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● *Original Contribution*

ASSESSMENT OF REPAIRED DIAGNOSTIC ULTRASOUND PROBES

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Abstract—A growing number of repaired and refurbished diagnostic ultrasound probes are supplied by a small number of original equipment manufacturers (OEMs) and many third-party vendors. OEMs ensure that their devices meet regulatory requirements; any repairs using non-OEM materials carry the risk of non-compliance. The aim of this study was to test examples of probe repairs using methods selected to illustrate their possible impact on function. Of 3212 used probes assessed, 21 were found to have undergone repair involving functional parts: 9 incorrectly wired, 11 non-OEM arrays and 1 relensed probe. For repairs not involving functional parts, before and after electronic probe testing may be sufficient to determine that no damage has occurred. For repairs involving functional parts, a more comprehensive suite of tests is necessary to determine that the materials, parts and final product match the performance of the OEM probe and meet regulatory requirements. (E-mail addresses: nick.dudley@ulh.nhs.uk, dudleyn5@gmail.com)

Key Words: **Ultrasound, Probe, Repair, Quality assurance.**

INTRODUCTION

There are an increasing number of repaired and refurbished diagnostic ultrasound probes in use. Probes are expensive items, and their functioning lifetime is often shorter than the lifetime of the ultrasound scanner itself. Annual probe fault rates of 14%–27% have been reported (Martensson et al. 2010; Hangiandreou et al. 2011). A range of probe repairs are offered by a small number of original equipment manufacturers (OEMs) and by a number of third-party repair vendors, some of whom outsource the repairs. The scope of repairs ranges from minor cosmetic repairs, through structural repairs such as cable strain relief replacement, to functional repairs such as cable re-termination, lens replacement and even replacement of the acoustic stack and cable.

The terms *repair, refurbishment* and *remanufacture* are used, but definitions vary between countries; in the United Kingdom, guidance is provided by the Medicines and Healthcare Products Regulatory Agency (MHRA 2016) as follows. The *manufacturer* is the person or company placing the device on the market (not necessarily the physical manufacturer). A *repair* restores the device to working condition and should not change the performance characteristics of the device, otherwise regulatory approvals will be invalidated; spare parts in this case can be considered to be medical devices requiring separate approval. *Refurbishment* is where the device has been rebuilt or made as new using parts from used devices; the person or company performing the refurbishment may be considered to be the manufacturer, and new regulatory approval may be required. *Remanufacture* is not defined by the MHRA but could be defined as a process that results in a new product and new regulatory approvals will be required. We recognise that there is overlap between these definitions; the aim of repair, remanufacture or refurbishment is to restore the probe to working condition, and so for simplicity we will use only the term *repair* to refer to any process intended to restore function of a damaged or worn probe.

Bigelow et al. (2018) highlighted the great care that OEMs take in designing probes to maximise sensitivity and to match probes to the ultrasound system design. Further, OEMs carry out extensive testing to ensure that their devices meet regulatory requirements for acoustic output, probe heating, electrical safety and biocompatibility. This group pointed out that any repairs that use non-OEM parts and materials may carry the risk of affecting compliance

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with these requirements. Their study simulated the potential effect of improper probe repairs on patient safety and image quality: firstly assuming the use of the correct materials in the acoustic stack but with errors in thickness; secondly assuming the use of incorrect materials but with the correct thicknesses. Their results revealed considerable losses of sensitivity and resolution and effects on probe heating. Results of testing repaired probes included a third-party acoustic stack, where the sensitivity of the replacement array was only 63% of that of the OEM array and sonographers reported that images were non-diagnostic; a poor flex circuit re-termination repair where the sonographers reported signal dropout and noise; and uneven layering of a replacement lens resulting in unacceptable image quality.

