



THE BRITISH MEDICAL ULTRASOUND SOCIETY

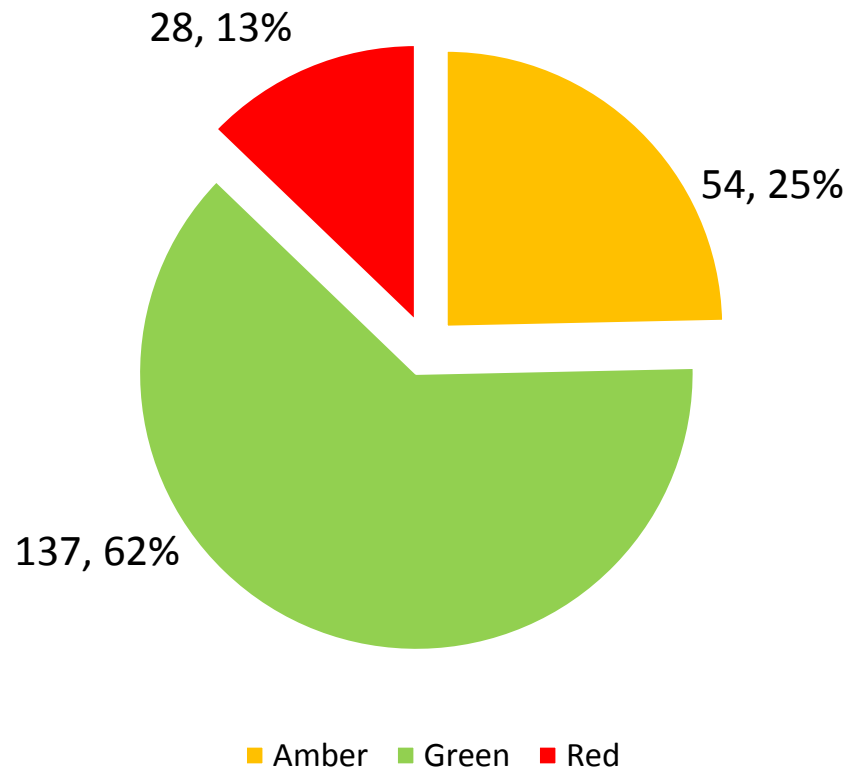
Equipment QA and fault management

Slides provided by Nick Dudley

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Why QA?

- Probe survey results
 - 12 centres, 80 scanners, 219 probes



>1 in 3 faulty

1 in 8 not fit for use

Other similar studies

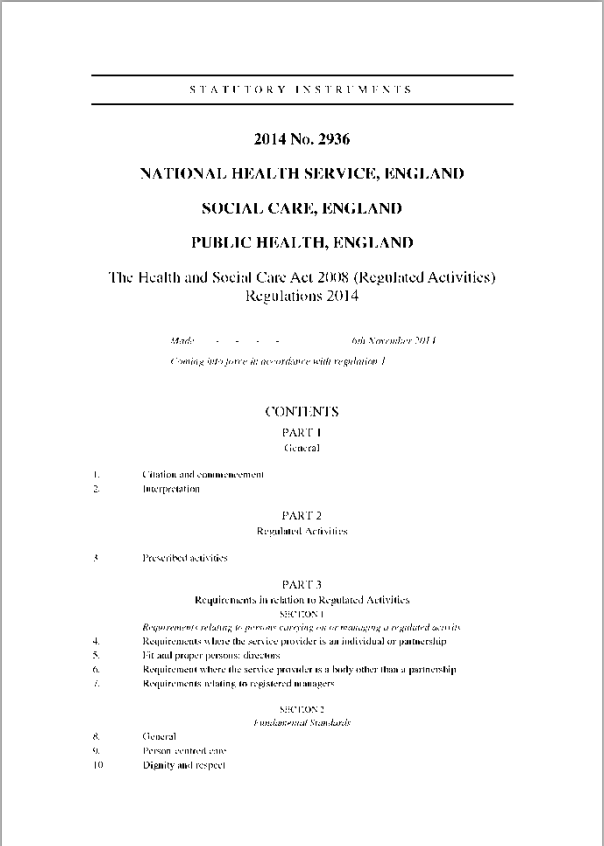
Footnote

Red classified probes were unfit for use due to image quality or electrical or infection risk.

Amber classified probes needed some remedial action or ongoing monitoring.

Regulatory Drivers - UK

- Comply with Health and Social Care Act 2008 (Regulated Activities) Regulations 2014
 - Regulation 15 - Premises and Equipment
 - Equipment shall be suitable for the purpose, and properly used and maintained
 - Regulation 17 – Good Governance
 - Systems must be established and operated to ensure compliance, including assessing, monitoring and mitigating risks relating to the health, safety and welfare



STATUTORY INSTRUMENTS

2014 No. 2936

NATIONAL HEALTH SERVICE, ENGLAND
SOCIAL CARE, ENGLAND
PUBLIC HEALTH, ENGLAND

The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014

Made: 6th November 2014
Coming into force in accordance with regulation 1

CONTENTS

PART 1
General

1. Citation and commencement
2. Interpretation

PART 2
Regulated Activities

3. Prescribed activities

PART 3
Requirements in relation to Regulated Activities

SECTION 1
Requirements relating to persons carrying on or managing a regulated activity

