APPENDIX 3E

LOT 5 SPECIFICATION
MOBILE IMAGE INTENSIFIERS AND ASSOCIATED OPTIONS AND RELATED SERVICES

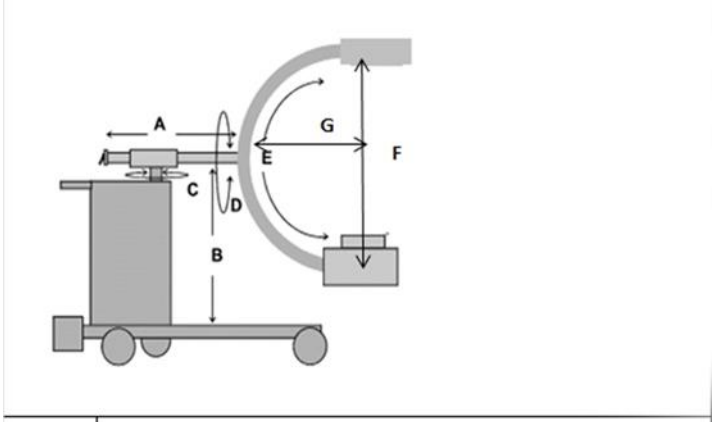
1. Introduction

1.1. This Lot is for the supply of mobile image intensifiers including C-arm or mini C-arm, O-arm image detector and the option for a display monitor cart to provide imaging systems to help guide percutaneous interventions and surgical procedures including cardiology, orthopaedics, vascular surgery, urology and neurology.

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

Line Number	
1	Mobile C-arm with Flat Panel Detector
2	Mobile C-arm with Image Intensifier
3	Mobile Mini C-arm
4	Mobile O-arm

1.3. For the purposes of this specification the below image (illustration for reference only) confirms the movements and directions prescribed.



Standard Movements and Dimensions of a C-Arm:-
A = Horizontal Movement
B = Vertical Movement
C = Swivel
D = Angulation Movement
E = Orbital Movement
F = Focus to Detector Distance
G = Depth

1.4. All patient contact areas must be sealed to prevent the ingress of bodily fluids and the whole X-Ray system must be easy to wipe clean.

1.5. Systems must conform to DICOM 3.

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

1.7. All systems must meet the following minimum safety and dose control requirements:

1.7.1. The mobile C-arm system must have dose indication and display the exposure time.

1.7.2. The mobile C-arm system must be supplied with a calculated or measured Dose Area Product (DAP) and must indicate the accumulated DAP.

1.7.3. 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.

1.7.4. The absorbed dose at the skin of a patient (20cm water) must not exceed 100 mGy min^{-1} for all available field sizes in fluoroscopy mode.

1.7.5. The mobile C-arm system must have automatic brightness control and variable dose selection.

1.7.6. The mobile C-arm system must be capable of dynamically detecting and adjusting the dose for optimal imaging.

2. Criteria applicable to Lines 1 and 2 only

2.1. If a monitor cart is to be supplied with a mobile C-Arm system to enable the visualisation and review of the image created, it must include the following features:

2.1.1. A high-resolution monitor, minimum 18" screen (measured diagonally corner to corner).

2.1.2. A digital image suitable for preview must be displayed within 10 seconds of exposure.

2.1.3. A measure of exposure received by the detector must be displayed after an image is taken.

2.1.4. The monitor cart must present two image displays at any one time – one live and one review image. Images to be viewed by one split screen display monitor or two monitors.

