Managing
Pediatric Fluoroscopic Imaging

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Introduction

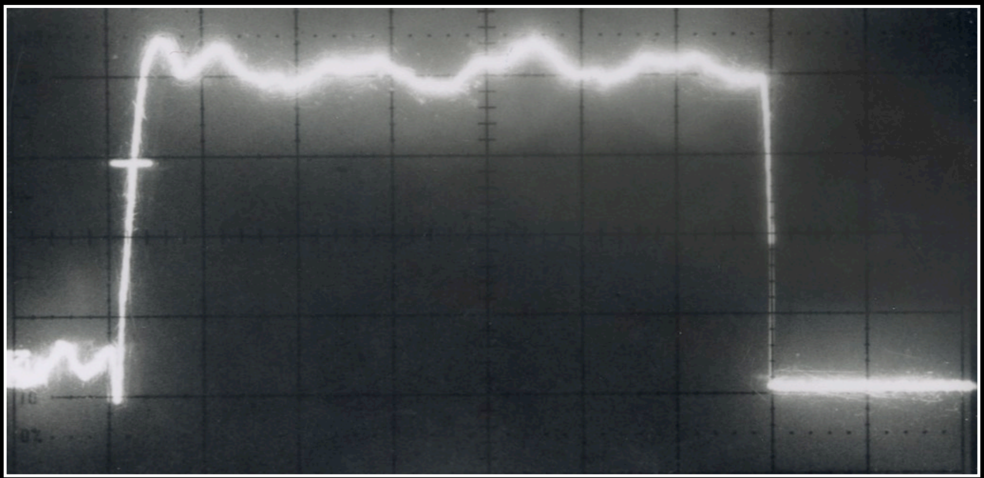
- Evolution of fluoroscopic equipment last 40 years
- Pediatric
  - Challenges
  - Advantage
- Teamwork between radiologist, technologist, qualified medical physicist (QMP), and equipment manufacturer
  - Roles
  - Impediments to positive teamwork
- Examples of successful reconfigurations

Tripping Through Memory Lane

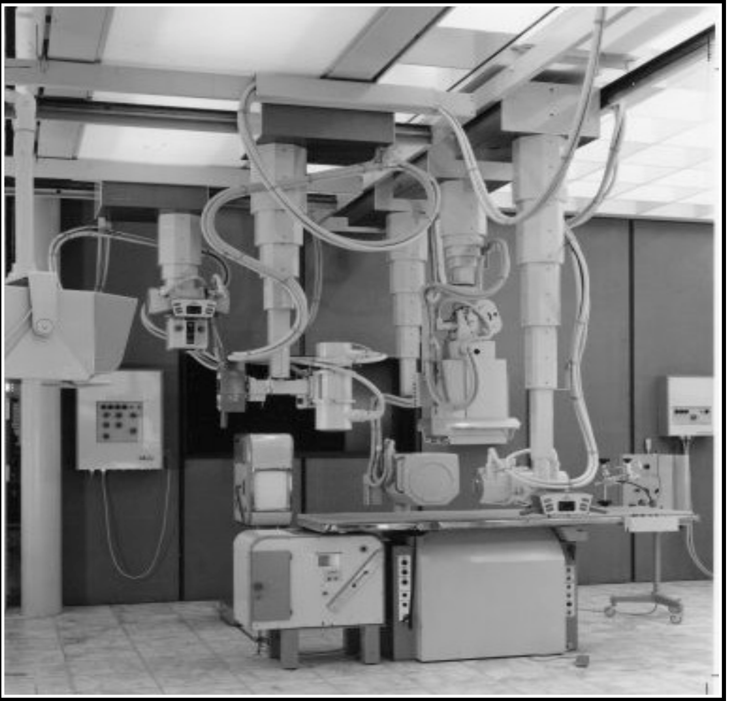
Compliance Testing Era:

- Last 40 years of 20th Century
- Equipment used open loop control logic

80 kVp Waveform



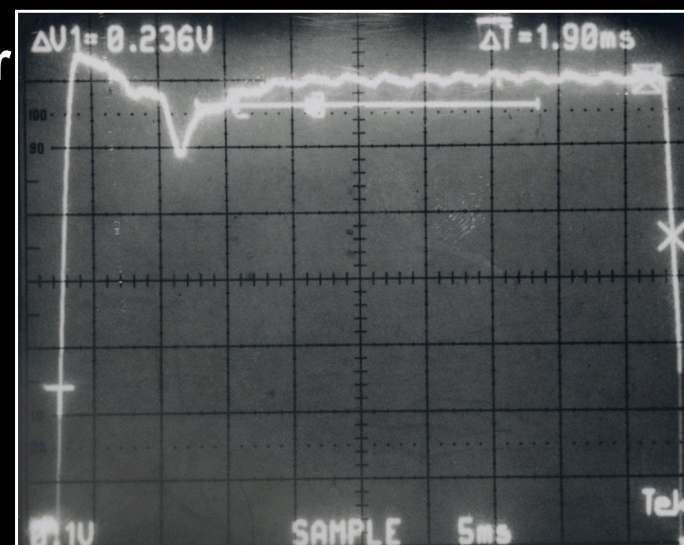
Biplane Diagnostic Angio ~ 1975



Tripping Through Memory Lane

Compliance Testing Era:

- Continuous fluoroscopy
  - Voltage and current changed in parallel responding to patient size
  - Selection of Field of View
  - 2 – 3 dose level settings to image receptor
- Equipment malfunctions
- Calibration errors
  - Manual vs automatic
  - Numerical values alone were inadequate