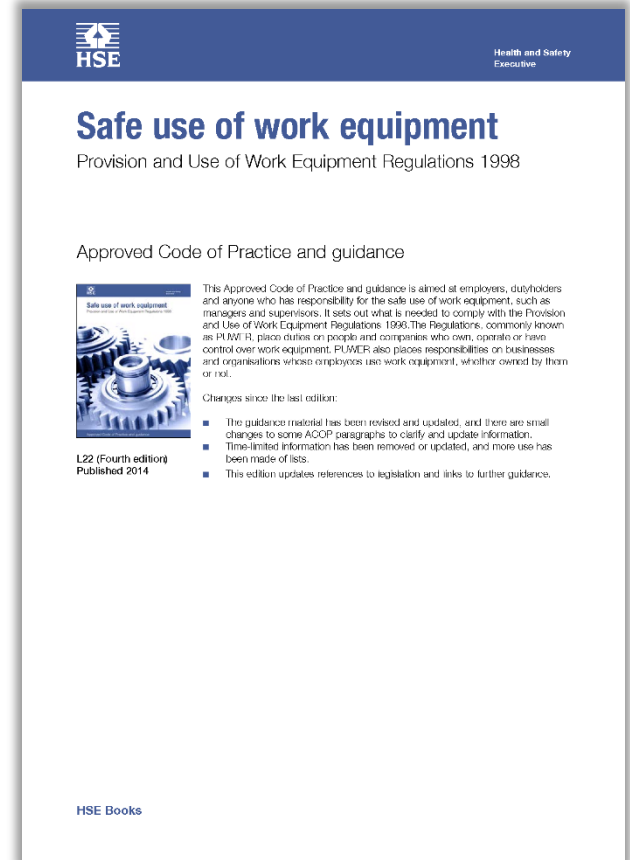
4. Requirements where the service provider is an individual or partnership
5. Fit and proper persons: directors
6. Requirement where the service provider is a body other than a partnership
7. Requirements relating to registered managers

SECTION 2
Functional Standards

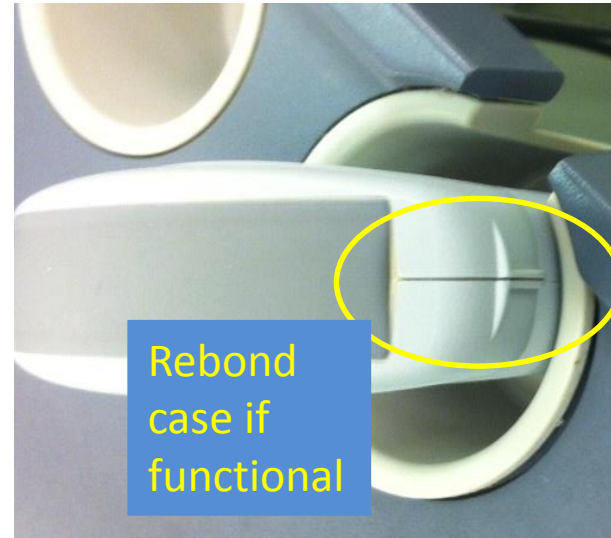
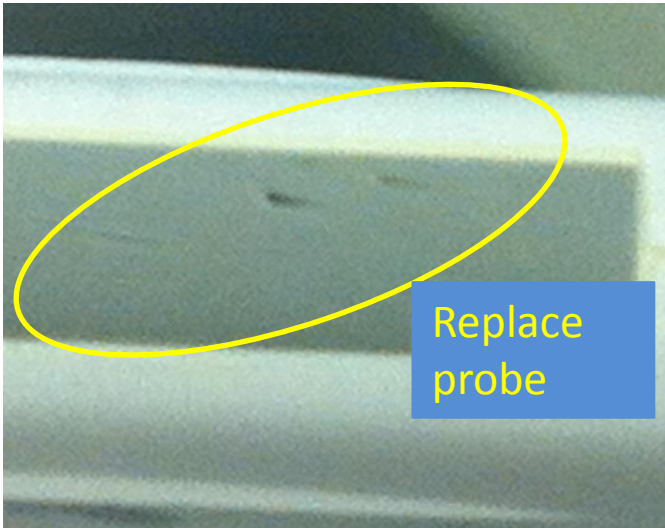
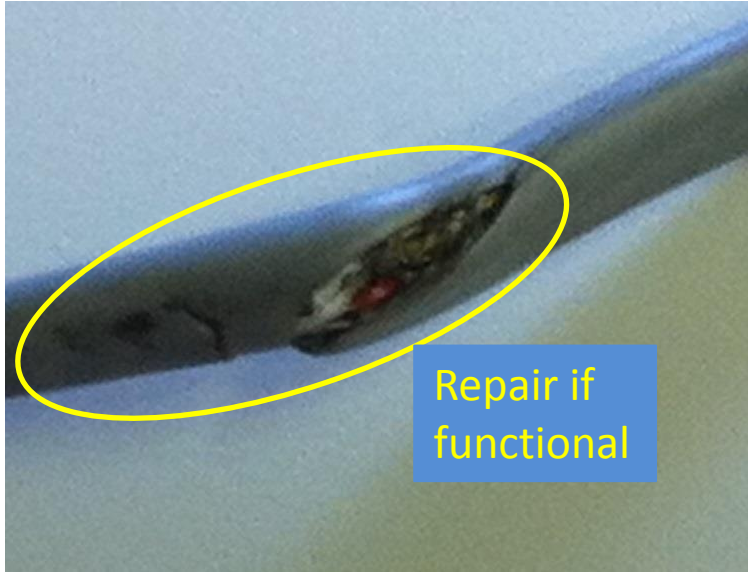
8. General
9. Person-centred care
10. Dignity and respect

