

## APPENDIX 3D

### LOT 4 SPECIFICATION

#### FLUOROSCOPY AND ASSOCIATED OPTIONS AND RELATED SERVICES

##### 1. Introduction

1.1. This Lot is for the supply of Fluoroscopy X-Ray systems with all associated options and accessories. Fluoroscopy systems will be used for real-time moving images of the internal structures of a patient for general diagnostic X-Ray guided studies.

1.2. The core product lines within this Lot are as follows:

Line Number	
1	Under Couch Radiographic / Fluoroscopy System
2	Under Couch Radiographic / Fluoroscopy System with Flat Panel Detector
3	Over Couch Radiographic / Fluoroscopy System
4	Over Couch Radiographic / Fluoroscopy System with Flat Panel Detector
5	Multipurpose Radiographic / Fluoroscopy System with Flat Panel Detector

1.3. Product line(s) must be supplied with a minimum 7 year expected lifecycle under proper use and maintenance.

##### 2. Line 1 – Under Couch Radiographic / Fluoroscopy System

2.1. This is the core technical specification for a conventional under couch radiographic / fluoroscopy system for general diagnostic X-Ray guided studies.

2.2. The core components of an under couch radiographic/fluoroscopic system:

2.2.1. X-Ray generator.

2.2.2. Integrated patient table with under couch X-Ray tube and over table fluoroscopy carriage.

2.2.3. Control area monitor(s) for review and post processing.

2.2.4. Safety requirements.

2.3. X-Ray generator

2.3.1. The fluoroscopy system must be supplied with a minimum of a 50kW high frequency generator.

2.3.2. The generator must include fully integrated controls (in a single console) for the following:

2.3.2.1. Conventional fluoroscopy.

2.3.2.2. DR Acquisition.

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- 2.3.3. The fluoroscopy system must have capabilities to adjust dose level and kV/mA curve and range of filters to enable optimised imaging across a range of applications to accommodate different sized patients and anatomical regions.
- 2.3.4. The fluoroscopy system must provide up to 6 pps (pulses per second) for fluoroscopy.
- 2.3.5. The fluoroscopy system must provide up to 7.5 fps for acquisition.
- 2.3.6. Fluoroscopy kV and mA must have automatic control based on patient attenuation.
- 2.3.7. The generator must be able to be operated in all of these modes:
  - 2.3.7.1. kV-Ma-mAs.
  - 2.3.7.2. kV-mAs.
  - 2.3.7.3. kV-mA (AEC (Automatic Exposure Control)).
- 2.3.8. Acquisition range must be at least 40 to 125kVp (peak Kilo Voltage).
- 2.3.9. Fluoroscopic range must be at least 60 to 110kVp.
- 2.3.10. The fluoroscopy system must be capable of storing at least 50 different organ programs for a range of clinical applications, anatomical regions and body sizes.

2.4. Patient table – general:

- 2.4.1. The patient table must be at least 200cm long.
- 2.4.2. The patient table must be at least 70cm wide.
- 2.4.3. The height of the patient table must be adjustable to a minimum of 90cm from the floor.
- 2.4.4. The patient table must tilt 90 degrees to the vertical position (patient upright).
- 2.4.5. The patient table must tilt 15 degrees reverse Trendelenburg.
- 2.4.6. The speed of table tilt must be at least 3 degrees per second.
- 2.4.7. The maximum patient weight without angulation must be at least 200kg.
- 2.4.8. The maximum patient weight with full angulation must be at least 140kg.
- 2.4.9. The patient table must have a floating top (motorised or equivalent with longitudinal and lateral motion).
- 2.4.10. The coverage for Bucky studies must be at least 140cm.

2.5. Under couch X-Ray tube:

- 2.5.1. The total filtration of the X-Ray tubes must be greater than 2.5mm Al equivalent.
- 2.5.2. The fluoroscopy system must provide a dual focus X-Ray tube with maximum focal spot sizes of 0.7mm for fine focus and 1.2mm for broad focus.
- 2.5.3. The X-Ray tube must include pulsing (up to 6pps).
- 2.5.4. The anode heat storage capacity must be at least 300kHU.
- 2.5.5. The anode heat dissipation rate must be at least 60,000 HU/minute.
- 2.5.6. The fluoroscopy system must have manual and/or automatic control of collimation.
- 2.5.7. The fluoroscopy system must have automatically selected filtration.

