The Regulation and Quality Improvement Authority

Performance Audit of Ultrasound Imaging Systems within Northern Ireland

August 2019

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Assurance, Challenge and Improvement in Health and Social Care

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Executive Summary

Background

Currently, there is no regional service in place in Northern Ireland providing routine physics testing on the Quality Assurance (QA) of ultrasound systems (US systems). It was unknown if local user QA was being implemented, as advised by national guidelines from both British Medical Ultrasound Society (BMUS)[1,2] and Institute of Physics and Engineering in Medicine (IPEM) [3]. Specialist support from a physics testing service at The Christie, NHS Foundation Trust, Christie Medical Physics and Engineering was required to enable this to be undertaken. The ultrasound physics service at the Christie has over 30 years' experience in testing US systems and probes and is currently responsible for over 800 systems at over 80 sites.

Ultrasound imaging technology is used routinely in the diagnosis of many conditions across a range of specialisms a hospital may typically have between 40 and 100 systems, for example; Radiology, Obstetrics, MSK, Urology, Neo-natal, A&E and Theatres. The audit identified that typically five major manufacturers of ultrasound machines and numerous models are in use across the Trusts, with additional smaller numbers of other makes.

Aims and Objectives

The aim of this audit was to assess the safety and performance of ultrasound imaging systems across the region and across various specialities.

There were three objectives

1. Determine the efficacy of local QA across various specialities
2. Determine the level of Physics QA identifiable faults present in the audit sample
3. Establish if there are possible issues with the efficacy of the current service/maintenance and service status of the systems

Key Findings

The target was to test 100 systems, approximately 23% of registered systems. The methodology was to ensure that the audit covered a range of clinical specialities and locations identified from a 2017 Northern Ireland regional tender review contract list. A total of 428 machines were listed as in use for each Trust: WHSCT (58), SHSCT (61), NHSCT (70), SEHSCT (101), BHSCT (138). In total 127 systems with 317 probes were tested across the five HSC Trusts. Key findings identified were as follows:

- Of the 127 systems 5 (4%) were confirmed as having a local QA in place
- Of the 127 systems tested 78 (61%) had faults identified
- Of the 317 probes tested 109 (34%) had recorded issues
- Of the 127 systems 83 (65%) were serviced through external Trust contracts identified by attached system labels

Although some systems and probes had more than one fault, the overall fault rate is 61% for systems and 34% for probes. From experience at the Christie and literature [5,6,7] these levels are typical for areas where no effective QA programme is in place. It is clear therefore that from the audit findings of high incidence of faults, there is no effective QA in place for the ultrasound systems in Northern Ireland. The indication is that staff are mostly unaware of system faults which may impact clinical outcomes and as a result patients are being scanned with no assessment of the likely impact of the issues present. It is unclear at what level service agents

are automatically repairing faults and whether they report issues considered minor, and so not requiring repair, or if they only repair issues identified by staff. Staff should be identifying any issue which could have a clinical impact but they may only be reporting inconvenience issues such as monitor or console movements not being stable.

Conclusions and Recommendations

The findings in this report clearly show that there is poor governance of ultrasound imaging equipment in Northern Ireland and without implementation of a QA and testing programme this is likely to worsen as ultrasound use expands.

It is important that the guidelines indicated by BMUS[(1)] are implemented for regular local QA for all ultrasound systems in Northern Ireland (NI), the system which was implemented for the N.I. Breast Screening Programme also includes regular medical physics checks. Implementation of these guidelines are effective in radiology and obstetric/gynae scanning services where skilled sonographers operate, and where a member of staff can be designated as responsible for ultrasound QA, but tend to be less effective or fails in peripheral departments where access to such specialists is not available as the staff tasked with the QA do not have the correct skill set and/or authority. Other methods or controls should be considered for these systems for example allocating a responsible specialist. The implementation of BMUS QA guidelines would also be required for the accreditation of services under the Imaging Services Accreditation Scheme (ISAS)

There were systems with issues, such as severe probe dropout or serious noise/interference, that could potentially have a direct clinical impact and in these cases the local staff were informed that their system may be unsafe to use. However, for many of the tested systems the appropriate action could not be taken or advised because it would require a QA management system to be in place.

Further, although ultrasound imaging systems should be subject to an annual service maintenance programme the QA results highlight the need for an annual medical physics testing ensuring that all systems are comprehensively tested and checked that they are serviced at least once a year. Medical physics expertise can then assist in a risk management approach to identify fault repairs or system replacement based on clinical risk, which would contribute to reducing overall life cycle costs by ensuring that repairs were necessary and systems replaced for clinical benefit.

It is therefore recommended that

1. Each Trust put in place an action plan to
    a. Implement a Trust ultrasound QA programme across all areas, following BMUS guidelines taking in to consideration the set-up of:
        i. Ultrasound Clinical Governance Board.
        ii. Designated QA leads for all ultrasound specialities
        iii. Operator QA checks
    b. Review, in collaboration with medical physics, system and probes issues identified in the report taking account of clinical applications.
    c. Ensure that all ultrasound systems are serviced according to schedule including electrical safety testing, and that repairs are effective.

2. Regional Medical Physics support is put in place to
    a. Perform base annual physics QA check, as per National Health Service Breast Screening Programme (NHSBSP) Report [(4)] on all ultrasound systems.
    b. Train staff for local QA implementation and regularly audit local QA testing provision.

c. Implement comprehensive acceptance and baseline testing as IPEM report [3] which will provide a framework for the safe management of ultrasound system faults.
d. Develop a programme of annual medical physics QA checks following the principle of the breast screening programme with tests appropriate to all clinical applications

Performance Audit Report

Background

Almost all medical imaging equipment is subject to regular quality assurance (QA) checks, usually as a result of requirements which follow from mandatory ionising radiation regulations. These checks are a mix of infrequent specialist medical physics checks and some more frequent local checks made by radiographers or imaging technicians. Imaging diagnosis in all these systems is made retrospectively on stored images; and a peer review of both the clinical findings and diagnostic quality of the images can be performed.

For ultrasound systems there are several differences

- The clinical diagnosis for most applications is made in real time and if images are stored they provide only a limited snapshot of the diagnostic scan. This makes peer review and audit of reporting standards unreliable unless they are undertaken in real time. There is no ionising radiation involved and consequently there has been no legal requirement to undertake imaging QA and as such many systems are not tested.

- All imaging, with ionising radiation and non-ionising MRI imaging, is performed by qualified specialist imaging staff such as radiographers and radiologists whereas ultrasound imaging can be performed by a wide range of clinical staff. This can also lead to a) there being no clear designated regular operator to undertake testing and b) poor awareness of the potential issues with the system if managed by someone who does not scan.

National guidelines from BMUS and IPEM advise that monthly local testing is in place and indicate that such testing can cover many issues but Manchester Christie medical physics experience has shown that, without regular oversight from a medical physics service, these processes soon become ineffective. Some specialist services such as the breast screening programme and abdominal aortic aneurism screening programmes have set prescribed testing programmes for ultrasound. This sets a precedent for similar applications of cancer or vascular disease detection to require similar testing standards, which is not presently in place.

