

Ensuring Clinical Efficacy and Patient Safety With Repaired Ultrasound Probes

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Abbreviations

FDA, Food and Drug Administration; IEC, International Electrotechnical Commission; ISO, International Organization for Standardization; OEM, original equipment manufacturer; TEE, transesophageal echocardiography

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The clinical importance of diagnostic ultrasound as a primary imaging modality has escalated dramatically over the past 20 years, driven in part by the development and integration of sophisticated high-speed computer technology as well as advanced image-processing algorithms into ultrasound system mainframes. Additionally, the creation and use of new composite and single-crystal transducer materials and methods of construction have substantially enhanced the sensitivity and bandwidth of the transducers (probes) used with the ultrasound mainframes.¹ Consequently, the breadth of the use of diagnostic ultrasound in ever-more-complicated clinical circumstances is well documented in the literature. Furthermore, clinicians now partly rely on the ultrasound results to direct management and treat patients with higher levels of quantification. Physicians and sonographers rely on the optimal performance of the probe to obtain a high-quality diagnostic image.

To that end, ultrasound original equipment manufacturers (OEMs) take great care during the design process to ensure the maximum possible transmit and receive sensitivity of the array inside the probe. The probe design is carefully and rigorously matched to the ultrasound system design to further ensure that the highest-quality ultrasound image and Doppler signal can be produced. In addition, because the US Food and Drug Administration (FDA) considers an ultrasound probe as a finished medical device,² OEMs are required to perform extensive testing of the probes to ensure that the acoustic output power of the probe³ is within acceptable levels for all imaging modes and that they are matching the mechanical index and thermal index values displayed on the ultrasound system's monitor. Original equipment manufacturers must also ensure that the temperature increase of the probe surface is less than 43°C, and the probe satisfies all biocompatibility and electrical leakage safety requirements. Furthermore, OEMs are required to perform extensive testing on their finished probes to validate what sterilization and disinfection protocols (and chemicals) should be used to ensure mitigation of cross-contamination risks, especially important with transesophageal and other invasive probes.

An important issue arises when an ultrasound transducer is in need of repair or has faults. Original equipment manufacturers as well as third-party repair vendors might be called on to assist when there is evidence of either internal or external transducer defects.

Unfortunately, non-OEM probe repair companies in the United States are not currently regulated by the FDA and are performing one or more repairs that could affect the performance and safety issues outlined above, putting both the patient and the user at risk. For example, acoustic arrays manufactured by entities other than the OEM that are used in some probe repairs may produce acoustic output values that are substantially variant from the displayed mechanical and thermal index values. These arrays may also be less efficient in transmitting acoustic energy, thereby giving up that energy as heat at the face of the aperture (patient contact area). The amount of heat may exceed that allowed by the FDA standards and could, depending on the clinical application, represent a patient safety issue (eg, transvaginal examinations in which excessive heat could result in tissue damage). Furthermore, if the design and/or geometry of the acoustic stack is altered, the measurements made using the imaging system may no longer be accurate, as the ultrasound software is calibrated for the specific probe. “Repair” companies that remanufacture OEM probes may also replace the probe housing and acoustic lens using non-OEM materials. These components that contact a patient’s skin are required by the FDA to be made from materials tested and proven to be biocompatible, including tests for the potential of cytotoxicity (Biological Evaluation of Medical Devices and 21 CFR, Part 58; International Organization for Standardization (ISO) 10993-10, Biological Evaluation of Medical Devices—Part 10: Tests for Irritation and Delayed Type Sensitivity; and ISO 10993-5, Biological Evaluation of Medical Devices—Part 5: Tests for Cytotoxicity). Also, when a non-OEM repair entity replaces a material with one of unknown origin and composition, the cleaning and disinfection recommendations provided by the OEM may no longer be valid and can potentially increase the risk of cross-contamination and/or probe damage.⁴ Last, improper electrical testing by any of the repair companies to verify insulation integrity may lead to an electrical leakage hazard to the patient. This factor is especially important with probes used for transesophageal echocardiography (TEE), which are inserted into the patient’s esophagus during heart surgery. Clearly, a device defect in this type of medical procedure could have fatal results.

The purpose of this document is to highlight the dangers and risks associated with a poorly repaired probe. To this end, we will first discuss ultrasound probe

nomenclature. We will then review the FDA approval process for ultrasound probes: specifically, the premarket testing and validation requirements. Numeric simulation results will then be provided, illustrating how even small changes in probe construction can substantially affect probe performance and safety. We will then give some examples of poor probe repair from third-party vendors, illustrating the severity of the problem. Last, we will conclude by providing some recommendations for third-party probe repairs in the future.

Probe Nomenclature

The configuration for a standard general imaging probe is shown in Figure 1, and a TEE probe is shown in Figure 2. Notable in each example is a connector that allows bidirectional transmission of electrical signals between the probe and ultrasound imaging system. The connection is needed to provide power and acoustic signal paths to the acoustic stack, consisting of the piezoelectric elements and their backing and matching layers. The connection must support precise phase control of the transferred signals. The acoustic stack is protected

Figure 1. Review of probe nomenclature for a standard probe.

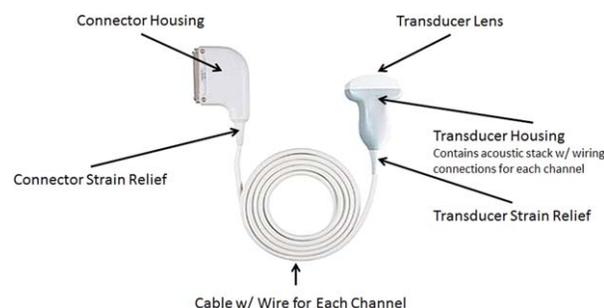
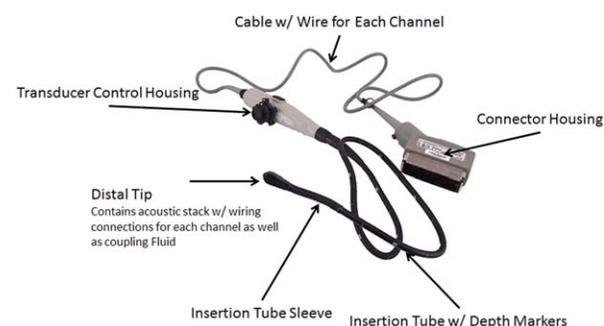


Figure 2. Review of probe nomenclature for a TEE probe.



and stabilized within the transducer housing (standard probe) or distal tip (TEE probe). It must provide precise positioning relative to the transducer lens. Some probes, such as those used for 3/4-dimensional fetal imaging (ie, wobblers) and TEE probes, also contain coupling fluid in the transducer housing/distal tip. In addition to providing electrical isolation from the patient, the lens on a standard probe can provide additional wave front shaping to achieve the desired ultrasound beam profile in the elevational direction, and it provides protection for the acoustic stack.

