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# **Ensuring Clinical Efficacy and Patient Safety The Case for Evidence-Based Ultrasound QA**

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## **Background:**

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 materials and methods of construction have significantly enhanced the sensitivity and bandwidth of the transducers (probes) used with the ultrasound mainframes. Consequently the breadth of usage for diagnostic ultrasound in ever more complicated clinical circumstances is well documented in the literature. Further, clinicians now partly rely on the ultrasound results to direct treatment and manage patients with higher levels of quantification. Unfortunately, the level of “in-practice” ultrasound quality assurance has not kept pace with the diffusion of this sophisticated and much relied upon imaging and Doppler technology. Because ultrasound is being used in so many diverse clinical applications and relied upon to provide quantitative data the need for evidence-based quality assurance for these devices has become apparent. Previous methods of in-practice quality assurance (QA) for ultrasound systems, if an in-practice program existed at all, have mainly consisted of using tissue-mimicking phantoms to subjectively evaluate image quality, and in some very limited circumstances the use of Doppler flow phantoms, used to validate the flow velocity accuracy of any given system. Although somewhat useful as quality and training tools both imaging and Doppler phantoms are often very subjective in nature, cannot be used to differentiate between a system problem and a transducer problem, can be difficult to use and generate results that can vary in consistency over time. These limitations, coupled with the increased technological sophistication of the ultrasound systems and probes have led to the design and development of new ultrasound test devices that directly measure the performance of probes and systems in a quantitative and repeatable fashion and can be used on a daily basis within a clinical environment.<sup>1</sup>

This White Paper will describe the key issues surrounding the need for diagnostic ultrasound quality control in the clinical environment and make recommendations relative to the successful development and implementation of a modern, hospital centered evidence-based quality assurance program including the required test tools.

## Introduction:

Due in part to the non-ionizing radiation characteristics of ultrasound there has been a long held belief within the medical imaging community that ultrasound is, by definition, safe for the patient. Potential patient safety issues related to bio-effects such as cavitation and localized thermal rises in soft tissue associated with the use of diagnostic ultrasound are well documented in the literature<sup>2</sup>. For systems sold in the United States these two indices are displayed on the ultrasound systems monitor as **MI** (mechanical index, related to cavitation) and **TI** (thermal index, related to localized heating) and the amount allowed for MI must be constrained within a range specified by the United States Food and Drug Administration (FDA)<sup>3</sup>. Other regulated safety parameters related to the use of ultrasound have to do with the biocompatibility of the patient contact materials (e.g., the lens material on a standard probe or the insertion tube material used with a transesophageal probe), temperature limits at the aperture of the transducer and with the amount of allowable electrical leakage<sup>4</sup>. Before a diagnostic ultrasound system can be legally sold in the United States, for human use, it must clear the FDA's 510(k) process<sup>5</sup>. The amount of testing and data necessary for this regulatory submission are quite extensive and are focused on satisfying two key components: the safety and equivalence (there must be a predicate device on the market) which inferentially relates to the clinical efficacy of the device. While there are numerous quality control (QC) requirements placed on the manufacturer during the design and prior to the commercial release of the product there are virtually no quality assurance (QA) requirements once the product is in the clinical setting<sup>6</sup>. And while a good deal of attention has been paid to the pre-market safety requirements mentioned above, there has been scant attention paid to post-installation clinical efficacy issues or potential safety issues beyond the very narrow scope of MI, TI, leakage current and biocompatibility.