Probe repair vendors often provide an electronic probe testing report to customers. The use of commercially available or in-house developed electronic probe testing devices is widespread as most, but not all, probes can be tested by these devices. The authors are unaware of any vendors not using this method, with the exception of probes that cannot be tested in this manner. The authors are aware that some vendors provide this information freely, and some only on request. In these reports, individual element sensitivity consistently above 75% of the mean and uniform capacitance are assumed to provide adequate validation of performance after repair. These reports do provide useful information. However, they do not provide comparison of sensitivity and capacitance with original OEM probes and so do not alone indicate equivalent sensitivity. Additional data provided by electronic probe testers, such as pulse width, centre frequency and bandwidth, are often ignored, despite providing important information about departures from OEM probe performance.

Probe repair vendors rarely provide other measures of performance or openly share their performance criteria. There are many ways in which repairs may affect image quality, some of which may not be easily detectable in use but will have consequences for clinical image quality. The aim of this study was to perform detailed testing of a range of probe repairs to identify some of the consequences of improper probe repair.

METHODS

Multi-Medix purchases new and used probes from a variety of suppliers and receives probes from customers for testing and possible repair. On receipt, probes are subject to cleaning, visual inspection, electrical safety testing and electronic probe testing. For approximately 80% of probes, ultrasound systems are available to enable a system test, including evaluation of the in-air reverberation (Dudley 2019) and checks for artefacts and noise in B-mode and Doppler modes. Where necessary, physical appearance and test results are compared with those of new OEM probes. Repaired probes are rejected unless appearance and performance match those of original OEM probes. Where a probe is suspected to have been repaired, image quality testing is necessary only if all other tests have been passed, but for the purposes of this study some image quality tests were performed to assess the functional impact of repairs. In this study, we have presented examples of repaired ultrasound probes tested using methods selected to illustrate the possible impact on function of improper repair.

Visual inspection

All probes were subject to a visual inspection, performed independently by two trained technicians under a certified quality system (International Organization for Standardization [ISO] 2016). Any damage or cosmetic defects were noted and photographed. Probes were flagged as potentially repaired where there were visible signs of repair or appearances differed from an original OEM probe (*e.g.,* cable length, probe case markings or finish, lens colour or finish).

Electronic probe testing

FirstCall electronic probe testers (Unisyn, Golden, CO, USA) were used. Testing was performed by attaching the probe connector to a dedicated adapter and driving the probe from a computer under software control. Each probe was mounted at the surface of a water bath with the probe face parallel to a steel reflecting plate. Generally three plates are available: a flat plate for linear and phased arrays, a plate with a large radius of curvature matched to typical convex arrays for abdominal use and a more tightly curved plate matched to typical endocavity probes. The system drives each probe element in turn by an excitation pulse, *via* the adapter, the returning echo is measured and the amplitude displayed. There is an initial alignment process, where selected elements along the array are fired to allow multiplanar adjustment of the probe position until all elements are equidistant to the plate (achieved by timing of echo return). The entire array is then pulsed, one element at a time, and a sensitivity plot is produced. The system then measures the capacitance of each element circuit and displays a capacitance plot. The capacitance results allow the user to determine whether low sensitivity is due to a short circuit, open circuit or damaged element. Once echo data have been stored, it is possible to extract and display further information such as pulse width, centre frequency and fractional bandwidth for each element.

It is also possible to determine whether correct sequencing of elements has been achieved, for example, when cables have been re-terminated. This is achieved by adjusting the separation between the probe and the reflective plate so that it is tilted in the direction of its long axis (Fig. 1), then measuring the time-of-flight