For the ultrasound probe, the acoustic stack is the most critical component for obtaining high-quality imaging and Doppler performance. It must be precisely manufactured with known array element sizes, spacing, frequency, and damping characteristics so that the ultrasonic waves can be properly focused on both the transmit and receive cycles.⁵ In addition, care must be taken to minimize element interference and “cross talk,” as these factors can degrade image quality. This interference can be both acoustical via surface waves and electrical via electromagnetic interference.^{5,6} Last, properly designed matching layers must be included between the piezoelectric elements used to generate the ultrasound and the lens/distal tip so that the ultrasonic energy can be effectively coupled into the patient for imaging.^{5,7}

Food and Drug Administration Clearance Process for Ultrasound Probes

The entirety of an ultrasound probe is the single most critical component of the diagnostic ultrasound system in developing clinically acceptable ultrasound images. The hardware and software driving the probe are only secondary to the design of a high-quality probe. Furthermore, the probe itself must prove to be safe, eg, have minimal electrical leakage and use biocompatible materials, as both the user and the patient come into contact with various probe components during an ultrasound examination. Additionally, probes are portable, meaning they can be used on multiple in-kind systems. Therefore, the FDA considers diagnostic ultrasound probes to be “finished medical devices”; thus, they are subject to the FDA 510(k) premarket clearance process.² The amount of testing and data necessary for this regulatory submission are quite extensive and are focused on satisfying 2 key components: safety and substantial equivalence (ie, there must be a predicate device on the market), which inferentially relates to the clinical efficacy of the device for its intended use. Those probes and ultrasound systems following the 510(k) track 3 process (also known as the output display standard) must meet specific compliance requirements related to maximum

Table 1. Relevant Safety Standards for FDA Clearance That Are Potentially Affected by Probe Repair

Probe Component	Electrical Safety, IEC 60601-1	Ultrasound-Specific Safety, IEC 60601-2-37	Bio-compatibility, ISO 10993-1, FDA 21 CFR, Part 58	Electrical Leakage, IEC 62353	Acoustic Output, IEC 62359	Disinfection Protocol
Plastic housing	X	X	X	X		X
Lens	X	X	X	X	X	X
Acoustic stack		X			X	
3-dimensional wobbler dome		X	X		X	X
Cable	X	X		X	X	X
Insertion tube (TEE)			X	X		X
Array tip and lens (TEE)		X	X	X	X	X
Bending neck rubber (TEE)			X	X		X
Articulation wires (TEE)						
Shaft plastic (endocavitary)		X	X			X
Thermal shielding		X				
Electromagnetic shielding		X				
Seam line adhesive			X			X
Connector	X	X		X	X	
Thermistor (TEE)					X	
Coupling fluid (3-dimensional wobbler)		X			X	
Coupling fluid (TEE)		X			X	

recommended acoustic outputs.^{2,8–10} Additionally, probes must meet patient contact temperature limits as well as requirements for biocompatibility. Thus, regulatory compliance, the accuracy of the results, and patient safety are all implicated in any substantive changes to these probes. Specifically, any changes in the probe components could potentially affect the results of the testing performed and validated by the OEM, as detailed in Table 1.

For example, the acoustic stack in an ultrasound probe contains an array of piezo-electric elements, which produce the acoustic energy that enters the patient. For a track 3 510(k) submission, the FDA’s maximum recommended level for the derated spatial-peak temporal-average intensity is 720 mW/cm². Replacing the OEM array, which is the active component of the probe, with a non-OEM array in a repair process raises the question of continuing compliance with this FDA acoustic output level. Moreover, other materials used in third-party probe repair processes (eg, those used in the probe housing, insertion tubes [TEE], and acoustic lens replacement) are subject to biocompatibility and electrical leakage testing requirements that may not have been adequately validated or precleared via a successful 510(k) filing.

Illustrative Simulations

Simulation Parameters

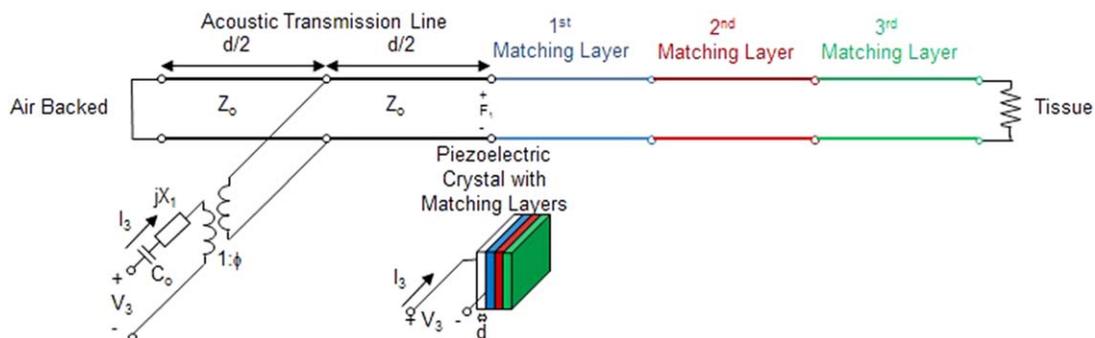
To better understand the potential impact of a poor probe repair on patient safety and image quality, simulations were conducted. For our illustrative example, a basic probe with 3 matching layers was selected to maximize the efficiency of sound transmission from the piezoelectric element to the tissue. The elements were assumed to have air backing to maximize power transmission into the medium and minimize losses in the probe. Other backing materials would have increased acoustic absorption within the probe itself, which could result in more substantial probe heating, particularly if there were errors made in probe repair. Therefore, our case was in some sense a “best-case” scenario for third-party vendors. The ideal impedances and thicknesses of the different layers were determined by binomial multi-section matching and are given in Table 2.^{5,7,11} For the simulations, an operating center frequency of 3.5 MHz was selected, as it is a typical operating frequency for ultrasound imaging probes used in general abdominal, obstetric, and gynecologic imaging. Some deep abdominal probes might operate as low as 2.5 MHz, whereas some specialty probes can operate as high as 15 MHz, but these probes are not as common. The simulations were conducted by using the KLM model for the transducer with the 3 matching layers added, as shown in Figure 3, as it is the simplest model for assessing the transmission through multilayer structures.^{12,13}

In this model, V_3 and I_3 are the respective voltage and current applied to the piezoelectric crystal, which produces the resulting acoustic forces and particle velocities at the faces of the crystal. The model parameters include the thickness of the crystal, d , the area of the

Table 2. Parameters of Matching Layers Used in Simulations

Layer	Acoustic Impedance, MRayl	Speed of Sound, m/s	Thickness, μm
Piezoelectric crystal	35.0	5000	714
Matching layer 1	15.1	5400	385
Matching layer 2	4.29	2800	200
Matching layer 3	1.85	1800	129
Tissue	1.5	1540	Infinite

Figure 3. KLM model with 3 matching layers for our illustrative example.