## Ultrasound Quality Assurance

The ultrasound clinical literature is replete with new, expanded and quantitative uses for diagnostic ultrasound. In some circumstances these quantitative uses have obviated the need for more invasive testing (e.g., echocardiography in lieu of cardiac catheterization), along with the morbidity and mortality risks associated with those tests. With these new clinical uses the need to ensure the proper operation of both the transducer (probe) and the ultrasound system has become pronounced. Published papers in this regard have shown that even subtle changes in transducer performance can potentially have a negative impact on the clinical efficacy of the ultrasound examination<sup>7</sup>. These changes may not be readily apparent to the human eye when the ultrasound examination is being performed, providing no indication to the sonographer or reading physician that the clinical data they are generating or reviewing may be compromised. For example, it has been demonstrated that as few as two consecutive dead elements within an array of 128 elements can materially impact the Doppler study results<sup>8, 9</sup>. In the clinical circumstance where the peak velocity of the Doppler signal is used to determine a pressure gradient across a stenotic valve an error in that peak velocity reading can cause a substantial miscalculation of the pressure gradient. For example, the modified Bernoulli equation for determining the pressure drop across a heart valve is  $4V^2$ , where V is the peak velocity as measured in the Doppler mode<sup>10</sup>. This would mean that a peak velocity reading of 4 meters per second would translate to a pressure gradient of 64mmHg ( $4 \times 4^2$ ). If, because of a transducer problem, the velocity reading were only 3.2m/sec (a 20% variance) the squaring error in the calculation would result in a gradient measurement of 41mmHg instead of the actual 64mmHg, a clinically significant variance that may alter the course of this patient's management. Although a faulty transducer is the most likely cause for error in this circumstance the ultrasound system too can have either a failure mode that impacts velocity readings<sup>11</sup>, or have a software bug which causes erroneous readings (which ultimately leads to a product recall)<sup>12</sup>.

In the hypothetical case above the lower than actual pressure gradient measurement may not be consistent with either the patient's symptoms or other clinical findings. When an echocardiography study is equivocal, such as the case above, the physician may refer the

patient on to a cardiac catheterization. Referring the patient on to a cardiac catheterization would have the impact of both raising the cost of diagnosis as well as needlessly subjecting the patient to an invasive modality with known morbidity and mortality risks, the most serious complications of which include stroke and myocardial infarction. Other complications include cardiac arrhythmias, pericardial tamponade, vessel injury, and renal failure<sup>13</sup>. In short, the diagnostic process is designed in such a manner that the patient is escalated through higher levels of potential risk (and expense) until a definitive diagnosis is made. It is, therefore, clear that the risk associated with the use of ultrasound should also include the real possibility that using undetected faulty equipment may expose the patient to harm or, at a minimum, unnecessary worry and expense.

### **Ultrasound Quality Assurance Technical Challenges**

The design characteristics of modern broadband high-element count transducers and technologically intensive ultrasound mainframes have significantly reduced the role of tissue mimicking phantoms (TMP) as ultrasound quality assurance tools<sup>14, 15</sup>. For example, with transducer element counts as high as 288 (or more in 1.5d and 2d arrays) in some linear arrays the ability to visualize the effects of a single or in some cases even multiple dead or weak elements in a transducer array on a TMP is simply not possible, even with computer aided visualization software<sup>16</sup>. Therefore a more effective, evidence-based method is required to detect element damage in an array before it has the chance to compromise a patient study. One commercially available product capable of directly interrogating each element within an array is the FirstCall device<sup>17</sup>. This device transmits an electrical pulse similar to that produced by an ultrasound system, receives the returning signal and then records the response of each element as shown in **Figure 1**.

