Patient Dose and the Modern Angiographic System

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Educational Objectives

- Review fluoroscopic dose quantities
- Understand the operation of kerma-area product meters
- Learn how to verify the accuracy of integrated dosimetry systems in fluoroscopy equipment
- Understand how to measure phantom entrance air kerma rates
- Review factors that affect fluoroscopy dose rates and image quality

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Motivation

- Display and recording of patient dose for fluoroscopically-guided interventional (FGI) procedures allows for:
  - Avoidance of skin injury
  - Determination of whether skin injury may occur
  - Compliance with regulations in many states
- Measurement of dose to standardized phantoms allows for:
  - Determination of integrated dosimetry accuracy
  - Optimization of dose rate settings for clinical use

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Motivation

U.S. Department of Health & Human Services www.hhs.gov

FDA U.S. Food and Drug Administration A-Z Index Search

Home | Food | Drugs | Medical Devices | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Radiation-Emitting Products | Tobacco Products

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Home > Radiation-Emitting Products > Radiation Safety > Radiation Dose Reduction

Radiation Safety
Radiation Dose Reduction
Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging

Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging

Like all medical procedures, computed tomography (CT), fluoroscopy, and nuclear medicine imaging exams present both benefits and risks. These types of imaging procedures have led to improvements in the diagnosis and treatment of numerous medical conditions. At the same time, these types of exams expose patients to ionizing radiation, which may elevate a person's lifetime risk of developing cancer. As part of a balanced public health approach, the U.S. Food and Drug Administration (FDA) seeks to support the benefits of these medical imaging exams while minimizing the risks.

Through the *Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging*, FDA is advocating the universal adoption of two principles of radiation protection: appropriate justification for ordering each procedure, and careful optimization of the radiation dose used during each procedure. Each patient should get the right imaging exam, at the right time, with the right radiation dose.

In support of this goal, FDA will use our regulatory authority and also collaborate with others in the Federal government and the healthcare professional community to:

1. Promote safe use of medical imaging devices;
2. Support informed clinical decision making; and

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Fluoroscopic Dose Quantities

- Air Kerma
  - Kerma accumulated in air at a specific point
- $K_{a,i}$ – incident air kerma *
  - Units: gray (Gy)
  - Without backscatter

* ICRU Report 74, "Patient Dosimetry for X Rays Used in Medical Imaging", 2005.

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Air Kerma

- $K_{a,r}$ – total air kerma at the reference point
  - Value is the total accumulated during a procedure
  - Reference point is approximate location of patient's entrance surface
  - Defined relative to the fluoroscopy gantry by IEC (2000 and 2008) and FDA (2009)

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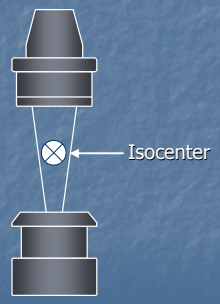
C-arm Reference Point Location

- 15 cm from isocenter toward x-ray tube
- Note that a manufacturer may specify a different reference point location



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Other System Reference Point Locations

- Undertable x-ray tube:
  - 1 cm above the tabletop
- Overtable x-ray tube:
  - 30 cm above tabletop
  - X-ray tube in lowest position possible
- Lateral type:
  - 15 cm from table centerline toward x-ray tube
  - X-ray tube in closest position

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Air Kerma-Area Product

- P_{KA} - Air kerma × x-ray beam area
  - Units: Gy-cm^2
  - Value is the total accumulated during a procedure
  - Without backscatter
  - Beam area is determined in a plane perpendicular to the central beam axis
  - Variations in air kerma over the beam area are averaged

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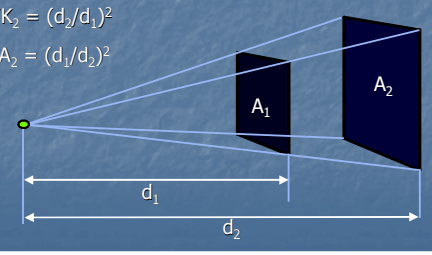
Air Kerma-Area Product

