Mammography Equipment Evaluation only)*
   - Low Contrast Detectability (LCD) *(Mammography Equipment Evaluation only)*
   - Linearity/Beam Quality Constancy *(Mammography Equipment Evaluation only)*
2. **ACR Phantom** *(Mammography Equipment Evaluation only)*

	Fibers	Specks	Masses
Phantom IQ Test on AWS			
Phantom IQ Test on RWS			

3. **Image Basic Test**
4. **Compression Device Confirmation**
5. **Viewbox Maintenance**
6. **Monitor Quality Control (Secondary/AWS)**
7. **Additive Lag Effects**
8. **Multiplicative Lag Effects (Ghost)**
9. **Visual and Functional Test**
10. **Spatial Resolution (Magnification)**
11. **kVp Accuracy and Reproducibility**
12. **Half Value Layer (HVL)**
13. **Collimation Assessment**
14. **Radiation Output**
15. **AEC Reproducibility**
16. **CNR Mode 1**
17. **AGD Mode 1**
18. **AGD-ACR Phantom**
    - Average glandular dose for average breast is ≤3 mGy (300 mrad) _____ mrad
19. **Review Workstation QC-Overall**
20. **Film Printer QC-Overall**

Gioto Image

Giotto

1. **Collimation Assessment**
2. **Artifact Evaluation**
3. **Automatic Exposure Control (AEC), Signal-To-Noise Ratio (SNR) & Contrast-To-Noise Ratio (CN**
   - SNR *(value)* [ ] ≥60
   - CNR *(value)* [ ] *(Required for both new unit Mammography Equipment Evaluations and Annual Surveys)*
   - CNR should not vary by more than ±20% *(NA for Equipment Evaluation)*
4. **AEC Reproducibility**
5. **ACR Phantom Image Quality**
   - Phantom image scores: Fibers [ ] Specks [ ] Masses [ ]
6. **Ghost Factor**
7. **Inactive Border at Chest Wall Edge**
8. **Flat Field Homogeneity**
9. **Detector Response Function and Noise Evaluation**
10. **Spatial Resolution**
11. **kVp Accuracy and Reproducibility**
12. **Tube Output**
13. **Exposure Time**
14. **Beam Quality (HVL)**
15. **Mean Glandular Dose (MGD)**
    - Average glandular dose for average breast is ≤3 mGy (300 mrad) [ ] mrad
16. **Viewbox Luminance**
17. **Diagnostic Review Workstation (RWS) QC** *(for all RWS, even if located offsite; NA if only hardcopy read)*
18. **Film Printer QC**

