



Fluoroscopy-Interventional Acceptance and Acceptability Testing

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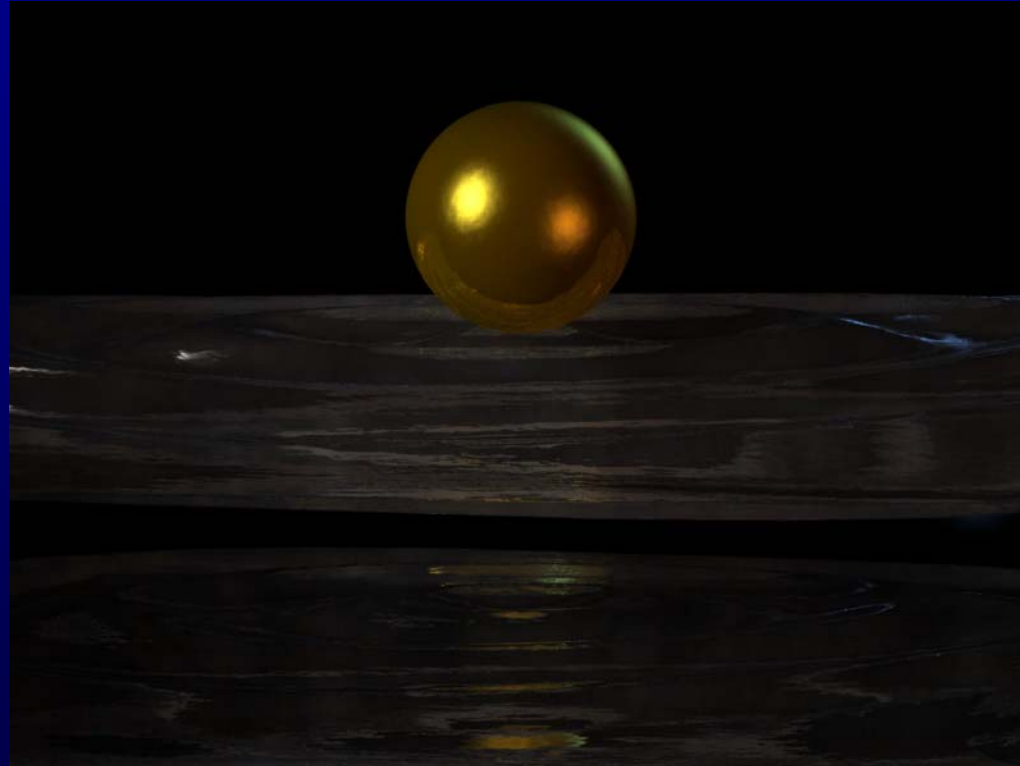
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Disclosures

Nothing to disclose





Acceptance Testing

- Is the room and its equipment legal?
- Does the equipment meet its manufacturer's specifications?
- Does the equipment fulfill all contractual requirements?
- Are required informatics interfaces functional?





Commissioning

- Most systems have extensive capabilities.
 - Delivered with many sets of procedure specific “factory” settings.
 - Default settings for x-ray and display factors vary widely depending on selected procedure.
 - OEM applications staff often “tune” settings “to meet facility clinical requirements” after acceptance testing is completed.
- Is the equipment properly configured for its intended clinical uses?
 - What are the actual configuration settings?





Acceptability for clinical use (QA)

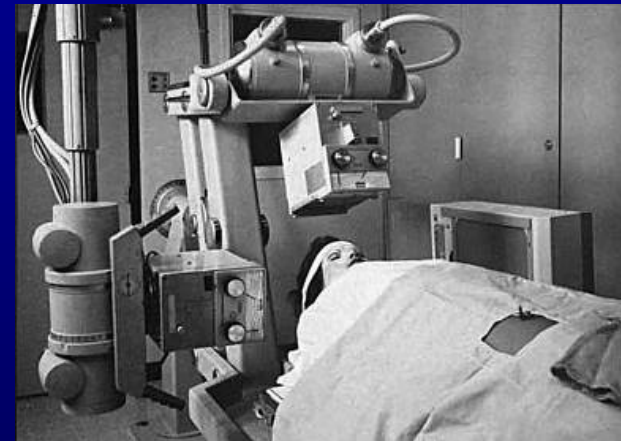
- Is the room and its equipment legal?
- Are there any safety issues?
- Current clinical use
 - Dose the medical physicist understand the actual clinical use of this system?
 - Does the current configuration of the equipment correspond to current clinical use?
 - Is the radiation production justifiable?
 - Is image quality acceptable?





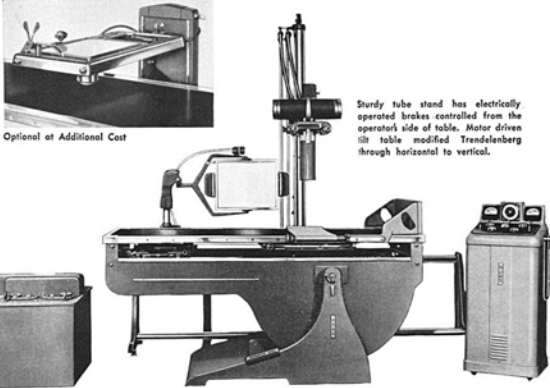
Traditional QA tests

- Essentially AAPM Report 4 [1977]
 - Based on then installed base of equipment
- Representative equipment c 1970
 - Manual control of equipment settings
 - **Automatic film processors**
 - Some filter slots were exposed
 - Mostly (small format) image intensifiers
 - Mirror or analog video viewing
 - Acquisition via some form of film
 - External (larger) film-changers
- Much regulatory QA is still based on this or earlier equipment



Equipment c 1970

SCHOLZ 2 IN 1 SPOT FILM DEVICE
 Features a fluoroscopic screen 8 1/2 x 8 1/2 inches. Has automatic cassette shift—fast, smooth, positive. Counterbalanced tower has single lever control for free travel and compression or positive locking in both directions. Foolproof mechanism—double exposures are impossible.



Optional at Additional Cost

Sturdy tube stand has electrically operated brakes controlled from the operator's side of table. Motor driven table modified Trendelenberg through horizontal to vertical.

- FULL WAVE RECTIFIED • 200 ma. at 100 P.K.V.
- AUTOMATIC MILLIAMPERE SELECTION • AUTOMATIC KILOVOLT DROP COMPENSATION • IDEAL WAVE FORM



ANGIO WARM UP RAD 1 RAD 2 FLURO BUCKY 1 BUCKY 2 ULTRA HIGH KV HIGH LOAD STEREO

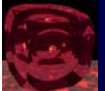
RADIOGRAPHIC TIMER

FLURO MA FI DENSITY

FLUROSCOPIC TIMER FLUROSCOPIC KV

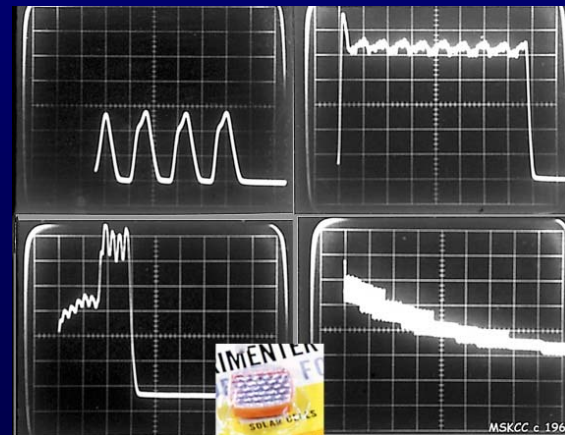
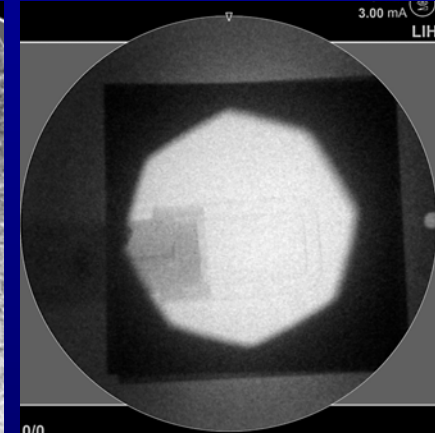
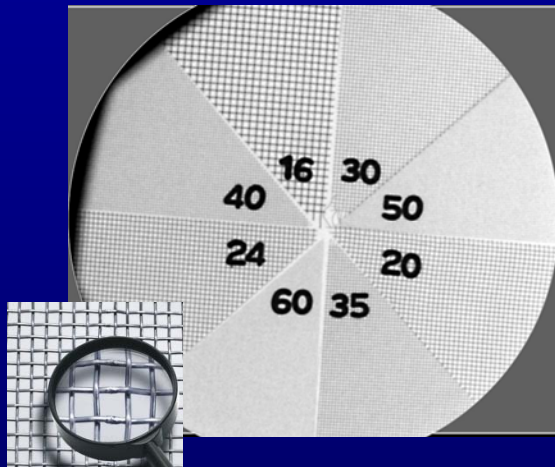
DELRAY

TECHNIQUE





Tools c 1970





Extracts from AAPM-4

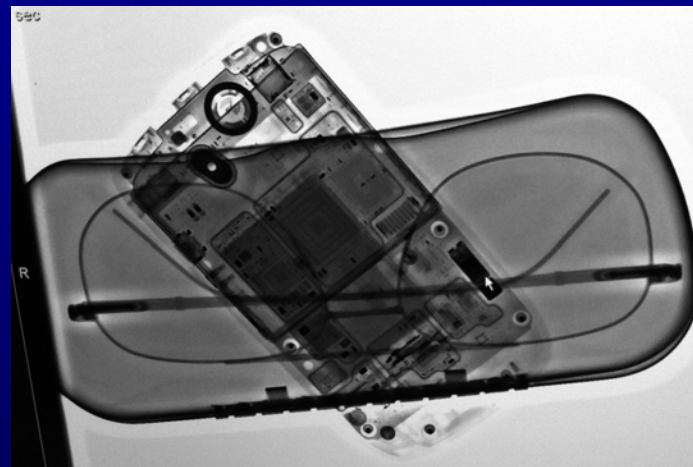
- Document designed to set up a viable QA program with minimal expense
 - technologist supervised by medical physicist.
- HCR & Focus:
 - Mesh placed close to the face of the image amplifier system.
- LCD:
 - Place the two 3/4in aluminum plates with the penetrameter plate between them on the support stand or rods.
- Outputs:
 - Image receptor to table top = 20”
 - Month to month stable ± 5 kVp with 38 mm Al.
 - Less than 10 R/min with Pb.