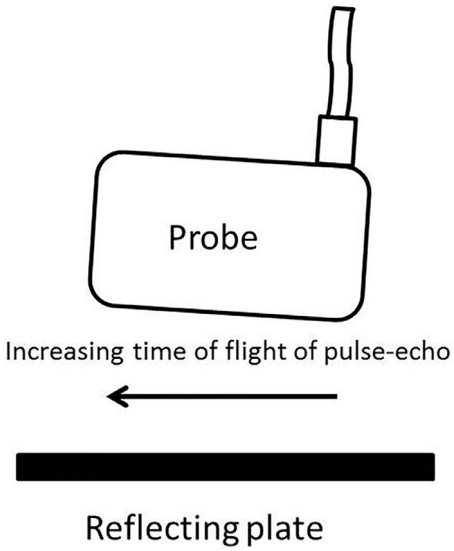

Fig. 1. Probe position for time-of-flight measurement to check array sequencing; time-of-flight should increase linearly from right to left of the diagram.

of echoes for each element; if elements have been incorrectly sequenced there are discontinuities in the progressive increase in time-of-flight along the array. The authors are not aware of other probe vendors providing a result of this test.

The FirstCall manual defines an acceptable probe array as having no more than four weak elements (40%–75% of mean sensitivity), no more than two consecutive weak elements and no more than one dead element (<10% of mean sensitivity); *green, yellow* and *red* lines are included on the sensitivity graph to represent the 75%, 40% and 10% levels, respectively. There are no widely accepted standards for probe acceptance criteria, and so different testing systems will use different criteria. For example, the authors are aware of a probe repairer using context-specific acceptance criteria, where probes with more than four consecutive weak elements, or an aggregate of three dead elements or two consecutive dead elements would not be repaired and stricter criteria apply for the purchase of new or used probes. It is also possible that testing centres will develop their own criteria; for example, in our practice, we have adopted a coefficient of variation (CoV) limit of 10% for sensitivity based on our own evidence of sensitivity variation illustrated in Figure 2.

For the purposes of this study we considered all available results from the FirstCall: sensitivity, capacitance, pulse width, centre frequency, fractional bandwidth and array sequencing. Probes were flagged as potentially repaired where array sequencing was incorrect or other results differed from an original OEM probe.

Imaging

Image quality was assessed using the Nottingham Ultrasound Quality Assurance (QA) software (Gibson et al. 2001). For probes under test, images of a test object appropriate to the imaging frequency were acquired

