GUIDANCE NOTES FOR THE ACQUISITION AND TESTING OF ULTRASOUND SCANNERS FOR USE IN THE NHS BREAST SCREENING PROGRAMME

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Editorial board

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CONTENTS

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1. INTRODUCTION

This publication updates the Medical Devices Agency (MDA) guidance on breast ultrasound scanners (*Further Revisions to Guidance Notes for Ultrasound Scanners Used in the Examination of the Breast, with Protocol for Quality Testing*), which was published in 1998.[1] The need for new guidance arises in part from changes in the performance and testing of scanners in the intervening years. The performance of modern breast ultrasound equipment comfortably exceeds the 1998 requirements. These requirements do not prevent many older and more limited scanners from remaining compliant and in service. This new guidance offers a clearer context in which to evaluate options for new scanners and on which to base the decommissioning of old ones.

The new guidance differs from the first in a number of key respects: measurements of absolute performance have largely been removed; clinical performance monitoring has been added; and the continued acceptability of a scanner is no longer assumed to depend solely on its compliance with physical performance standards. At the heart of the 1998 guidelines were tests for cyst visualisation, axial resolution and lateral resolution. Today physical measurements of absolute performance are less often seen as clinically relevant, wholly reliable, quantitative and reproducible.[2] The new guidance notes thus rely more on evidence-based quality assurance, while acknowledging the continuing value of physical measurements in baseline testing.

This move away from physical measurements for defining and monitoring performance has led to an increased reliance on clinical measures. These guidance notes include a report form for the systematic recording and review of poor clinical performance. The evidence this form provides of deteriorating performance or other clinical problems, persistent or irreparable technical faults, inadequate functionality, ageing and general obsolescence effectively charts the declining acceptability of a scanner.

These guidance notes are designed to encourage the development and implementation of evidence-based methods for testing ultrasound scanners. They set out a framework for the quality assurance process, outline the recommended test regimes and standards, and provide guidance on how tests should be administered. They are not prescriptive, however, and recognise that some physics support services are not yet in a position fully to adopt the methods recommended. With a programme of regular review to maintain their validity, however, it is hoped that this guidance will help over time to raise standards.

2. CLINICAL AND TECHNICAL REQUIREMENTS FOR BREAST ULTRASOUND EQUIPMENT

2.1 Clinical requirements

The final diagnosis of a breast lesion currently rests on histopathology derived from image-guided needle biopsy. B-mode scanning, with its two-dimensional cross-sectional displays, is consequently of greater clinical value than Doppler, elastography or three-dimensional (3D) imaging and is given greater prominence in this guidance. Other operating modes should not be discounted, however, particularly where information derived from them is likely to help significantly with the final diagnosis.

- Breast ultrasound equipment must be able to distinguish between solid and cystic lesions
- Scanners must be able to demonstrate low-contrast lesions and disruption in tissue planes. They should be capable of registering the shape and margin of a lesion, its degree of echogenicity and the presence or otherwise of calcification
- The ability to detect microcalcification clusters may become increasingly valuable. Stereotactic biopsy is time consuming, and leads to more upgrade at surgery
- Breast cancers as small as 2 mm should be detectable, expediting image-guided biopsy and pre-operative diagnosis
- The ability to image a localisation wire is highly desirable. It permits fast and accurate placement of pre-operative hookwires and also allows surface marking of the end of the hookwire with the patient in the surgical position
- Scanners must be able to image a fine needle clearly and without significant artefact.
- Biopsy guides are optional, as needles are often guided manually and without difficulty.
- The ability to measure using callipers remains important, although the accuracy required is less than suggested in the previous guidelines:[1] ± 1 mm will maintain an acceptable clinical standard without triggering unnecessary intervention
- The breast ultrasound equipment should be able to image in a mode that will show acoustic shadowing behind solid lesions, as this is a diagnostic feature.

2.2 Equipment specification, selection, supply and support

2.2.1 Overview

The scanner must be optimised for breast applications. High-quality and high-resolution two-dimensional (2D) greyscale imaging is essential. Additional power Doppler, tissue harmonic imaging and spatial compounding are desirable, especially at Breast Screening Units (hereafter Units), where applications for them have been identified.

All scanners must have a high-frequency linear probe, although some Units may also want a lower frequency probe with a larger footprint. Both types must be able to differentiate cysts from solid lesions, to visualise lesion edge and fill characteristics, and to image biopsy and fine needles accurately.

The scanner must include a read and write zoom function and be able to zoom and measure on frozen or cine loop images. The measurement package must provide multiple linear distance measures, areas and circumferences.

It is essential that the display screen provides high-quality wide-angle viewing and is flexible and easy to position. The monitor should incorporate test patterns for quality assurance purposes. The operator ergonomics must be of a high standard, enabling height positioning of the keyboard and minimising repetitive strain. Wherever possible, standard operations should be provided by means of remote controls to reduce strain and promote easy use.[3–5]

The scanner must be DICOM 3 (Digital Imaging and Communications in Medicine) enabled (including print, store and worklist functions). It should include on-board image management and a storage facility (via CD-RW, DVD or USB port).

The scanner must conform to appropriate formal standards for safety and performance (see section 2.2.4). The design of the scanner must be environmentally sensitive, both in normal operation and over its life cycle.

2.2.2 Detailed requirements

Probe
The footprint for the linear probe should be in the range 40–80 mm. The slice width characteristics for a fixed acoustic lens design must be accurately specified and appropriate. The provision of active electronic focusing in the Z plane is desirable but not essential. A second probe may be required if the local scanning technique warrants it.

Broadband design
Broadband should be provided and should allow at least three selectable options for the nominal operating frequency.

Image display
A rectilinear display and a minimum field of view range of 2–10 cm should be provided. Alternative display options (eg extended field of view or trapezoidal) are desirable but not essential.

Callipers
Callipers are required that provide linear measurements accurate to within ±1 mm. Facilities to measure or estimate circumference (±2 mm), area (±0.05 cm^2) and volumes (no specified tolerance as systems vary widely) are also needed.

Zoom
To maximise resolution, a write (as well as a read) zoom option is needed.

Focusing and frame rates
A wide and flexible range of multiple zone focusing is needed. The frame rate must be displayed at all times and the options available should permit optimal balance between spatial and temporal resolution (eg by increasing or decreasing line density).

Image processing
The scanner must offer a range of image processing options, both spatial and temporal, including edge enhancement, smoothing and persistence.

Post processing and review
Options should include freeze frame, loops and modified image processing.

Menu presets
Comprehensive menu presets must be available to allow scanning regimes to be programmed, stored and recalled. These presets should be optimised for individual users, procedures or breast types. The storage arrangements for menu-based protocols must be secure; it should not be possible to change a protocol casually or inadvertently, especially if doing so could degrade the image.

Safety
The scanner must comply with the output display standard (ODS)[6] and show the mechanical index (MI) and the thermal index (TI) when appropriate. Wherever possible, the scanner selected should incorporate safety-aware design features, eg offering high gain and low output as a default starting point and switching off transmission when the probe is idle.

Ergonomics
Scanner operation and specification must be designed so as to minimise the risk of work-related musculoskeletal disorders.[4,5]

Extended features and functionality
Doppler and tissue harmonics functionality is highly desirable. There is insufficient evidence to comment on elastography, four-dimensional (4D) or fusion imaging at the present time.

Clinical applications support
Full clinical applications support from the supplier is essential during the commissioning of the scanner. Preference should be given to suppliers who place minimal reliance on local cascade training and offer continuous support with the initial clinical cases through the scanner. Clinical applications support must be maintained throughout the lifetime of the equipment, both in response to any reported difficulties and for scheduled reviews.

Engineering support
Adequate, timely and well-informed engineering support for the scanner is essential. Preference should be given to support arrangements that include remote diagnostics, downtime guarantees (or penalties) and a readiness to respond to issues highlighted during local quality assurance procedures.

Updates and upgrade pathways
Preference should be given to suppliers who offer clear and guaranteed pathways for updates and upgrades. Updates should normally be viewed as a form of maintenance and be provided free of charge; upgrades will add functionality to the system and so will usually need to be purchased.

Technical and operating manuals
Scanners must be provided with comprehensive documentation covering their operation and technical support.

2.2.3 Scanner selection and purchase

Units are advised to evaluate the options carefully before purchase. Full evaluation helps to secure the most suitable equipment specification, optimal choice from the range available, acceptability to all intended users and value for money. The specifications set out in these guidance notes should be considered carefully, for while the basic scanner requirements may be modest the options can be extensive.

Clinical assessment is best achieved by visiting a Unit where the scanner (or a near equivalent) is already in service. This is especially valuable if it includes permission to scan under supervision rather than bring in a scanner for a local trial. The advantage of the first is that the scanner will be fully commissioned and used by trained colleagues who can supply an unbiased and independent opinion.

Wherever possible, physical measurements should be carried out on the scanner under evaluation. Any results must be treated with caution, however, given the current shortage of robust proof as to their value. These checks might include confirmation that the equipment meets the basic physics specification and, where additional features are sought, that these are included. Penetration over the available frequency range of the probe(s) may also be measured if a suitable tissue equivalent test object (TETO) is available. However it should be borne in mind that the characteristics of the test object may affect the measurement.

2.2.4 Formal standards

When purchasing a scanner

- all systems (including any peripheral/auxiliary equipment supplied) must be CE marked and comply with current European and UK specifications for medical equipment, including IEC60601-1-1,[7] IEC 60601-1-2[8] and IEC 60601-2-37[9]
- acoustic power outputs and displays should meet the national and international standards set down by the National Electrical Manufacturers Association (NEMA)/American Institute of Ultrasound in Medicine (AIUM),[6] Medicines and Healthcare products Regulatory Agency (MHRA),[10] the American Association of Physicists in Medicine (AAPM)[11] and Insitute of Physics and Engineering in Medicine (IPEM)[12,13]
- the equipment should comply with the industry standard for the prevention of work-related musculoskeletal disorders in sonography.[4]

3. RECOMMENDED FRAMEWORK FOR THE ACCEPTANCE, COMMISSIONING, ROUTINE TESTING AND QUALITY CONTROL OF BREAST ULTRASOUND SCANNERS

This section provides a framework for assuring and managing scanner quality, acceptance, commissioning and routine testing. It aims to ensure that the equipment delivered is to the right specification, that it works correctly, that it is set up optimally and that performance quality is maintained. It also sets out reasoned and appropriate grounds for replacing the scanner at the end of its working life. The regime for quality assurance and the standards for scanner performance are detailed in section 4 below, while guidance on how to carry out user and physics testing appears in Appendix 1.

This section offers a broad assessment of performance based on both physical and clinical considerations. It acknowledges that physics tests alone are currently of limited value, while clinical assessment may be subjective and operator or patient dependent. It also recognises that work is continuing to improve physics test protocols and provide more objective grounding for the clinical perception of breast ultrasound scanner performance; and it aims to provide a more sound basis for these developments.