crystal, A , and the characteristic impedance of the acoustic transmission line (ie, the radiation impedance) modeling the piezoelectric crystal, Z_o . To complete the model, it is also necessary to include a capacitor, C_o , impedance, jX_1 , and a transformer with the ratio $(1:\phi)$ that converts the electrical signal into the appropriate acoustical values. C_o results from the resonator consisting of a dielectric, the piezoelectric crystal, between 2 excited conducting surfaces. The values for these parameters are given by

$$\begin{aligned} Z_o &= \rho c A \\ C_o &= \frac{\epsilon A}{d} \\ X_1 &= \frac{h^2}{\omega^2 Z_o} \sin\left(\frac{\omega \cdot d}{c}\right), \\ \phi &= \frac{\omega Z_o}{2h} \operatorname{cosec}\left(\frac{\omega \cdot d}{2c}\right) \end{aligned} \quad (1)$$

where ϵ is the permittivity of the piezoelectric under no applied voltage; h is the piezoelectric pressure constant for the crystal [$\text{ie}, h = (-\partial T / \partial D)_S$]; ρ is the density; and c is the speed of longitudinal sound waves in the crystal.^{13,14}

With the use of the KLM model, both the transmitted pressure waveform into the tissue and the total power lost in the acoustic stack was calculated, as our “repaired” probes deviated from the ideal case when the probe was excited by a single-cycle pulse at the resonance frequency (3.5 MHz) for V_3 using custom code programmed in MATLAB (The MathWorks Inc, Natick, MA). In all of our simulations, the voltage amplitude of this single-cycle pulse was kept constant. This approach is a simplification of the problem, as changes in the properties of the matching layers could affect this voltage depending on the output impedance of the driving circuitry connected to the probe. However, given the potential for numerous drive configurations, this complication was not included in our illustrative example. To assist in our comparison between the optimal and repaired probes, the pulse duration and peak-peak pressure amplitude values were calculated. For our purpose, we defined the pulse duration as the time beyond which the oscillations were equal to or greater than 10% of the peak value. The pulse duration directly relates to the axial resolution of the imaging system, whereas the peak-peak pressure amplitudes would directly relate to the radiated acoustic power and the sensitivity of the

imaging system. Likewise, the power absorbed by the acoustic stack would be directly related to probe surface heating. The pulse duration, peak-peak pressure amplitude, and total power absorption were then normalized with respect to the quantities when there were no errors in the repair process.

After developing the model, 2 different sets of simulations were conducted. For the first set, it was assumed that the probe repair was conducted with the correct types of materials (same acoustic impedance, speed of sound, and attenuation), but errors were introduced in the thicknesses of the different matching layers. Specifically, the error in each matching layer was varied from -50% to $+50\%$ in steps of 5%, and 2 possible scenarios were evaluated. In the first scenario, the overall thickness of the matching layers was kept constant. Therefore, for this case, if the thickness of the middle layer increased by 50% or 100 μm , then the thickness of the first and third layers decreased by 50 μm each so that the total thickness was maintained at 714 μm . Likewise, if the thickness of the first layer decreased by 50% or 192.5 μm , then the thickness of the second and third layers would both increase by 96.25 μm . This “constant-thickness” scenario would be analogous to a probe repair shop that was able to fit all of the original components into the original packaging so that the probe looked identical to the original OEM probe. For the second scenario, the thickness of each layer was allowed to change without any corresponding change from the other layers. Therefore, a 50% or 100 μm increase in the middle layer would mean that the acoustic stack would now be 100 μm thicker. As a result, these repaired probes would not fit in the original packaging, and a new lens cap would need to be manufactured by the repair house.

For the second set of simulations, it was assumed that the probe repair was conducted with the correct thicknesses, but errors were introduced in the selection of the materials. Specifically, the errors in the acoustic impedance of the materials varied from -50% to $+50\%$ in steps of 5%. These ranges are reasonable for the type of composites typically used for matching layers.¹⁵ In addition, the attenuation for the acoustic stack was varied as 0.25 dB/cm-MHz (lower attenuation for the acoustic stack), 0.75 dB/cm-MHz (original attenuation for the acoustic stack), and 2.25 dB/cm-MHz (higher attenuation for the acoustic stack). These values are typical for materials used in ultrasound probes.^{16,17} To simplify our simulations, the entire acoustic stack was

assumed to have the same attenuation even though the attenuation of the different layers of the probe would vary dramatically.

Simulation Results

The results for the first set of simulations are shown in Figures 4–6. In each of these figures, the horizontal axis is the percent error in the matching layer thickness, whereas the vertical axis is the normalized values for power absorption, the pulse duration, and the output

Figure 4. Normalized power absorption relative to the optimal case as a function of the error in the corresponding matching layer thickness. The results for both constant acoustic stack thickness and variable acoustic stack thickness are shown.

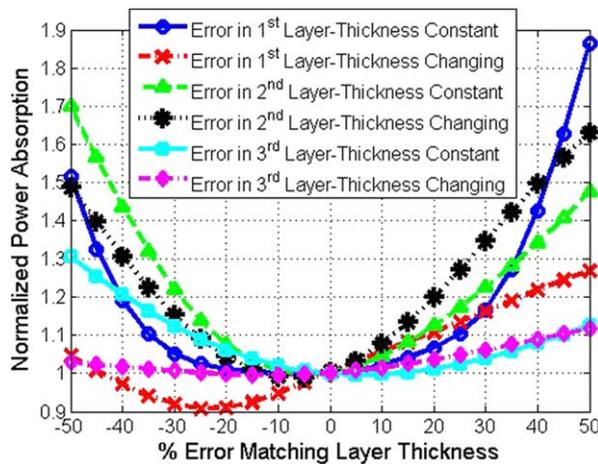
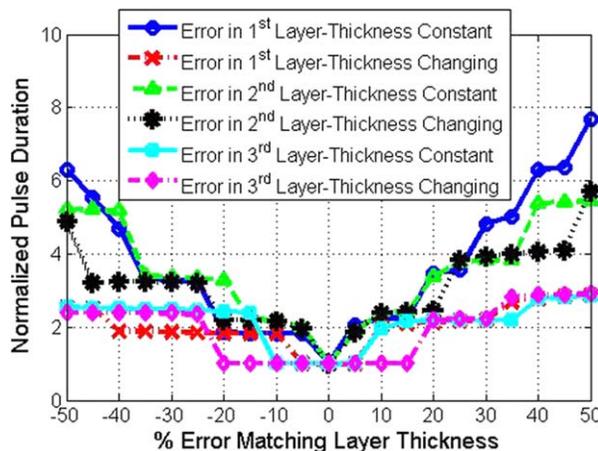


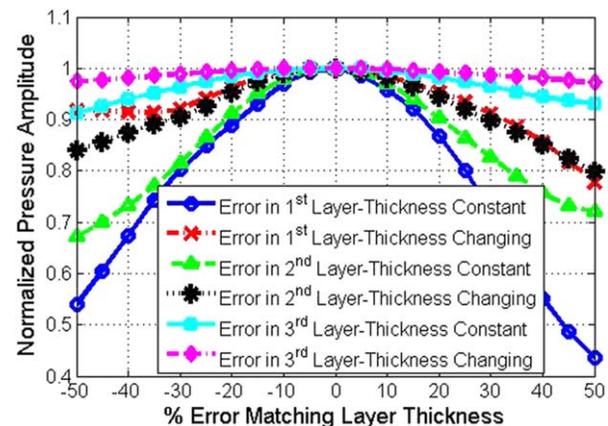
Figure 5. Normalized pulse duration relative to the optimal case as a function of the error in the corresponding matching layer thickness. The results for both constant acoustic stack thickness and variable acoustic stack thickness are shown.



peak-peak pressure amplitude, respectively. The step changes in Figure 5 are expected on the basis of our definition of pulse duration. If you recall, the pulse duration was set as the time during which the amplitude of the pulse was equal to or greater than 10% of its maximum value. Therefore, the pulse duration will jump by approximately half of the wave period as subsequent acoustic cycles increase in amplitude with the degradation of probe performance. From these figures, it is clear that errors in the thickness of the second matching layer consistently result in the largest degradation in probe performance and safety. The degradation that occurs due to errors in the first layer thickness when the overall thickness is kept constant is likely an artifact caused by the constant-thickness constraint due to the change in the second-layer thickness to compensate for the changes in the first-layer thickness. Recall that the constant-thickness scenario required the second and third layers to change along with the first layer so that the overall thickness remained the same.