NYS Guide (2004) – Other States similar

- QA Manual & records
- Standard output data
- Collimator
- Fluoro 5 min timer
- Exposure rates
- Spatial resolution
- Low contrast performance
- Half-Value Layer



A Basic Quality Assurance Program for Small Diagnostic Radiology Facilities.
FDA 83-8218.





2012 Fluoroscope

- CsI based flat-panel detector
 - Few new image-intensifiers
(for middle to high end systems)
- All imaging via the same digital channel.
- Clinical mode technique selection
 - Functionality determined by software.
 - May not have manual adjustment of x-ray factors/filtration.
- Many have clinical outputs $> 1 \text{ Gy/min}$
- Mandatory dose indicator displays





2012 Test Equipment

- Ionization chamber systems
- Solid-state detector systems
- Non-invasive kV meters
- Resolution bar patterns
- Aluminum contrast phantoms
- Leeds tools (mainly in Europe)
- Early tools for digital IQ analysis





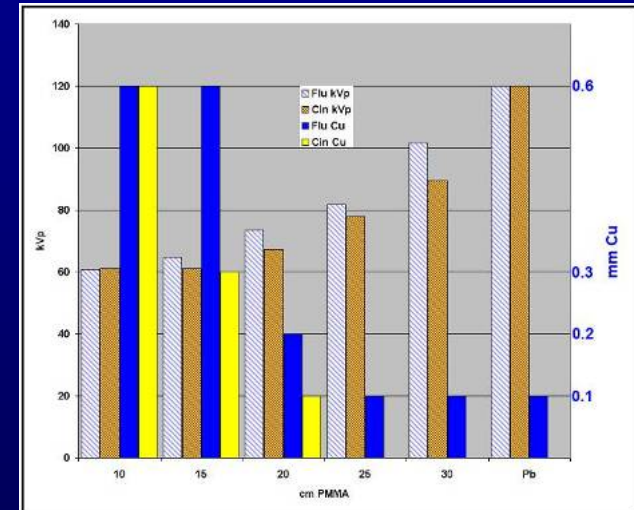
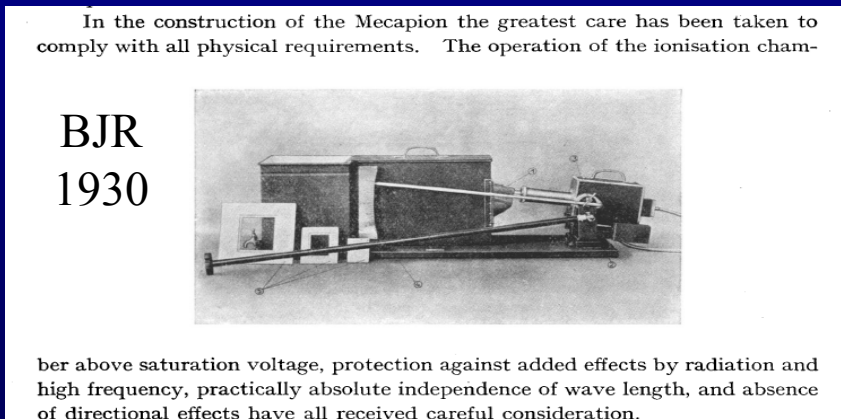
2012 Fluoroscope Beam Quality

- Many systems add Cu or similar filters
 - Variable thickness as a function of mode
 - Thickness may be controlled by ADRC
 - Filter changers fail.
- kV and filter programmed to maximize Iodine contrast
- Systems with variable filters tend to reduce filter thickness as kV increases.
- See report of AAPM TG-125 for details



Energy response of test equipment

- National laboratory calibration beams are typically based on a Tungsten target, usually filtered with modest thickness of Aluminum.



- Instruments can have unpredictable response if the actual spectrum is substantially different than the calibration spectrum.



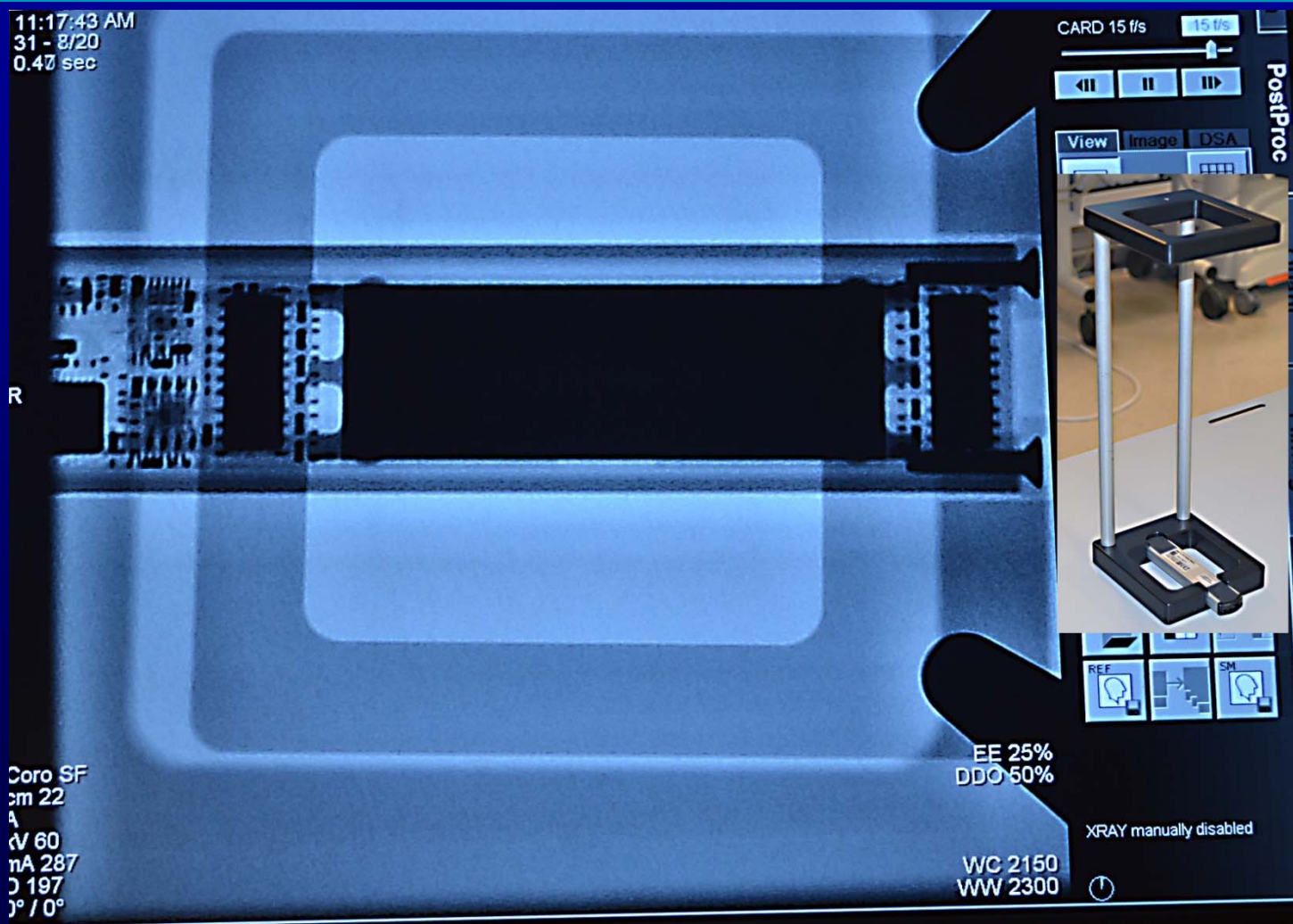
Measuring field effects

- Fluoroscopes operating under ADRC define a fraction of the maximum active image receptor area as the measuring field.
- Using too small a working field size can confuse the measuring field.
- Instruments in (or near) the measuring field often influence results.





Too much in the measuring field





No worldwide protocols are available

- IEC has withdrawn its acceptance and constancy test standards
 - *Least common denominator testing is inappropriate for advanced systems.*
 - Wide country to country variability in philosophy and regulations.
- RP-91 [162] defines suspension criteria (EU)
- Requirements for all fluoroscopes (US & EU)
 - No fluoroscopic screens
 - Five minute timer required
 - Integrated radiation display required





More information and protocols are in:

- AAPM Reports
 - 04 Basic DX QA [1977]
 - 15 DSA [1985]
 - 60 DX Instrumentation [1998]
 - 70 Cath Lab Performance [2001]
 - TG-125 ADRC [2012]
- IPEM Report 91
 - Routine performance testing of DX [2005]
- EU RP- 91 [1997] (162 {2012})
 - Acceptability and suspension criteria.