Konica-Minolta

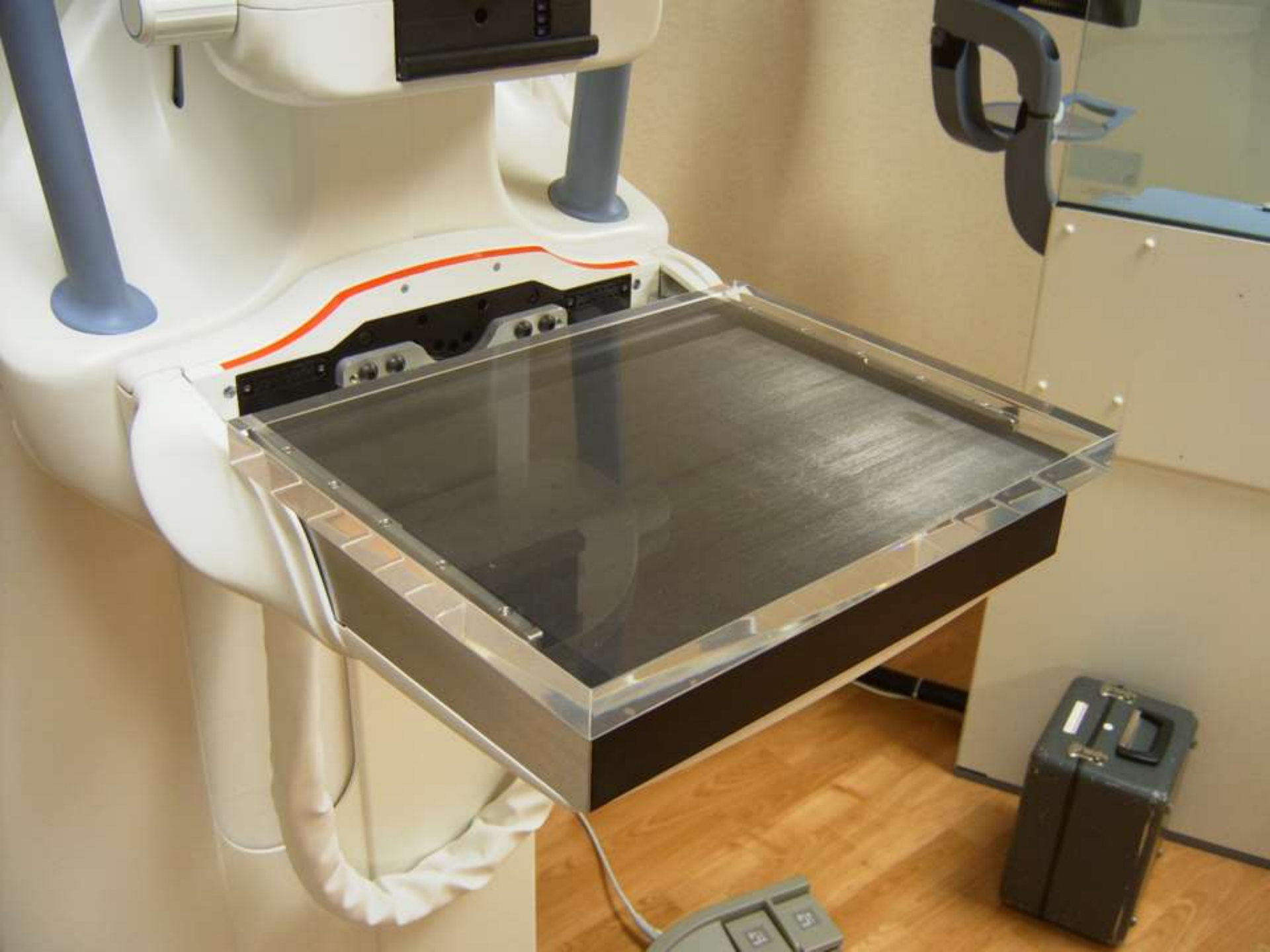
Xpress CR - Contact Mammography Upgrade

Konica Minolta

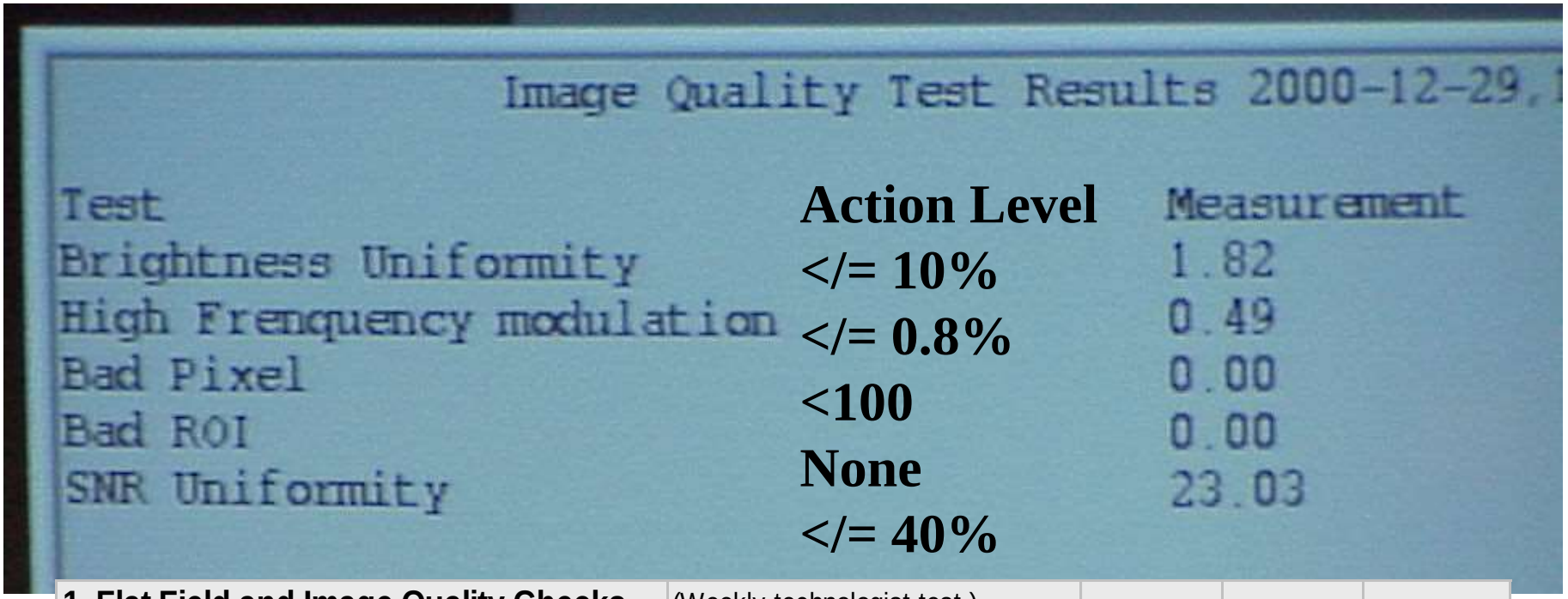
1. **Physical Inspection**
2. **Tube Voltage Measurement and Reproducibility**
3. **Beam Quality**
4. **Radiation Output Rate**
5. **Average Glandular Dose**
   - Average glandular dose for average breast is ≤3 mGy (300 mrad) [ ] mrad
6. **View Boxes and Viewing Conditions**
7. **Monitor QC (CR Console Monitor)**
8. **Dark Noise**
9. **Ghost Image Evaluation**
10. **S value Response Indicator**
    - S value variation: ±20%
11. **AEC Performance Checks**
    - Stability and Reproducibility: mAs CV ≤5%
    - Thickness Tracking: CNR (2cm) >100%, CNR (6cm) >75%, S value variation ≤20%
12. **Collimation Assessment**
13. **CR Reader Scanner Performance**
14. **Spatial Resolution**
15. **Artifact Evaluation**
16. **Inter-Plate Consistency**
    - SNR variation: ±15%
    - S value variation: ±15%
17. **Phantom Image Quality**
    - Phantom image scores: Fibers [ ] Specks [ ] Masses [ ]
    - Density Check: S value variation ±20%; background density change ±20; density difference change ±0.05
    - Thickness Check: ±0.5 cm
18. **Review Workstation QC-Overall**
19. **Film Printer QC-Overall**

QC PHANTOMS AND AUTOMATED ANALYSIS PROGRAMS: GE

flat field test
AOP and SNR
IQST (Image Quality Signature Test) Phantom- MTF and CNR



Flat Field Tests AWS Screen Results



1. Flat Field and Image Quality Checks (Weekly technologist test.)

a. Flat Field: 2.5 cm thick uniform PMMA;26 kVp; 200mAs; Mo/Mo. Phantom evaluated on AWS.

Test	Results	Status	Objects	Observed	Status
Brightness Uniformity < 10%	**1.82**	**Pass**	**Fibers**	**5.5**	**Pass**
High Freq Modulation < 0.8	**0.49**	**Pass**	**Specks**	**4**	**Pass**
Bad Pixel < 100	**0**	**Pass**	**Masses**	**4**	**Pass**
Bad ROI = 0	**0**	**Pass**			
SNR Uniformity < 40%	**23.03**	**Pass**			

b. Phantom Image Quality (Print, AWS and RWS).

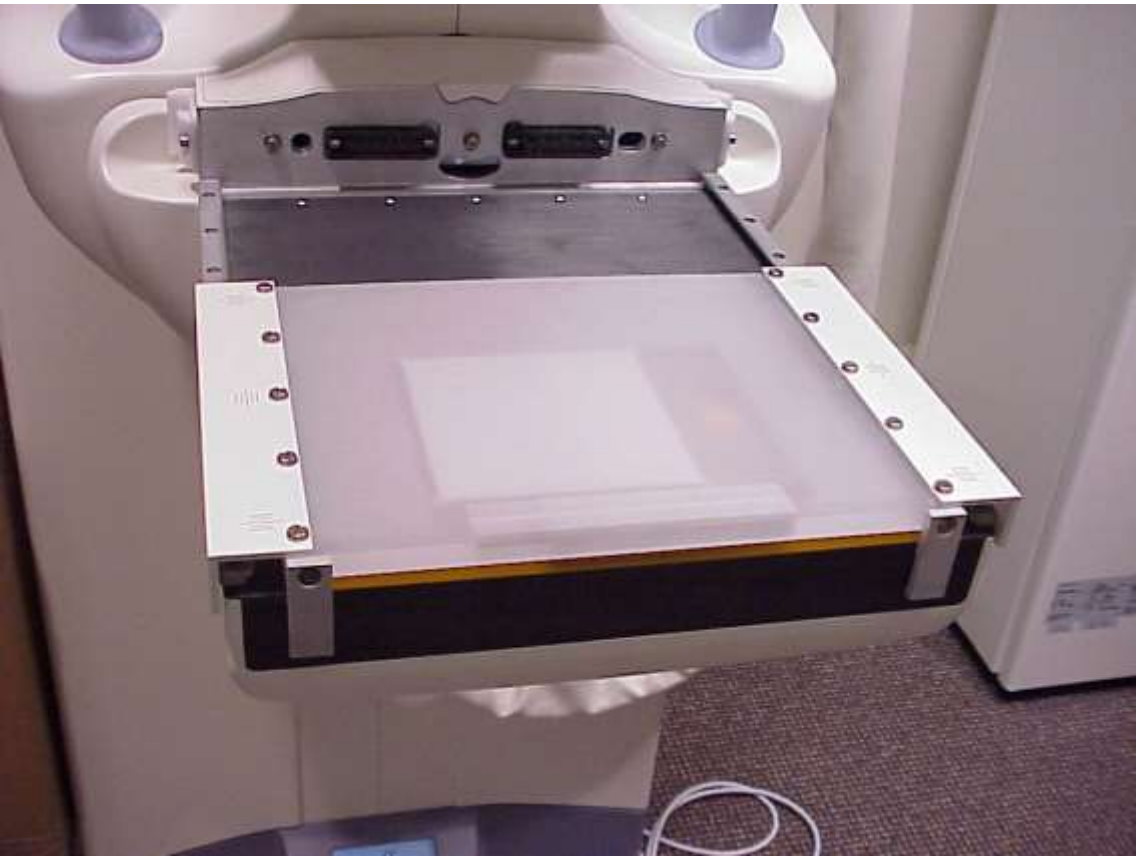
RMI Model156 Phantom: 26 kVp;125 mAs, Mo/Mo.