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2.6. Over table fluoroscopy carriage:

- 2.6.1. The fluoroscopy carriage must have adjustable height above the patient table.
- 2.6.2. The gap between the table top and fluoroscopy carriage must be at least 45cm.
- 2.6.3. Full motion controls must be included on the fluoroscopy carriage.
- 2.6.4. The longitudinal travel must be at least 80cm.
- 2.6.5. The lateral travel must be at least 20cm.
- 2.6.6. All controls must be ambidextrous.
- 2.6.7. The fluoroscopy carriage must include a retractable compression cone where applicable.
- 2.6.8. The fluoroscopy carriage must include an anti-scatter grid.
- 2.6.9. A range of image receptor sizes must be available. The maximum size available must be at least 33cm (diameter).
- 2.6.10. The image receptor must have at least 3 additional magnification settings.
- 2.6.11. The smallest field size must not be greater than 20cm.
- 2.6.12. The spatial resolution in the centre of the field of view of the largest field size must be greater than 2.1lp/mm.
- 2.6.13. The maximum detective quantum energy (DQE) must be at least 60%.
- 2.6.14. A charged-couple device (CCD) camera must be connected to the output of the image receptor.
- 2.6.15. The CCD must have at least 1024 x 1024 pixels.
- 2.6.16. The CCD must have an image depth of at least 12bits.

2.7. Control area monitor(s) for review and post processing.

- 2.7.1. A minimum of one in-room review monitor, minimum 17" screen (measured diagonally corner to corner) with lockable brightness and contrast controls must be supplied.
- 2.7.2. The in-room monitor must either be ceiling supported or supplied with a monitor cart.
- 2.7.3. Additional monitors to be supplied in accordance with individual customer requirements.
- 2.7.4. The fluoroscopy system must automatically set image parameters based on the ordered exam information.
- 2.7.5. The fluoroscopy system must have last image hold functionality.
- 2.7.6. Post-processing must include:
  - 2.7.6.1. Image processing customised to match exam.
  - 2.7.6.2. Image annotation.
  - 2.7.6.3. Window and level.
  - 2.7.6.4. Image reversal.
  - 2.7.6.5. Image rotation and flip.
  - 2.7.6.6. Electronic collimation.

2.8. Safety requirements:

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- 2.8.1. The fluoroscopy system must have a dose indication and display exposure time.
- 2.8.2. The fluoroscopy system must have automatic brightness control and variable dose selection.
- 2.8.3. The fluoroscopy system must have the following dose reduction features:
  - 2.8.3.1. Pulsed/continuous fluoroscopy (with maximum of 6 Fps/pps).
  - 2.8.3.2. Variable image receptor dose levels.
  - 2.8.3.3. A range of kV and mA operating characteristics to optimise patient dose.
- 2.8.4. The fluoroscopy system must be supplied with a dose area product (DAP) (can be calculated or measured) and must indicate the accumulated DAP.
- 2.8.5. The radiation beam must be confined to within the image reception area with a maximum overlap not greater than 15% of the image reception area.
- 2.8.6. The absorbed dose at the skin of a patient (20cm water) must not exceed 100mGy min<sup>-1</sup> for all available field sizes (in fluoroscopy or equivalent calibration method).
- 2.8.7. The fluoroscopy system must have automatic brightness control and variable dose selection.
- 2.8.8. The fluoroscopy system must have software and/or mechanical anti-collision protection.
- 2.8.9. The fluoroscopy system must be capable of dynamically detecting and adjusting the dose for optimal imaging.
- 2.8.10. The table top must be sealed to prevent the ingress of bodily fluids and the whole fluoroscopy system must be easy to clean.

**3. Line 2 – Under Couch Radiographic / Fluoroscopy System with Flat Panel Detector**

- 3.1. This is the core technical specification for a conventional Under Couch Radiographic / Fluoroscopy System for general diagnostic X-Ray guided studies equipped with a Flat Panel Digital Detector for radiography studies.
- 3.2. The core components of an under couch radiographic / fluoroscopy system with flat panel detector:
  - 3.2.1. X-Ray generator.
  - 3.2.2. Integrated patient table with under couch x-ray tube and over table fluoroscopy carriage.
  - 3.2.3. Flat panel digital detector with control console.
  - 3.2.4. Radiographers workstation.
  - 3.2.5. In-room image monitor.
  - 3.2.6. Control area monitor(s) for review and post processing.
  - 3.2.7. Safety requirements.
- 3.3. X-Ray Generator:
  - 3.3.1. The fluoroscopy system must be supplied with a minimum of a 50kW high frequency generator.

