THE SOCIETY FOR VASCULAR TECHNOLOGY OF GREAT BRITAIN AND IRELAND

Vascular Technology Professional Performance Guidelines

Ultrasound Equipment Quality Assurance

This guideline was prepared by Dr. Nick Dudley in collaboration with the Professional Standards Committee (PSC) of the Society for Vascular Technology (SVT) to aid the clinical vascular scientist/vascular sonographer and other interested parties. It can be used in conjunction with local protocols agreed between local departments. It may be used in part or in its entirety with suitable additions made by local policy implementers.

Suggestions for improvement of this guideline are welcome and should be sent to the Chair of the PSC – see www.svtgbi.org.uk for current chair details.

Setting up a Quality Assurance (QA) programme may seem a daunting prospect but is well within the capabilities of clinical professionals. The literature shows that over 90% of faults may be detected simply by a physical inspection of the equipment and an assessment of in-air uniformity.[1-3] Activities that clinical professionals do as a matter of routine are components of a QA programme: keeping the equipment clean; careful stowage of probes and cables; recording and reporting any equipment malfunction, defect or damage.

Background and purpose

QA is a requirement of The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, which states that "Equipment must be suitable for purpose and properly maintained".[4] Regulation is by the Care Quality Commission who require Health and Safety risk assessments and "equipment to be maintained to be sound, operationally safe and exhibiting only minor deterioration". In order to demonstrate this, regular inspection and testing of equipment is essential. This requirement is reinforced by the specifications of national screening programmes and the guidance of professional bodies and societies. The absence of a QA programme, or ineffective QA, has been shown to have consequences for the condition of equipment in clinical use.[5]

The aim of this guideline is to provide a framework for the implementation of a QA programme for ultrasound equipment based on published guidance and recent developments.[6-12]

Implementation of a QA programme

A QA programme should be implemented in manageable stages. Firstly, look at what you are already doing. Your team are probably keeping the equipment clean; looking after probes and cables; recording and reporting any faults or damage. You may wish to write these processes into a brief procedure and it is important to keep records of faults, damage and remedial action. Make sure you have a maintenance contract with the equipment supplier or a third party; note that most maintenance contracts do not include QA as described here. By doing these things you are reducing the risk of damage and you are protecting the patient from the consequences of using damaged or faulty equipment.
The next step is to initiate a formal process of "User QA", with a periodic visual inspection of the equipment and simple checks of uniformity and sensitivity. Together with the actions you are already taking this should allow you to detect over 90% of faults.

The final stages are to build towards a full QA programme. Acceptance testing and audit are essential elements. The acceptance test includes the same visual inspection and uniformity checks done for User QA, safety checks usually carried out by Equipment Management departments, together with more rigorous acceptance testing of accuracy in B-mode and Doppler. Accuracy checks where measurements are used clinically are essential, so for vascular scanners where absolute velocities are used these should be checked. Annual tests should include an assessment of imaging. Audit is important to ensure that routine QA has been carried out and that fault reports have been acted on. Images should be stored electronically as appropriate for future reference at all stages of QA.

When implementing a QA programme it is good practice to carry out acceptance testing on equipment already in use in order to discover any historic issues.

Table 1 shows the components of a QA programme; Table 2 shows the suggested implementation stages and objectives; Figure 1 shows flowcharts for User QA and a full QA programme.

