

Update on the ACR FFDM QC Manual

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University of Colorado Hospital

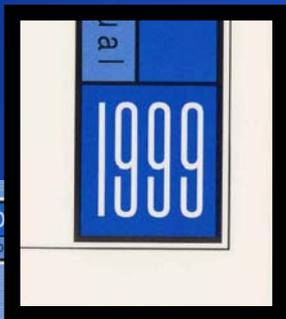
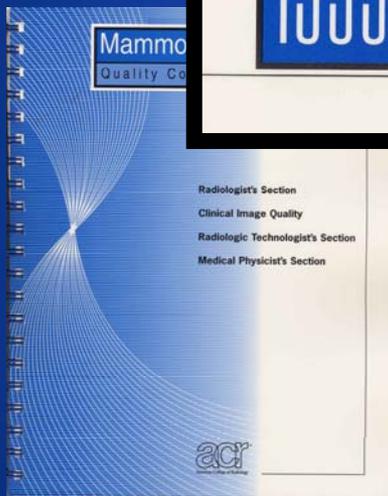
Denver Health Medical Center

Denver, CO

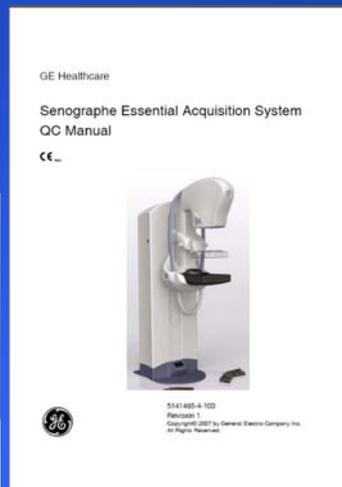
FDA's Current FFDM QC Requirements

- Follow latest version of mfr's QC manual procedures for unit tested
- Meet mfr's performance standards
- Failures must be fixed before use on patients
 - Most mfrs applied for alternative standards to allow 30 days for some QC tests

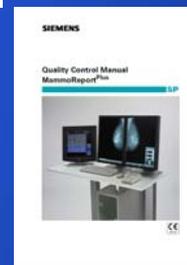
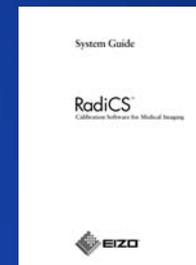
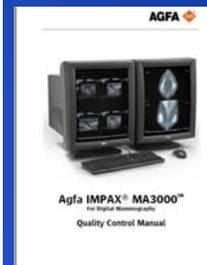
ACR FFDM QC Manual



VS.



Workstations Monitors Printers



ACR FFDM QC Manual Project

- ACR Subcommittee on Quality Assurance
 - Clinical Representatives
 - MITA Representatives
 - ACR Staff

ACR Subcommittee on Quality Assurance

- ACR Clinical Representatives

- Eric Berns, PhD – University of Colorado - **Chair**
- Chris Adent-Delaney, RT - Northwestern Memorial Hospital
- Jay Baker, MD – Duke University Medical Center
- Lawrence Bassett, MD – UCLA Medical Center
 - Chair, Joint Committee on Breast Imaging for Appropriateness Criteria and Guidelines
- Shelli Dixon, RT – The Women’s Imaging Center of Denver
- R. Edward Hendrick, PhD – University of Colorado Hospital
- Debra Monticciolo, MD – Texas A&M Health Sciences Center
 - Chair of ACR Accreditation Program Chairs
 - Chair of ACR Mammography Accreditation
- Douglas Pfeiffer, MS – Boulder Community Hospital
- Margarita Zuley, MD – University of Pittsburgh Medical Center

Subcommittee on Quality Assurance

- MITA Representatives

- Gail Rodriguez, PhD - MITA
- John Sandrik, PhD (Ret.) – GE Medical Systems
- Robert Uzenoff - FUJIFILM Medical Systems
- Stephen Vastagh – (Ret.) - MITA
- Moustafa Zerhouni – Computerized Imaging References Systems

- ACR Staff

- Marion Boston, RT – Assistant Director, ACR Breast Imaging Accreditation
- Priscilla Butler, MS – Senior Director, ACR Breast Imaging Accreditation Programs

ACR FFDM QC Manual Project

- Subcommittee Charge:
 - Design ACR Accreditation Phantom for FFDM
 - Write QC Manual for ACR FFDM Mammography Accreditation Program

ACR FFDM QC Manual Project

- Subcommittee Goals:
 - Standardize all QC tests for all digital manufacturers
 - Standardize test frequencies
 - Standardize performance criteria

ACR FFDM QC Manual Project

- Subcommittee Goals:

- QC Tests:

- Tests come from a variety of sources (MQSA, ACR SFM Manual, ACRIN DMIST Results, Manufacturer's QC programs, MITA, European Guidelines, AAPM TG18, subcommittee clinical experience, etc.)
- Clinically relevant
- User friendly

- Hope manufacturers will adopt this manual

- This manual will become basis of new regulations

ACR FFDM QC Manual Project

- Subcommittee Goals:
 - Realize critical component of the ACR MAP
 - Account for all past, present, and future FFDM systems
 - Reasonable and appropriate for mass implementation
 - Eliminate unnecessary complicated procedures & analysis
 - Maximize user experience
 - Especially for Techs, Rads, & Facilities
 - Philosophy
 - Measurements be made with external equipment
 - Dosimeters, photometers, etc.
 - Minimal software requirements
 - CNR & SNR

ACR Digital QC Draft Manual

- Structure of Manual:
 - Radiologist's Section
 - Clinical Image Quality Section
 - Radiologic Technologist's Section
 - Medical Physicist's Section
 - Educational, Guidance, and Troubleshooting Section
 - Glossary
 - References
 - Index

What Will Be New?

- Radiologist Section
 - Image ID regulations
 - Hanging protocols (left vs. right)
 - Monitor and viewing conditions guidance
 - Section on diagnostic tools for analyzing poor images
 - How to score the ACR FFDM Phantom
 - Guides for understanding their role and responsibility for overseeing the QC program

What Will Be New?

- Tech Section
 - Enhanced positioning and image quality section
 - New Test: Monitor QC for the Radiologist
 - New Test: Facility QC Review
 - New Format: Corrective Action Log
 - New Documentation: Facility Equipment Inventory
 - Improved QC Forms
 - Instructions for Mobile Units
 - Eliminate calculations (TBD)

What Will Be New?

- Medical Physicist Section
 - **Theme:** provide better documentation and communication
 - Single MP Summary Form
 - For Facility, ACR, State and MQSA Inspectors
 - Include an Action Item Summary
 - MP form for Tech for Operating Levels (if app.) and QC instructions
 - Procedures for evaluating and documenting Tech QC
 - MP letter to the Radiologist
 - MP to use same Corrective Action Log form as Techs

What Will Be New?

- Medical Physicist Section
 - Provide QC forms in both PDF and Excel Worksheets
 - Will include guidance on how to test
 - Multiple units (FFDM's, AW's, RW's, Printers, etc)
 - Multiple facilities

What Will Be New?