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- 3.3.2. The generator must include fully integrated controls (in a single console) for the following:
    - 3.3.2.1. Conventional fluoroscopy.
    - 3.3.2.2. DR Acquisition.
  - 3.3.3. The fluoroscopy system must have capabilities to adjust dose level and kV/mA curve and range of filters to enable optimised imaging across a range of applications to accommodate different sized patients and anatomical regions.
  - 3.3.4. The fluoroscopy system must provide up to 6 pps for fluoroscopy.
  - 3.3.5. The fluoroscopy system must provide up to 7.5 fps for acquisition.
  - 3.3.6. Fluoroscopy kV and mA must have automatic control based on patient attenuation.
  - 3.3.7. The generator must be able to be operated in all of these modes:
    - 3.3.7.1. kV-Ma-mAs.
    - 3.3.7.2. kV-mAs.
    - 3.3.7.3. kV-mA (AEC).
  - 3.3.8. Acquisition range must be at least 40 to 125kVp.
  - 3.3.9. Fluoroscopic range must be at least 60 to 110kVp.
  - 3.3.10. The fluoroscopy system must be capable of storing at least 50 different organ programs for a range of clinical applications, anatomical regions and body sizes.
- 3.4. Patient table – general:
- 3.4.1. The patient table must be at least 200cm long.
  - 3.4.2. The patient table must be at least 75cm wide.
  - 3.4.3. The height of the patient table must be adjustable to a minimum of 90cm.
  - 3.4.4. The patient table must tilt 90 degrees to the vertical position (patient upright).
  - 3.4.5. The patient table must tilt 15 degrees reverse Trendelenburg.
  - 3.4.6. The speed of table tilt must be at least 3 degrees per second.
  - 3.4.7. The maximum patient weight without angulation must be at least 200kg.
  - 3.4.8. The maximum patient weight with full angulation must be at least 140kg.
  - 3.4.9. The patient table must have a floating top (motorised or equivalent with longitudinal and lateral motion).
- 3.5. Under couch X-Ray tube:
- 3.5.1. The total filtration of the X-Ray tubes must be greater than 2.5 mm Al equivalent.
  - 3.5.2. The fluoroscopy system must provide a dual focus X-Ray tube with maximum focal spot sizes of 0.7mm for fine focus and 1.2mm for broad focus.
  - 3.5.3. The X-Ray tube must include pulsing (up to 6pps).
  - 3.5.4. The anode heat storage capacity must be at least 300kHU.
  - 3.5.5. The anode heat dissipation rate must be at least 60,000 HU/minute.
  - 3.5.6. The fluoroscopy system must have manual and or automatic collimation.
  - 3.5.7. The fluoroscopy system must have automatically selected filtration.

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3.6. Over table fluoroscopy carriage:

- 3.6.1. The fluoroscopy carriage must have adjustable height above the patient table.
- 3.6.2. The maximum gap between the table top and fluoroscopy carriage must be at least 50cm.
- 3.6.3. Full motion controls must be included on the fluoroscopy carriage.
- 3.6.4. The longitudinal travel must be at least 90cm.
- 3.6.5. The lateral travel must be at least 20cm.
- 3.6.6. All controls must be ambidextrous.
- 3.6.7. The fluoroscopy carriage must include an anti-scatter grid.
- 3.6.8. The detector must have a nominal input diameter of at least 33cm.
- 3.6.9. The detector must have at least 3 additional magnification settings.
- 3.6.10. The smallest field size must not be greater than 20cm.
- 3.6.11. The spatial resolution in the centre of the field of view of the largest filed size must be greater than 2.1lp/mm.
- 3.6.12. The maximum DQE must be at least 60%.

3.7. Flat panel digital detector with control console:

- 3.7.1. The system must be equipped with a digital flat panel detector suitable for radiography acquisitions.
- 3.7.2. The digital detector must have a sensitive area of at least 35cm x 41cm.
- 3.7.3. The flat panel detector must be fixed or be able to be inserted into the explorator.
- 3.7.4. The Bucky grid must be matched to the digital detector to avoid interference.
- 3.7.5. The spatial resolution must be at least 2.1lp/mm.
- 3.7.6. The minimum DQE must be at least 60% at 0lp/mm and measured using RQA5 beam quality.
- 3.7.7. The detector must have an image digitisation resolution of at least 14bits.
- 3.7.8. The patient contact area must be sealed to prevent the ingress of bodily fluids and the whole system must be easy to clean.

3.8. Radiographer's workstation:

- 3.8.1. A high-resolution review monitor with a minimum 17" screen (measured diagonally corner to corner) 500 cd/m<sup>2</sup> and at least 1 megapixel resolution must be included and be suitable for image quality assessment and annotation.
- 3.8.2. A digital image suitable for preview must be displayed within 10 seconds of exposure.
- 3.8.3. A measure of the exposure received by the detector must be displayed. (The measure must conform to BS EN 62494-1:2008 (as amended))
- 3.8.4. Post-processing must include:
  - 3.8.4.1. Image processing customized to match exam.
  - 3.8.4.2. Image annotation.
  - 3.8.4.3. Window and level.

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- 3.8.4.4. Image greyscale inversion.
- 3.8.4.5. Image rotation and flip.
- 3.8.4.6. Virtual collimation.
- 3.8.4.7. Zoom.

3.8.5. The fluoroscopy system must include a DVD or USB slot to store images and digital video runs.

3.8.6. The fluoroscopy system must export images in conformance to DICOM 3.0.

3.9. In-room image monitor:

3.9.1. A minimum of one in-room review monitor, minimum 17" screen (measured diagonally corner to corner) with lockable brightness and contrast controls must be supplied.