3.1 Management of quality assurance

If adequate quality assurance is to be attained and maintained, the staff involved must have the right skills, training, duties, contacts and communications channels, and must be supported by an effective management structure.

3.1.1 User tests and local responsibilities

A log file* (as described in test set 7, Appendix 1) should be provided locally for each scanner and kept up to date with all relevant information and reports. A supervisor should be nominated in each Unit to ensure that the staff who conduct local tests have the training, time and competence to do so effectively and to report any suspected problems. *Good practice point: colleagues undertaking user tests should be members of the clinical team, eg advanced practitioners qualified in ultrasound or radiologists.* Where resources make this impracticable, the staff who undertake user testing must be trained appropriately. In either case, it is recommended that a radiologist or breast sonographer assist with the maintenance and periodic review of clinical problem reporting (see section 5). All local results should be sent routinely to the physics service and prompt action should be taken if problems arise.

*The log file contains all scanner data (including forms for recording clinical and technical problems, physics and user test results, service reports etc), plus details of personnel and their responsibilities.

3.1.2 Medical physics support service

Physics testing should be performed only by suitably experienced and qualified staff. Staff who conduct tests should carefully log all results and all the scanner settings and ambient conditions that might affect them (see test methods and forms in Appendices 1 and 2). All reports, whether routine or reactive, should be sent to the breast screening supervisor or other nominated person and copied to the regional Quality Assurance Reference Centre (QARC). The medical physics support service should investigate any problems reported and take action to resolve them either directly or via the department supervisor or scanner manufacturer, depending on the nature of the problem. The physics service should monitor user tests and the log file and address any problems relating to the scanner(s) or the quality assurance process. It should also provide training, where necessary, for local staff who perform user tests.

3.1.3 Upgrades and system/personnel changes

The physics service must be notified of any software or hardware changes to the scanning system or its environment (particularly lighting); checks can then be carried out to ensure that these changes have not adversely affected image quality. This will involve repeating certain acceptance checks and may include clinical evaluation if changes in performance are known or suspected. Changes in key personnel should also be recorded. It is essential that new radiologists or sonographers are trained to use the scanner, preferably by the supplier's clinical applications specialist. If there is a change or rotation in the staff who conduct user tests, inter-operator checks should be performed to ensure continuity of methods and results. When changes occur, personnel contacts data (Appendix 5) and quality assurance responsibilities data (Appendix 6) should be updated in the log file.

3.1.4 System faults or suspected deterioration

In the event of faults or a suspected deterioration in performance, prompt action is essential and all the staff involved have a duty to respond. The Unit supervisor should be told of any problems highlighted by the local operators. The physics support service should also be notified, and a plan of action should be agreed and implemented. This may involve repair or replacement of the faulty equipment, or a change in procedures or training. It should be made clear on the report form in Appendix 4 what action is being taken to resolve the problem and by whom. If necessary the problem should be escalated to the Unit's clinical director. Where issues prove difficult to resolve the regional quality assurance representative should be involved.

It is essential that the log file is referred to and updated at each stage of any remedial action.

3.2 Acceptance testing

Acceptance tests should be completed on a new scanner system, or if a probe is replaced or added, or if the system has a software upgrade that might affect imaging performance. This is to ensure that the specifications set out at procurement or modification are met and that the scanner is functioning correctly. Tests that should be included at this stage include callipers, image uniformity, functionality, monitor geometry and set-up, hard/soft copy, a general inspection of the scanner and probes, and a demonstration of all operating modes. These tests are carried out by the medical physics service and should be completed before clinical use of the scanner.

3.3 Commissioning and clinical acceptance

The purpose of commissioning is to ensure that the scanner is set up optimally for clinical work and performs to an acceptable standard. Clinical evaluation of new equipment should ensure that the necessary clinical specifications are met and that the system as a whole is fit for purpose. Clinical applications support staff from the supplier or manufacturer must attend and liaise with users to ensure that presets match the breast imaging needs of the department. Initially, low acoustic outputs are preferred where possible and all presets should be recorded and backed up. Continuing applications support must be available, particularly if scanners are upgraded or new system users are introduced. Although commissioning should be arranged and overseen by local staff, the outcomes must be shared with the physics support service and entered in the log file.

Where the scanner will be connected to a network, or where a memory stick or other external data transfer device is to be used, the local IT department must be involved in commissioning. It is important to ensure the security of patient data and protect the system against viruses.

3.4 Baseline testing

Baseline measurements characterise and record performance when a new scanner, probe or software is installed. They typically consist of performance features rather than absolute physical measurements. As a consequence no pass or fail tolerances are applied initially, although tolerances associated with relative performance (eg following modifications to the initial condition) are established for use during routine or extended testing.

When establishing baselines factory presets should be used as they are likely to provide a stable point of reference. Measurements should also be made in the most commonly used clinical preset mode, to ensure that clinical image quality is maintained. A record should be kept of factory and clinical presets used for baseline measurements.

All scanner settings, test object details[†] (including temperature) and viewing conditions must be carefully recorded. This enables measurements to be reproduced if necessary and ensures that any variation results from changes in performance rather than different settings or conditions. If hard or soft copy is used, this should be representative of the monitor display. Details of these test procedures and a sample proforma are provided in the appendices. An assessment report should be sent to the system user or supervisor and copied to the QARC.

In addition, baselines should be set for the user tests (Appendix 1, test sets 1 and 2). If necessary, training should be given to the staff who will perform the tests.

3.5 User testing

User testing is a quality assurance procedure designed to monitor equipment against agreed standards and ensure continuous optimal performance. The tests should be carried out by a member of the clinical team (see section 3.1.1). In case of a fault or query, relevant forms and contact details are provided in Appendices 4–6 and should be available in the scanner log file.

[†]The test object should be a TETO with targets suitable for high-frequency probes. No specification is given here because measurements are relative to the baseline.

3.5.1 Weekly user tests

The weekly tests are basic inspections that are designed to identify any potential risks to the user, patient or diagnostic quality. All staff are encouraged to report potential problems promptly, to aid speedy resolution.

The recommended weekly tests are

- inspect scanner (mains and video cables, filters and vents etc)
- inspect probe
- check monitor
- image uniformity (including element drop-out check).

The supervising radiographer (or other nominated person) should be told as soon as possible of any unusual observations. If there are potential safety implications the system should be taken out of service with immediate effect and advice should be sought on what action is needed.

3.5.2 Monthly user tests

These are designed to detect any changes in overall scanner or probe performance. As with weekly tests, no specialist experience of ultrasound is necessary but appropriate training must be given. Aspects to be tested include

- reverberation lines
- hard/soft copy
- B-mode noise
- colour power Doppler (CPD) noise (if applicable)
- preset and log file check.

Test results should be sent to the medical physics support service for evaluation and logging. Any unusual results should be reported as soon as possible to the supervising radiographer or other nominated person.

3.6 Physics checks (six-monthly or reactive)

Routine physics tests are designed to pick up more subtle or gradually emerging problems that user tests may miss, or to confirm consistent levels of performance. Additional, reactive, visits may be arranged to investigate specific problems, eg concerns about image quality or clinical performance. These tests must be performed by people with sufficient understanding of ultrasound physics and current experience of ultrasound testing.

Aspects to be tested or checked include

- scanner (including mains and video cables, filters and vents etc)
- probe
- monitor
- image uniformity
- reverberation lines
- hard/soft copy

- B-mode noise
- CPD noise (if applicable)
- presets and log file
- sensitivity (low-contrast penetration)
- functional checks: focal zones, time gain control (TGC), nominal frequency settings, frame rate variation, safety indices
- selected aspects of anechoic and low-contrast target visibility
- timeliness of electrical safety checks.

Extended testing may also be undertaken, either as an optional routine or in response to reported problems. Tests may include

- resolution images
- other local tests as required.

Differences between an extended test outcome and that measured at commissioning should not be taken in isolation as reliable evidence of change. Despite this, extended tests are recommended because useful evidence may be gained from the pattern and correlation of physical test outcomes and the clinical problems reported.

The physics service must follow up any suspected faults or deterioration in performance, whether reported or identified through user tests. Where training needs or weaknesses in quality assurance procedures are identified these should be addressed with local staff.

Physics reports should be sent to the system user or supervisor and copied to the QARC and the log file.

4. RECOMMENDED PERFORMANCE STANDARDS FOR THE PHYSICAL TESTING OF BREAST ULTRASOUND EQUIPMENT

The following tables set out the recommended tests, standards and remedial action and cover all the stages or situations that are likely to be encountered. Detailed guidance on how the tests should be performed appears in Appendix 1, while test result proformas and other log file forms can be found in Appendices 2–6.

The tests are listed in numbered sets. The definition of each set, combined with guidance on the pattern of work for acceptance and commissioning testing, should help staff to identify which tasks are carried out only initially, which are physics tests only, and which are common to the physics and local test regimes.

Phase/test type	Documents to complete	Test sets (Appendix 1)	Staff
Acceptance	Appendix 2c	1, 3, 5 (part I)	Medical physics
Commissioning	Log file	7	Local staff
Baseline			
• Essential tests	Appendices 2a, 2b, 2d	4, 5 (part II)	Medical physics
• Extended tests		6 and others (optional)	Medical physics
Routine			
• Physics (essential tests)	Appendices 2a, 2b, 2e	1, 2, 3, 4	Medical physics
• Physics (extended tests)		6 and others (optional)	Medical physics
Weekly user tests	Appendix 2a	1	Local staff
Monthly user tests	Appendix 2b	2	Local staff

In each situation recorded here, if a test indicates that remedial action is needed this fact and the remedial action proposed should be reported. The matter should be discussed with appropriate staff at the Unit and the log file should be checked for possible correlation with reported clinical or technical problems. It is crucially important that problems which cannot be successfully resolved are logged and highlighted.

Specialist Units may want to use or develop objective test methods other than those recommended here, and this is positively encouraged if there is peer-reviewed evidence to show that the alternative is at least as reliable and efficient as the method recommended. If objective methods are in development, however, they should be used in parallel with the recommended method until enough evidence exists to confidently replace it.