Regulatory Drivers - UK

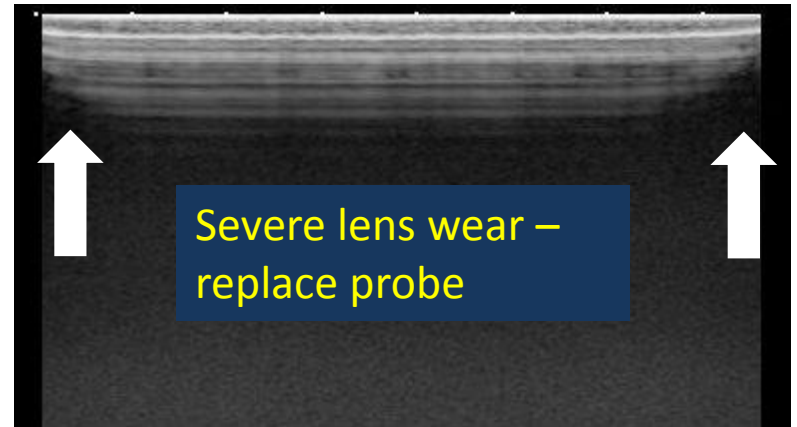
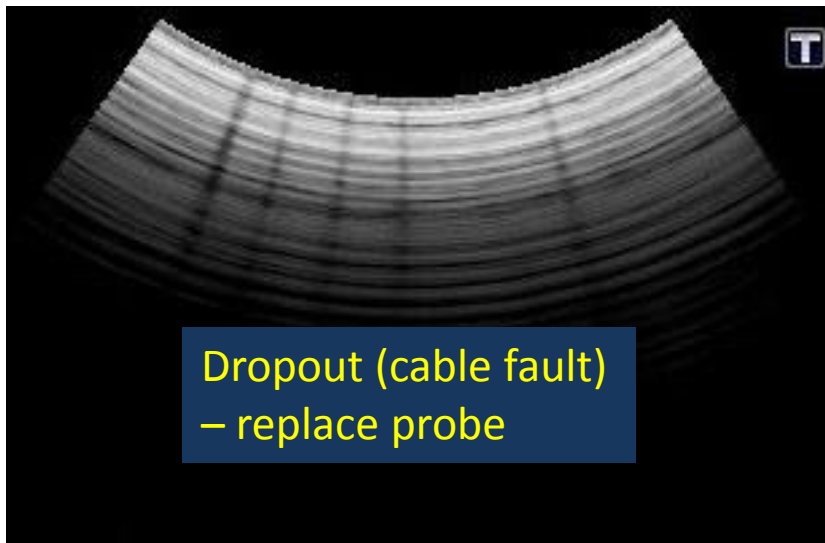
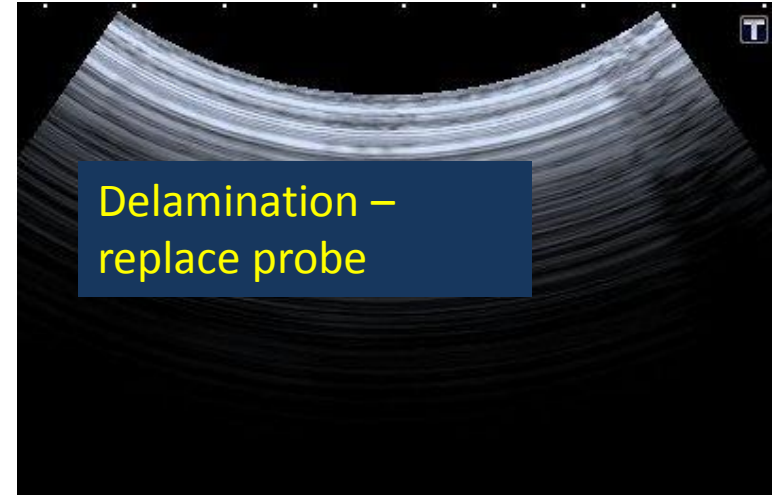
- Comply with HSE PUWER 1998 Legislation
 - Safety
 - Users, public and patients
 - Function
 - Fitness for purpose
 - Methods to manage deterioration
 - Applicability
 - CEO's
 - Directors
 - Managers
 - Lead Sonographers
 - Users



Faults – visual inspection



Faults - uniformity



QA priorities

1. Over 90% of faults may be detected by:
 - visual inspection of the system
 - inspection of the in-air reverberation pattern (scanner settings are very important for this!)
2. Simple tests for sensitivity and noise
3. Phantom tests for sensitivity

1 and 2 are described in the BMUS guidelines; 3 is described in IPEM Report 102.