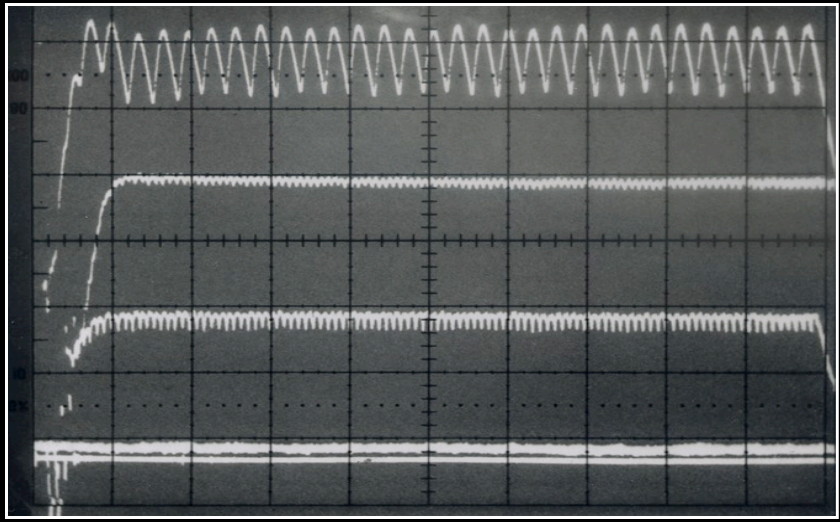


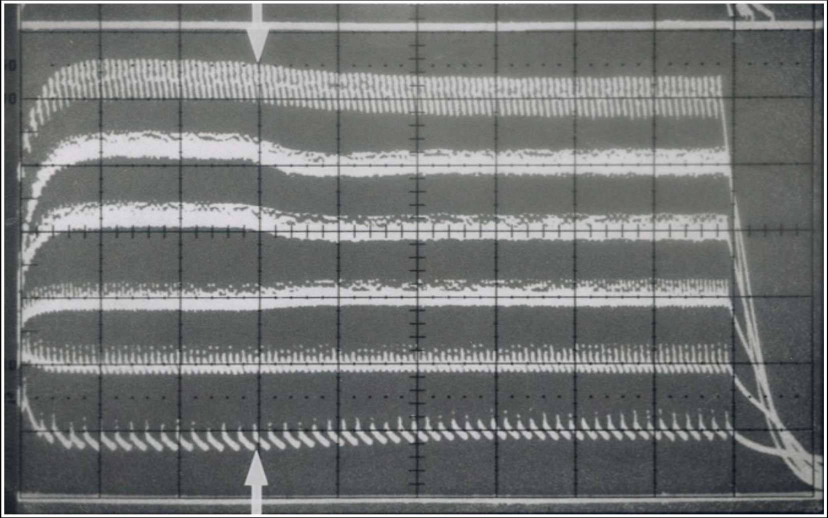
Tripping Through Memory Lane

Configuration/Operations Era:

- First years of 21st Century
- Equipment used computer controlled, feedback-stabilized control logic

Mid Frequency Generator: kV left; mA right



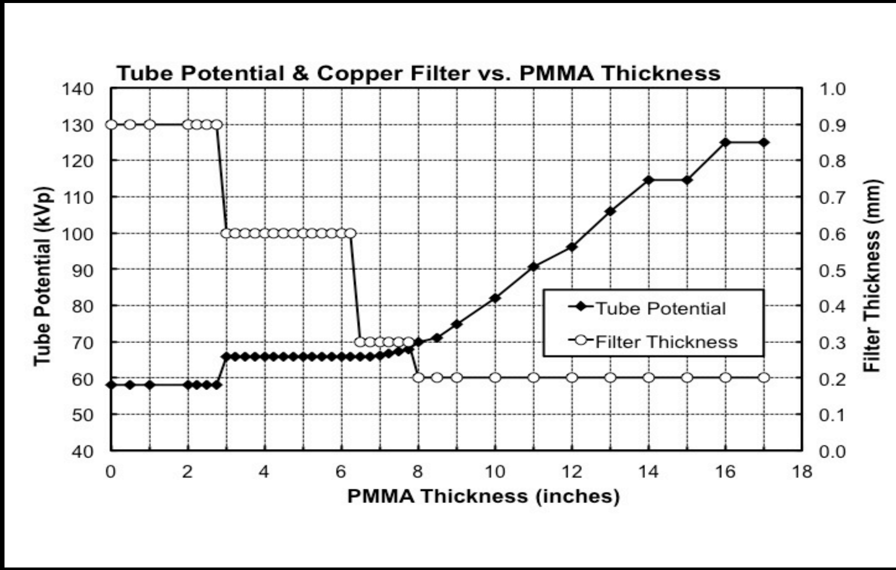


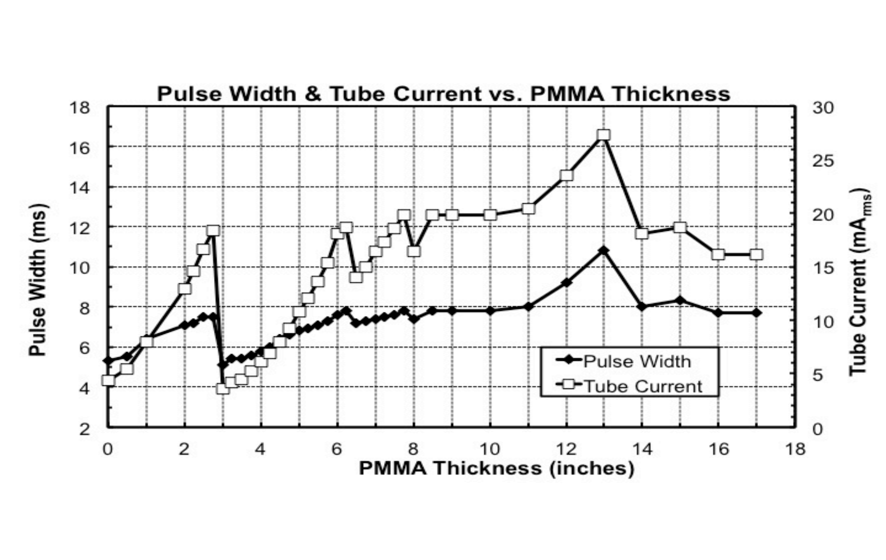
Tripping Through Memory Lane

Operational Parameters

- Type of Exam
- Patient Size: Does one button select all?