Additional protocols and information

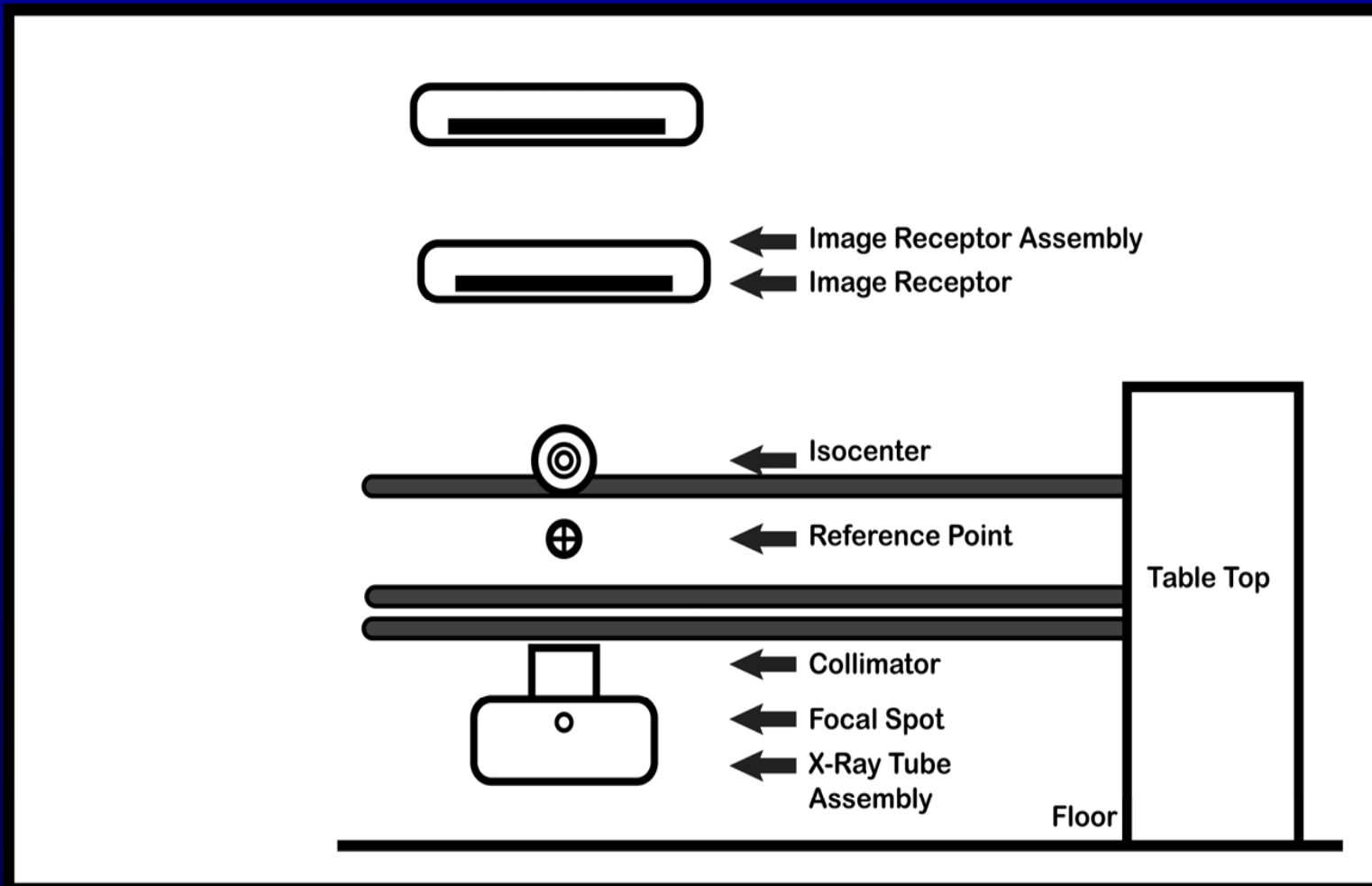
- IAEA Materials
- NCRP Reports
- FDA Regulations and Guidance
- State Regulations
- CRCPD Materials
- Scientific Literature
- Manufacturers' IFU

There are inconsistencies ! ! !





Sample IFU geometry





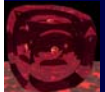
Sample IFU dosimetry



Description	Setup
Anti-scatter grid	in position
Distance focal spot to entrance surface of the phantom	960 mm (37.80 inch)
Distance focal spot to image receptor	<ul style="list-style-type: none"> 1195 mm (47.04 inch) frontal 1310 mm (51.57 inch) lateral
Distance focal spot to interventional reference point	660 mm (25.98 inch) frontal and lateral
Distance focal spot to isocenter	<ul style="list-style-type: none"> 810 mm (31.88 inch) frontal 765 mm (30.12 inch) lateral
Measuring device	Unfors Mult-O-Meter with sensor placement in X-ray beam, outside the systems measuring field (see figure 2.1)
Patient support	out
Phantom	Rectangular block(s) of PMMA, total thickness 200 mm (7.87 inch), sides equal to or greater than 250 mm (9.84 inch)
Single shot exposure	after radioscopy (stabilized kV/mA)
Wedge filter	de-selected
X-ray beam orientation	<ul style="list-style-type: none"> Rotation: 90° LAO Angulation: 0° CAUD

Selectable modes of Operation for Radiography			Reference Air Kerma [mGy/frm]		
			Receptor format in cm		
			Frontal Plane		
Procedure	Patient type		25	20	15
Left Coronary 15 fps	Default		0.207	0.275	0.339
Left Coronary 30 fps	1		0.046	0.064	0.084
Right Coronary 15 fps	2		0.078	0.099	0.120
Right Coronary 30 fps	3 to 5		0.125	0.168	0.209
User selectable modes of Operation for Radioscopy			Reference Air Kerma [mGy/s]		
			Receptor format in cm		
			Frontal Plane		
Application	Mode	Patient type	25	20	15
Cardiac	Low	Default	0.263	0.360	0.465
Cardiac ECO Dose	Normal		0.549	0.727	0.936
Cardiac Special	High		0.758	0.994	1.220

Patient type	
1	Baby <5 kg
2	Child 5-15 kg
3	Child 15-40kg
4	Very small 40-55 kg
5	Small 55-70 kg
6	Normal 70-90 kg
7	Large >90kg





MITA QA mode under development

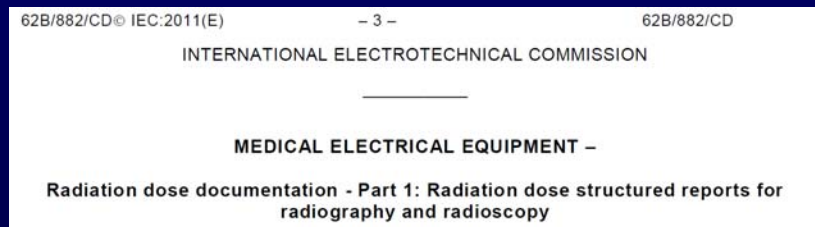
- A MITA standard is under development that will provide physics test support.
 - Manual control of factors
 - Configuration documentation
 - Access to digital images for QA
 - Ability to enter dosimetric factors (\pm).
- Prudent safety limitations will always apply.



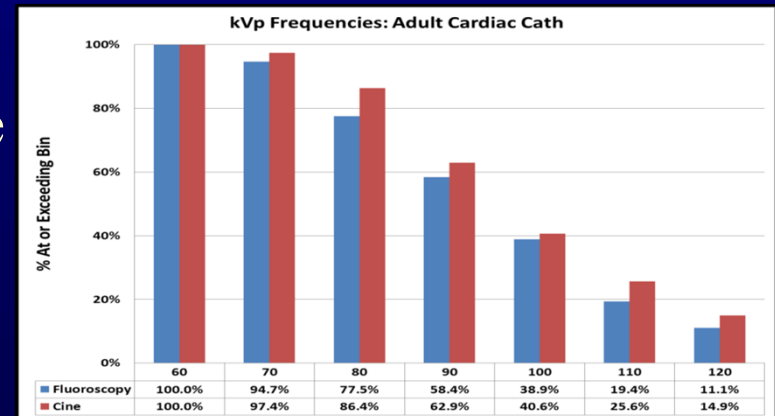


Radiation Dose Structured Report

- Increasing availability on new interventional systems in 2012
- Summary and detailed data included
- QA uses
 - Actual factors while testing
 - Documentation of clinical use



Committee Draft (CD) out for comments





My routine testing outline

- Visual safety inspection
- Doors, interlocks, warnings, paperwork
- Operational mechanical performance
- Configuration check
- Monitor performance
- Image receptor uniformity
- Beam alignment and confinement
- “Table top” outputs and SID tracking
- Integrated dose indicators
- Low contrast detectability
- Bar pattern resolution including focal-spot effects.





Most used mode(s)

- Testing should be limited to the specific lab's most commonly used clinical mode(s)

1 CARD 3040	Coro 3040 15 F/s	LV 3040 15 F/s	Coro 3040 Log 15 F/s	IC Stent 15 F/s	10 DSA Body	Body 1 1 F/s	Body 2 2 F/s	Body 4 4 F/s	Single Single
		FL - 3040 15 P/s	FL 3040 15 P/s	FL+ 3040 10 P/s				FL - Angio 7.5 P/s	FL Angio 10 P/s
2 CARD 3040 CTO	Coro CTO-SF 15 F/s	LV 2020 cto 15 F/s		IC Stent 15 F/s	11 LD DSA Body	CARE Body.1 1 F/s	CARE Body.2 2 F/s	CARE Body.4 4 F/s	CARE Single Single
		FL - CTO 10 P/s	FL CTO 15 P/s	FL + CTO 10 P/s				FL - Angio 7.5 P/s	FL Angio 10 P/s
3 CARD EP	Coro 2020 15 F/s	Coro LD 10 F/s	Coro 3040 15 F/s	IC Stent 15 F/s	12 DSA Special	DSA 7.5 7.5 F/s	DSA long 2 F/s	DSA Venous 4 F/s	DR ACQ 2 F/s
		FL - EP 7.5 P/s	FL EP 7.5 P/s	FL+ EP 10 P/s				FL - Angio 7.5 P/s	FL Angio 10 P/s
4 CARD DSA	Coro 2020 15 F/s	LV 2020 15 F/s	Card DSA 30 F/s	DSA 3 3 F/s	13 DSA Chest	Pulmonalis 4 F/s	Selective 2 F/s		Single Single
		FL - Card 15 P/s	FL Card 15 P/s	FL+ Card 10 P/s				FL - Angio 7.5 P/s	FL Angio 10 P/s
5 CARD HDR	Coro HDR 15 F/s	LV HDR 30 F/s		Card-Spin 2.5 *F	14 Neuro	Arch 4 F/s	Carotid 4 F/s	Vertebral 4 F/s	Single Single
		FL - HDR 15 P/s	FL HDR 15 P/s	FL + HDR 10 P/s				FL - Neuro 7.5 P/s	FL Neuro 10 P/s





Acceptance & Post Repair

- ❖ Match with specifications and PO
- ❖ Electrical and mechanical safety
- ❖ Radiation protection survey
- ❖ Attenuation of table and mattress
- ❖ Half-value-thickness
- ❖ Image receptor input dose rate
- ❖ Configuration
- ❖ IT support





Seldom

- Kilovoltage accuracy
 - Limited or no user-level access to primary x-ray controls
 - Non-invasive kV meters may be inaccurate due to spectral mismatch
- DSA
 - AAPM 15 [1985] – Many analog components then.
- Scatter field around table
 - Annual testing provides no new information.





