Testing the Misfits: What Physicists Need to Know About the Medtronic O-Arm

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Disclosures

None

1 What is an O-arm?

2 Hands on with the O-arm

3 Measuring output (Fluoroscopy and CT)

4 Assessing Image Quality

5 What do I NEED to measure?

What exactly is an O-arm?

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O-arm

FDA 510K approval with substantial equivalence for predicate fluoroscopy system

Initially cleared in 2005 with substantial equivalence to Siemens SIREMOBIL

Main Components

Figure 8: The O-arm® O2 Imaging System (IAS = ①; MVS = ②)

Two parts: O-arm Image Acquisition System (IAS) and Mobile View Station (MVS)

Conforms to IEC 60601-2-43 for X-ray Equipment for Interventional Procedures

O-arm

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FDA 510K approval with substantial equivalence for predicate fluoroscopy system

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510(k) Number *(if known)*
~~N/A~~ K151000

Device Name
O-arm® O2 Imaging System

Indications for Use *(Describe)*
The O-arm® O2 Imaging System is a mobile x-ray system designed for 2D fluoroscopic and 3D imaging for adult and pediatric patients weighing 60 lbs or greater and having an abdominal thickness greater than 16cm, and is intended to be used where a physician benefits from 2D and 3D information of anatomic structures and objects with high x-ray attenuation such as bony anatomy and metallic objects.

The O-arm® O2 Imaging System is compatible with certain image guided surgery systems.

Main Components

Figure 8: The O-arm® O2 Imaging System (IAS = ①; MVS = ②)

Interventional Procedures

What exactly is an O-arm?

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Located in Operating Rooms

Mobile

Primarily used for surgical guidance

- **Orthopedic Surgery**
- **Spine Surgeries**
- **With localization hardware/software**

It is NOT a Diagnostic CT Scanner

Journal of X-Ray Science and Technology 17 (2009) 305–317 305
DOI 10.3233/XST-2009-0231
IOS Press

Dosimetric characterization of a cone-beam O-arm™ imaging system

Jie Zhang*, Victor Weir[1], Liliosa Fajardo, Jingying Lin, Hsiang Hsiung and E. Russell Ritenour
Medical Physics Section, Department of Radiology, University of Minnesota, Minneapolis, MN, USA

Acquisition Modes: 2D

Auto Brightness or Manual Technique Options

Standard Fluoroscopy 30 f/s

High Level Fluoroscopy 30 f/s (limited to 30s continuous)

Low Level Fluoroscopy (15 f/s)

Multi-plane 2D Mode

Acquires fluoro images at 4 pre-set locations

Includes Last Image Hold

Noise Reduction option with multiple levels

Collimator adjustments (large steps)

Handswitch or Pedal to apply radiation dose

From O-arm O2 Manual

Acquisition Modes: 3D

Standard 3D Mode (391 Projections over 13 Seconds)

Low Dose 3D Mode (35% less dose than Standard)

High Definition 3D Mode (745 projections over 26 seconds)

Enhanced Cranial 3D Mode (745 projections and better IQ)

Stereotaxy mode (High Def 3D) for localization purposes

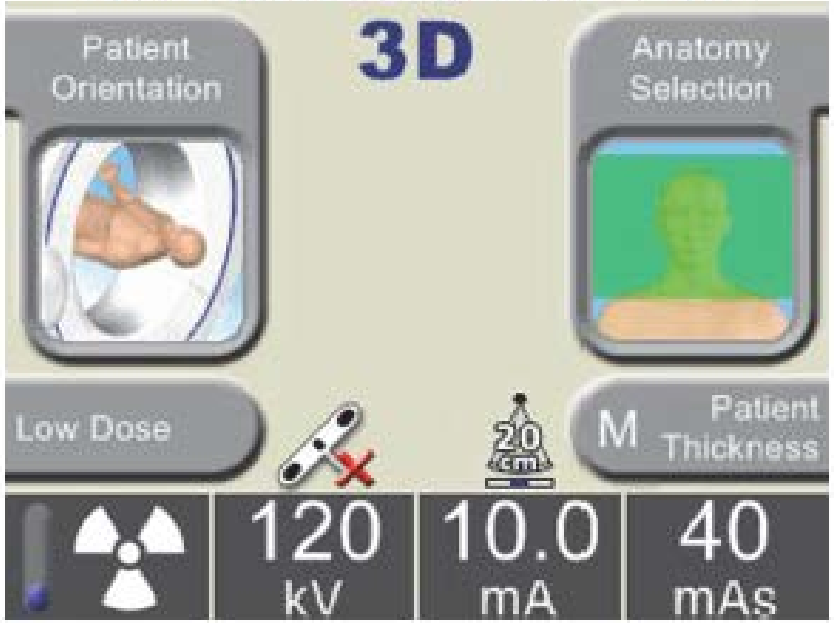
20 or 40 cm FOV

Multiple Patient Thicknesses Settings (Changes mAs)

Anatomy Selection (Changes mAs)

- **Head**
- **Chest**
- **Abdomen/Pelvis**
- **Extremity**

Figure 107: Pendant setting in low dose 3D mode



From O-arm O2 Manual

Multiple Versions

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Original O-arm 510(k) clearance in 2005

O-arm 1000 510(k) clearance in 2009

O-arm O2 510(k) clearance in 2015

O-arm O2 includes new features:

- **Low Dose 3D Mode**
- **40 cm FOV for 3D imaging**
  - **Half Fan Acquisition**
  - **High Definition Acquisiton**

	Subject Device O-arm® O2 Imaging System	Predicate O-Arm® 1000 Imaging System (K092564)
Cone Beam CT	The O-arm® O2 Imaging System is a mobile cone-beam x-ray system with isocentric motion options. It allows 3D image reconstruction using a 360 degree rotation of the x-ray source and detector within closed gantry.	The O-arm® Imaging System is a mobile cone-beam x-ray system with isocentric motion options. It allows 3D image reconstruction using a 360 degree rotation of the x-ray source and detector within closed gantry.
Detector Technology	40 x 30 cm (RoHS compliant, Flat-Panel Detector using a CsI scintillation)	40 x 30 cm (Flat-Panel Detector using a CsI scintillation)
Generator Technology	32 kW, RoHS compliant generator with improved electrical interface.	32kW Generator
2D Imaging	2D Fluoroscopic	2D Fluoroscopic
3D Imaging (20 cm FOV)	Full Fan (20cm FOV) scan acquisition	Full Fan (20cm FOV) scan acquisition
3D Imaging Protocols (20 cm FOV)	Available presets: 1. Standard 3D 2. HD3D (High Definition) 3. Enhanced Cranial 4. Low Dose 3D	Available presets: 1. Standard 3D 2. HD3D (High Definition) 3. Enhanced Cranial
3D Imaging (40 cm FOV)	Half-fan single scan acquisition	No 3D Imaging at 40cm FOV
3D Imaging Protocols (40 cm FOV)	Available presets: 1. HD3D (high definition) equivalent to 750 projections	No 3D Imaging at 40cm FOV

Limitations

Requires Performance Checks and possibly Maintenance after collision

Type	Check	Description	Frequency	Method
Operational	Calibration	Check fluoro and RAD gain	Monthly	8 and 9
Operational	Alignment	Collimator alignment	Yearly (PM)	7
Operational	Dose indication	X-ray quality assurance testing	Yearly (PM)	6
Operational	Image quality	Check performance	Yearly (PM)	1
Operational	Labels	Check for legibility	Yearly (PM)	1
Operational	Mechanical	Fasteners, cables, all mechanical stops, wheels, wheel alignment, cable deflectors, brakes, and locks	Yearly (PM)	1
Operational	X-ray control	X-ray quality assurance testing	Yearly (PM)	6

High patient entrance dose rate at Isocenter (3D position)

Which regulations should really apply?

2 Hands on with the O-arm

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Transport and Power up
GET HELP! (Especially Your First time!)

Battery assisted drive of IAS using handle

Wheel brakes need to be dis-engaged

Transport IAS and MVS separately

Position IAS in room (lock brakes)

Need imaging (Radiolucent) table setup in operating room or wherever testing

Powering UP:

- Connect MVS to power
- Then IAS to MVS
- Then power up

Figure 64: Gantry door fully open – side view

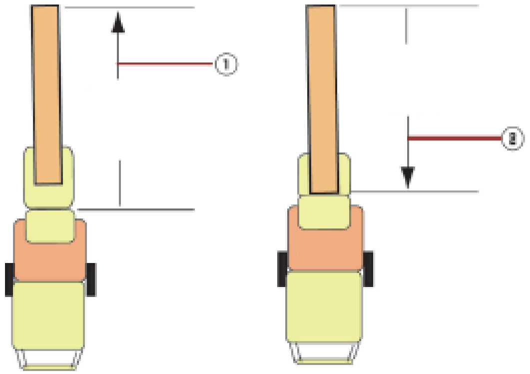
Positioning and Closing the O-arm

Moving the Gantry in a Transverse Direction

gantry
reaches the desired position.

Moving the Gantry in a Transverse Direction

Figure 81: Transverse motion (top view)



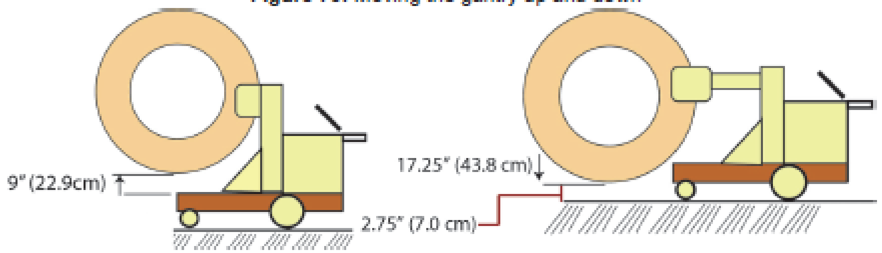
Press and hold the top of the button to move the gantry transversely (out) away from the cabinet ①.