AAPM TG125





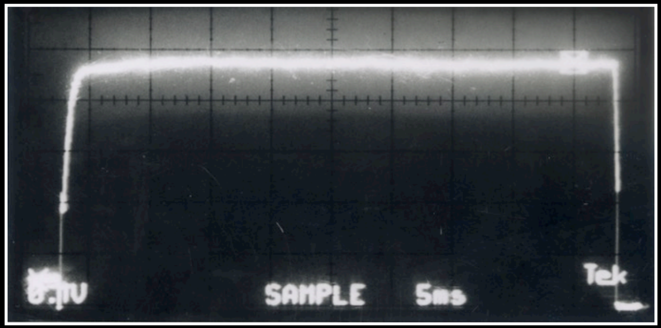
Current General Challenges

Image quality requirements unique as a function of:

- Exam type and **Patient Size**

Configuration Choices

- Focal spot size
- X-ray beam filtration
- Geometry: patient vs equipment
- Grid management
- Pulse rates and widths
- Detector air kerma rates
- Appropriate image processing



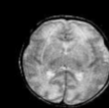
Pediatric Challenges

- Fluoroscope
  - Patient irradiation

Adult	Pediatric
45 – 140 kg	2 – 140 kg
26 – 42 cm[1]	5 – 42 cm[1]
5 HVL: 32	11 HVL: 2048

Automatic Brightness Systems (ABS) struggle with the larger range of required radiation required for pediatric size variance.

335 lb 16 yo



Neonate

[1]Kleinman PL, et. al. Patient Size Measured on CT Images as a Function of Age . . . AJR2010;194:1611-1619.

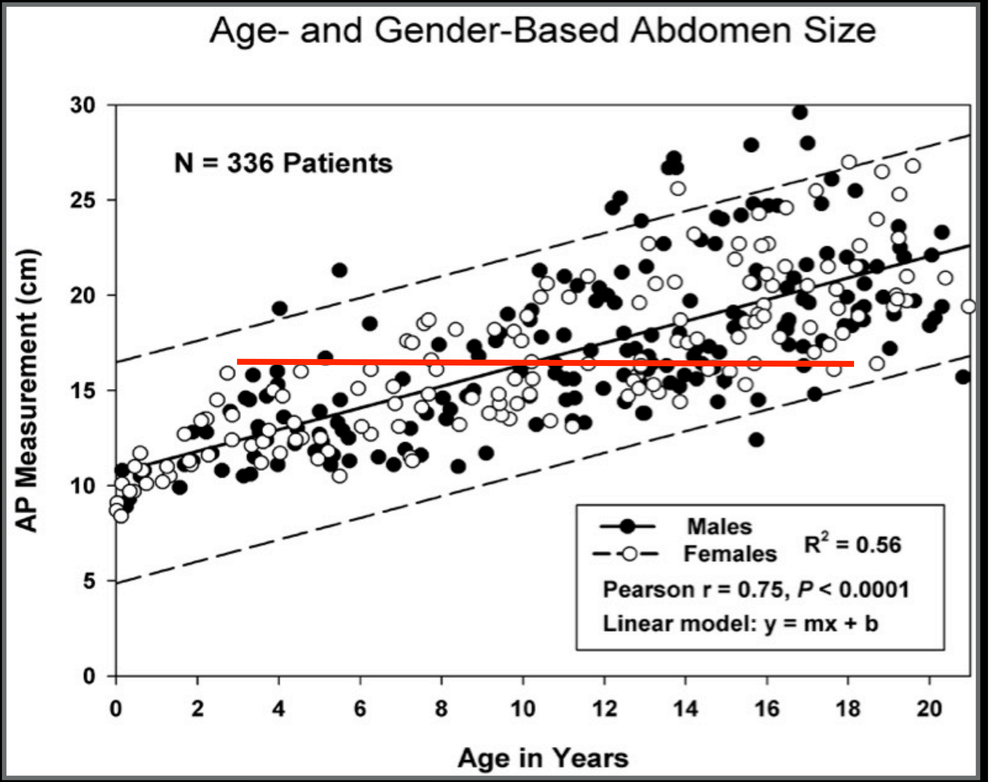
Pediatric Challenges

Same age patients vary dramatically in size.

- **Abdomens of:**
  - **Largest 3 year olds and**
  - **Smallest adults are**

  the same size.

- **Patient cross section size, not age, should be used.**



Pediatric Challenges

Imaging equipment is well

- Designed and
- Configured[1]
- ‘out of the box’ for imaging adult patients.

BUT

- The same can not be said about configurations for pediatric imaging!
- Has vendor developed pediatric specific configurations?

[1]Insuring the use of design strengths while compensating for design weaknesses for a specific size patient and imaging task.

Pediatric Challenges

Why should your child or grandchild receive less consideration during imaging than that of their parents or grandparents?

- **Majority** of imaging equipment sold is installed in **adult facilities**, but eventually all these units will perform **some pediatric imaging**.
- ~ 80% of all pediatric imaging is performed in adult hospitals

Maximize Benefit/Risk = manage image quality/manage patient dose

- **Increasing** image quality and **decreasing** patient dose is not always the answer when configuring fluoroscopic equipment!

