APPENDIX 3L

LOT 12 SPECIFICATION
MAMMOGRAPHY IMAGING SYSTEMS AND ASSOCIATED OPTIONS AND RELATED SERVICES

1. Introduction

1.1. This Lot is for the supply of digital mammography imaging systems or alternative technologies competing with mammography for the screening and assessment of patients. A radiation based mammography system will be expected to include a fixed gantry, an X-Ray generator, tube, compression device and digital detector, a control console and acquisition workstation and a radiation shield for the operator. Alternative technologies will be evaluated on clinical evidence compared to mammography and compliance with the provided specifications.

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

Line Number	
1	Digital Mammography System
2	Alternative Technologies for Breast Imaging

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

2. Line 1 – Digital Mammography System

2.1. As a minimum, a Digital Mammography System will incorporate:
- 2.1.1. Gantry that can be fixed if required
- 2.1.2. Control Console and Acquisition Workstation
- 2.1.3. Radiation Shield

2.2. Gantry
- 2.2.1. The X-Ray tube must have a suitable anode target material according to the design of the equipment. System must be able to image a minimum of 12 women per hour with 4-view mammography, without over-heating.
- 2.2.2. The nominal focal spot for screening mammography must be no larger than 0.3mm.
- 2.2.3. The system must have a means of automatically selecting the optimum exposure factors, dependent upon the X-Ray absorption characteristics of the breast under examination, and the post-exposure factors must be displayed to the operator.
- 2.2.4. Manual selection of exposure factors must be possible.
- 2.2.5. The Automatic Exposure Control (AEC) dose must be adjustable by the supplier or operator (if requested by users on the advice of the Medical Physics Expert).

2.2.6. The irradiated area must be indicated with a direct means (e.g. collimator light). The x-ray field must not overlap the image by more than 5mm or by less than 0mm on any side. The x-ray field and light field must not be misaligned by more than 5mm along any edge.
2.2.7. The gantry height and angle movement must be motorised.
2.2.8. Movement locks must be included to prevent movement when compression is applied.
2.2.9. The minimum height of the top of breast support surface from the floor must not exceed 0.75 metres. Tube head must not hit the floor when inverted
2.2.10. The height adjustment controls must be easily accessible while the Mammographer is adjusting the gantry height for the patient.
2.2.11. The gantry must rotate by at least +/- 90 degrees.
2.2.12. The distance between the source and detector must be at least 60cm.
2.2.13. The collimation must automatically adjust to match the chosen image size (at the detector).
2.2.14. The compression device must have a safety interlock to prevent over compression of the breast tissue.
2.2.15. The compression device must be motorised but manual adjustment must also be possible.
2.2.16. The compression paddles must have foot pedal controls.
2.2.17. The maximum motorised compression force must not exceed 200N.
2.2.18. The maximum compression force applied to the patient must be user configurable.
2.2.19. In the event of malfunction or power loss it must be possible to manually release the compression paddle.
2.2.20. The digital detector must be capable of acquiring an image area of at least 23cm x 26cm in a single exposure.
2.2.21. The detector must have detective quantum efficiency (DQE) of 60% or more at a spatial frequency of 0.5mm^{-1}, as measured using IEC standard (62220-1-2:2007).
2.2.22. The pixel size must be no more than 0.1mm in each dimension.
2.2.23. The digitisation of the images must be at least 14bits.
2.2.24. It must be possible to perform an exposure within 60 seconds of the previous exposure.
2.2.25. The mean (average) glandular dose must not exceed the levels recommended in the relevant EUREF guidance (Reference: European protocol for the quality control of the physical and technical aspects of mammography screening chapter, 2b digital mammography 2017).
2.2.26. The imaging performance of the detector must comply with the relevant recommendations as given in the following NHSBSP, National and European Guidelines, and any subsequent revisions of these documents that are adopted by the NHSBSP: (1) Kulama E, Burch A, Castellano I et al. Commissioning and Routine Testing of Full Field Digital Mammography Systems (NHSBSP Equipment Report 0604, Version 3) Sheffield: NHS Cancer Screening Programmes, 2009; (2) van Engen R, Young KC, Bosmans H et al. The European protocol for the quality control of the physical and technical

aspects of mammography screening. In: European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis, 4th Edition. Luxembourg: European Commission, 2006; (3) van Engen R, Bosmans H, Dance D et al. Digital mammography update: European protocol for the quality control of the physical and technical aspects of mammography screening. In European guidelines for quality assurance in breast cancer screening and diagnosis, Fourth edition – Supplements. Luxembourg: European Commission, 2013; (4) The commissioning and routine testing of mammographic x-ray systems 2005 (Institute of Physics and Engineering in Medicine Report 89)

2.2.27. There must be a back-up timer or similar means to enable the termination of excessively large exposures.

2.2.28. The total inherent filtration of the X-Ray tube and shield must not be greater than 1mm of Beryllium or equivalent.

2.2.29. The total permanent filtration must not be less than 0.5mm Al or equivalent.

2.2.30. The width of missed tissue at the chest wall edge must not exceed 5mm.

2.2.31. The distance between the edge of the detector and the breast support must not exceed 5mm.

2.3. Control Console and Acquisition Workstation:

2.3.1. The control console must have security features that prevent unauthorised access to the equipment.

2.3.2. The control console must display the estimated average radiation dose received by the glandular tissues of the breast during the exposure.