Table 1. Components of a QA programme

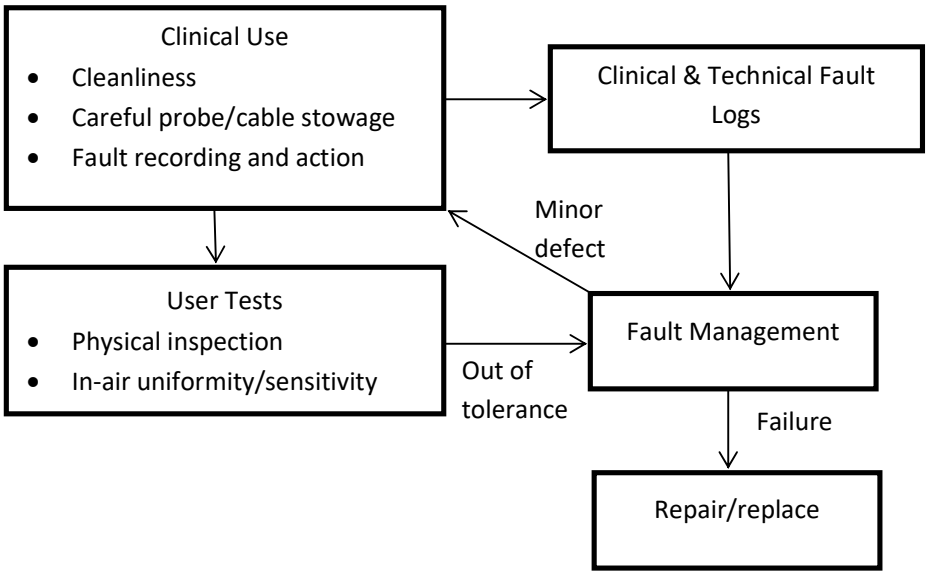
User QA Programme	Full QA Programme
Equipment cleanliness	Acceptance testing
Careful stowage of probes and cables	Annual testing (user tests plus basic imaging checks)
Physical inspection of scanner and probes	Planned preventative maintenance
In-air uniformity and sensitivity assessment	Audit
Record and report faults	
Repair/replacement or ongoing monitoring of faults	

Table 2. Implementation stages, activities and objectives.

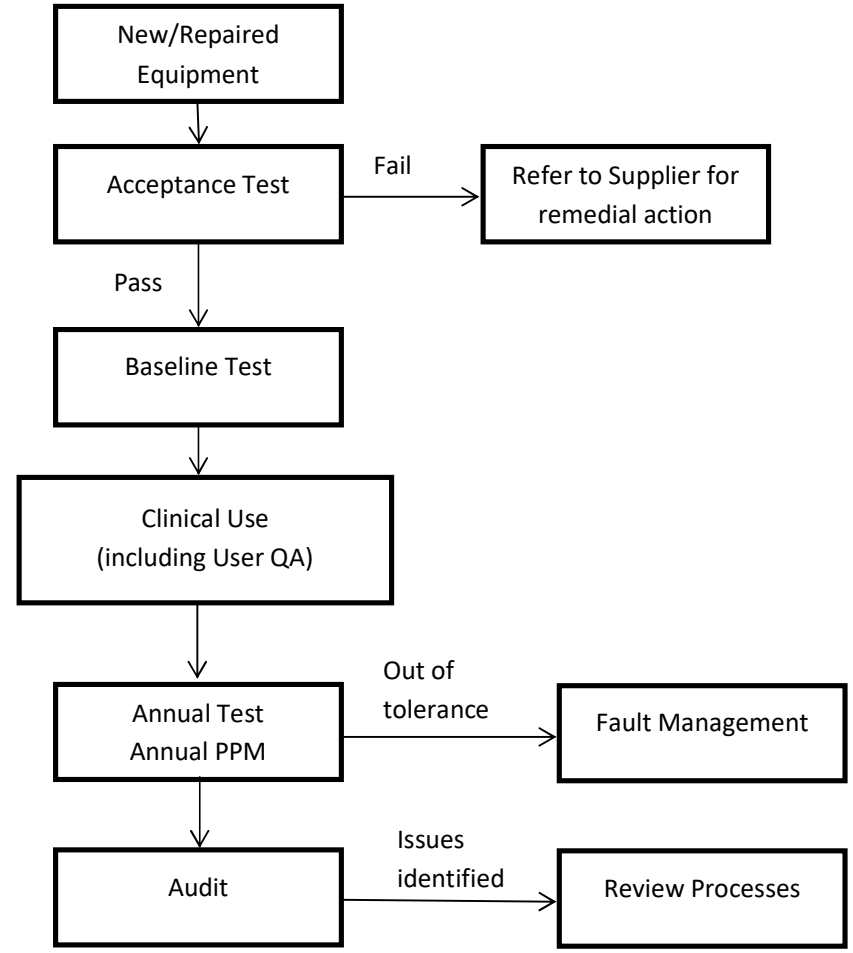
Stage	Activities	Objectives
1	Day-to-day care; maintenance contract; fault management	Some damage/faults prevented; some faults reported and managed
2	Basic acceptance testing; formal user QA; formal fault management	Faulty equipment not used; >90% of faults detected; failures remedied and minor faults monitored
3	Audit; basic annual testing	QA programme maintained; more faults detected
4	Full acceptance testing; full annual testing	Accuracy assured; all significant faults managed