Press and hold the bottom of the button to move the gantry transversely (in) towards the cabinet ②.

Observe the motion of the gantry when the button is pressed, and release the button when the gantry reaches the desired position.

Moving The Gantry Up and Down

Figure 75: Moving the gantry up and down



Press and hold the top part of the button to move the gantry linearly upward.

Press and hold the bottom part of the button to move the gantry downward. To move the gantry to its lowest position, it must first be transversely extended to its maximum distance away from the cabinet in order to clear its docking platform, as shown on the right in Figure 75. See "Moving the Gantry in a Transverse Direction" on page 121.

Positioning

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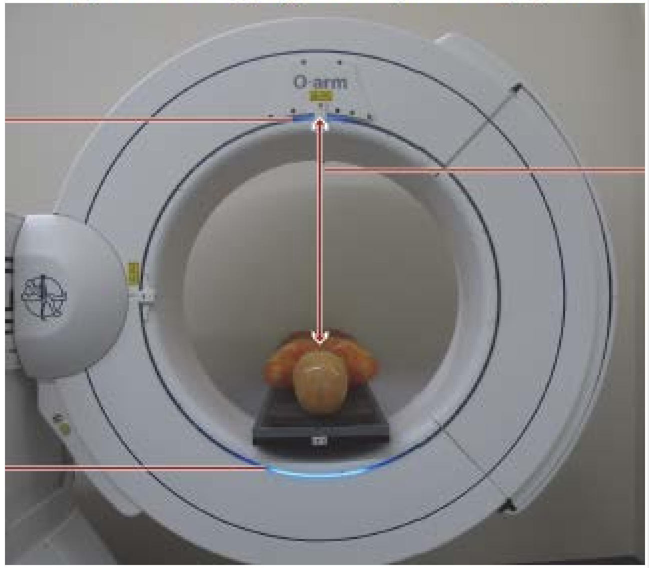
Figure 66: Correct gantry positioning for 2D imaging: PA shots



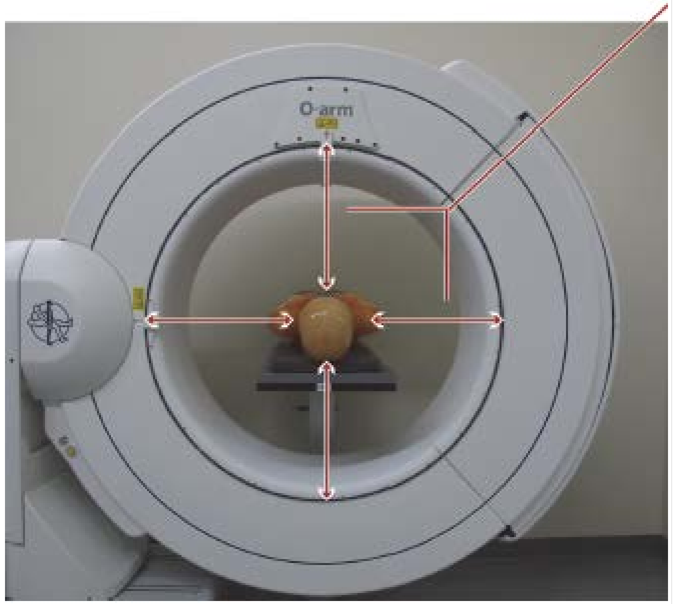
The Patient Spacer

During fluoroscopy, use the supplied Patient Spacer to help ensure that the patient is positioned at least 13 cm from the gantry cover on the x-ray source side; this will ensure that there is at least 30 cm between the patient and x-ray source. The Patient Spacer is composed of stainless steel and is 13.33 cm (5.25 in) in length, with tapered ends (see Figure 65).

Note: If using the Patient Spacer, make sure to sterilize it before the Patient Spacer enters the sterile field (see Sterilizing the Patient Spacer on page 107).

Figure 65: The Patient Spacer

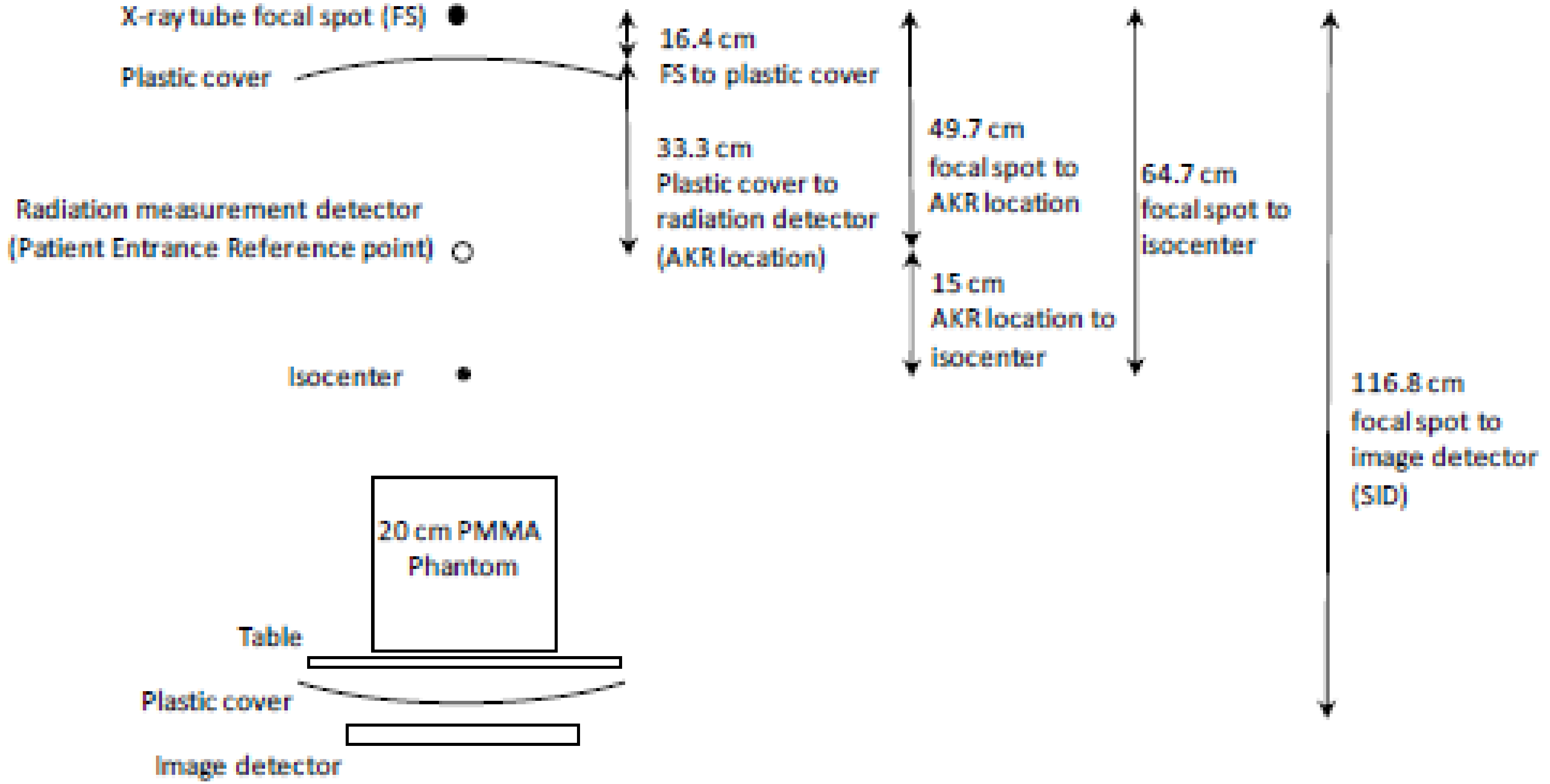
Warning: Always verify that the distance between the patient and gantry cover on the x-ray source side is at least 13 cm (and 30 cm from the x-ray source). Failure to maintain the minimum source-to-skin distance may increase radiation exposure to the patient and result in deterministic effects.



3 Measuring Output (Fluoroscopy and CT)

Imaging Geometry

Figure 4. Schematic diagram of 2D fluoroscopy mode compliance measurements under IEC standards (not to scale)



Manufacturer Reported Air Kerma Rates (Patient at Isocenter)

Air Kerma Rates

Skin entry dose for patient positioned at iso-center.

Note: mA, Air Kermas approximate values.