2.3.3. The control console must incorporate a minimum 3 megapixel greyscale monitor (minimum 19" screen measured diagonally corner to corner), the actual size and resolution must be sufficient to assess the diagnostic quality of the image.

2.3.4. The maximum brightness of the monitor must be at least 200cd/m2.

2.3.5. The monitor must be calibrated to the DICOM greyscale display function.

2.3.6. The control console must be able to display an image within 30 seconds of an exposure.

2.3.7. The control console must have the ability to add digital annotations to images.

2.3.8. The console must have the ability for image data to be exported on to either portable hard-drive, USB 3.0 or DVD R/W and must also include at least 200GB hard disk storage. The console must have the ability to anonymise images before export.

2.3.9. The control console must be designed to prevent the loss of received image data in the event of power loss.

2.3.10. The digital mammography system must support:

2.3.10.1. DICOM mammography image storage for presentation

2.3.10.2. DICOM mammography image storage for processing

2.3.10.3. DICOM modality Work list

2.3.11. The control console must include quality assurance monitoring tools.

2.3.12. The system must have "deadman" functionality such that X-ray exposure ceases when the operator releases the exposure button during an exposure.

2.4. A lead glass radiation shield must be provided as part of the overall system and its thickness must be equivalent to at least 0.1mm of lead at 50 kVp. The dimensions of the shield including the console must be a minimum of 60cm width and 180cm height.

2.5. The system must be capable of populating the relevant DICOM tags for radiation dose monitoring and transferring these to PACS with images.

2.6. Mammography imaging systems must be supplied with product specific test phantoms as required to enable calibration and test the performance of the system.

3. Line 2 - Alternative Technologies for Breast Imaging

3.1. Alternative breast imaging solutions will incorporate:

3.1.1. A complete solution incorporating all hardware and software components to acquire an image of the full breast volume within a single acquisition process.

3.1.2. The solution must include all software and hardware components required to control and verify acquired images.

3.1.3. The solution must be supplied with any QA components such as Phantoms that would be required to verify the acquired image quality on a daily/weekly or monthly basis.

3.2. System requirements:

3.2.1. The complete system must operate from regular UK power outlets 220-240v, 50-60Hz.

3.2.2. The solution must be able to image a range of breast sizes and include as standard any components to facilitate the imaging of standard breast sizes.

3.2.3. The system must be capable of imaging a complete breast without the operator needing to set any imaging factors or physically move any components to acquire the full volume. (fully automated solution).

3.2.4. The system must not use ionizing radiation and must only use frequencies between 20KHz to 10GHz (Ultrasound to Radio-wave spectrum).

3.2.5. The system must have enough interlocks and fail safes so that automated control of moving components that could make contact with the patient cannot occur whilst a patient examination is taking place.

3.2.6. All equipment used for patient positioning actions must be motorised to minimise risk of repetitive strain.

3.2.7. Chairs, beds or couches supplied as part of the solution to allow for a seated or prone imaging position must have a minimum load bearing of at least 120Kg.

3.2.8. Any compression of the breast must not exceed 200N.

3.2.9. The height adjustment controls must be easily accessible while the operator is positioning the breast to be imaged.
3.2.10. In the event of malfunction or power loss there must be nothing that impedes the patient from releasing themselves from the equipment.
3.2.11. The width of missed tissue at the chest wall edge must not exceed 5mm.
3.2.12. The system must require an operational space of no more than 3m by 4.5m.
3.2.13. Complete scan time for an individual breast examination must be less than 1 minute 30 seconds.

3.3. Control Console or Acquisition Workstation:
3.3.1. The control console / acquisition workstation must be able to receive and utilise a DICOM modality worklist provided by a RIS or worklist broker.
3.3.2. DICOM attributes from the worklist must be included in DICOM images generated by the system. At a minimum the system must be able to utilise the following:
3.3.2.1. Patient name.
3.3.2.2. Patient ID.
3.3.2.3. Study ID.
3.3.2.4. Date of birth.
3.3.2.5. Operator name.
3.3.3. The control console / acquisition workstation must have security features that prevent unauthorised access to the equipment.
3.3.4. The control console / acquisition workstation must be able to display all processed breast images including 3D volume within 5 minutes of capture.
3.3.5. The control console / acquisition workstation must be able to control and acquire further studies (Imaging of the contralateral breast) whilst processing or handling data from previous acquisitions.
3.3.6. Images generated by the system must include as a minimum:
3.3.6.1. 3D maximum intensity projection breast volume with variable threshold.
3.3.6.2. 2D projections in AP (Antero-Posterior), ML (Medio-Lateral) & CC (Cranio-Caudal) projections.
3.3.7. The control console/ acquisition workstation must have the ability to add digital annotations to images.
3.3.8. The control console/ acquisition workstation must be designed to prevent the loss of received image data in the event of power loss.
3.3.9. The control console must incorporate a minimum 2-megapixel colour monitor with a minimum 19” screen (measured diagonally corner to corner). The actual size and resolution must be sufficient to assess the diagnostic quality of the image.
3.3.10. The maximum brightness of the monitor must be at least 250cd/m2.
3.3.11. The monitor must support DICOM greyscale display function and DICOM tonal value protocols.
3.3.12. The breast imaging system must support:
3.3.12.1. DICOM modality Work list.

3.3.12.2. DICOM image storage for presentation.

3.3.13. The control console/ acquisition workstation must include quality assurance monitoring tools.