Fault management

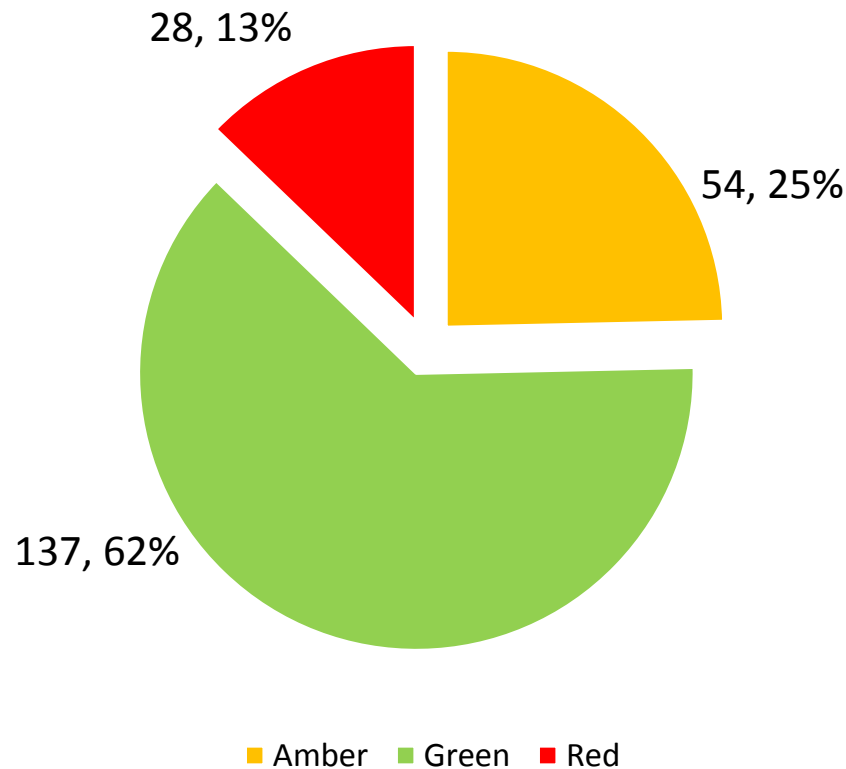
- Keep fault records
 - evidence that you're doing QA
 - record of risk mitigation actions taken¹
- Pragmatism required
 - prioritise patient service
 - this includes considering patient safety and diagnostic quality
- Maintenance contract essential
 - include probe replacements, pooled if possible²

¹If you decide to continue using a probe, you should provide a risk assessment and rationale to protect yourself and the organisation.

²Some contracts offer probe replacements per scanner; if these can be pooled across all scanners under contract this gives more flexibility.

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Fault management - Red

Fault	Action
Scanner control fault affecting image quality	Urgent repair by maintenance provider
Scanner brakes faulty	Repair by maintenance provider, timescale depends on risk
Mains cable damage	Replace immediately
Significant dropout (central, multiple or large)	Replace probe
Lens membrane damage	Replace probe
Lens membrane non-uniformity (>5% thickness variation)	Replace probe
Cable fault	Replace probe
Delamination	Replace probe

Fault management - Amber

Fault	Action
Scanner control fault not affecting image quality	Non-urgent repair by maintenance provider
Scanner body damage	Risk assess; non-urgent repair by maintenance provider
Minor non-uniformity in reverberation pattern	Compare with baseline, monitor for change
Peripheral dropout (small area)	Monitor for change, act if becomes significant
Minor lens membrane wear	Monitor for change, act if becomes significant (>5% depth or hole appears)
Split case	Risk assess; repair possible
Lens membrane sealant broken	Infection risk; repair possible
Damaged grommet/strain relief	Will lead to cable damage; repair possible

Rise to the Challenge

- **BMUS QA guidelines**

Dudley N, Russell S, Ward B and Hoskins P; BMUS QA Working Party. BMUS guidelines for the regular quality assurance testing of ultrasound scanners by sonographers. *Ultrasound* 22, 8-14, 2014

The aim of the QA guidelines is to empower sonographers to take a leading role in demonstrating the consistency of performance of their equipment for the benefit of their patients.

BMUS QA Guidelines

- Sonographers should note that in signing off a report, they are certifying that their equipment is fit for purpose
- User testing gives sonographers the opportunity to establish their own QA programme, even where there is no physics support for further testing and no test equipment

BMUS QA Guidelines

- The tests are not time consuming
- Some elements will already be carried out in departments complying with local infection control and equipment management requirements

BMUS QA Principles

- The purpose of quality assurance (QA) of ultrasound systems is:
- to ensure that consistent, reliable results are provided
- to check for deterioration of equipment performance.

BMUS QA Principles

- Misconception exists that many of the issues QA looks for can readily be observed during routine scanning
- Whilst this may have been the case several years ago, the level of processing applied to routine presets on a modern ultrasound scanner often masks such issues.

BMUS QA

- There are three levels of QA:
- Level 1 Infection control and scanner damage
- Level 2 Basic scanner and transducer testing
- Level 3 Further scanner and transducer testing

BMUS QA – Level 1

Level 1 procedures have a two-fold purpose:

1. To ensure that the scanner is clean and that infection control risks to patients and staff are minimised.
 - Infection control measures are relevant for every patient so that some of these actions are performed several times each day.
2. To detect any damage to the scanner, especially to the transducers and their cables.
 - Checks for scanner damage are performed weekly.