Figure 1. QA Flowchart

User QA



Full QA



The QA programme – Acceptance and baseline testing

Acceptance testing – Safety, functionality and uniformity

Acceptance tests are designed to check the safety and functionality of equipment, with a pass/fail outcome, and should be performed for all equipment, including new, repaired or replacement probes. Results should be recorded, defects reported, including controls that do not work as expected, and any unsafe parts rejected.

Electrical safety testing is outside the remit of clinical staff and will not be described here; it must be carried out by qualified staff, usually in the local equipment management department. Physical inspection and functional tests are within the capabilities of professional clinical staff but may be within the remit of local or third party physics or engineering staff.

A thorough physical inspection of the probes, cables, scanner body, console and display screens should be carried out, looking for any damage or defects. The in-air uniformity of each probe should then be inspected. The procedure for this differs for conventional linear/curvilinear arrays, phased arrays and multi-row arrays. The clean and dry probe is operated in air with no gel, using a clinical preset and the highest available fundamental frequency, with TGC set to mid-range, compounding and real-time image processing turned off and gain adjusted to clearly show the structure of the first few reverberations. The suggested starting settings for this test are shown in Table 3. Toggling through the frequencies should show any non-uniformity. Table 4 shows possible anomalies in the in-air reverberation pattern.

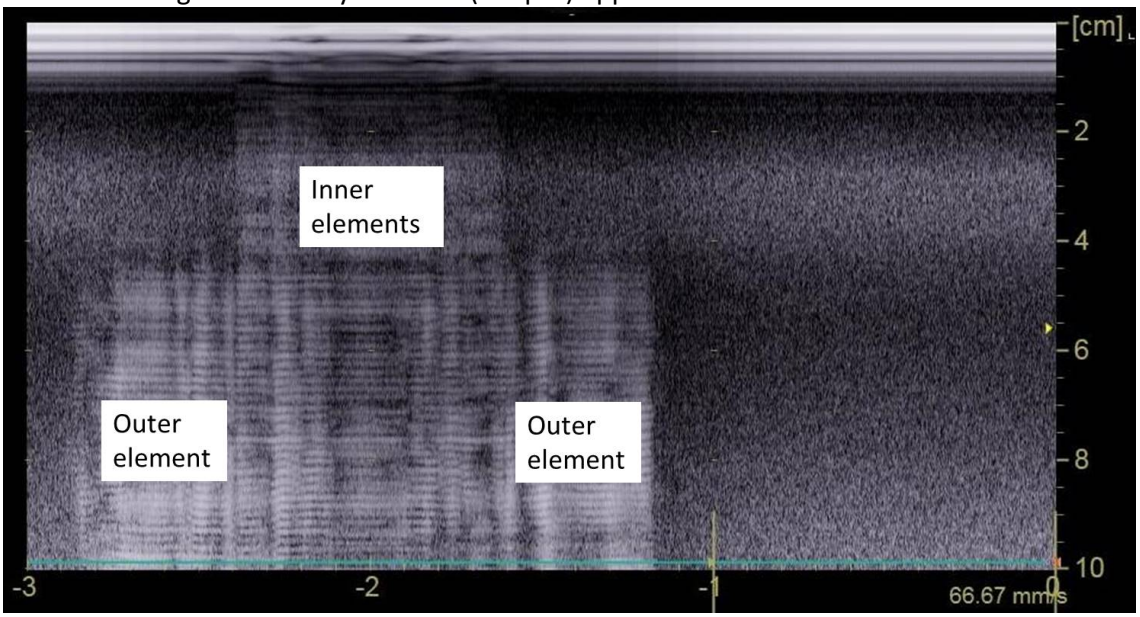
The “paperclip test” should be carried out for any conventional linear/curvilinear array showing axial banding in the in-air reverberation and for all multi-row and phased arrays in order to confirm or detect non-functioning elements. For conventional linear/curvilinear arrays the test involves simply sliding the long edge of a paperclip, held at 90^0 to the long axis of the probe, along the probe face; a “comet tail” reverberation pattern is seen that will dim or disappear as the paperclip crosses non-functional elements, confirming “drop-out”. This test should be done carefully as the lens is easily damaged; slight wetting with water may help the paperclip slide more easily.