2.1.5. The viewing angle must be at least +/- 160 degrees on the display monitors.

2.1.6. The fluoroscopy acquisition must have last image hold.

2.1.7. It must be possible to export image data via DVD and/or USB media.

2.1.8. It must be possible to store a minimum of 1,000 digital images.

2.1.9. The monitor cart must be manoeuvrable on full swivel wheels that can be locked if required.

3. Line 1 – Mobile C-arm with Flat Panel Detector

3.1. All mobile C-arm systems with flat panel detectors must also have the following features:

3.1.1. The horizontal movement (A) must be at least 20cm.

3.1.2. The vertical movement (B) must be motorised or counterbalanced.
3.1.3. The vertical movement (B) must be at least 40cm.
3.1.4. The swivel (C) must be at least 10 degrees in each direction.
3.1.5. The angulation (D) must be at least 185 degrees in each direction.
3.1.6. The orbital motion (E) must be at least +90 degrees /- 40 degrees.
3.1.7. The focus to detector distance (F) must be at least 90cm.
3.1.8. The depth immersion (G) must be at least 65cm.
3.1.9. Distance between the X-Ray tube housing and the detector must be a minimum of 75cm.
3.1.10. The X-Ray generator must be high frequency with a power of at least 2.0kW.
3.1.11. The kVp (peak Kilo-voltage) range must be at least 40 to 110kVp.
3.1.12. The small focal spot size must be no greater than 0.6mm in diameter, larger focal spots may be included if required by the user.
3.1.13. The X-Ray tube must be capable of delivering continuous fluoroscopy for at least 10 minutes without limitations due to heat generation.
3.1.14. The X-Ray mobile C-arm system must have predefined exam specific X-Ray settings.
3.1.15. The mobile C-arm system must be equipped with pulsed fluoroscopy with a rate of at least 8pps (pulses per second).
3.1.16. The mobile C-arm system must be equipped with automatic brightness control.
3.1.17. The mobile C-arm system must be supplied with a user grid or secondary radiation grid.
3.1.18. The mobile C-arm system must be capable of radiographic acquisitions.
3.1.19. The mobile C-arm system must be supplied with a UK standard power connector.
3.1.20. The image detector must be a flat panel detector.
3.1.21. The detector must be at least a 20cm x 20cm, with 2 additional zoom settings.
3.1.22. The digital digitisation resolution must be at least 12bit.
3.1.23. Monitors supplied as the primary image display of the system must have a brightness of at least 240cd/m^2 to allow image quality assessment.
3.1.24. To ensure safe operation the system must have the following dose reduction features:
3.1.24.1. Last image hold.
3.1.24.2. Pulsed fluoroscopy.
3.1.24.3. Variable image receptor dose levels manually set.
3.1.24.4. A range of kV and mA operating characteristics to optimise patient dose.

4. Line 2 – Mobile C-arm with Image Intensifier

4.1. All mobile C-arm with Image Intensifier systems have the following features:

4.1.1. The horizontal movement (A) must be at least 20cm.
4.1.2. The vertical movement (B) must be motorised or counterbalanced.
4.1.3. The vertical movement (B) must be at least 40cm.
4.1.4. The swivel (C) must be at least 10 degrees in each direction.
4.1.5. The angulation (D) must be at least 185 degrees in each direction.
4.1.6. The orbital motion (E) must be at least +90 degrees /- 30 degrees.
4.1.7. The focus to detector distance (F) must be at least 90cm.
4.1.8. The depth immersion (G) must be at least 60cm.
4.1.9. Distance between the X-Ray tube housing and the detector must be a minimum of 75cm.
4.1.10. The X-Ray generator must be high frequency with a power of at least 1.4 kW.
4.1.11. The kVp range must be at least 40 to 120kVp.
4.1.12. The small focal spot size must be no greater than 0.6mm in diameter, larger focal spots may be included if required by the user.
4.1.13. The X-Ray tube must be capable of delivering continuous fluoroscopy for at least 10 minutes without limitations due to heat generation.
4.1.14. The X-Ray mobile C-arm system must have predefined exam specific X-Ray settings.
4.1.15. The mobile C-arm system must be equipped with pulsed fluoroscopy.
4.1.16. The mobile C-arm system must be equipped with automatic brightness control.
4.1.17. The image detector must be an image intensifier.
4.1.18. The detector must be a minimum of 22cm in diameter with at least 1 additional zoom settings.
4.1.19. A CCD detector with at least 1024 x 1024 resolution must be used for image detection.
4.1.20. The digital digitisation resolution must be at least 12bit.
4.1.21. The mobile C-arm system must be supplied with a user grid or secondary radiation grid.
4.1.22. The mobile C-arm system must be capable of radiographic acquisitions.
4.1.23. The mobile C-arm system must be supplied with a UK standard power connector.
4.1.24. The mobile C-arm system must be supplied with a video signal output facility.
4.1.25. To ensure safe operation the system must have the following dose reduction features:
    4.1.25.1. Last image hold.
    4.1.25.2. Pulsed fluoroscopy for general mobile C-arm systems.
    4.1.25.3. Pulsed fluoroscopy for vascular imaging.
    4.1.25.4. Variable image receptor dose levels.
    4.1.25.5. A range of kV and mA operating characteristics to optimise patient dose.