BMUS QA – Level 2

- Level 2 procedures ensure appropriate setting of video monitor controls for consistency of imaging.
- They also provide a first-line evaluation of scanner performance but without the use of test tools or test objects.
- These tests are performed daily.

BMUS QA – Level 3

- Level 3 procedures provide further evaluation of scanner performance using a very simple test tool.
- These checks are designed to look for scanner faults
- These tests are performed monthly.

BMUS QA

- Level 1 and 2 tests should form part of the ongoing activities of the sonographer and should not require dedicated time to be set aside, other than for simple documentation at the end of the day.
- Level 3 tests do require the sonographer to set aside dedicated time.
- Trialling of these guidelines suggest that this is no more than 15 minutes per week per scanner to perform the tests, document the results, undertake any follow-up action and return the scanner settings to their usual values

BMUS QA – Level 1

LEVEL 1		
Identifier	Task	Frequency
1.1	Clean ultrasound gel and body fluids from scanner console, transducers and cables after every patient use	Multi-Daily
1.2	Ensure transducers are stored securely when not in use	Multi-Daily
1.3	Ensure transducer cables are properly stowed and not at risk of being run over by scanner or bed	Multi-Daily
1.4	Clean monitors of dust, gel etc including probe holders	Daily
1.5	Check operation of main scanner controls	Daily
1.6	Inspect the transducers used during the session for damage	Daily
1.7	Inspect switches, knobs and other controls for damage	Weekly
1.8	Inspect all probe, power and network cables for damage include examination couch and sockets	Weekly
1.9	Inspect the ultrasound system for damage such as cracks and dents	Weekly
1.10	Test brake and wheel functions	Weekly
1.11	Check air filters for dust and fluff	Weekly

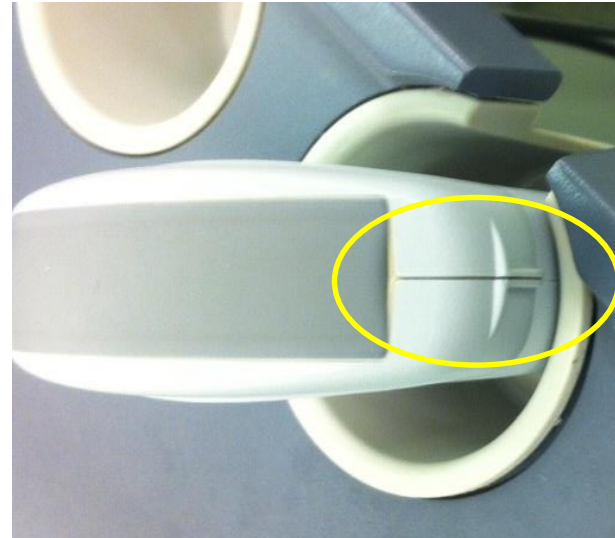
BMUS QA – Level 1 tests

Idiots guide to Ultrasound QA

Level 1

- Daily cleaning and inspections for damage.