- Facility

- Guidance on how to handle multiple units at multiple locations.
- Guidance on who/what/when tests need to be performed when “major” and “minor” repairs are performed on unit.
- Facility QC Review (Tech Test) – Quarterly

ACR Digital QC Draft Manual

Technologist QC Tests

Test Number	Name (# of Test Elements)	Minimum Frequency	Required Corrective Action
1	ACR Phantom Image Quality (5)	Weekly	Before Clinical Use
2	Acquisition Workstation (AW) Monitor QC (3)	Weekly	Before Clinical Use
3	Radiologist Workstation (RW) Monitor QC (5)	Weekly	Before Clinical Use
4	Laser Printer QC (5)	Weekly	Before Clinical Use
5	Viewbox Cleanliness (1)	Weekly	Before Clinical Use
6	Visual Checklist (1)	Monthly	Before Clinical Use
7	Repeat Analysis (1)	Quarterly	Within 30 Days
8	Monitor QC for the Radiologist (1)	Quarterly	Before Clinical Use
9	Facility QC Review (1)	Quarterly	Not Applicable
10	Compression Force (1)	Semiannual	Before Clinical Use
11	Manufacturer Detector Calibration (If Applicable)	Per Mfr Recommendation	Before Clinical Use
Supplemental Forms			
	Corrective Action Log		
	Facility Equipment Inventory Form		

ACR Digital QC Draft Manual

Medical Physicists QC Tests

Test Number	Name (# of Test Elements)	Minimum Frequency	Required Corrective Action
1	ACR Phantom Image Quality (6)	Annual	Before Clinical Use
2	Ghost Image Evaluation (1)	Annual	Before Clinical Use
3	Spatial Resolution (1)	Annual	Before Clinical Use
4	Automatic Exposure Control System Performance (2)	Annual	Before Clinical Use
5	Collimation Assessment (3)	Annual	Within 30 Days
6	kVp Accuracy and Reproducibility (1)	MEE Only	Before Clinical Use
7	Beam Quality (Half-Value Layer) Assessment (1)	Annual	Within 30 Days
8	Average Glandular Dose (2)	Annual	Before Clinical Use
9	Unit Checklist (1)	Annual	Before Clinical Use
10	Evaluation of Site's Technologist QC Program (1)	Annual	Within 30 Days
11	MQSA Equipment Requirements (1)	MEE Only	Before Clinical Use
12	Computed Radiography (If Applicable) (3)	Annual	Before Clinical Use
13	Acquisition Workstation (AW) Monitor QC (6)	Annual	Before Clinical Use
14	Radiologist Workstation (RW) Monitor QC (11)	Annual	Before Clinical Use
15	Laser Printer QC (7)	Annual	Before Clinical Use
16	Viewbox Luminance and Room Illuminance (2)	Annual	Before Clinical Use
17	Evaluation of Off-Site Technologist QC Program (If Applicable)	Annual	Before Clinical Use

The ACR FFDM Phantom Prototype

Design Summary

- Phantom Prototype Design Principles
 - Base on existing ACR Accreditation Phantom
 - Similar imaging and scoring to current SFM phantom
 - Build on experience of QC techs and physicists at 8000+ US facilities who already know how to use and score the existing phantom
 - Can be used on both SFM & FFDM
 - Total attenuation matched to current SFM phantom
 - Similar thickness
 - Similar total dose
 - Permits testing of 3.0 mGy dose limit

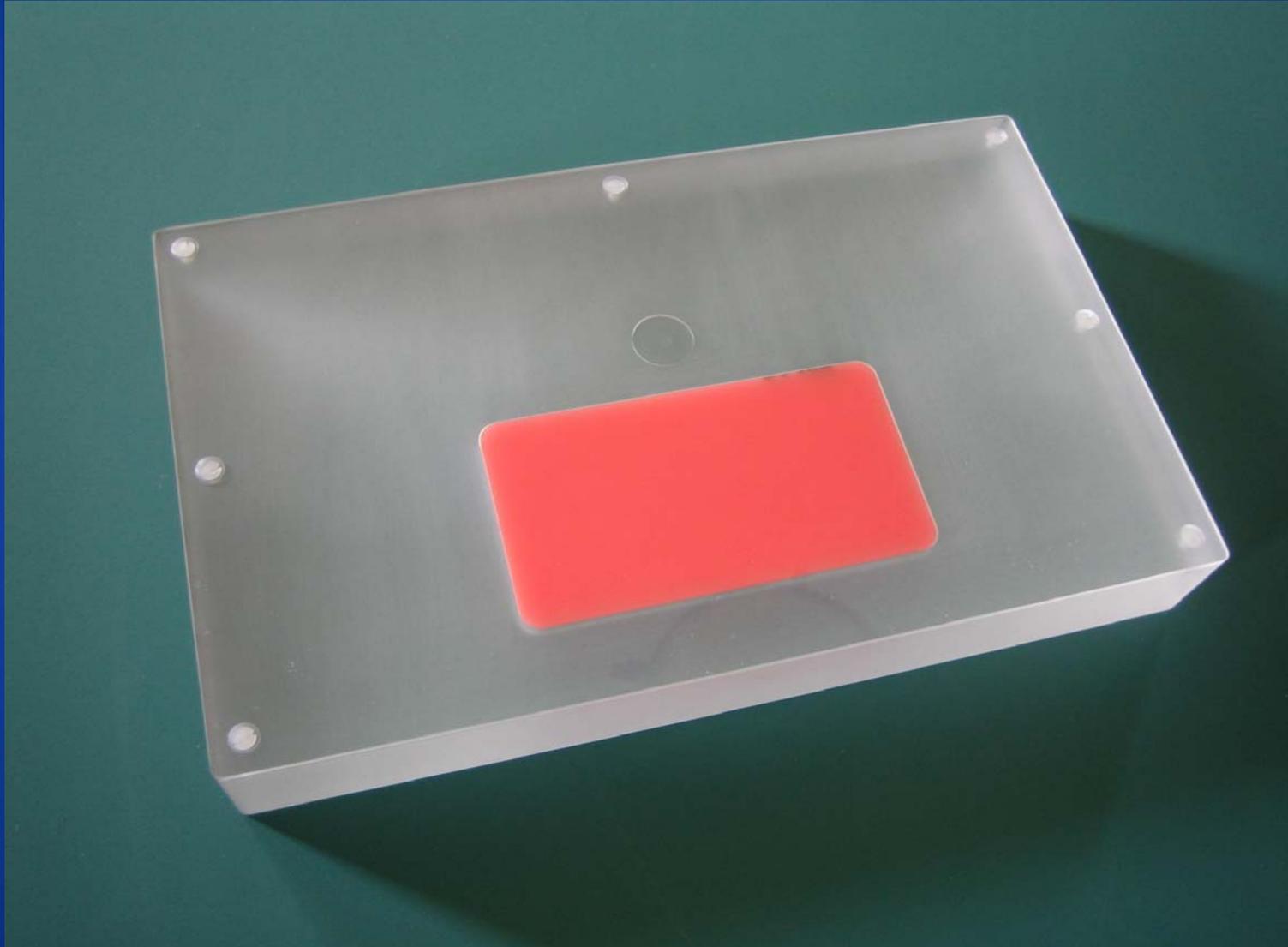
Design Summary

- Phantom Prototype Design Principles
 - Cover all (or most) of detector on all digital systems
 - Single exposure results in all relevant information
 - All evaluation (including artifacts) can be done at one WW, WL
 - Provide detailed specifications to manufacturer's
- Manufacturing will be open to all qualifying vendors
 - Must receive approval from ACR (ACR will test sample phantom)