5. Line 3 – Mobile Mini C-arm

5.1. A mobile mini C-arm system can include an image detector and must have the following features:

5.1.1. The mini C-arm and any ancillary equipment must be mounted on a mobile trolley that is lockable in position.

5.1.2. An X-Ray foot switch must be supplied.

5.1.3. The C-arm must be mounted on an articulated arm.

5.1.4. The orbital rotation must be at least 120 degrees.

5.1.5. The vertical motion (B) must be at least 50cm.

5.1.6. The swivel (C) must be at least 90 degrees in each direction.

5.1.7. The angulation (D) must be at least 185 degrees in each direction.

5.1.8. The orbital rotation (E) must be at least 120 degrees.

5.1.9. The focus to detector distance (F) must be at least 40cm.

5.1.10. Distance between the X-Ray tube housing and the detector must be a minimum of 75cm.

5.1.11. The depth (G) must be at least 40cm.

5.1.12. The X-Ray generator must be high frequency and have a minimum power of least 7.5W.

5.1.13. The kVp range must be at least 40 to 70 kVp

5.1.14. The focal spot size must be no greater than 0.06 mm in diameter

5.1.15. The mini C-arm system must be equipped with automatic brightness control.

5.1.16. The image detector must be an image intensifier or flat panel detector.

5.1.17. The detector must be at least 15cm in diameter, with one additional zoom setting.

5.1.18. A CCD detector with at least 1024 x 1024 resolution must be used for image detection (0.140mm pixel size for flat panel detector).

5.1.19. The digital digitisation resolution must be at least 12bit.

5.1.20. Any monitors supplied must have a brightness of at least 250cd/m^2.

5.1.21. The fluoroscopy acquisition must have last image hold.

5.1.22. Image acquisition tools must include as a minimum:

5.1.22.1. Last image hold.

5.1.23. Image processing tools include as a minimum:

5.1.23.1. Pan and zoom.

5.1.23.2. Image enhancement filters.

5.1.24. The mini C-arm system must conform to DICOM 3.0.

5.1.25. Image data must be exportable using DVD and/or USB media.

5.1.26. The system must have digital storage for at least 4,000 images.

5.1.27. The mini C-arm system must be supplied with a UK standard power connector.

5.1.28. To ensure safe operation the system must have the following dose reduction features:

5.1.28.1. Last image hold

5.1.28.2. Variable image receptor dose levels.
5.1.28.3. A range of kV and mA operating characteristics to optimise patient dose.

6. Line 4 – Mobile O-arm

6.1. All mobile O-arm systems with flat panel detectors must also have the following features:

6.1.1. The horizontal movement (A) must be at least 20cm.
6.1.2. The vertical movement (B) must be motorised or counterbalanced.
6.1.3. The vertical movement (B) must be at least 40cm.
6.1.4. The swivel (C) must be at least 10 degrees in each direction.
6.1.5. The angulation (D) must be at least 185 degrees in each direction.
6.1.6. The orbital motion (E) must be at least +90 degrees /- 40 degrees.
6.1.7. The focus to detector distance (F) must be at least 90cm.
6.1.8. The depth immersion (G) must be at least 65cm.
6.1.9. Distance between the X-Ray tube housing and the detector must be a minimum of 75cm.
6.1.10. The X-Ray generator must be high frequency with a power of at least 2.0kW.
6.1.11. The kVp (peak Kilo-voltage) range must be at least 40 to 110kVp.
6.1.12. The small focal spot size must be no greater than 0.6mm in diameter, larger focal spots may be included if required by the user.
6.1.13. The X-Ray tube must be capable of delivering continuous fluoroscopy for at least 10 minutes without limitations due to heat generation.
6.1.14. The X-Ray mobile O-arm system must have predefined exam specific X-Ray settings.
6.1.15. The mobile O-arm system must be equipped with pulsed fluoroscopy with a rate of at least 8pps (pulses per second).
6.1.16. The mobile O-arm system must be equipped with automatic brightness control.
6.1.17. The mobile O-arm system must be capable of radiographic acquisitions.
6.1.18. The mobile O-arm system must be supplied with a UK standard power connector.
6.1.19. The image detector must be a flat panel detector.
6.1.20. The detector must be at least a 20cm x 20cm, with 2 additional zoom settings.
6.1.21. The digital digitisation resolution must be at least 12bit.
6.1.22. Monitors supplied as the primary image display of the system must have a brightness of at least 240cd/m^2 to allow image quality assessment.
6.1.23. To ensure safe operation the system must have the following dose reduction features:
6.1.23.1. Last image hold.
6.1.23.2. Pulsed fluoroscopy

6.1.23.3. Variable image receptor dose levels manually set.

6.1.23.4. A range of kV and mA operating characteristics to optimise patient dose.