Focusing on the second layer, errors in layer thickness on the order of 20% to 30% (only 40–60 μm) result in a 20% to 35% increase in power absorption by the matching layer material. Therefore, if under normal conditions a standard imaging probe was warmed from room temperature (≈22°C) to approximately 40°C, the repaired probe could have approximately a 20% to 35% higher increase in temperature, bringing it to approximately 45°C. This temperature is beyond the safety limit and has the potential to burn the patient. In addition,

Figure 6. Normalized peak-peak pressure amplitude relative to the optimal case as a function of the error in the corresponding matching layer thickness. The results for both constant acoustic stack thickness and variable acoustic stack thickness are shown.



errors in the second-layer thickness of 20% to 30% will result in a 4-fold increase in the pulse duration. Since the pulse duration is directly related to the axial resolution in the imaging system, a 4-fold increase in the pulse duration corresponds approximately to 4 times poorer axial resolution for the imaging system. Therefore, the reduction in image quality with errors in probe repair is even more pronounced than the potential safety concerns. Last, there is some decrease in the peak-peak pressure amplitude with errors in layer thickness. Since the peak-peak pressure amplitude values only decrease under the

limitations of the simulation parameters considered in this example, the field values are not anticipated to exceed the FDA level of 720 mW/cm^2 . However, the reduction in pressure amplitudes would mean a loss of sensitivity and a loss of imaging depth for the probe.

The results for the second set of simulations are shown in Figures 7–9. For these results, the thicknesses were assumed to be the same as the optimal probe configuration, but the acoustic impedance of the layers and attenuation of the acoustic stack were varied. From Figure 7, it is clear that changes in the attenuation of the

Figure 7. Normalized power absorption relative to the optimal case as a function of the error in the corresponding matching layer impedance for acoustic stack attenuations of 0.25 (A), 0.75 (B), and 2.25 (C) dB/cm-MHz.

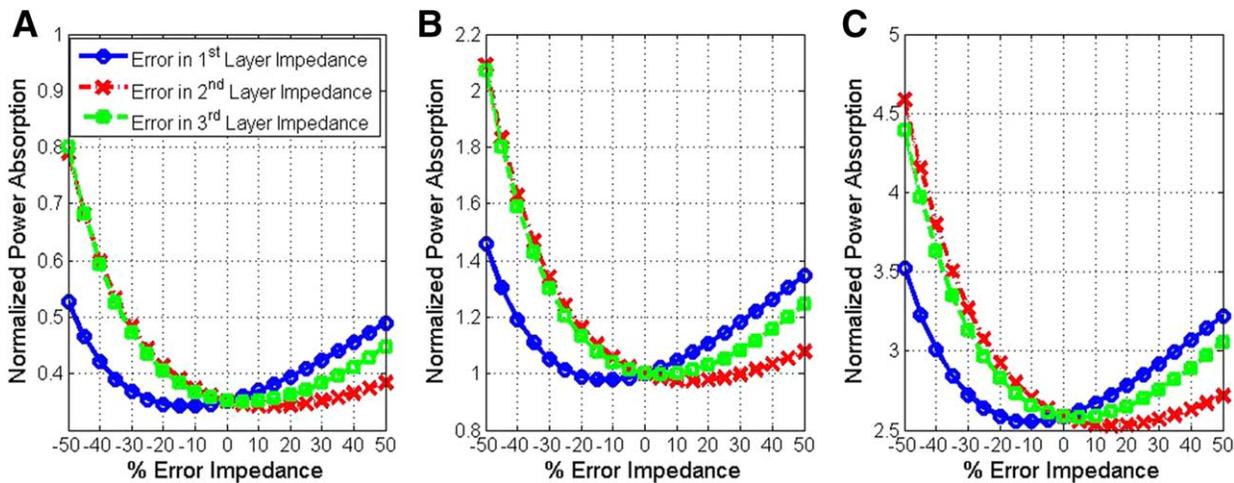
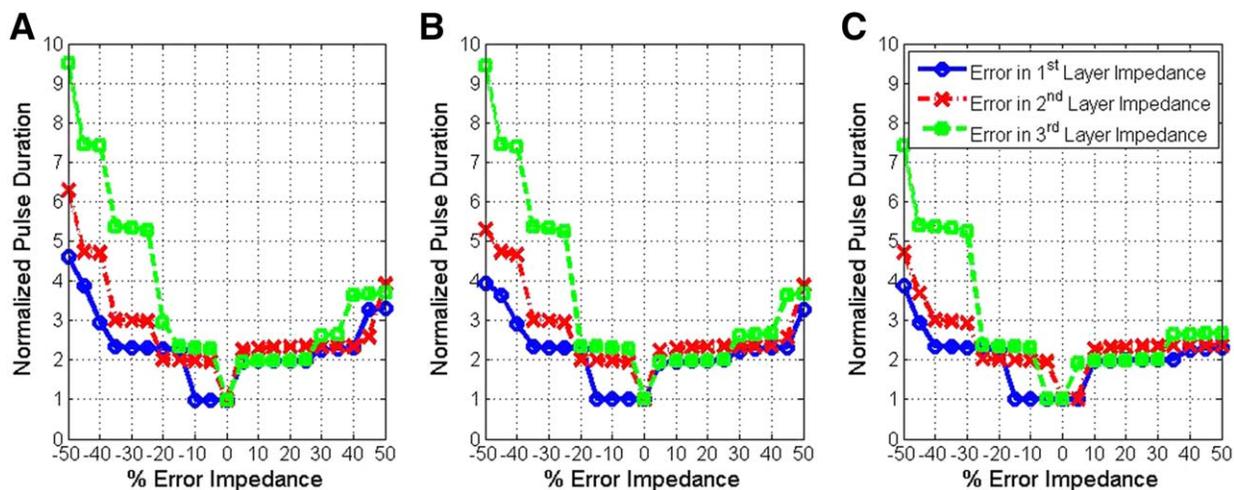


Figure 8. Normalized pulse duration relative to the optimal case as a function of the error in the corresponding matching layer impedance for acoustic stack attenuations of 0.25 (A), 0.75 (B), and 2.25 (C) dB/cm-MHz.



acoustic stack dramatically affect the power absorbed within it; consequently, probe heating as the power is absorbed is 2.5 to 4 times higher for the more-attenuating material. Therefore, if a probe repair facility selects a lossy substitute layer material, probe heating can be dramatically higher than it was in the original OEM configuration. This factor is especially a concern for some epoxy composites, given their higher attenuation values. Errors in matching layer impedance are much less substantial but can still result in dramatically increased heating for large impedance mismatches. For example, a 30% drop in impedance can result in a 30% increase in power absorbed.

