

**SURVEY of MAMMOGRAPHIC EQUIPMENT:  
PART 1**

**Dedicated Stereotactic Breast Biopsy Units**

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**SBB-Testing Requirements**

- Currently exempt from FDA certification and ACR accreditation.
- Some states require testing, all tests that are applicable.
- We will focus on the dedicated units with digital image receptor.

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**SBB Testing**

- The ACR-SBB manual contains testing procedures for technologists and physicists. There are options for screen-film units and those with digital receptors.
- Dedicated prone table units are made by Fischer and Hologics (formally TREX, formally just Lorad). Other re-salers have put their label on the Lorad unit.

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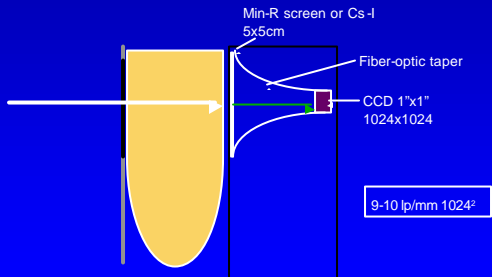
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## Fischer Mammotest




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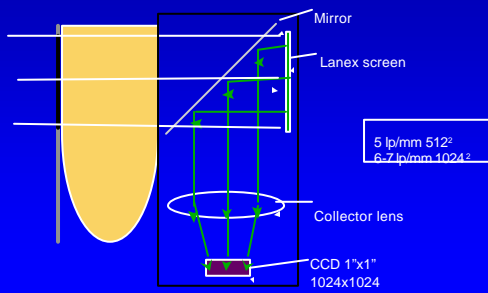
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## Lorad Stereoguide




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## EQUIPMENT TESTING

1. Unit assembly evaluation
2. Collimation assessment
3. Focal spot performance
4. kVp performance
5. Half -value layer
6. AEC or manual exposure performance
7. Digital image uniformity
8. Breast dosimetry
9. Image quality
10. Artifact evaluation
11. Localization accuracy

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## 1. Unit Assembly Evaluation

- Mechanically stable
- All moving parts move smoothly
- All locks and detents work properly
- Image receptor holder assembly is free from vibrations
- Image receptor is held securely by assembly
- Compressed breast thickness scale accurate to 5 mm
- Patient or operator is not exposed to sharp or rough edges or other hazards

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## 2. Collimation Assessment

- Radiation field to digital image alignment
- Radiation beam confinement to image receptor
- Coin method or collimator test tool

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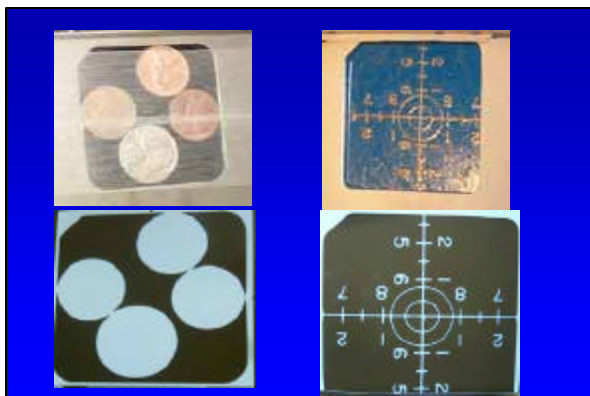
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## Collimation Tolerance

- Compare film image to monitor image.
- The radiation field should extend beyond the image receptor.
- But, not more than 5 mm on any edge.

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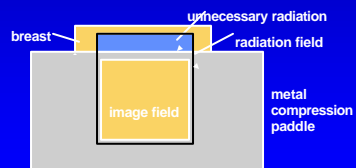
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## Radiation Beam Confinement

- Often, the radiation field will exceed the image receptor at the chest wall.