Housekeeping

- Use stored fluoro whenever available
- Archive all stored images to PACS
 - Store full quality data if this is supported.
 - Standard archive settings may degrade the matrix size, bit depth, or both.
- Digital camera documentation during testing can be helpful
 - Where system thinks collimators are compared to actual x-ray field (caution – electronic shutters)
 - Safety issues





Monitor Performance

- All monitors using integrated SMPTE.
 - May need service level to access pattern.
- Visual inspection is usually sufficient
 - Monitor at default.
 - 0-5% & 95-100%
 - Steps visually OK
 - LC resolution seen
 - Minimal video noise or artifacts.

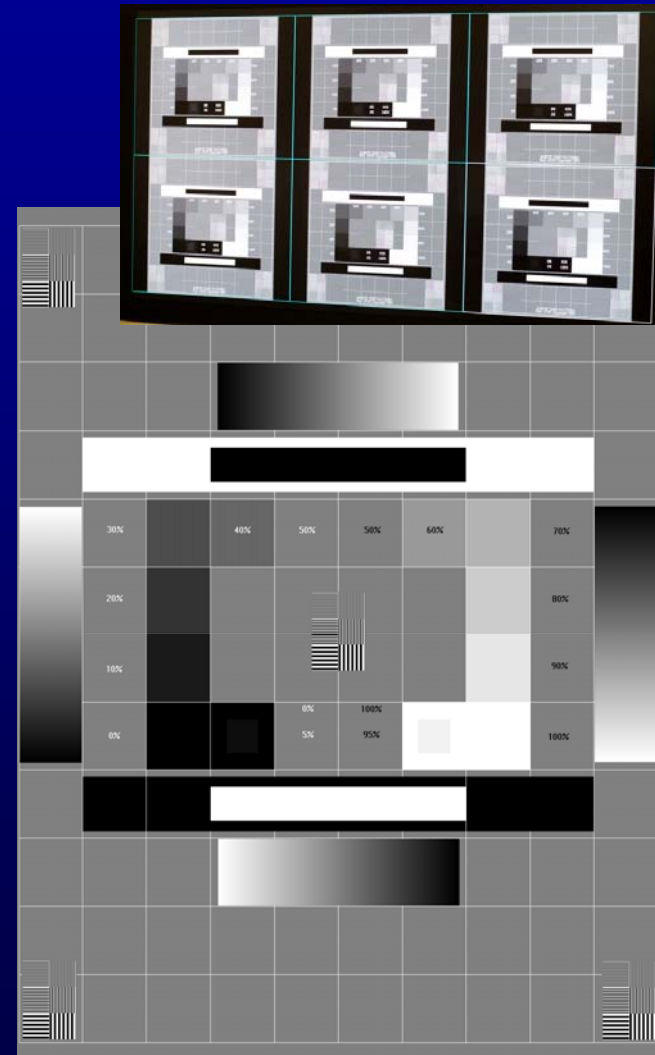




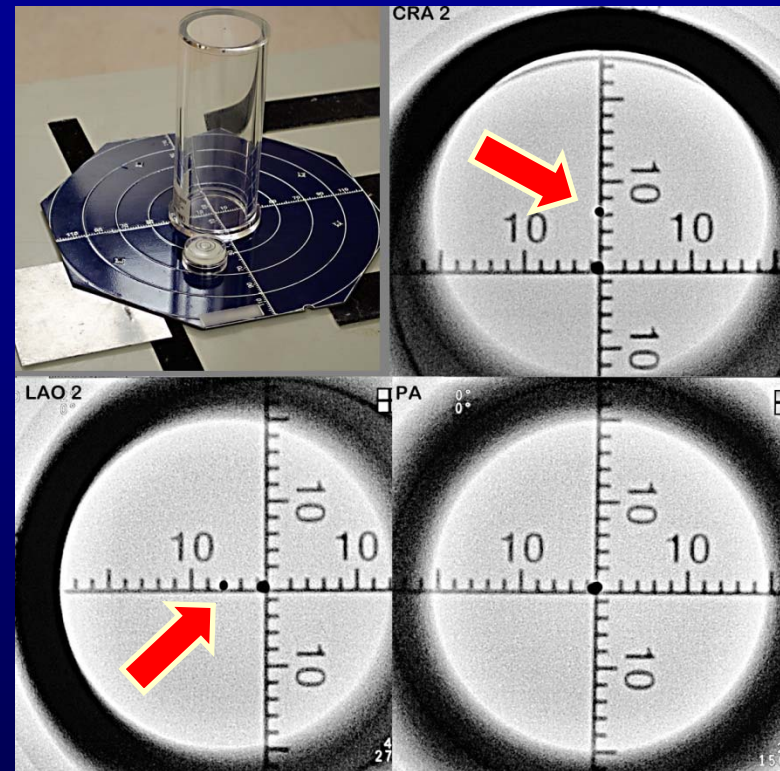
Image Receptor Uniformity

- Minimize material in beam path
- Grid is in place
- Maximum SID
- Load 38 Al at tube
- Acquire and save for all modes (ADRC)
- Non-uniformity?
 - Visual evaluation
 - Use window and level



Beam Alignment

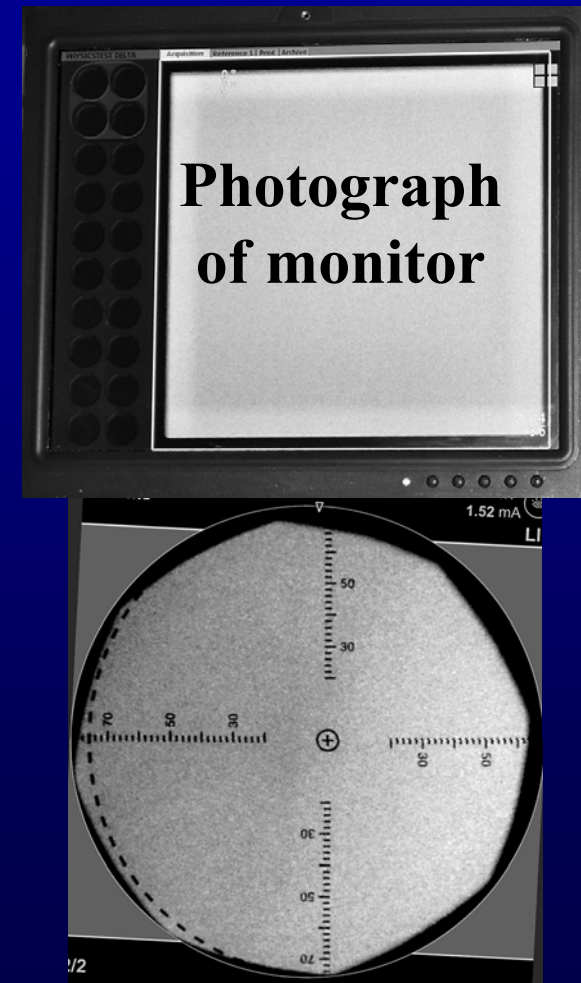
- Table height as for dose measurements
- Gantry set to 0°
- Maximum SID
- Small FOV
- Level test tool
- Pan table until markers align
- Evaluate marker position.