Figures 8 and 9 show that changes in attenuation have a relatively minimal impact on the pulse duration and the peak-peak pressure amplitude. Therefore, changes in image quality and sensitivity would not be clearly identifiable if the only deviation in material properties were the attenuation. However, substantial changes in attenuation would likely be accompanied by changes in acoustic impedance, which would result in poor spatial resolution (Figure 8) and a reduction in imaging sensitivity (Figure 9). For example, a 30% drop in impedance would give more than a factor of 5 increase in the pulse duration (Figure 8), resulting in a factor of 5 loss in image resolution as well as a 10% loss in pressure amplitude (Figure 9). The lack of dependence of the peak-peak pressure amplitude on attenuation is likely due to the relative thinness of the layers.

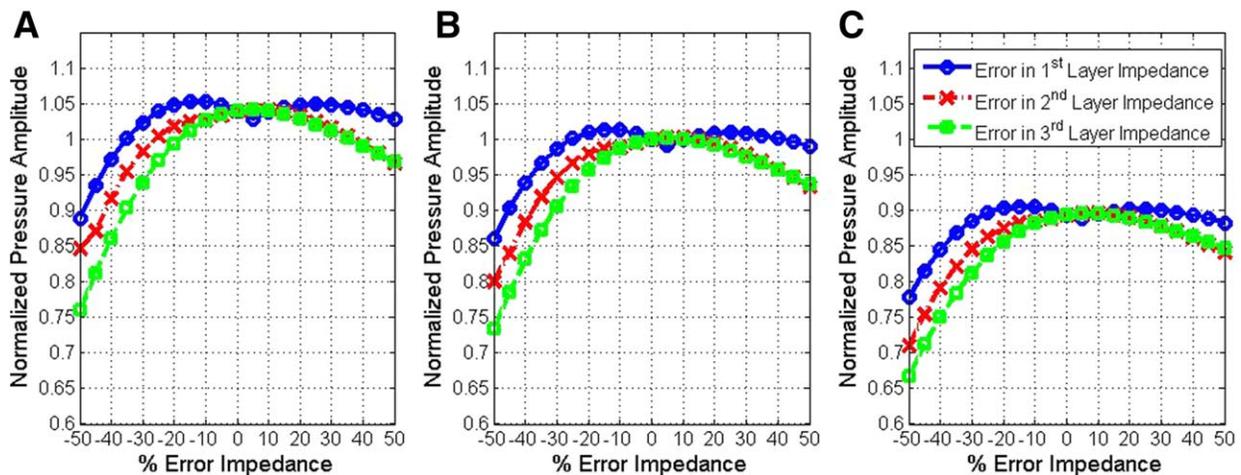
Examples of Poor-Quality Probe Repairs

Now that our simulations have illustrated how relatively small changes in probe construction can have a dramatic impact on ultrasound image quality and probe heating, consider some examples of actual poor-quality probe repairs. To begin, consider a third-party repaired probe in which the OEM acoustic stack was replaced with an array made by a third-party manufacturer. Also, a new transducer housing was used that had no label and, because of improper fit and design, no longer allowed the original biopsy guide to be used (Figure 10). This change could potentially create a substantial hazard to the patient, as a misregistered biopsy guide could result in sampling of the wrong tissue for biopsy, which could result in a wrong diagnosis as well as damage to sensitive tissue structures.

In addition to noting the new housing, the sensitivity of the non-OEM array was assessed with an electronic transducer tester (FirstCall; Acertara Acoustic Laboratories, Longmont, CO), which measured the echo amplitude from a reflecting surface for each element. The results shown in Figure 11 indicate that the sensitivity response was only 63% of that of the OEM array. The sonographers reported that this probe produced non-diagnostic-quality images, and they ceased using it.

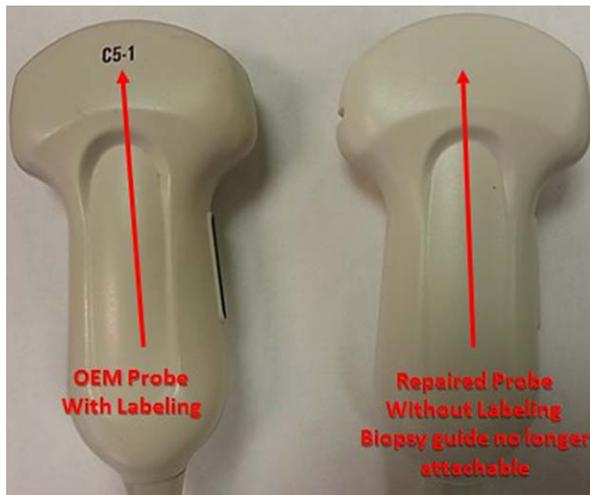
If we compare this reduction in sensitivity with our prior simulations, as well as consider the fact that the

Figure 9. Normalized peak-peak pressure amplitude relative to the optimal case as a function of the error in the corresponding matching layer impedance for acoustic stack attenuations of 0.25 (A), 0.75 (B), and 2.25 (C) dB/cm-MHz.



probe did not fit in the original case, it is very likely that the repaired probe had errors in layer thicknesses of 50% or greater. Therefore, it is likely that in addition to poor sensitivity, this probe would have poor imaging

Figure 10. Original OEM probe next to a poor-quality repaired probe. The repaired probe had only 63% sensitivity relative to the original probe, was not properly labeled, and had a new case that did not allow the biopsy guide to be used.



resolution and a substantially greater risk of probe heating.

Another poorly repaired probe example is shown in Figure 12 for an endocavitary transducer. The white dome (shown on the left) was replaced with a non-OEM part, and the new configuration had dramatically different signal attenuation losses from the original, ranging from 1 dB at 1 MHz to 20 dB at 15 MHz. This non-OEM replacement dome was tested for 1-way transmission loss using time delay spectrometry on an ARTIS time delay spectrometry system (Acertara Acoustic Laboratories)¹⁸ and compared to the transmission loss of an OEM dome. In clinical use, these losses are 2 way, transmit and receive, and substantially affect the clinical utility of the probe, with loss of the depth of penetration. Changes in probe material attenuation (ie, insertion loss) can also result in substantial increases in probe heating, as demonstrated by our simulations.