Pediatric Advantage

X-ray units designed to image adult patients produce a higher air Kerma rate than required to penetrate small pediatric bodies; choices of

- **Focal spot**
- **Beam filter**
- **Grid**
- **Voltage, current and pulse width combination**
- **Air Kerma rate at image receptor**
- **Patient positioning (geometric magnification)**

Teamwork

- Team
  - Radiologist
    - Ultimate responsibility for overall patient care
    - Controls the patient’s dose depending on modality
  - Technologist
    - Impacts patient care during the imaging process
    - Controls the patient’s dose depending on modality

- Both are primarily focused on patient care.
- Both need better training on the implications to patient care due to the design and configuration of the imaging equipment.
- Both may expect too much from equipment manufacturer!

Teamwork

- Team
  - Qualified Medical Physicist
    - Interpreter: different understanding of imaging process by front line care givers vs design engineers of imaging equipment
      - Unique imaging needs of the practice (patient needs)
      - Strengths and weaknesses of design of offered equipment
    - Surprises should be greatly reduced.
    - Compliance testing seldom improves patient care.
    - Acceptance testing crucial to determine proper configuration of complex imaging equipment.

Teamwork

- Team
  - Representatives of equipment manufacturer
    - Sales representatives:
    - Product Specialists:
    - Product Managers: lowest level of decision makers/changers
    - Design Engineers
    - Imaging Physicists
  - All vendor employees must operate within a business model
    - Focus on profit may limit configuration changes.
    - Litigation concerns may stifle creativity in the field.

Challenge

- Team members have different primary goals
  - Customer seeks improved patient care
    - Quality exacts a price
      - Hardware change
      - Software change
      - Labor to alter configuration
  - These changes are opposed by equipment manufacturers
    - . . . our FDA 510k approval does not allow field changes!

Solution?

- **FDA's** reaction to 510k stalemate:

Pediatric Information for X-ray Imaging Device Premarket Notifications

Guidance for Industry and Food and Drug Administration Staff

Document issued on November 28, 2017.

Contains Nonbinding Recommendations

For previously 510(k) cleared x-ray imaging devices, optimization of imaging parameters and provision of pediatric-specific protocols by manufacturers solely at the request of end users generally does not by itself necessitate submission of a new 510(k) submission.

Challenge

- Team members have different primary goals
  - Customer seeks clinical image quality at managed dose
    - Technology's best images may not always be necessary!
    - Trade image quality for dose savings
    - New paradigm
  - Manufacturer must compete with competitors
    - Desire to produce best possible images at all times

Challenge

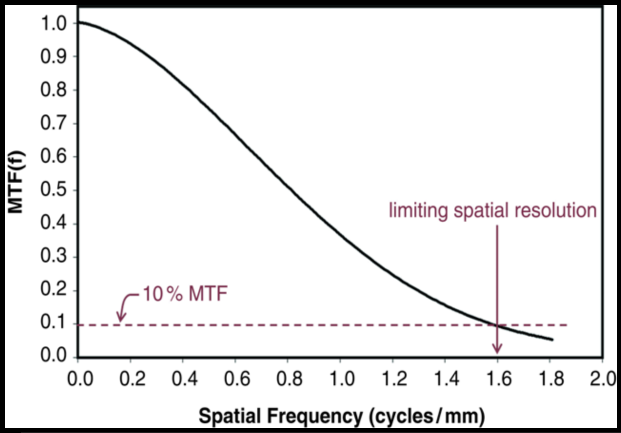
- Team members have different primary goals
  - Qualified medical physicist needs better understanding of equipment’s design features
  - Manufacturer guards equipment design feature details
    - Non disclosure agreements may be difficult to negotiate

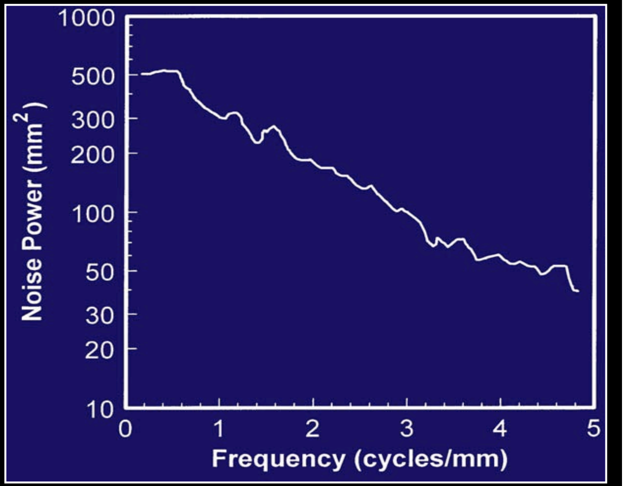
Challenge

Qualified medical physicist needs quantitative test tools

- Quantitative assessment of image quality with inexpensive phantoms is desired.
  - Modulation Transfer Function (MTF)
  - Noise Power Spectrum (NPS)