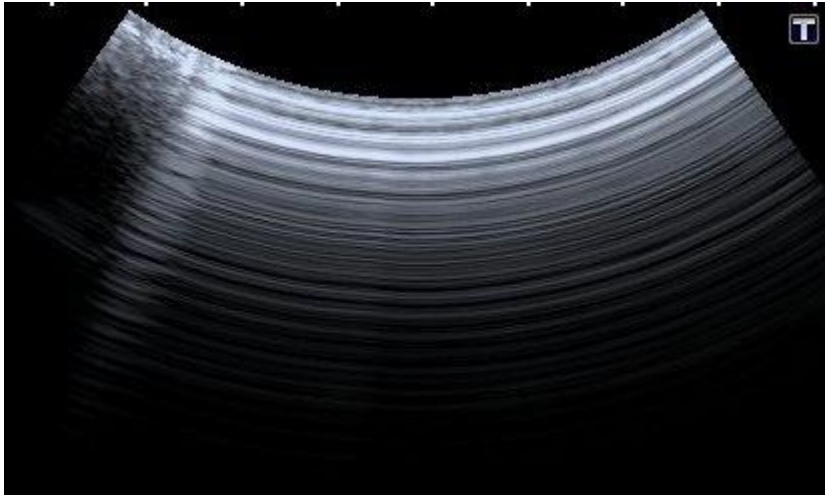
Level 1 – visual inspection



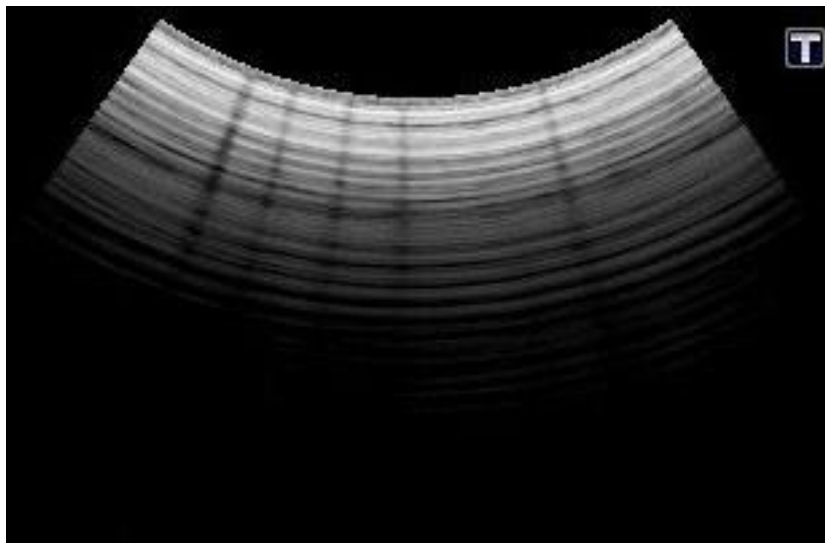
BMUS QA – Level 2

LEVEL 2		
2.1	Check that the video monitor's brightness and contrast controls have been appropriately adjusted	Daily
2.2	Check grey scale bar is fully displayed	Daily
2.3	Check grey levels on the ultrasound system monitor is matched by grey levels on PACS system monitors	Daily
2.4	Inspect reverberation images for shadows and streaks caused by transducer dropout for all transducers in use that day	Daily

Level 2 – Drop out



Damaged array
(dropped)



Dropout (cable fault)

BMUS QA – Level 2

Idiots guide to Ultrasound QA

- Check that the video monitor's brightness and contrast controls have been appropriately adjusted
 - Use factory Preset
- Check grey scale bar is fully displayed
 - Has to be white at one end and the darkest grey at the other. Yes or No.
- Check grey levels on the ultrasound system monitor is matched by grey levels on PACS system monitors (if used)
- Inspect reverberation images for shadows and streaks caused by transducer dropout for all transducers in use that day

BMUS QA – Level 3

LEVEL 3		
3.1	Air reverberation pattern (sensitivity)	Monthly
3.2	Element dropout test (to be done monthly of if fault suspected in daily test 2.4)	Monthly
3.3	Electronic noise assessment (B Mode, Doppler and colour flow)	Monthly
3.4	Date of electrical safety testing	Monthly

BMUS QA – Level 3

Idiots guide to Ultrasound QA

Air reverberation Test

- Dry Transducer
- Factory preset or QA preset
- Take harmonics off- fundamental frequency
- Power 100%
- Gain maximum
- TGC central – central click
- Focus at most superficial setting
- Take off post processing i.e. compounding, precision
- Turn off wide view for linear probes- make sure sector width at maximum for curvilinear
- Dynamic range- mid range at 60
- Reverberation pattern is a series of parallel lines. Any change may indicate dropout.

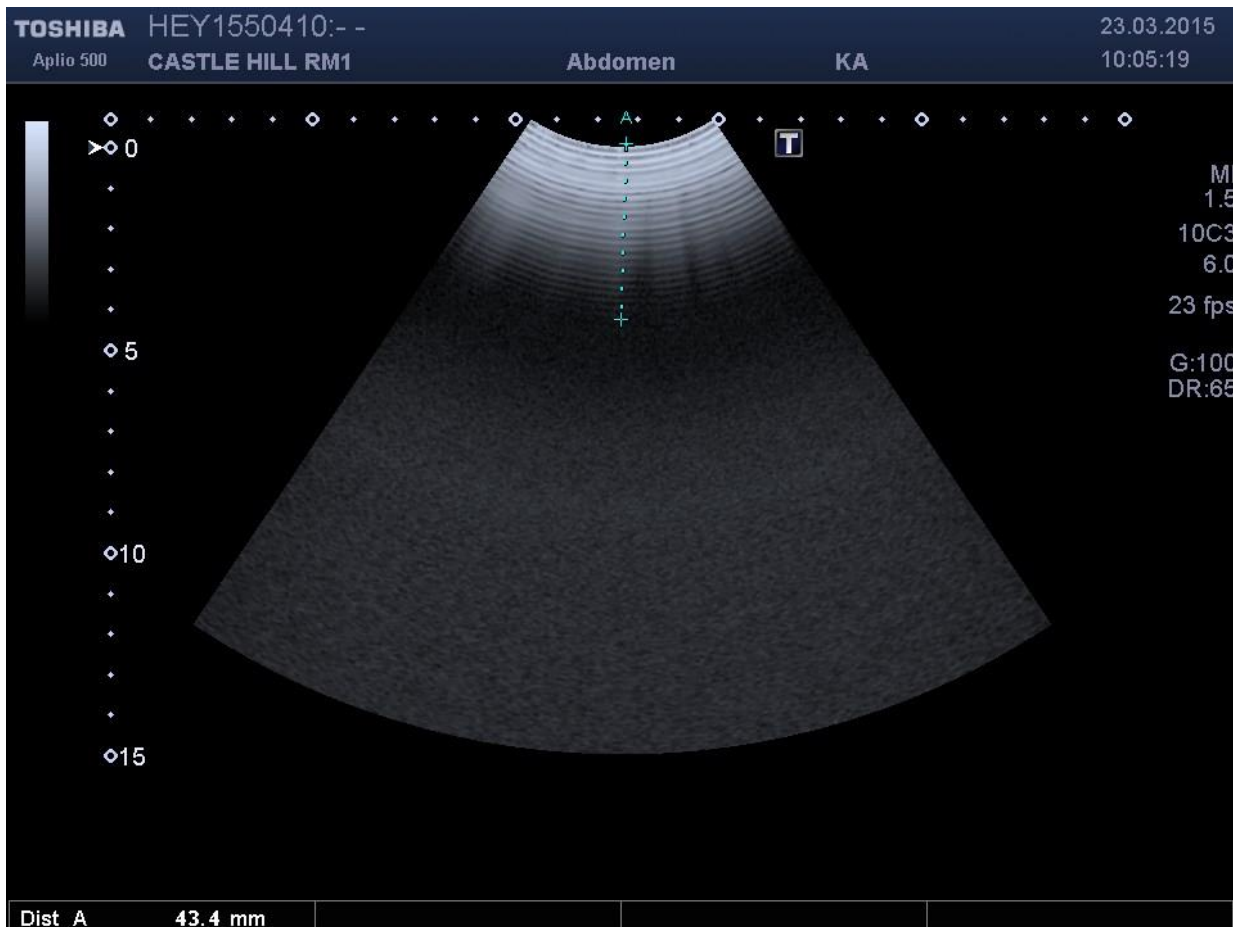
- Change depth so reverberation pattern is 25% of the screen- use measurement tool at the side of the image.