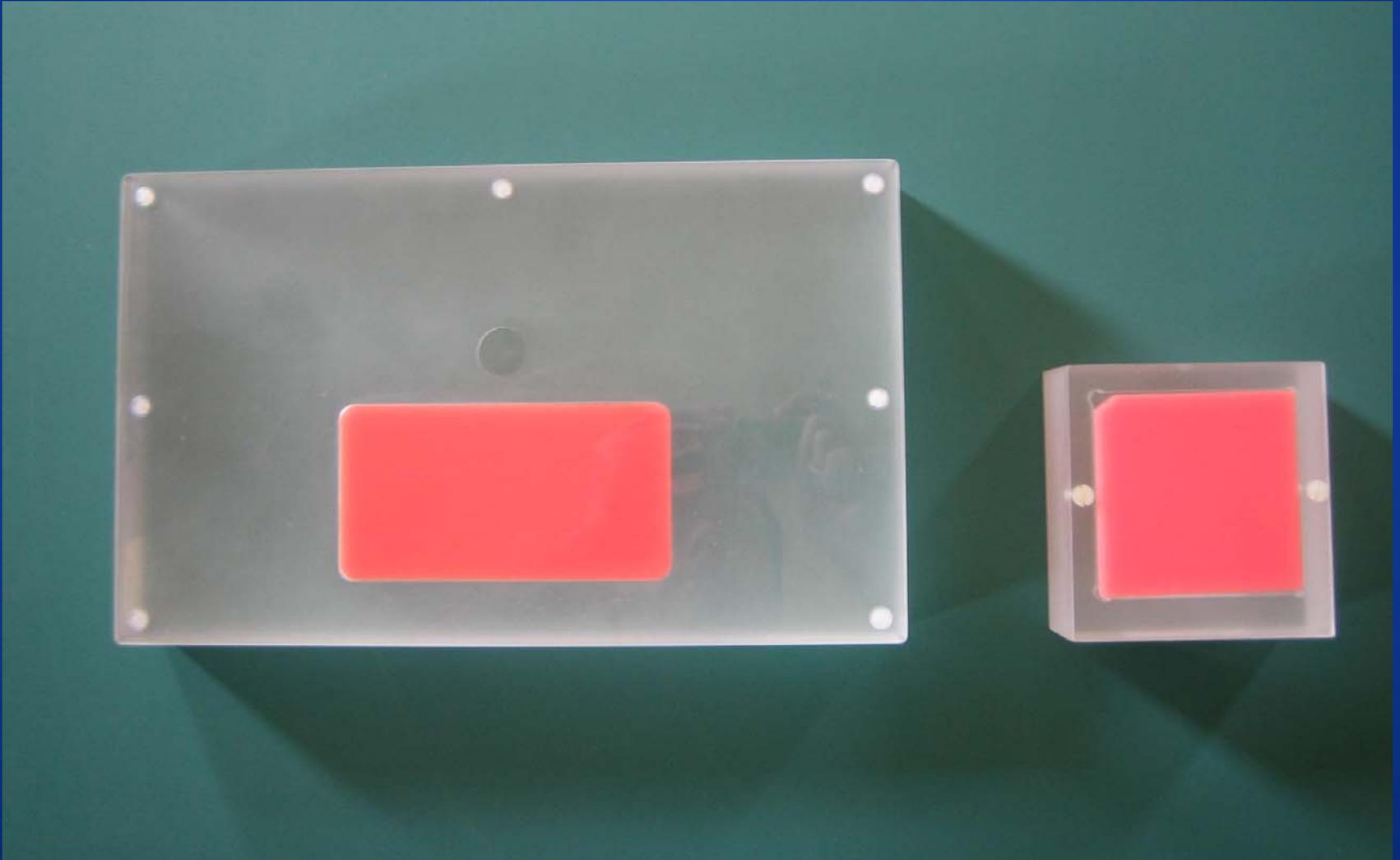
Proposed Scoring Changes

- Differences from screen-film phantom
 - Eliminate subtraction for artifacts
 - Add "Fail" for artifacts
 - Improve specific rules for scoring
 - Change pass/fail criteria from
 - 4,3,3
 - To: 2,3,2
 - **But, objects are the same (effective) size as SFM Phantom