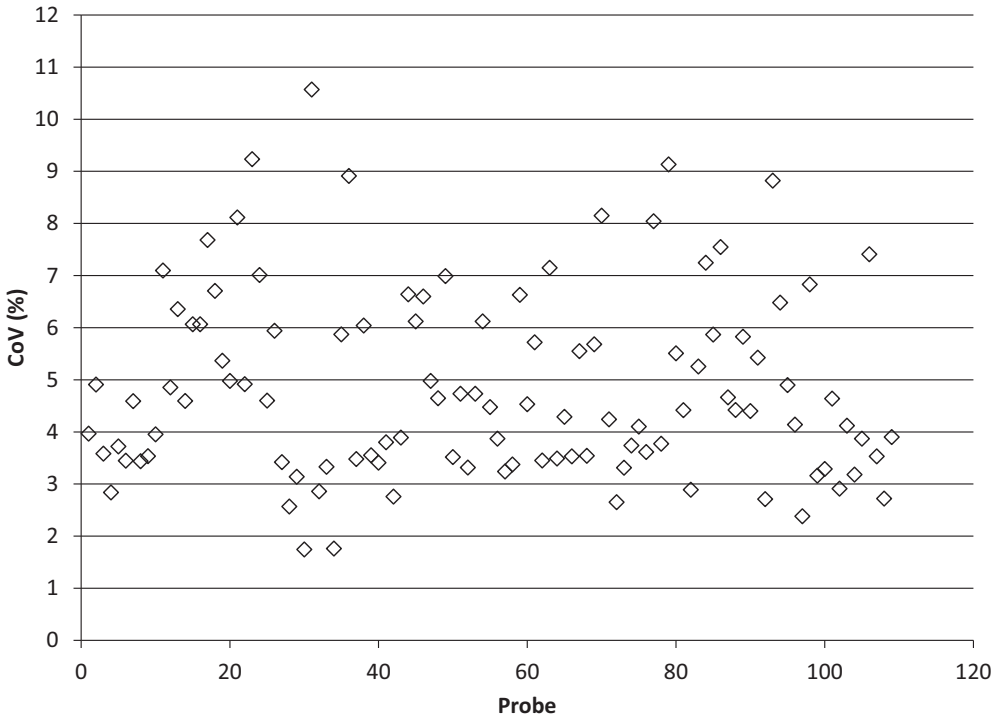

Fig. 2. Coefficient of variation of sensitivity for 55 linear arrays and 54 convex arrays. CoV = coefficient of variation.

using a scanner preset programme for a typical clinical application of the probe. Where comparisons with OEM probes were made, images from all probes were acquired on the same scanner using identical settings. Test objects used were a Gammex 404 GS-LE, a Gammex 403 GS-LE (Gammex Inc, Middleton, WI, USA) and an ATS 539 (ATS Laboratories Inc, Bridgeport, CT, USA), the specific test object used depending on availability. Images were stored in Digital Imaging and Communications in Medicine format for subsequent analysis.

The measurements made were lateral resolution, slice thickness and mean image background grey level (Gibson et al. 2001; Dudley and Gibson 2017). Lateral resolution was measured as the full width at half-maximum of the background-subtracted image profile of nylon filament targets. Slice thickness was measured using the method of Skolnick (1991), rotating the probe through 45˚ and measuring the full-width at half-maximum of the background-subtracted image profile of nylon filament targets. Mean grey level was measured as the mean background speckle signal over the same depth as the resolution measurement. The rationale for this group of measurements was that they were most likely to reveal changes in resolution, because of inappropriate element spacing in curved arrays or speed-of-sound differences in the acoustic stack, and sensitivity caused by different material thickness and attenuation relative to OEM probes.

Images were also qualitatively assessed for any visible imaging anomalies, such as misregistration of targets.

RESULTS

Tables 1 and 2 outline the number of used probes received by Multi-Medix between January 2017 and May 2019 and the number of repairs involving functional parts detected.

Non-OEM arrays were initially identified from probe appearance and confirmed by differences in electronic probe testing, notably in centre frequency that differed from OEM centre frequency by typically more than 20%. Some probes with non-OEM arrays were sold to us as OEM originals, from three different suppliers, and these suppliers have been excluded from the approved supplier list. Probes with non-OEM arrays were seen from four different customers who had purchased the probes without knowing that they were non-OEM; these have all been taken out of use.

Table 1. Used probes purchased for stock January 2017 to May 2019 and numbers found to have been repaired

Year	No. of probes purchased	No. of non-OEM arrays	No. of incorrectly repaired cables
2017	915	4	6
2018	843	1	0
2019	221	2	2

OEM = original equipment manufacturer.

Table 2. Probes received from customers for testing and/or repair January 2017 to May 2019 and numbers found to have been previously repaired

Year	No. of probes received	No. of non-OEM arrays	No. of incorrectly repaired cables
2017	509	1	1
2018	491	0	0
2019	230	3	0

OEM = original equipment manufacturer.

All incorrectly repaired cables were confirmed by the time-of-flight array sequencing test. The six purchased in 2017 were from two suppliers but the probes were all of the same model (Toshiba PVT-375 BT, Toshiba Medical Systems, Tokyo, Japan) and an identical fault was found on each, suggesting a single source of repair. The two incorrectly repaired probes purchased in 2019 were from another supplier, and the faults differed slightly. All three suppliers have been excluded from the approved supplier list.

Three used probes have been received by United Lincolnshire Hospitals over a 5-y period. Two exhibited no signs of repair and passed acceptance testing. A probe supplied as a replacement for a faulty probe under a lease agreement was suspected to have been relensed on the basis of sensitivity and elevational beam profile measurements in a test object, and this was confirmed by the supplier, who subsequently provided a new OEM probe.