3.9.2. The in-room monitor must either be ceiling supported or supplied with a monitor cart.

3.9.3. Additional monitors to be supplied in accordance with individual customer requirements.

3.9.4. The fluoroscopy system must automatically set image parameters based on the ordered exam information.

3.9.5. Dose monitoring must as a minimum include:

- 3.9.5.1. Dose area product.
- 3.9.5.2. Cumulative dose area product.
- 3.9.5.3. Cumulative fluoroscopy time.

3.9.6. The fluoroscopy system must have last image hold functionality.

3.9.7. Post-processing must include:

- 3.9.7.1. Image processing customised to match exam.
- 3.9.7.2. Image annotation.
- 3.9.7.3. Window and level.
- 3.9.7.4. Image reversal.
- 3.9.7.5. Image rotation and flip.
- 3.9.7.6. Electronic collimation.

3.10. Control area monitor(s) for review and post processing:

3.10.1. A control area monitor must be supplied with the system.

3.10.2. At least one control area review monitor with a minimum 17" screen (measured diagonally corner to corner) and lockable brightness and contrast controls must be supplied.

3.10.3. Distance and angle measurements must be displayed.

3.10.4. The fluoroscopy system must have the ability to adjust collimation using last image hold (virtual collimation).

3.10.5. The fluoroscopy system must conform to DICOM 3.0.

3.11. Safety requirements:

3.11.1. The fluoroscopy system must have a dose indication and display exposure time.

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- 3.11.2. The fluoroscopy system must automatic brightness control and variable dose selection.
- 3.11.3. The fluoroscopy system must have the following dose reduction features:
  - 3.11.3.1. Pulsed/continuous fluoroscopy (with maximum of 6 Fps/pps).
  - 3.11.3.2. Variable image receptor dose levels.
  - 3.11.3.3. A range of kV and mA operating characteristics to optimise patient dose.
- 3.11.4. The fluoroscopy system must be supplied with a DAP (can be calculated or measured) and must indicate the accumulated DAP.
- 3.11.5. The radiation beam must be confined to within the image reception area with a maximum overlap not greater than 15% of the image reception area.
- 3.11.6. The absorbed dose at the skin of a patient (20cm water) must not exceed 100mGy min<sup>-1</sup> for all available field sizes (in fluoroscopy or equivalent calibration method).
- 3.11.7. The fluoroscopy system must automatic brightness control and variable dose selection.
- 3.11.8. The fluoroscopy system must have software and/or mechanical anti-collision protection.
- 3.11.9. The fluoroscopy system must be capable of dynamically detecting and adjusting the dose for optimal imaging.
- 3.11.10. The table top must be sealed to prevent the ingress of bodily fluids and the whole fluoroscopy system must be easy to clean.

**4. Line 3 – Over Couch Radiographic / Fluoroscopy System**

- 4.1. This is the core technical specification for an over couch radiographic / fluoroscopy system for general diagnostic X-Ray guided studies.
- 4.2. The core components of an over couch radiographic / fluoroscopy system:
  - 4.2.1. X-Ray generator.
  - 4.2.2. Integrated patient table with over couch X-Ray tube and under table fluoroscopy carriage.
  - 4.2.3. Control area monitor(s) for review and post processing.
  - 4.2.4. Safety requirements.
- 4.3. X-Ray generator:
  - 4.3.1. The fluoroscopy system must be supplied with a minimum of a 50kW high frequency generator.
  - 4.3.2. The generator must include fully integrated controls (in a single console) for the following:
    - 4.3.2.1. Conventional fluoroscopy.
    - 4.3.2.2. DR Acquisition.
  - 4.3.3. The fluoroscopy system must have capabilities to adjust dose level and kV/mA curve and range of filters to enable optimised imaging across a range of applications to accommodate different sized patients and anatomical regions.