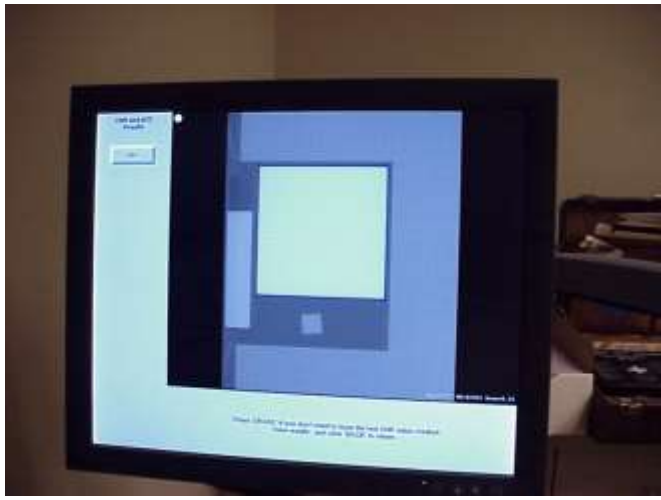
Image Quality Test Results 2009-05-19,09:31:20,CDT

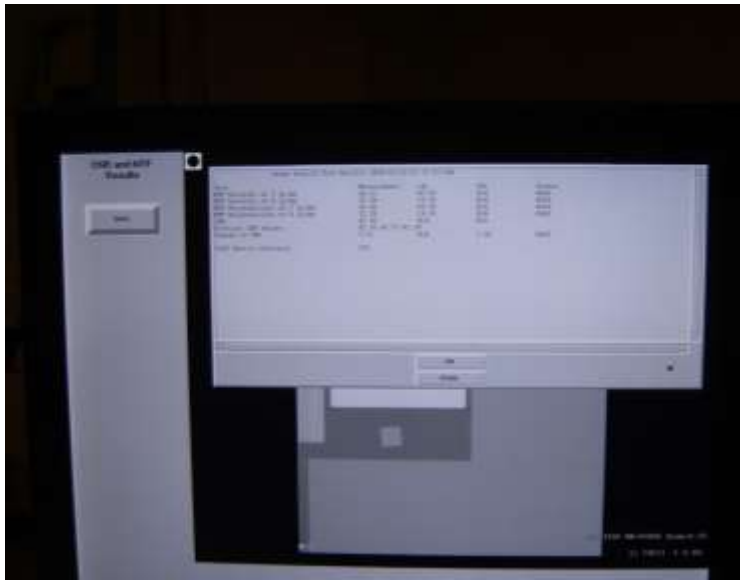
Test	Measurement	LSL	USL	Status
Brightness Non Uniformity	1.66	N/A	10.00	PASS
High Frequency Modulation	0.49	N/A	0.80	PASS
Bad Pixel	0.00	N/A	100.00	PASS
Bad ROI	0.00	N/A	0.00	PASS
SNR Non Uniformity	28.67	N/A	40.00	PASS

OK

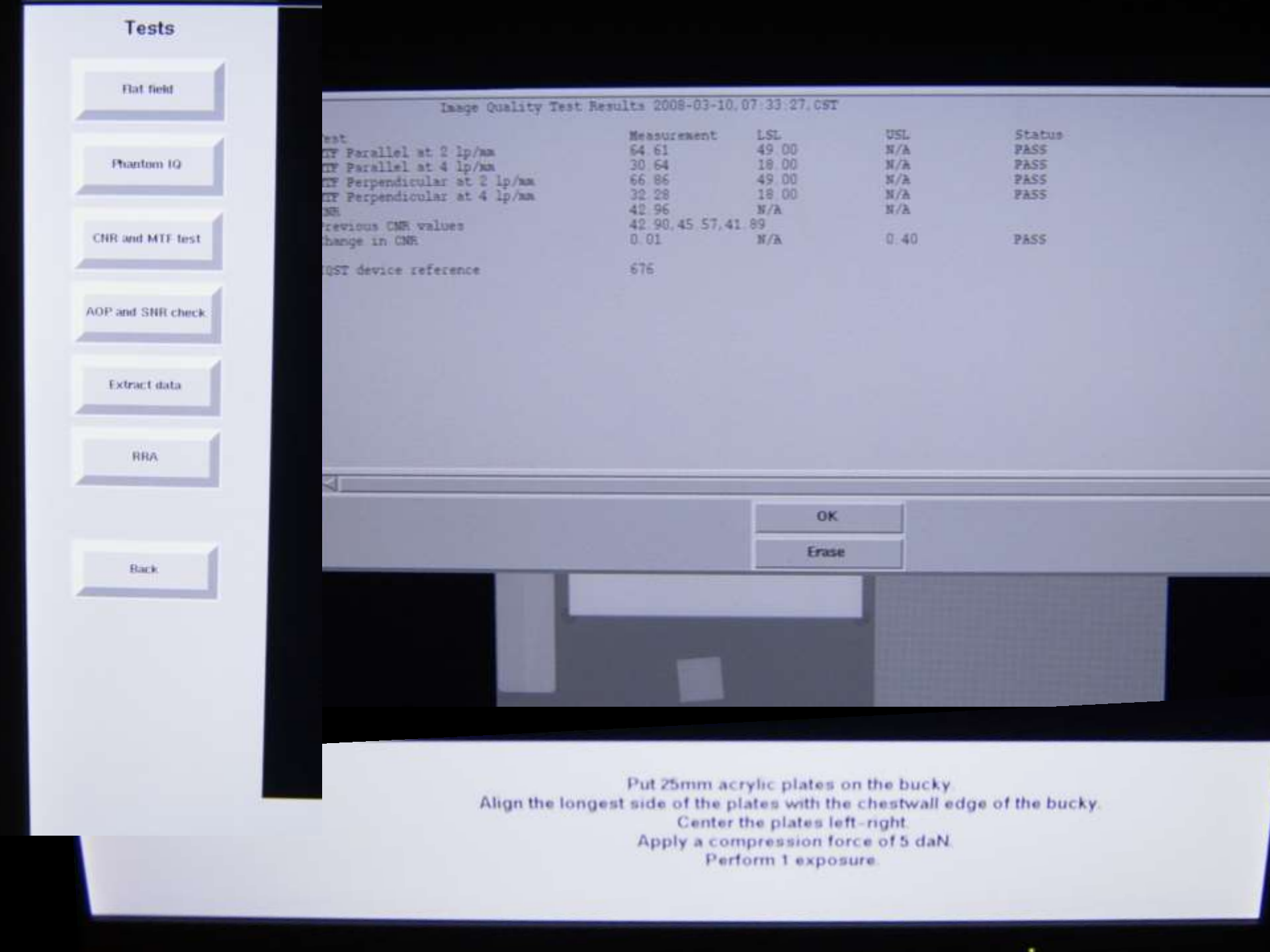

AOP and SNR check Results
Back
Image Quality Test Results 2010-03-01,12:19:11,GMT
Test
Measurement
LSL
USL
Status
AOP 25mm
Mo/Mo/26kv
Mo/Mo/26kv
PASS
MAS 25mm
32.50
20.00
60.00
PASS
SNR 25mm
81.22
50.00
N/A
PASS
OK