Table 45: Typical air kerma rates at air kerma reference location,15 cm from the iso-center towards th x-ray tube

Fluoroscopy Mode	Patient Size	kVp	mA	Displayed Air Kerma Rate mGy/min
Low Level	Small	53.0	9.1	13.0
	Medium	67.0	9.8	26.4
	Large	78.0	10.4	38.1
	XLarge	122.0	12.2	113.0
Standard	Small	54.0	9.1	27.4
	Medium	69.0	9.9	54.8
	Large	81.0	10.6	84.1
	XLarge	124.0	12.3	234.0
High Level (Boost mode)	Small	56.0	17.0	64.0
	Medium	72.0	18.5	128.0
	Large	85.0	19.5	193.0
	XLarge	124.0	22.0	472.0

NOT at the FDA defined position for maximum exposure rate calculations

Patient entrance exposure rate when at Isocenter can be SCARY HIGH for fluoroscopy

Very important for operator education and patient safety

System (properly calibrated) does comply with maximum dose limits defined by FDA

Comparison of Fluoroscopy Dose Measurements

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kV	Protocol	Frame Rate	kV	mA	Dose Rate (R/min)
Low Level Fluoro	Default	15	119	12.2	3.6
Normal Fluoro	Default	30	125	12.5	7.8
High Level Fluoro	Default	30	125	22	15.7
Cine					NA
Patient Entrance Exposure	Default	30	76	10	2.33

Ziehm Vision

kV	Protocol	Frame Rate	kV	mA	Dose Rate (R/min)
Low Level Fluoro	Bone/Trunk	12.5	120	4	0.78
Normal Fluoro	Bone/Trunk	8	120	30	7.75
High Level Fluoro	Bone/Trunk	25	120	150	17.56
Cine	Bone/Trunk	8	120	30	7.51
Patient Entrance Exposure	Bone/Trunk	12.5	80	16.4	1.18

Siemens Artis Zeego

kV	Protocol	Frame Rate	kV	mA	Dose Rate (R/min)
Low Level Fluoro	fl - angio	30	123	104	6.3
Normal Fluoro	fl angio	30	123	104	6.3
High Level Fluoro	fl + angio	30	125	104	12
Cine	LD Body	7.5	70	428	22.3
Patient Entrance Exposure	RM Angio Clear	7.5	71	247	1.45
Patient Entrance Exposure	fl neuro	10	65	141	1.1
Patient Entrance Exposure	fl neuro smooth	10	75	68	0.573
Patient Entrance Exposure	fl angio sharp	7.5	67	188	0.775
Patient Entrance Exposure	fl angio clear	7.5	68	210	0.78

Typical Outputs 3D Modes

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Table 16: Dose Settings for Head

Dose	Field of View	Patient Size	kVp	mAs	CTDIw (mGy)*
Low	20 cm	Small	120	40	6.34
		Medium	120	40	6.34
		Large	120	64	10.15
		XLarge	120	80	12.68
Standard	20 cm	Small	120	100	15.86
		Medium	120	100	15.86
		Large	120	128	20.30
		XLarge	120	128	20.30
Enhanced Cranial	20 cm	Small	100	600	64.80
		Medium	100	750	81.00
		Large	110	600	80.04
		XLarge	120	472	77.88
HD3D (Small)	20 cm	Small	120	150	24.18
		Medium	120	150	24.18
		Large	120	188	30.22
		XLarge	120	240	38.68
HD3D (Large)	40 cm	Small	120	150	13.76
		Medium	120	150	13.76
		Large	120	188	17.20
		XLarge	120	240	22.02
Stereotaxy	40 cm	Small	120	150	13.76
		Medium	120	150	13.76
		Large	120	188	17.20
		XLarge	120	188	17.20

*The CTDIw estimates are based on a 16 cm phantom.

Table 15: Dose Settings for Chest

Dose	Field of View	Patient Size	kVp	mAs	CTDIw (mGy)*
Low	20 cm	Small	120	64	5.49
		Medium	120	80	6.87
		Large	120	100	8.58
		X Large	120	160	13.73
Standard	20 cm	Small	120	128	10.99
		Medium	120	160	13.73
		Large	120	200	17.17
		XLarge	120	320	27.47
HD3D (Small)	20 cm	Small	120	188	16.36
		Medium	120	240	20.94
		Large	120	300	26.17
		XLarge	120	472	41.87

Table 14: Dose Settings for Abdomen

Dose	Field of View	Patient Size	kVp	mAs	CTDIw (mGy)*
Low	20 cm	Small	120	64	5.62
		Medium	120	80	7.02
		Large	120	160	14.05
		X Large	120	200	17.57
Standard	20 cm	Small	120	128	11.24
		Medium	120	200	17.57
		Large	120	320	28.11
		XLarge	120	400	35.13
HD3D (Small)	20 cm	Small	120	188	16.47
		Medium	120	300	26.35
		Large	120	472	42.15
		XLarge	120	600	52.70
HD3D (Large)	40 cm	Small	120	300	21.20
		Medium	120	375	26.50
		Large	140	375	36.95
		XLarge	140	472	47.30

*The CTDIw estimates are based on a 32 cm phantom.

Example Measurements (3D)

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3D Imaging Transaxial FOV of 16 cm

$CTDI_{100}$ measurements do not capture all of dose

$CTDI_{100,w}$ measured with 100 mm chamber and CTDI Phantoms at center and periphery can be used to compare to reference values (manual and console)

Centering phantom can be challenging

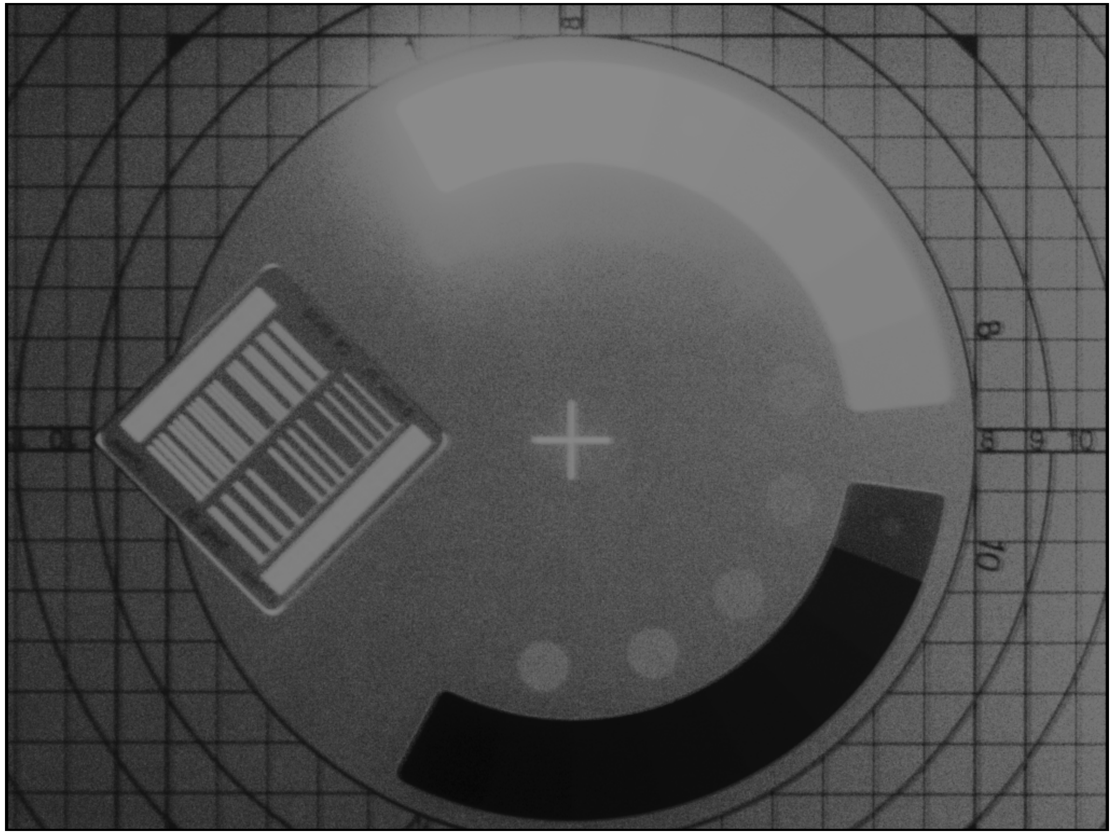
Stabilize phantom!

- Flat table + Heavy Cylinder = CRASH!

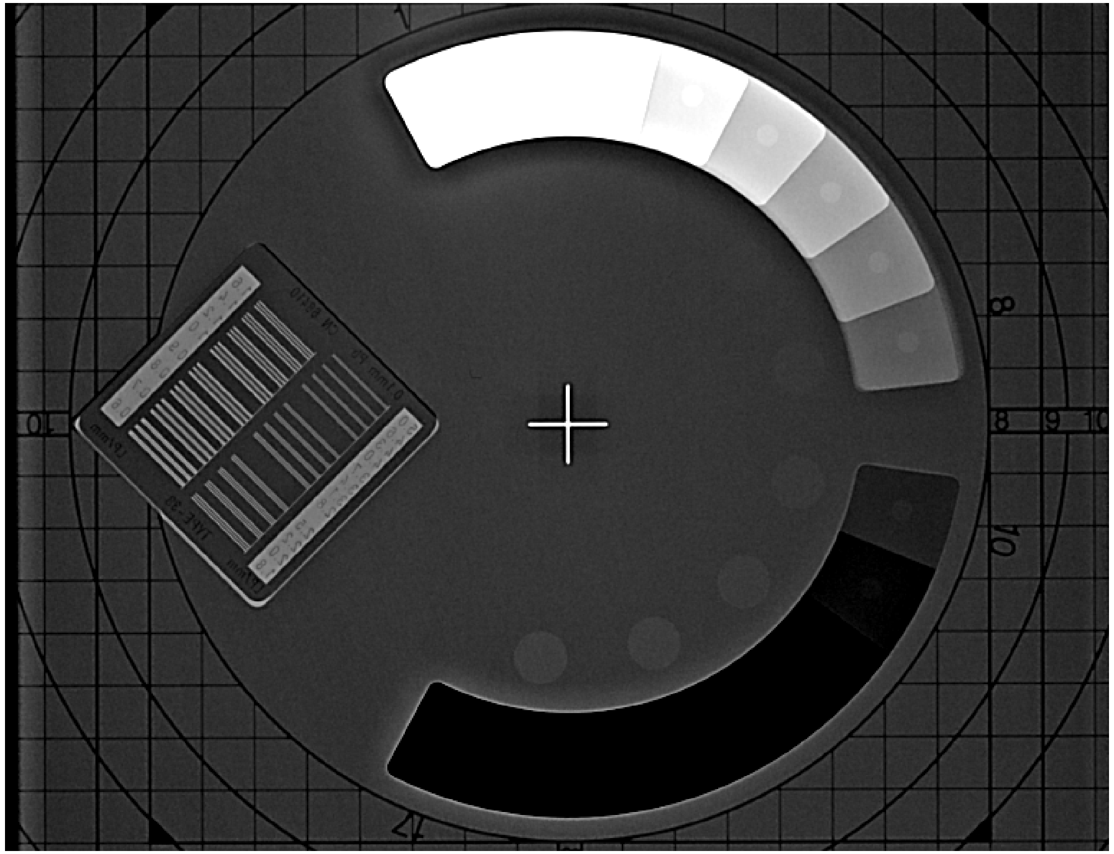
In air measurements or phantom with small chamber dose measurement options