The following are examples of improper repair: re-termination, where a damaged cable had been cut and re-soldered to the flex circuit of the array; re-lensing, where a damaged lens had been removed and replaced; replacement of the cable and acoustic stack, where the only remaining parts of the OEM probe were the connector and the probe case.

Re-termination

Figure 3 illustrates array sequencing data for an incorrectly re-terminated probe (Toshiba PVT-375 BT, Toshiba Medical Systems, Tokyo, Japan); the supplier (not Toshiba) had stated that this probe had been tested and was fit for use. There are discontinuities in the gradient, indicating that elements had been incorrectly wired with odd and even connections transposed in six areas. Figure 4 illustrates the consequential misregistration of superficial targets in a test object.

Re-lensing

Figure 5 illustrates the effect on slice thickness of an improper third-party lens repair (GE M5 S, GE

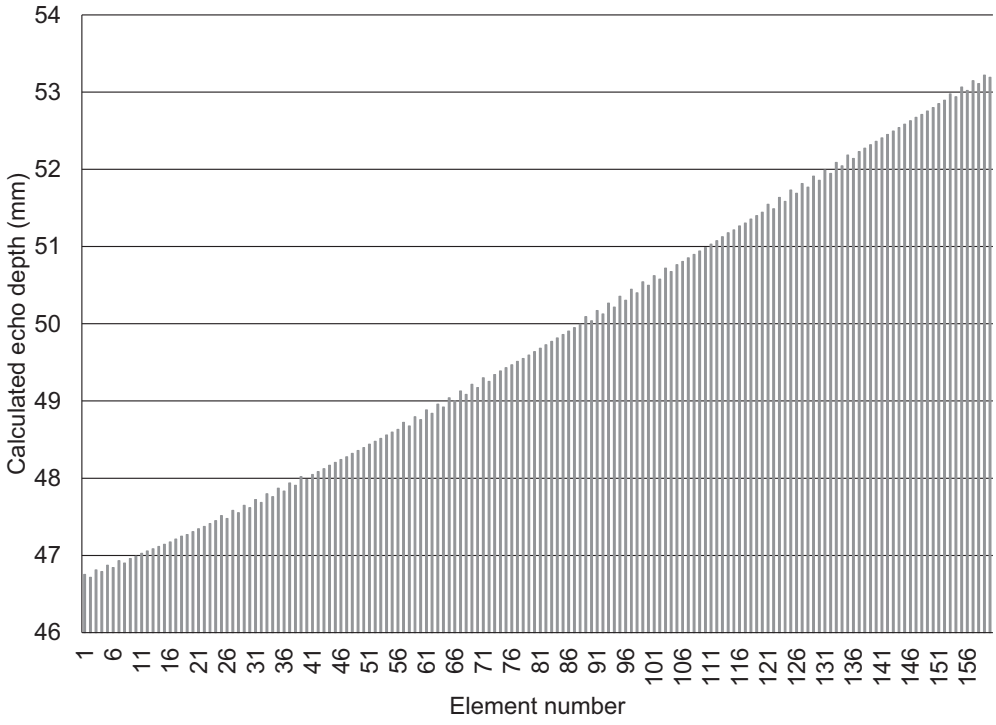

Fig. 3. Array sequencing revealing discontinuities in the progression of echo time-of-flight along the array (Toshiba PVT-375 BT, Toshiba Medical Systems, Tokyo, Japan).

Healthcare, Hatfield, UK). The slice focus is in a different position compared with that of an original OEM probe. Additionally, the sensitivity of the probe was affected, the penetration depth (the depth at which the speckle signal fell to twice the noise level; Gibson et al. 2001) being 112 ± 6 mm for the re-lensed probe compared with 122 ± 4 mm for an original OEM probe.