- P_{KA} is the same value at any distance from the x-ray source

$K_1/K_2 = (d_2/d_1)^2$

$A_1/A_2 = (d_1/d_2)^2$



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Peak Skin Dose

- $D_{skin,max}$ – Dose to the most highly-irradiated local area of skin, includes backscatter
- Corrections needed to estimate $D_{skin,max}$ from $K_{a,r}$:
  - Backscatter
  - Actual source-skin entrance distance
  - Table and pad attenuation
  - Mass attenuation coefficient ratio air: tissue
  - Account for movement of the x-ray beam
  - Addl. discussion in Tues,Thurs R/F CE sessions

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Regulations: FDA

- 21 CFR Part 1020.32: Performance standards for ionizing radiation emitting products. Fluoroscopy equipment. (2009)
- For fluoroscopes manufactured after June 2006:
  - Display of $K_{a,r}$ (mGy) and $K_{a,r}$ rate (mGy/min) at the operator's working position
  - Note P_{KA} is not required

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Regulations: IEC

- IEC 60601-2-43: Particular Requirements for the Safety of X-Ray Equipment for Interventional Procedures (2000) and 2nd edition (2010)
  - Display of $K_{a,r}$ (mGy) and $K_{a,r}$ rate (mGy/min) at the operator's working position
  - Display of P_{KA}
    - need not be at the operator's working position

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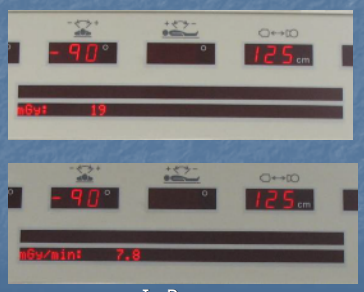
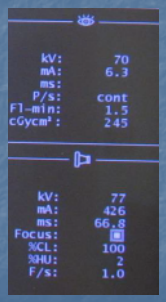
Example Integrated Dosimetry Displays



In Room



On control console

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DICOM Dose Structured Report

- Includes fields for dosimetry system information

Supplement 94: Diagnostic X-Ray Radiation Dose Reporting (Dose SR)
Page 19

5	>>	HAS CONCEPT MOD	CODE	EV (113724, DCM, "Dose Measurement Device")	1-n	M		DCID (10010) Dose Measurement Devices
6	>>	CONTAINS	DATETIME	EV (113723, DCM, "Calibration Date")	1	M		
7	>>	CONTAINS	NUM	EV (113722, DCM, "Calibration Factor")	1	M		Units = EV (1, UCUM, "no units")
8	>>	CONTAINS	NUM	EV (113721, DCM, "Calibration Uncertainty")	1	M		Units = EV (%, UCUM, "Percent")
9	>>	CONTAINS	TEXT	EV (113724, DCM, "Calibration Responsible Party")	1	M		
10	>	CONTAINS	NUM	EV (113722, DCM, "Dose Area Product Total")	1	M		Units = EV (Gym2, UCUM, "Gym2")
11	>	CONTAINS	NUM	EV (113725, DCM, "Dose (RP) Total")	1	M		Units = EV (Gy, UCUM, "Gy")
12	>	CONTAINS	NUM	EV (113726, DCM, "Fluoro Dose Area	1	MC	IFF TID(10003) Row 3 value = (P5-00000, SRT	Units = EV (Gym2, UCUM, "Gym2")

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Kerma-Area Product Units

- Be aware that the units for P_{KA} from integrated dosimetry systems vary with manufacturer and software revision:
  - mGy-cm^2
  - µGy-m^2
  - cGy-cm^2
  - dGy-cm^2
  - Gy-cm^2
  - mGy-m^2
- IEC 60601-2-43 2nd edition specifies Gy-cm^2

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Integrated Dosimetry Methods

