Antenatal Screening Wales Specification for Ultrasound Systems

This specification has been developed by Antenatal Screening Wales in collaboration with NHS Wales Shared Services Partnership **(**NWSSP-SES**).** Andrew.ward2@wales.nhs.uk

This specification is relevant for ultrasound systems used for antenatal screening scans as defined in the Antenatal Screening Wales standards and protocols. In addition, this specification may be suitable for other obstetric scans but this must be assessed locally in each Health Board.
Ultrasound systems procured for antenatal screening scans must be capable of producing images of high diagnostic quality and include, as a minimum, the following characteristics:

- Display/ screen size for sufficient clear visualisation
- Magnification facility
- Cine loop function
- Callipers that have a millimetre precision to one decimal point i.e. 0.1mm
- Adjustable signal processing facilities
- Tissue specific pre-sets for individual clinical applications
- Sector/ linear/ curvy-linear/ transvaginal probe relevant to gestational age
- Pulse, colour Doppler and tissue harmonic imaging

Details of minimum requirements

Clinical requirements

Clinical tasks:

Fetal measurements and visualisation of fetal anomaly as defined within the scope of the Antenatal Screening Wales standards and protocols.

Technical requirements

Physical and ergonomic features, the system should:

- be a room based wheeled unit
- have display/ screen size for sufficient clear visualisation (see RCR guidelines)
- have a variable position monitor (height, rotation and angle)
- have a variable position central console (height, rotation and angle)
- have controllable console illumination intensity

The system must have the following scan modes and imaging features:

- B mode
- Tissue harmonic imaging
- Colour and power Doppler
- Multiple image display – facility to display at least two images in the same mode simultaneously

- Multiple mode display - simultaneous display of B and M mode, spectral, colour and power Doppler modes

The system must have a range of transducers to meet the clinical requirements relevant to the antenatal screening population.

The system must have the following measurement capabilities and calculation tables:

- Multiple sets of pairs of '+' shaped callipers with a precision of 0.1mm or better, with continuous motion at all magnification levels
- Callipers of dynamically varying contrast compared to background
- Ellipse circumference measurement
- Measurement on frozen images
- Obstetric calculation and measurement package using nationally approved charts and tables
- User definable tables

The system must have the following controls and features:

- An image freeze facility with playback of multiple last frames
- A read and write zoom on live and still images
- A cine- loop facility
- A footswitch
- Control of freeze, zoom, store and print with sufficient post processing to allow optimum visualisation for accuracy required for combined screening
- The automatic generation of measurements by the ultrasound machine must be disabled.
- A standard RJ45 network port with a minimum capability of 100Mbs
- An on-board image management system with a minimum storage capacity of 500 Gb
- A thermal paper printer
- The machine must have the capability to re-measure images reviewed post examination.

The system must have the ability to be safely used and stored in locations with an operating temperature of +18 to +23.

Note – where air filters are fitted to the equipment these must be easily removable for cleaning and the frequency of cleaning and method of cleaning specified.

Safety and standards:

- Acoustic power outputs must meet national and international standards. The Food and Drug administration centre for Devices and Radiological Health (FDA) imposes upper limits on the acoustic output of diagnostic ultrasound machines. The majority of ultrasound equipment manufacturers comply with these standards for all their markets and it is expected that all equipment used in the UK should conform to this[1 2]
- Mechanical index (MI) and thermal index (TI) safety indices should be displayed on the image
- Manufacturer and user defined system presets must include an option for adjustable power output with the lowest output value set as the default

- Biological safety: details must be given of the recommended methods of cleaning and where applicable, sterilisation of all transducers and other parts of the system. A detailed protocol and list of approved cleaning materials should be provided.
- Full DICOM services for print, store, worklist, retrieve, display and presentation as a minimum.

Equipment replacement:

- There is no longer specific age advice available from any national body recommending when ultrasound equipment should be replaced. Each NHS Wales organisation should ensure that an annual formal quality assurance (QA) programme to monitor ultrasound machine performance is implemented in line with the recommendations set out by the Royal College of Radiologists, the Society and College of Radiographers and British Medical Ultrasound Society. A formally agreed equipment review and replacement programme is highly desirable[1].

(2014) Standards for the provision of an ultrasound service

(2021) Guidelines for Professional Ultrasound Practice

[1] The Royal College of Radiologists, the Society and College of Radiographers. Standards for the Provision of an Ultrasound Service. London. The Royal College of Radiologists 2014

[2] U.S. Department of Health and Human Services Food and Drug Administration Centre for Devices and Radiological Health. Marketing Clearance of Diagnostic Ultrasound Systems and Transducers. Guidance for Industry and Food and Drug Administration Staff. June 2019.