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- 4.3.4. The fluoroscopy system must provide up to 6 pps for fluoroscopy.
  - 4.3.5. The fluoroscopy system must provide up to 7.5 fps for acquisition.
  - 4.3.6. Fluoroscopy kV and mA must have automatic control based on patient attenuation.
  - 4.3.7. The generator must be able to be operated in all of these modes:
    - 4.3.7.1. kV-Ma-mAs.
    - 4.3.7.2. kV-mAs.
    - 4.3.7.3. kV-mA (AEC).
  - 4.3.8. Acquisition range must be at least 40 to 125kVp.
  - 4.3.9. Fluoroscopic range must be at least 60 to 110kVp.
  - 4.3.10. The fluoroscopy system must be capable of storing at least 50 different organ programs for a range of clinical applications, anatomical regions and body sizes.
- 4.4. Patient table – general:
- 4.4.1. The patient table must be at least 200cm long.
  - 4.4.2. The patient table must be at least 75cm wide.
  - 4.4.3. The height of the patient table must be adjustable to a minimum of 90cm.
  - 4.4.4. The patient table must tilt 90 degrees to the vertical position (patient upright).
  - 4.4.5. The patient table must tilt 15 degrees reverse Trendelenburg.
  - 4.4.6. The speed of table tilt must be at least 3 degrees per second.
  - 4.4.7. The maximum patient weight without angulation must be at least 200kg.
  - 4.4.8. The maximum patient weight with full angulation must be at least 140kg.
  - 4.4.9. The patient table must have a floating, motorised or equivalent top (longitudinal and lateral motion).
- 4.5. Over couch X-Ray tube:
- 4.5.1. The height of the X-Ray tube above the table must be adjustable.
  - 4.5.2. The X-Ray tube must be able to be angled at least +/- 30 degrees.
  - 4.5.3. The maximum X-Ray source to detector distance must be at least 1.5 metres.
  - 4.5.4. The total filtration of the X-Ray tubes must be greater than 2.5mm Al equivalent.
  - 4.5.5. The fluoroscopy system must provide a dual focus X-Ray tube with maximum focal spot sizes of 0.7mm for fine focus and 1.2mm for broad focus.
  - 4.5.6. Additional filtration must be automatically selected based on the patient's size and study.
  - 4.5.7. The X-Ray tube must include pulsing (up to 6pps).
  - 4.5.8. The anode heat storage capacity must be at least 300kHU.
  - 4.5.9. The anode heat dissipation rate must be at least 60,000 HU/minute.
  - 4.5.10. The collimation must automatically adjust with changes to the source to image distance.
  - 4.5.11. The fluoroscopy system must have automatic collimation and manually or automatically selected filtration.

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- 4.5.12. The X-Ray system must have a retractable compression cone where applicable.
- 4.6. Under table fluoroscopy carriage:
- 4.6.1. The flat panel detector must acquire both fluoroscopic and radiographic images.
  - 4.6.2. The longitudinal travel must be at least 100cm.
  - 4.6.3. The lateral travel must be at least 20cm.
  - 4.6.4. The movement of the flat panel detector must be linked with the X-Ray tube.
  - 4.6.5. The flat panel detector must include an anti-scatter grid.
  - 4.6.6. The flat panel detector must have a sensitive area of at least 35cm x 41cm.
  - 4.6.7. The spatial resolution must be at least 2.1lp/mm (radiography acquisition).
  - 4.6.8. The minimum DQE must be at least 60% at 0lp/mm and measured using RQA5 beam quality.
  - 4.6.9. The detector must have an image digitization resolution of at least 14bits.
  - 4.6.10. The patient contact area must be sealed to prevent the ingress of bodily fluids and the whole fluoroscopy system must be easy to clean.
- 4.7. Control area monitor(s) for review and post processing:
- 4.7.1. At least one in-room review monitor, minimum 17" screen (measured diagonally corner to corner) with lockable brightness and contrast controls must be supplied.
  - 4.7.2. The fluoroscopy system must automatically set image acquisition parameters based on the ordered exam information and patient characteristics.
  - 4.7.3. Dose monitoring must be included (dose area product, cumulative dose area product, and cumulative fluoroscopy time).
  - 4.7.4. The fluoroscopy system must have last image hold functionality.
  - 4.7.5. Post-processing must include as a minimum:
    - 4.7.5.1. Image processing customised to match exam.
    - 4.7.5.2. Image annotation.
    - 4.7.5.3. Window and level.
    - 4.7.5.4. Image reversal.
    - 4.7.5.5. Image rotation and flip.
    - 4.7.5.6. Electronic collimation.
  - 4.7.6. A control area monitor must be supplied with the system.
  - 4.7.7. At least one control area review monitor with a minimum 17" screen (measured diagonally corner to corner) and lockable brightness and contrast controls must be supplied.
  - 4.7.8. Distance and angle measurements must be displayed.
  - 4.7.9. The fluoroscopy system must conform to DICOM 3.0.
- 4.8. Safety requirements:

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- 4.8.1. The fluoroscopy system must have a dose indication and display exposure time.
- 4.8.2. The fluoroscopy system must include automatic brightness control and variable dose selection.
- 4.8.3. The fluoroscopy system must have the following dose reduction features:
  - 4.8.3.1. Pulsed/continuous fluoroscopy (with maximum of 6 Fps/pps).
  - 4.8.3.2. Variable image receptor dose levels.
  - 4.8.3.3. A range of kV and mA operating characteristics to optimise patient dose.
- 4.8.4. The radiation beam must be confined to within the image reception area with a maximum overlap not greater than 15% of the image reception area.
- 4.8.5. The absorbed dose at the skin of a patient (20cm water) must not exceed 100mGy min<sup>-1</sup> for all available field sizes (in fluoroscopy or equivalent calibration method).
- 4.8.6. The fluoroscopy system must have automatic brightness control and variable dose selection.
- 4.8.7. The fluoroscopy system must have software and/or mechanical anti-collision protection.
- 4.8.8. The fluoroscopy system must be capable of dynamically detecting and adjusting the dose for optimal imaging.