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## 3. Focal Spot Performance

- The focal spot performance is tested with the resolution pattern and film (no screen).
- $\geq 11$  lp/mm perpendicular to the anode-cathode axis
- $\geq 13$  lp/mm parallel to the anode-cathode axis



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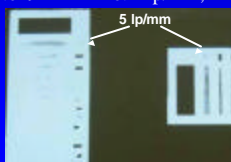
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### System Resolution (Digital)

- The resolution pattern is then used with the digital receptor to find limiting resolution.
- For 512 image, pixel size is 0.098 mm = 5.1 lp/mm, Nyquist frequency = 2.6 lp/mm
- For 1024 image, pixel size is 0.049 mm = 10.2 lp/mm, Nyquist frequency = 5.1 lp/mm
- (Pattern should be 3-10 lp/mm)



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### 4. kVp Accuracy and Reproducibility

- Mammography units should have clinically used kVp accuracy to within 5% of the indicated kVp.
- From four measurements at most commonly used kVp, compute mean, s.d., and coefficient of variation (sd/mean).
- C.V. should be within 0.02.

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### 5. Half-Value Layer

- Use lead backer and high-purity Al plates. Logarithmic interpolation or graphical methods are used to calculate HVL.
- The HVL should be above  $HVL \geq kVp/100$  (mm Al).
- The ACR suggests an upper limit of  $HVL < kVp/100 + 0.12$  (mm Al) for Mo/Mo.
- At 28 kVp,  $0.40 \geq HVL \geq 0.28$

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## 6. AEC Performance (if used)

- For the performance test, 4, 6, and 8 cm of lucite is evaluated with clinical technique factors ( $\leq 2$  seconds).
- For film systems:
  - read the OD
  - variance should be within  $\pm 0.15$  OD of the average
- For digital systems:
  - read the signal value in the center of the image
  - signal from 6 and 8 cm should be within  $\pm 20\%$  of the 4 cm reading

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## 7. Digital Image Uniformity

- 4 cm lucite image
- Signal analysis in center and quadrants
  - Signal
  - Standard deviation (sd)
  - SNR
- Calculate quadrant deviance from the center values.
- Systems without ROI capability, use wire mesh pattern.

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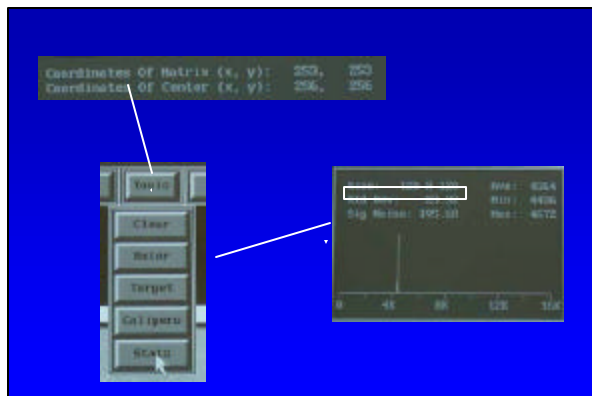
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## Lorad Tolerances

- SNR in each corner  $\pm 15\%$  of center (manual shows 128x128 box). I've found that most Lorad units will not pass with this protocol.
- A "preliminary test protocol" from TREX, issued later, suggests using a 32x32 box and specifies the corner areas to sample. The specified tolerance was that the SNR in each corner not exceed  $\pm 20\%$  of the central SNR. Most units will pass with these parameters.

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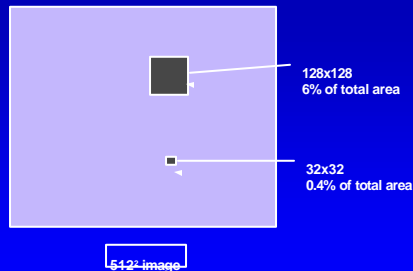
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## Newer Lorad Units

- On newer units, the operator manual indicates to take signal in the center of 1024 image with 32x32 box (0.1% of total area). This also requires significantly more radiation to keep signal at 4k, when quadrupling image matrix.
- Signal in each quadrant should be within 5% of the center. All of them appear to be able to pass this protocol.

