NHS Fetal Anomaly Screening Programme

Specification for Diagnostic Ultrasound Equipment for NT / Fetal Anomaly Screening

Note to Suppliers: Please respond to this document using the same numbering scheme as below with full details of all technical features as indicated in the tables. Please indicate whether a feature is included as standard on the system or is an option with additional costs.

1 Clinical Requirements

Suppliers - The equipment provided must be capable of allowing the user to perform Nuchal translucency measurements.

Users/Purchasers – The checked boxes indicate the minimum required tasks for an ultrasound scanner for NT / Fetal Anomaly Screening. Please add any additional requirements as appropriate to your department.

Clinical Task	1st Trimester	2nd Trimester
1.1 Fetal Measurement	✓	✓
1.2 Visualisation of Fetal Anatomy	✓	✓
1.3 OTHER ***(please describe)***		

2 Technical Requirements

Users/Purchasers – The checked boxes indicate the minimum required features for an ultrasound scanner for NT / Fetal Anomaly Screening, please add any additional requirements as appropriate to your department. Indicate any feature you wish to consider as an option with "O".

Feature	
2.1 Physical and Ergonomic Features The system offered should meet the recommendations outlined in the Society and College of Radiographers Publication "Prevention of Work Related Musculoskeletal Disorders in Sonography", SoR, 2007.	
2.1.1 *Room based wheeled unit	✓
2.1.2 Screen with ultrasound image area f.o.v. 12cm x 15 cm with a matrix of 512 x 512 and effective pixel size of no less than 500. See Royal college of Radiologist specification guidelines.	✓
2.1.3 Slave Monitor	✓
2.1.4 Flexible Position Monitor (height and angle)	✓
2.1.5 Flexible position control console (height and angle)	✓
2.1.6 Subdued console lighting	✓
2.1.7 OTHER (please describe)	

Feature	
2.2 Scan Modes	
2.2.1 B-Mode	✓
2.2.2 Tissue Harmonic Imaging	✓
2.2.3 Spatial Image Compounding	
2.2.4 M-Mode	
2.2.5 Colour & Power Doppler	✓
2.2.6 Spectral Doppler	
2.2.7 3-D Imaging	
2.2.8 Real-Time 3-D	
2.2.9 Split Screen Imaging	✓
2.2.10 OTHER (please describe)	

Feature	
2.3 Transducers – sufficient transducers should be supplied to meet the clinical requirements outlined in section 1	
2.3.1 Convex	✓
2.3.2 Trans Vaginal	✓
2.3.3 OTHER (please describe)	

Feature	
2.4 Measurement / Calculation Tables – these should be sufficient to meet the clinical requirements outlined in section 1	
2.4.1 Multiple "+" shaped callipers of minimum precision 0.1 mm with continuous motion	✓
2.4.2 Callipers of dynamically varying contrast compared to background.	✓
2.4.3 Small sized callipers for measurements < 5mm	✓
2.4.4 Ellipse Circumference / Area Measurement	✓
2.4.5 Freehand Circumference / Area Measurement	
2.4.6 Measurement on real time (non-frozen) images	
2.4.7 Measurement on frozen images	✓
2.4.8 Off-line measurement (on saved images)	
2.4.9 Obstetric Calculation and measurement Package	✓
2.4.10 User definable tables	✓
2.4.11 Fetal Cardiac Measurement Package	
2.4.12 Fetal vascular Measurement Package	
2.4.13 OTHER (please describe)	

Feature	
2.5 Controls and Other Features	
2.5.1 Freeze image facility Read and Write Zoom	✓
2.5.2 Read and Write Scroll	✓
2.5.3 Cine-frame review	✓
2.5.4 Footswitch control of freeze / zoom / store / print* *Delete as applicable	✓
2.5.5 Where air filters are fitted to the equipment these must be easily removable for cleaning and the frequency and method of cleaning specified	
2.5.5 Other (please describe)	

Feature	
2.6 Image Storage and Output Options	
2.6.1 Network port with a minimum capability if 100 MBits /s	✓
2.6.2 Large capacity on-board image management system (storage > 40Gb)	✓
2.6.3 *USB / CD / DVD *Delete as applicable	
2.6.4 Thermal Paper Printer	✓
2.6.5 Confirmed Dicom compatibility for Print, Store, Work list, Retrieve, Display, and Presentation.	✓
2.6.6 OTHER (please describe)	

3 General Requirements

3.1 Environmental / Room Conditions

3.1.1 The Machine must have the ability to be safely used in rooms and to be safely stored in areas with a minimum temperature of 21ºC ± 1ºC.

3.2 Safety and standards

3.2.1 All systems (including any peripheral/auxiliary equipment supplied) must be CE Medical marked and comply with current European and UK specifications for medical equipment including IEC60601-1-1, IEC60601-1-2 and IEC60601-2-37.

3.2.2 Acoustic power outputs must meet national and international standards set down by AIUM/NEMA ("Acoustic output Measurement Standard for diagnostic ultrasound equipment"). NEMA Standards Publication UD2-2004. Published by National Equipment Manufacturer's Association, 1300 North 17th Street, Suite 1847, Rosslyn, Virginia 22209-3806 USA. (www.nema.org)

3.2.3 Manufacturer and user defined system presets must include an option to default to low acoustic output power in all modes.

3.2.4 Biological safety – Details must be given of the recommended methods of cleaning and, where appropriate, sterilisation of all transducers and other parts of the system. A detailed protocol and list of approved cleaning materials should be provided.

3.3 Training, Documentation and Support

3.3.1 A full set of operators' manuals for the system and all ancillary equipment must be provided. Additional "quick guide" booklets or cards should also be provided.

3.3.2 The manufacturers must provide adequate training and support to ensure that all primary users of the equipment are familiarised with all aspects of the system operation within a reasonable period of time following installation. The proposal for meeting this requirement should be outlined.

3.3.3 The numbers and base locations of applications staff available to the users should be provided.

3.3.4 Guaranteed post-sales user support is essential.

3.4 Warranty and Maintenance

3.4.1 A statement of the warranty period for the equipment and specifically for the probes should be included with the supplier response. Extended warranty options should be quoted to include first-line in-house service and maintenance by hospital staff (including training as described above) if available.

3.4.2 Full details of each maintenance contract should be supplied including response time, hours of availability and numbers and availability of appropriately trained engineering staff. Also the options for transducer cover (accidental and wear-and-tear) and software upgrades should be given.