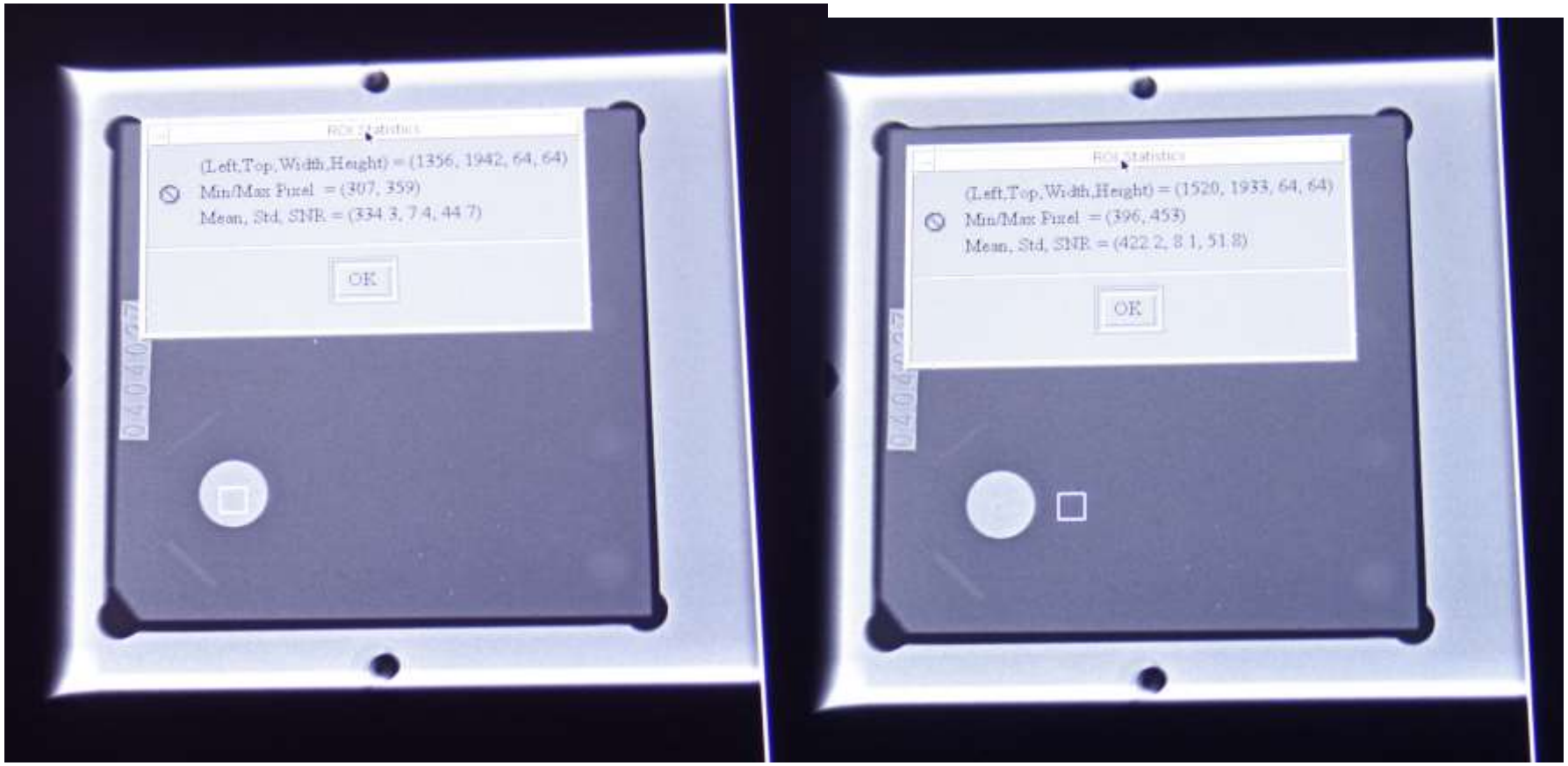
DS IQ Signature Test
automates SNR and MTF


Tests
Flat field
Phantom IQ
CNR and MTF test
AOP and SNR check
Extract data
RRA
Back
Image Quality Test Results 2008-03-10,07:33:27,CST
Test
TF Parallel at 2 lp/mm
TF Parallel at 4 lp/mm
TF Perpendicular at 2 lp/mm
TF Perpendicular at 4 lp/mm
NR
revious CNR values
hange in CNR
QST device reference
Measurement
64.61
30.64
66.86
32.28
42.96
42.90,45.57,41.89
0.01
676
LSL
49.00
18.00
49.00
18.00
N/A
N/A
0.40
USL
N/A
N/A
N/A
N/A
Status
PASS
PASS
PASS
PASS
PASS
OK
Erase
Put 25mm acrylic plates on the bucky.
Align the longest side of the plates with the chestwall edge of the bucky.
Center the plates left-right.
Apply a compression force of 5 daN.
Perform 1 exposure.