4.1 Acceptance (medical physics service)

Test		Standard	Remedial action if standard not met
Scanner inspection (test set [TS] 1)		No observable concerns with mains or video cables, filters and vents, sharp edges, potential infection control problems etc. No damage to any parts	Ask equipment supplier to rectify before acceptance
Probe inspection (TS1)		Full compliance with the purchasing specification and no evidence of physical damage to the probe, cable or connector	Raise with supplier, requesting probe change (if necessary) before acceptance
Monitor set-up and geometry (TS5)		Evidence that the monitor settings are optimised and the full range of grey levels is represented. Performance is consistent and viewing is not compromised by poor ambient light conditions Monitor geometry ratio (should be 1 ± 0.1)	Ask equipment supplier to rectify before equipment enters clinical use
Image uniformity (TS1 part 1.4 and TS3 parts 3.1 and 3.3b)		Even greyscale appearance: no demonstrable evidence of axial or lateral banding using either test	Ask equipment supplier to evaluate possible causes • axial banding: element failure, transmission or reception fault (short of failure) • lateral banding: TGC or beam forming problem. If uniformity falls significantly short of supplier or clinical performance criteria then the fault must be rectified before acceptance (eg change the probe)
Functional checks (TS3)	Focal setting and zones	Lateral resolution optimised, good correlation with indicated position of focus/foci. Focal point moves with indicated focus	Ask equipment supplier to rectify before acceptance (eg if focus generation or indication fault)
	TGC	Demonstrable range and ability to adjust for an even grey scale through a TETO. No evidence of persistent banding in clinical images that cannot be removed by adjustment	Ask equipment supplier to investigate cause and rectify before acceptance
	Frequency settings	Relative speckle/target size and penetration through a TETO are unequivocally consistent with the nominal frequency setting	Ask equipment supplier to investigate cause and rectify before acceptance

Test		Standard	Remedial action if standard not met
	Frame rate variation	Frame rate variation is consistent with multiple zone focusing variation and raises no other concerns (eg not persistently low, ie >10 fps)	Ask equipment supplier to investigate cause and rectify before acceptance
	Safety indices	Displayed values are consistent with ODS,[6] IPEM[13] and BMUS guidelines[14] and with scanner specifications	Ask equipment supplier to investigate cause and rectify before acceptance
Hard/soft copy (TS3, TS5)		Evidence of an even grey scale and optimised brightness and contrast, representative of the monitor image. Last reverberation visible. Geometry ratio should be 1 ± 0.1	Investigate cause (eg scanner or hard/soft copy device) and rectify before acceptance
Axial, lateral, circumference and area calliper accuracy (TS5)		Linear: accurate to within ± 1 mm Circumference and area: accurate to within ± 2 mm and ± 0.05 cm^2 respectively	Ask equipment supplier to improve calibration. Retest. If it remains below required accuracy then report, discuss significance with clinical users and log outcome

BMUS, British Medical Ultrasound Society; fps, frames per second.

4.2 Commissioning (local staff)

Action	Standard	Remedial action if standard not met
Menu presets (optimisation) (TS7)	Evidence that breast-specific protocols are installed, adequate and secure (eg protocols present, clear provision and user understanding of specialised and/or generic settings, specialised settings for large and small breasts, confirmation of clinical applications set-up, no evidence that protocols may be easily changed unwittingly or without notification)	Report and discuss with clinical users. Ask supplier's clinical applications support to rectify if necessary
Training of clinical staff and arrangements for local quality assurance (TS7)	Member of staff assigned to local quality assurance with adequate training and enough time to complete duties	Report need for staffing allocation to be addressed. Training to be supplied if necessary by medical physics service or external source

4.3 Baseline testing

For standards and remedial actions relating to these baselines see section 4.4.1. Details of how to conduct the tests are set out in Appendix 1.

a) Essential test baselines (TS4, TS5)
   - Monitor and uniformity
   - Reverberation lines
   - B-mode noise
   - CPD noise
   - Preset recording
   - User quality assurance training
   - Sensitivity (low-contrast penetration) – TETO
   - Anechoic and low-contrast target visibility

b) Extended test baselines (TS6)
   - Resolution images

4.4 Physics testing

4.4.1 Six-monthly or reactive testing and inspection (essential)

Test	Standard	Remedial action
Scanner inspection (Test set [TS] 1)	No observable concerns with mains or video cables, filters and vents, sharp edges, potential infection control problems etc. No damage to any parts	Request engineering intervention to rectify before acceptance
Probe inspection (TS1)	No evidence of physical damage to the probe, cable or connector	Raise with local staff, requesting probe change (if necessary) and withdraw from clinical use if safety concerns
Monitor checks (TS1)	Evidence that the monitor settings are optimised and the full range of grey levels is represented. Performance is consistent and viewing is not compromised by poor ambient light conditions	Request engineering intervention to investigate whether monitor is performing below specification as set by supplier or agreed standard (eg AAPM[11]). Rectify or replace if necessary
Image uniformity (TS1, TS3)	Even greyscale appearance: no demonstrable evidence of lateral banding that cannot be adjusted, using either test. No axial banding in the central third of the image. No more than one element fault in the outer thirds of the image	Request engineering intervention to evaluate possible causes • axial banding: element failure, transmission or reception fault (short of failure) • lateral banding: TGC or beam-forming problem If uniformity falls significantly short of clinical performance criteria then the fault must be rectified (eg change the probe)

Test		Standard	Remedial action
Reverberation lines (TS2)		No more than one measurement different by ± the distance between reverberation planes, with confirmation that no upgrades have been performed and that monitor performance is acceptable	If values have increased, investigate possibility of probe damage or delamination. If values have decreased, investigate possible amplifier fault or probe damage. Explore clinical log for possible correlation. Request engineering intervention if applicable
B-mode and CPD noise (TS2)		Within the normal range established at baseline	If performance cannot be improved, check other results for possible correlation. Report and discuss findings with clinical users, especially if they relate to clinical problems (eg poor cyst or lesion visualisation). Request engineering intervention to investigate cause and rectify
Hard/soft copy (TS2, TS3)		Evidence of an even grey scale and optimised brightness and contrast, representative of the monitor TETO image. Last reverberation visible and black/white levels	Investigate cause (eg scanner or hard/soft copy device) and rectify. Request engineering intervention if required
Sensitivity (low-contrast penetration) (TS4)		No reduction in the low-contrast penetration by 5% or 5 mm, whichever is the greater	Check for correlation with the reverberation test. Repeat at factory settings. Report and discuss findings with clinical users. Request engineering intervention if applicable
Functional checks (TS3)	Focal setting and zones	Lateral resolution optimised, good correlation with indicated position of focus/foci	Request engineering intervention to rectify (eg if focus generation or indication fault)
	TGC	Demonstrable range and ability to adjust for an even grey scale through a TETO. No evidence of persistent banding in clinical images that cannot be removed by adjustment	Request engineering intervention to investigate cause and rectify
	Nominal frequency changes	Relative penetration through a TETO is unequivocally consistent with the nominal frequency setting	Request engineering intervention to investigate cause and rectify
	Frame rate variation	Frame rate variation is consistent with multiple zone focusing variation and raises no other concerns (eg not persistently low, ie > 10 fps)	Request engineering intervention to investigate cause and rectify

Test		Standard	Remedial action
	Safety indices	Displayed values are consistent with ODS,[6] IPEM[13] and BMUS[14] guidelines, and with scanner specifications	Request engineering intervention to investigate cause and rectify
Anechoic and low-contrast target visibility (TS4)		No reduction in the size of the smallest anechoic target seen No reduction in the number of low-contrast targets seen	Repeat at factory settings. Carry out extended tests to establish whether there is a problem. If confirmed, request engineering support to evaluate possible causes (eg reduced amplifier performance). Check other test results for possible correlation (eg increased noise, reduced resolution)
			Report and discuss findings with clinical users, especially those involving clinical problems (eg poor cyst or lesion visualisation). Assess and log outcome
Preset and log file checks (TS2)	Inspect local quality assurance records	Evidence of persistent failures or problems that may be clinically or technically significant	Discuss with local quality assurance staff to establish whether there is a scanner problem. If findings are confirmed, report and discuss issues with clinical users
	Inspect fault and problem log	No evidence of any increase in reported problems, problems that are clinically or operationally significant, or possible correlation between problems logged and adverse findings from physical tests	Report and discuss any concerns with the clinical users and investigate as necessary
	Ensure electrical safety checks are in date	Safety checks in date (where due-date specified) or have been carried out within the previous 12 months	Report immediately to local representative to expedite the necessary checks. Consider recommending suspension if an electrical safety hazard is suspected

4.4.2 Extended or investigative tests (optional)

Test		Standard	Remedial action
Resolution images (TS6)	Axial resolution, lateral resolution and slice thickness	No visible change to images of filament targets compared with baseline	Investigate possible causes (beam formation, probe, image processing) and correlations with user report forms. Report and discuss findings with clinical users

4.5 User tests (weekly)

Test	Standard	Remedial action* if standard not met
Scanner inspection (TS1)	No observable concerns with mains or video cables, filters and vents, sharp edges, potential infection control problems etc	Log damage and request urgent engineering intervention to rectify any issues immediately affecting patient or staff safety. Schedule remedial action for issues not immediately affecting safety
Probe inspection (TS1)	No evidence of physical damage to the probe, cable or connector	Log damage and request urgent engineering intervention and probe change (if necessary). Withdraw probe from clinical use if there are safety concerns
Monitor test (TS1)	Dark grey background, peak white not saturated, all grey scales discernible	Log concerns and request reactive physics test; rectify or replace if necessary
Image uniformity (TS1)	Even greyscale appearance – no evidence of previously unreported axial banding using either test	Log concerns and request engineering or physics intervention to evaluate possible causes (eg element failure, transmission or reception fault, delamination). If loss in uniformity is significant (see 4.4.1 above) the fault must be rectified (eg change the probe)

*Remedial action should normally be agreed with the physics service *before implementation*. Actions are outlined here as a guide only.

4.6 User tests (monthly)

Test	Standard	Remedial action* if standard not met
Reverberation lines (TS2)	No more than one measurement different by ± the distance between reverberation planes, with confirmation that no upgrades have been performed and that monitor performance is acceptable	If values have changed, check for probe damage. Examine clinical log for possible correlation. Check all settings are as baseline. Log fault and request physics reactive checks
Hard/soft copy (TS2)	Evidence of an even grey scale and optimised contrast	Investigate cause (eg scanner or hard/soft copy device). Rectify or log fault and raise it with appropriate staff
B-mode noise (TS2)	Within the normal range established at baseline	Log fault and request engineering intervention or physics reactive checks to investigate the cause and rectify it. Assess and log outcome
CPD noise (optional) (TS2)	Within the normal range established at baseline	Log fault and request engineering intervention or physics reactive checks to investigate the cause and rectify it
Preset and log file (TS2)	Evidence that breast-specific presets remain installed, are adequate and have not unwittingly been changed. Clinical problem reports, quality assurance records and engineering reports are updated and acted upon as necessary. Quality assurance personnel records up to date and blank report sheets provided. Electrical safety tests in date	Address any outstanding actions

*Remedial action should normally be agreed with the physics service *before implementation*. Actions are outlined here as a guide only.

5. MANAGEMENT OF CLINICAL AND TECHNICAL PROBLEMS

This section offers guidance on logging and making use of information on clinical and technical problems. (See also section 6 on equipment replacement.)

5.1 Clinical problems

The approach recommended here is designed to make reporting clinical problems more straightforward, systematic and amenable to audit. It uses a proforma to characterise and rank clinical problems, facilitating the periodic review of clinical performance. This, in turn, may be used as evidence of the continued acceptability of the scanner or as grounds for remedial action, intervention or planned replacement.