**5. Line 4 – Over Couch Radiographic / Fluoroscopy System with Flat Panel Detector**

- 5.1. This is the core technical specification for an over couch radiographic / fluoroscopy system with flat panel detector for general diagnostic X-Ray guided studies.
- 5.2. The core components of an over couch radiographic / fluoroscopy system with flat panel detector:
  - 5.2.1. X-Ray generator.
  - 5.2.2. Integrated patient table with over couch X-Ray tube and under table flat panel detector carriage.
  - 5.2.3. Control area monitor(s) for review and post processing.
  - 5.2.4. Safety requirements.
- 5.3. X-Ray generator:
  - 5.3.1. The fluoroscopy system must be supplied with a minimum of a 50kW high frequency generator.
  - 5.3.2. The generator must include fully integrated controls (in a single console) for the following:
    - 5.3.2.1. Conventional fluoroscopy.
    - 5.3.2.2. DR Acquisition.
  - 5.3.3. The fluoroscopy system must have capabilities to adjust dose level and kV/mA curve and range of filters to enable optimised imaging across a range

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of applications to accommodate different sized patients and anatomical regions.

- 5.3.4. The fluoroscopy system must provide up to 6 pps for fluoroscopy.
- 5.3.5. The fluoroscopy system must provide up to 7.5 fps for acquisition.
- 5.3.6. Fluoroscopy kV and mA must have automatic control based on patient attenuation.
- 5.3.7. The generator must be able to be operated in all of these modes:
  - 5.3.7.1. kV-Ma-mAs.
  - 5.3.7.2. kV-mAs.
  - 5.3.7.3. kV-mA (AEC).
- 5.3.8. Acquisition range must be at least 40 to 125kVp.
- 5.3.9. Fluoroscopic range must be at least 60 to 110kVp.
- 5.3.10. The fluoroscopy system must be capable of storing at least 50 different organ programs for a range of clinical applications, anatomical regions and body sizes.

5.4. Patient table – general:

- 5.4.1. The patient table must be at least 200cm long.
- 5.4.2. The patient table must be at least 70cm wide.
- 5.4.3. The height of the patient table must be adjustable to a minimum of 90cm.
- 5.4.4. The lowered table top height must be a minimum of 80cm from the ground.
- 5.4.5. The patient table must tilt 88 degrees to the vertical position (patient upright).
- 5.4.6. The patient table must tilt 17 degrees reverse Trendelenburg.
- 5.4.7. The speed of table tilt must be at least 3 degrees per second.
- 5.4.8. The maximum patient weight without angulation must be at least 200kg.
- 5.4.9. The maximum patient weight with full angulation must be at least 140kg.
- 5.4.10. The patient table must have a floating, motorised or equivalent top for lateral motion.

5.5. Over couch X-Ray tube:

- 5.5.1. The height of the X-Ray tube above the table must be adjustable.
- 5.5.2. The X-Ray tube must be able to be angled at least +/- 30 degrees.
- 5.5.3. The maximum X-Ray source to detector distance must be at least 1.5 metres.
- 5.5.4. The total filtration of the X-Ray tubes must be greater than 2.5 mm Al equivalent.
- 5.5.5. The fluoroscopy system must provide a dual focus X-Ray tube with maximum focal spot sizes of 0.7mm for fine focus and 1.2mm for broad focus.
- 5.5.6. Additional filtration must be automatically selected based on the patient's size and study.
- 5.5.7. The X-Ray tube must include pulsing (up to 6pps).
- 5.5.8. The anode heat storage capacity must be at least 300kHU.
- 5.5.9. The anode heat dissipation rate must be at least 60,000 HU/minute.

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- 5.5.10. The collimation must automatically adjust with changes to the source to image distance.
  - 5.5.11. The fluoroscopy system must have automatic collimation and manually or automatically selected filtration.
  - 5.5.12. The X-Ray system must have a retractable compression cone where applicable.
- 5.6. Under table flat panel detector carriage:
- 5.6.1. The flat panel detector must acquire both fluoroscopic and radiographic images.
  - 5.6.2. The longitudinal travel must be at least 100cm.
  - 5.6.3. The lateral travel can be either, at least 20cm, or performed by moving the table.
  - 5.6.4. The movement of the flat panel detector must be linked with the X-Ray tube.
  - 5.6.5. The flat panel detector must include an anti-scatter grid.
  - 5.6.6. The flat panel detector must have a sensitive area of at least 35cm x 41cm.
  - 5.6.7. The spatial resolution must be at least 2.1 lp/mm (radiography acquisition).
  - 5.6.8. The minimum DQE must be at least 60% at 0lp/mm and measured using RQA5 beam quality.
  - 5.6.9. The detector must have an image digitization resolution of at least 14bits.
  - 5.6.10. The patient contact area must be sealed to prevent the ingress of bodily fluids and the whole fluoroscopy system must be easy to clean.
- 5.7. Control area monitor(s) for review and post processing:
- 5.7.1. At least one in-room monitor, minimum 17" screen (measured diagonally corner to corner) with lockable brightness and contrast controls must be supplied.
  - 5.7.2. The fluoroscopy system must automatically set image acquisition parameters based on the ordered exam information and patient characteristics.
  - 5.7.3. Dose monitoring must be included (dose area product, cumulative dose area product, and cumulative fluoroscopy time).
  - 5.7.4. The fluoroscopy system must have last image hold functionality.
  - 5.7.5. Post-processing must include:
    - 5.7.5.1. Image processing customised to match exam.
    - 5.7.5.2. Image annotation.
    - 5.7.5.3. Window and level.
    - 5.7.5.4. Image reversal.
    - 5.7.5.5. Image rotation and flip.
    - 5.7.5.6. Electronic collimation.
  - 5.7.6. The fluoroscopy system must conform to DICOM 3.0.
  - 5.7.7. A control area monitor must be available.