For phased arrays the paperclip test is performed in M-mode with the M-line centrally placed;[13] any dark axial band(s) appearing in the M-mode trace indicates non-functional elements. If no signal is obtained in the outer 25% of the array the scale and/or focal depth should be increased to ensure that the whole aperture is active (note b in Table 3).

For multi-row arrays, which may be linear, curvilinear or phased, the paperclip test uses the short curved end of the paperclip and is performed in B-mode for linear/curvilinear arrays and in M-mode for phased arrays. The test is performed in 2 steps, firstly to identify the rows and secondly to test each row. To identify the rows the paperclip is moved along the short axis at the middle of the probe; step changes in the signal (due to the outer rows being activated later on reception and/or with lower output) show the transitions between outer and inner rows, as seen in Figure 2. At this point if the outer rows appear to be

inactive it is necessary to increase the scale and/or focal depth until the outer rows become active (see note c in Table 3).

Figure 2. Paperclip sweep across the short axis of a 4-row phased array in M-mode, outer elements being identified by the later (deeper) appearance of reverberation.



New or replacement probes with drop-out, atypical drop-out (see Table 4) or non-parallel reverberation lines should be rejected and replaced. Other anomalies may require discussion with the supplier and evidence based reassurance regarding probe performance requested.

Table 3. Scanner starting settings for Acceptance and User QA Baseline testing.

Control	**Linear/curvilinear**	**Phased**	**Multi-row**
Scale	In-air reverberation 20-50% of display[a]	Start at 100 mm[b]	Start at 60 mm[c]
Focus	Close to probe	At least 50 mm[b]	At least 30 mm[c]
Compounding	Off	N/A	Off
Automatic image optimisation	Off	Off	Off
Real-time image processing	Off	Off	Off
Frequency	Start at highest fundamental frequency		
Output	Maximum		
TGC	Mid-range		

Notes:

a) Ensure that the ends of the probe are in the image.
b) Ensure that the whole aperture is active; deeper scale/focus may be necessary.
c) Ensure that the outer rows of the array are active on reception; deeper scale/focus may be necessary.

Table 4. Definitions of anomalous in-air reverberation patterns.

Qualitative criteria	Semi-objective criteria
Failed paperclip test (dropout)	Amplitude of reverberations from paperclip is reduced at the area of dropout
Dropout appearance with passed paperclip test (atypical dropout)	Clear axial band but amplitude of reverberations from paperclip is not reduced at the area of dropout
Reverberation lines not parallel	>10% variation (ratio of maximum to minimum) in depth of selected reverberation line across array
Asymmetric phased array reverberation	Reverberation pattern deviates increasingly to left or right with depth
Lateral discontinuities in brightness	Discrete discontinuities or localised blurring of the reverberation pattern

Acceptance testing – Accuracy

B-mode caliper accuracy should be checked in a test object containing a medium with speed of sound 1540 $m.s^{-1}$. Measurements should be made using clinically relevant methods and distances and tolerances should be based on the clinical accuracy required.