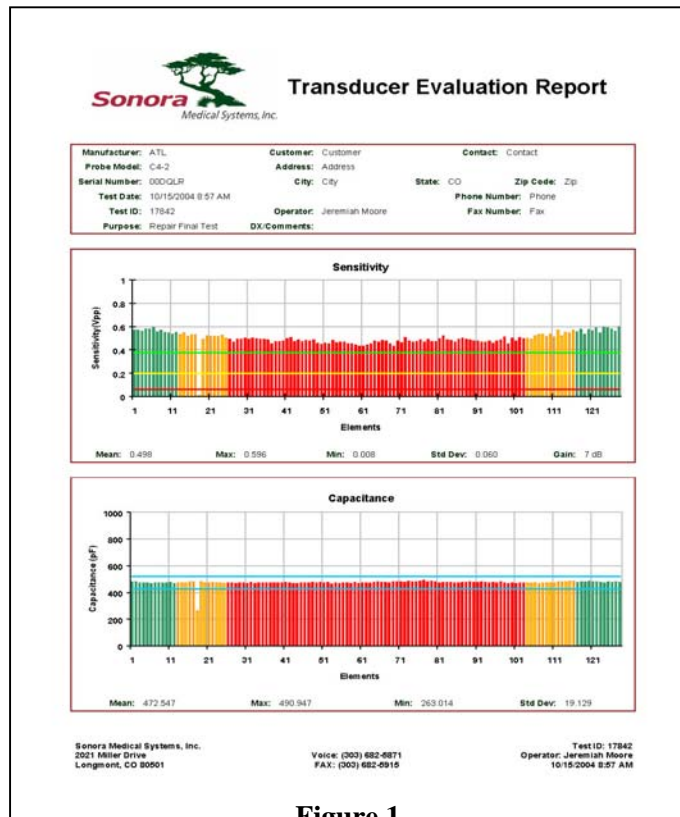


Figure 1

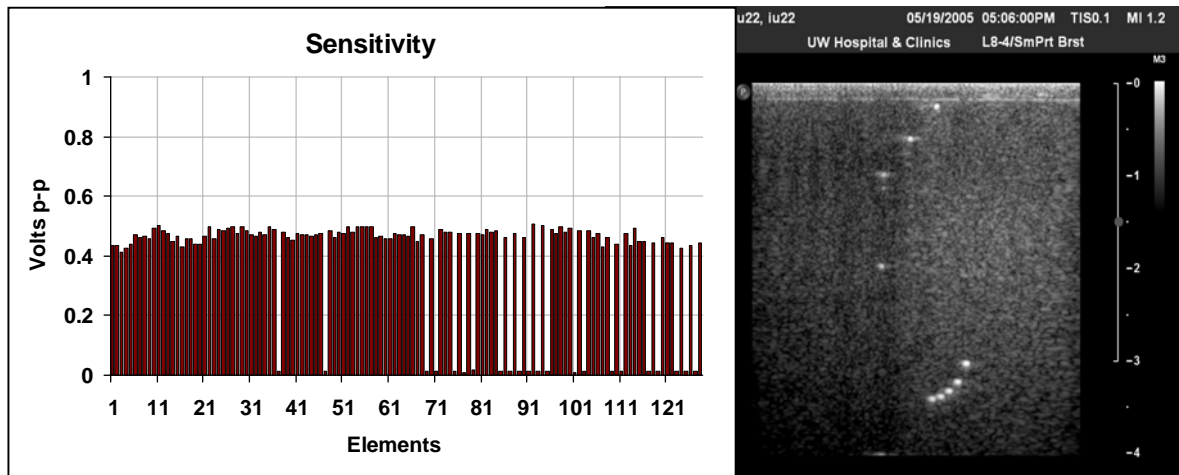
Recently published data from one major hospital in the United States showed that of 57 probes tested with the FirstCall device 14 probes were found with more than 2 dead elements and 7 had more than 5 dead elements or roughly 25% of the probes that were being used on a daily basis<sup>18</sup>. Another published paper indicates that as many as 25% of **all** ultrasound transducers currently in clinical use may have some form of undiagnosed performance-inhibiting or structural problem<sup>19</sup>.

A proposed rationale for a comprehensive ultrasound QA/QC program was recently introduced by E. Boote, PhD, et al.<sup>20</sup> In this published work his group outlined the following as several reasons for such a program:

- 1) Probe Acceptance Testing
  - a) Matching to Vendor Specifications
  - b) Matching to Purchasing Specifications
  - c) Establishing Acceptance Criteria
- 2) On-going Quality Control via regular scheduled testing
- 3) Problem solving – As noted by operators (sonographer or physician)

Probe acceptance testing is a key component of a comprehensive ultrasound QA program in that some ultrasound original equipment manufacturers (OEMs) ship probes with known dead elements without revealing that fact to buyers<sup>21</sup>. The primary motivation for shipping probes with dead elements is articulated in a United States Patent “...where the ability to improve the performance of the probe in the presence of dead or weak elements may lead to an increased yield and lower cost during the production cycle.” OEM’s acknowledge that dead elements impact the clinical performance “...the effect of dead elements on the image quality can be significant, particularly in the near field of the image where a fewer number of elements are used to form the beam. In this case a dead or weak element becomes a significant part of the aperture used to create the image, resulting in an intensity loss at the acoustic line in question”<sup>22</sup>. Recognizing the clinical importance of a fully functional probe the ability to independently test each element within the array before the transducer is placed into clinical service becomes self-evident. And if a transducer is received from the OEM with dead elements, the biomedical engineer or medical physicist should reject that probe in favor of one with no dead elements. The ability to test probes at the element level puts the hospital in control when establishing acceptance criteria for these probes as suggested by Dr. Boote, cited above. This incoming acceptance process will also serve to mitigate any legal exposure to the hospital relative to using sub-optimal devices. Dr. Boote went on to say that once the probe is accepted into clinical use a “...routine QA program will baseline acceptance data for comparison.” This on-going testing is important as it is known that even electronic array transducers have a finite life and degrade (i.e., lose sensitivity) as a function of use. One primary driver of the life expectancy of an ultrasound transducer is heating of the array elements, this occurs when the probe is in use due to the driving pulse from the system. As Shirasaka, et al put it, “The more the elements are heated (i.e., the more they are in use), the shorter the lifetime of the transducers”<sup>23</sup>. Therefore a well-established evidence-based ultrasound QA program would include appropriate transducer testing intervals predicated, in part, on the frequency of use of any given transducer to insure its performance is at clinical expectation. Dr. Boote commented that by doing this you can, “...instill confidence in imaging devices and uncover problems before they are clinically obvious.”<sup>24</sup> **Figure 2** demonstrates an example of a probe that was in clinical use, but was discovered by the FirstCall device to have