It was expected that neither local nor physics testing of ultrasound systems were currently being undertaken in Northern Ireland except for systems within the breast screening programme. The purpose of the audit was to assess the status of a significant sample of the equipment in use. The testing was based on a subset of tests used for over 20 years by the Christie Medical Physics services in the North West of England so that a sufficient number of systems could be tested within the allotted timescale.

Aims

The aim of this audit was to assess the safety and performance of ultrasound imaging systems across the region and across various specialities.

There were three objectives

1. Determine the efficacy of local QA by establishing if user QA testing was being routinely undertaken and if user QA identifiable faults had been identified and actioned.

2. Determine the level of Physics QA identifiable faults present in the audit sample by measuring basic imaging parameters including resolution and penetration to identify issues and establish references for future measurements.
3. Establish if there are possible issues with the efficacy of the current service/maintenance and service status of the systems

Standards/Guidelines

1. Guidelines for Professional Ultrasound Practice, BMUS Mar 2019
   https://www.bmus.org/static/uploads/resources/SCoR__BMUS__Guidelines_Amend_Mar_2019_final_DecHwyx.pdf

2. Ultrasound Clinical Governance, BMUS Oct 2008.
   https://www.bmus.org/static/uploads/resources/ClinicalGovernanceInUltrasound-061108.pdf

3. Quality Assurance of Ultrasound Imaging Systems, IPEM Report 102, 2010
   https://www.ipem.ac.uk/ScientificJournalsPublications/IPEMReportSeries/AvailablePublications.aspx

4. NHSBSP Breast screening: acquisition and testing of ultrasound scanners Report 70, April 2011
   https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/441722/nhsbsp70.pdf

Methodology

The audit used equipment lists produced by each Trust in a 2017 regional maintenance contract tender for Ultrasound Imaging. A total of 428 machines were identified, breakdown of numbers by Trust as follows: WHSCT (58), SHSCT (61), NHSCT (70), SEHSCT (101), BHSCT (138). Manchester Christie in collaboration with RMPS agreed that a pseudo random selection method would be used to ensure that the audit covered a range of clinical specialities and locations.

Each Trust project member of the Audit Team were provided with the 2017 equipment lists, and identified machines to be tested, 2-3 months prior to visit in order that lists could be checked, and clinical areas informed of the visits. One week audit visits were arranged with each Trust, as follows:

1 day - Radiology (4- 5 systems),

1 day - Maternity main ultrasound (4-5 systems)

0.5-1 day - Cardiology (2-4 systems)

Remaining days - Clusters of systems from other modalities (Theatres, A&E, Intensive care, Rheumatology, Urology, peripheral maternity (Delivery, special care, IVF etc)

A target of performing QA testing of four to five systems per day was agreed depending on the number of probes assigned to each system. Allowance was made for identified systems not being available, and testing of alternate systems in use within the location.

The **QA audit** comprised of the following:

<u>Pre-visit Questions</u>

1. Date of last electrical safety test – confirm test included probes
2. Date of last service visits
3. Is there a local QA programme in place (if yes please ensure a copy of recent results is available for the QA audit assessment visit)
4. Is there a system fault management log (if yes please ensure a copy is available for the QA audit assessment visit)

Trust Audit Visits General

1. If there is a local QA programme - determine if it complies with BMUS/IPEM guidelines
2. If there is a local QA programme - record the frequency of testing
3. If there is a system fault management log available - confirm that it is up to date

System QA

Medical Physics checks and testing completed are detailed as follows:

1. Appendix A QA System Audit Checks
2. Appendix B Physics Test Measurements

Discussion

The methodology worked well with the exception of the pre-visit questions, responses from equipment operators were not always available prior to the visits. Some of the questions were resolved on site through identifying equipment service labels for electrical safety testing and planned maintenance. In many cases the staff member responsible for the systems was either not available, or not identified, to question and the documentation was not present with the system. In addition, pre-visit responses were not relevant due to changes in systems being available for testing. It is likely, given the findings on the systems that it would not alter the conclusions of this report. A working QA system would generally mean that all of the questions asked in the pre visit questionnaire would be on documentation kept with the systems.

Comprehensive B-mode physics testing achieved with a test object (along with some basic tests) and equivalent to those which form part of most local ultrasound QA programmes can identify a wide range of issues; from those where a clinical impact would be expected, to those where a fault is identified but which is unlikely to alter the clinical efficacy of the ultrasound system. In the former scenario (i.e.) where a clinical impact would be expected a process to adjust the clinical use of the system would be required and for the latter scenario (i.e.) where a fault is unlikely to alter the clinical efficacy more frequent monitoring would be advised. Such testing has been the subject of several publications including (IPEM 102) (AIUM Routine Quality Assurance for Diagnostic Ultrasound Equipment) and (BMUS QA guidelines) over a number of years and is the de-facto standard for assessing ultrasound imaging systems.

Specific values for resolution, penetration and contrast target imaging have not been established in ultrasound as it is difficult to reference them to clinical efficacy. These measurements are instead used to establish baseline values where clinical performance can be re-evaluated when a change is seen or the values can be reassessed in the case of a perceived drop in clinical performance. They are a method for reaffirming confidence or confirming suspicions. There is additionally considerable value in the process of making the measurements on real time images where numerous issues with controls or processing can be identified.

The Medical Physics QA Test Measurements carried out are summarised below and detailed in Appendix B

Penetration Measurements

Penetration values can be affected by changes in output or gain due to system faults and are also subject to change as the probe lens wears or if a probe is refaced.

The one-off audit testing results show consistency for the majority of same probe models, with some with below average values. If this was a part of an established programme these tests would be regularly performed, annually at minimum, which would add considerable sensitivity to the ability to reference against clinical efficacy. Within the examples, shown in Appendix B, there are a number of probes which would warrant further investigation and this was found to be the case for all the probes tested where there was a large enough sample (this would be around 10 to 15 systems generally but the exact number would depend on how many were found with

variation). For the probes tested in smaller numbers it would not be possible to identify such issues without sequential testing. Samples would all increase if all systems in Northern Ireland were tested enabling greater sensitivity over a wider range of probe models.

Resolution Measurements Resolution is a difficult subject in ultrasound as there are three base resolutions, axial (along the axis of the beam), lateral (across the width of the beam) and slice (across the depth of the beam perpendicular to the image plane). These resolutions are specific to a probe rather than the system and vary with depth and system settings in particular the frequency, focus and harmonic settings.

The results show:

- potentially significant changes but without baseline measurements these are not large enough to be acted upon without some clinical concern first arising.

- some of the variations will be due to differences in the calibre of systems these probes are attached to, this could be due to older designs or lower cost systems with fewer channels or processing capacity. If these were within a QA programme then several of these probes would warrant further investigation. Again the limited sample size in some models would be alleviated in sequential testing or by including larger numbers of systems in use. For any particular system/probe combination the sensitivity will be influenced by the number of that combination measured and by the length of time for which it has been measured.