The accuracy of Doppler velocities should be checked at clinically relevant values over a range sufficient to assess linearity, e.g. 50 – 200 $cm.s^{-1}$. A string phantom is the preferred method; a calibrated flow phantom may be used but the range of arterial velocities in clinical practice will not be achieved.

Test phantoms should be used according to manufacturers' instructions. An angle of less than 60^0 between Doppler beam and motion should be used and angle correction employed. When using a string phantom low output and gain are necessary to avoid saturation of the signal. The range gate length should be set to include all flow, a minimum of 3 mm for string and of 10 mm for flow are suggested. Automatic trace facilities should be used to measure mean velocity and this should be compared with set velocity for the phantom, taking care that the trace is not affected by noise or spike artefacts. A tolerance of ±5% is suggested based on the strictest manufacturers' specifications and personal experience.

Note that IPEM Report 102 recommends comparing the maximum measured string velocity with the manufacturer's specification.[6] This is likely to show errors in excess of 20% due to spectral broadening, resulting in the rejection of all scanners. The report also recommends measuring spectral broadening, but this measurement has no clinical relevance since spectral broadening is an artefact and will be far greater for a highly reflecting, single velocity string than for weakly scattering blood with a range of velocities

Baseline testing – User QA

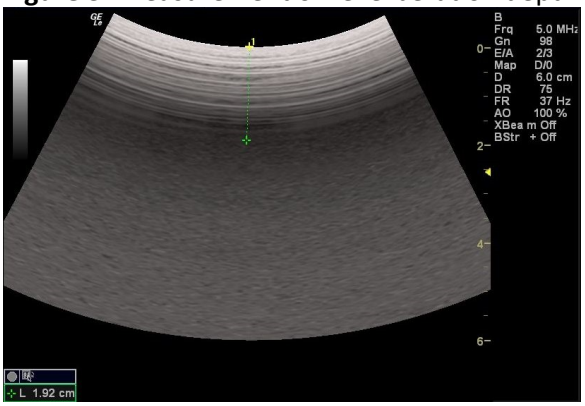
For each probe the in-air reverberation is used to make an assessment of changes in sensitivity. The procedure for this differs for conventional linear/curvilinear arrays, phased

arrays and multi-row arrays. The clean and dry probe is operated in air with no gel, using a clinical preset and the highest available fundamental frequency, with TGC set to mid-range, compounding and real-time image processing turned off. The optimum starting settings for this test are shown in Table 2.

The test requires identification of the deepest in-air reverberation. If it is easy to reproducibly determine the position of the deepest reverberation echo, the current frequency is suitable for user tests. If it is not easy to reproducibly determine the position of the deepest reverberation echo, then toggle through the frequencies (preferably fundamental) to find the one where it is easiest. If it is still not easy to reproducibly determine the position of the deepest reverberation echo, select the best setting found so far and reduce the overall gain to eliminate ambiguous reverberation lines. This will then be the baseline gain setting for future routine measurements. Save these settings as a User QA preset.

Freeze the image and measure vertically from the probe surface to the deepest visible reverberation line in the middle third of the image as shown in Figure 3, ignoring reverberations at the edge of the image. Record the measurement to 2 significant figures and the tolerance as $\pm$ half the distance to the adjacent reverberation plane. Unfreeze the image and turn the overall gain down to the point where the deepest reverberation line just disappears – the "reverberation threshold". Repeat until you are confident that you have the correct value. Record this as the baseline reverberation threshold with a tolerance of $\pm$4 gain increments.

Figure 3. Measurement of reverberation depth.



Baseline testing – Annual QA

Annual QA includes a repeat of the User QA tests together with image quality assessment using a tissue mimicking test object with speed of sound 1540 $m.s^{-1}$. The tests should be performed for each probe.

Select a preset appropriate to the probe (preferably factory) that gives a uniform image of the test object, i.e. with programmed TGC appropriate to a uniform attenuation. Set output to 100% and TGC to default (for sliders this is achieved at mid-range). Turn off automatic image optimisation, real time image processing and speed of sound correction. For linear arrays

ensure that no beam steering, e.g. trapezoidal imaging, is enabled. Record all displayed settings; save these as an Annual QA preset.