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### Fischer Tolerances

- SNR or signal in each corner  $\pm 15\%$  of center (ACR manual shows 128x128 box).
- Most units will pass this tolerance.

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### Wire Mesh Method

- Place wire mesh (film-screen contact) on 4 cm lucite.
- Evaluate image for pincushioning.
- Observe image with narrow window to look for non-uniformities and defects.

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### 8. Breast Exposure, Dose, Reproducibility

- Find technique factors that give manufacturer recommended signal values for the ACR phantom.
- Position ion chamber in port at 4.5 cm from breast support. Measure exposure 4 times.
- Calculate average, s.d., and c.v. ( $< 0.05$ )

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## Breast Dosimetry

- Calculate the average glandular dose from look-up table in ACR manual (kVp vs HVL) for Mo/Mo. Typical conversion factor is 0.18 at 28 kVp.
- Dose should be less than 3.0 mGy (300 mrad).

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## 9. Image Quality

- Make a manual/AEC exposure of the ACR phantom using the kVp and density normally used clinically for a 4.5 cm compressed breast with a 50% adipose / 50% glandular composition. Verify before exposure that the photocell is located under the center of the phantom.
- For the standard ACR phantom, image in each quadrant to determine IQ score.
- For the ACR mini-phantom, only one image is needed.

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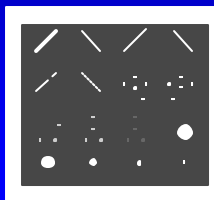
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## ACR Phantom

- Screen-film: 4.0 fibers, 3.0 specks, 3.0 masses
- Digital: 5.0 fibers, 4.0 specks, 3.5 masses




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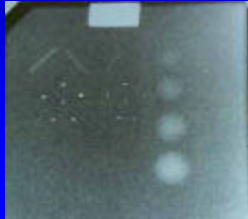
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### Mini-Phantom

- Screen-film: 2.0 fibers, 2.0 specks, 2.0 masses
- Digital: 3.0 fibers, 3.0 specks, 2.5 masses



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### Score Subtraction for Artifacts

- If a fiber-like artifact is as apparent as an actual fiber, it is subtracted from the last half or full fiber.
- If speck-like artifacts are present, they are deducted on a one for one basis from the last group counted.
- If a mass-like artifact is as apparent as an actual mass, it is subtracted from the last real mass.

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### 10. Artifact Evaluation

- For digital IR – image lucite sheet large enough to cover IR
- Adjust the window width and level to look for defects in the image



Very narrow window

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## 11. Localization Accuracy

- The MP should test the system's ability to identify and adequately sample suspicious tissues.
- After performing the coordinates calibration, a phantom containing masses/specks is imaged and samples taken with a core needle or vacuum-assisted (Mammotome) device.

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## Gel Phantom



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## Scout Image (0°)



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### Stereo Scouts (+15°, -15°)



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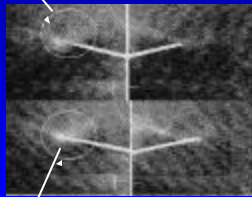
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Pre-Fire



Post-Fire

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### Technologist's QC

- Daily Coordinates Calibration
- Phantom Images and Hardcopy
- Visual Checklist
- Compression Testing
- Repeat Analysis

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## SUMMARY

- SBB-ACR accreditation is voluntary, for now...
- Even though exempt from FDA testing regimen, dedicated units should be tested routinely by the Medical Physicist, and may be required by other regulatory agencies.
- Digital image uniformity and localization accuracy are more complex tests, but should also be included.

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## SURVEY of MAMMOGRAPHIC EQUIPMENT: PART 2

### Screen-Film Systems

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## SCREEN-FILM SYSTEM SURVEYS

- Equipment evaluation (before initial use)
- Annual survey
- Additional testing (after repair)

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## Equipment Evaluation

- New equipment must be tested by MP before patient use.
- Equipment requirements in US 21CFR900.12(b) and (e)
- All failures must be corrected before patient use.
- Following major repairs, MP must conduct on-site survey before use.

