The Need for Evidence-based Quality Assurance in the Modern Ultrasound Clinical Laboratory

G. Wayne Moore, Amanda Gessert & Mark Schafer
Sonora Medical Systems, Longmont, Colorado, USA

A quick review of the specification sheets for new technologically intensive diagnostic ultrasound systems reveals a substantial number of fairly impressive operational performance claims. In at least one manufacturer's published material, the system specifications boasts of a dynamic range of 180 dB.[1] To put that number in perspective, a device capable of 180 dB of dynamic range of resolution would be able to detect the flutter of a butterfly's wing in the middle of a thermonuclear explosion. How does one verify such an astounding performance claim using currently available ultrasound testing devices such as a tissue-mimicking phantom and what is the explicit clinical significance of such dynamic range? Additionally, while most of us were focused with amazement in leapfrog advances in system technology, diagnostic ultrasound transducers were also undergoing radical changes in array material composition and design. Most modern composite transducer specifications claim fractional bandwidths of 85%, and more and element counts as high as 2500.[2] While the great technological strides made in ultrasound system design have been impressive, all of the computational and processing power of the 'all-digital' ultrasound device is singularly dependent on the output and input characteristics of the ultrasound transducer. Published data shows that the ultrasound transducer is subject to degradation in performance, as well as element failure, potentially leading to patient misdiagnosis or under-diagnosis.[3] The need to regularly test transducers for performance variances will be explored within this paper. Additionally, the key areas of transducer performance as they relate to image and Doppler quality will be defined.

Introduction

For the ultrasound acoustic engineer the task of generating performance specifications for today's multi-element transducers is, perhaps, one of the most difficult challenges in all of medical ultrasound. The reason is two-fold:

- there are no standards for such specifications;
- the effects of system operational parameters upon the image quality are highly complex and often difficult to predict.

Also problematic is the fact that optimizing an operational parameter to provide a 'better' gray scale image may, in fact, reduce Doppler performance, so achieving a balance in aggregate performance is often the driving design factor. Nonetheless, it is still possible to establish parameters that affect ultrasound performance quality, and define how those parameters might be measured, tested and validated as part of an overall evidence-based quality assurance (QA) programme within the hospital.

For the ultrasound sonographer, the over-arching goal is to obtain high quality, accurate and quantitative ultrasound information using B-mode gray scale imaging, spectral Doppler and colour flow imaging. The goal of high quality gray scale imaging is to determine the size, shape, position, texture and dynamics of soft tissue structures, organs and masses. Doppler goals include source of flow, and the velocity and direction of flow as a function of time. With colour flow imaging the clinician is looking for changes in: colour direction, colour velocity, changes within a flow channel, absence of flow where it should be, and the presence of flow where it should not be. To achieve these goals, each major modality contains well-defined elements of 'quality' that a clinician strives to produce.[4]

A clinician's ability to produce clinically acceptable gray scale or colour flow images and spectral Doppler waveforms ultimately depends upon the proper functioning of the ultrasound scanner and transducers they are using. While advances in system performance are often cited as improving both imaging and Doppler, little attention has been paid to the most critical component of the diagnostic imaging chain, the transducer.[5] Modern electronic array transducers have also made significant advances in materials and construction. Understanding the potential clinical implications of transducer operation and failure requires a review of their properties and capabilities.

Probe Technology

A brief review of the fundamental principles of operation of a single element transducer will help in the understanding of the more complex multi-element composite array. The classic description of a transducer is a device that changes one form of energy to another. Piezoelectric materials take electrical energy and convert it to mechanical, and likewise take mechanical energy and convert it to electrical as is shown in Fig. 1.

Piezoelectric materials can be made from both natural, e.g. quartz, as well as from man made sources, e.g. lead zirconate titanate and polymers. Modern diagnostic ultrasound transducers are exclusively constructed from man-made materials in order to obtain the optimal balance between transmit and receive sensitivities. Transducers are designed to vibrate in the thickness mode, such that the resonant frequency is determined by the thickness of the transducer element. Pulsing the transducer element with a single high voltage spike causes the element to vibrate at its natural resonant frequency. Figure 2 illustrates the relationship between transmit and receive signals.