Need unprocessed images from image receptor



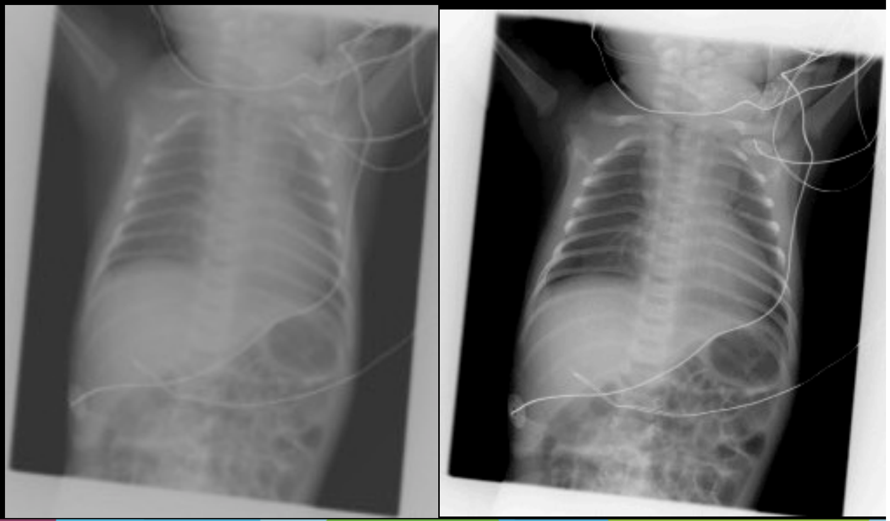


Solution

- **Qualified medical physicist needs better tools . . .**
  - **Four major components**
    - **Single exposure control of Voltage, tube current, exposure time, focal spot, added filtration**
    - **Export of 'For Processing' images**
    - **Electronic documentation of system configuration**
    - **Calibration factors within RDSR report for air Kerma and Kerma area product dose display**

NEMA XR 27-2012
X-ray Equipment for Interventional Procedures User Quality Control Mode

JT Bushberg, JA Seibert, EM Leidholdt, Jr., JM Boone



Reality

NEMA XR 27-2012
X-ray Equipment for Interventional Procedures
User Quality Control Mode

- Standard published in 2012
- Available only on most recent purchases
- Treated as a revenue opportunity by one manufacturer
  - Charged significant dollars for feature
  - Extra not charged for service logs or troubleshooting routines
- Why are XR27 features treated differently?

Successful Example

- How impactful are end user driven reconfigurations when cooperation from manufacturer is won?
  - General Pediatric Fluoroscopy (VCUG)
    - 1995: Continuous Fluoroscopy: 3 – 6 mGy air Kerma[1]
    - 2001: Pulsed Fluoroscopy: 0.4 – 0.6 mGy air Kerma[1]
    - 2015: Reduced pulse rates: 0.25 – 0.45 mGy air Kerma

1. Ward VL, et. al., Pediatric Radiation Exposure . . .Radiology 249:3, 12/08, pp. 1002 – 9.

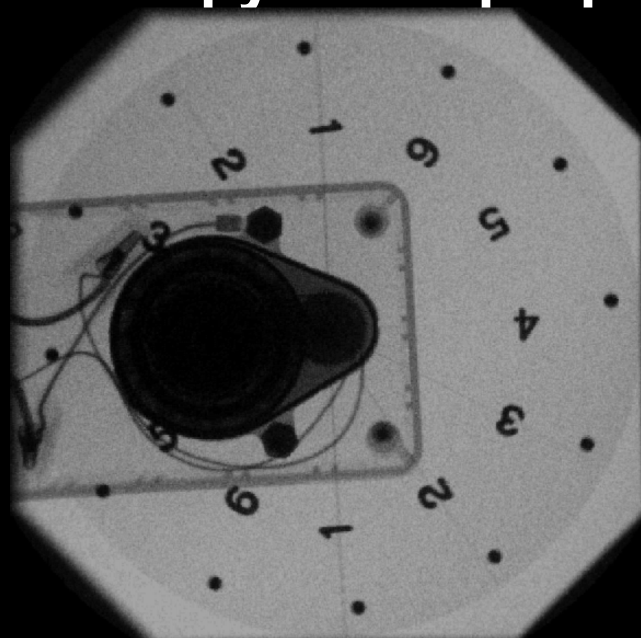
Solution

- International Electro-Technical Commission (IEC)
  - International standards organization with working groups that develop and maintain standards for the different modalities of imaging.
    - Some European nations promulgate IEC standards into law.
    - FDA is beginning to adopt IEC standards as opposed to rewriting outdated FDA regulations
  - Positive example:

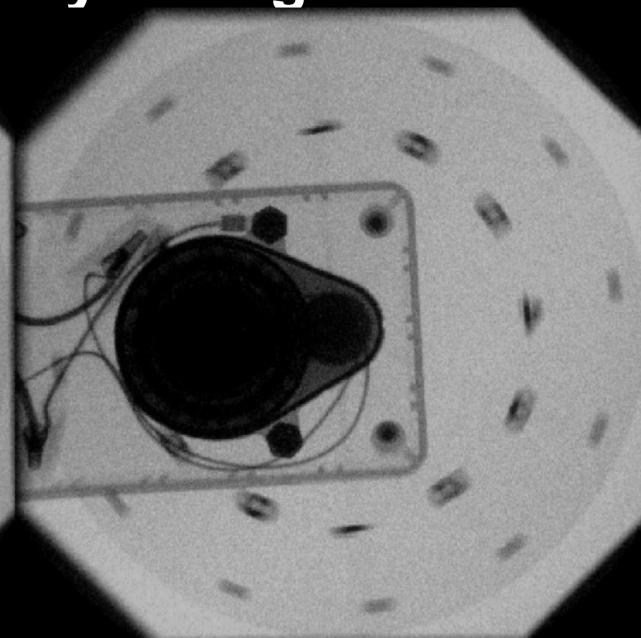
    IEC CT working group currently developing a standard for the calculation and display of Size Specific Dose Estimate (SSDE) on all future CT scanners in support of pediatric imaging.

Successful Reconfigurations

- Pulsed fluoroscopy that is not preferred by radiologists to continuous fluoroscopy is not properly configured.