In addition to the third-party repair company's obvious lack of a quality control system, as demonstrated by a nonvalidated, non-OEM acoustic stack and the presence of probe materials that affect acoustic transmission, poor-quality repairs can also be evidenced by the lack of high-quality workmanship. For example, Figure 13 shows an example of a third-party flex circuit retermination repair at the acoustic stack, where thick solder

Figure 11. Sensitivity comparison of an original OEM probe (A) and a poorly repaired probe (B). Sensitivity is defined as the echo signal amplitude (volts peak-peak) produced by each element in the array for a smooth reflecting interface.

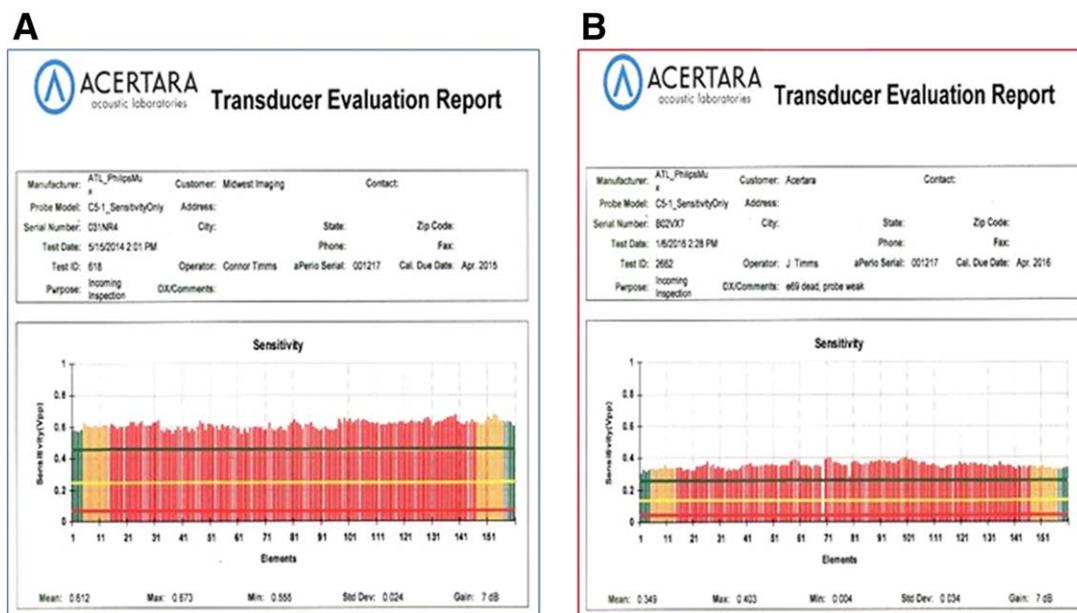


Figure 12. Dome transmission loss comparison between an original OEM probe dome (blue line) and a non-OEM dome used in a repair (red line).

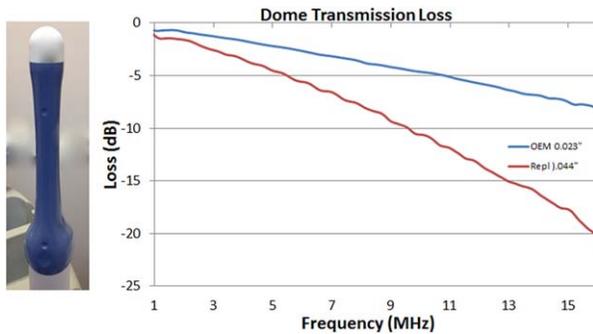
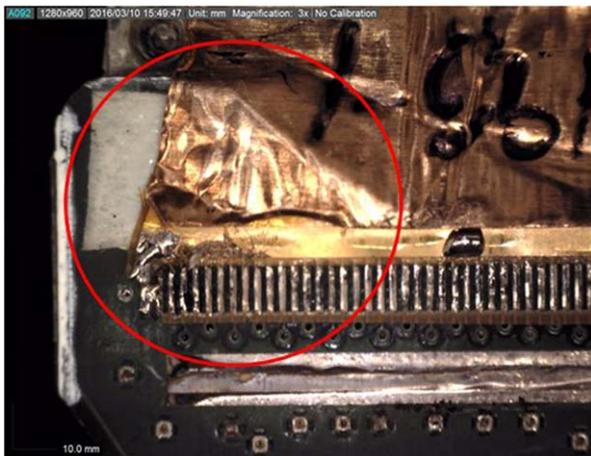


Figure 13. Poor-quality termination repair that resulted in signal dropout and increased speckle noise.



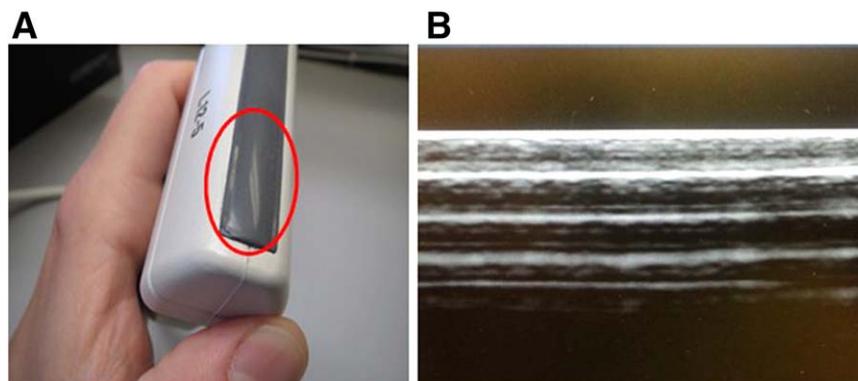
joints and electrical tape are found. When the clinical user received this repaired probe back, signal dropout and speckle noise were immediately noticed in the B-mode image and on color flow Doppler imaging compared to results from an identical OEM transducer. The probe was sent to an acoustics laboratory for forensic evaluation, and tests revealed the very poor retermination attempt.

Figure 14 shows another example of a repaired probe episode, in which material used to form a replacement lens was not evenly layered across the face of the transducer (one end of the lens was more than twice as thick as the opposite side). This repair resulted in a tilt in the image, multiple reverberations (Figure 14B), and unacceptable image quality. Figure 15 shows another example of a 2-dimensional array transducer (X5-1; Philips Healthcare, Bothell, WA), which was returned to Philips because of poor performance. The lens material had been replaced, as had the strain release between the cable and probe, which had cracked. A piece of the handle had also cracked, probably when the nose of the probe was removed during the repair. The nose was also poorly glued back on with a large gap.

Finally, poor-quality repairs are not limited to degradation of imaging performance. For example, Figure 16 shows a TEE probe repaired by using heat shrink material to cover the insertion tube. This material came apart while in use, and fragments were found in the patient's mouth on probe extraction, resulting in a substantial choking hazard to the patient.

Figure 17 shows another example of improper material selection (non-OEM) for the replacement lens of an E8C-RS transvaginal probe (GE Healthcare,

Figure 14. Improper layering of the lens material (A) resulting a tilt in the image, multiple reverberations (B), and unacceptable image quality.