By simultaneously pulsing multiple transducer elements within an array, we can create an acoustic beam similar to that

Correspondence: W. Moore, Sonora Medical Systems, 2021 Miller Drive, Longmont, CO 80501, USA. gwm@4sonora.com

DOI: 10.1179/174313405X53752

Ultrasound ULT13.302.3d 21/6/05 18:50:56
The Charlesworth Group, Wakefield +44(0)1924 369598 - Rev 7.51n/W (Jan 20 2003)

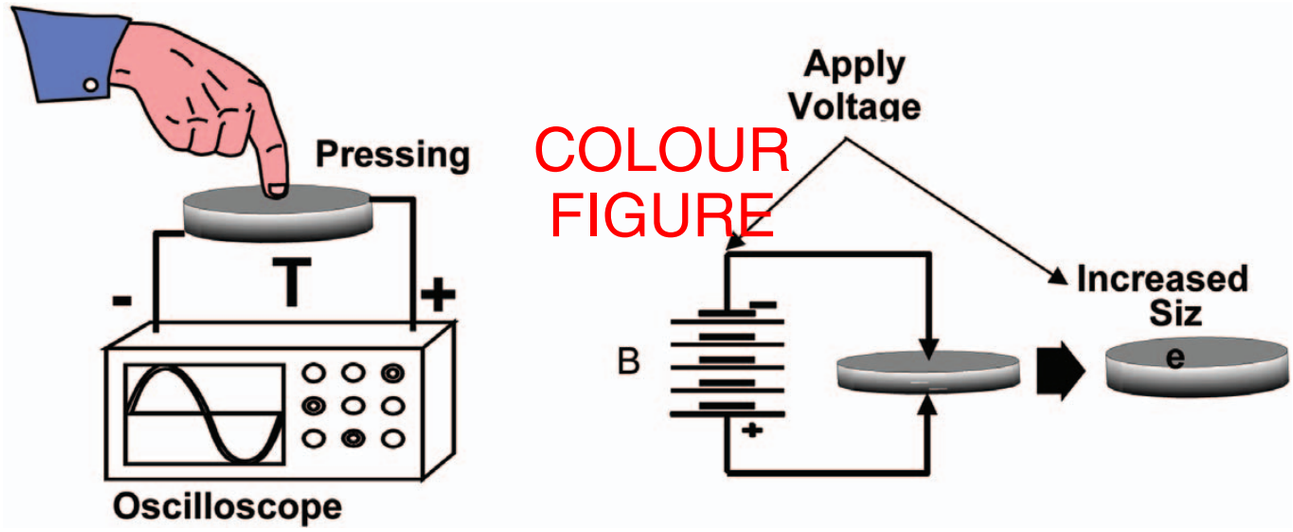

Figure 1. The piezoelectric effect (T—transducer material; B—battery).

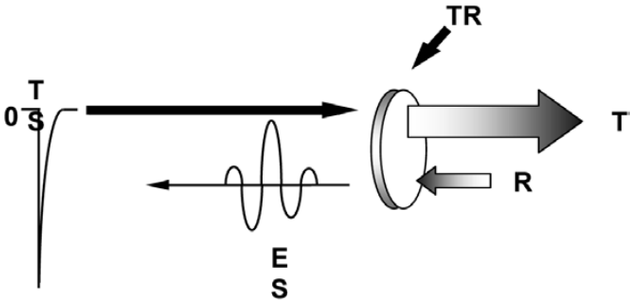

Figure 2. Transmit and receive. TS, transmit pulse; TR, transducer element; ES, echo signal; T, transmit energy; R, received signal.

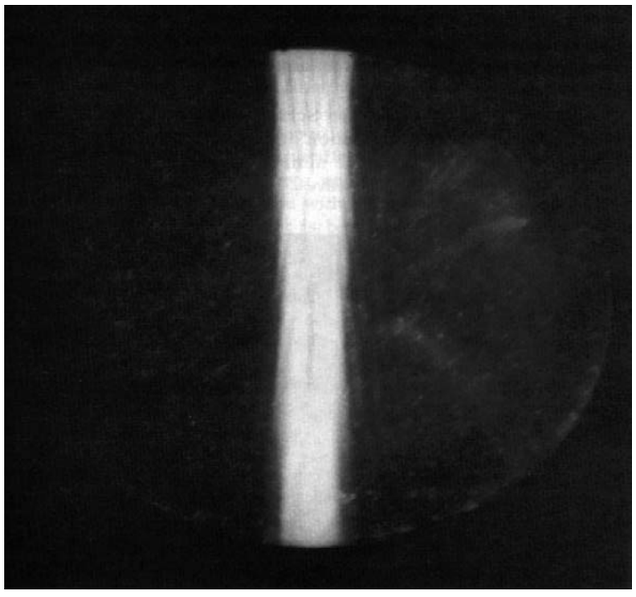

Figure 3. Schlieren image of an ultrasound beam.

shown in Fig. 3. With linear sequential arrays, a sub-aperture number of elements are electrically excited in succession to scan or 'walk' the beam across the entire aperture, creating the rectangular image format we see on the system monitor as shown in Fig. 4. In other words, only a small subset of the array elements is used to form each line of information. With phased linear arrays, the delay in the firing sequence of the individual elements results in a steered beam and a sector display format. Curved arrays are simply linear sequential arrays that are formed with various radius of curvature depending upon the intended clinical application (e.g. a tightly curved array or small radius of curvature for endo-cavitary applications).