Findings

The target was to test 100 systems, approximately 23% of systems identified on the asset register in use across Northern Ireland. In total 127 systems with 317 probes were tested across the five Trusts. Key findings were identified as follows:

1. Local QA: Five systems (4%) were confirmed as having a local QA in place, and of these the Medical Physics QA found
   a. No system faults were found.
   b. 11 probe faults (52%) were identified across the 21 probes attached to these systems.
2. No Local QA: 122 (96%) systems were confirmed as having no local QA in place, and of these the Medical Physics QA found
   a. 78 faults were identified which is a 61% (78 out of 127) fault rate
   b. 78 identified issues many of these 60% (47 out of 78) were physical including missing or damaged controls, ergonomic adjustments failing and damaged consoles. Others had more serious issues where controls were not functioning correctly, probe ports were inoperative and noise/interference was occurring across all probes.
   c. Many of the faults (31) were minor in nature with 15 being missing key/Time Gain Compensation (TGC) covers and 16 being console damage such as missing or damaged panels
   d. Others were more serious faults 13% (10 out of 78) with four cases of probe connection issues, four cases of noise/interference at a system level and two Software related issues one of which made the system unusable.
   e. For the remaining 37 faults 47% (37 out of 78) there were 15 cases of controls issues (these included insensitive or erratic controls or sticking keys), 16 cases of failed ergonomic adjustments such as monitors not holding position, three brake/wheel faults, two cases of cable damage and one of mains plug fault.
   f. In addition to this, 20% (26 of the 127) systems were found to have filters clogged with dust which were not logged as a fault. In all these cases the filters were cleaned. Although this was not within the remit of the audit, clogged filters can cause serious system issues with overheating. Additionally clogged filters indicate either ineffective

servicing or dusty environments where additional user cleaning of filters would be advised.

g. For 35% (44 of 127) the systems tested there was no system evidence of servicing and for an additional 12% (15 out of 127) the service dates detailed they were significantly overdue.

3. Overall for the 317 Probes tested there were 109 recorded issues which is a 34% fault rate.
   a. 50% (54 out of 109) were due to crystal dropout where a part of the array fails to function correctly.
   b. 20% (22 out of 109) were membrane damage usually holes either in the membrane or in the membrane lifting.
   c. 13% (14 out of 109) were cable damage with the cable split or torn.
   d. 10% (11 out of 109) were noise this could be arcing from a breakdown of earth in the probe, crosstalk from the transmit side to the receiver or radiofrequency interference.
   e. 6% (7 out of 109) were probe casing damage with splits or cracks in the probe body
   f. 0.9% (1out of 109) air-bubble was found (the air bubble issue is a rare fault as there are very few oil filled probes in use mostly these are 3D probes).

The labelling of systems was inconsistent with some systems labelled for both electrical safety and servicing, and some with only one or other label. The type and quantity of faults found and the poor labelling consistency would indicate that the servicing is not currently effective. The systems found were frequently different from those indicated on the registered list.

Some of the issues identified will have been noted by the users as they are obvious but without a formal QA programme it is unlikely that any documented evidence exists. In particular, there should be a documented assessment of the likely impact of the issue and decisions taken about continued use. If a fault could impact clinical performance then the documented evaluation needs to further consider the clinical applications for which the system remains suitable. For many of the faults we identified as serious enough to require immediate notification of the local staff it was clear that in most cases they were previously unaware of the issue or its likely impact.

Although some systems and probes had more than one fault the overall fault rate found was 61% for systems and 34% for probes. These levels are typical for areas where no effective QA programme is in place, as per Manchester Christie experience and literature [5,6,7].

For all systems where a dropout/noise fault was identified it is recommended that a clinical assessment of the probe concerned is made against its current clinical application. Similarly, it is recommended that probe applied parts electrical safety testing is carried out. Each Trust has been provided with a list of all system and probes faults for review and follow up action. Figures 1 and 2 show the fault status of systems and probes for each Trust. For the system faults listed the 10 faults detailed in section 2(e) and the 15 cases of control issues would only be identified during physics testing, the remainder could be identified with a rigorous visual inspection, including checking movements and positioning.

For the system measurements, systems which show significantly high values for resolution or low values for penetration should be investigated clinically. Examples of these can be seen in Appendix B.

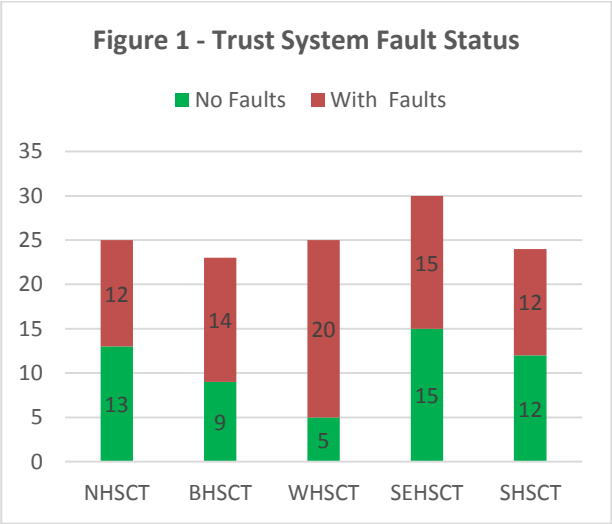
Figure 1 - Trust System Fault Status
No Faults
With Faults
35
30
25
20
15
10
5
0
12
13
14
9
20
5
15
15
12
12
NHSCT
BHSCT
WHSCT
SEHSCT
SHSCT

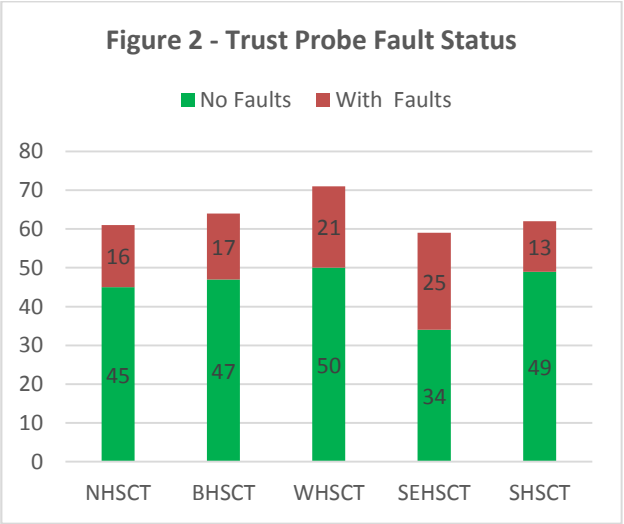
Figure 2 - Trust Probe Fault Status
No Faults
With Faults
80
70
60
50
40
30
20
10
0
16
45
17
47
21
50
25
34
13
49
NHSCT
BHSCT
WHSCT
SEHSCT
SHSCT

Conclusions and Recommendations

There are clear guidelines indicated by BMUS and IPEM recommending regular local QA. In addition, the IPEM report recommends, as a minimum, physics based acceptance testing with baseline measurements established and a reactive service to support queries generated clinically or by a local QA service. Since these reports were written it has become clear that any local QA programme needs to be regularly audited by medical physics and that a "catch all" annual test is essential for systems used in peripheral services as they often do not have the resources, skill set or in the case of clinician's time to undertake testing. With such a testing regime in place, to cover these peripheral services, it is obvious that it would have to apply to the core imaging systems as they could not be subjected to a lower level of testing rigour. The breast screening programme has set this precedent of requiring both local QA and medical physics testing of systems.

