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?
O-arm

FDA 510K approval with substantial equivalence for predicate fluoroscopy system
Initially cleared in 2005 with substantial equivalence to Siemens SIREMOBIL

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

FDA 510K approval with substantial equivalence for predicate fluoroscopy system
Initially cleared in 2005 with substantial equivalence to Siemens SIREMOBIL

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.

Interventional Procedures
What exactly is an O-arm?

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
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**
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
Multiple Versions

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 Acquisition
Limitations

Requires Performance Checks and possibly Maintenance after collision

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<th>Description</th>
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<th>Method</th>
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High patient entrance dose rate at Isocenter (3D position)
Which regulations should really apply?
2 Hands on with the O-arm
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
Positioning and Closing the O-arm
Moving the Gantry in a Transverse Direction

Figure 74: 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

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 length, with tapered ends (see Figure 65).

Note: Placing the Patient Spacer, make sure to sterile glove before the Patient Spacer enters the sterile field over sterilizing the Patient Spacen on page 107.

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 patient-to-skin distance may result in unnecessary radiation exposure to the patient and result in deterministic effects.
3 Measuring Output (Fluoroscopy and CT)
Figure 4. Schematic diagram of 2D fluoroscopy mode compliance measurements under IEC standards (not to scale)

- X-ray tube focal spot (FS)
- Plastic cover
- Radiation measurement detector (Patient Entrance Reference point)
- Isocenter
- 20 cm PMMA Phantom
- Table
- Plastic cover
- Image detector
- 16.4 cm FS to plastic cover
- 33.3 cm Plastic cover to radiation detector (AKR location)
- 49.7 cm focal spot to AKR location
- 15 cm AKR location to isocenter
- 64.7 cm focal spot to isocenter
- 116.8 cm focal spot to image detector (SID)
Manufacturer Reported Air Kerma Rates (Patient at Isocenter)

- 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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<th>Ziehm Vision</th>
<th>Siemens Artis Zeego</th>
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### Typical Outputs 3D Modes

#### Table 14: Dose Settings for Abdomen

<table>
<thead>
<tr>
<th>Dose</th>
<th>Field of View</th>
<th>Patient Size</th>
<th>kVP</th>
<th>mAs</th>
<th>CTDIwr (mGy)</th>
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<tr>
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<td>Small</td>
<td>120</td>
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<td>120</td>
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<td>13.33</td>
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#### Table 15: Dose Settings for Chest

<table>
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<th>Dose</th>
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<th>Patient Size</th>
<th>kVP</th>
<th>mAs</th>
<th>CTDIwr (mGy)</th>
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<td>13.73</td>
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#### Table 16: Dose Settings for Head

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<th>Field of View</th>
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<th>kVP</th>
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<td>160</td>
<td>13.73</td>
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The CTDIwr estimates are based on a 16 cm phantom.

*The CTDIwr estimates are based on a 22 cm phantom.*
Example Measurements (3D)

3D Imaging Transaxial FOV of 16 cm
CTDI\textsubscript{100} measurements do not capture all of dose
CTDI\textsubscript{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

120 kV  
78.2 mAs  
6.87 mGy

120 kV  
298 mAs  
26.17 mGy
Spatial Resolution Dependent on Acquisition Mode

120 kV
78.2 mAs
6.87 mGy

120 kV
298 mAs
26.17 mGy
O-arm vs CT Scanner Corgi Phantom (Body)

O-arm
120 kV and 195 mAs
CTDI: 17.2 mGy
Phantom Dose: 34 mGy (single axial)

CT Scanner
120 kV and 190 mAs
CTDI: 13.7 mGy
Phantom Dose: 37.4 mGy (helical)
O-arm vs CT Scanner Corgi Phantom (Head)

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

Fig. 3. Dose distributions ("maps") for the five cone-beam computed tomography systems with nominal scan protocols: (a) orthopedics 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.
Noise Power Spectrum

Fig. 7. Noise-power spectrum in: (a) orthopedics 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.
Fig. 4. Axial plane image uniformity in: (a) orthopedics 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.
Cone-beam CT dose and imaging performance evaluation with a modular, multipurpose phantom

J. H. Siewerdsen and A. Uneri
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A. M. Hernandez, G. W. Burkett, and J. M. Boone
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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%.

O-arm Overall System ASsessment

**O-arm Overall System ASsessment**

### System, Protocol

- **System**: Mechatronic O-arm
- **Tube voltage**: 120 kV
- **Tube current**: 25 mA
- **Pulse width**: 10 ms
- **# projections**: 399
- **Orbital pitch**: 26.9°
- **Exposure x Time**: 97.5 mAs
- **Dose (D_{eq})**: 18.3 mGy

### Uniformity

- **Spatial Resolution**: 0.9 mm
- **Noise, CNR**
  - Insert 1 (LDPE): 10.9
  - Insert 2 (PA): 4.9
  - Insert 3 (FC): 1.6
  - Insert 4 (POM): 10.0

### Cone-Beam Artifact

- **Dose**
  - D_{eq}: 17.4 mGy
  - D_{eq,1}: 20.6 mGy
  - D_{eq,2}: 18.0 mGy
  - D_{eq,3}: 17.1 mGy
  - D_{eq,4}: 18.3 mGy
  - D_{eq}: 18.3 mGy

### Cone-Beam Artifact

### Sensitometry

- **Noise**

### Dosemetry

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

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5 What do I NEED to measure
Fluoroscopy Tests

Classified and registered as fluoroscopy system

- Patient entrance at 30 cm from input
- Maximum exposure rates
- Reference 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

$\text{CTDI}_{100}$

$\text{CTDI}_{\text{free,air}}$ values not available in Technical Reference Manual