The ideal beam profile behaviour of a multi-element array would be identical to that of a similar-sized single element. This requires that there be very little variation in element-to-element sensitivity.[6] If this uniformity is not good enough, we effectively create a random array with random element spacing giving rise to undesirable side lobes as is shown in Fig. 5.

Non-working (i.e. dead) elements within the array effectively change the acoustic beam profile into something other than what was intended and would, by definition, be unpredictable in its performance. This could potentially negatively impact the resultant clinical study.[3]

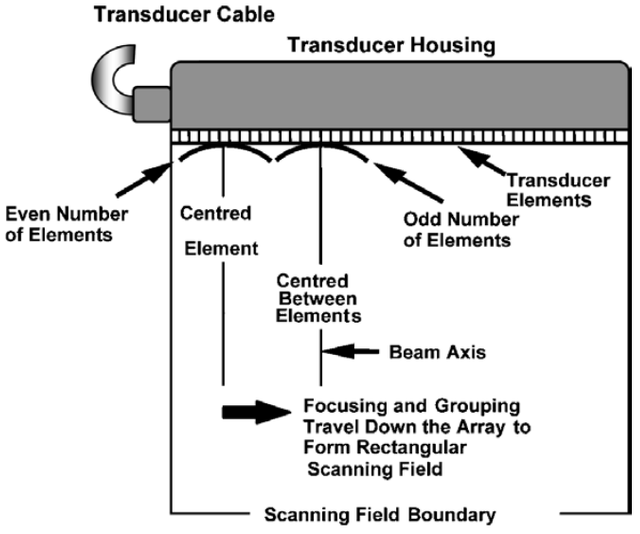

Figure 4. Formation of the linear scanning field.

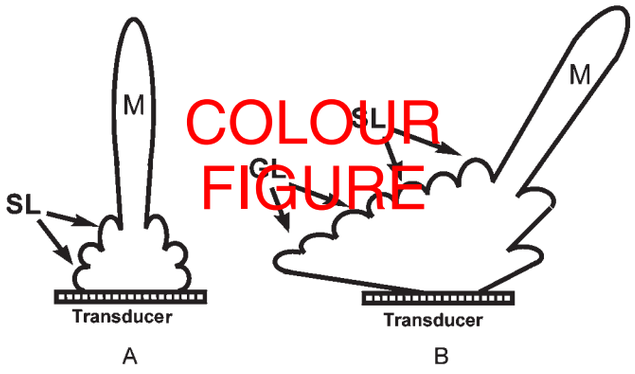

Figure 5. Side lobes (SL), grating lobes (GL) and main lobe (M) for arrays with uniform (A) and non-uniform (B) element-to-element sensitivity.

The electro-acoustically active part of a finished probe is referred to as an acoustic stack. An acoustic stack is compromised of: outer lens, matching layers, the piezoelectric block and backing material. The acoustic stack is shown in Fig. 6. The outer lens is used to provide physical and electrical isolation between the active components of the acoustic stack and the patient. It also keeps other environmental agents, such as cleansing materials and acoustic gel out of the transducer. Because of the large difference in material properties between the face of the transducer and the soft tissues of the body matching layers are used to permit more efficient transfer of acoustic energy. The piezoelectric block comprises the actual elements of the array. Finally, the backing material placed on the rear of the piezoelectric block damps the resonant nature of the piezoceramic, thereby decreasing the number of cycles in the ultrasound pulse. This action decreases the spatial pulse length and pulse duration, and improves the axial resolution.

Arrays can be damaged in the clinical environment through a number of mechanisms including:

- sharp impact on the acoustic lens;
- by dropping the probe or hitting it against something during scanning;
- chemical damage through sterilization if there is a small hole in the lens of the probe;
- manufacturing defects in the acoustic stack that become exacerbated during scanning;
- in some cases, even static electric discharge from the operator through the acoustic lens.

In addition to dead and reduced sensitivity elements there are other probe-related problems, that can materially impact on image quality and Doppler accuracy these include:

- acoustic lens delamination;
- lens swelling;
- matching layer delamination;
- backing material delamination;
- fluid infiltration into or behind the acoustic stack;
- damaged cable wires and damage to connector electronics.