multiple dead elements. The tester concluded that the sonographer using a spatial compounding algorithm resident within the system may have “...hidden the flaws during clinical work”<sup>25</sup>.



**Figure 2**  
**FirstCall Test**  
**Showing Multiple Dead Elements**

At a Poster presentation given at the 2005 Radiological Society of North American (RSNA) meeting, Z F Lu, PhD, et al.<sup>26</sup> looked carefully at the various methods and tools of ultrasound QA and said this about the FirstCall device “...because the transducer is separated from the ultrasound scanner for a direct element-by-element evaluation, the device is much more efficient in identifying defects in transducers than phantom testing.” So, although there have been some related historical technical challenges to establishing an evidence-based ultrasound QA (EBQA) program within the hospital there are currently commercially available quantitative testing tools that address many of those issues.

In addition to the patient safety and clinical efficacy issues outlined previously there are also several other important business, legal and logistical reasons for establishing an ultrasound EBQA program within a hospital, and for having an appropriately trained and qualified individual in charge and accountable for its implementation and success.

## Misbranding and Counterfeit Medical Ultrasound Devices

In the diagnostic ultrasound market, as with many other markets, there are non-OEM companies that are manufacturing counterfeit replacement parts. As health care professionals try to reduce their costs of operations they often turn to alternate markets for replacement parts (sometimes described as the “after-market”). While there are many reputable after-market parts and service providers, there are also, unfortunately, some that may not be quite so reputable. In an attempt to fool the buyer counterfeit parts are designed to look and feel very similar to the original product. Often these counterfeit parts either have “look-alike” OEM labels, altered OEM labels or no labeling at all, see **Photo 1**. One of the most visible (and sometimes not so visible) counterfeit parts sold into the ultrasound market is the transducer. Companies that produce these counterfeit probes often go to great lengths to insure that the look and feel of the outside of the probe is as close to the OEM’s as possible. It is obviously important for the clinical user to know that the probe they are using is an OEM probe or an FDA cleared replacement probe. Counterfeit probes may not perform within the acoustic output power limits and other safety guidelines established by the FDA. Knowingly using probes that may be out of compliance with regulatory agency requirements could put both the hospital and patient at undue risk, both from a legal and clinical perspective. At our probe analysis and repair facility we have seen many counterfeit probes and adulterated “repairs” and have conducted extensive acoustic testing on these products to determine how they compare with an in-kind OEM probe. We have also identified several techniques to readily, and quantitatively determine if a probe is either a counterfeit or has undergone an adulterated acoustic array replacement. We have concluded that there can be significant performance variances between counterfeit probes and OEM probes as well as OEM probes that have had an acoustic stack replacement with a non-OEM array. To limit the exposure of health care professionals purchasing and using such products a comprehensive counterfeit probe detection and testing device has been designed and now exists for use at the point of exchange, at the time of exchange, or for pre-purchase assessment.<sup>27</sup>



**Photo 1**  
Counterfeit Probe at Left

At a July, 2003 presentation to the National Electrical Manufacturers Association (NEMA) Michele Forzley, JD, MPH stated that counterfeit medical device represents “...an unrecognized public health problem with particular consequences in the area of injury, mortality and morbidity.”<sup>28</sup> A robust and vigilant EBQA program within a hospital can significantly reduce the possibility of introducing an adulterated or counterfeit product into patient care, thereby limiting patient risk as well as the legal liability to the hospital.