- Measure and record the distance from the top of the reverberation to the bottom in the centre.

- Record measurement on Report and QA log.

BMUS QA – Level 3

Air reverberation Test



BMUS QA – Level 3

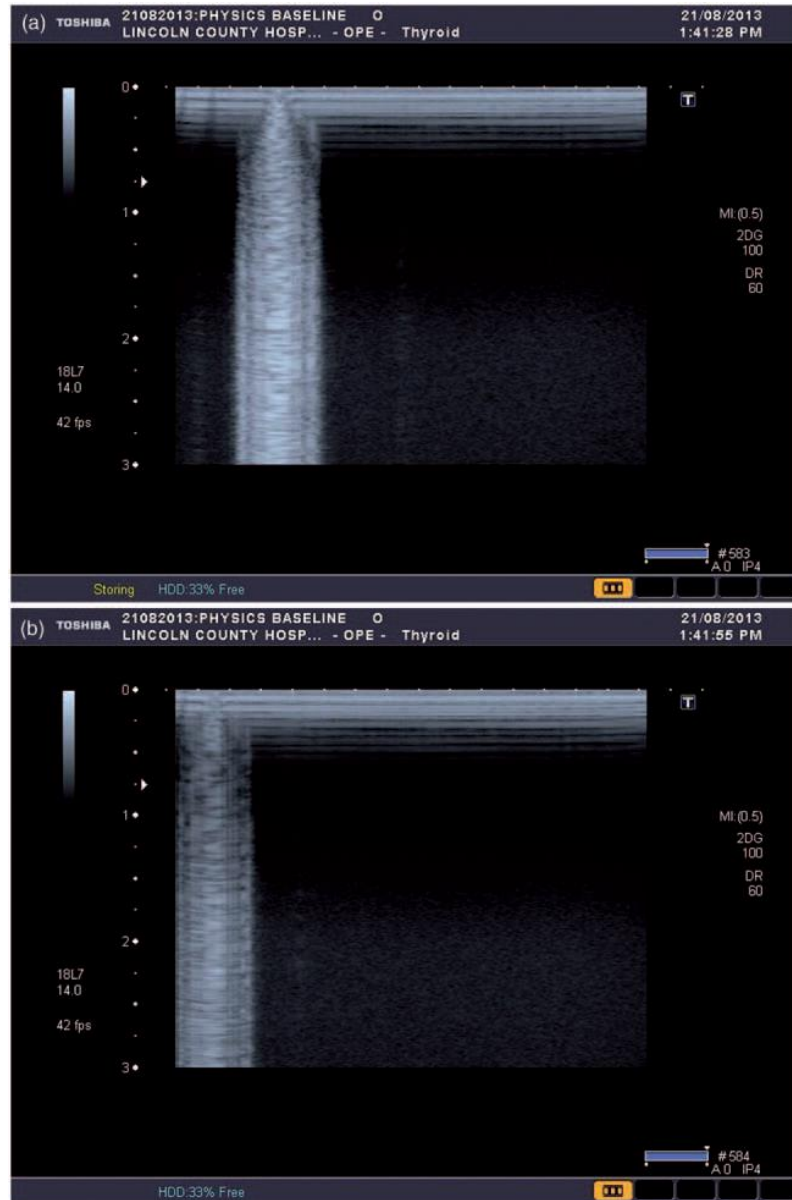
Idiots guide to Ultrasound QA

Element dropout test- only if dropout is suspected

- Run the smooth edge of a paperclip across transducer face- the grey soft bit. Any loss of echoes indicates dropout.

- Report if necessary.