It is clear from the audit findings that there is no effective QA in place for the ultrasound systems in Northern Ireland. The indication is that staff are mostly unaware of system faults and, as a result, patients are being scanned with no assessment of the likely impact of the issues present.

It is recommended that there should be a combination of both physics service annual testing with auditing of the local QA programme. The findings in this report clearly show that there is poor technical governance of ultrasound imaging equipment in Northern Ireland and without implementation of a testing programme this is likely to worsen as ultrasound use expands. It is recommended that medical physics support is put in place as soon as possible to provide a service covering acceptance testing, baseline measurements, an annual physics QA check, staff training for local QA implementation and an annual audit of the local QA provision.

Proposed Recommendations:

1. Each Trust to put in place an action plan to
    a. Implement a Trust ultrasound QA programme across all areas, following BMUS guidelines and taking into consideration the establishment of:
        i. An Ultrasound Clinical Governance Board.
        ii. Designated QA leads for all ultrasound specialities
        iii. Operator QA checks
    b. Review, in collaboration with medical physics, system and probes issues identified in the report taking account of clinical applications and ensure that they are fully received.
    c. Ensure that all ultrasound systems are serviced according to schedule including electrical safety testing, and that repairs are effective.
    d. Ensure that information with respect to ultrasound systems is captured in respect of Asset IDs, service maintenance and fault records

2. Regional Medical Physics support is put in place to
    a. Perform base annual physics QA check, as per NHSBSP Report[4] on all ultrasound systems.
    b. Train staff for local QA implementation and annually audit local QA testing provision.
    c. Implement comprehensive acceptance and baseline testing as IPEM report[3] which will provide a support framework for the safe management of ultrasound system faults
    d. Develop a programme of annual medical physics QA checks following the example of the breast screening programme but with tests appropriate to all applications

References

5. Dudley NJ, Woolley DJ. A multicentre survey of the condition of ultrasound probes. *Ultrasound* 2016; 24:190-197
6. 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.
7. 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

APPENDIX A: QA System Audit checks

System

Visual Inspection
The inspection should be performed in daylight or with bright artificial lighting. The cart, keyboards, monitors and probe holders are inspected for visible damage. Fans are checked for operation either audibly or where possible visually. The filters are checked for cleanliness.

Controls and switches
The controls and switches are checked for signs of abrasion or wear. Non sealed knobs, sliders or switches are inspected for ingress of scanning gel.

Cables and connectors
The cables attaching to the main console and any attached peripherals are inspected for signs of damage. The cables are examined visually for cuts, abrasions, twisting or deformation of outer sleeves and stress (often seen as a change in shade or colour of the outer sleeve). A tactile inspection of the cable may reveal damage or stress internal to the cable and is also advised. The finger tips and the tip of the thumb can form a triangle which encompasses the cable and can be moved evenly from one end to the other revealing internal twisting, abrasion damage and splits. The connectors are checked for physical damage and signs of stress (e.g. twisted or misaligned pins, abrasion, film deposits or corrosion for surface connections).

Wheels and brakes
The console is checked for stability (namely that the brakes are holding it securely), the brakes are unlocked and the system checked for smooth movement ensuring that there is no pull or drag the brakes are then re-engaged at the working position and the system checked for stability.

Probes

Visual Inspection

The probes are inspected for signs of external damage. The front membrane is checked for signs of abrasion or general wear, any cuts, splits or gouges are noted. The hard case of the probe is checked for cracks or splits and the seams are checked for seal integrity. The probe cables and strain relief are checked from the neck of the probe to the connector for splits or cuts and any crush or bending damage is noted. The probe connector is inspected for case integrity and the pins are inspected for alignment along with the action of the locking mechanism. In the case of new pinless probe connectors the surfaces are inspected for signs of oxidation, corrosion or abrasion. Mechanical sector/mechanical 3D probes are checked for air bubbles. This is completed by holding the probe vertically with the face pointing up. Observe the reverberation echoes on the screen. Gently rock the probe through ± 90^{o}. The reverberation echoes should not change in appearance.

Noise

All transducers are tested for susceptibility to noise. The power output is reduced to the minimum setting (maximum gain is sometimes only available at this setting) and the gain is then raised to maximum and the system frame averaging (scan correlation) is reduced to a minimum or ideally zero. The probe is then left running scanning air whilst resting in the probe holder. The noise should be a subdued low level speckle in the background it will most commonly show a characteristic area in the near field where the noise level is low or negligible and then at some point there will be a marked increase which will continue escalating to the far field. Spikes or patterns in the image usually indicate noise problems which may be from internal or external interference. The test is then repeated with the power set to maximum. The test is further

repeated with the tissue harmonic imaging mode on at both maximum and minimum power settings.

Interference

All transducers are tested for susceptibility to interference. The gain and power output are raised to maximum and the system frame averaging (scan correlation) is reduced to a minimum or ideally zero. The probe is then left running scanning air whilst held in the hand and the noise level in the background observed for around two minutes. There will usually be classic background noise as seen in the earlier noise test but in this test the purpose is to watch for noise which is structured. It may form a pattern within the image or appear as flashes. This test is repeated for each of the probe frequencies with harmonics both on and off.

Imaging checks

The checks are made using a Gammex RMI Type 403 Test Object. Probe coupling is made using water. The checks are made using a pre-set typical to the probe/system combination but with advanced imaging modes turned off, the frequency should be set to the mid value, (higher of the two for even numbered mid value) for the pre-set or gen for (res, gen, pen option). The pre-set and frequency used are recorded.

Uniformity

For stepped multi-element array probes (not phased or annular) a test is/may be made of the crystals to ensure that they are all firing/receiving. The probe face is cleaned, dried, and left to stand in air. The power output and gains are increased to a level which produces a classic reverberation pattern. The pattern is inspected for uniformity, it should be symmetrical about the centre of the image with no weak dark bars in the image. If any areas are suspect then a second test may be performed either using a so called “key test” or a Gammex test. For the “key test” the probe face is coated with a small quantity of water and a narrow metal object (fine paper clip) moved across the face of the probe. A single, even, white vertical bar should be seen on the real time image with no areas where the bar fades. The probe is then further tested using the Gammex test object to determine the likely impact using both static and motion imaging of a uniform area of the test object.