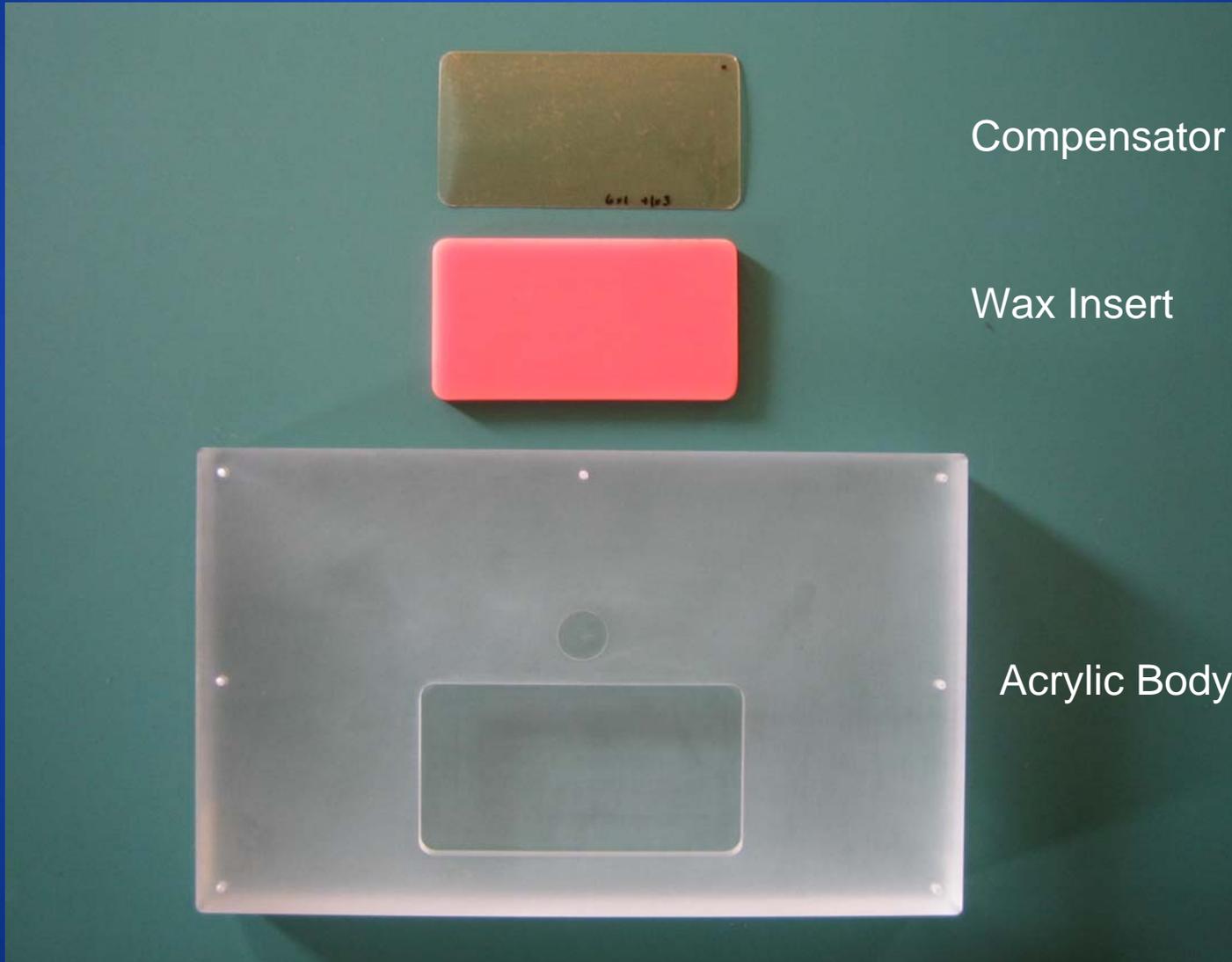
The ACR FFDM Phantom Prototype



The ACR FFDM Phantom Prototype vs. SFM ACR Phantom



The ACR FFDM Phantom Prototype

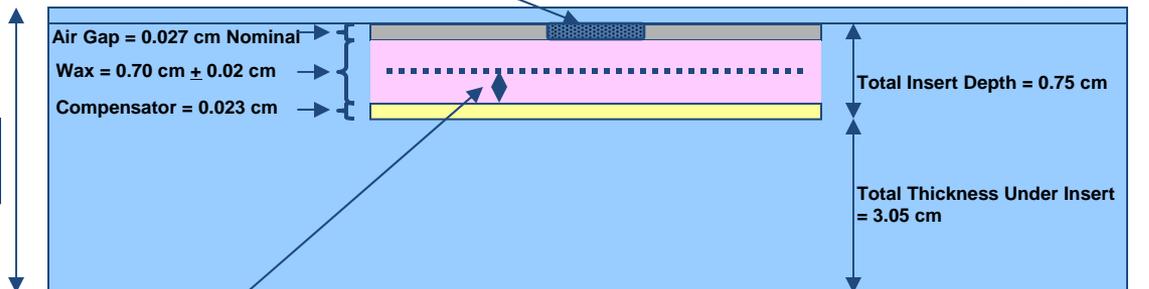


ACR Phantom Prototype

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.

Depth of CNR Cavity = 0.1 ± 0.005 cm

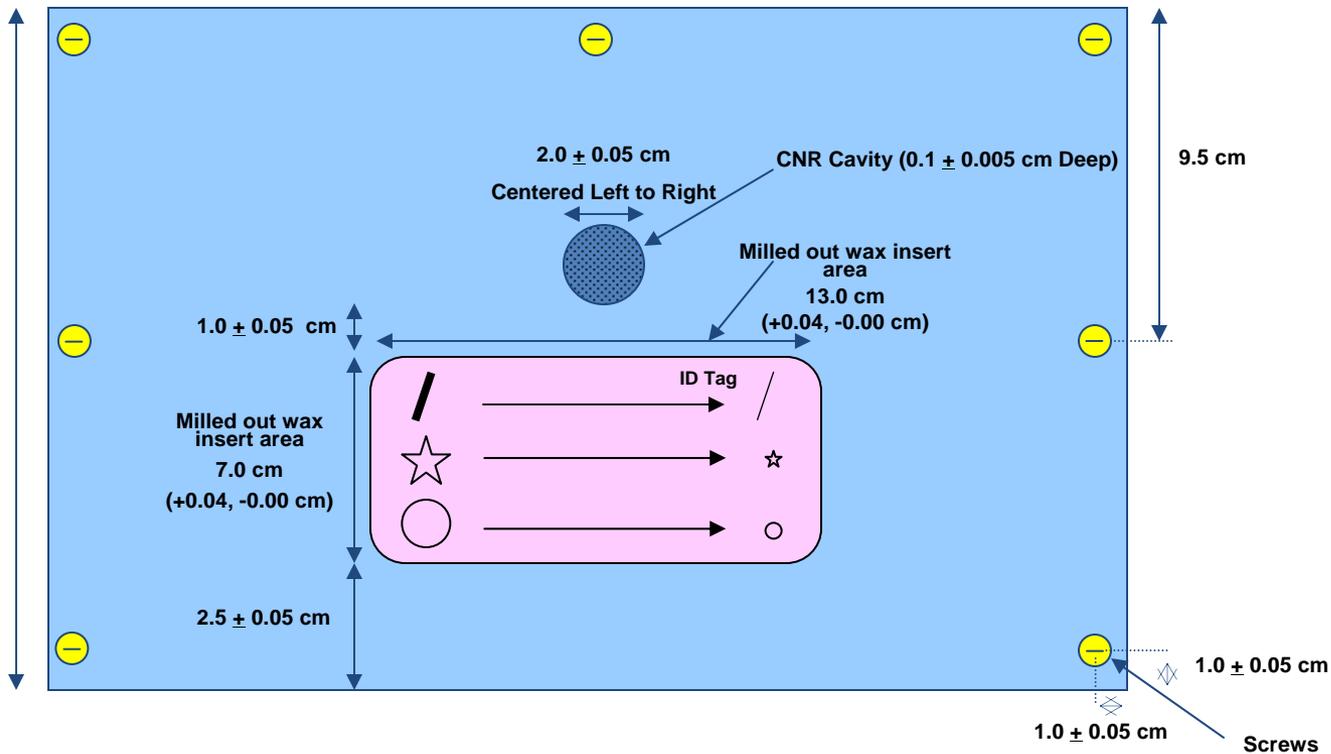


Cover = Nominal 0.3 cm

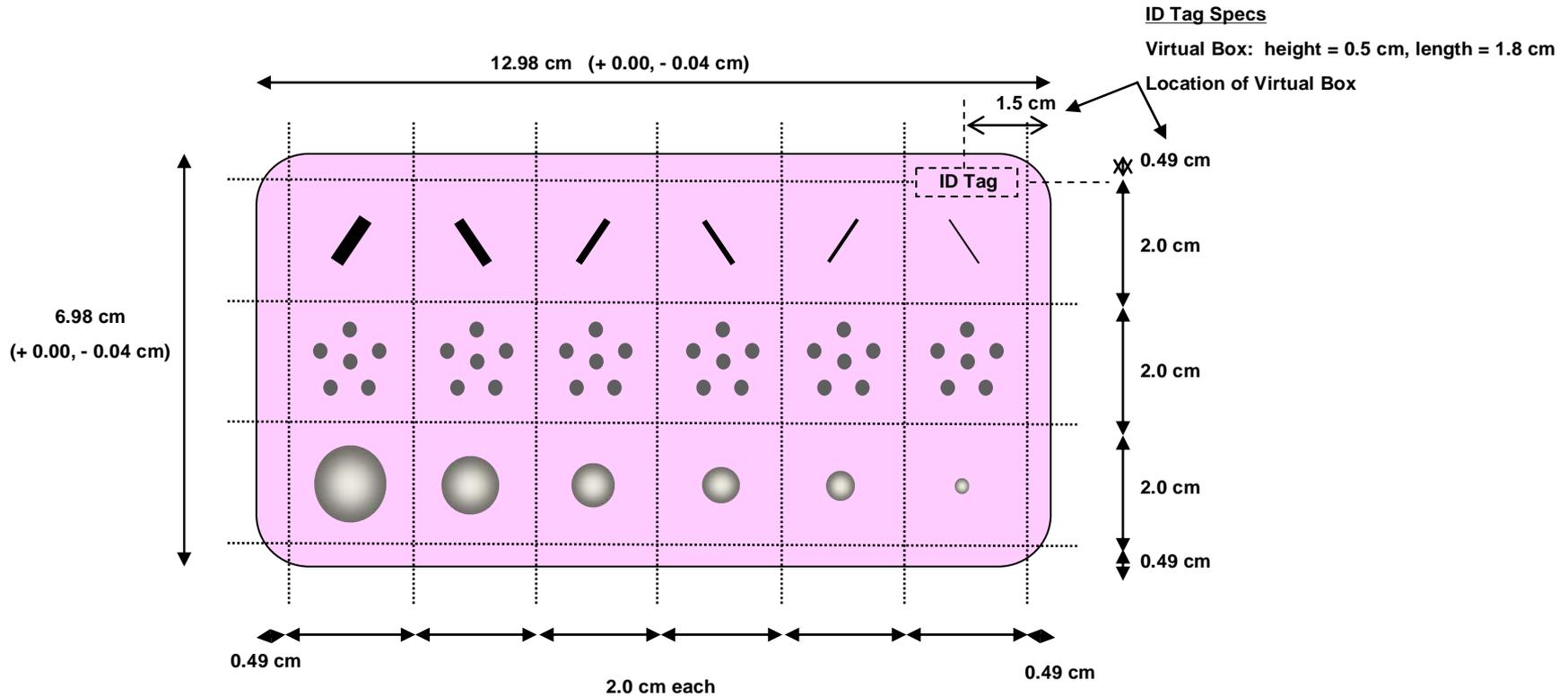
Test object distance from base of wax = 0.35 ± 0.10 cm