Level 3 – Drop out



- a) Normal paperclip reverberation pattern;
- b) Reduced paperclip reverberation brightness in dropout region

BMUS QA – Level 3

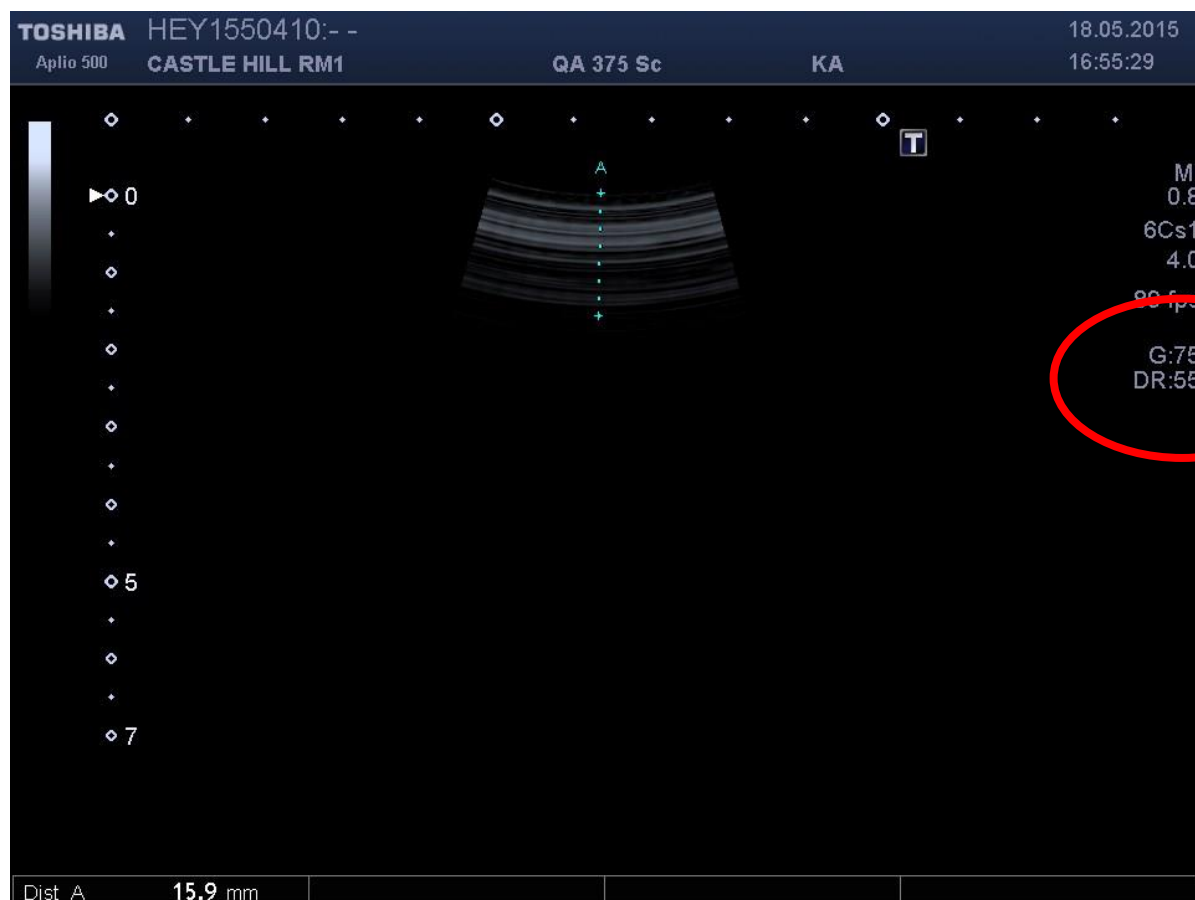
Idiots guide to Ultrasound QA

Electronic noise assessment

- 2D Imaging assessment:
- Use settings same as reverberation test.
- Then..... reduce overall gain to the point at which noise has just disappeared from the image.
- Record the gain value (2DG at the right of the screen) as the noise threshold.
- PW Doppler assessment:
- Neutral gate; turn gain to full and reduce until noise disappears then note value.
- CDI assessment:
- Standard colour box, move to bottom of the screen, turn gain to maximum then reduce until colour noise disappears. Note value.
- No need to repeat power/dynamic range.

BMUS QA – Level 3

Electronic noise assessment



BMUS QA

Summary

- Level 1 & 2 tests are simple; you are doing them already (one hopes)
- Level 3 tests require time but are simple
- Record results
- Look for trends / changes
- Report changes / degradation to local equipment support
- Use data as evidence to replace equipment

References

- **High probe failure rates: 37% to 50%**

1. Dudley NJ, Woolley DJ. A multicentre survey of the condition of ultrasound probes. *Ultrasound* 2016; 24:190-197
2. Martensson M, Olsson M, Segall B, Fraser AG, Winter R, Brodin L. High incidence of defective ultrasound transducers in use in routine clinical practice. *Eur J Echocardiogr* 2009; 10:389-94.
3. Martensson M, Olsson M, Brodin L. Ultrasound transducer function: annual testing is not sufficient. *Eur J Echocardiogr* 2010; 11:801-805
4. Hangiandreou NJ, Stekel SF, Tradup DJ, Gorny KR, King DM. Four-year experience with a clinical ultrasound Quality Control program. *Ultrasound Med Biol* 2011; 37:1350-1357

- **Clinical impact of faults**

5. Weigang B, Moore GW, Gessert J, Phillips WH, Schafer M. The Methods and Effects of Transducer Degradation on Image Quality and the Clinical Efficacy of Diagnostic Sonography. *J Diagnostic Medical Sonography* 2003;19:3-13
6. Vachutka J, Dolezal L, KollmannC, Klein J. The effect of dead elements on the accuracy of Doppler ultrasound measurements. *Ultrasonic Imaging* 2014; 36:18-34