- Various methods for determining $K_{a,r}$ and P_{KA} are in use:
  1. P_{KA} meter with calculation of $K_{a,r}$ from area determined by known collimator positions
  2. P_{KA}-$K_{a,r}$ dual chamber meter
  3. Calculation of $K_{a,r}$ from kVp, mA(s) and pre-determined air kerma output values, with calculation of P_{KA} from known collimator positions

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P_{KA} Meter

- Transmission, parallel plate ionization chamber
- Not visible in the image
- Transparent to allow for light field use

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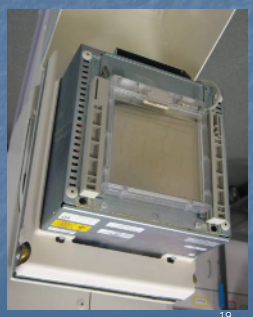
P_{KA} Meter

- Mounted on collimator housing
  - Since P_{KA} is the same at any distance from the x-ray source
- Covers the entire x-ray beam area



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P_{KA}-$K_{a,r}$ Dual Chamber Meter

- P_{KA} meter with a small air kerma measurement area in center
  - Mounted in the same manner
  - Air kerma value at the reference point is determined by inverse square distance correction
- Tracking of collimator positions not needed
- Measures $K_{a,r}$ at the center of the beam
  - Instead of beam average when exposure is not uniform

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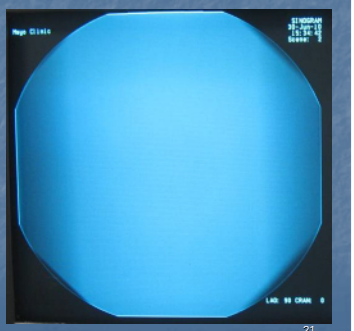
Use of Wedge Filters



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Use of Wedge Filters

- Wedge filters (equalization filters) are located in front of the P_{KA} meter
- Locations are typically not tracked like the collimator locations used to define the irradiated field size
- For integrated dosimetry using a P_{KA} meter, when wedge filters are used:
  - P_{KA} value is averaged over beam area
  - $K_{a,r}$ will be underestimated

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Integrated Dosimetry System Validation

- Laboratory conditions used to calibrate P_{KA} meters will vary from clinical conditions
  - Value is affected by scattered and extra-focal radiation, which vary with x-ray tube, P_{KA} meter position and x-ray energy
- Accuracy of integrated dosimetry systems should be verified under clinical conditions
  - Initially and after service affecting dose monitoring (e.g. P_{KA} meter or x-ray tube replacement)

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Integrated Dosimetry System Validation

- Method described here was adopted from the RAD-IR Study *
- RAD-IR study
  - Patient dose data was recorded for over 2,000 interventional radiology procedures over 3 years at 7 facilities with 16 imaging planes
  - Protocol developed to validate consistency and accuracy of P_{KA} and $K_{a,r}$ readout

* Balter et al, JVIR 2004; 15:909

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Materials

- PMMA attenuator blocks
  - At least 25 x 25 cm to fully cover the beam field of view at the image receptor
  - Sheets to make up 10, 20 and 30 cm thicknesses
- Field size measuring plate
- Ionization chamber dosimeter and holder
- Tape measure

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Dosimeter Selection

- Ionization chamber is recommended
  - Provides a flat energy response over a wide x-ray energy range
  - For solid state detectors with energy compensation, there are no NIST specified calibration beams that match the typical Cu-filtered interventional fluoroscopy beam

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Methods

- Determine the source-to-isocenter distance for the C-arm to be tested
  - From manufacturer's specifications or
  - Manually by positioning an object so that it is centered in both vertical and horizontal projections of the C-arm
- Note that isocenter locations vary, e.g.
  - Siemens Artis and Philips Allura : 75 cm
  - Multistar: 80 cm, Siemens Artis Zee: 78.5 cm

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Methods

- Determine the location of the reference point for the C-arm to be tested
  - From the manufacturer's specifications or
  - Assume the FDA/IEC definition of 15 cm from isocenter toward the x-ray source