31.0 ± 0.1 cm

19.0 ± 0.1 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

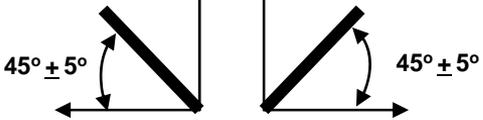
Fiber specifications

Fiber Length = 1.0 cm ± 0.1 cm

Fiber Diameter = See Table

Fiber

Fiber



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

The ACR FFDM Phantom Prototype

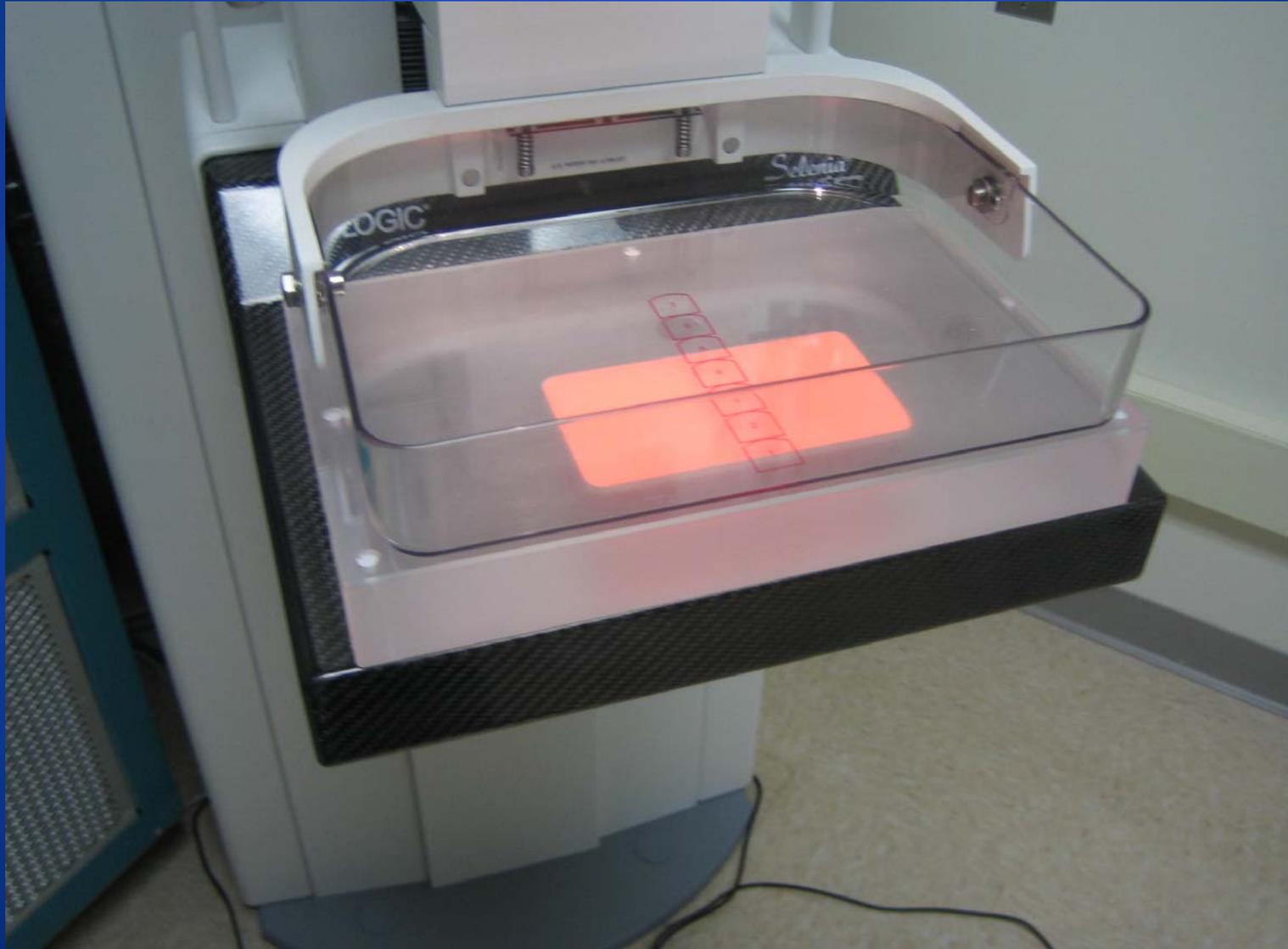
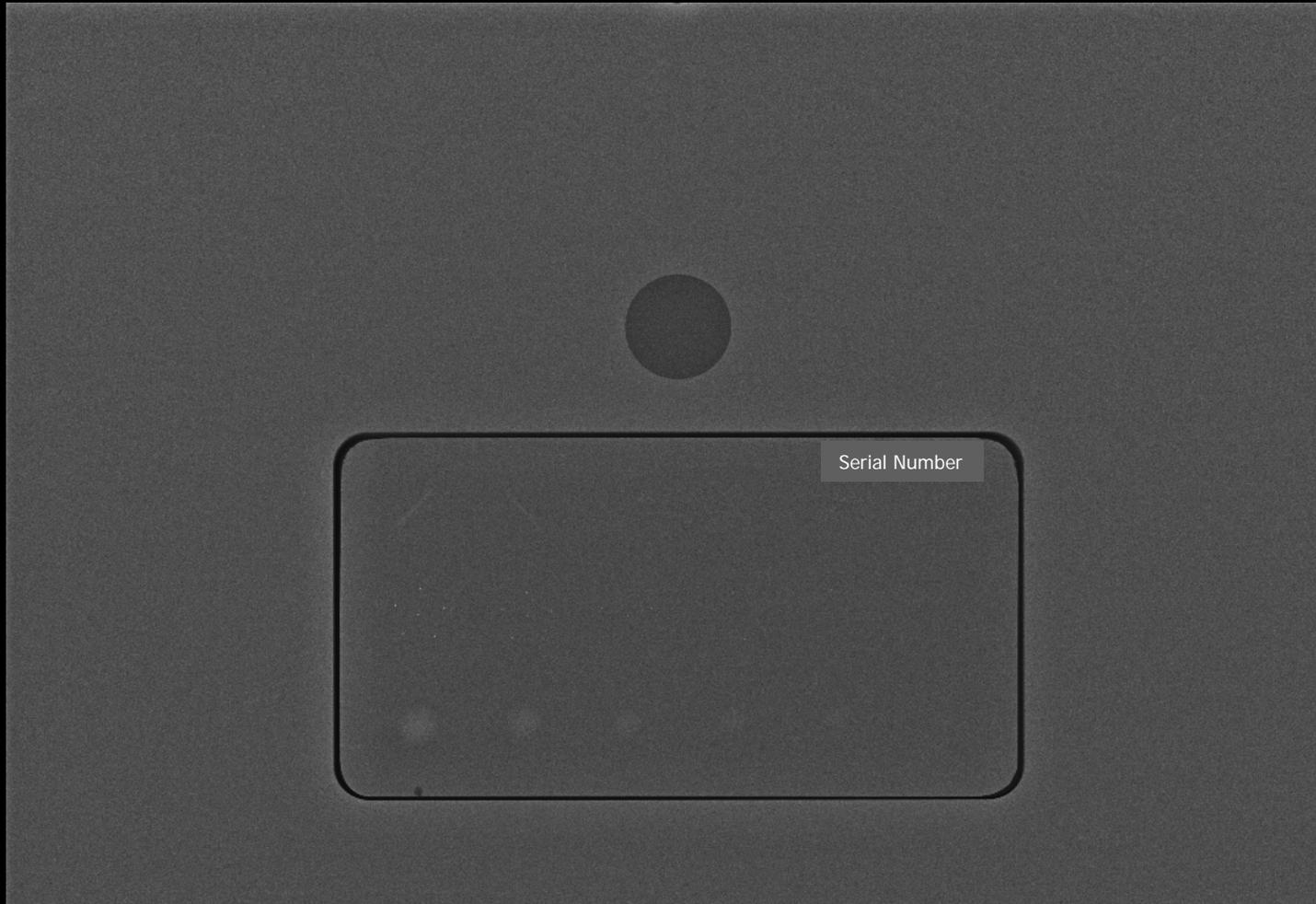