## Medico/Legal

In every clinical application where imaging or Doppler, or one of their derivative modalities is used in a quantitative manner the clinician should have a reasonable expectation that the data derived using the ultrasound system is accurate within the published specifications for the device. In general the absence of a well-defined EBQA this may not be the case, and in the absence of an EBQA process it will continue to not be the case. One can ask the question “Would you use a probe on a patient if you knew it was defective?” the answer of course is no. The follow-up question would then be “Then why would you use a probe on a patient without knowing if it was defective?”

A general search of the literature finds that historically most clinical ultrasound litigation has been related to obstetrics. However with the expanded use of ultrasound into more and more complex clinical situations with increased risk of an adverse event it seems reasonable to predict that it is only a matter of time before some form of legal action, whether meritorious or not, is brought against a hospital, involved individuals (e.g., sonographer) or imaging center on behalf of an injured patient for failure to implement reasonable EBQA processes. For example the recent adoption and growing popularity of using of imaging contrast media into ultrasound has given rise to new safety concerns relative to the destruction of micro-bubbles using ultrasound and the potential effects related to immediate rupture of micro-vessels.<sup>29</sup>

Unfortunate as it can sometimes be once litigation begins the discovery process will certainly uncover what processes and procedures are in place in the hospital to insure the proper operation of all the devices in question. Obviously the best defense in this regard is to be proactive and have a strong EBQA program that documents, objectively, that equipment is being tested on a reasonable and periodic basis and only used if it meets OEM specifications. Having a system under a service contract with the OEM may not be an affirmative defense for not having an in-house EBQA program. The only certainty in this regard is that the OEM will also be named in the litigation.

## **Preventative Maintenance is not Quality Assurance: QA ≠ PM ≠ QC**

System manufacturers often provide preventative maintenance (PM) calls on systems under warranty or under service contract. However it should be remembered that a PM is normally not a quality control audit, nor is it a system or a transducer calibration process. In fact many OEM PM's procedures that I have reviewed are limited in scope to what they actually test on the system and probe, usually consisting of checking error fault logs in the system diagnostics, cleaning fan filters, checking various power supply voltages, sometimes using a phantom to look at images (although this is increasingly rare), talking to the sonographer and sometimes the physician to see how things are going with the system, any problems, etc., cleaning the keyboard and probes and lastly visually inspecting for obvious physical damage to the system, peripheral devices (color printers, etc) and probes. If an institution is intending to rely upon the ultrasound manufacturer to provide periodic performance guarantees then it would be well advised to fully understand exactly what is being provided and what the differences between the OEM PM and an industry accepted QA audit are, and have complete documentation from the OEM after each PM or QA audit.

## Software Upgrades

When an OEM performs a software upgrade (or simply a software change) on the ultrasound system the question that must be asked is which person within the hospital is responsible to insure that the software change did not impact some performance characteristic or basic operation of the system not identified within the scope of the actual software upgrade?

As with any software change, in medical products or other products, software changes can come with unidentified bugs, or “clean ups” that were not well documented in the release. Some of these bugs could include a direct patient safety issue<sup>30, 31</sup> others may have slightly changed the behavior of an automated function (e.g., auto-populating the report page). The potential for a lawsuit against the hospital for committing a secondary error based in part on an unrecognized change in the system is real.<sup>32</sup> There have also been errors in the ultrasound measurement software that led to recall notices.<sup>33</sup> It has also been reported that a software “upgrade” performed on an ultrasound scanner to correct some “bug” issues, etc also introduced (quite unintentionally I’m sure) a degradation in B-mode image quality – degraded to the level that the customer actually asked the OEM to de-upgrade their system<sup>34</sup>.

The point is that someone within the hospital should be functionally responsible for ensuring software upgrades do not impact the pre-upgrade work-flow of the sonographer, compromise image or Doppler quality, or introduce a “bug” that impacts patient reports or on-board calculations. Never assume the OEM field service engineer installing the upgrade has complete knowledge of the upgrade or its impact on any of the above variables.