Although they inevitably involve some subjective judgement on the part of the operator, imaging problems logged in clinical cases may be a useful indicator of performance. Where the majority of ultrasound procedures undertaken (locally or more widely) deliver all or most of their intended benefits, such logs may reveal a pattern of localised problems that warrants investigation.

The proforma recommended for logging clinical problems appears in Appendix 3. A completed example of section 2 of this form is shown below. Units are advised to keep (both blank and completed) copies with the log file and close to the scanner for ease of use.

5.1.1 Completed example: Ultrasound scanner: clinical problem report form

Scenario: a moderate problem was encountered when trying to image a large cyst before aspiration. It was not clear whether the cyst contained particulate matter or whether the image was simply noisy. The level of acoustic enhancement behind the cyst was unexpectedly low and the needle could not be demonstrated clearly. The scan path was long through a large breast.

2. Nature of problem			
Problem relates to	*Level*	*Problem relates to*	*Level*
Lesion detection		Acoustic shadowing	
Lesion characterisation		Acoustic enhancement	1
Differentiation of noise and particulate matter in a cyst	2	Tissue plane distortion	
Lesion at depth	2	Biopsy/localisation procedure	
Approx size of lesion (mm): 10 mm			
Comments Large cyst, noisy image, difficult aspiration. Difficult scan conditions – large breast, long scan path, no enhancement shown			

The comment might help to identify this as an unusual problem or prompt improvements in the set-up for deep path scanning.

5.2 Technical problems

A log of technical problems may provide valuable information on the management of the scanner, especially in relation to rare or intermittent problems, and should serve as a resource for all staff. A simple form for logging technical problems appears at Appendix 4. As with all fault logs, the colleague completing it may have limited understanding of the likely cause of the problem, or difficulty in describing it. The pattern of faults described in a well-maintained log may nevertheless yield useful information.

5.3 Periodic review of problems

The log file should normally be reviewed as part of monthly quality assurance and shortly before a six-monthly physics test. This will underline the volume and severity of problems recorded and identify any trends, most critically in relation to problems ranked 3 or higher in the clinical log. The review should be succinct – a sentence or brief paragraph wherever possible – and accompanied by a summary of the total problems logged and their scores. Wherever possible this should be carried out by the local quality assurance tester, with outcomes confirmed and agreed with the lead radiologist. The physics assessor should read this summary as part of the six-monthly testing procedure and investigate issues where necessary. Every effort should be made to identify correlations between clinical or technical problems and the outcomes of the physics tests, as this will help to make these outcomes more meaningful and more robust.

6. EQUIPMENT REPLACEMENT

The main purpose of monitoring a scanner is to identify unacceptable performance and (where relevant) provide evidence-based grounds for replacement. The approach recommended here is to agree a set of considerations against which acceptability can be judged. All relevant staff (eg scanner operators, local users, physics and engineering support) should contribute to this process, which should be initiated when there are shared concerns about a scanner's overall performance. These considerations should include

a) *Clinical problems* – review of the volume and severity of reported clinical problems (especially trends and evidence of deterioration); where possible these reports should be linked to the requirements set out in section 2.1.

b) *Technical faults* – volume and severity of technical faults; downtime; impact on patient care (including treatment delay); the existence of faults that cannot be rectified.

c) *Substandard or deteriorating performance (inferred from physical measurements)* – persistent or irreparable failures against standards; failures against baselines that indicate deterioration.

d) *Correlation* – parallels between clinical or technical problems (reported in the log file) and poor performance (demonstrated during physical testing) that reinforce concerns about the scanner.

e) *Ageing* – a five-year age limit[15] is recommended *not* as an unequivocal deadline for replacement but as a prompt to consider planned replacement at each subsequent six-monthly review.

f) *Obsolescence* – evidence that the original, or any other, supplier is unable to support the system adequately (absence of updates or upgrades, design features no longer consistent with best practice, unavailability of spare parts).

g) *Restricted or inadequate functionality* – evidence of limited or inappropriate functionality when compared with current technology; significant concerns about ability to deliver best practice, either in the department (ie relative to other scanners) or in comparison with NHSBSP services elsewhere.

In the absence of suitable objective measures of performance, testing a scanner against a full range of relevant factors produces a full and robust assessment of its continued suitability. When considering these factors, it should be borne in mind that progress in clinical expectations and standards may justify the replacement of a scanner even where there is no evidence of significant deterioration in performance. It is therefore essential that the extent of these changing expectations and standards is fully reflected in regular updating of the clinical requirements set out in section 2.1.

7. FUTURE UPDATES TO THESE GUIDELINES

The updating of the 1998 guidance was long overdue and this may have had an impact on the acquisition and planned replacement of ultrasound scanners. The Working Group that produced these new guidance notes therefore proposes to review them every three years, in collaboration with NHSBSP colleagues.

The following areas will be considered in the next revision of the guidance

- *Objective performance testing:* there is a need to identify more objective, robust and widely applicable test methods so that specific methods can be recommended in national guidance.
- *Image quality test objects:* the limitations of conventional tissue equivalent test objects are widely recognised. Evidence is required of newly developed and, especially, readily available objects that provide reliable and reproducible results
- *Correlation:* information is needed on correlations between reported clinical problems and physical test outcomes, as this may support the development of more objective standards based on physical tests
- *Clinical acceptability:* a clearer understanding is needed of the relationship between equipment management decisions and the review of clinical problems. Gathering evidence in this area may help to produce more objective guidelines concerning the number and severity of problems reported
- *Operating modes:* feedback is required on advances in the use of Doppler, elastography, 4D, fusion imaging and similar techniques, for inclusion in the guidelines if appropriate.

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APPENDIX 1: TESTING PROCEDURES

1 TEST SET 1

Components

1.1 Scanner inspection
1.2 Probe inspection
1.3 Monitor checks
1.4 Image uniformity

Test set 1 should be performed by physics staff at acceptance. **It should be repeated at least once a week by local staff in the scanning department**. Local physics support staff will provide training for these staff to enable them to complete the task. A proforma for weekly test results is provided at Appendix 2a and a results sheet for acceptance tests can be found at Appendix 2c. Guidance on remedial action, where action is necessary, appears in the tables in section 4. No test object is needed to complete these tests.

1.1 Scanner inspection

a) With the scanner power off* inspect the scanner, peripherals and all cables for visible mechanical, electrical or infection hazards, eg sharp edges, loose components, visible damage. Check the mains and video cables for signs of wear and tear such as loose plugs or torn sheathing. Note any signs of damage to the scanner, monitor etc.
b) Check filters and vents on the scanner for signs of blockage; clean and clear if necessary. Turn on the scanner to allow warm-up for monitor checks.

*Wait for the shutdown process to end before turning off the mains switch.

1.2 Probe inspection

a) Clean the probe if dirty or contaminated. Use the materials recommended by the manufacturer and observe local health and safety and infection control guidelines.
b) Check each probe and its cable and connector for signs of damage. Look particularly for cracks or chips in the probe housing and tears in the cable (eg where it may have been caught under a wheel). The scanning face should be examined by gently running a finger along the surface to detect small regions of non-uniformity; these might indicate a crack or a region where the front layer has become detached. Using a magnifying glass may reveal hairline fractures at an early stage and is recommended as part of the six-monthly probe inspection.
c) At acceptance, ensure that the probes comply with the purchase order. Items found damaged should not be accepted for clinical use.

1.3 Monitor checks

Allow the monitor to warm up for a minimum of five minutes, dim the room lighting to normal scan levels (see 5.3(a) below), then perform the set-up procedure below

a) observe the monitor brightness and contrast settings and note any changes from baseline settings as recorded on the test sheet. (The baseline settings should have been optimised at acceptance by physics support staff – see test set 5 below – and recorded on the weekly test sheet)

b) ensure that the background on the monitor is very dark grey, but not black. (The monitor border is often black and can be used as a reference if visible.) Adjust the *Brightness* control if necessary

c) ensure that all the grey levels are discernible and that the peak white level is not saturated. Use the grey bar on the monitor to check this, if displayed, or a frozen clinical image. Adjust the *Contrast* control if necessary. (Some monitors may not have a *Contrast* control; in this case a single control must be used to achieve optimised grey levels from background to peak whites)

d) record the final control settings. They should normally be close to the baseline monitor settings. If there is no reference mark to indicate settings, use ink or Tipp-Ex® to create one.

1.4 Image uniformity

Ensure that the probe is clean and dry and scanning in air, then perform this test on each probe

a) select the preset as indicated on the proforma at Appendix 2a. (This preset will not use advanced processing modes and will have been identified at baseline by physics support staff. See test set 5 below)

b) unfreeze the image and observe the echoes from the surface of the probe. Adjust the B-mode/2D gain up and down. The reverberation echo pattern should be uniform and symmetrical across the scanhead; compare it with the original image in the log file if necessary. The number of reverberations may vary between the centre and edges of the image, but should not vary by more than two reverberations. Any vertical dark bands may indicate element drop-out. If in doubt, or to confirm drop-out, perform the test indicated below

   - run a narrow target such as an unfolded paper clip slowly across and in contact with the face of the array, taking care not to damage the probe face. The target must be perpendicular to the length of the array
   - reduce the gain so that the reverberations are visible but not bright
   - check that the narrow band of bright echoes is uniform across the display as the target moves along the probe face (see Figure 1)
   - if a fault is found, check that it originates with the probe by repeating the test with the probe connected to another port on the scanner (if possible). Before reconnecting, ensure that there are no bent pins on the probe connector plug. If the fault persists, it should be reported and appropriate remedial action taken
   - repeat this process for each probe.

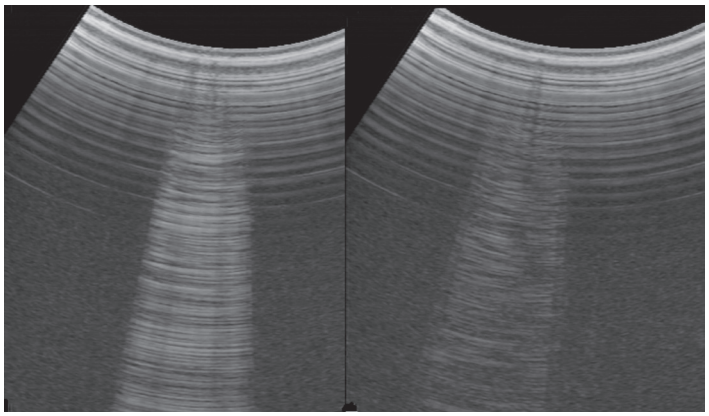

Figure 1 Image showing axial banding in air (left) and the reduced intensity of echoes over the fault shown by the 'paperclip test' (right).