QC PHANTOMS AND AUTOMATED ANALYSIS PROGRAMS: Hologic

Auto SNR and CNR

Contrast to Noise Ratio

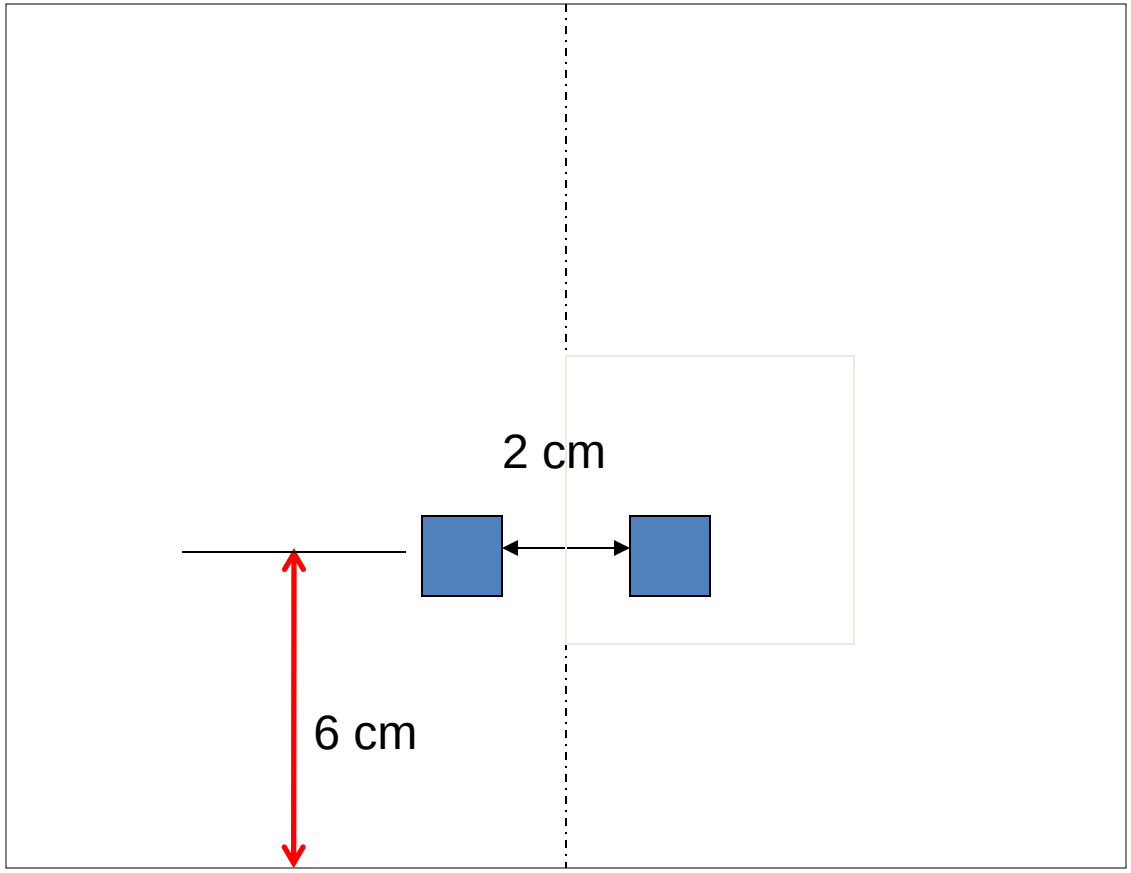



SNR: 48.92
CNR: 11.64
Comments
ROI

QC PHANTOMS AND AUTOMATED ANALYSIS PROGRAMS: Fuji CR

Auto SNR and CNR


Westcott

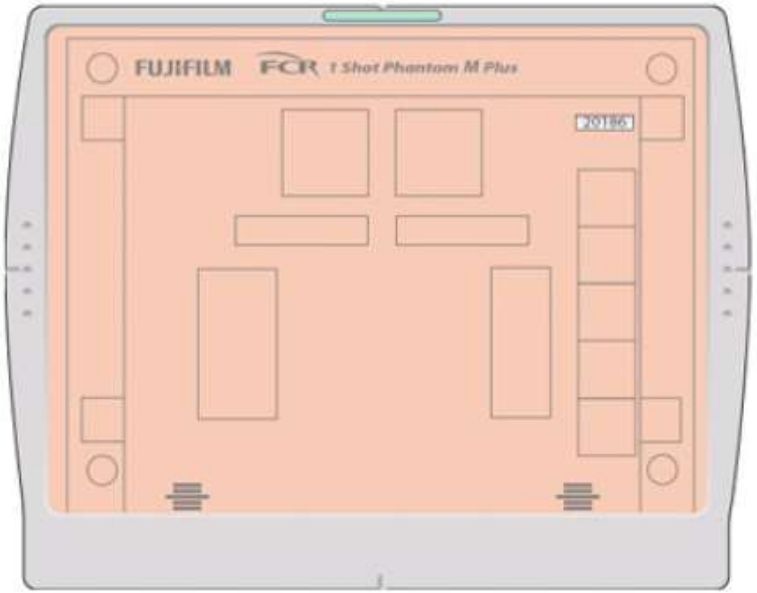

2 cm
6 cm

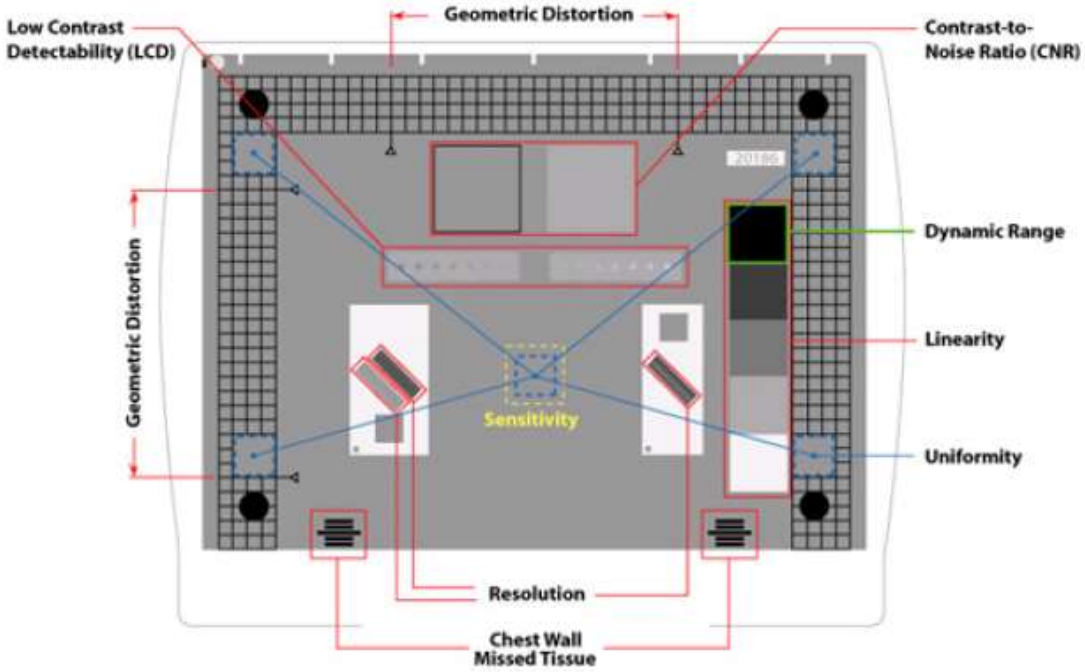
QC calculation tool - offline

QC PHANTOMS AND AUTOMATED ANALYSIS PROGRAMS: Fuji DR

Fuji One Shot phantom and auto QC program

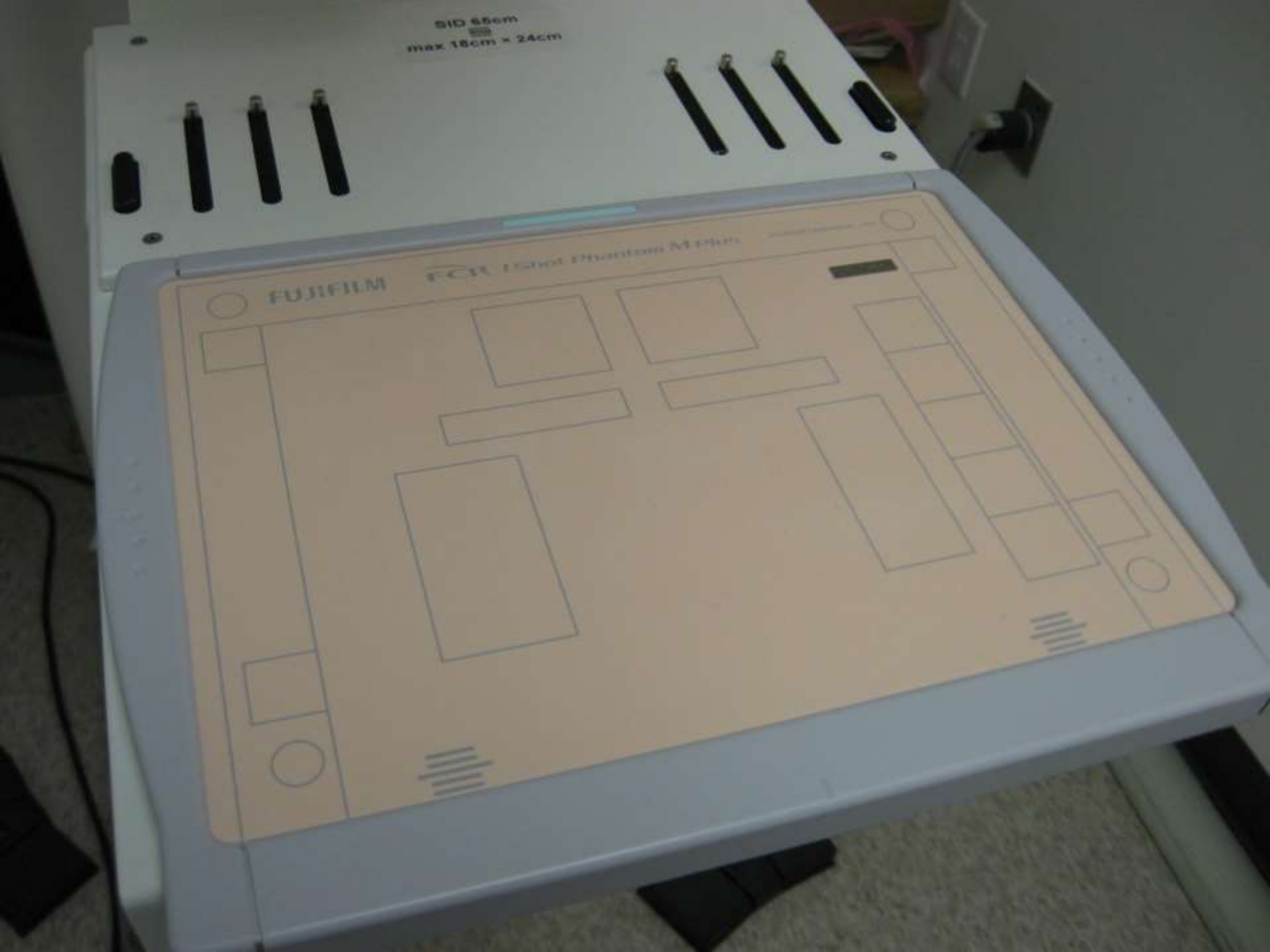
Fuji 1 Shot Phantom M Plus weekly constancy test tool