## Operational Expense: Top-Line and Bottom-Line

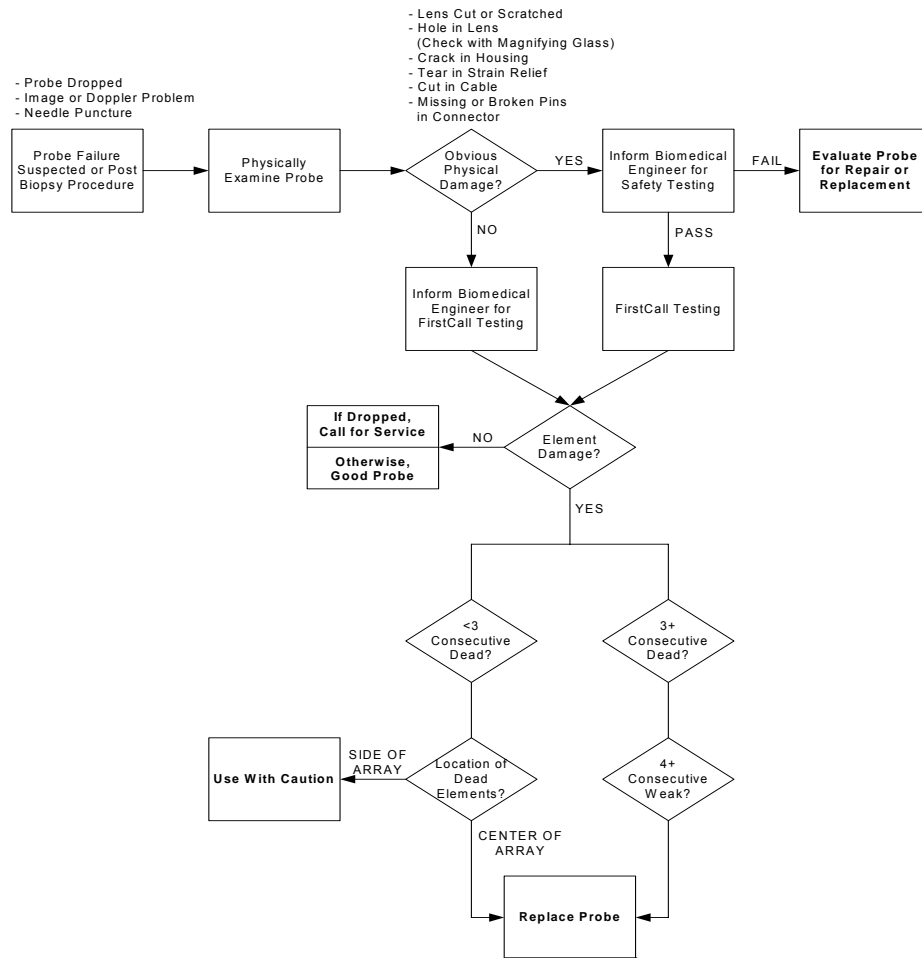
The transducer is the most sensitive and most often damaged link in the ultrasound image quality chain. Because the sonographer or physician handles the transducer during the ultrasound examination, it is susceptible to all manner of physical damage resulting from accidental dropping, aggressive cleaning methods, or other traumatic occurrences such as banging. Many antiseptic solutions, and even seemingly innocuous “perfumed” coupling gels, can have a negative long-term impact on both the acoustic lens bonding of a transducer, which can cause either lens de-lamination or material decomposition, and the actual molecular composition of the lens itself, resulting in a change in its’ acoustic transmission and reception characteristics. The end result of either occurrence is a shorter transducer life. In our experience, high-use ultrasound transducers often display some form of performance compromising anomaly within 18 to 24 months after being placed into service. During the ten-year (120 months) operational life span of a premium quality ultrasound system, a transducer could potentially be replaced up to five times, simply due to “normal” use. At an average cost of ~ \$10,000 per transducer, the financial impact of replacing transducers to the hospital or clinic becomes quite apparent. An active and comprehensive ultrasound EBQA program can potentially lower costs, substantially, for hospitals by identifying probes **early** enough in the failure process that they can be repaired rather than replaced. For example, a new transesophageal (TE) probe can cost as much as \$40,000 or more and a replacement (meaning the damaged one is exchanged for another one) TE probe normally costs as much as \$24,000 from the OEM. If the TE probe is damaged and the damage discovered in time so that it is repairable, the repair cost is normally 25% or less than the cost of replacement, or \$6,000. Over the ten-year lifespan of the ultrasound system in this scenario it would mean the difference between \$120,000 in replacement costs versus \$30,000 in repair costs, or a difference of \$90,000 for one probe alone. That \$90,000 comes directly off the bottom-line of the hospital’s profit. For a hospital operating on a 4% margin that would mean an additional \$2,250,000 of top-line billings would have been required to generate that \$90,000. And that is for one probe. Typically a hospital with a cardiac surgical service would have multiple TE probes thereby compounding the financial impact.