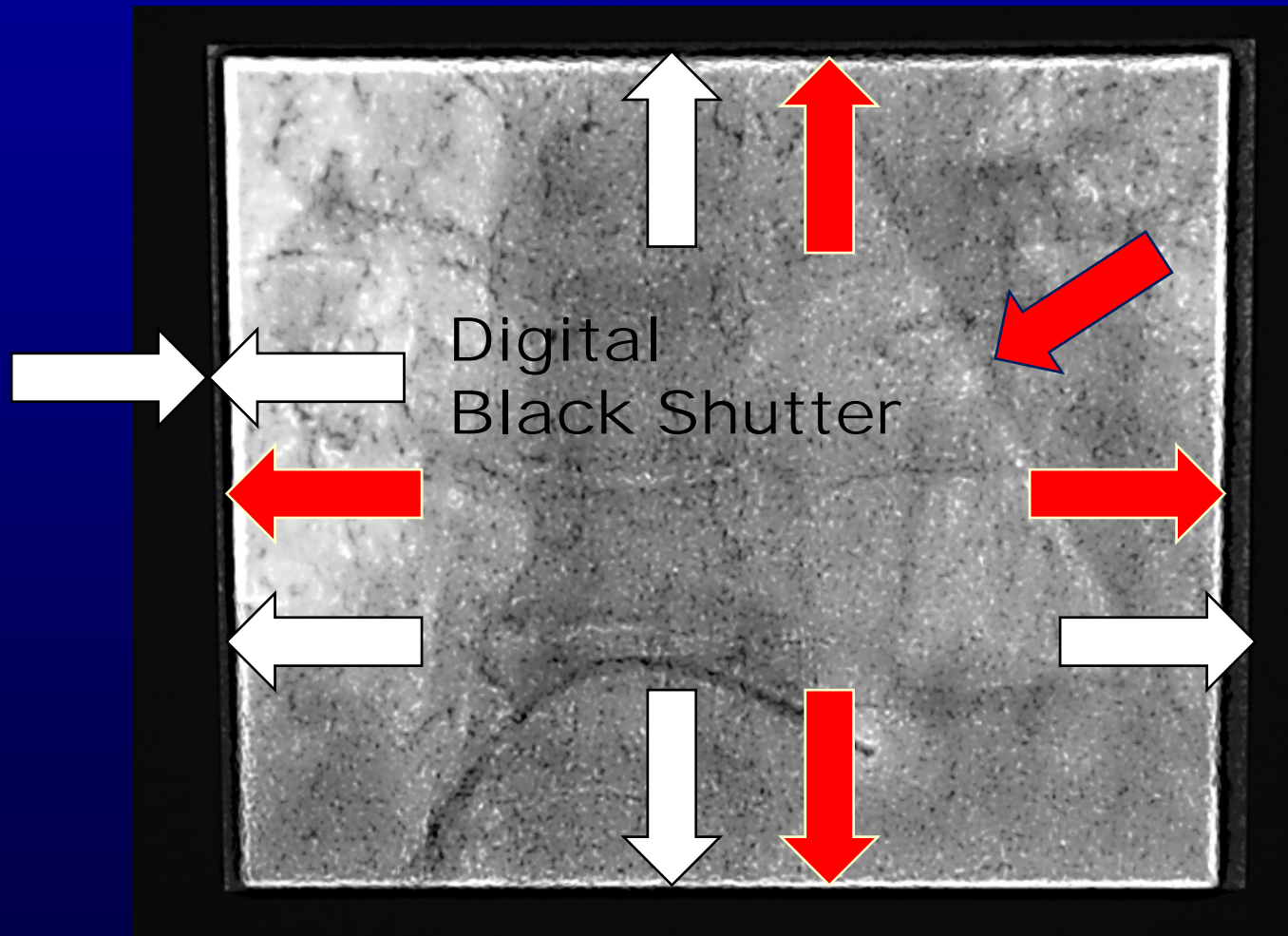
Beam Confinement

- For each FOV.
- Min & max SID
- Unirradiated margin visible on all sides?
- If not, use ‘film’ and markers to simultaneously document the visual and radiation fields.
- Evaluate with FDA criteria





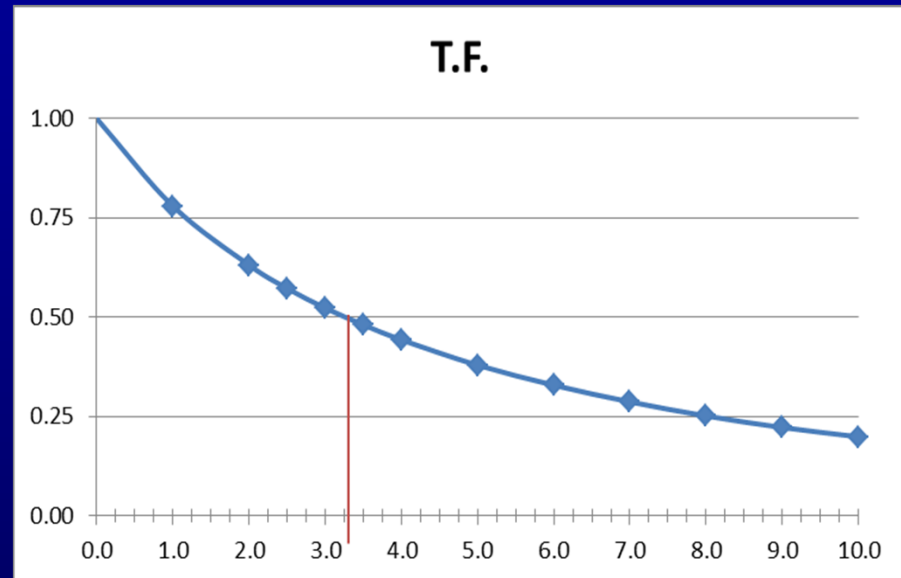
Clinical beam confinement





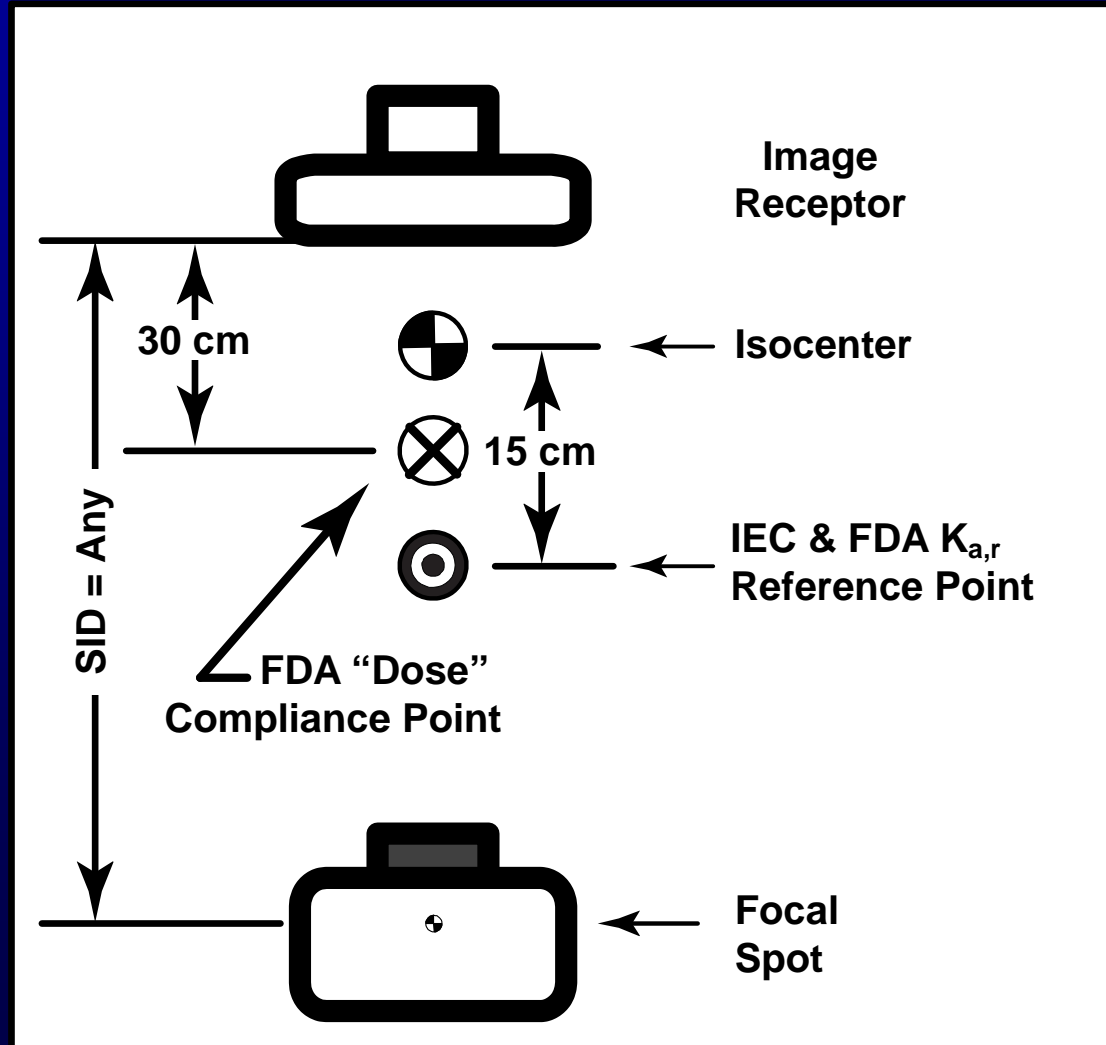
Half-value thickness (when needed)

- All removable attenuators out
- Maximum SID
- Fixed 80 kVp, mAs
- Measure TF in steps to $< 20\%$
- Graphically determine first HVT
- Compare to IEC/FDA regs. (Minimum HVL 2.3 mm Al)





Reference point locations (IEC/FDA)





'Table top' outputs 1

- Test with most common clinical mode(s)
- Minimum SID
- Appropriately position detector
- 30 cm from detector to image receptor surface
- Collimate to smallest field size that does not perturb measuring field.





'Table top' outputs 2

- Low scatter geometry
- Test all FOVs
- Test both fluoro and acquisition
- Attenuators (NYS list)
 - 19 mm Al (for peds use)
 - 38 mm Al
 - 38 mm Al + 0.5 Cu
 - 38 mm Al + 2.0 mm Cu
 - Lead (if possible) or 38 mm + 10 mm Cu



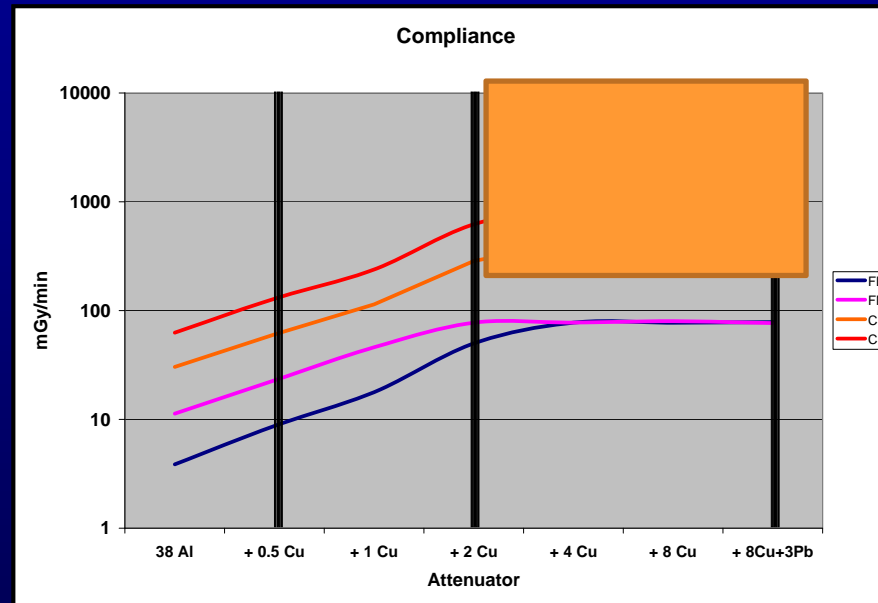
EU





'Table top' outputs 3

- Important to test acquisition modes at full output



- NOTES

- Develop your own process to collect dose-rate data when the generator 'hunts'
- FDA limits may only be applicable with the table out of the beam.