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Methods

- Position the C-arm horizontally
  - Use maximum SID
  - 30 cm PMMA next to image receptor on the tabletop
- Position the field size measuring plate
  - Perpendicular to and centered on the central beam axis and
  - At the reference point

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Methods

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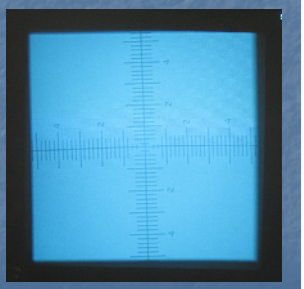
Methods

- Select the medium FOV mode and collimate to an approximately 10 x 10 cm field
- Record the actual field dimensions to determine irradiated area



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Methods

- Remove the field size measuring plate and place the dosimeter probe at the reference point location

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Methods

- Record initial P_{KA} and $K_{a,r}$ readings
- Fluoro using dose accumulate mode on dosimeter until accumulated air kerma is at least 100 mGy
- Record final P_{KA} and $K_{a,r}$ readings and calculate difference
- Multiply probe air kerma by irradiated area to determine probe air kerma-area product
- Compare probe readings with integrated dosimetry values for P_{KA} and $K_{a,r}$

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Methods

- Repeat air kerma measurement for cine or digital acquisition mode
- Remove 10 cm PMMA without moving the dosimeter probe
  - Repeat fluoro and acquisition dose measurements with 20 cm PMMA
- Remove 10 cm more PMMA and repeat

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Control Limits

- FDA(2009)
  - $K_{a,r}$ shall not deviate > ± 35% for > 100 mGy
- IEC(2000)
  - $K_{a,r}$ shall not deviate > ± 50% for > 100 mGy
  - P_{KA} shall not deviate > ± 50% for > 2.5 Gy-cm^2
- IEC(2010)
  - $K_{a,r}$ shall not deviate > ± 35% for > 100 mGy
  - P_{KA} shall not deviate > ± 35% for > 2.5 Gy-cm^2

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Measurement Accuracy

- Uncertainty in external dose measurements
  - Uncertainty in probe readout (±5%)
  - Error in probe position (±2 mm or 3%)
  - Error in irradiated area (±2 mm per side or 3%)
  - Total uncertainty for $K_{a,r}$: ±6%
  - Total uncertainty for P_{KA} : ±7%

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Integrated Dosimetry System Validation

- Alternative method using an external P_{KA} meter:
  - Place at least 20 cm from collimator to avoid scatter
  - Select x-ray beam size to be completely within the external ionization chamber
  - Use a P_{KA}-$K_{a,r}$ dual chamber meter to simultaneously measure $K_{a,r}$ values

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Field Adjustment of P_{KA} and $K_{a,r}$

- Some manufacturers provide a method of adjusting P_{KA} and $K_{a,r}$ values on individual imaging systems in the field
  - Manual adjustment (older models only)
  - Software calibration
- If no field adjustment is possible, a correction factor for P_{KA} and $K_{a,r}$ values can be calculated as the integrated dosimetry system readout to probe ratio

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Integrated Dosimetry System Validation

- Clinical implementation
  - Validation procedure has been used at our facility to test 11 C-arm imaging planes annually for the past 7 years
  - Includes 2 fluoroscopy system manufacturers and 5 equipment models

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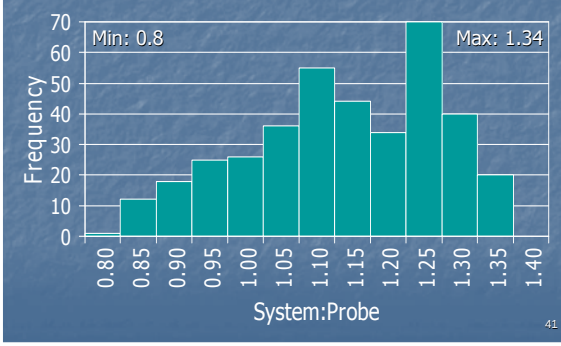
$K_{a,r}$ Correction Factor