4 Image Quality

Fluoroscopy Image Quality

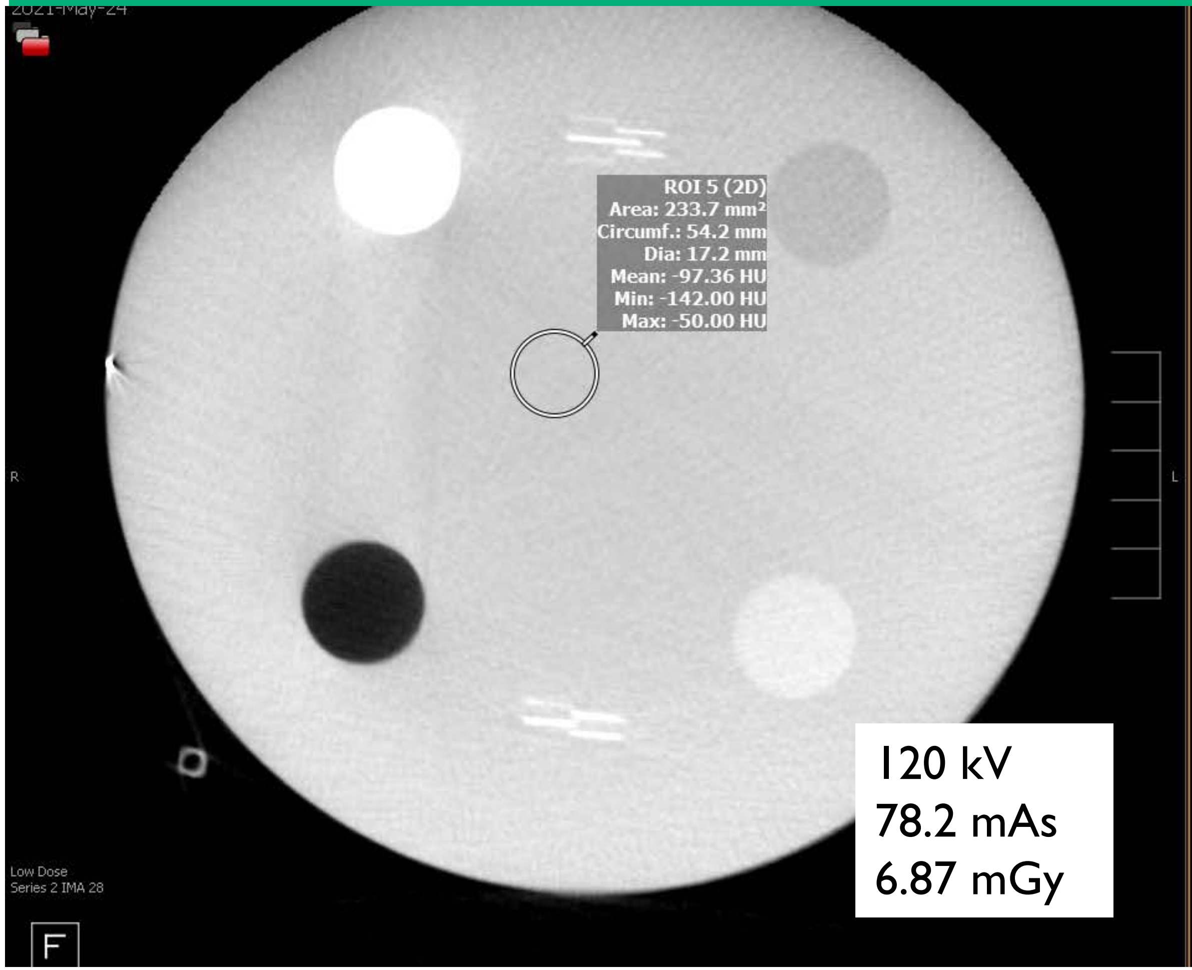


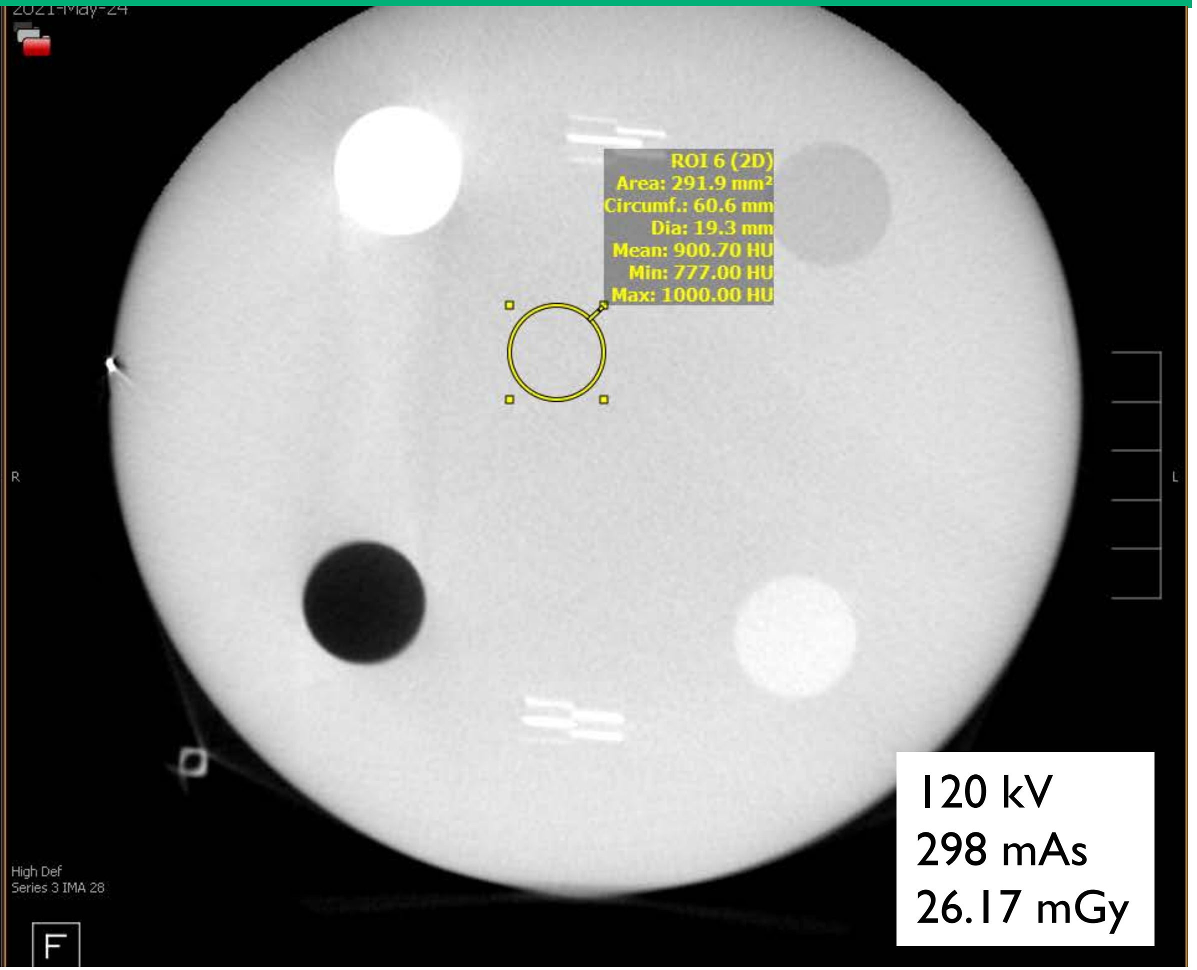
Standard Fluoro O-arm 1000



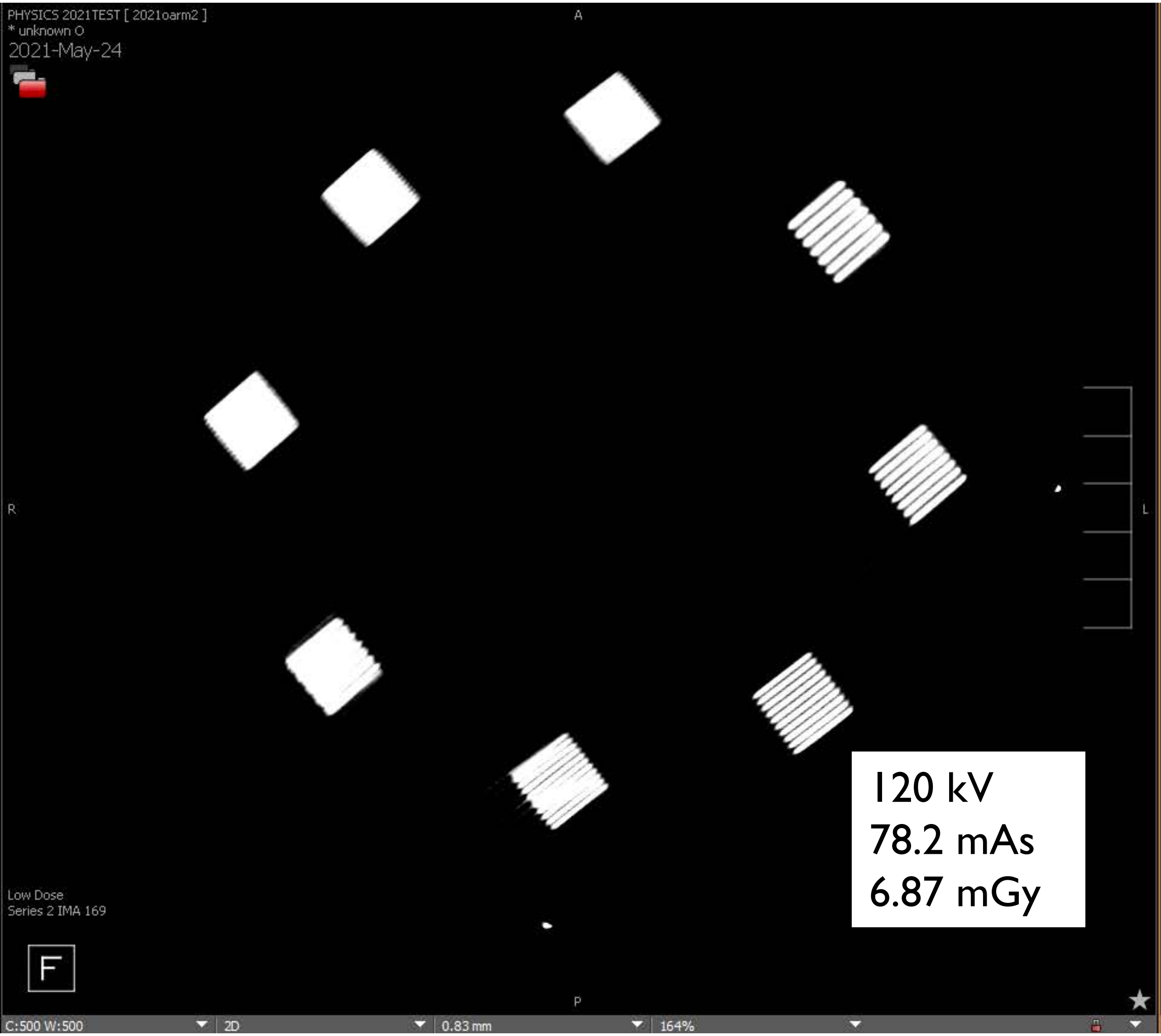
Standard Fluoro Ziehm Vision

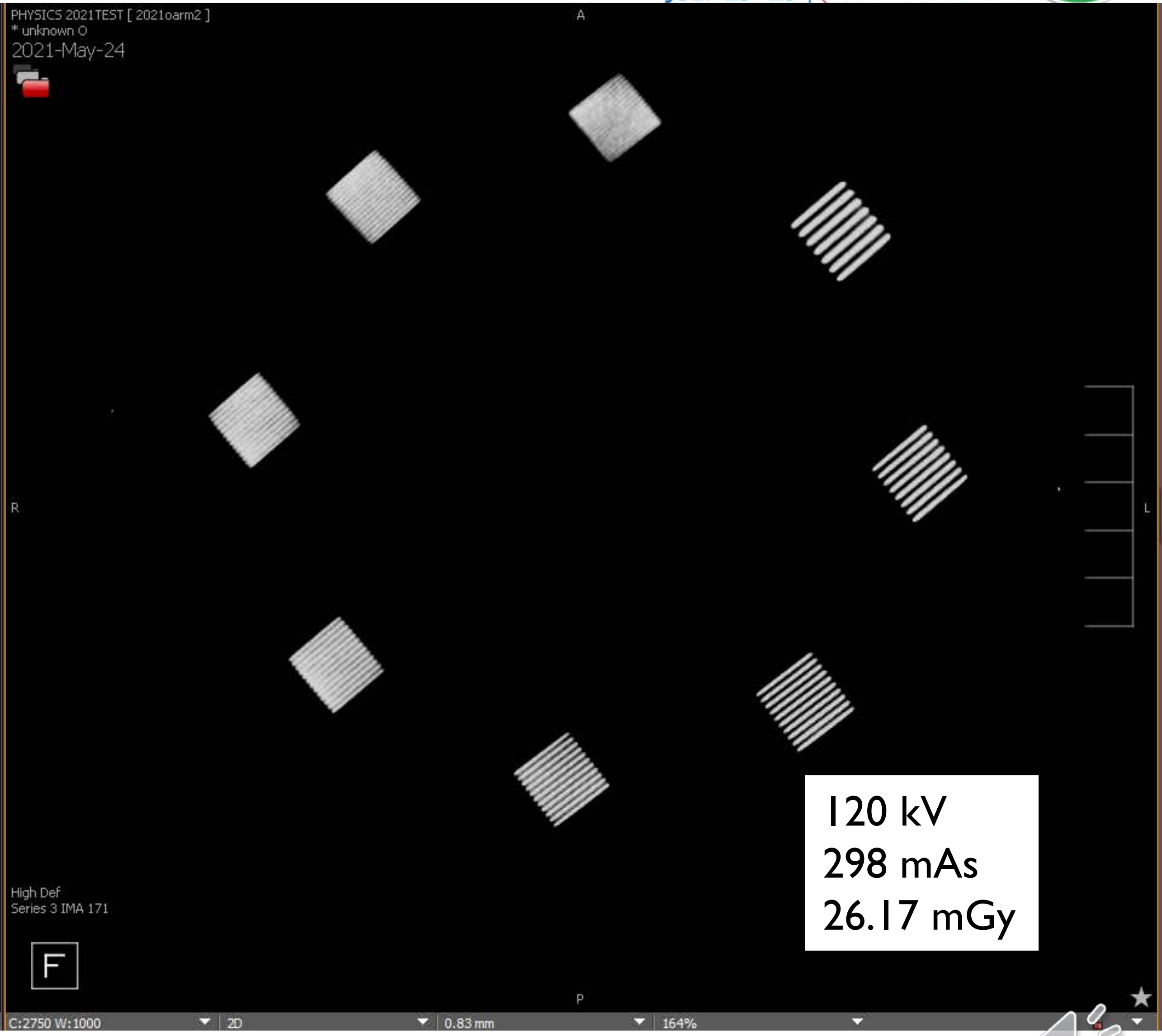