2 TEST SET 2

Components

2.1 Preset and log file checks
2.2 Reverberation lines
2.3 Hard/soft copy check
2.4 B-mode noise
2.5 Colour power Doppler (CPD) noise (optional)

Test set 2 should be performed monthly after baseline figures have been established. Test 2.5 (CPD noise) is an optional monthly check for scanners on which CPD is used for routine clinical work. **Test set 2 should be repeated at least once a month by local staff in the scanning department**. A separate test sheet should be completed for each probe, using the proformas at Appendix 2b. The results should not differ significantly from the baseline figures (which should be inserted in the first column on every proforma sheet). If in doubt, contact physics support staff. No test object is needed for these tests.

2.1 Preset and log file checks (proforma section A)

a) Ensure that presets are as recorded on baseline log sheets.
b) Check the clinical and technical report forms in the log file and ensure that any issues have been addressed. Review with physics staff.
c) Ensure that there is a supply of blank forms for logging future incidents.
d) Check that the latest quality assurance records are included in the log file (including those just completed) and that any actions have been addressed.
e) Make sure the lists of 'Contacts' and 'quality assurance responsibilities' are still current and revise them if necessary.
f) Ensure that the scanner electrical safety test is in date. This should be indicated by a sticker on the scanner or a reference in the log file (eg on the service sheet).

2.2 Reverberation lines (proforma section D)

a) Select the preset (eg *Breast*) as set at baseline and indicated on the form. (See test set 5.) If the scanner has been used and left in this preset, re-select it in order to normalise any settings that may have been altered.
b) Ensure that the probe face is clean and dry, and positioned so it is scanning in free air (ie in the holders provided).
c) Ensure all scanner settings are as recorded on the test sheet. (The scanner settings are those determined at baseline by physics support.) Observe the pattern of reverberation echoes from the probe/air interface.
d) Use the scanner callipers to measure from the top of the image to the last reverberation visible in the centre of the image. Ignore lines at the edges of the image. Take a hard copy showing this measurement. Results should be within one reverberation of previous results.
e) Repeat steps (a) to (d) above for each probe.
f) Leave an image of the reverberation calliper measurement on screen for the hard-copy checks.

2.3 Hard/soft copy (proforma section B/C)

a) Using the reverberation image referred to in 2.2(f), compare the monitor display with the hard/soft copy. This needs to be done with one probe only, but record which is used. 'Hard copy' refers to film or printed images (eg from laser imager or thermal printer). 'Soft copy' refers to Picture Archiving and Communications System (PACS) or other archive review station where images are viewed on a monitor other than the scanner monitor.
b) Compare the background black levels, which should be just above black (ie a dark grey).
c) Compare the peak white levels; the writing should be white and sharp.
d) Ensure that the reverberation indicated by the calliper is visible.
e) Record the hard/soft copy settings where possible.
f) Make any necessary adjustments and repeat.
g) Check that clinical images are acceptable using these settings.
h) Repeat for all hard/soft copy devices.

2.4 B-mode noise (proforma section E)

a) Start with all the gains at maximum and with the clean probe scanning in free air.
b) Adjust the room lighting to that used for scanning.
c) Adjust TGC and depth/scale setting to that recorded on the test sheet. The correct adjustment is set at baseline by physics support to show noise only in the distal image (see test set 5).
d) Reduce the overall/master gain until the noise in the image just disappears at the bottom of the screen. Record the gain setting at this point, employing the terminology used for the recorded baseline.
e) Repeat for each probe.

2.5 CPD noise – optional (proforma section F)

a) Start as set at completion of test 2.3 (B-mode noise) and turn on the CPD mode.
b) Position the colour box centrally at the bottom of the image.
c) Increase the colour gain until colour-noise is visible in the colour-box.

d) Reduce the colour gain until the colour-noise in the colour-box just disappears.
e) Record the colour gain setting at this point. (It is usually displayed on the screen.)
f) Repeat for each probe.

3 TEST SET 3

Components

3.1 TETO uniformity checks
3.2 TETO hard/soft copy checks
3.3 Functional checks
- Focal zones
- TGC
- Frequency settings
- Frame rate variations
- Safety indices

Tests 3.1 and 3.3 should be administered by physics support staff for the system or replacement probes, and test 3.2 for hard-copy devices, when they are new. The results should be recorded using pages 2–4 of the proforma at Appendix 2c and repeated at six-monthly intervals using pages 2–4 of the proforma at Appendix 2e. Where remedial action is needed, guidance on the form it should take appears in table form in section 4. A TETO is needed for these tests.

3.1 TETO uniformity checks

a) Ensure that the probe is clean and dry.
b) Image a TETO using a suitable clinical preset. (The TGC may require optimisation during imaging.) An optimised image should show uniform mid-grey level in the tissue-mimicking material throughout the useful penetration depth. Moving the probe along its long axis while imaging in real time will often emphasise axial banding effects.
c) This test should be performed on each probe.

Lateral banding will appear as a horizontal zone (or zones) of relatively increased or decreased brightness. It is usually possible to correct this by adjusting the relevant TGC control. Lateral banding may be associated with focusing, where the higher intensity of the beam occurs around the focal depth. Well-designed scanners will automatically correct for this as the focus is adjusted.

The magnitude of an axial banding fault may be assessed by running a narrow, smooth, metal object such as a paperclip or the back of a thin key along the probe (as described in test set 1, 1.4) to reveal reduced echo levels in the defective area. (See Figure 1.)

3.2 Hard/soft copy TETO test

a) Acquire an image from a TETO showing the extremes of available grey scales, with filament targets at peak white and low-level noise beyond the low-contrast penetration depth. This can be seen in Figure 2, where mid-grey speckle is visible and the greyscale bar is displayed; the

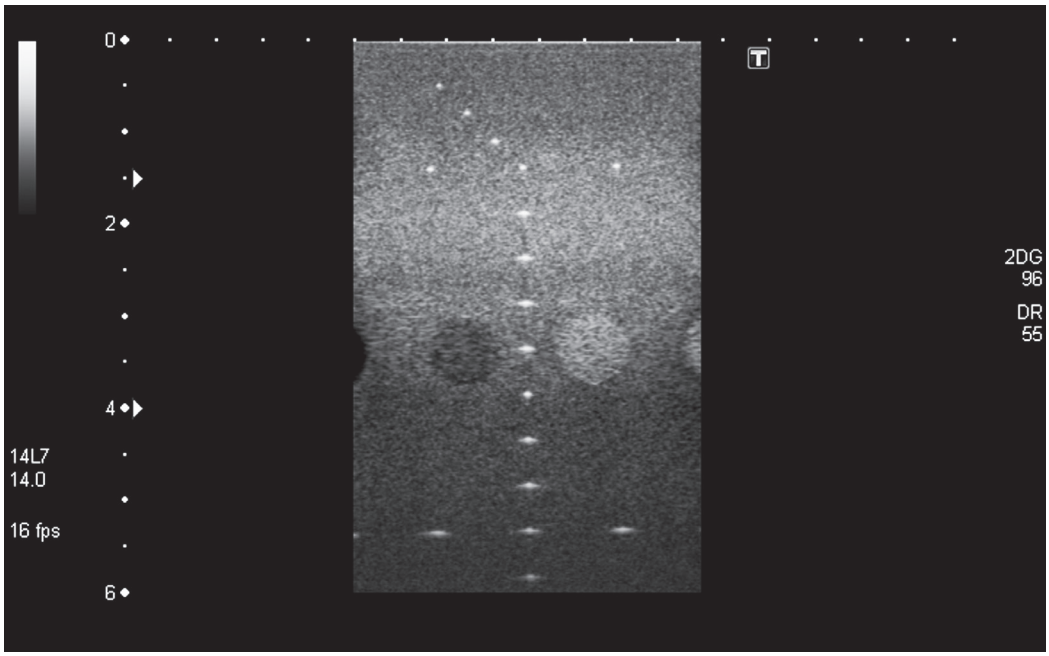

Figure 2 Image showing the greyscale bar (top left of image), the filament targets at peak white, mid-grey speckle and low-level noise beyond the low-contrast penetration depth. The expected sharpening of filament images at the focal depths (1.5 cm and 4 cm) is also shown. Note also the lateral banding (brighter region at approximately 2 cm depth), which, in this case, could be corrected using TGC.

bar should be referred to when logging the adjustment. Take a hard copy and also transfer the image to any available external storage and viewing system, such as PACS.

b) Compare the hard-copy image with the displayed image and adjust the hard-copy device if necessary. Note that the greyscale performance of some hard-copy devices (eg thermal printers) does not permit the monitor image to be faithfully reproduced. This means that some compromise will be necessary when adjusting the device, requiring liaison with clinical users. Check for image uniformity on hard copy and note any axial or lateral banding that may be caused by, for example, the print mechanism. Record the final settings. Any non-uniformity should be reported so that corrective action can be taken.

c) Compare the externally viewed (PACS) image with the scanner-displayed image. Resolving any differences between them will require discussion between the ultrasound supplier and local ICT support.

3.3 Functional checks

a) Focal zones

Acquire an image from a TETO, using a suitable clinical preset, and select a single focal zone. Move the focal zone to different positions, noting the effect on the images of the vertical column of filaments and any small anechoic targets. The image should sharpen at or near the focal depth. (See Figure 2.) If the chosen clinical preset has more than one focal zone, return to the preset and move the focal zones to different positions, again noting the effect on the image.

b) TGC

Acquire an image from a TETO, using a suitable clinical preset. Adjust each TGC control to ensure that it has an effect on image brightness at the relevant depth. Adjust overall gain and TGC to achieve a uniform grey scale throughout the useful field of view.

c) Frequency settings

Acquire an image from a TETO, using a suitable clinical preset. Cycle through the available frequencies (or equivalent settings, eg Pen, Gen, Res) observing the effect on speckle appearance, target sharpness and low-contrast penetration.

In general, speckle size and low-contrast penetration will be reduced, and small targets will appear sharper, as the frequency is increased. If the change in image appearance is unequivocally inconsistent with changes in frequency, the equipment should not be accepted for clinical use and the issue should be discussed with the supplier.

In test objects where the relation of attenuation to frequency is not linear, bear in mind that low-contrast penetration will not change in direct proportion to frequency.

d) Frame rate variation

Acquire an image from a TETO, using a suitable clinical preset. Adjust controls that are likely to affect the frame rate (eg increase scanning depth, line density and the number of focal zones). Note the direction of change of the displayed frame rate and the effect on the image of probe movement. Image blurring should be noted at very low frame rates and the moving image should remain sharp at high frame rates.

If frame rates do not change as expected, this may be due to advanced image formation or processing methods, in which case frame rates should remain high.

e) Safety indices

Referring to the acoustic output table in the user manual, find and reproduce settings at which maximum MI and TI should be displayed. Compare the displayed values with those in the manual.

Reduce settings that should reduce MI and/or TI (eg output or imaging mode) to ensure that the displayed values fall as expected.

Discuss any discrepancies with the supplier. The supplier's clinical applications specialist should be able to assist in finding the settings for maximum TI and MI.