For Phased/Matrix array probes a key test is performed in M-mode with the focus set as close to the probe face as possible. For the “key test” the probe face is coated with a small quantity of water and a narrow metal object (fine paper clip) moved across the face of the probe smoothly at an even pace to match the M-mode scan speed. The freeze button is pressed at the end of the sweep and by scrolling back a solid block image should be seen on the stored trace with no areas where the bar fades.

Calliper

The system is set onto a linear measurement mode. The first calliper is placed over the centre of one of the imaged wires in the vertical column.

The second calliper is set to a deeper wire 20mm further down and the distance given by the system recorded.

The callipers are placed over the centre of one of the group of horizontally spaced wires and the second calliper is placed on one of the imaged wires in the horizontal row, separated by 30mm.

The ellipse measurement mode is selected if available and a circle drawn which passes through the centre of each of the three corners of a two by three triangle. The area should be 10.2 cm^2 and the circumference 113 mm

Penetration

The penetration measurements are made at two levels; the background penetration or low level echo and the wire penetration or high level echo.

Low level echo penetration is performed by measuring the maximum depth at which background detail can be distinguished. It is either the point at which the background speckle can no longer be seen. The controls are set to maximise this value and the distance recorded.

The settings are left as they are to then measure the high level echo penetration. High level echo penetration is measured by recording the depth to the deepest wire visualised.

Axial and lateral resolution

The probe is placed to image the vertical set of wires in the phantom (Figure 3), and adjust the TGC and overall gain to obtain a uniform background image of the scatter, with a peak background at approximately 50% brightness.

Identify the wire at 20mm deep and set the focus as close to this depth as possible. Only a single focus should be used during this test. Increase the zoom, keeping the wire in the centre of the image, until the zoom is maximised.

Adjust the probe so that it is perpendicular to the wire and the imaging plane is at right angles to the wire. This should be when the axial echo is strongest and the lateral echo narrowest

Using the calliper function of the machine, measure the size of the wire in the axial direction, (axial resolution) the callipers should be placed at the maximum extent of where an increased intensity over peak background can be seen, as shown in figure 4.

In some instances reverberations will be visible. These are characterised by a series of light and dark patches below the wire. If the dark band is lower than peak background then the measurement should be made to this band, if it is above peak background then the measurement should be made over the full lateral extent, this will most commonly result in a value approximately twice that expected but the measurement will be reproducible.

Using the calliper function of the machine, measure the size of the wire in the horizontal direction (lateral resolution). As for axial resolution the callipers should be placed at the maximum extent of where an increased intensity over peak background can be seen, as shown in figure 5.

Deeper measurements are made when the low echo penetration is >10mm over the proposed measurement depth.

If low echo penetration depth >50 mm repeat the measurement as above at 40mm*, with focus to as close to this depth as possible.

If low echo penetration depth >70 mm repeat the measurement as above at 60mm*, with focus to as close to this depth as possible.

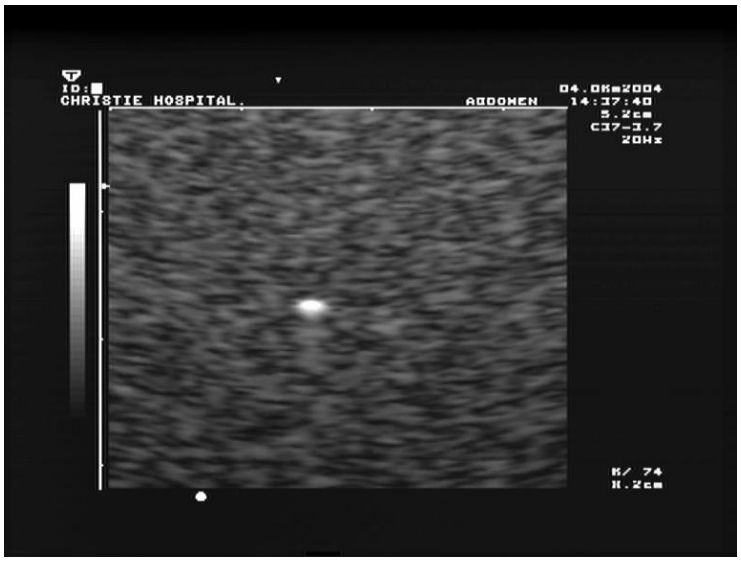

Figure 3 - **S**ample image, zoomed in on single wire

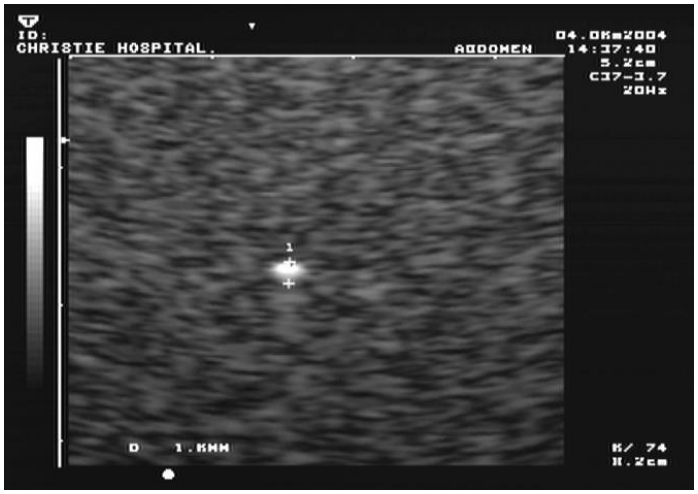

Figure 4 - Axial Resolution Measurement

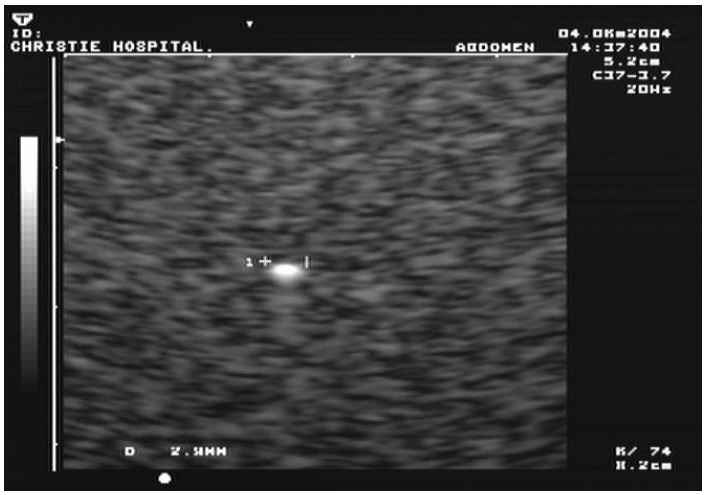

Figure 5 - Lateral Resolution Measurement

Cyst Visibility

There are anechoic rod based cyst structures within the test object at three depths. The rods are in three sizes at each depth (2,4 and 6mm) for each depth the image is optimised to give the best view of the rod without utilising advanced imaging and the smallest rod which can be clearly distinguished from the background is recorded for each depth.