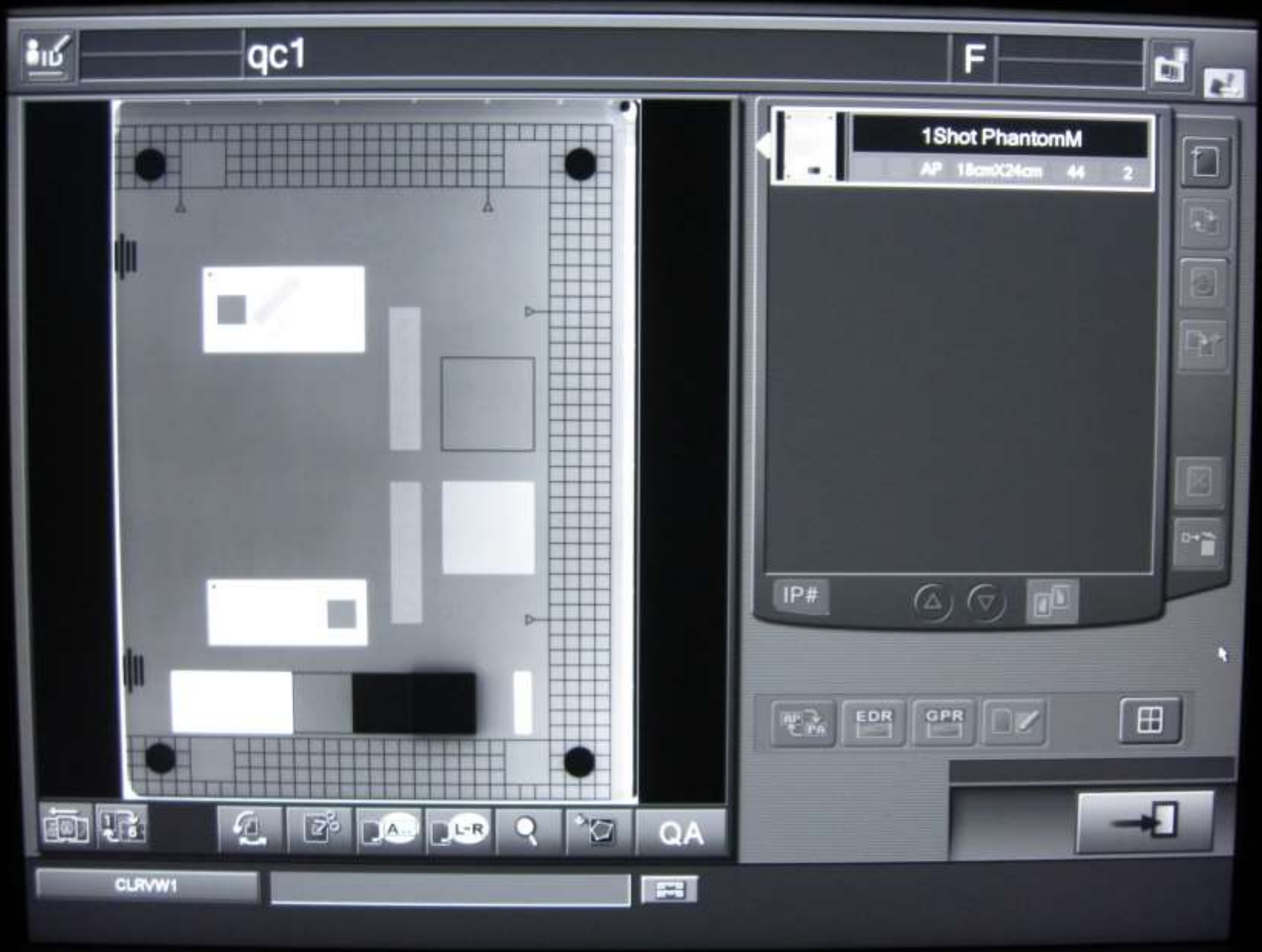




9.1 Specification Outline of 1Shot Phantom M Plus

Test Contents	Applicable Phantom	Outline of Calculation Method
Missed tissue on chest wall edge	Bar patterns (1 mm spacing)	The amount of missed tissue on the chest wall-side edge is calculated by using coordinate information of the slit.
CNR	Al (0.2 mm)	CNR is calculated according to the definitional equation described in IEC 61223-3-2.
1Shot Phantom sensitivity constancy	Uniform exposure region at 60 mm from the chest wall-side edge	A calculation area (20 x 20 mm) is set at the lateral center and also at 60 mm from the chest wall-side edge. Based on the pixel value in this calculation area, the value inversely proportional to the air kerma is calculated. Note: Although this value is calculated in the same way as S value, this value and S value need to be discriminated.
Geometric distortion	Lines indicated with triangle markers (100 mm spacing)	The distance between the two lines is calculated.
System artifact evaluation	Uniform exposure region made of metal and plastic (The transmission factor becomes equivalent to 40-mm PMMA phantom at 28kVp, Mo/Mo.)	N/A
Uniformity (Uniform Exposure Region)	Uniform exposure region at 60 mm from the chest wall-side edge and uniform exposure regions at four corners of the phantom	A calculation area (10 x 10 mm) is set at the lateral center and also at 60 mm from the chest wall. Based on this calculation region, the pixel value and relative SNR value are calculated in the calculation regions (10 x 10 mm each) at four corners of the phantom.
Dynamic range	The lightest region of the step wedge	The pixel value in the highest density region of the step wedge is calculated. According to IEC 61223-3-2, calculation is executed only in the highest density region.
Spatial Resolution (SR)	Bar patterns slanted at 45 degrees (2, 4 and 8 cycles/mm)	SCTF is calculated according to the definitional equation described in IEC 61223-3-2.
Low Contrast Detectability (LCD)	PMMA phantom (φ2 mm, contrast 1.4%)	A cross-correlation factor is calculated based on the reference image (ideal image).
Linearity/Beam quality constancy	Five step-wedge patterns forming a density region in the range of the center density plus or minus about one digit	The pixel value is calculated in each step of the step wedge and then the difference between the adjacent steps is calculated.