Note that where indices cannot exceed 0.4 they need not be displayed and, in some cases, will not be seen at all in B-mode. Note MI and TI values in clinically used presets and compare with British Medical Ultrasound Society (BMUS) recommended levels.[14]

4 TEST SET 4

Components

4.1 Sensitivity (low-contrast penetration)
4.2 Anechoic and low-contrast target visibility

These tests should be performed on each probe by physics support personnel. They should be undertaken when the scanner/probe is new, or after a major upgrade or repair, using both clinical and factory presets. (See the results proforma at Appendix 2d.) It may also be useful at baseline to record images with any special acquisition or processing features (eg compounding and speckle reduction) switched on and switched off. These images will be useful for future reference in case of a suspected fault. Tests should be repeated at the six-monthly visit using the main clinical preset, and with factory preset if a fault is suspected. (See the results proforma at Appendix 2e.)

4.1 Sensitivity (low-contrast penetration)

a) Acquire an image from a homogeneous region of a TETO. Select a scanner factory preset that provides a uniform TGC slope, as this should be well matched to the attenuation properties of the test object. Use maximum output, turn all TGC to mid-range and adjust overall gain to achieve a mid-grey speckle level in as much of the test object as possible. (If there is no mid-range click, then maximum settings may be a suitable reproducible alternative; note this, if used.) Adjust the scale setting so that the speckle/noise boundary is visible near the bottom of the image. Record all scanner settings, test object details and viewing conditions on the test sheet at Appendix 2d.
b) Assess the position of the boundary between speckle and B-mode noise, ignoring isolated regions of speckle. Use the scanner's callipers to measure the distance from the top of the test object to the boundary between speckle and noise. On some scanners it may be necessary to freeze the image in order to use the callipers, but where possible a live image should be used as this enables differentiation of speckle and noise.
c) Record the depth of the speckle–noise boundary (low-contrast penetration) as the baseline for subsequent tests. The acceptable reduction in low-contrast penetration for future tests is 5% or 5 mm, whichever is greater.
d) Record an image for future reference.
e) Repeat the sensitivity measurement for the main clinical setting.

4.2 Anechoic and low-contrast targets

a) Scan a TETO, using the factory preset as in 4.1(a) above. Record images of anechoic and low-contrast targets for a number of frequencies, including harmonics if available. Retain images for future reference.
b) Record images using the main clinical preset. It may also be useful to record images with any special acquisition or processing features (eg compounding and speckle reduction) switched on and switched off. These images will be useful for future reference in case of a suspected fault.

5 TEST SET 5

Components

Part I (Acceptance: see proforma at Appendix 2c)

5.1 Monitor and hard/soft-copy geometry
5.2 Calliper accuracy

Part II (Baseline: see proforma at Appendix 2d)

5.3 Set up baselines for test set 1: monitor and uniformity
5.4 Set up baselines for test set 2: reverberation, B-mode noise and CPD noise
5.5 Record values set in clinical presets
5.6 Train local staff in weekly and monthly testing and recording methods

These tests are carried out when the scanner is new. They are not routine tests, but may be repeated if a fault is suspected or if the scanner has a major repair or upgrade. Part I requires a test object with a sound speed of 1540 m s^{-1} and targets at known, accurate, separation; these should include a circular target of known, clinically realistic, diameter (eg 5–10 mm).

5.1 Monitor and hard/soft-copy geometry

Position two equidistant pairs of callipers on the screen, one vertical and one horizontal (as in Figure 3). Using a ruler or marked sheet of paper check that the vertical and horizontal distance between each pair of callipers is equal. The ratio of the measurements should be 1 ± 0.1. Repeat the check on available hard/soft-copy devices.

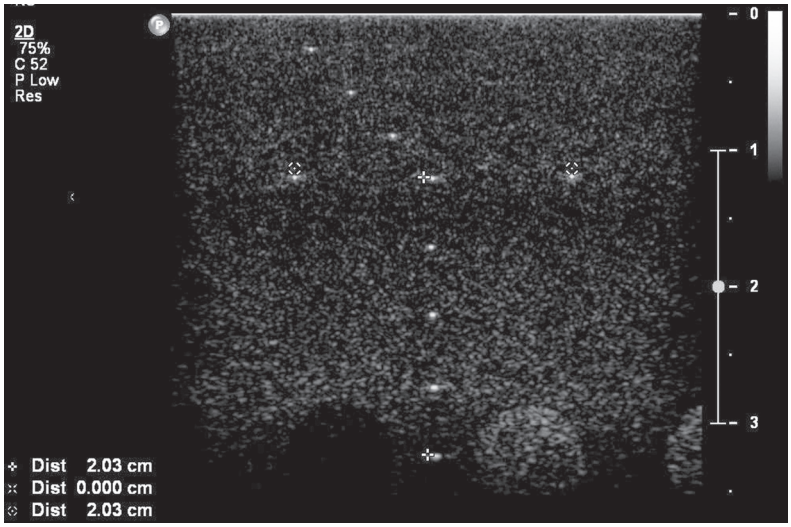

Figure 3 Calliper accuracy check, with equidistant vertical and horizontal callipers for geometry test.

5.2 Calliper accuracy

This test should be performed on each probe.

a) Image the test object at a clinically suitable magnification and take measurements between targets at clinically realistic distances (ie up to 20 mm). Adjust overall gain and TGC to reduce the level of speckle and noise around targets, so that they are clearly distinguished and do not saturate the grey scale. Measure from leading edge to leading edge in the axial direction and centre to centre of targets in the lateral direction (see Figure 3). Record values as displayed and compare with the known distances.
b) It is possible that measurements may be affected by scale setting, as pixel sizes will be rescaled by the scanner's software. It is impractical to test callipers on every possible scale setting, but a subset of measurements should be repeated on a small range of clinically realistic scale settings (at least two) and in at least one zoom setting.
c) An accuracy of ± 1 mm is required. Any failure must be confirmed by repeat testing.
d) Having established that the accuracy of the linear callipers is acceptable, image a circular target magnified to occupy at least 25% of the image depth. Carefully measure its axial and lateral diameters and calculate its circumference and area. Measure the circumference and area using tracing callipers and any other method in routine use.
e) An accuracy of ± 2 mm for circumference and 0.05 cm^2 for area is required. Any failure must be confirmed by repeat testing.

5.3 Setting baselines for test set 1

(a) Monitor baseline set-up

This is designed to optimise settings for the monitor and, where applicable, give guidance on viewing conditions. The monitor should be allowed to warm up for at least 15 minutes before adjusting or recording settings.

- Ensure that room conditions allow the monitor to be viewed in uniformly dim light: low ambient light levels are essential during testing and clinical use, and there should be no reflections from the monitor. (IPEM guidelines recommend a maximum ambient light level of 15 lux for diagnostic viewing;[12] however levels of 5 lux are more typical in many ultrasound scan rooms.) Discuss any issues with the manager of the Unit and/or seek advice from medical physics colleagues
- Some practitioners use a second monitor for ease of viewing during biopsies. This, and any other secondary monitor used in the diagnostic process, should be included in this assessment
- Dim the room lights and acquire an image of a TETO showing the extremes of available grey scales: eg filament targets at peak white or low-level noise beyond the low-contrast penetration depth. (See Figure 2 above.) Optimise brightness and contrast, as described in section 1.3 above, to achieve a dark grey background with low-level echoes visible and unsaturated peak whites
- Record the final monitor settings for reference on the weekly test sheet.

(b) Image uniformity baseline checks

This procedure is designed to determine the preset to be used for the weekly check.

- Select the most commonly used clinical preset
- Operate the probe in air, ensuring that it is clean and dry. Take care to switch off advanced imaging functions (especially spatial compounding, spatial smoothing and speckle reduction

imaging) as these may mask fundamental problems with the probe. If advanced imaging functions are used in the default breast preset it may be useful to set up a 'reverberation test' preset, for local use, with these switched off
- Turn overall gain to maximum and turn all TGC controls to mid-range. If there is little or no reverberation and noise, or the controls do not click into position at mid-range, set TGC to maximum and record this for future reference. Select a scale/depth setting that allows measurement of the full depth of probe reverberation, allowing a few centimetres extra for possible changes
- Record the scanner settings for weekly user tests
- Inspect the reverberation pattern for axial banding, which indicates a localised transmission/reception fault
- Take a reverberation image for the file showing symmetry and uniformity
- Repeat for each probe.

5.4 Setting baselines for test set 2

(a) Baseline reverberation lines

Although it is not a direct measure of scanner sensitivity, this test does reflect sensitivity and is a useful indicator of change. It may be less reproducible for harmonic frequencies on some scanners, and where this is the case it should be performed only for fundamental frequencies. No test object is required.

- If it is not possible to set controls exactly as described here, record any departure from the standard methods so that settings and results may be reproduced
- Start with a suitable factory preset (eg *Breast*) and with the lowest frequency or the setting that is expected to give the deepest penetration. Set overall gain and TGC controls as in 5.3 above. If there is little or no reverberation and noise, set TGC to maximum and record this for future reference. Select a scale/depth setting that allows measurement of the full depth of probe reverberation, allowing a few centimetres extra for possible changes. Record the settings
- Freeze the image and measure vertically from the top of the image (probe surface) to the lower limit of the deepest visible reverberation plane in the middle third of the image. Ignore reverberations at the edge of the image and any deeper reappearance of reverberations after they have initially faded to background
- Record and take an image of this measurement with an acceptable range (tolerance) indicated for future reference tests of ± the distance to the adjacent reverberation plane
- Repeat at a higher frequency
- Repeat with the settings achieved above in 5.3(b). This is the value that should be recorded on the test sheet and used for the monthly repeat test. Ensure that scanner settings and preset are recorded on the monthly test sheet
- Ensure that reverberation is visible on the hard/soft-copy device to be used in user testing.
- Repeat for each probe.

(b) B-mode noise

- Start with the factory preset, frequency, gain and scale setting as in (a) above for the reverberation lines. Ensure that room lighting is low and that overall gain is at maximum. TGC should remain set as for the reverberation test. (In some cases it may be helpful to reduce TGC to the minimum over the region of reverberation in the image so that noise in the distal image is clearly visible. Record these settings.) Reduce overall gain to the point where all noise in the distal

part of the image is eliminated. Record the overall gain setting. If it is not displayed estimate the distance, in tenths of a setting, between marked settings on the control knob (eg if halfway between markings 2 and 3, record 2.5); if settings are not marked, count the number of clicks
- Perform this measurement several times to establish an acceptable range. If any isolated values are very different from the others, discard them and repeat
- Record the range of measurements (smallest and largest) as the acceptable range for routine tests. Record the scanner settings used on the monthly test sheet (Appendix 2b)
- Repeat at a higher frequency
- Repeat with the settings achieved above in 5.3(b). This is the value that should be recorded on the test sheet and used for the monthly repeat test. Ensure that scanner settings and preset are recorded on the monthly test sheet
- An alternative method has been proposed by IPEM[12] where the above method is impractical. Set the scanning depth, TGC and overall gain to maximum. If the image is entirely saturated (white), reduce the TGC to the mid-point. The screen should be filled with noise, increasing in intensity with depth. Measure the distance from the probe face to the point where noise reaches a peak white level. This can be done by taking a small piece of card with a 2 cm square hole cut in it and moving it down the image until the noise within the hole becomes uniform.