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## EQUIPMENT TESTING

1. Unit assembly evaluation
2. Collimation assessment
3. System resolution
4. AEC system performance
5. Uniformity of screen speed
6. Artifact evaluation
7. Image quality
8. kVp performance
9. Half -value layer
10. Breast dosimetry
11. Viewbox Luminance /Illuminance

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## 1. Unit Assembly Evaluation

- Free-standing dedicated unit is mechanical stable
- All moving parts move smoothly
- All locks and detents work properly
- Image receptor holder assembly is free from vibrations
- Image receptor is held securely by assembly
- Image receptor slides smoothly into holder assembly
- Compressed breast thickness scale accurate to 0.5 cm
- Patient or operator is not exposed to sharp or rough edges or other hazards

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## 2. Collimation Assessment

- Radiation to light-field alignment
- Radiation beam confinement to image receptor, except chest wall edge
- Compression paddle alignment to chest wall edge of film
- Test all target and contact film size combinations

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## Radiation to Light-Field Alignment

- The projected light field can be compared for congruence with the x-ray field, by placing radiopaque objects (coins) at the inside edges of the light field on the top cassette.
- An exposure is made and a comparison obtained by reading the top film. The FDA requires that the x-ray field/light field misalignment be within 2% total in each direction.

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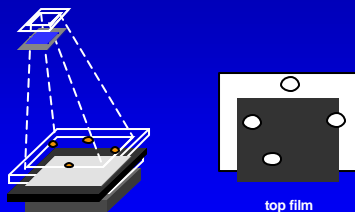
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## Radiation to Light-Field Alignment



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### Radiation Beam Confinement

- The x-ray beam at the plane of the image receptor must not extend more than 2% of the SID past any edge of the image receptor.
- The radiation field should extend past the chest wall to prevent image cutoff.

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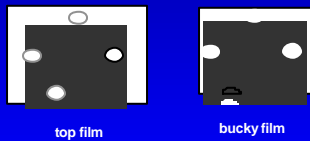
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### Radiation Beam Confinement



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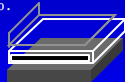
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### Compression Paddle Alignment

- The chest wall edge of the compression paddle should also be aligned just beyond the chest wall edge of the film to within + 1%.



- The chest wall edge of the paddle must not be visible on the test films.

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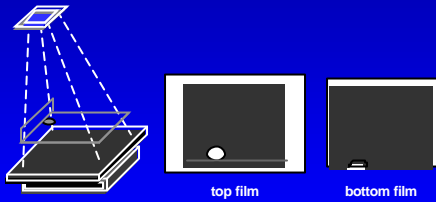
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### Compression Paddle Alignment



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### 3. System Resolution

- Focal spot sizes are evaluated by using a high contrast resolution pattern (after 10-28-02).
- A slit camera can be used for acceptance testing or after tube replacement, to ensure that the focal spot dimensions meet NEMA standards.
- Test all target and focal spot size combinations and screen-film combinations.

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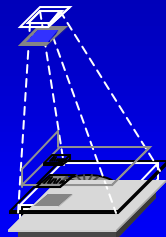
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### Resolution Pattern

- The high contrast resolution bar pattern is also used in the field to evaluate the effective focal spot blur.
- Tolerances:
  - 11 lp/mm perpendicular to A-C
  - 13 lp/mm parallel to A-C



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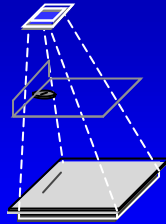
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### Slit Camera

- The slit camera is the preferred method used by manufacturers and physicists to ensure compliance with NEMA tolerances.