Place the probe over a column of filaments. Adjust the probe so that the filaments are seen, at the middle of the image, as clearly as possible. Freeze and store the image. Store images of any other features in the phantom, e.g. resolution, cystic and grey scale targets. These images are the baseline for future qualitative comparison.

If possible measure the average grey level in a uniform part of the image with no targets. This provides a quantitative baseline for sensitivity.[14] Free image processing packages provide an easy solution, e.g. ImageJ.[15] Note that IPEM Report 102 recommends measurement of low contrast penetration as a measure of sensitivity;[6] performed manually this is a subjective measurement and prone to inter-observer variation; automated methods provide more reproducible results.[16,17]

The QA programme – User QA

Day-to-day equipment care

The equipment should be kept clean to prevent cross-contamination and possible damage from more vigorous cleaning if, for example, gel is allowed to dry on probes. Cleaning should be in accordance with manufacturers' guidance, including the use of the correct cleaning materials (some cleaning agents will damage the equipment). The probe lens should be wiped gently and never rubbed. Where probes may come into contact with body fluids disinfection is required; a best practice summary has been produced by the British Medical Ultrasound Society and may be found at https://www.bmus.org/policies-statements-guidelines/professional-guidance/ultrasound-transducer-decontamination/.

Probes are expensive and delicate items and should be handled with care; probe cables contain over 100 wires. It is important to stow probes and cables using the holders provided, without stressing or tangling cables. Care should be taken that cables do not touch the floor or hang where they may be trapped. It is good practice to inspect equipment before and after use and to record and report faults, defects and damage; further guidance on fault management is given below.

Monthly QA

Formal User QA should be carried out and documented at a minimum of monthly intervals. Quantitative probe testing must be carried out on the same scanner as baseline testing. A thorough physical inspection of the probes, cables, scanner body, console and display screens should be carried out, looking for any damage or defects not already recorded. The function of wheels and brakes should be checked. Filters may require cleaning. For each probe an assessment of uniformity and sensitivity is required. The procedure for this differs for conventional linear/curvilinear arrays, multi-row arrays and phased arrays; Table 2 shows starting settings for each type of array, these will have been refined and stored as a User QA preset at baseline testing.

Using the User QA preset the in-air reverberation should be inspected for uniformity, with reference to images stored at baseline as appropriate. Confirm any drop-out using the

paperclip test described previously. Drop-out may be due to connector issues which may be resolved by disconnecting and reconnecting or changing ports. Gently manipulating cables, particularly at stress points, may detect cable faults, as drop-out may be intermittent. Check for delamination, seen as local disruption to the in-air reverberation, and lens wear, seen as variation in the depth of reverberation lines, most commonly at the ends of the array. Measure vertically from the probe surface to the deepest visible reverberation line in the middle third of the image as shown in Figure 3. Reduce gain until the deepest reverberation just disappears and record gain as the reverberation threshold. If either result is out of tolerance, repeat; if confirmed record and report as a fault.

Enable colour Doppler with a full width colour box and gain showing slight colour speckling. Flex the cable at strain reliefs and damaged areas, looking for streaks of flashing colour which may indicate a cable fault.

The QA programme – Annual QA

Annual QA includes a repeat of the User QA tests together with image quality assessment using a tissue mimicking test object with speed of sound 1540 $m.s^{-1}$. These tests may also be performed reactively if faults found during User QA require further evaluation. The tests should be performed for each probe.

Perform the monthly User QA checks and record any defects, damage or faults. Using the Annual QA preset, or reproducing the settings recorded at baseline, acquire a set of images equivalent to the baseline images. Compare these and any quantitative assessment of sensitivity with baseline results. Record any changes from baselines and refer to the section on fault management.

The QA programme – Fault management

The terms “fault” and “failure” are often used interchangeably. Here a “fault” is any physical defect identified in the equipment or perceived or measured change to imaging performance. A “failure” is where a fault is determined either by definition or by risk assessment to be more than minor deterioration. It is good practice to record all faults, together with an action plan and confirmation of remedial actions.