(c) Colour power Doppler noise

- If colour power Doppler (CPD) mode is used clinically, set the baselines for CPD noise as for B-mode noise in (b) above, but use the default-sized colour box positioned centrally at the bottom of the image and note the colour gain setting at which noise disappears. Set a tolerance as in (a) above
- When activated, CPD noise may use a different frequency to the B-mode image. Take care to observe and record the CPD frequency and not the B-mode frequency.

5.5 Record values set in clinical presets

Once the applications specialist has set up local presets, back up these settings electronically if possible and place them in the log file for reference in test set 2. For the main clinical preset, record values for all possible parameters on the test sheet provided at Appendix 2d. Record any other parameters that may be specific to the scanner.

5.6 Training local staff in weekly and monthly testing and recording methods

Ensure that the baseline values are recorded on the proformas for test sets 1 and 2. Advise the nominated local person on the completion and use of test sets 1 and 2.

6 TEST SET 6 (OPTIONAL)

Component

6.1 Resolution images

These tests are optional extended baseline tests and may prove useful when trying to evaluate future faults or queries relating to image quality. They may also clarify the potential usefulness of test object images. This list is not exhaustive and local protocols, if any, may be included here and filed for reference.

6.1 Resolution images

a) Acquire an image using a TETO and a suitable clinical preset.
b) Record three images of the column of filaments for lateral and axial resolution and three images at 45° for slice thickness.
c) Record settings on screen and save the images for future reference.

7 TEST SET 7

Components

7.1 Presets
7.2 Log file

These tests and tasks are performed at commissioning and overseen by clinical or clinical support staff in the scanning department.

7.1 Presets

a) Liaise with users and applications specialists to ensure that at least one breast-specific preset is available that meets the requirements set out in sections 3.3 and 4.2 of the guidance.
b) Ensure that all presets are backed up and settings recorded.

7.2 Log file

a) Provide a ring-binder or other file to hold key documents relating to the ultrasound equipment, its testing and use.
b) Place in this log file
    - documents relating to the purchase of the scanner (order, delivery note listing items etc)
    - manufacturer/supplier installation report and any subsequent service or maintenance reports
    - documents relating to physics acceptance and baseline testing and any subsequent physics reports
    - blank (and any completed) forms for
        - test set 1 results (weekly)
        - test set 2 results (monthly)

  - clinical reports
  - technical reports
- back-up of presets, in a protective envelope or other packaging
- completed forms from Appendix 5 (Personnel contacts) and Appendix 6 (Quality assurance responsibilities)

c) Place the log file in a safe and convenient location accessible to all clinical and technical staff.

APPENDIX 2A

ULTRASOUND WEEKLY TEST RESULTS

Scanner make, model and ID_____

Location_____

A. Inspection and monitor set-up (TS1.1, TS1.3)

Date	Baseline				
Mains cable secure: no damage/wear	–				
Other cables: no damage/wear	–				
Filters/vents clear?	–				
Monitor *Brightness* setting					
Monitor *Contrast* setting					
Tester					

Comments on visual inspection

B. Probe 1 inspection (TS1.2) Model and ID: Preset:

Date					
Probe–scanner connection satisfactory?					
No damage to probe cable					
No damage to probe casing/face					
Uniformity satisfactory?					
Tester					

B. Probe 2 inspection (TS1.2) Model and ID: Preset:

Date					
Probe–scanner connection satisfactory?					
No damage to probe cable					
No damage to probe casing/face					
Uniformity satisfactory?					
Tester					

APPENDIX 2B

ULTRASOUND MONTHLY TEST RESULTS

Page 1 of 2

Scanner make, model and ID_____

Location_____

A. Preset/safety/log checks (TS2.1)

Date	Baseline				
Preset ID _____ As log file	–				
Preset ID _____ As log file	–				
Report forms up to date	–				
Blank report form available					
Quality assurance records present and actioned					
Safety tests next due					
Personnel details correct					
Tester					

B. Hard/soft copy 1 (TS2.3) Type and make:

Date	Baseline				
Brightness setting					
Contrast setting					
Black level transfer satisfactory	–				
White level transfer satisfactory	–				
Marked echo visible? (probe ID: _____)					
Clinical images satisfactory?	–				
Tester					

Comments on hard/soft copy 1:

C. Hard/soft copy 2 (TS2.3) Type and make:

Date	Baseline				
Brightness setting					
Contrast setting					
Black level transfer satisfactory	–				
White level transfer satisfactory	–				
Marked echo visible? (probe ID: _____)					
Clinical images satisfactory?	–				
Tester					

Comments on hard/soft copy 2:

Page 2 of 2 (Use a separate sheet for each probe)

Scanner make, model and ID _____

Location _____

Probe model and ID _____

Enter baseline figures in the shaded columns.

D. Reverberation lines (TS2.2)

Settings (these should be set as they were at baseline)

Preset/application		Master gain	
Probe frequency		TGCs	
Depth/scale setting		Focus/foci	
Power output		Other:	

Date	Baseline				
Scanhead clean and dry?	–				
Settings as above?	–				
Deepest reverberation line at					
Hard copy taken?	–				
Tester					

E. B-mode noise (TS2.4)

Settings (application, frequency, power, focus and TGCs) as for reverberation lines above

Depth setting = _____ Room lighting = _____

Date	Baseline				
Settings as reverberations, depth as above?	–				
B-mode noise gone at gain =					
Tester					

F. Colour power Doppler noise (if applicable) (TS2.5)

Settings (application, frequency, power, focus and TGCs) as for reverberation lines above

Depth setting = _____ Room lighting = _____

Colour box at default size, positioned down mid-line at bottom of image (tick) _____

Date	Baseline				
Settings, depth and lighting as above?	–				
Colour-mode noise gone at gain =					
Tester					

APPENDIX 2C

ULTRASOUND ACCEPTANCE TEST RESULTS

Page 1 of 5

Scanner make, model and ID _____

Location _____

Date of acceptance test _____

Tester _____

A. Inspection and monitor set-up (TS1.1, TS1.3, TS5.1)

Item	Result	Comments
Mains cable secure: no damage/wear	Y/N	
Other cables: no damage/wear	Y/N	
Filters/vents clear?	Y/N	
Monitor *Brightness* setting		
Monitor *Contrast* setting		
Monitor geometry ratio		(1 ± 0.1) Pass/fail

Do not proceed unless acceptable results have been obtained

B. Probe 1 inspection (TS1.2, TS1.4) Model and ID: _____

Item	Accepted	Comments
Probe–scanner connection satisfactory?	Y/N	
No damage to probe cable	Y/N	
No damage to probe casing/face	Y/N	
Uniformity drop-out test satisfactory	Y/N	

B. Probe 2 inspection (TS1.2, TS1.4) Model and ID: _____

Item	Accepted	Comments
Probe–scanner connection satisfactory?	Y/N	
No damage to probe cable	Y/N	
No damage to probe casing/face	Y/N	
Uniformity drop-out test satisfactory	Y/N	

Do not use a probe unless acceptable results have been obtained

ULTRASOUND ACCEPTANCE TEST RESULTS

Page 2 of 5

Scanner make, model and ID _____

Location _____

Date of acceptance test _____

TETO model, ID, temperature _____

Tester _____

C. Probe 1 tests (TS3.1, TS3.3)

Model and ID:_____

Clinical preset used:_____

Item	Accepted	Comments
No lateral banding after TGC adjustment	Y/N	
No axial banding	Y/N	
Image consistent with focal zone position	Y/N	
TGC functions as expected, uniform image	Y/N	
Images consistent with frequency	Y/N	
Frame rate change as expected (and >10 fps)	Y/N	

Safety indices

Note settings for max TI/MI (from user manual)	TI_S		MI	
	Expected	Displayed	Expected	Displayed
Comments				

Clinical preset	Default TI_S	Default MI

ULTRASOUND ACCEPTANCE TEST RESULTS

Page 3 of 5

Scanner make, model and ID _____

Location _____

Date of acceptance test _____

TETO model, ID, temperature _____

Tester _____

C. Probe 2 tests (TS3.1, TS3.3)

Model and ID:_____

Clinical preset used:_____

Item	Accepted	Comments
No lateral banding after TGC adjustment	Y/N	
No axial banding	Y/N	
Image consistent with focal zone position	Y/N	
TGC functions as expected, uniform image	Y/N	
Images consistent with frequency	Y/N	
Frame rate change as expected (and >10 fps)	Y/N	

Safety indices

Note settings for max TI/MI (from user manual)	TI_S		MI	
	Expected	Displayed	Expected	Displayed

Comments

Clinical preset	Default TI_S	Default MI

ULTRASOUND ACCEPTANCE TEST RESULTS

Page 4 of 5

Scanner make, model and ID _____

Location _____

Date of acceptance test _____

Probe model and ID_____

Tester _____

D. Hard/soft copy 1 (TS3.2, TS5.1) Type and make:_____

Initial *Brightness* setting		Final *Brightness* setting (if adjusted)	
Initial *Contrast* setting		Final *Contrast* setting (if adjusted)	
Black level transfer satisfactory	Y/N	White level transfer satisfactory	Y/N
Low-level noise visible	Y/N	Geometry ratio (1 ± 0.1)	

Detail any actions required to resolve differences between hard/soft copy images and scanner-displayed images

D. Hard/soft copy 2 (TS3.2, TS5.1) Type and make:_____

Initial *Brightness* setting		Final *Brightness* setting (if adjusted)	
Initial *Contrast* setting		Final *Contrast* setting (if adjusted)	
Black level transfer satisfactory	Y/N	White level transfer satisfactory	Y/N
Low level noise visible	Y/N	Geometry ratio (1 ± 0.1)	

Detail any actions required to resolve differences between hard/soft-copy images and scanner-displayed images

ULTRASOUND ACCEPTANCE TEST RESULTS

Page 5 of 5

Scanner make, model and ID _____

Location _____

Date of acceptance test _____

TETO model, ID, temperature _____

Tester _____

E. Probe 1 calliper accuracy (TS5.2)

Model and ID: _____

Clinical preset used:_____

Scale/zoom/ method	Lateral		Axial		Accepted
	Expected	Actual	Expected	Actual	
					Y/N
					Y/N
	Circumference		Area		
	Expected	Actual	Expected	Actual	
					Y/N
					Y/N

E. Probe 1 calliper accuracy (TS5.2)

Model and ID: _____

Clinical preset used:_____

Scale/zoom/ method	Lateral		Axial		Accepted
	Expected	Actual	Expected	Actual	
					Y/N
					Y/N
	Circumference		Area		
	Expected	Actual	Expected	Actual	
					Y/N
					Y/N

Declaration: the equipment has passed/failed acceptance testing

List any outstanding actions:

Tester: _____ Date: _____

APPENDIX 2D

ULTRASOUND BASELINE TEST RESULTS

Page 1 of 5

Scanner make, model and ID _____

Location _____

Date of baseline test _____

Tester _____

A. Baselines for test sets 1 and 2 (weekly and monthly) (TS5.3, TS5.4)

Tick to indicate that the settings/results have been recorded on the relevant sheets.