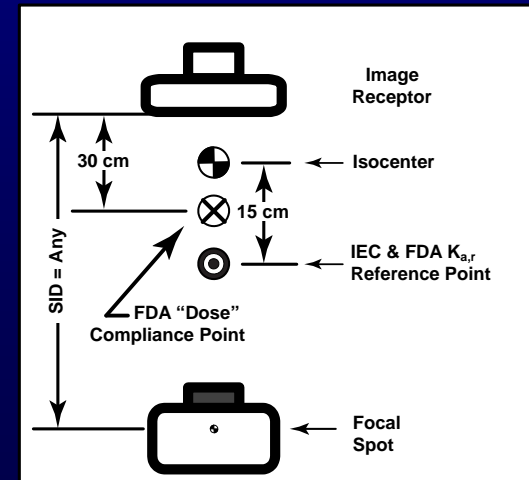




'Table top' outputs 4: SID tracking

- For a C-arm, FDA limits are defined 30 cm in front of the IR at any SID
- Additional measurement at maximum SID
 - Do not move detector
 - FOV large enough to see the detector at max SID
 - All fluoro modes
 - Acquisition mode

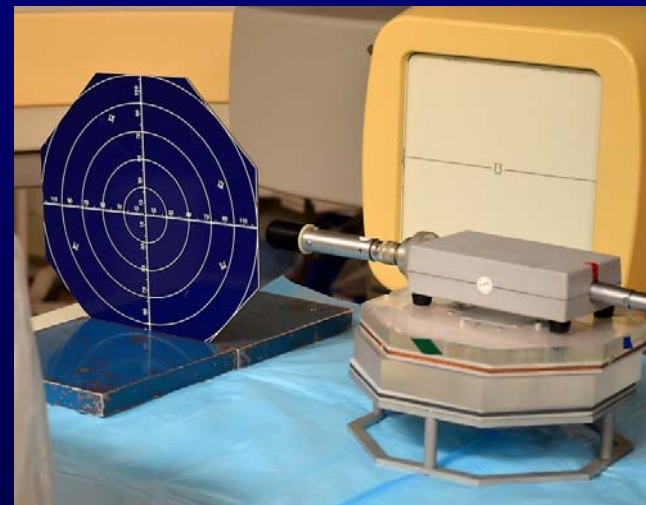
SID	86	117
Fluoro (N)	70	
Cine	1700	





Integrated 'dose' displays 1 (TG-190)

- Obtain focus to isocenter distance.
- Place detector at isocenter.
- 4 mm Cu at IR
- Table out of beam
- Medium FOV
- Collimate well inside
- Test both fluoro and acq.
- Accumulate $\sim 50 - 100$ mGy on integrated display

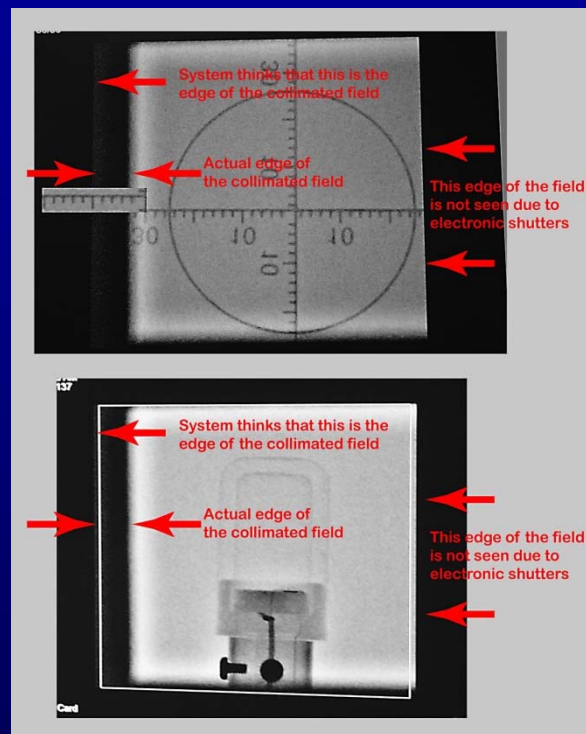




Integrated 'dose' displays 2

- Without touching collimator
- At isocenter: replace x-ray detector with field-size plate
- Record image of field-size plate using system.
- Measure field-size (at isocenter) using stored image shown on system monitor.

CAUTION – Digital Shutters



Above is not acceptable because all four sides of the beam are not seen





Calculations

- Integrated dose at the reference point

$$R_{\text{measured}} = M_{\text{mGy@iso}} \left(\text{SID} / (\text{SID} - 15) \right)^2$$

- Air Kerma Area Product

$$\text{KAP}_{\text{measured}} \cong M_{\text{mGy@iso}} * \text{Field Size}_{\text{iso}}$$

- Factors

$$f(R) = R_{\text{measured}} / R_{\text{system}}$$

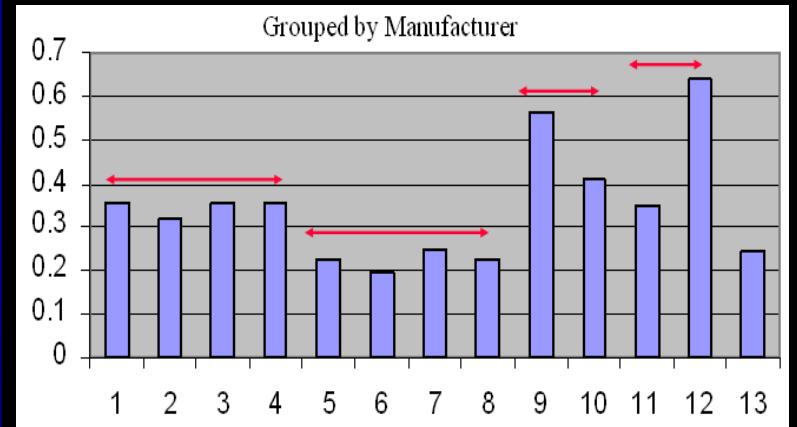
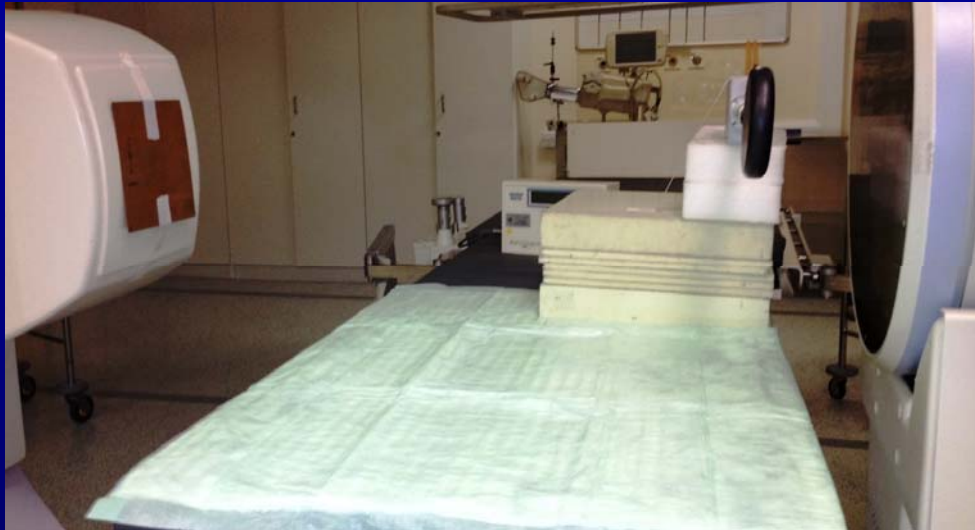
$$f(\text{KAP}) = \text{KAP}_{\text{measured}} / \text{KAP}_{\text{system}}$$

- Factors (IEC/FDA) $\pm 35\%$





Detector AK rate data – cont. Fluoro mode



EU Input Receptor Entrance Rates		
Range:	0.2 – 0.65μGy/sec	EU DIMOND project
Majority:	0.2 – 0.4μGy/sec	Dowling et al, 2004
Note IPEM remedial 1 μGy/sec; suspension 2 μGy/sec		





Experimental setup for detector \pm grid



Mode	μGy	Frames	nGy/f
FLU	25.6	157	61
	22.9	137	62
	23.7	143	62
CIN	75.3	61	460
	78.5	62	471
	76.1	61	462





Image Quality Testing

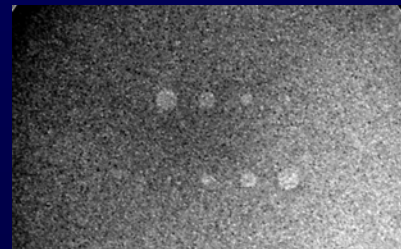
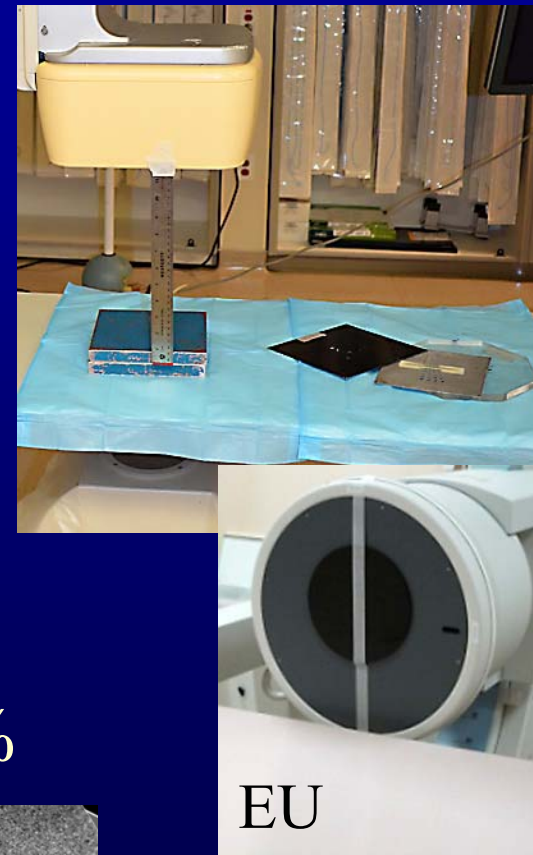
- Primarily visual observations
 - Test monitors (SMPTE) before testing IQ
 - Manage room lighting during evaluations
 - Expect improved/better digital image based tools by the end of the decade.
- All observations should be made under dynamic conditions
 - Stored fluoroscopy should be used whenever available
- Digital or optical magnification is helpful when evaluating images