System Functions

The system functions are checked for an appropriate expected visual effect on the image of the test object. Including core advanced functions harmonics, crossbeam and speckle reduction.

Results are re-coded for any function with anomalous behaviour.

APPENDIX B: Medical Physics Test Measurements

Penetration Measurements

Penetration values can be affected by changes in output or gain due to system faults, but they are also subject to change as the probe lens wears or if a probe is refaced. The examples shown below are samples of three of the most popular probes tested including a curved array abdominal probe, a high frequency linear probe and an endovaginal probe. They have been ranked by penetration depth and are the values for low echo penetration; which is the measured depth at which background speckle can be seen. The age of the probes in respect of their time in clinical use was not available but it is likely that those with lower penetration will be the older probes. Penetration drops due to lens wear will also result in a reduction in contrast especially for smaller targets. These measurements are usually made as a system is installed to establish a baseline, significant changes in measured penetration would prompt a clinical evaluation of the probe.

Alternatively, questions raised clinically over the penetration performance of the system can be confirmed by checking against these baselines. During testing there were no values which would prompt action as without baseline values or complaints from the clinical staff these would have to be greater than the changes seen. It can be seen from Figures 6-8 that most of the systems produce remarkably consistent results. Clinical evaluation would be advised for those probes with lower than average values which would be improved with an established QA programme to provide additional probe measurements over time.

For the measurements below in Figure 6, 7 & 8 several of the probes with significant lower than average readings would warrant clinical investigation.

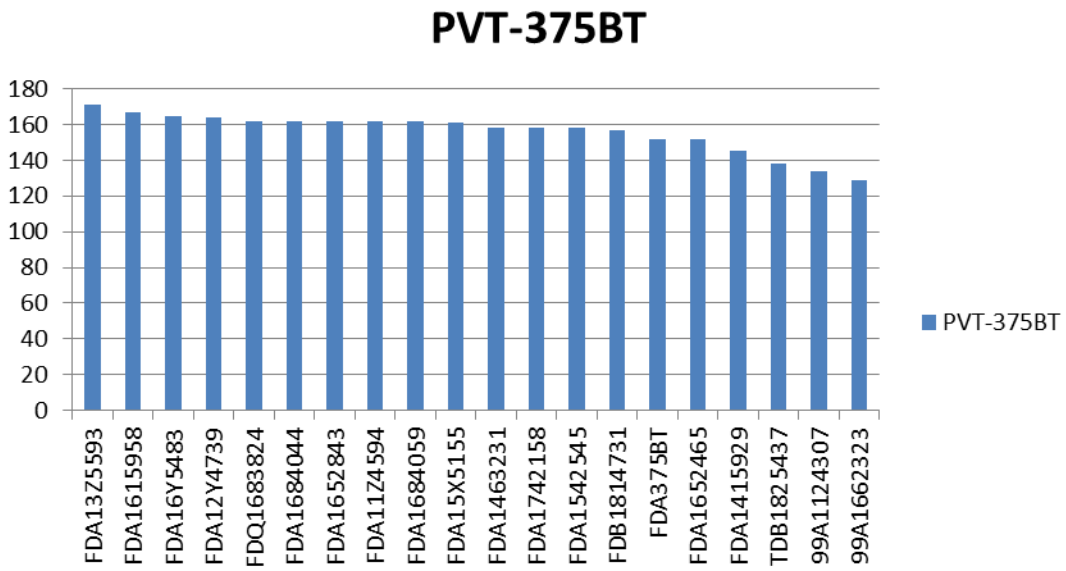

Figure 6 - shows low echo penetration values for PVT-375BT curved array abdominal probes, identified by Serial Number.

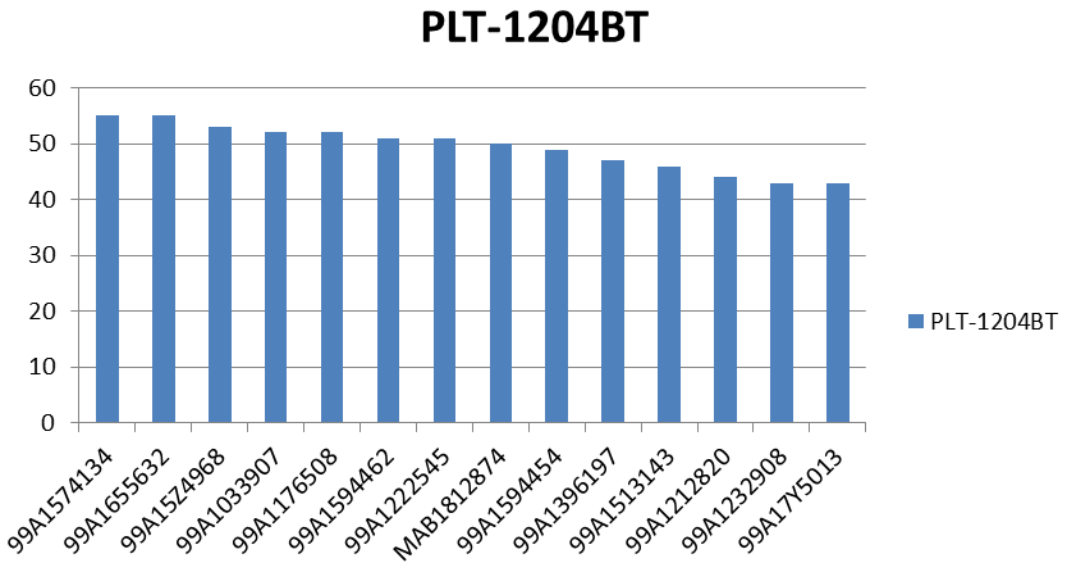

Figure 7 - shows low echo penetration values for PLT1204BT/SX high frequency linear probes, identified by Serial Number.