Tests	✓
Test set 1 Monitor settings; image uniformity image. Settings below: C	
Test set 2 Scanner settings; hard/soft-copy settings; reverberation lines and tolerance; B-mode noise and tolerance; colour power Doppler noise (if applicable). Setting for reverberation and noise below: D	
Nominated local person advised/training provided	

B. Image uniformity preset for test set 1 (TS5.3b) Name: _____

Parameter	Value	Parameter	Value
Output			
Overall gain			
Scale			
Frequency			
Focal depth(s)			
Dynamic range			
…			

ULTRASOUND BASELINE TEST RESULTS

Page 2 of 5

Scanner make, model and ID _____

Location _____

Date of baseline test_____

Tester _____

C. Factory preset for reverberation lines (TS5.4) Name:_____
(for reactive tests and for TS4 below)

Parameter	Value	Parameter	Value
Output			
Overall gain			
Scale			
Frequency			
Focal depth(s)			
Dynamic range			
…			
		TGC	Mid-range/maximum*

*Delete as applicable.

Frequency/setting		
Deepest reverberation line at (mm)	±	±
Overall gain (B-mode noise)	±	±

Frequency/setting		
Colour gain (CPD noise)	±	±

ULTRASOUND BASELINE TEST RESULTS

Page 3 of 5

Scanner make, model and ID _____

Location _____

Date of baseline test _____

Tester _____

D. Clinical preset for reverberation lines (TS5.4, 5.5) Name:_____
(for monthly tests: TS2; and for log file reference)

Parameter	Value	Parameter	Value
Output			
Overall gain			
Scale			
Frequency			
Focal depth(s)			
Dynamic range			
…			
		TGC	Mid-range/maximum*

*Delete as applicable.

Frequency/setting	
Deepest reverberation line at (mm)	±
Overall gain (B-mode noise)	±

Frequency/setting	
Colour gain (CPD noise)	±

ULTRASOUND BASELINE TEST RESULTS

Page 4 of 5

Scanner make, model and ID _____

Location _____

Date of baseline test _____

TETO model, ID, temperature _____

Tester _____

E. Probe 1 tests (TS4) Model and ID:

Factory preset used:

Settings	✓ **or detail settings**
Maximum output	
Mid-range TGC	
Scale (adjust to see LCP)	
Focal depths (when scale adjusted)	
Overall gain setting for mid-grey	
Viewing conditions	
Low-contrast penetration (LCP) =	mm Pass/fail

Images recorded	Frequency/ special feature	Frequency/ special feature	Frequency/ special feature	Frequency/ special feature
Anechoic targets				
Low-contrast targets				

Clinical preset used:

Settings	✓ **or detail settings**
Maximum output	
Mid-range TGC	
Scale (adjust to see LCP)	
Focal depths (when scale adjusted)	
Overall gain setting for mid-grey	
Viewing conditions	
Low-contrast penetration (LCP) =	mm Pass/fail

Images recorded	Frequency/ special feature	Frequency/ special feature	Frequency/ special feature	Frequency/ special feature
Anechoic targets				
Low-contrast targets				

ULTRASOUND BASELINE TEST RESULTS

Page 5 of 5

Scanner Make, model and ID _____

Location _____

Date of baseline test _____

TETO model, ID, temperature _____

Tester _____

E. Probe 2 tests (TS4)

Model and ID:

Factory preset used:

Settings	✓ **or detail settings**
Maximum output	
Mid-range TGC	
Scale (adjust to see LCP)	
Focal depths (when scale adjusted)	
Overall gain setting for mid-grey	
Viewing conditions	

Low-contrast penetration (LCP) =	mm	Pass/fail

Images recorded	Frequency/ special feature	Frequency/ special feature	Frequency/ special feature	Frequency/ special feature
Anechoic targets				
Low-contrast targets				

Clinical preset used:

Settings	✓ **or detail settings**
Maximum output	
Mid-range TGC	
Scale (adjust to see LCP)	
Focal depths (when scale adjusted)	
Overall gain setting for mid-grey	
Viewing conditions	

Low-contrast penetration (LCP) =	mm	Pass/fail

Images recorded	Frequency/ special feature	Frequency/ special feature	Frequency/ special feature	Frequency/ special feature
Anechoic targets				
Low-contrast targets				

APPENDIX 2E

ULTRASOUND PHYSICS TEST RESULTS

Page 1 of 4

Scanner make, model and ID _____

Location _____

Date of physics test _____

Tester _____

A. Safety test dates (TS2.1)

Date of last test	Next test due	Action required/taken

B. Quality assurance records including fault and problem log (TS2.1)

Item	Response	Comments
Weekly quality assurance completed	Y/N	
Monthly quality assurance completed	Y/N	
Summarise clinical and technical faults (Quality Assurance and problem logs)		
Summarise remedial actions taken		
Further actions necessary (include action plan)		

ULTRASOUND PHYSICS TEST RESULTS

Page 2 of 4

Scanner make, model and ID _____

Location _____

Date of physics test _____

TETO model, ID, temperature _____

Tester _____

C. Probe 1 tests (TS3.1, 3.3, 4) Model and ID:

Factory preset used:

Settings	✓ **or detail settings (as per baseline)**
Maximum output	
Mid-range TGC	
Overall gain setting for mid-grey	
Viewing conditions	

Item	Accepted	Comments
No lateral banding after TGC adjustment	Y/N	
No axial banding	Y/N	
Image consistent with focal zone position	Y/N	
TGC functions as expected, uniform image	Y/N	
Images consistent with frequency	Y/N	
Frame rate change as expected (and > 10 fps)	Y/N	
Low-contrast penetration = mm	Y/N	(5% or 5 mm tolerance)

Images compared	Frequency/ special feature	Accepted	Frequency/ special feature	Accepted
Anechoic targets		Y/N		Y/N
Low-contrast targets		Y/N		Y/N

ULTRASOUND PHYSICS TEST RESULTS

Page 3 of 4

Scanner make, model and ID _____

Location _____

Date of physics test _____

TETO model, ID, temperature _____

Tester _____

C. Probe 2 tests (TS3.1, TS3.3, TS 4)

Model and ID:

Factory preset used:

Settings	✓ **or detail settings (as per baseline)**
Maximum output	
Mid-range TGC	
Overall gain setting for mid-grey	
Viewing conditions	

Item	Accepted	Comments
No lateral banding after TGC adjustment	Y/N	
No axial banding	Y/N	
Image consistent with focal zone position	Y/N	
TGC functions as expected, uniform image	Y/N	
Images consistent with frequency	Y/N	
Frame rate change as expected (and >10 fps)	Y/N	
Low-contrast penetration = mm	Y/N	(5% or 5 mm tolerance)

Images compared	Frequency/ special feature	Accepted	Frequency/ special feature	Accepted
Anechoic targets		Y/N		Y/N
Low-contrast targets		Y/N		Y/N

ULTRASOUND PHYSICS TEST RESULTS

Page 4 of 4

Scanner make, model and ID _____

Location _____

Date of physics test _____

Tester _____

D. Hard/soft copy 1 (TS3.2) Type and make:

Initial *Brightness* setting		Final *Brightness* setting (if adjusted)	
Initial *Contrast* setting		Final *Contrast* setting (if adjusted)	
Black level transfer satisfactory	Y/N	White level transfer satisfactory	Y/N
Low-level noise visible	Y/N		

Detail any actions required to resolve differences between hard/soft-copy images and scanner-displayed images

D. Hard/soft copy 2 (TS3.2) Type and make:

Initial *Brightness* setting		Final *Brightness* setting (if adjusted)	
Initial *Contrast* setting		Final *Contrast* setting (if adjusted)	
Black level transfer satisfactory	Y/N	White level transfer satisfactory	Y/N
Low-level noise visible	Y/N	Geometry ratio (1 ± 0.1)	

Detail any actions required to resolve differences between hard/soft-copy images and scanner-displayed images

The equipment has passed/failed physics testing.

Tester: _____ Date: _____

APPENDIX 3

ULTRASOUND SCANNER – CLINICAL PROBLEM REPORT FORM

Please type or print responses

1. General

Operator's name	
Date	
Scanner type/details	
Patient reference	

	Key to reported problem level Enter relevant number in box; complete as many boxes as required
1.	Minor problem, confidence maintained
2.	Moderate problem, reduced confidence – did not repeat scan
3.	Major problem, no confidence – scan repeated

2. Nature of problem

Problem relates to	Level	Problem relates to	Level
Lesion detection		Acoustic shadowing	
Lesion characterisation		Acoustic enhancement	
Differentiation of noise and particulate matter in a cyst		Tissue plane distortion	
Lesion at depth		Biopsy/localisation procedure	
Approximate size of lesion (mm):			
Comments			

3. If a second scan is performed, please complete the following

Operator's name				
Date				
Scanner type/details				
Outcome (please tick as appropriate)	Same		Better	
If better, please give details				

APPENDIX 4

ULTRASOUND SCANNER – TECHNICAL PROBLEM REPORT FORM

Please type or print responses

Person reporting problem		Date reported
Scanner type/details		Installation date
Description of problem		
Action proposed/taken (delete as applicable)		

APPENDIX 5: PERSONNEL CONTACTS

This (or a similar) table should be completed for each scanner, listing all those involved in its quality assurance. It should kept in the scanner log file and be made available to all relevant colleagues.

Name	Position	Location	Contact details	Initials
	Superintendent or nominated supervisor	Breast Screening Unit (BSU)		
	Local quality assurance tester	BSU		
	Physics support			
	Person responsible for electrical safety testing			
	Lead radiologist	BSU		
	QARC regional representative			
	Clinical director			

APPENDIX 6: QUALITY ASSURANCE RESPONSIBILITIES

This table is designed to indicate the responsibilities of people involved in breast screening quality assurance for a particular scanner. On the top row, insert the initials of key personnel as listed in Appendix 5. In the columns alongside each duty, at least one person should be indicated as taking responsibility for the task. A second person may be indicated where appropriate to cover in case of absence.

Duties / Insert initials																
Overseeing of USER TESTS to be done by																
Weekly USER TESTS to be performed by																
Monthly USER TESTS to be performed by																
USER TEST results to be sent to																
USER TEST queries to be reported to																
USER TEST training to be given by																
Safety tests overdue to be reported to																
PHYSICS TESTS to be performed by																
PHYSICS reports to be written by																
PHYSICS reports to be countersigned by																
PHYSICS reports to be sent to																
System upgrades/changes to be reported by																
System upgrades/changes to be reported to																
System faults/deterioration to be reported by																
System faults/deterioration to be reported to																