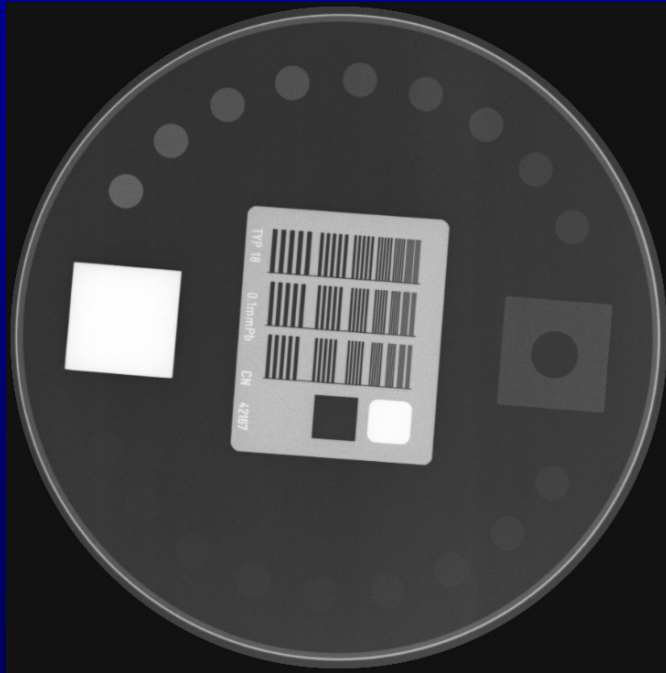
Low Contrast Detectability: 1

- Standard phantom
 - 1/32in, Al target plate
3/32in, 1/8in, 3/16in, 1/4in
 - 19 or 38 mm Al Base
4%, 2 % physical contrast
- Placed at nominal dosimeter geometry.
 - Some test at IR face
- CsI based systems seldom fail @ 2 %





Low contrast tools



Leeds TOR 18FG QA



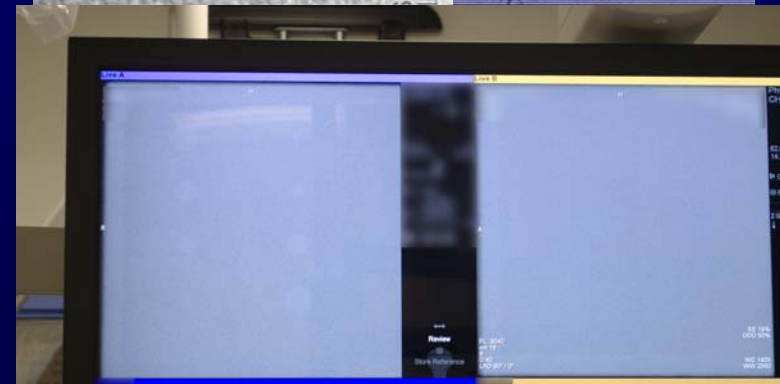
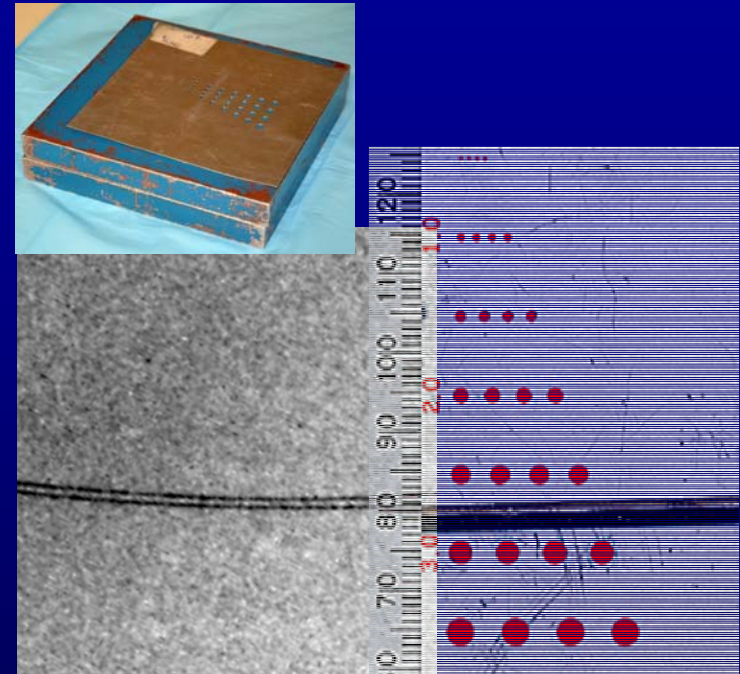
Leeds TO16 threshold contrast
detail detectability





Low Contrast Detectability: 2

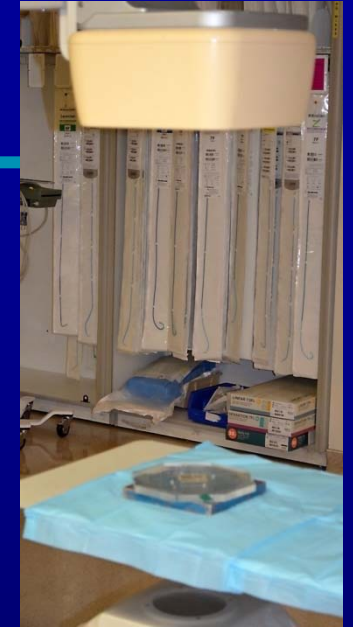
- Custom phantom
 - 0.5 Al
 - Holes 5.0 – 0.5 mm
 - 38 mm Al base
 - Physical contrast 1.3%
- Same geometry.
- Good viewing conditions !
- Usually 3.0 mm or smaller
 - 1.0 mm sometimes in fluoro
 - 1.0 mm almost always in cine
 - Partial volume effect





High Contrast Bars: 1

- Standard phantom
 - Thickness 0.1 mm Pb
 - 19 mm Al attenuator
- Geometry
 - Placed at nominal dosimeter geometry (NY requirement).
 - Many test at IR face
- Bars at 45° to matrix
 - Consistent orientation of phantom



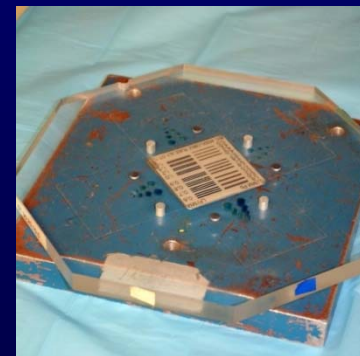
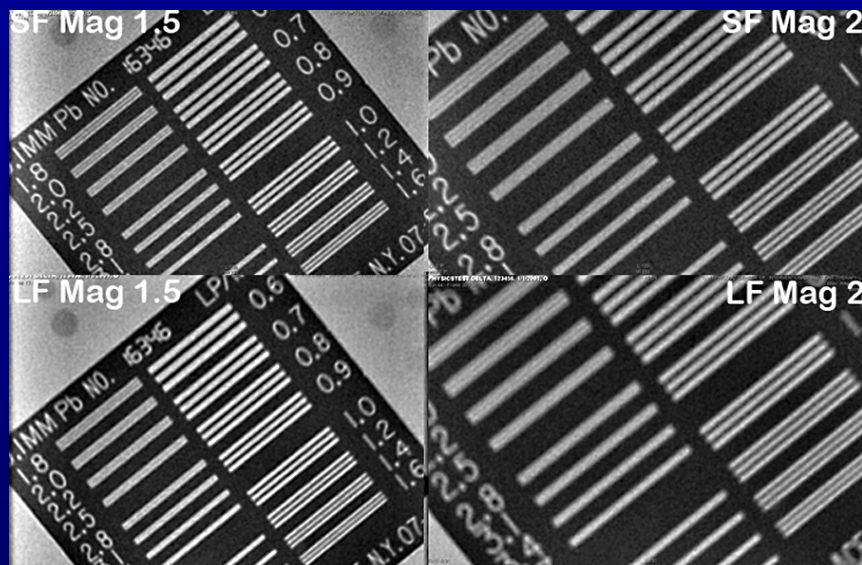
EU





High Contrast Bars: 2

- Test all focal-spots
- Test all FOVs
- Test at minimum and maximum SID
- Rotate phantom 90° and repeat with small FOV at min & max SID.
 - Provides an impression of focal-spot asymmetry





High Contrast Bars: Influences

- Magnification
 - II resolution scaling with FOV only applicable when pattern is on II input surface
- Image receptor
 - FP may use the same pixels for all FOVs
 - FP may ungroup pixels for small FOVs
- Image matrix
(caution when evaluating PACS images)
- Display characteristics
- Image processing algorithms
- Observer's visual system