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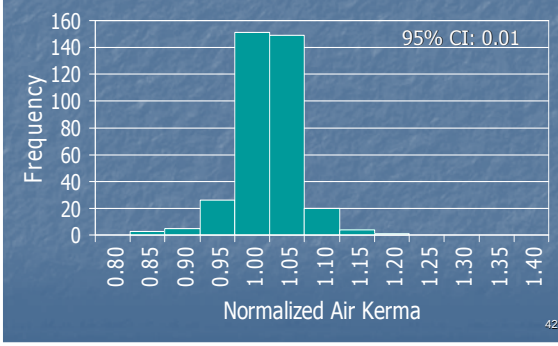
$K_{a,r}$ Consistency Over Time



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Integrated Dosimetry System Validation

- Results
  - System dose readout error found to be quite high (-20% to +34%)
  - Dose readout is relatively consistent over 7 year period

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Table and Pad Attenuation

- Note that some manufacturers include table attenuation in P_{KA} and $K_{a,r}$ readout values
- One manufacturer applies a correction factor weighted for x-ray tube under-table and over-table/lateral angulation:
  - Table attenuation 0.86, 50%/50% under/over-table use assumed
  - Therefore, probe:system ratio expected is 0.93 using protocol described above

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Table and Pad Attenuation

- To perform skin dose estimates from $K_{a,r}$ values, a correction for table and pad attenuation should be included
  - Alternatively, the integrated dosimetry system readout can be calibrated to include table and pad attenuation if the x-ray tube is generally under the table clinically

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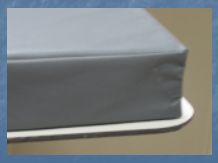
Table and Pad Attenuation

- Typical table and standard pad attenuation factor is 0.7 - 0.8
- Heavily attenuating pads (gel pads) can be as high as 0.5 *



* Geiser, Huda and Gkanatsios, Medical Physics 1997

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Integrated Dosimetry Systems

- Additional information and guidance is coming
- AAPM Task Group 190: Accuracy and Calibration of DAP meters in Diagnostic Radiology
  - Chair: Pei-Jan P. Lin
  - Charge:
    - Develop integrated dosimetry evaluation protocol
    - Survey clinical fluoroscopic equipment: accuracy and calibration methods

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Phantom Air Kerma Rate

- Why measure phantom fluoroscopy entrance-surface air kerma rate (EAKR)?
  - Verify appropriate dose rates are available when acceptance testing new equipment
  - Compare to other equipment
  - Compare to benchmark values
  - Quality control monitoring of equipment performance

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EAKR Measurement

- Use clinical exposure conditions
  - Patient-equivalent attenuator (produces an exit beam with adequate scatter)
  - Range of phantom thicknesses
  - Clinical source-to-image receptor distance

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Materials

- PMMA attenuator blocks
  - At least 25 x 25 cm to fully cover the beam field of view at the image receptor
  - Sheets to make up 10, 20 and 30 cm thicknesses
- Ionization chamber dosimeter
- Tape measure

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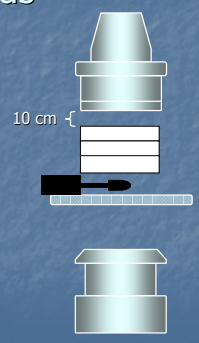
Methods

- Use 10 cm air gap between phantom and image receptor, adjust SID for each thickness
- Measure EAKR for all magnification modes and all clinically-used dose modes



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Benchmark EAKR Values

- From survey of 41 fluoroscopy systems, mean (quartiles) EAKR for 15-18 cm FOV *:
  - 20 cm thickness – 26 (14-38) mGy/min
  - 30 cm thickness – 110 (67-150) mGy/min
- Additional benchmark data is needed
  - CRCPD NEXT Cardiac Catheterization results will be available soon

* Laskey, Wondrow, Holmes, Variability in fluoroscopic x-ray exposure in contemporary cardiac cath lab, JACC 2006