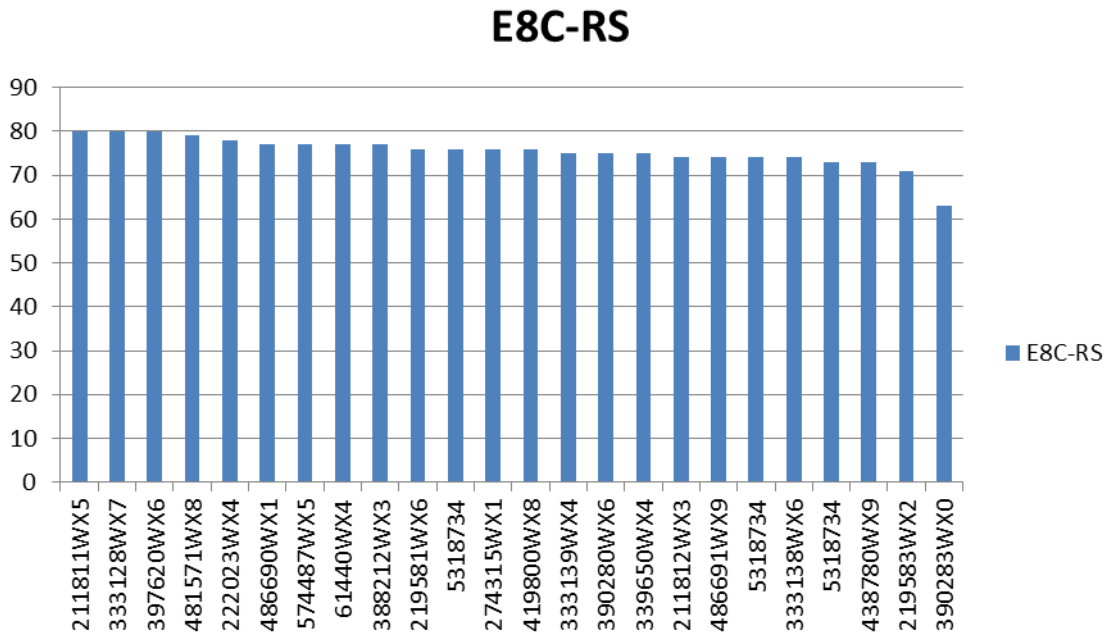

Figure 8 - shows low echo penetration values for E8C-RS endovaginal probes, identified by Serial Number.

Resolution Measurements

Resolution is a difficult subject in ultrasound as there are three base resolutions axial (along the axis of the beam), lateral (across the width of the beam) and slice (across the depth of the beam perpendicular to the image plane). These resolutions are specific to a probe not the system and vary with depth and system settings in particular frequency, focus and harmonic settings. For this report the axial and lateral resolutions were measured at three depths except for very high frequency probes which would not penetrate deep enough. As for penetration the usual application of this methodology is to make baseline measurements, advise on changes observed and to evaluate against clinical queries of resolution performance. For axial measurements this is a particular issue as reverberation artefacts often mean the measured resolution is twice that expected and for measurements on a particular probe type the values can fluctuate between 0.7mm and 1.4mm. It is easy to see which case applies when making the measurement and therefore both would be acceptable. There is less of an issue in lateral measurements but the position of the wires within the image for curved array probes can influence the values found. Where queries are raised direct A/B comparisons between similar systems with the same test object should be undertaken to confirm indicated findings.

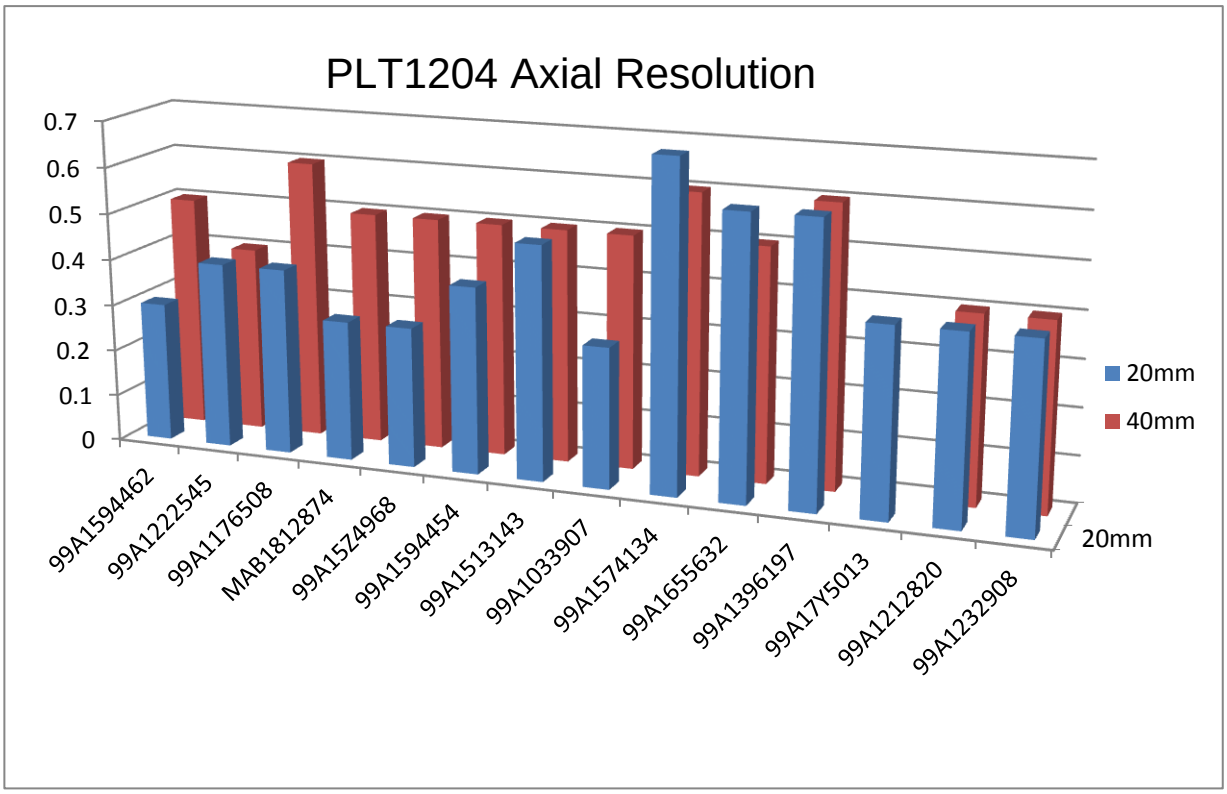

Figure 9 - shows axial resolution values for PLT1204BT/SX high frequency linear array probes, identified by Serial Number