## An EBQA Environment

Quality assurance for the complete sonograph (transducer and signal processor) historically relied upon a tool such as a tissue-mimicking phantom (TMP) with a known set of targets available to test overall system performance. The testing protocol generally included: detail resolution (axial and lateral) (also known as the point spread function), contrast resolution, sensitivity, dynamic range and temporal resolution (e.g., frame rates, temporal filters, persistence, and compounding multiple frame averaging). All of these tests, however, assume the transducer to be working correctly and they don't address Doppler performance. There has been no easy way of moving from subjective image quality analysis to a detailed evaluation of the transducer. That requires a different tool, specifically FirstCall.

As was discussed briefly earlier in this paper it is important to understand that Quality Assurance, Quality Control and Preventative Maintenance are often interchanged words, but are not functionally the same. PM may include cleaning and inspection but often does not include detailed QA or QC testing. A manufacturer (OEM) may not move from its standard PM program until the user complains about a reduction in image or Doppler quality or if there is a functional failure. In the process of developing, manufacturing, and using technology, two opportunities for quality assessment occur: 1) testing specific components of a technological ensemble such as a scanhead assembly during manufacturing; and 2) testing an integrated subsystem or the wholly integrated system such as a complete sonograph in clinical use. Testing modular components or an entire ultrasound system represents a *Quality Assurance* (QA) program. Thus, an ultrasound QA program is a protocol of tests designed to ensure that the system and probes are working to expected clinical specifications. In contrast, a *Quality Control* (QC) program focuses on ensuring that the system and its transducers meet manufacturing specifications. QC is a set of rules different from testing a system in a clinical setting, which is QA. For example **Figure 3** depicts a flow chart that indicates when to call in the Biomedical Engineer to execute a detailed test of a suspected transducer. The branching points are all binary (yes or no, pass or fail, etc.).

Transducer testing begins with a visual inspection of the probe contact or wear-surface. As the name implies, frequent use can wear or damage this surface, permitting caustic fluids, gels, or microorganisms admittance to the inner portions of the transducer. A simple magnifying glass is needed for this inspection.



**Figure 3**

## **Who should be in Charge of the QA Program?**

It is recommended that clinical facilities appoint an individual to be responsible (establish accountability trail) for the program. If a medical physicist, clinical engineer or biomedical engineer is available, this individual is usually trained in general QA techniques and could successfully organize and maintain the program. Some QA procedures are those that are routinely carried as good clinical ultrasound practice; for example, inspection of transducers for cracks or taking steps for proper cleaning. Furthermore, sonographers usually are more familiar with complex ultrasound equipment and how to set it up properly for scanning. Therefore, physicists or engineers must work closely with clinical personnel in running a program, and a partnership between a designated QA sonographer is recommended.

Many facilities do not have a medical physicist, clinical engineer or biomedical engineer available to do ultrasound QA procedures. In this circumstance a sonographer is usually designated to organize and run the program.

## Conclusion

For any published ultrasound product specification there is an implication that the specification is relevant to some function in the system that ultimately leads to some demonstrable end-user (e.g., ergonomic) or clinical (e.g., the ability to see disease process earlier) benefit. For example the iU22 general imaging system from Philips/ATL specifies a front-end dynamic range of 180dB. The question is, specifically, which ultrasound modality does that number have relevance to? And if it has relevance to a specific modality, e.g., imaging, spectral Doppler, color flow, etc., how does a negative change in that dynamic range value impact the clinical information obtained while using that modality? Once the relevance of that specification has been established the question then shifts to how one goes about objectively testing the system for this performance parameter. Without the ability to independently and objectively verify this performance claim how does the physician assure himself that the system, in this regard, is performing correctly?

If these technical claims have specific clinical relevance then tools must be created for the biomedical engineer and medical physicist to verify all clinically related performance claims and couple that with the development of a systematic approach for regularly testing the system and the probes.

While both the complexity of ultrasound system architectures and transducers have dramatically increased over the last two decades, until recently our collective ability to test these devices in a simple, repeatable and quantitative manner have not. As the diagnostic prowess of ultrasound continues to expand and as this technology continues to diffuse into more and more hands the need for evidence-based quality assurance of these systems and their attendant transducers is crucial.

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