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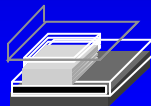
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### 4. AEC System Performance

- 2, 4, 6, and 8 cm of lucite are phototimed in contact mode at the clinically appropriate kVps.
- Most systems have automatic selection of kVp. Four films would be generated.



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### AEC System Performance

- The film optical densities for the 2, 4, and 6 cm films must be within 0.3 O.D. of the average.
- This tolerance drops to 0.15 O.D. on 10-28-2002.
- The ACR recommends that 2-8 cm be within 0.3 OD variance.

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## Multiple Detectors

- FDA requires testing on all AEC detectors. For twin wing system, test both 18x24 and 24x30cm AECs for thickness tracking (2-8cm) and reproducibility.
- For multiple detectors on one bucky, test the most commonly used detector for thickness tracking and reproducibility, and record the mAs reproducibility on all the others to determine detector balance.

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## AEC - Equipment Evaluation

- During an **Equipment Evaluation**, the AEC must also be tested in the other configurations used clinically using 1 of 3 methods:
  1. Conduct performance test in contact mode. Then test other configurations per manufacturer's standards for each configuration
  2. Across configurations - Compare 4 cm film OD from 24x30cm and magnification to the mean OD from 2-6cm on 18x24cm bucky ( $\pm 0.3OD$  after 10-02)
  3. Within configurations - Verify that performance meets  $\pm 0.3OD$  ( $0.15 OD$  by 10-28-02) for each configuration

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## Phantom Material

- Lucite (PMMA) vs. BR-12 vs. BR-50/50
- A system calibrated with one material may not pass the tolerances with another material.
- Does size or shape matter ?

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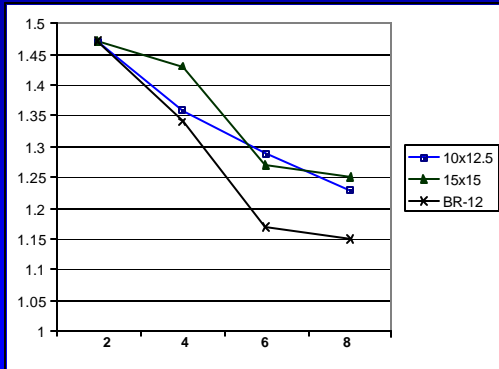
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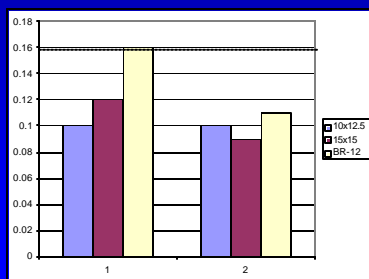
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### Maximum Variation from Average (2-6 cm)




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## 5. Uniformity of Screen Speed

- All cassettes are exposed in AEC mode at the most commonly used kVp. The density control function setting that gives an O.D. from 1.1 to 1.5 is selected.
- The lowest and highest density is determined for all cassettes. The range must be less than 0.3 O.D., or the cassette must be grouped or removed from service.
- Any new cassettes put into service must have this test done (on all like sized cassettes or batch of cassettes).

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## 6. Artifact Evaluation

- 2 flat field films are obtained for each target/filter combination using a uniform lucite phantom.
- Process each film 90° to its match. If artifacts are present, and rotate 90°, the processor is suspect. If artifacts don't rotate, the mammography unit is suspect.

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## 7. Image Quality

- Make a phototimed exposure of the ACR phantom using the clinical kVp and AEC density setting.
- Process film, measure optical density. Verify film density is that needed or recommended for proper contrast.
- Score phantom with ACR method.

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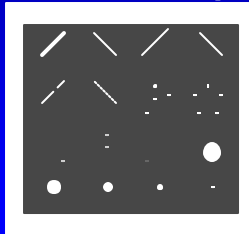
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## ACR Phantom

- Minimum resolution is 4 fibers, 3 speck groups, and 3 masses.