Replacement of the cable and acoustic stack

Figure 6 illustrates the lateral resolution of a high-frequency linear array (Philips L12-5, Philips, Amsterdam, The Netherlands) with a non-OEM acoustic stack and cable, sold as a suitable equivalent to the OEM probe. The resolution is poor compared with that of OEM probes. Figure 7 illustrates the resolution of a repaired transvaginal probe (Philips C10-3 v, Philips, Amsterdam, The Netherlands), where the resolution is again poor compared with that of the OEM probe.

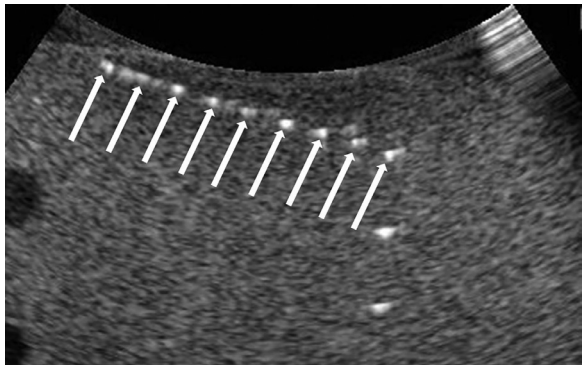

Fig. 4. Misregistration (true targets *arrowed*) caused by incorrect array sequencing (Toshiba PVT-375 BT, Toshiba Medical Systems, Tokyo, Japan).

DISCUSSION

Although only 0.6% of probes received were found to have undergone repair involving functional parts, this may not represent the full picture. These were all sold as used original OEM probes, and so there may be many ultrasound users unaware that the used probes they have purchased have been repaired. The supplier approval process itself, which provides a set of standards and requires completion of a supplier questionnaire, and removal of non-compliant suppliers from the approved suppliers list reduce the risk of further non-acceptable probes being received. Having actively sought repairers who can restore probes to original OEM performance, we consider the risk that high-quality repairs have been missed by our processes to be low.

Re-termination

After re-termination it is essential to perform tests to confirm that elements have been connected in the correct

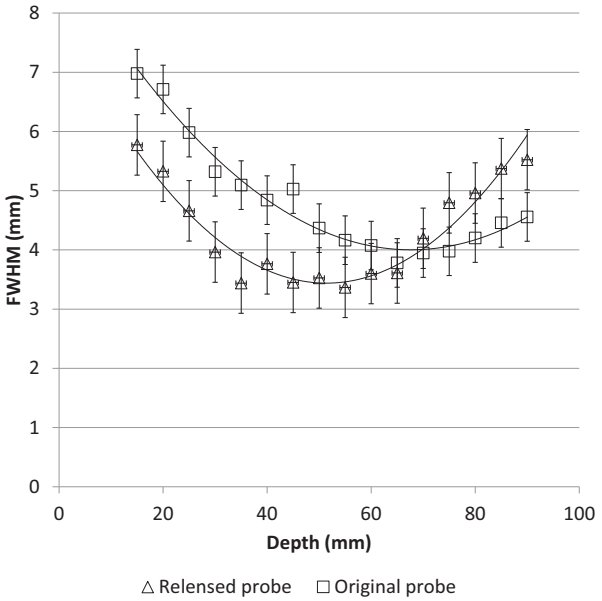

Fig. 5. Full width at half-maximum (FWHM) in the slice direction with second-order polynomial fits to illustrate change in focal depth (GE M5 S, GE Healthcare, Hatfield, UK). Error bars represent ±1 standard deviation.