SID 65cm
max 18cm × 24cm
FUJIFILM


qc1
F
1Shot PhantomM
AP 18cmX24cm 44 2
IP#
EDR
GPR
QA
L-R
CLRVW1


Daily/Weekly test
Semi-Annual test
Annual test 1-1
Annual test 3-1
Annual test 3-2
Annual test 3-3
ACR Phantom image confirmation
Density at center of Phantom
Density inside the disk
Density outside the disk
Fibers Score
Specks Score
Masses Score
Step Phantom image confirmation
Visible step wedge Step
Specks Step
Masses Step
1Shot Phantom image confirmation
Geometric distortion Fail Pass
Artifact Fail Pass
Good practice
X-ray equip.cleanliness Fail Pass
IP / Cassette cleanliness Fail Pass
Screen cleanliness Fail Pass
Viewing box cleanliness Fail Pass
Cancel
OK

FUJIFILM

QC TEST SOFT M

X-ray equipment: SIEMENS MAMMOMAT 3000NC

Image reader: CLRVWCS

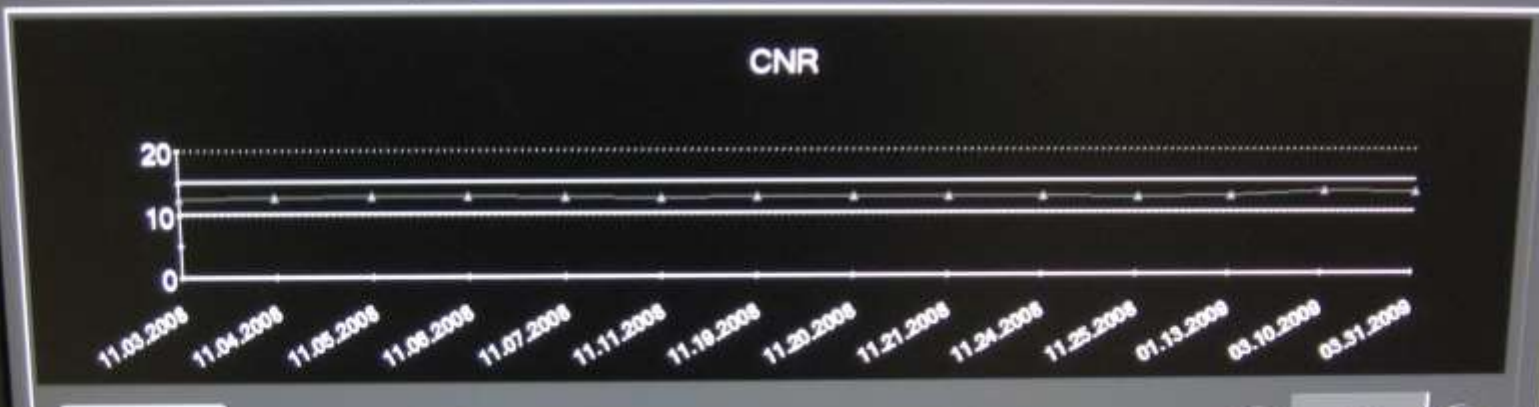
Quality control item: Daily/Weekly test

Close

Scale setting

Graph setting

Record setting



1/1

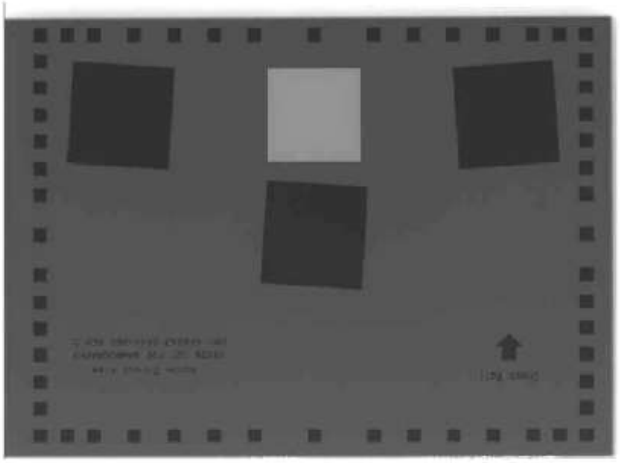
Test contents	Judgment items	Lower limit	Baseline	Upper limit	03.31.2009	03.10.2009	01.13.2009	11.25.2008	11.24.2
					■	■	■	■	■
Missed tissue on chest wall edge	Missed tissue on chest wal...	-	-	5.0	2.8	2.8	2.8	2.8	
	Missed tissue on chest wal...	-	-	5.0	2.8	2.4	2.4	3.0	
CNR	CNR	10.057	12.571	15.085	13.160	13.346	12.655	12.423	12
Sensitivity const.	System sensitivity	44	67	90	79	72	81	68	
Geometric distortion	Dimension (Scan direction)...	100.9	103.0	105.1	103.1	103.1	103.0	103.0	
	Dimension (Sub scan direc...	101.0	103.1	105.2	103.1	103.2	103.1	103.1	
	Geometric distortion	-	-	-	-	-	-	-	-
System artifact evalua...	Artifact	-	-	-	-	-	-	-	-
Uniformity	Pixel value ratio (Top-Right...	-34.02	-19.02	-4.02	-21.16	-20.30	-19.22	-18.84	
	Pixel value ratio (Top-Left)[...	-31.02	-16.02	-1.02	-12.87	-11.21	-16.83	-16.26	
	Pixel value ratio (Bottom-Ri...	-24.53	-9.53	5.47	-11.98	-11.23	-9.27	-9.43	
	Pixel value ratio (Bottom-L...	-20.72	-5.72	9.28	-2.10	-0.06	-5.92	-6.08	
	SNR ratio (Top Right)[%]	-25.73	-10.73	4.27	-10.91	-10.08	-11.15	-8.99	

QC PHANTOMS AND AUTOMATED ANALYSIS PROGRAMS: Carestream

CR Mammo TQT

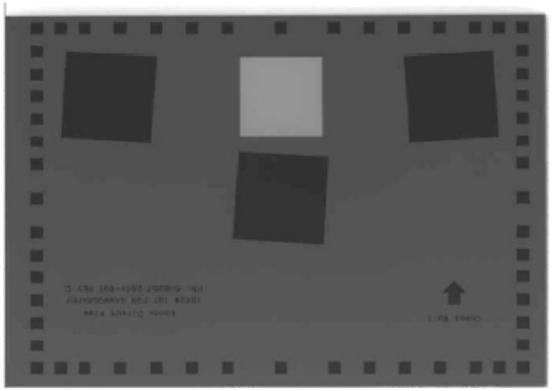
Manual QC Procedure vs. CR Mammo TQT

The DIRECTVIEW Total Quality Tool (TQT) enables you to perform objective image tests and QC measurements with the same interface used for examinations.