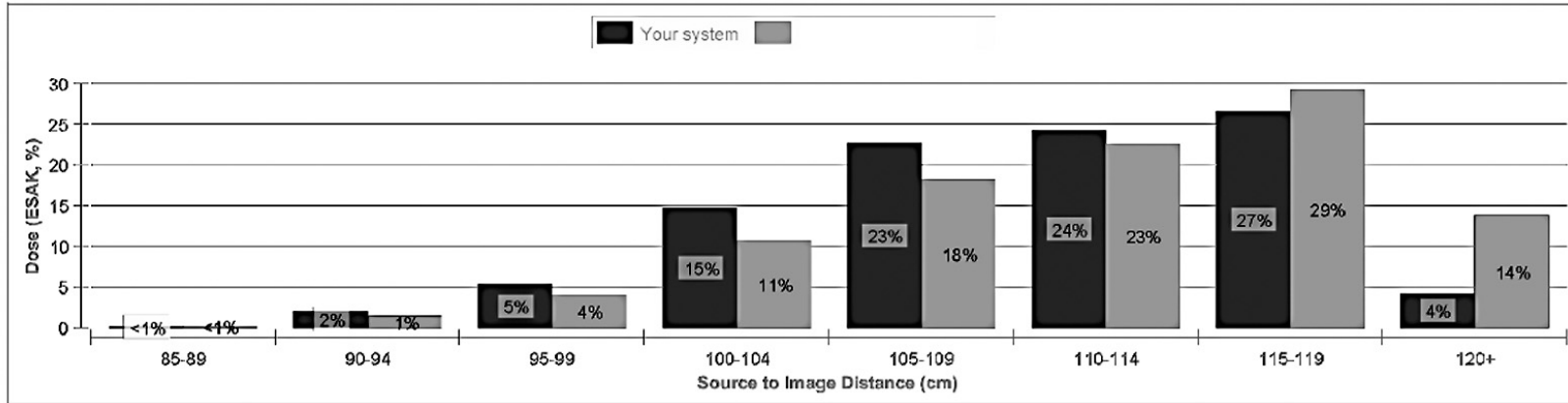




SID Matters

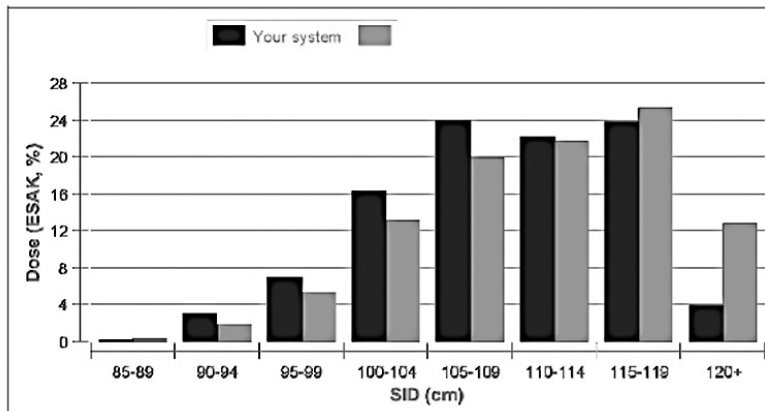
Source to image distance benchmark

Sample size N=641



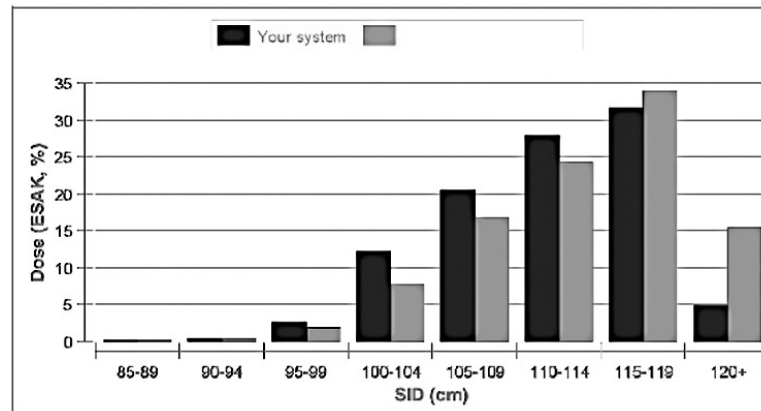
Fluoro

Sample size N=641



Cardiac

Sample size N=597



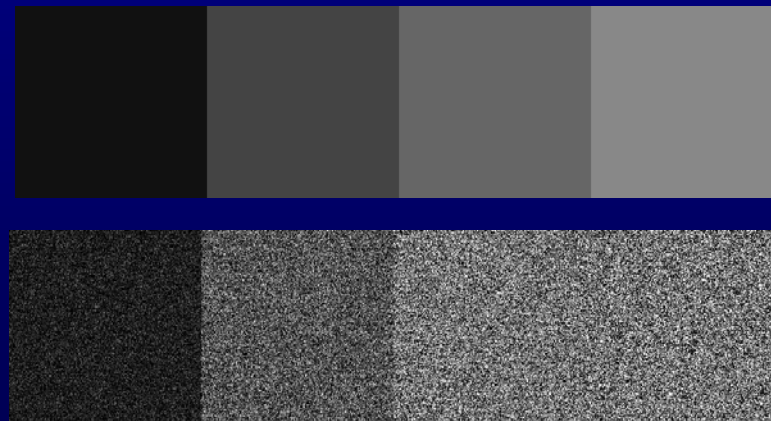
SAD on this system = 72 cm





DSA using noiseprint

- What will happen if either of these images (of the same “stepwedge”) is subtracted from itself?



Photoshop modeling



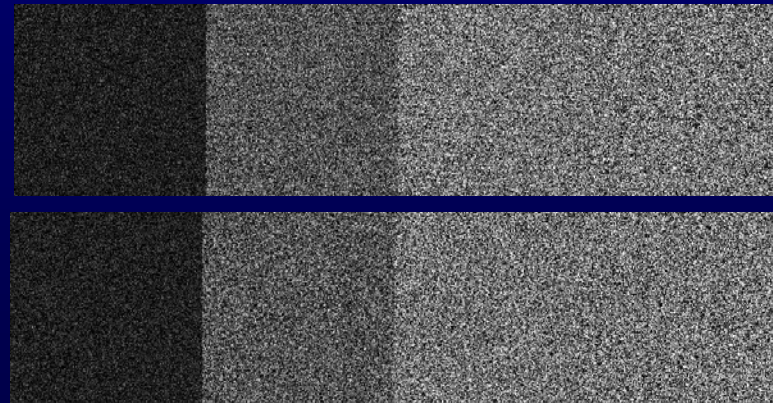


DSA using noiseprint

- Subtracted image(s)



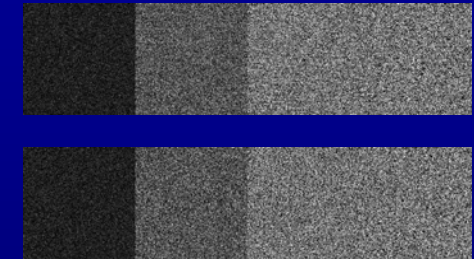
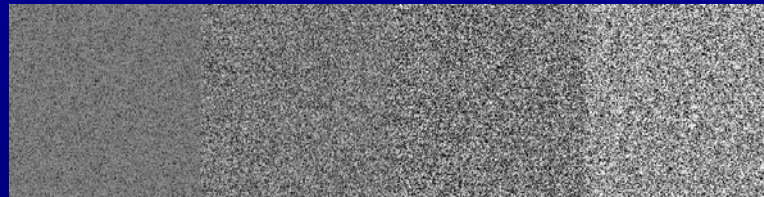
- Subtract two separate images of the same stepwedge?



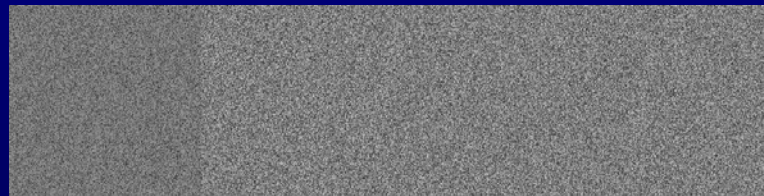


DSA using noiseprint

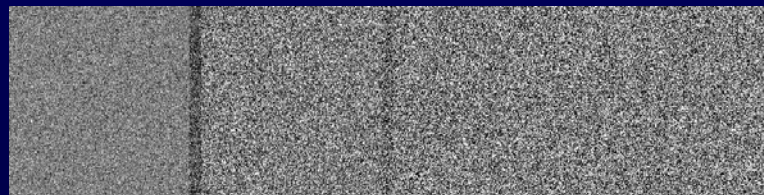
- If quantum limited:



- If non-quantum noise dominates:

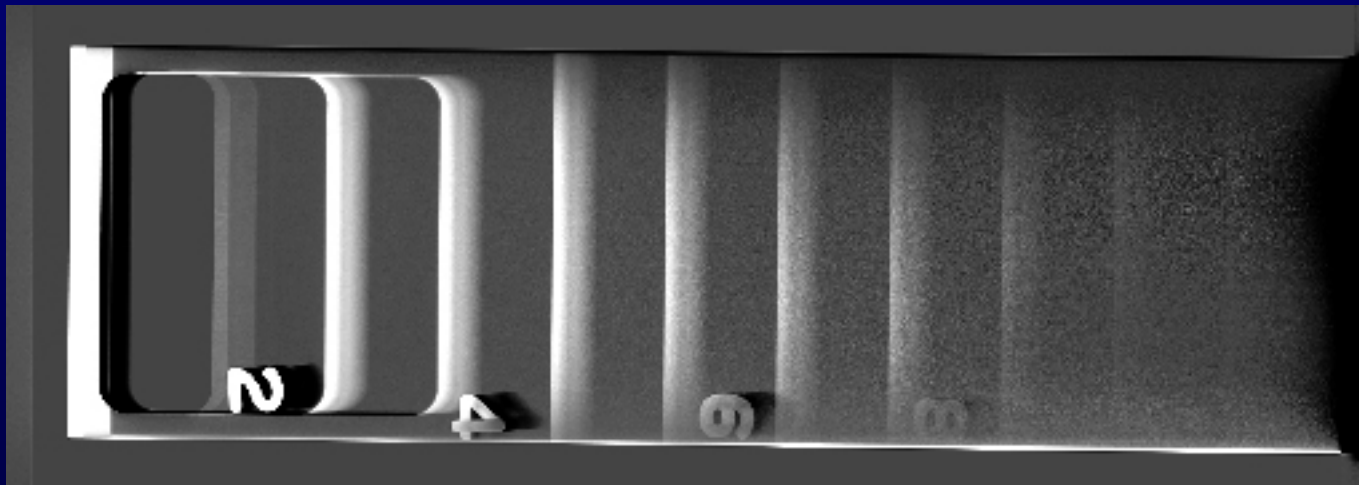


- If quantum limited and not registered:





Sample fluoroscopic images





Notes

- Modern feedback-controlled systems are remarkably stable over years.
- Additional testing should be performed any time key components are serviced
 - Outputs, HVL, Confinement, Resolution?, Dose Meter?
 - Generator, x-ray tube, or collimator service
 - High & Low Contrast characteristics
 - Image receptor, or configuration service
- Configuration files
 - After service or application visits