One study[3] has shown empirical data that as many as 25% of all probes in use have some form of performance inhibiting defect. This paper showed that Doppler, not image quality, is the modality most sensitive to changes in probe performance.

Evidence-based Quality Assurance

In spite of the potential for misdiagnosis or under-diagnosis using defective probes, very few ultrasound laboratories have developed evidence-based QA programmes designed to detect these problems or monitor probe performance as a function of time. In fact, those laboratories that do have some form of QA programme typically use a tissue- mimicking phantom to test the aggregate performance of the ultrasound system's imaging chain, but have no means of testing or verifying adequate Doppler performance. Additionally, the QA programmes in place normally test the probe and the system functionality together. This can have the effect of masking certain probe failures, i.e. those failures that would only manifest themselves in the Doppler mode, but would look 'normal' in an image QA procedure.

One must ask the question 'why are we still trying to use tissue phantoms for quality control when data has shown that transducer element failures manifest themselves in Doppler quality long before one can see a demonstrable change in the image?' Another soon to be published study from England will demonstrate that, even when using a computer-aided image, analysis system coupled with a tissue phantom, under tightly-controlled laboratory conditions the computer was unable to detect changes in the image quality parameters in the presence of two consecutive dead elements yet these same two dead elements caused significant spectral broadening in the pulsed Doppler mode. Using current tissue phantom based QA methodologies, the QA person would have concluded based on phantom results that the system and probe were working fine. They would have been very wrong, and the clinical value of all Doppler/colour flow studies obtained using that probe would have been compromised.

As the use of diagnostic ultrasound continues to proliferate in virtually every clinical application, and as the complexity and performance levels of the system, and the probes increase geometrically, the need for evidence-based quality control becomes apparent. Meaningful, objective and verifiable QA in diagnostic ultrasound has been overlooked for far too long. In our view, this can be partially explained because of

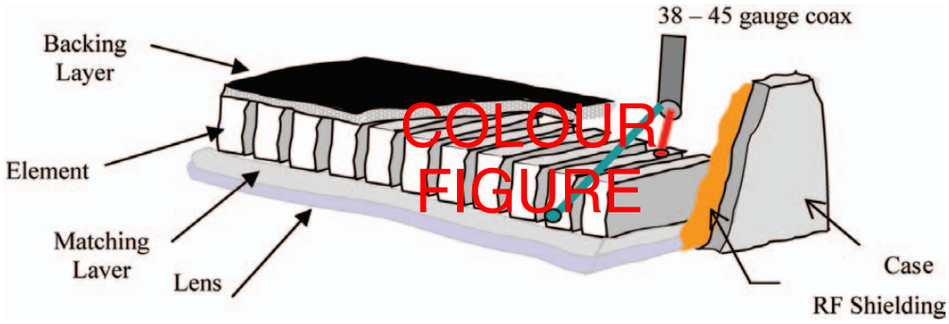

Figure 6. Acoustic stack.

Ultrasound ULT13.302.3d 21/6/05 18:51:06
The Charlesworth Group, Wakefield +44(0)1924 369598 - Rev 7.51n/W (Jan 20 2003)

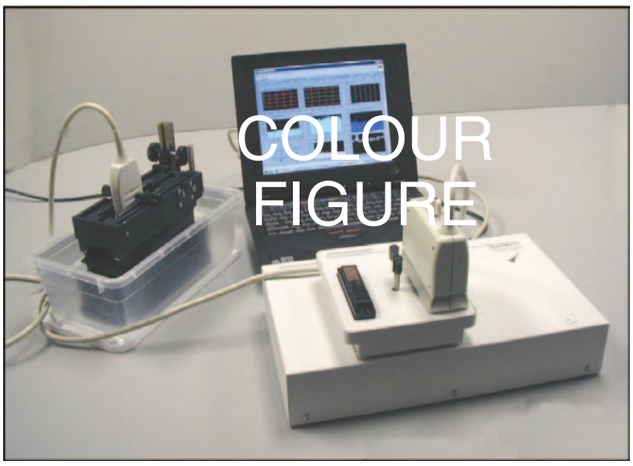

Figure 7. FirstCall2000 probe testing device.