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Fluoroscopy Mode Options

- Modern fluoroscopy units include multiple optional modes
- Parameter selection can significantly affect dose rates and image quality
- Adjustments in parameter selection may be needed when measured dose rates are above 75th percentile benchmark values

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Fluoroscopy Mode Options

- Several different dose modes should be available for selection by the operator
  - Low: for positioning fluoro, high contrast object placement and sensitive patients
  - Medium: for routine work
  - High: for selective use in difficult imaging conditions

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Fluoroscopy Mode Options

- Variable rate pulsed fluoroscopy
- Spectral beam filtration
- kVp selection
- Automatic dose rate control algorithms
- Image processing

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Spectral Beam Filtration

- Extra filtration added to reduce low energy x-rays absorbed in patient tissue
  - Copper (Cu) is most common
  - Tantalum (Ta) is also used
- Reduces patient entrance air kerma rate
- Minimal effect on image quality

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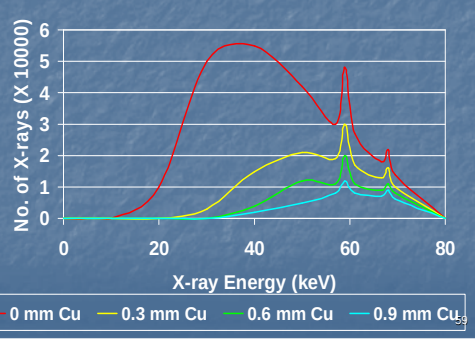
Spectral Beam Filtration



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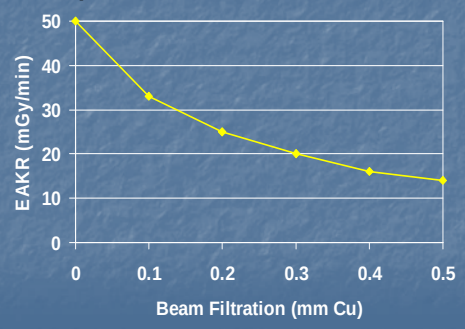
Spectral Beam Filtration



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Spectral Beam Filtration

- Optimum filtration thickness depends on patient attenuation
  - More filtration for smaller patients and body parts
  - Less filtration for thicker patients to avoid tube overheating
- Requires use of higher mA for adequate penetration

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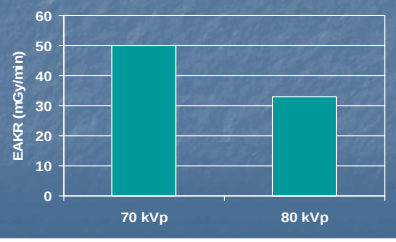
kVp Selection

- Increase from 70 to 80 kVp decreases entrance-surface air kerma rate by 33%
  - Disadvantage: Contrast decreases also



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Automatic Dose Rate Control

- Automatic variation in kVp, mA, pulsewidth and filtration thickness
- Different algorithms are available to optimize fluoroscopic image quality for different procedure types, body parts, pediatrics

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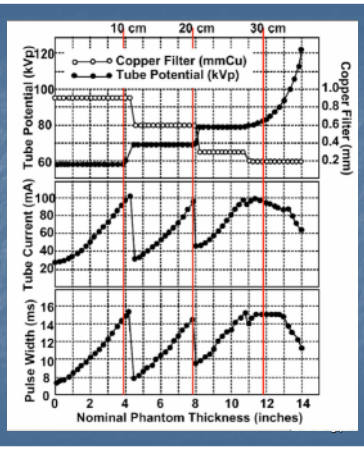
Automatic Dose Rate Control



Reference: Lin, Medical Physics 2007

Image Processing

- Allows partial retrieval of image quality loss from use of dose reduction options
- Includes:
  - Video frame averaging
  - Edge enhancement
  - Contrast enhancement

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Conclusions

- Validation of the accuracy of air kerma-area product and reference point air kerma display values is recommended
- Measurement of fluoroscopy phantom entrance-surface air kerma rate is a valuable way to optimize and benchmark performance

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References (1)

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References (2)

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