Image of Entire Phantom



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

Expanded view of Wax Insert



Wax Insert

ZV 475



Expanded view of Wax Insert



Pass Criteria:

2 Fibers, 3 Specks, 2 Masses

Equivalent to SFM Phantom:

4 Fibers, 3 Specks, 3 Masses

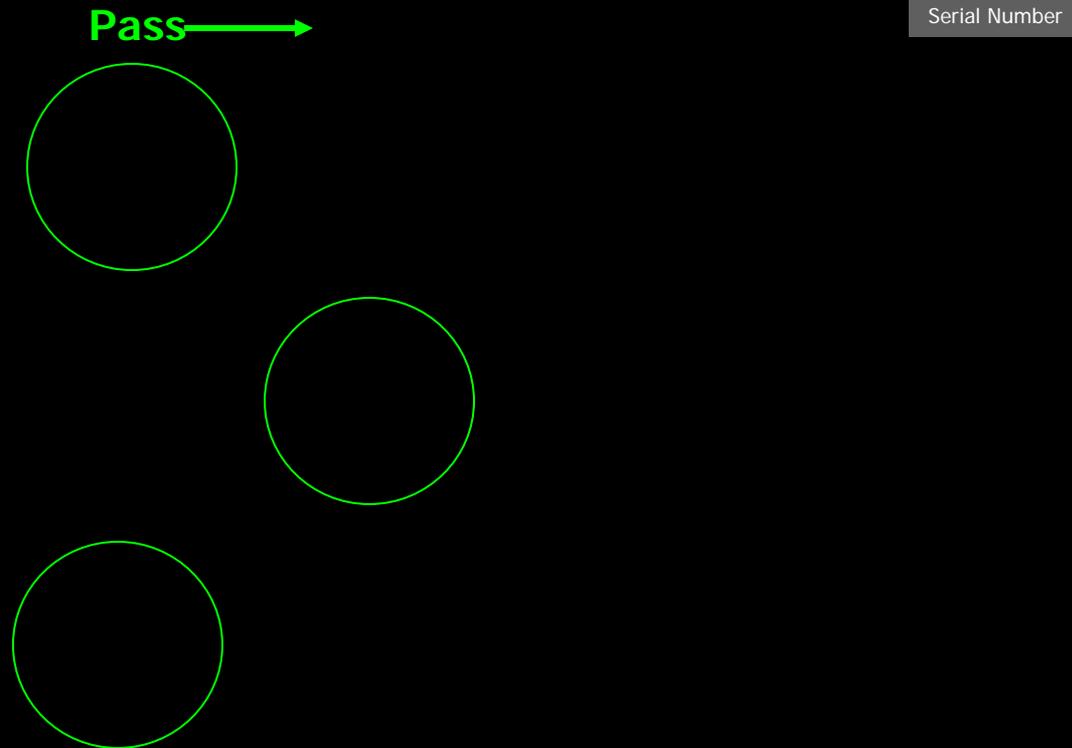


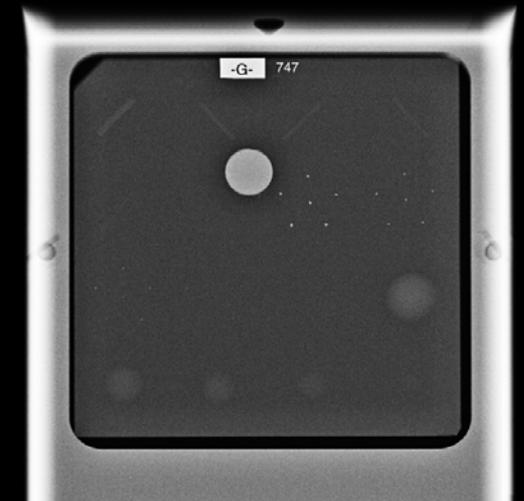
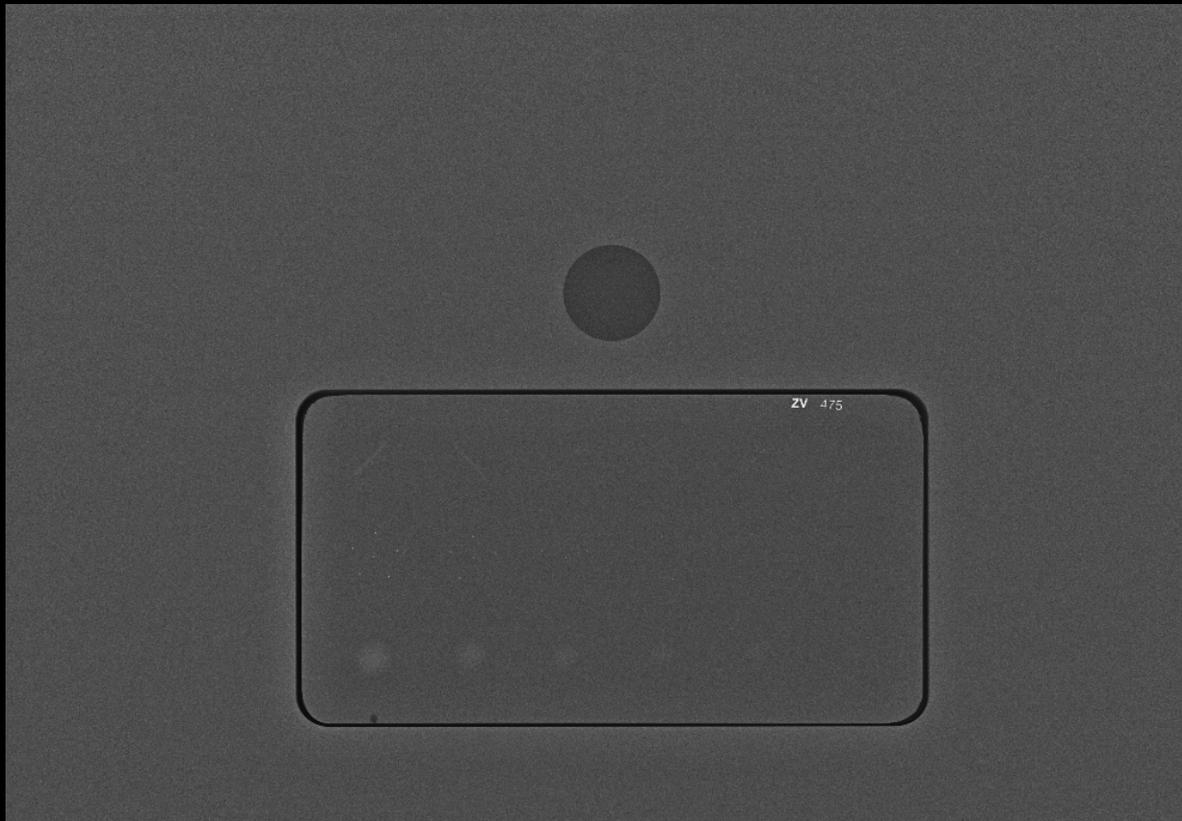
Image of Entire Phantom Prototype

CNR



The ACR FFDM Phantom Prototype

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.