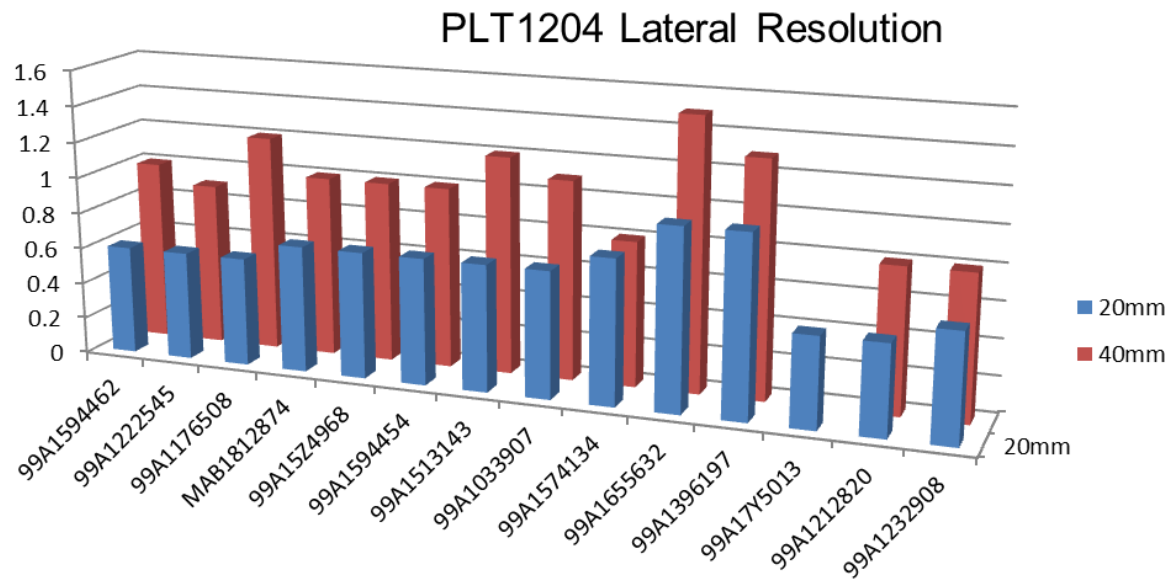

Figure 10 - shows lateral resolution values for PLT1204BT/SX high frequency linear array probes, identified by Serial Number

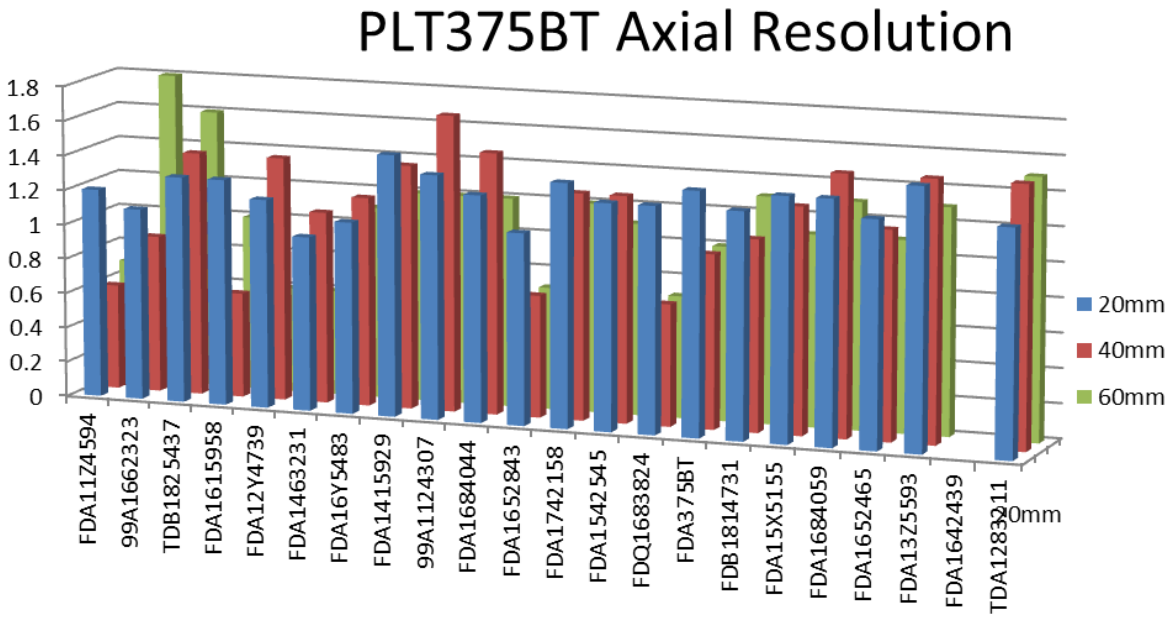

Figure 11 - shows Axial resolution values for PLT375BT/ST curved array abdominal probes, identified by Serial Number

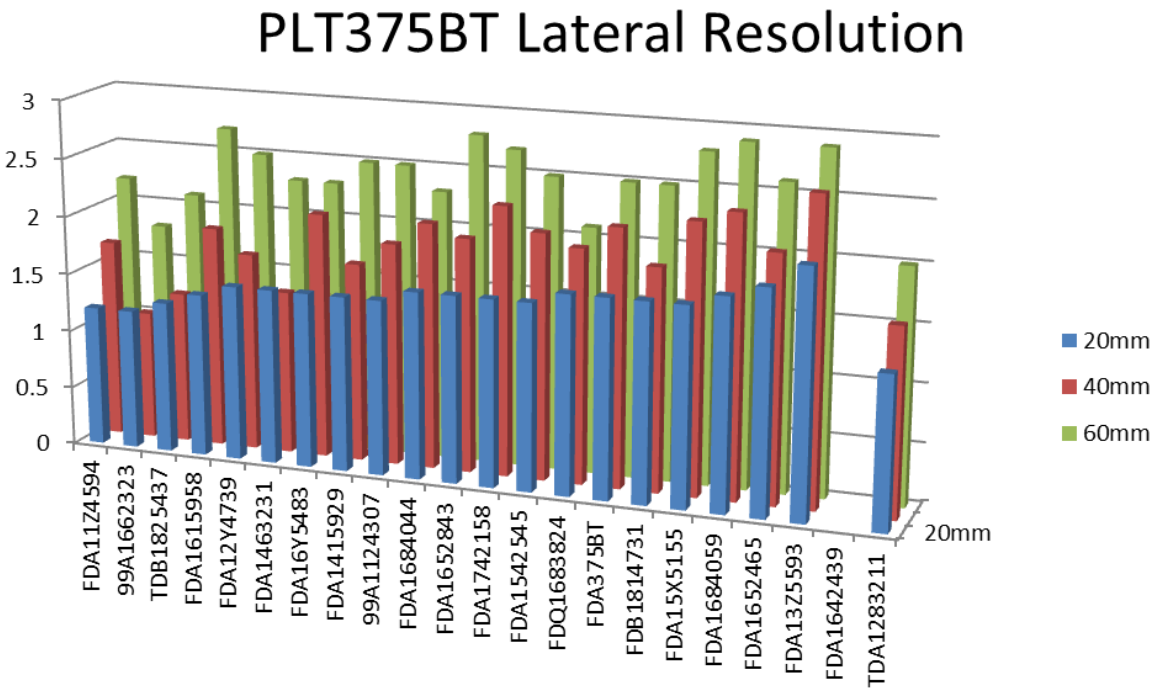

Figure 12 - shows lateral resolution values for PLT375BT/ST curved array abdominal probes, identified by Serial Number.

The resolution measurements were ordered on the 20mm lateral resolution measurements for all four plots. The improvement in lateral resolution for the PLT1204 probes at the end of the plot in figure 10 is due to the fact that these are SX variant probes on newer systems and this would be expected. Likewise, for the PVT375 where the last probe in that case is an ST variant. The plots do show potentially significant changes but without baseline measurements these are not large enough to be acted upon without some clinical concern first. Some of the variations will be due to differences in the calibre of the systems these probes are attached to. If these were within a QA programme then several of these probes with high readings for resolution would warrant further investigation.

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