CT#s Acquisition Mode Dependent



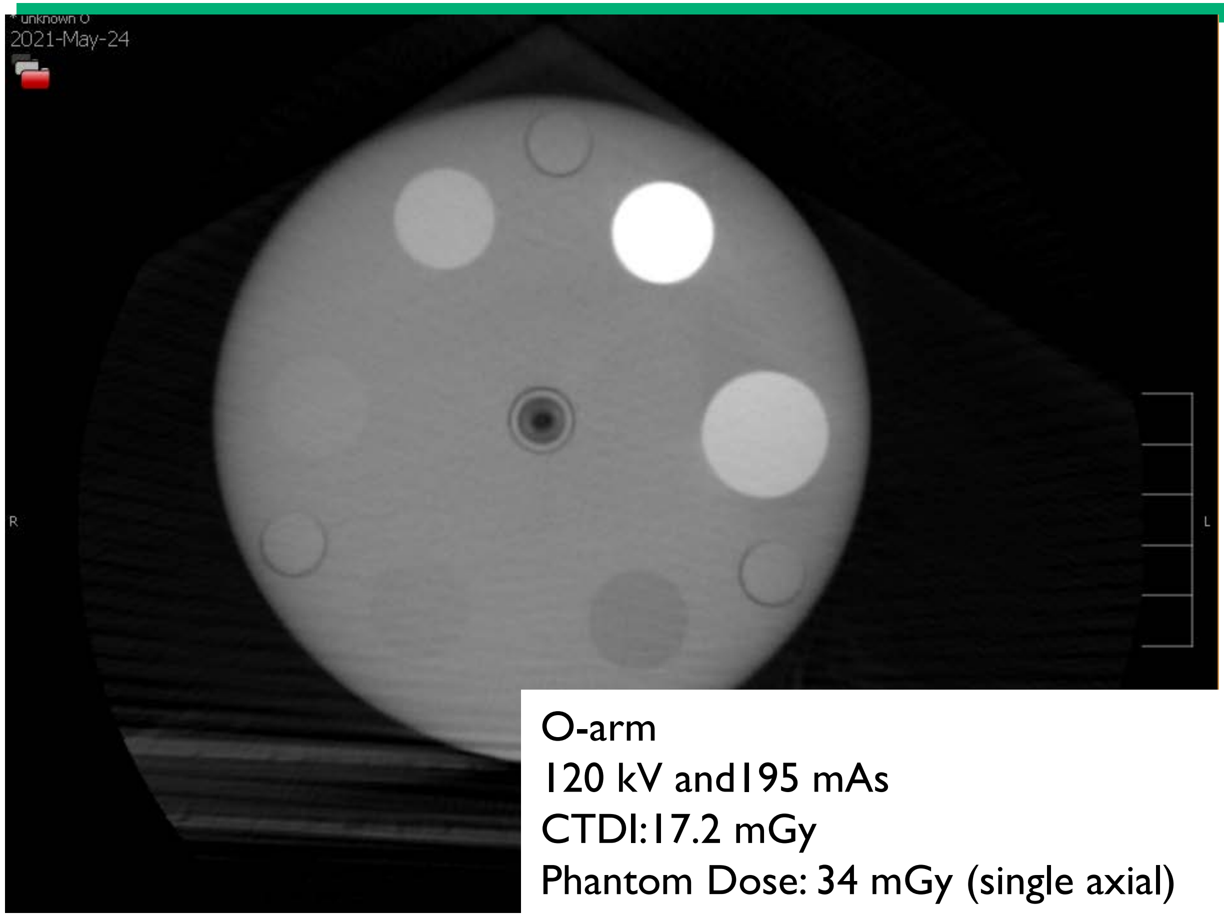


Spatial Resolution Dependent on Acquisition Mode

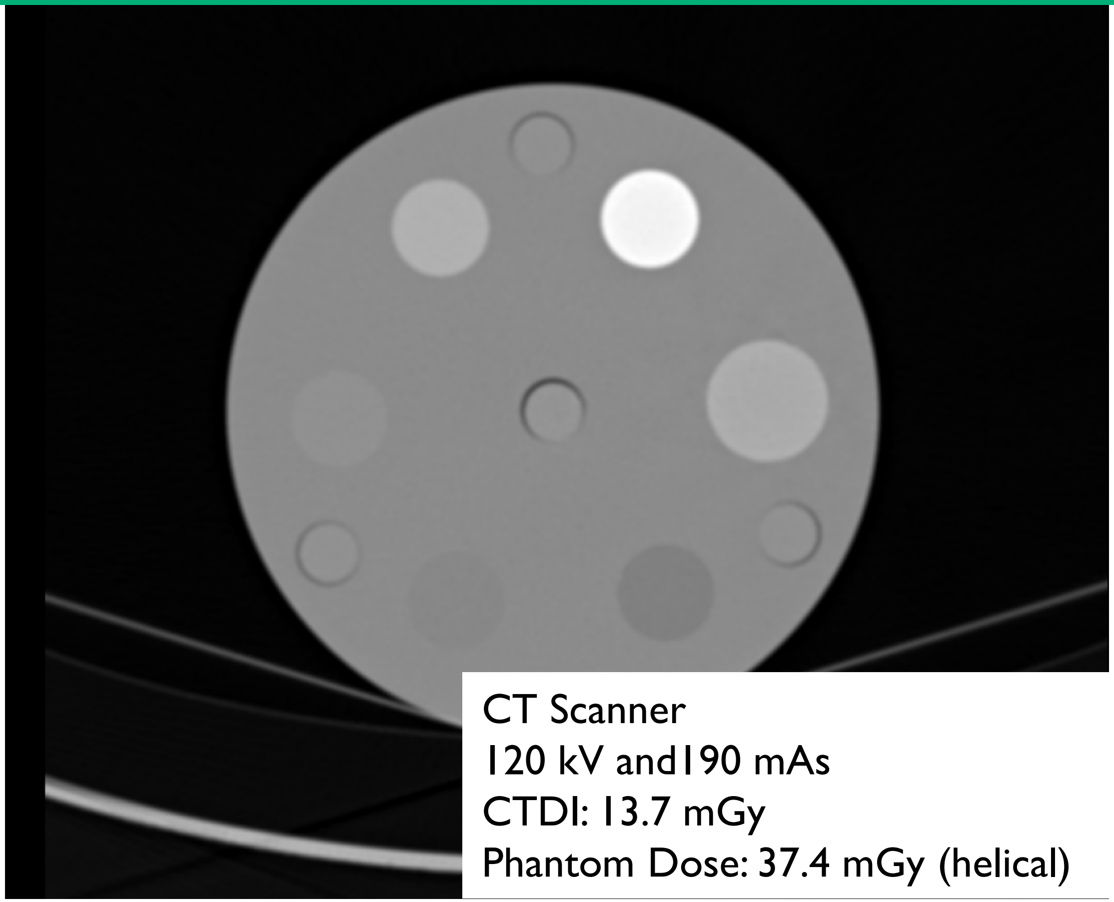




O-arm vs CT Scanner Corgi Phantom (Body)



O-arm
120 kV and195 mAs
CTDI:17.2 mGy
Phantom Dose: 34 mGy (single axial)