Milwaukee, WI). Because of the validation testing performed by GE, the OEM probe can be safely cleaned with the Trophon disinfection system (Trophon EPR; Nanosonics Ltd, Lane Cove, New South Wales, Australia). However, when the repaired probe with different non-OEM lens material was used, the probe was damaged by the Trophon system. Therefore, a previously approved method of disinfection was no longer valid. Without proper cleansing, the risk of infection from cross contamination is substantial. It is also important to note that both the adhesion epoxies and lens materials require proper curing to be biocompatible. The FDA requires testing on any of these materials that are process dependent to confirm biocompatibility.

Tests of Probes in the Clinical Setting

Given the complexity of ultrasound probes, it is vital to regularly test their imaging performance. This process is especially true after a probe has been repaired. Ultrasound laboratory accreditation programs, such as those of the American College of Radiology and the American Institute of Ultrasound in Medicine, proscribe a quality control program for each scanner associated with the facility. An important component of these programs is routine testing of the scanner using a phantom or test object or, in some cases, thorough preventive maintenance assessments done by engineers affiliated with the scanner manufacturer. Evaluation of each transducer used by the facility is a major part of every testing program. Transducer assessments include visual inspection of the cable, housing, and transducer surface (Figures 14–17), testing for the probe sensitivity usually by a

maximum–depth of visualization experiment using a phantom, and determining whether there are noticeable artifacts caused by dead or malfunctioning elements. Because of their dramatic effect on the B-mode image, dead elements are usually the most prominent ultrasound system faults discovered by clinical personnel in quality control tests.

A simple way to test for dead elements is to scan a uniform region in a tissue-mimicking phantom coupled very uniformly to the ultrasound transducer. For linear array probes, this process is done very easily by using a conventional tissue-mimicking phantom, since most phantoms have flat scanning windows, enabling contact with the entire surface of the transducer. One scans the uniform phantom while looking for “shadows” emanating from the transducer surface (Figure 18). Even minor faults due to one or more dead elements usually can be spotted by creating images in which the speckle signals are smoothed out. An effective way to do this assessment is to record a cine clip while the probe is translated over the phantom (note: the user should turn off image compounding during this test). Visual inspection, or creating either an average image from the clip or, as in the case shown below, a median image helps document the element dropout.¹⁹

Special scanning windows or even scan wells are available on some tissue phantoms to enable the entire scanning surface to be in contact with tissue-mimicking material. Figure 19 shows a median image recorded from a 150-image cine loop for an endocavitary transducer. The phantom was a simple Uniformity TE phantom (Gammex RMI, Middleton, WI) from a manufacturer. Although difficult to spot on clinical

Figure 15. Poor-quality nose removal/reattachment with poor quality strain release.



images, both phantom images vividly show nonuniformities, presumably caused by element dropout.

Conclusions

The technological complexity and clinical utility of ultrasound systems and their attendant probes have dramatically increased over the last decade, providing

amazing insights into disease processes and earlier non-invasive diagnoses. At the same time, cost pressures on medical facilities have placed a premium on finding ways to lower the maintenance and service expenses associated with all medical imaging devices. This situation has led to a rise in the number of third-party repair companies in the United States as well as internationally. On the basis of conversations with OEMs, third-party repair companies, and written information in advertisements,

Figure 16. Use of nonbiocompatible materials on a TEE probe that came apart while in use.



Figure 17. Use of different materials on a transvaginal probe eliminated the approved method of disinfection.



Figure 18. Median image from a cine loop obtained with a linear array transducer scanning a tissue mimicking phantom, showing element dropout (median image created with UltraQ; Cablon Medical, Leusden, the Netherlands).

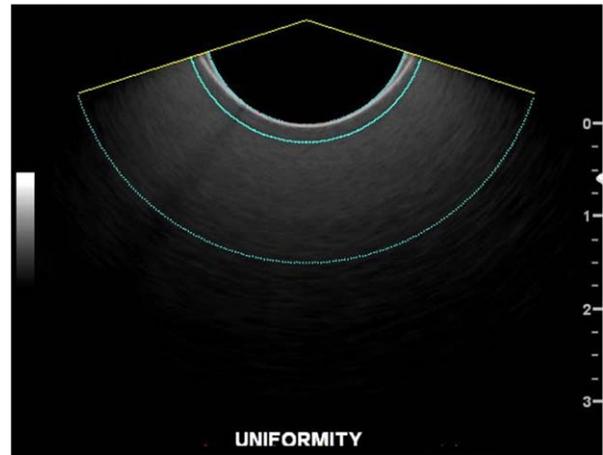
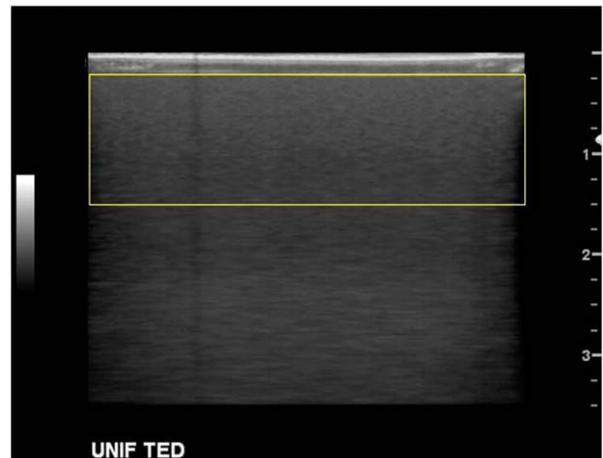


Figure 19. Median image from a cine loop obtained with a curvilinear probe scanning a tissue mimicking phantom, showing element dropout (median image created with UltraQ).



there are approximately 20,000 to 30,000 probes being repaired each year by non-OEM repair entities. Currently, there is no FDA regulatory oversight on the after-market repair of most imaging systems including ultrasound transducers. The transducer is the most sensitive and most often damaged component in the ultrasound image quality chain. Because the sonographer or physician handles the transducer during an ultrasound examination, it is susceptible to all manner of physical damage resulting from accidental dropping, aggressive cleaning methods, and other traumatic occurrences, such as breaking the cable. Furthermore, over time, even the recommended cleaning and disinfecting of the probes can also be potential sources of damage.

However, ultrasound probes are considered finished medical devices by the FDA and require regulatory clearance to be legally sold in the United States. The lack of FDA oversight on the repair of ultrasound transducers has made the use of third-party probe repair companies a risky proposition for medical facilities. By using these repaired probes, the medical facility puts both the patient and user at potential risk in several areas, including electrical shock, cross contamination, and production of sub-optimal clinical images. Ensuring repair efficacy and safety is the responsibility of the medical facility. This responsibility is even more critical when using third-party repair services, as the FDA does not currently regulate these service providers. However, repairs made by OEMs should also be scrutinized for quality assurance. Therefore, we make the following recommendations to protect patients and ensure the best and most-affordable medical care.

Recommendation 1: All ultrasound probe repair entities should be held to the same regulatory and compliance standards as applied to the original equipment. This means that third-party transducer repair facilities should be held to the same regulatory and compliance standards as OEMs. Repair processes, materials used, and components such as acoustic arrays should be tested and validated to demonstrate substantial equivalence to the OEM probe. This testing should be documented and provided to the clinic on return of the repaired probe. If a repaired probe does not meet the imaging standards of the original OEM probe, then the probe should be regarded as not repaired. Paying for a repair that was not properly done only lowers the quality of the medical care while raising the cost.