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### Score Subtraction for Artifacts

- If a fiber-like artifact is as apparent as an actual fiber, it is subtracted from the last half or full fiber.
- If speck-like artifacts are present, they are deducted on a one for one basis from the last group counted.
- If a mass-like artifact is as apparent as an actual mass, it is subtracted from the last real mass.

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### 8. kVp Performance

- Mammography units must have clinically used kVp accuracy to within 5% of the indicated kVp.
- From four measurements at most commonly used kVp, compute mean, s.d., and coefficient of variation (sd/mean).
- C.V. should be within 0.02

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### 9. Half-Value Layer

- Use compression paddle, narrow beam, and lead backer. High-purity Al should be used. Logarithmic interpolation or graphical methods are used to calculate HVL.
- The HVL must be above 0.30 mm Al at 30 kVp (FDA) for all target/filter combinations.
- The HVL at the clinical kVp (phantom) should be between  $HVL \geq kVp/100 + 0.03$  (mm Al) and  $HVL < kVp/100 + 0.12$  (mm Al); for Mo/Mo (ACR).

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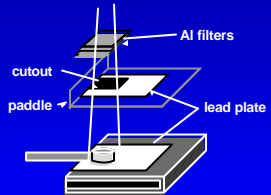
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## Half-Value Layer




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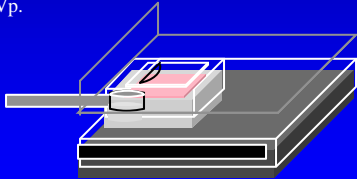
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## 10. Breast Dosimetry

- Measure the entrance skin exposure ( $X_{ESE}$ ), in R, with ion chamber 4.5 cm above Bucky surface, for clinical kVp.




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## Breast Dosimetry

- Determine the glandular dose/R entrance exposure (mrad/R),  $D_{gN}$ , from ACR Conversion Table 1 (Mo, 4.5 cm, 50/50, clinical kVp and HVL).
- Calculate mean glandular dose:  

$$D_g = D_{gN} * X_{ESE}$$
- The ACR accreditation limit for average glandular dose is currently 3.0 mGy (300 mrad).

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### AEC Reproducibility

- Record the exposure and mA-s from 4 AEC exposures of the phantom.
- The reproducibility C.V. must be  $\leq 0.05$

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### Radiation Output

- Measure the entrance exposure at 4.5 cm above the breast support device (contact mode).
- 28 kVp for 3.0 seconds
- Must be  $\geq 500$  mR/s now and  $\geq 800$  mR/s by 10-28-02

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### 11. Viewbox Luminance / Illuminance

- ACR recommendation only
- Calibrated photometer
- Mammo viewbox luminance  $\geq 3000$  nit ( $\text{cd/m}^2$ )
- Room illuminance  $\leq 50$  lux

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### QC Program Review

- The MP should review the QC data for the last year to ensure that the tests are being done correctly and are documented properly.
- An analysis of corrective actions taken should be conducted.

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### Report

- The summary report indicating test findings and recommendations for correction or improvement must be sent to the facility within 30 days of the survey.
- However, many deficiencies must be corrected within the same 30 day period, so it is wise to identify problems immediately after the survey .

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### Corrective Action

- **Breast dose** failure requires immediate correction
- All others within 30 days

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### Additional Testing Required

- If major repairs are made, the MP must conduct an on-site visit for the following replaced parts:
  - Mammo unit (new or reassembly)
  - X-ray tube
  - Filter
  - Collimator or blades
  - AEC detector or board
  - kVp board or high-tension tank
  - Film processor (new or reassembly)
- If any of the required tests fail, correction must be made and compliance verified before used clinically

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### Summary

- Screen-film mammography requires comprehensive equipment testing by the Medical Physicist.
- The MP should expect to be a crucial part of the mammography team, having a technical expert's role with regard to clinical image quality and the quality control program.
- The MP should impress upon the facility that they must be consulted on regulatory compliance issues.

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