CT Scanner
120 kV and190 mAs
CTDI: 13.7 mGy
Phantom Dose: 37.4 mGy (helical)

O-arm vs CT Scanner Corgi Phantom (Head)

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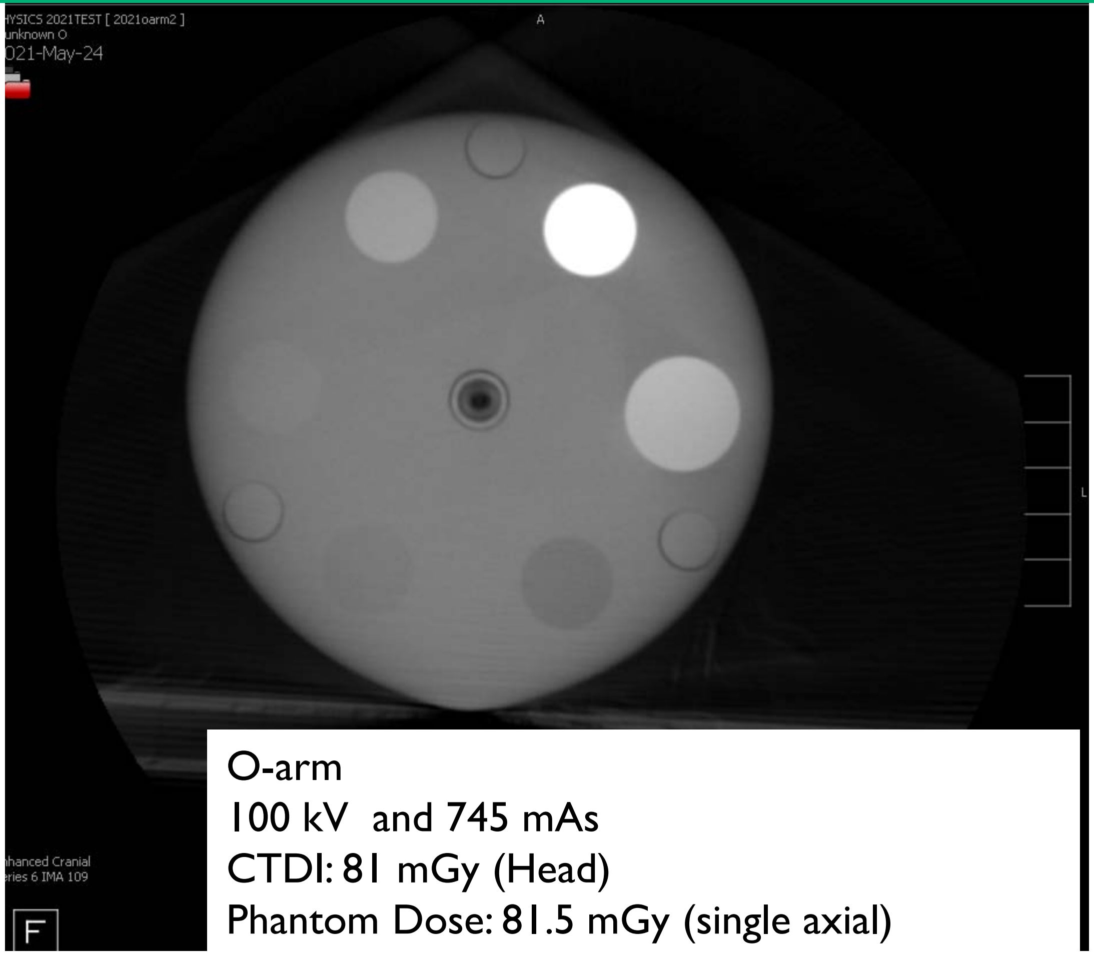
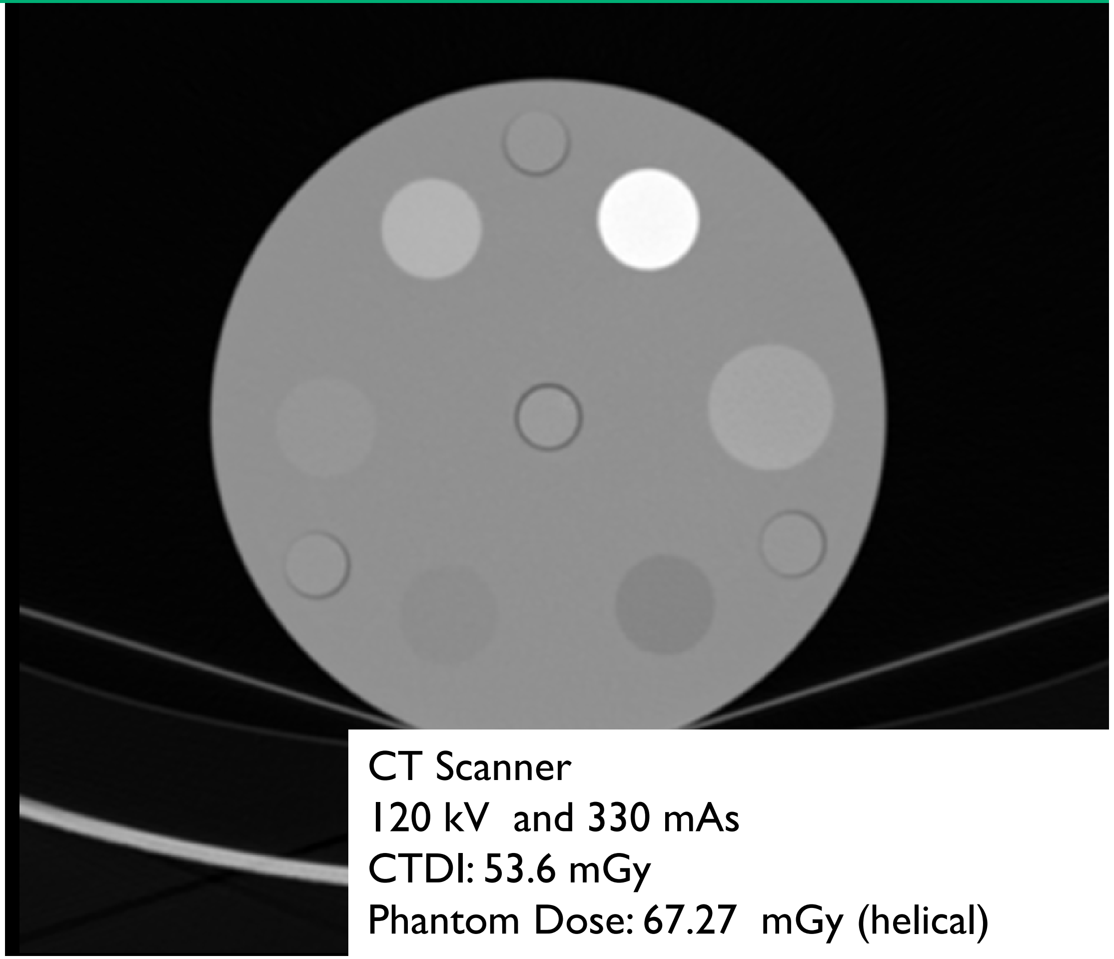