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- 5.7.8. A control area monitor with a minimum 17" screen (measured diagonally corner to corner) and lockable brightness and contrast controls must be supplied.
- 5.7.9. Distance and angle measurements must be displayed.

5.8. Safety requirements:

- 5.8.1. The fluoroscopy system must have an appropriate dose indication and displayed exposure time.
- 5.8.2. The fluoroscopy system must include automatic brightness control and variable dose selection.
- 5.8.3. The fluoroscopy system must have the following dose reduction features:
  - 5.8.3.1. Pulsed/continuous fluoroscopy (with maximum of 6 Fps/pps).
  - 5.8.3.2. Variable image receptor dose levels.
  - 5.8.3.3. A range of kV and mA operating characteristics to optimise patient dose.
- 5.8.4. The radiation beam must be confined to within the image reception area with a maximum overlap not greater than 15% of the image reception area.
- 5.8.5. The absorbed dose at the skin of a patient (20cm water) must not exceed 100mGy min<sup>-1</sup> for all available field sizes (In fluoroscopy or equivalent calibration method).
- 5.8.6. The fluoroscopy system must have automatic brightness control and variable dose selection.
- 5.8.7. The fluoroscopy system must have software and/or mechanical anti-collision protection.
- 5.8.8. The fluoroscopy system must be capable of dynamically detecting and adjusting the dose for optimal imaging.

**6. Line 5 - Multipurpose Radiographic / Fluoroscopy System with Flat Panel Detector**

- 6.1. This is the core technical specification for a multipurpose radiographic / fluoroscopy system with flat panel detector.
- 6.2. The core components of a multipurpose radiographic / fluoroscopy system with flat panel detector:
  - 6.2.1. X-Ray generator.
  - 6.2.2. X-Ray tube housing.
  - 6.2.3. Flat panel detector and X-Ray tube.
  - 6.2.4. Patient table.
  - 6.2.5. Control area monitor(s) for review and post processing.
  - 6.2.6. Safety requirements.
- 6.3. X-Ray generator:
  - 6.3.1. The fluoroscopy system must be supplied with a minimum of a 50kW high frequency generator.

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- 6.3.2. The generator must include fully integrated controls (in a single console) for the following:
    - 6.3.2.1. Conventional fluoroscopy.
    - 6.3.2.2. Integration to OTC and or wall Bucky.
    - 6.3.2.3. Wireless Flat Panel Detector.
    - 6.3.2.4. DR Acquisition.
  - 6.3.3. The fluoroscopy system must have capabilities to adjust dose level and kV/mA curve and range of filters to enable optimised imaging across a range of applications to accommodate different sized patients and anatomical regions.
  - 6.3.4. The generator must provide a range of pulses per seconds and frame rates for fluoroscopy and acquisition modes suitable for the intended clinical application.
  - 6.3.5. Fluoroscopy kV and mA must have automatic control.
  - 6.3.6. The generator must be able to be operated in Fluoroscopy and acquisition modes.
  - 6.3.7. Acquisition range must be at least 40 to 125kVp.
  - 6.3.8. Fluoroscopic range must be at least 60 to 110kVp.
  - 6.3.9. The generator must have fluoroscopic setting of radiography exposure values.
  - 6.3.10. The fluoroscopy system must be supplied with a wired or wireless foot switch to control both fluoroscopic and radiographic image acquisition.
  - 6.3.11. The fluoroscopy system must be capable of storing at least 50 different organ programs for a range of clinical applications, anatomical regions and body sizes.
- 6.4. X-Ray tube housing:
- 6.4.1. The total filtration of the X-Ray tubes must be greater than 2.5 mm Al equivalent.
  - 6.4.2. The fluoroscopy system must provide a dual focus X-Ray tube with maximum focal spot sizes of 0.7mm for fine focus and 1.2mm for broad focus.
- 6.5. Flat panel detector and X-Ray tube:
- 6.5.1. All movements must be motorised and controlled from the tableside.
  - 6.5.2. The fluoroscopy system must have a minimum of 4 pre-programmable positions.
  - 6.5.3. The focus to detector distance (FDD) must be adjustable.
  - 6.5.4. The range of rotation in the left/right anterior oblique (LAO/RAO) projections must at least 40/90 degrees each with a minimum speed of 5 degrees per second.
  - 6.5.5. The range of cranial/caudal (CRA/CAU) angulations must be at least +/-35 degrees with a minimum speed of 5 degrees per second.
  - 6.5.6. The image field of the flat panel detector must be at least 30cm x 30cm in size.
  - 6.5.7. The detector must have a removable anti-scatter grid.