Fault management requires a degree of pragmatism. The clinically conservative approach to probe faults is that if we have no positive evidence that image quality is not affected and that there is no risk, the probe should be withdrawn from use; this approach is certainly appropriate in cases of delamination or full thickness lens damage. The economically conservative approach is that if we have no evidence that image quality is affected and our risk assessment indicates low risk, we should continue to use the probe; this is reasonable where the fault is determined to be minor, e.g. peripheral single element failure.

Some faults will require immediate remedy, where there is a clinical diagnostic risk, e.g. significant drop-out (the literature suggests that 2 dead elements affect Doppler performance[18,19]), or an electrical or cross-contamination risk from case, lens or cable damage. Monitoring for fault progression or managed replacement may be possible in some cases, e.g. peripheral drop-out.

Table 5 shows a traffic light system for classifying faults. Red faults are failures and require immediate action, e.g. call engineer or order probe replacement. Amber faults require some further action, e.g. risk assessment, further testing, monitor fault progression. A green classification is given where no fault has been found. Fault classification and management may require reactive testing, e.g. sensitivity measurement. Table 6 shows examples of test outcomes and further actions.

Table 5. Fault classification examples.

Red	Amber
Scanner control fault affecting image quality	Scanner control fault not affecting image quality[2]
Scanner brakes faulty	Scanner body damage[2]
Mains cable damage	Minor non-uniformity in reverberation pattern
Significant dropout (multiple or single large area)	Single line of peripheral dropout
Lens damage, major wear or sealant damaged[1]	Minor lens wear
Delamination	Damaged grommet/strain relief[2]
Split case[1]	Reverberation threshold out of tolerance
Probe cable internal fault (intermittent dropout)	Annual tests out of tolerance
Probe cable wiring exposed	

[1]Potential electrical hazard; electrical safety test essential. Cross-contamination risk if cleaning compromised.

[2]Repair recommended.

Table 6. Test outcomes and further actions.

Fault	Cause / Further test	Action
Single line of dropout	Likely due to failure of single element or its electrical circuit.	Monitor for deterioration.
Several, separate lines of dropout	Likely due to cable fault. Gently shake and manipulate the cable; dropout coming and going confirms cable fault.	Replace probe.
Larger area of dropout	Likely due to impact damage.	Replace probe.
Reverberation threshold out of tolerance	Likely due to probe degradation. Measure sensitivity or assess image brightness.	Refer to sensitivity fault below
Resolution and/or contrast images unequivocally inferior to baseline images	Possibly due to probe degradation.	Refer to supplier or service agent
Sensitivity fault	Penetration or grey level loss of >10% or visibly reduced image brightness.	Risk assess clinical impact. If gain near or at maximum when scanning, refer to supplier or service agent.

Fault management – Probe repairs

Replacement of probes is expensive and there is an increasing number of probe repair companies offering an alternative. It is unlikely that these companies have access to manufacturers' materials and parts. Original Equipment Manufacturers (OEMs) ensure that their devices meet regulatory requirements; any repairs using non-OEM materials carry the risk of non-compliance and so caution is required. For repairs not involving functional parts before and after electronic probe testing may be sufficient to show that no damage has occurred. For repairs involving functional parts a more comprehensive suite of tests is necessary to show that the materials, parts and final product match the performance of the OEM probe and meet regulatory requirements. When purchasing a probe repair it is essential to seek evidence of validation of repair methods and the final repair.[20,21]

The QA programme – Audit

Test and fault records should be periodically audited. The frequency of audit may be locally determined but when QA processes are introduced into a new area an initial frequency of quarterly is advised, reducing in stages to annually once the processes have become embedded.

Audit should include: checking that planned preventative maintenance have been carried out to schedule and any faults resolved; inspection of User QA and Annual QA records, noting whether completed to schedule, any results out of tolerance, any actions arising from QA, and any clinical or technical faults logged and the actions taken, noting any further actions required.

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