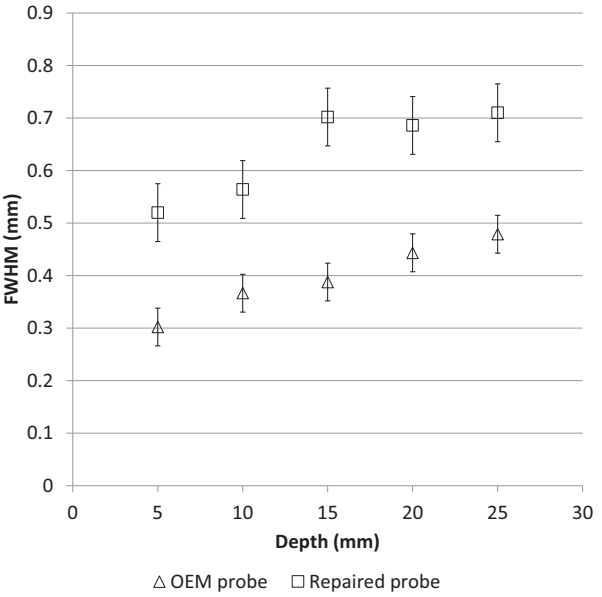

Fig. 6. Lateral full width at half-maximum (FWHM) of nylon target profiles versus target depth for original equipment manufacturer (OEM) and repaired high-frequency linear arrays (Philips L12-5, Philips, Amsterdam, Netherlands). Error bars represent ±1 standard deviation.

order. This may be qualitatively assessed by imaging and looking for misregistration of targets, but this requires operator skill and experience. The array sequencing test, with the probe tilted relative to the reflector in the direction of its long axis, provides an objective assessment; there should be no discontinuities in the echo time of flight gradient. This test is outside the capabilities of most hospitals or clinics and should be performed by the repairer or repair vendor, either as validation of their technique or as confirmation of the efficacy of repair.

Re-lensing

The lens is a critical functional component of an ultrasound probe. It is designed to focus the ultrasound beam into the scan plane at a depth appropriate to the intended clinical applications. Use of an incorrect material with a speed of sound that differs from the design specification will affect the depth of the slice focus. Similarly, if the convex surface of the lens is shaped inappropriately, then the depth of the slice focus will be affected. It is theoretically possible to redesign the shape of a lens that has an incorrect speed of sound to make a correction, but a detailed knowledge of the original design and materials is needed. Lens materials also affect the sensitivity of the probe, as different materials have different attenuation and acoustic impedance. It may be within the capabilities of QA service providers to perform tests of slice thickness and sensitivity, but it is more appropriate for repairers to carry out these tests to validate their technique.

It is also essential to meet the regulatory requirement that materials in contact with patients are biocompatible in accordance with ISO 10993-1:2018 (ISO 2018) and important to ensure that materials are compatible with OEM-recommended cleaning agents and methods.

Additionally, the lens material will affect probe self-heating and thermal and mechanical indices if its properties differ from those of the OEM material (Bigelow et al. 2018). Again it is important that repairers measure probe surface temperature and confirm that thermal and mechanical indices displayed by the scanner still accurately represent the probe output.

Replacement of the acoustic stack

OEMs expend considerable resources in designing probes to maximise sensitivity and to match probes to the ultrasound system design (Bigelow et al. 2018). As a result, replacing the acoustic stack with non-OEM materials can have significant consequences. Failure to match ultrasound travel times in the acoustic stack of a linear array has an effect on focusing, as illustrated in Figure 6, as the delay lines are no longer matched to the layers in the probe. For a curved array, using materials of different thickness to the OEM design has the additional consequence of altering the pitch of the array and, therefore, the geometry of the image.