The ACR FFDM Phantom Prototype

CR 24x30

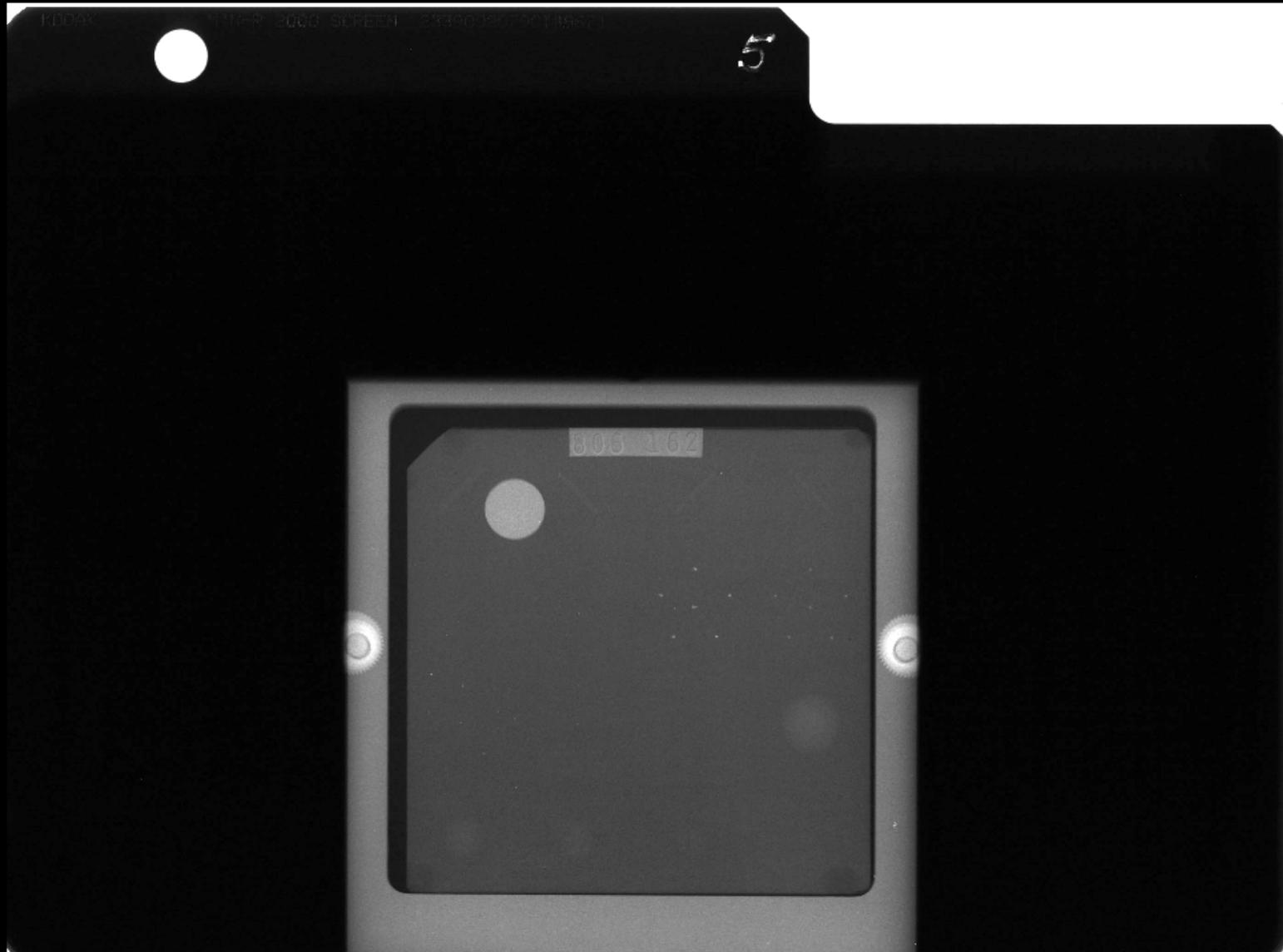
24X30

27KV@93MAS MO/MO



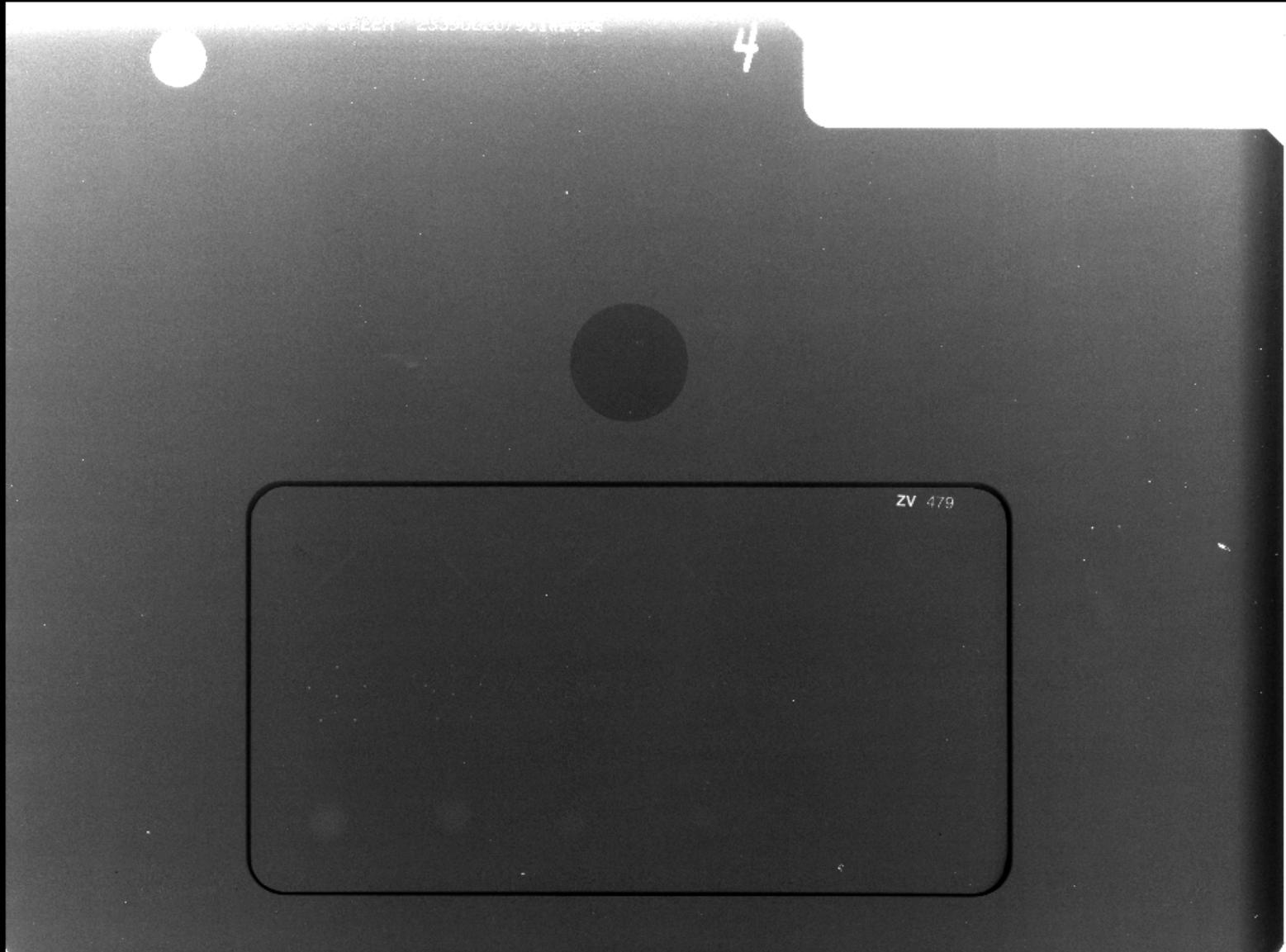
The ACR Prototype

Screen-Film 18x24



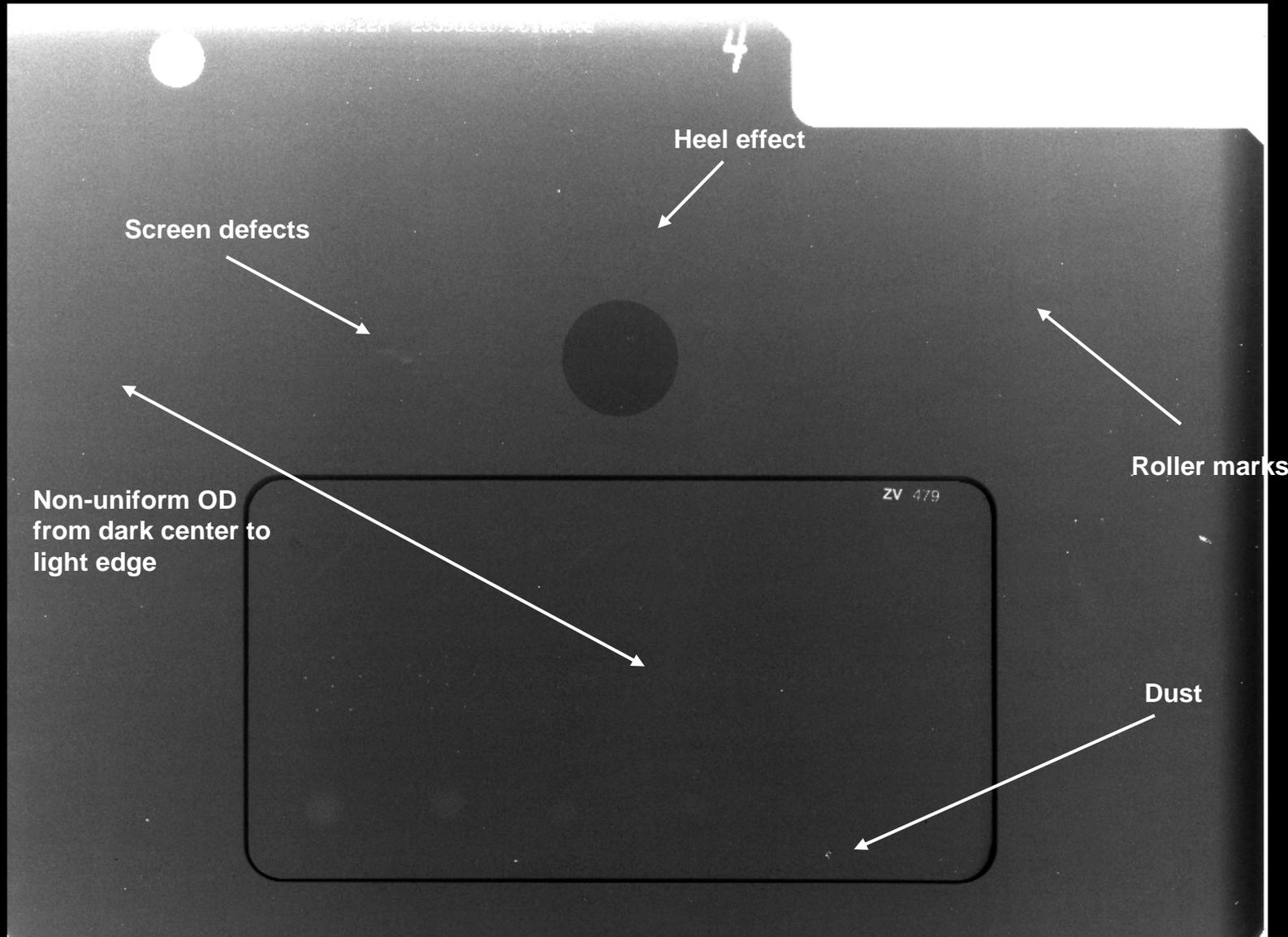
The ACR Prototype

Screen-Film 18x24



The ACR Prototype

Screen-Film 18x24



Manual Technique Signal Comparison

	Lorad – Mo	
Mode	Manual	
Phantom	FFDM Prototype	SFM
Target/Filter	Mo/Mo	Mo/Mo
kVp	29	29
mAs	65	65
Signal Wax	542.0	546.5
St. Dev. Wax	9.7	9.7

Design Summary

- Measurements using the FFDM Phantom

- Phantom used in

- 3 of 11 Tech tests

50% Tech Tests

- 12 of 24 Tech sub-tests

- 7 of 17 Physicists tests

41% Physics Tests

- 19 of 48 Physicist sub-tests

ACR Digital QC Draft Manual

- Benefits of Prototype Phantom Design
 - Provides view of entire detector – artifact evaluation
 - W/L optimized for test objects optimizes for artifact eval
 - Finer gradations of test objects
 - Test objects go to smaller sizes
 - AGD measurement & limit same as SFM – Meets MQSA
 - Provides single image/exposure for evaluation(s)
 - Minimal training (~ 25,000 Techs currently trained)
 - Provides basis for monitor and laser printer QC
 - ACR Physics Reviewers
 - Can see scores and artifacts on single submitted film (or image)
 - Do not need different WW/WL settings

Challenges

- Accounting for, and incorporating, all the different FFDM technologies
- Handling offsite equipment
- Predicting and accounting for future FFDM systems
- Ensuring all necessary tests are included, meaningful, and relevant

What's Next

3 Steps

- When ready, draft will be sent to manufacturers, FDA, and select reviewers for preliminary feedback
- Subcommittee to review comments and edit manual
- Final draft to be sent to FDA from ACR to apply for alternative standard under current regulations
 - Alternative standard will allow facilities to use this instead of the manufacturer's manuals
 - Potential for ACR QC Manual to be basis for new MQSA Regulations

Preemptive Questions

- Cost of phantom?
 - Don't know. Reason to believe it will be affordable.
- Implementation and roll-out?
 - ACR to develop a plan to include some sort of training.
- When?
 - Preliminary review December 2011/Jan 2012

End of Presentation

Questions?