O-arm
100 kV and 745 mAs
CTDI: 81 mGy (Head)
Phantom Dose: 81.5 mGy (single axial)



CT Scanner
120 kV and 330 mAs
CTDI: 53.6 mGy
Phantom Dose: 67.27 mGy (helical)

Comparison of dose distributions

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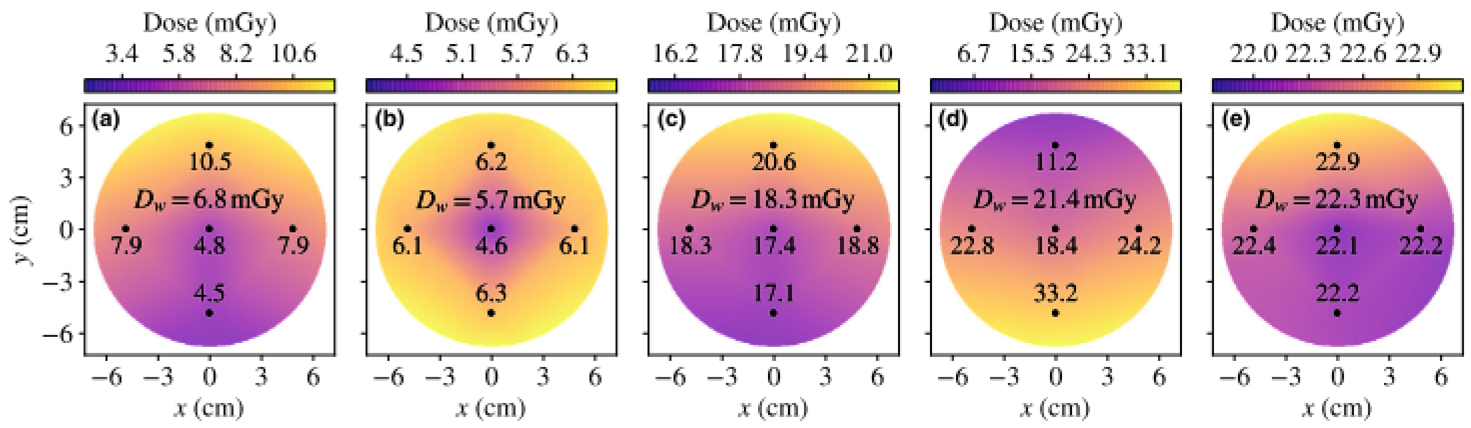

FIG. 3. Dose distributions ("maps") for the five cone-beam computed tomography systems with nominal scan protocols: (a) orthopaedics system; (b) breast system; (c) image-guided surgery system; (d) angiography system; and (e) image-guided radiation therapy system. Note the differences in spatial distribution of dose for various systems and source-detector orbits — for example, radially symmetric for (b, c, e) 360° orbits, and asymmetric for (a, d) half-scan orbits.

Cone-beam CT dose and imaging performance evaluation with a modular, multipurpose phantom

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Med Phys. 2020 Feb; 47(2):467-479

Noise Power Spectrum

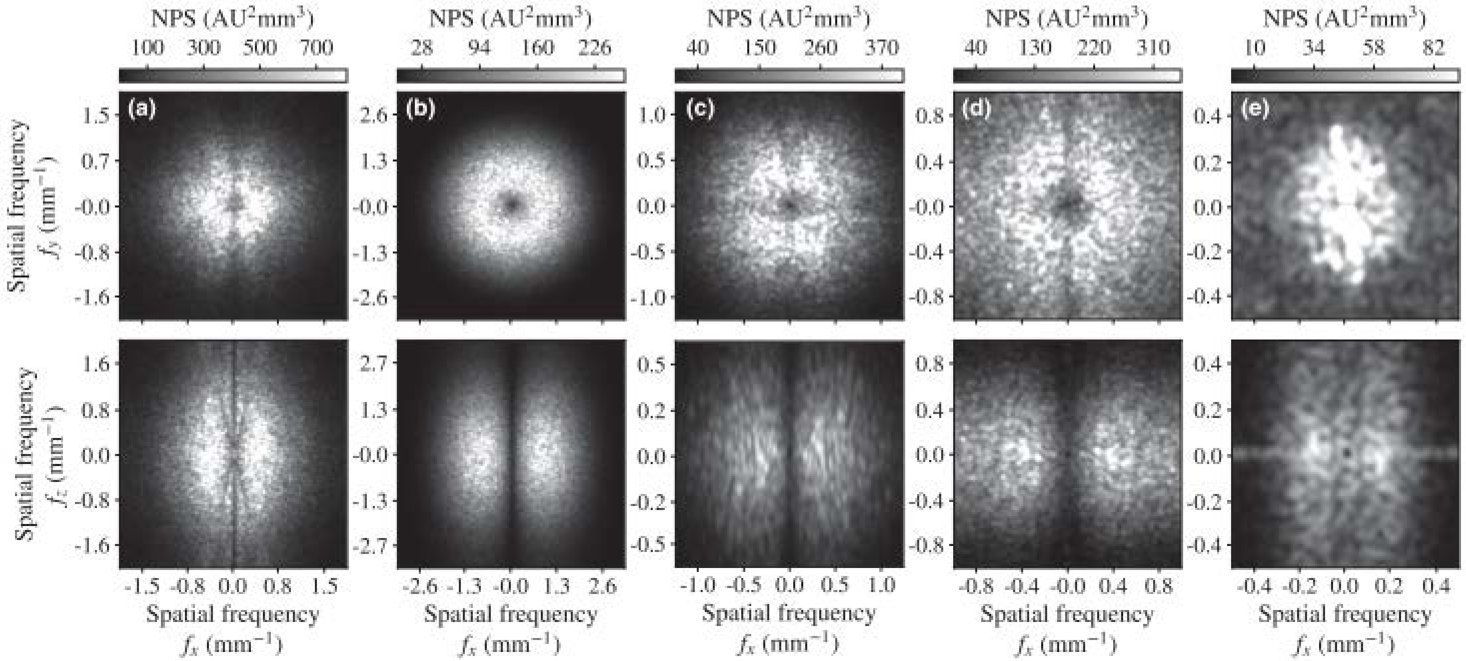

FIG. 7. Noise-power spectrum in: (a) orthopaedics system; (b) breast system; (c) image-guided surgery system; (d) angiography system; and (e) image-guided radiation therapy system. Top row shows central axial and the bottom row shows the central coronal slices of the three-dimensional noise-power spectrum for each system.