Responsibilities of the repairer

Medical device sales and repair suppliers have an obligation to ensure that regulatory compliance is not

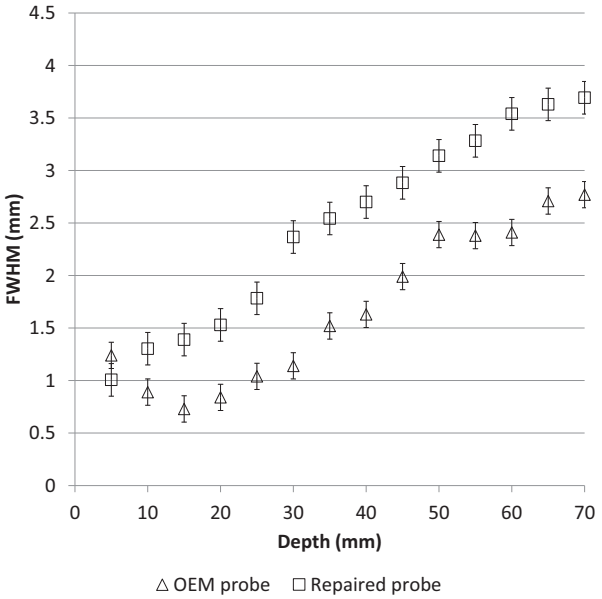

Fig. 7. Lateral full width at half-maximum (FWHM) of nylon target profiles versus target depth for original equipment manufacturer (OEM) and repaired transvaginal probes (Philips C10-3 v, Philips, Amsterdam, Netherlands). Error bars represent ±1 standard deviation.

compromised by their activities; this includes performance and safety of the medical device. This is most commonly by certification to the relevant international quality standard, which is currently ISO 13485:2016. It may be that a supplier is not certified, but working toward it, or to a quality system consistent with it. This quality system will include suitable risk assessments for all activity that affects medical devices. Whilst an appropriate quality system may not provide total assurance, customers should look for this in suppliers and also expect reasonable responses to a supplier evaluation process.

A repair should restore the device to working condition and should not change its performance characteristics; otherwise regulatory approvals will be invalidated. Repairers must therefore validate their techniques and potentially each repair to indicate that performance is equivalent to the original OEM probe and that safety indices remain accurate. It may be that such equivalence can be achieved only by the same type of testing the OEM performs before placing the device on the market.

CONCLUSIONS

A range of probe repairs are possible and available. For repairs that do not affect functional parts, a simple before and after electronic probe test may be sufficient to indicate that no damage to elements or cables has occurred. For repairs involving functional parts, a more comprehensive suite of tests is necessary to determine that the materials, parts and final product match the performance of the OEM probe and meet regulatory requirements. OEMs have to demonstrate robust quality management systems (ISO 13485:2016) to place devices on the market and ensure safety and compliance; we should expect repairers to demonstrate the same.

Conflict of Interest—Multi-Medix is a probe sales and repair company.

REFERENCES

Bigelow TA, Moore GW, Zagzebski JA. Ensuring clinical efficacy and patient safety with repaired ultrasound probes. J Ultrasound Med 2018;37:315–328.

Dudley NJ. Ultrasound probe acceptance testing using the in-air reverberation pattern. Ultrasound Med Biol 2019;45:1475–1482.

Dudley NJ, Gibson NM. Is grey level a suitable alternative to low contrast penetration as a serial measure of sensitivity in computerized ultrasound quality assurance? Ultrasound Med Biol 2017;43:541–545.

Gibson NM, Dudley NJ, Griffith K. A computerised quality control testing system for B-mode ultrasound. Ultrasound Med Biol 2001;27:1697–1711.

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.

International Organization for Standardization (ISO). ISO 13485:2016. Medical devices—Quality management systems—Requirements for regulatory purposes. Geneva: Author; 2016.

International Organization for Standardization (ISO). ISO 10993-1:2018. Biological evaluation of medical devices—Part 1. Evaluation and testing within a risk management process. Geneva: Author; 2018.

Martensson M, Olsson M, Brodin L. Ultrasound probe function: Annual testing is not sufficient. Eur J Echocardiogr 2010;11:801–805.

Medicines and Healthcare Products Regulatory Agency (MHRA). Guidance on legislation. Borderlines with medical devices. London: MHRA, 2016

Skolnick ML. Estimation of ultrasound beam width in the elevation (slice thickness) plane. Radiology 1991;180:286–288.