Recommendation 2: When repairing/replacing probes, select a quality vendor that is ISO certified. For our purposes, the 2 relevant ISO standards are ISO 9001:2008 and ISO 13485:2003.

ISO 9001:2008 establishes the criteria for an overall quality management system. It can be used by any organization, large or small, regardless of its field of activity (eg, from an auto body shop to a zoo). Although this standard does audit many essential aspects of a business operation, it is not in itself enough for medical devices (a regulated industry). For example, a company that is only ISO 9001:2008 certified cannot truthfully claim or even imply that it is ISO certified to repair ultrasound probes or ultrasound systems. This type of claim requires successfully passing one more standard with specific requirements, known historically as the medical device directives involving both the ISO 13485:2003 standard as well as 2007/47/EC. Compliance with these standards is also necessary for European Conformity labeling of products to be sold into the European market.

ISO 13485:2003 specifies those particular requirements for a quality management system in which an organization must demonstrate through objective evidence its ability to provide medical devices and related services that consistently meet both customer and regulatory requirements applicable to medical devices and related services. For example, a company that wishes to claim, and advertise, probe repair in its ISO scope must have passed a detailed ISO 13485:2003 audit in which the auditor is focused on those elements of the quality system and relevant regulatory requirements (eg, International Electrotechnical Commission [IEC] 60601-2-37) related to probe manufacturing and repair. All requirements of ISO 13485:2003 are specific to organizations providing medical devices, regardless of the type or size of the organization.

All issued ISO certificates mentioned above come with the scope of the quality management system and are worded “The quality management system is applicable to,” followed by the various components of the business’s offering that were in fact audited against the standard. Examples are “Design and Development of Processes, Technologies, Fixtures, and Tools Used in the Repair and Refurbishment of Medical Imaging Equipment;” and “Design and Development, Distribution, and Servicing of Test Instruments for Medical Imaging Equipment.” Therefore, ISO certification is not a

“blanket” certification that applies to all aspects of a facility’s business but is specific to the audited components of the business’s offering. Thus, it is critical to obtain a copy of the company’s certification to see exactly what the scope of that certification covers to ensure that it matches what you need.

Recommendation 3: The clinic should track the performance of its ultrasound imaging probes by regularly scanning a tissue-mimicking phantom target. Such scans not only will help show when a probe needs to be repaired but also will allow the clinic to independently determine whether a repaired probe has been returned to a reasonable performance level. The scans should include the following:

1. Assessment of imaging element dropout by recording a cine loop as the probe is translated over a homogeneous region of the tissue mimicking phantom;
2. Assessment of imaging resolution by scanning a phantom with wire targets of varying separation and noting the wire separation that can be distinguished on the B-mode image; and
3. Assessment of measurement accuracy by scanning a phantom with either wire targets of known separation or spherical occlusions of known size and measuring the distances in the B-mode images.

Also, if a repaired probe is to be used with a biopsy guide, the performance of the guide should be verified by using an ultrasound biopsy phantom before use on patients.

References

1. Powis RL, Moore GW. The silent revolution: catching up with the contemporary composite transducer. *J Diagn Med Sonogr* 2004; 20: 395–405.
2. US Food and Drug Administration. *Guidance for Industry and FDA Staff: Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers*. Silver Spring, MD: US Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health; 2008.
3. Schafer ME, Lewin PA. A computerized system for measuring the acoustic output from diagnostic ultrasound equipment. *IEEE Trans Ultrason Ferroelectr Freq Control* 1988; 35:102–109.
4. Levy PY, Teyssere N, Etienne J, Raoult D. A nosocomial outbreak of *Legionella pneumophila* caused by contaminated transesophageal echocardiography probes. *Infect Control Hosp Epidemiol* 2003; 24:619–622.
5. Cobbold RSC. *Foundations of Biomedical Ultrasound*. New York, NY: Oxford University Press; 2007.
6. Delannoy B, Bruneel C, Haine F, Torguet R. Anomalous behavior in the radiation pattern of piezoelectric transducers induced by parasitic Lamb wave generation. *J Appl Phys* 1980; 51:3942–3948.
7. Desilets CS, Fraser JD, Kino GS. The design of efficient broad-band piezoelectric transducers. *IEEE Trans Sonics Ultrason* 1978; 25:115–125.
8. American Institute of Ultrasound in Medicine, National Electrical Manufacturers Association. *UD 2-2004 (R2009): Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment*. Rev 3. Laurel, MD: American Institute of Ultrasound in Medicine; Rosslyn, VA: National Electrical Manufacturers Association; 2009.
9. International Electrotechnical Commission. *Medical Electrical Equipment—Part 2-37: Particular Requirements for the Basic Safety and Essential Performance of Ultrasonic Medical Diagnostic and Monitoring Equipment*. Geneva, Switzerland: International Electrotechnical Commission; 2015. IEC 60601-2-37, ed 2.1.2015-06.
10. International Electrotechnical Commission. *Ultrasonics—Field Characterization: Test Methods for the Determination of Thermal and Mechanical Indices Related to Medical Diagnostic Ultrasonic Fields*. Geneva, Switzerland: International Electrotechnical Commission; 2010. IEC 62359, ed 2.2010.
11. Pozar DM. *Microwave Engineering*. 2nd ed. New York, NY: John Wiley & Sons; 1998.
12. Cobbold RSC. Ultrasound transducers. In: *Foundations of Biomedical Ultrasound*. New York, NY: Oxford University Press; 2007:329–412.
13. Krimholtz R, Leedom DA, Matthaei GL. New equivalent circuits for elementary piezoelectric transducers. *Electron Lett* 1970; 6:398–399.
14. Berlincourt DA, Curran DR, Jaffe H. Piezoelectric and piezomagnetic materials and their function in transducers. In: Mason WP (ed). *Physical Acoustics: Principles and Methods*. New York, NY: Academic Press; 1964:170–270.
15. Beerman HP. Optimizing matching layers for a three-section broad-band piezoelectric PZT-5A transducer operating into water. *IEEE Trans Sonics Ultrason* 1981; 28:52–53.
16. Biwa S, Idekoba S, Ohno N. Wave attenuation in particulate polymer composites: independent scattering/absorption analysis and comparison to measurements. *Mech Mater* 2002; 34:671–682.
17. Jen, C.-K., Chung CJ, Shapiro G, Monchalin JP, Langlois P, Bussiere JF. Acoustic characterization of poling effects in PZT ceramics. *J Am Ceramic Soc* 1987; 70:C–256–C–259.
18. Pederson PC, Lewin PA, Bjorno L. Application of time-delay spectrometry for calibration of ultrasonic transducers. *IEEE Trans Ultrason Ferroelectr Freq Control* 1988; 35:185–205.
19. International Electrotechnical Commission. *Ultrasonics—Pulse-Echo Scanners: Simple Methods for Periodic Testing to Verify Stability of an Imaging System’s Elementary Performance*. Geneva, Switzerland: International Electrotechnical Commission; 2016. IEC TS 62736.