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- 6.5.8. The spatial resolution of the flat panel detector must be at least 2.1lp mm<sup>-1</sup> in all directions.
- 6.5.9. The maximum DQE must be at least 60%.
- 6.5.10. The flat panel detector must have multiple fields of view.
- 6.5.11. The flat panel detector must have a matrix size of at least 1024 x 1024 pixels.
- 6.5.12. The flat panel detector must have an image depth of at least 12bits.

6.6. Patient table:

- 6.6.1. The table top must be at least 55cm wide by 200cm long.
- 6.6.2. The table must tilt +90 to -20 degrees.
- 6.6.3. The tilt speed must be at least 2 degrees per second.
- 6.6.4. The fluoroscopy system must have a low absorption table top (maximum absorption of 2.0mm Al equivalence at 100kVp).
- 6.6.5. The table top must be capable of supporting at least a 150kg patient at maximum extension.
- 6.6.6. The table top must be sealed to prevent the ingress of bodily fluids.
- 6.6.7. The table top must be supplied with footstep which can be attached by a simple operation at the foot end of the table.
- 6.6.8. The minimum height of the footstep must be less than 15cm with the table top vertical.
- 6.6.9. The table top height must cover a range of at least 70cm to 100cm from the floor.
- 6.6.10. The lateral coverage using the table top and/or detector movement must give a combined total coverage of at least 20cm.
- 6.6.11. The longitudinal coverage using the table top and/or detector movement must give a combined total coverage of at least 120cm.
- 6.6.12. Patient handles/rails must be supplied which attach to the accessory rails or table top.
- 6.6.13. The patient table must be designed with a view to patient transfer by hoist, PATSLIDE or similar device.

6.7. Control area monitor(s) for review and post processing:

- 6.7.1. An in-room review monitor with a minimum 17" screen (measured diagonally corner to corner) and lockable brightness and contrast controls must be supplied.
- 6.7.2. The fluoroscopy system must automatically set image parameters based on the ordered exam information.
- 6.7.3. Post-processing must include:
  - 6.7.3.1. Image processing customised to match exam.
  - 6.7.3.2. Image annotation.
  - 6.7.3.3. Window and level.
  - 6.7.3.4. Image reversal.
  - 6.7.3.5. Image rotation and flip.
  - 6.7.3.6. Electronic collimation.

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- 6.7.4. The in-room monitor must either be ceiling supported or supplied with a monitor cart.
  - 6.7.5. At least one control area review monitor with a minimum 17" screen (measured diagonally corner to corner) with lockable brightness and contrast controls must be supplied.
  - 6.7.6. Post-processing must include distance and angle measurements.
- 6.8. Safety requirements:
- 6.8.1. The fluoroscopy system must have an appropriate dose indication and displayed exposure time.
  - 6.8.2. The fluoroscopy system must have automatic brightness control and variable dose selection.
  - 6.8.3. The fluoroscopy system must have the following dose reduction features:
    - 6.8.3.1. Pulsed/continuous fluoroscopy (with maximum of 6 Fps/pps).
    - 6.8.3.2. Variable image receptor dose levels.
    - 6.8.3.3. A range of kV and mA operating characteristics to optimise patient dose.
  - 6.8.4. The fluoroscopy system must be supplied with a dose area product (can be calculated or measured) and must indicate the DAP rate as well as the accumulated DAP.
  - 6.8.5. The radiation beam must be confined to within the image reception area with a maximum overlap not greater than 15% of the image reception area.
  - 6.8.6. The absorbed dose at the skin of a patient (20cm water) must not exceed 100mGy min<sup>-1</sup> for all available field sizes. (In fluoroscopy or equivalent calibration method).
  - 6.8.7. The fluoroscopy system must have automatic brightness control and variable dose selection.
  - 6.8.8. The fluoroscopy system must have software and/or mechanical anti-collision protection.
  - 6.8.9. The fluoroscopy system must be capable of dynamically detecting and adjusting the dose for optimal imaging.
  - 6.8.10. The table top must be sealed to prevent the ingress of bodily fluids and the whole fluoroscopy system must be easy to clean.

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