Cone-beam CT dose and imaging performance evaluation with a modular, multipurpose phantom

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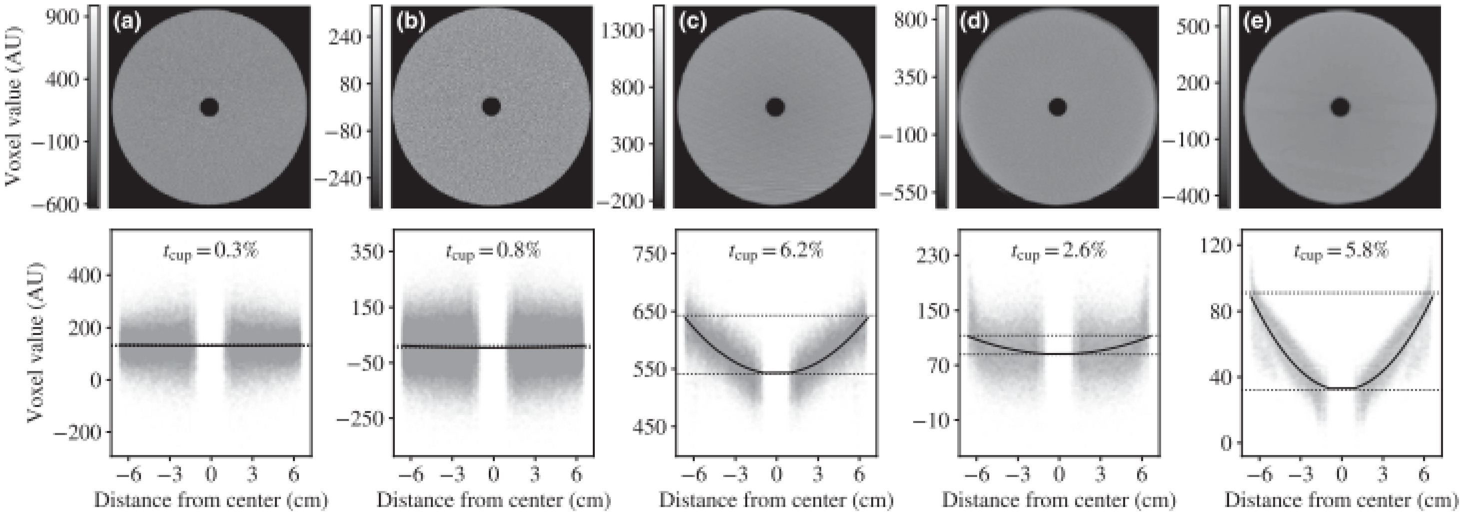

FIG. 4. Axial plane image uniformity in: (a) orthopaedics system; (b) breast system; (c) image-guided surgery system; (d) angiography system; and (e) image-guided radiation therapy system. Top row shows axial slices at the center of the uniform module that is proximal to the source plane for a given system. Bottom row shows radial profiles of image intensities used to quantify the cupping artifact magnitude.

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MTF

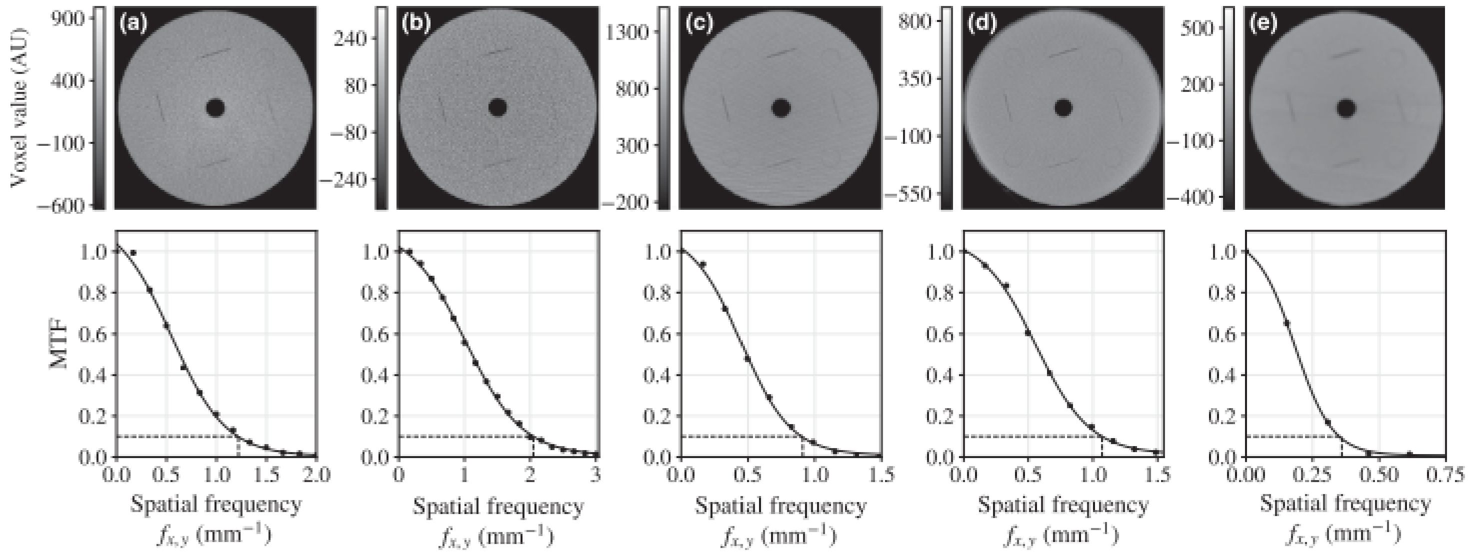

FIG. 8. Modulation transfer function (MTF) in: (a) orthopaedics system; (b) breast system; (c) image-guided surgery system; (d) angiography system; and (e) image-guided radiation therapy system. Top row shows the central axial slice of the line spread function module. Bottom row shows MTF, with dotted line marking the spatial frequency corresponding to MTF = 10%.

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O-arm Overall System ASsessment

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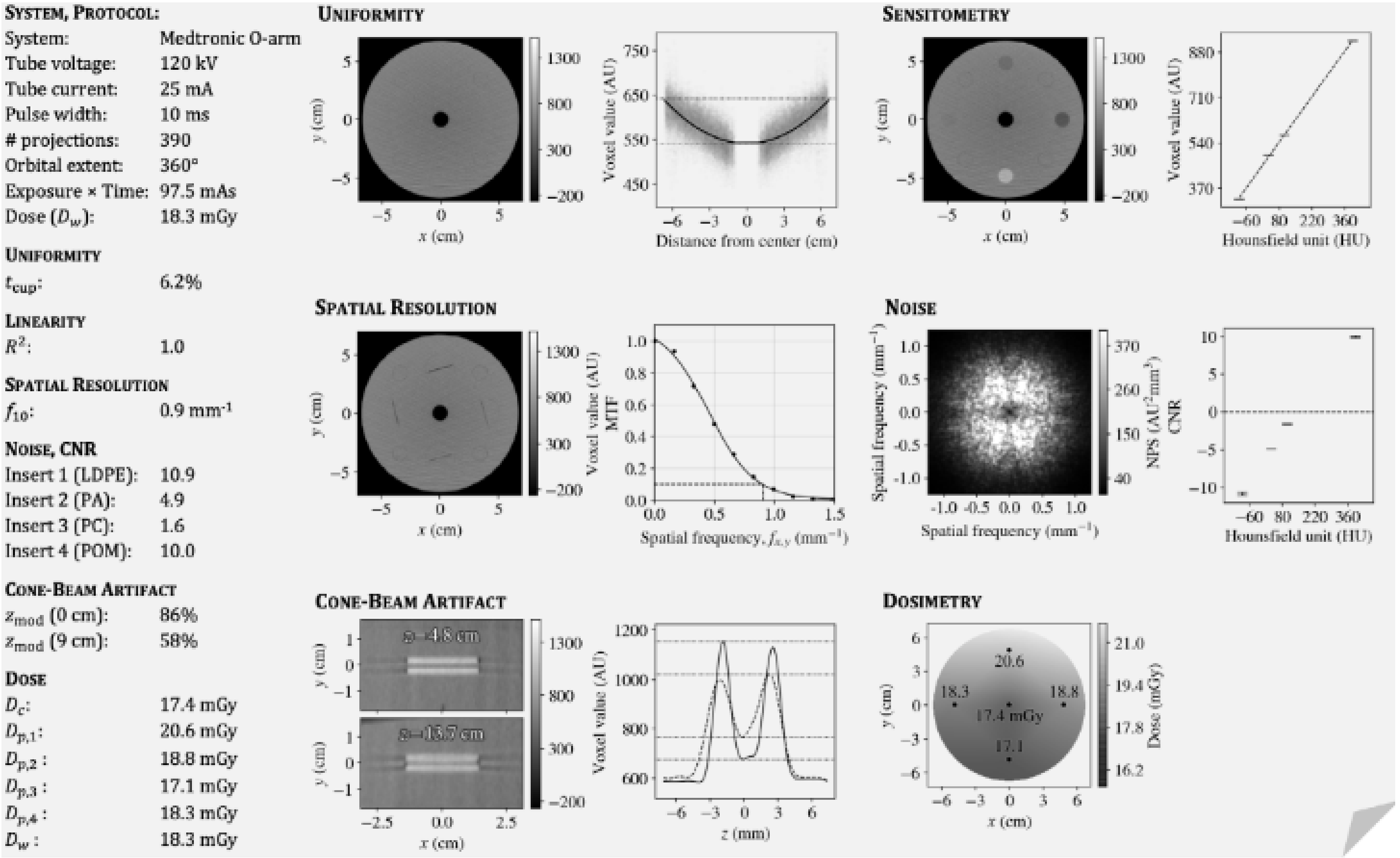

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5 What do I NEED to measure

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Fluoroscopy Tests

Classified and registered as fluoroscopy system

- Patient entrance at 30 cm from input
- Maximum exposure rates
- Refence point air kerma accuracy
- DAP accuracy
- High contrast resolution (mag modes)
- Low contrast resolution
- Output Reproducibility
- HVL
- Tube potential accuracy
- X-ray field/collimation accuracy and alignment
- Display Monitor

Computed Tomography Tests

Not required but recommended to treat it like non-diagnostic CT scanner

Image quality

- **Low and high contrast resolution**
- **Uniformity**
- **(Not CT # accuracy)**
- **NPS, MTF, Cone Beam Artifacts, Cupping (with appropriate phantom)**

Can measure Dose in air or other phantom if benchmarked to acceptance $CTDI_{100}$

- **$CTDI_{free,air}$ values not available in Technical Reference Manual**

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RUSH

Excellence is just the beginning.