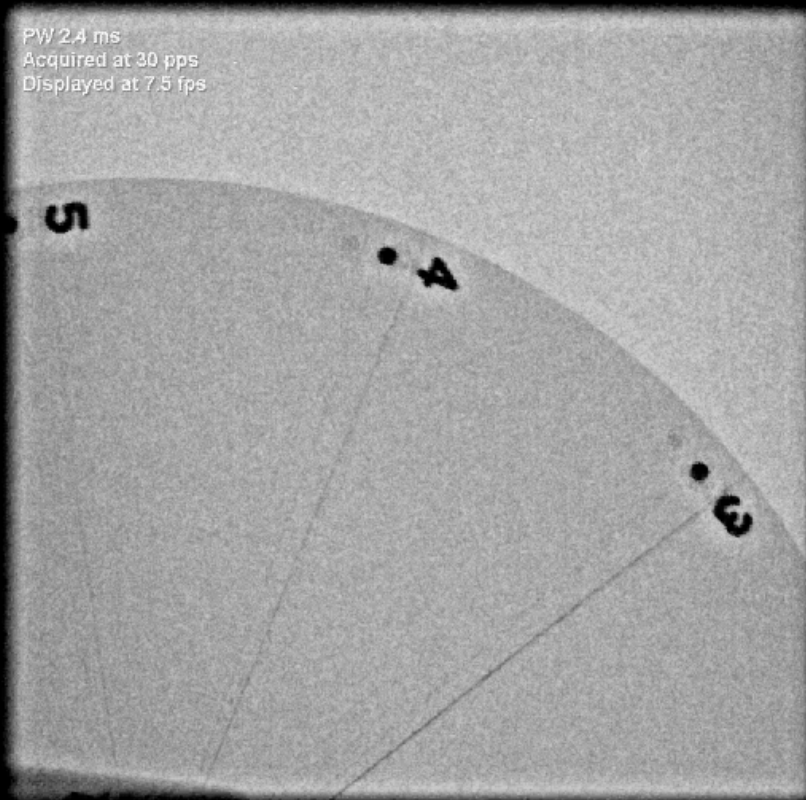


Pulsed Fluoro - 30pps



Continuous Fluoro

AFFECT OF PULSE WIDTH



PW 2.4 ms
Displayed 7.5 fps

PW 7.4 ms
Displayed 7.5 fps

Successful Reconfigurations

- Manufacturers have added spectral filtration
  - Thin Copper sheets paired with 1 mm Aluminum
  - Reduces patient air Kerma relative to detector air Kerma.
  - Multiple thicknesses: larger thickness = less patient dose
  - Pulse width increased to produce adequate air Kerma at detector.
  - Motion unsharpness in image.
    - Pediatrics: 1 – 5 msec
    - Adults: 3 – 10 msec
    - Bariatrics: 10 – 20 msec
  - Typically a software as opposed to field modification.

Successful Reconfigurations

- Manufacturers tend to configure excessive pulse **rates**.
  - With practice, operators can adapt to lower pulse rates

  - Interventional fluoroscopy
    - 30 and 15 pps have been replaced by 15 and 7.5 pps in children

  - General fluoroscopy
    - 8 and 4 pps have been replaced by 4 and 2 pps in children