Manual QC Procedure vs CR Mammo TQT

- Manual QC procedure satisfies 21 CFR 900, TQT does not
- TQT is a scanner test only
- Performed by Service upon install
- Recommended for sites to perform twice a year
- Some states make it a yearly requirement
- Does not change the QC testing that has to be performed

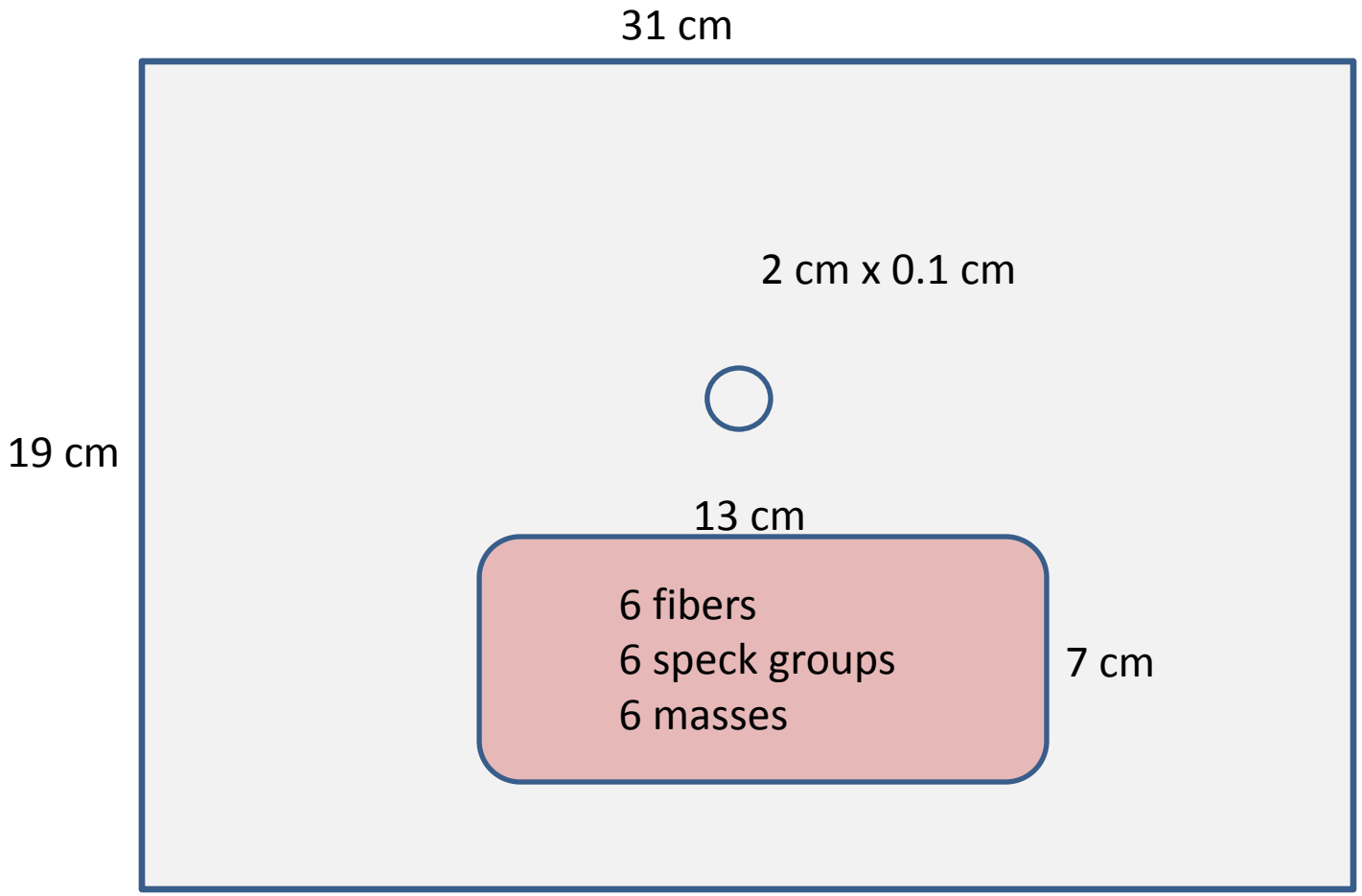



[S]ignal:
Mean: 1594.8
StdDev: 61.5
SNR: 25.9
[B]ackground:
Mean: 1730.0
StdDev: 64.4
SNR: 26.8
Contrast: 8.48%
CNR: 2.199
[S]ignal:
Mean: 1873.3
StdDev: 67.6
SNR: 27.7
[B]ackground:
Mean: 1728.8
StdDev: 64.4
SNR: 26.8
Contrast: -7.71%
CNR: -2.136
S

Potential future changes

- ACR FFDM QC program
- Universal phantom
- Alternative standard (MQSA)

New ACR accreditation phantom (proposed)



Who determines the QC requirements for a new mammography modality?

1. FDA
2. ACR
3. Imaging system manufacturer
4. On-site physicist
5. **Image receptor manufacturer**

21 C.F.R. 900.12(e)(6)

Which of the following are new modalities- requiring 8 hours of initial training before use?

1. Screen/film and stereo mammography
2. **Full-field digital mammography and digital breast tomosynthesis**
3. Stereotactic biopsy
4. Digital stereotactic biopsy
5. Automated breast ultrasound

www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/Guidance/PolicyGuidanceHelpSystem/ucm136925.htm
www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/FacilityCertificationandInspection/ucm243765.htm

The 5 year survival for a minimal breast cancer is

1. Less then 50%
2. 60-70%
3. 70-80%
4. 80-90%
5. **Greater than 90%**

American Cancer Society. *Cancer Facts & Figures 2013*. Atlanta: American Cancer Society; 2013

The most reliable indication of breast cancer in a mammogram is

1. Architectural distortion
2. Clustered calcifications
3. Linear and branching calcifications
4. **Spiculated mass**
5. Skin thickening

Tabar L, Tot T, Dean PB. Breast cancer: the art and science of early detection with mammography. Stuttgart, Germany, Thieme Verlag, 2005

What performance parameter(s) does MQSA specify for FFDM quality assurance?

1. Phantom dose < 3.0 mGy for one CC view
2. Phantom dose < 2.0 mGy for one CC view Image
3. Image quality must exceed S/F IQ
4. **Dose can't exceed max. allowed S/F dose**
5. Patient dose ≤ 3.0 mGy for one CC view

21 C.F.R. 900.12(e)(6); 21 C.F.R. 900.12(e)(5)(vi)