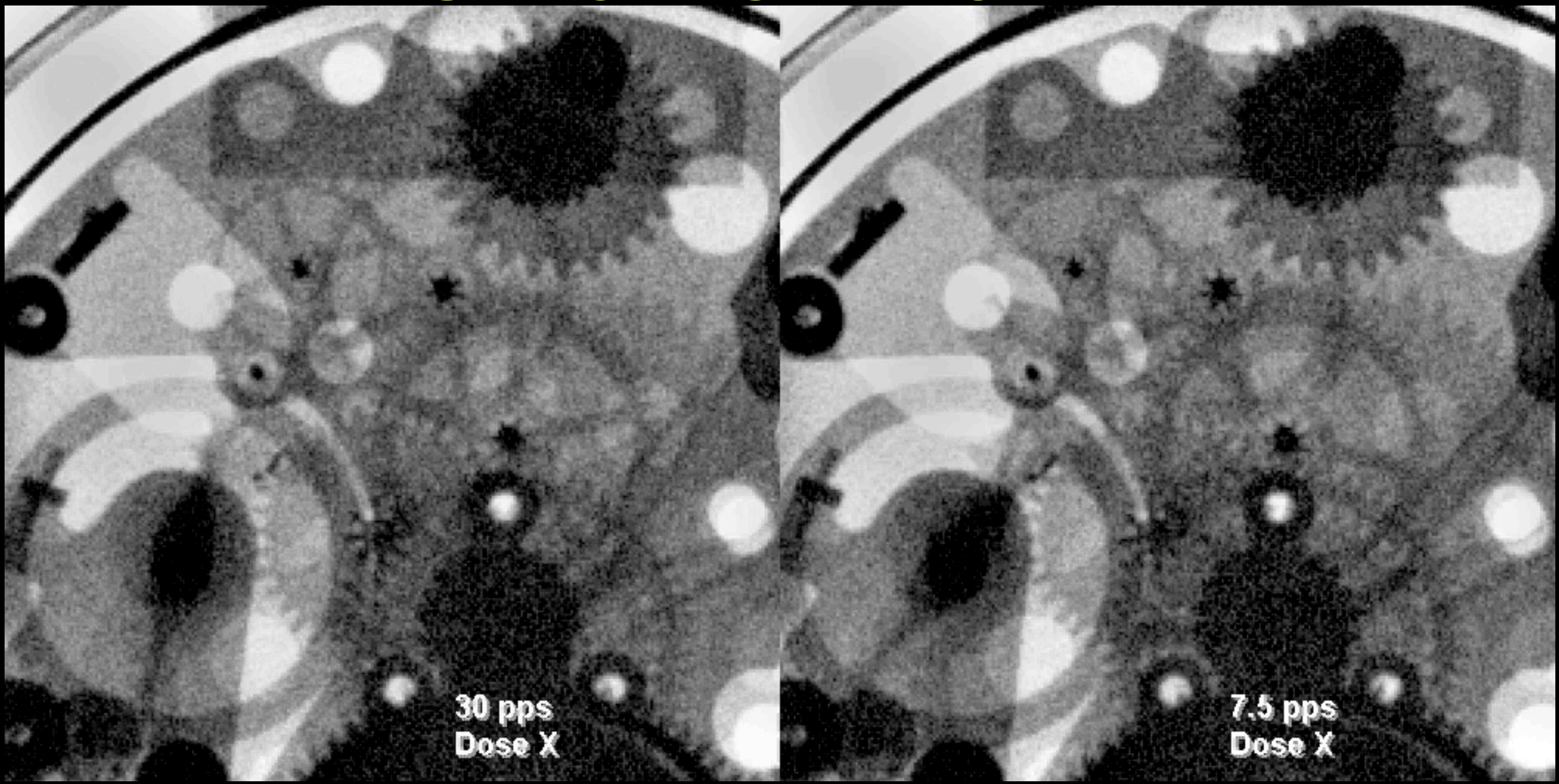
Successful Reconfigurations

- Air Kerma at Image Receptor (AKIR)
  - During Variable Rate Pulsed Fluoroscopy
  - Increased Perceived Noise With Decreased Pulse Rates,
  - Not loss of Temporal Resolution is
  - Primary cause for rejection of low pulse rate fluoroscopy

  - Increase in AKIR / Frame[1] α (30/Pulse Frequency)$^{1/2}$
    Maintains perceived noise due to less frame integration by eye/brain function when pulse rate > 7.5 p/s.

1. Aufrichtig R, et. al. Perceptual comparison of pulsed and continuous fluoroscopy. Med Phys 1994 21(2): p 246 – 56.

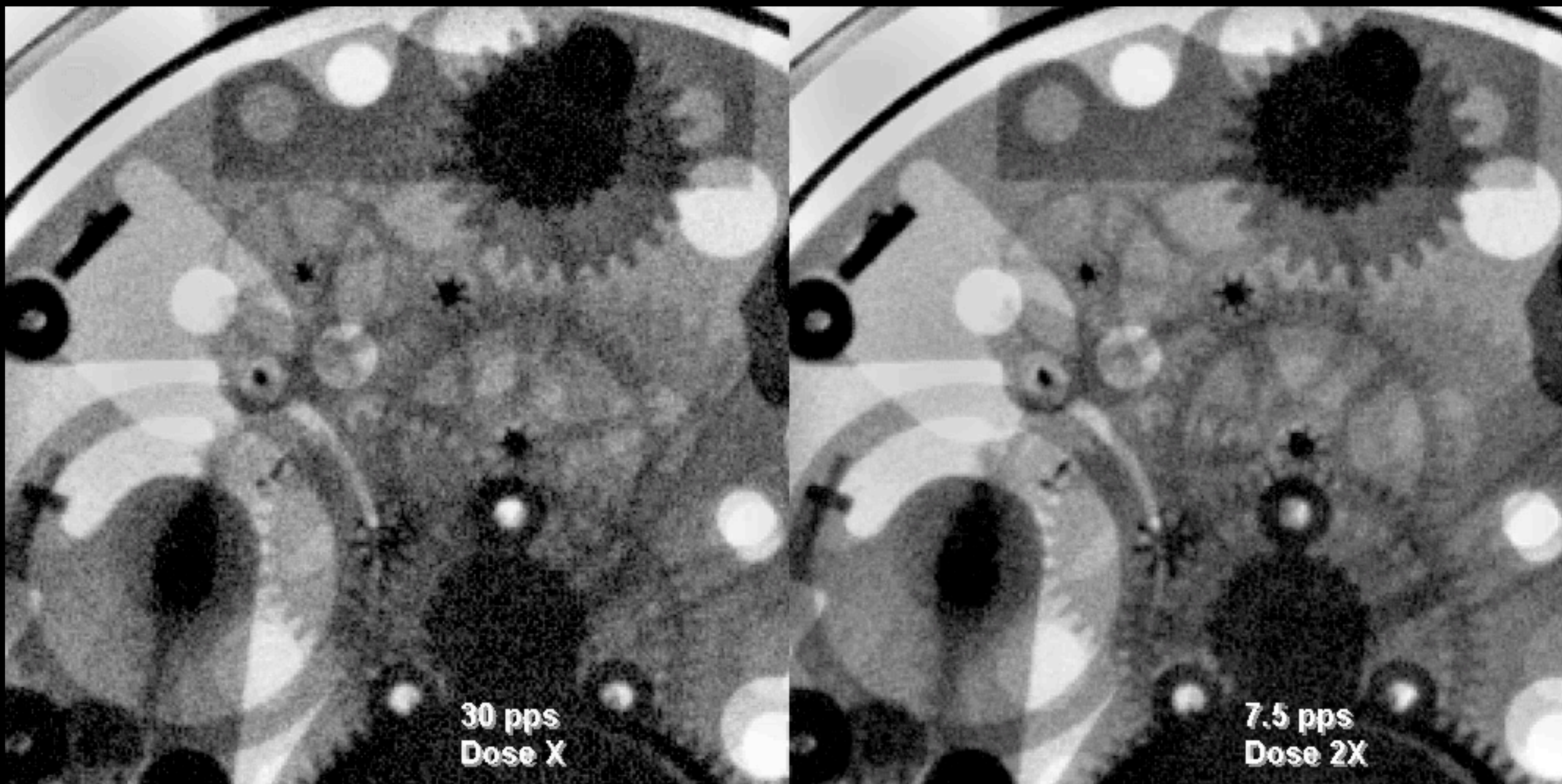
AUFRICHTIG PRINCIPLE



IR Exp/frame = X **Patient Exp Rate <u>Reduced</u> 4X**

Images courtesy of Phil Rauch

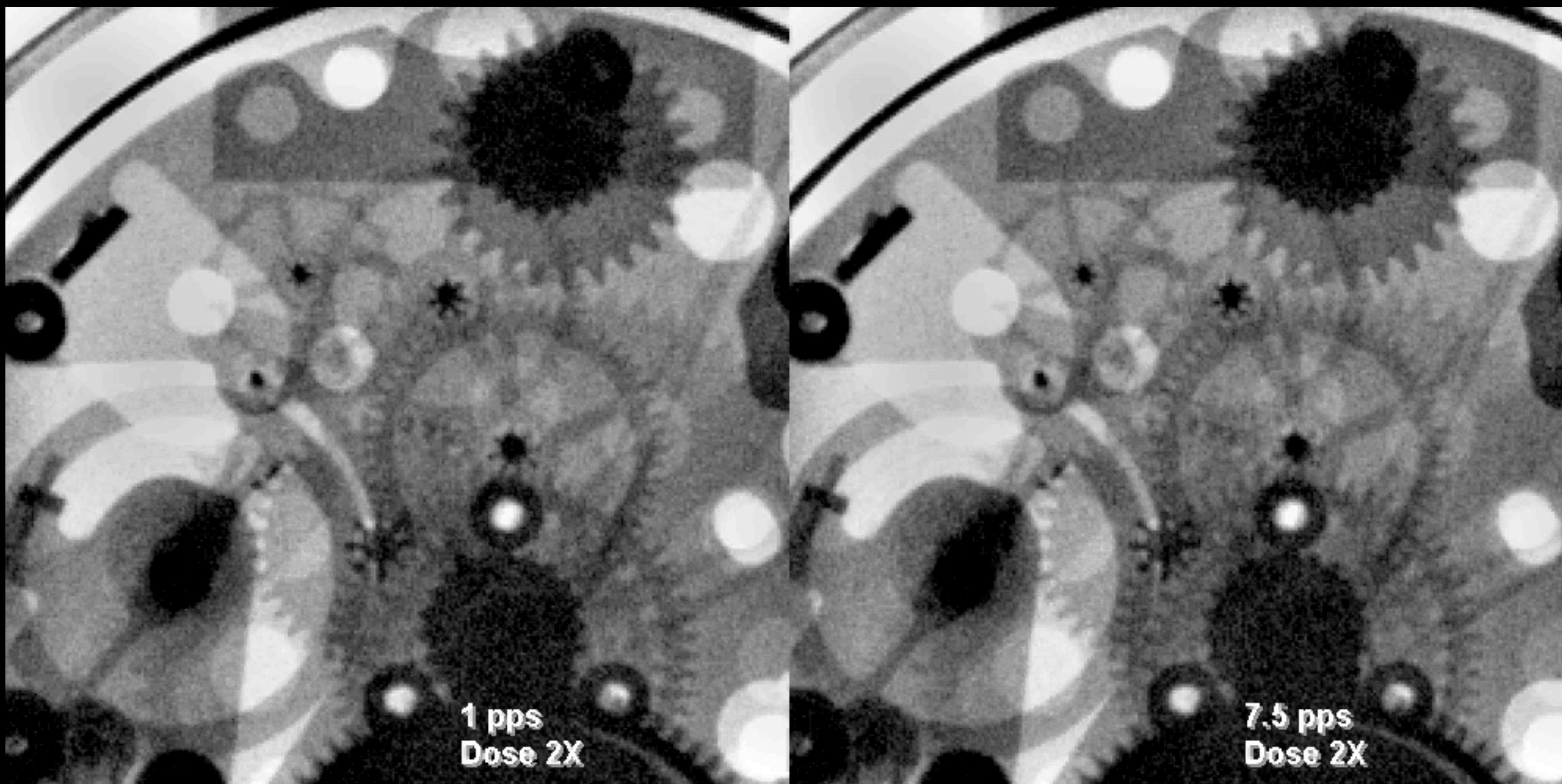
AUFRICHTIG PRINCIPLE



IR Exp/frame = X vs 2X **Patient Exp Rate Reduced 2X**

Images courtesy of Phil Rauch

AMMENDED AUFRICHTIG PRINCIPLE



IR Exp/frame = 2X vs 2X **Patient Exp Rate <u>Reduced</u> 7.5X**

Images courtesy of Phil Rauch

Technique Optimization

•Control of air KERMA rate at Image Receptor (AKIR)

- During Variable Rate Pulsed Fluoroscopy
  - Exposures Relative to "Normal": 30 p/s
    - AKIR / Frame α (30/Pulse Frequency)$^{1/2}$
      - Different relationship for < 7.5 pulses/second
      - AKIR / Frame α Constant

- Aufrichtig Principle classic example or dose management as opposed to pure reduction

Successful Reconfigurations

- Triple as opposed to dual focused x-ray tubes provide more control of x-ray production as a function of patient size
  - Smaller focal spot matched to a small body minimizes geometric unsharpness
  - 0.3 mm focal spot allows use of geometric magnification without a grid for smallest patients
  - 0.3 mm focal spot provides adequate kW for cardiac catheterizations of infants and babies < 1 year of age

- Manufacturer may still have triple focus angiographic tube designed for neuro work which is a better cath lab choice!

Conclusions

- Configuration and design **changes** of imaging equipment can **improve** image quality and/or **better manage** patient dose of pediatric patients.
- Tailored equipment configurations to the patient's imaging needs are essential and only result from **teamwork**.

Max **Benefit/Risk** = **managed** image quality/**managed** patient dose

- **END USERS** NEED AN **EFFECTIVE** WORKING RELATIONSHIP WITH THEIR EQUIPMENT VENDOR & MEDICAL PHYSICIST.

Thank you

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