the widespread belief that ultrasound is a safe non-ionizing modality and, therefore, strict QA processes, like those implemented with X-ray devices, are both unnecessary and simply an added expense. This is fiction. Simply using acute bio-effects as the single measure of ultrasound-related patient safety is both myopic and potentially dangerous. In the diagnostic process, a patient's management is escalated through higher levels of potential risk until a definitive diagnosis is made. For example, an equivocal Doppler echocardiography study may lead to a cardiac catheterization, where there is a risk for morbidity or mortality, albeit low. In fact, in every clinical application where Doppler or one of its derivative modalities, is used as a quantitative modality, the clinician should have a reasonable expectation that the data derived using the ultrasound system is accurate within the published specifications for the device. This is currently not the case and unless there are changes to tissue-phantom centric QA processes, it will continue to not be the case. Furthermore, the recent adoption and use of imaging contrast media into ultrasound has also underscored the need for tighter internal QA controls within the ultrasound department (e.g. the generation of PVC's during MCE high MI 'flash-echo' studies).[7]

Consequently, it is our position that every ultrasound laboratory committed to quality control should develop an evidence-based programme that objectively measures those performance parameters that materially impact clinical performance both in the probe and in the system. To achieve this, new QA processes must be developed and consistently followed within the ultrasound laboratory. There is at least one device on the market, FirstCall 2000 (Fig. 7),[8] that performs objective testing on diagnostic ultrasound transducers in a clinical setting. This device tests the functionality of the probe without the need for the ultrasound system. FirstCall pulses each individual element within the array testing for:

- sensitivity—each element should have like sensitivity characteristics to produce a noise free image;
- pulse width, which is an indicator of contrast resolution within the image;
- fractional bandwidth, which is an indicator of the frequency response of the system and good Doppler performance;
- centre frequency, which determines depth of penetration and spatial resolution;
- pulse shape, a well-behaved pulse shape insures low noise in the image and good colour flow Doppler registration within the image.

A report (Fig. 8) is then generated for the test that allows for serial tests and performance comparisons for that probe as a part of an overall ultrasound QA programme.

Additional test devices will be needed in the near future to objectively and independently test the ultrasound system to verify the performance claims listed in the manufacturers specifications and to test periodically to insure that there has been no degradation to those performance parameters.

System manufacturers often provide preventative maintenance (PM) calls on systems under warranty or under service contract. However, it should be remembered that a PM call is not a QA audit, nor does it provide a system or a transducer calibration. In fact, most PM's are very superficial in what they actually test on the system and probe. They usually consist of:

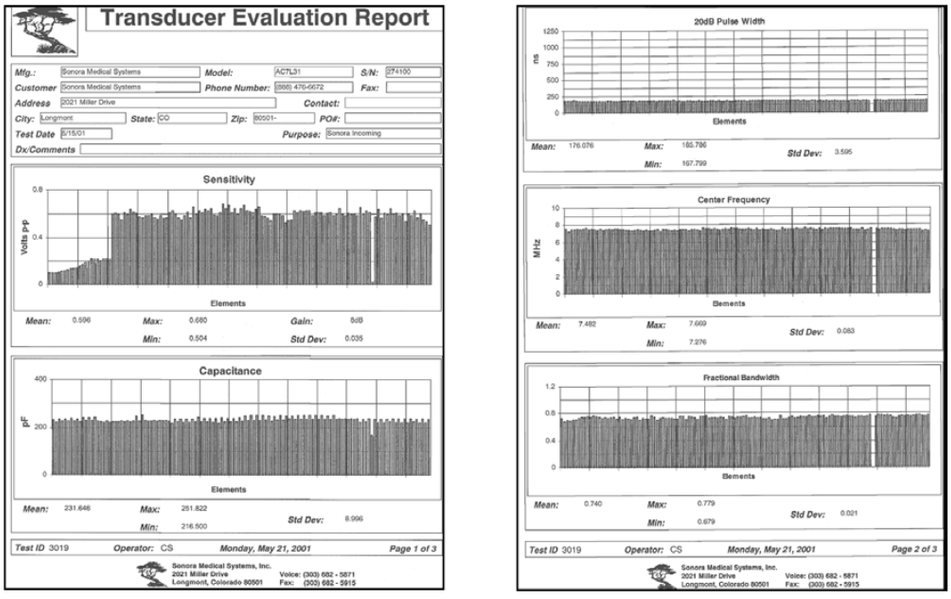

Figure 8. FirstCall2000 test report.

- checking error fault logs in the system diagnostics;
- cleaning fan filters, perhaps checking some power supply voltages, sometimes using a phantom to look at images (although this is increasingly rare);
- cleaning the keyboard and visually inspecting for obvious physical damage to the system and probes.

If a clinical laboratory intends to rely upon the manufacturer to provide performance guarantees, then it should detail what their expectations are prior to signing a service agreement. With respect to probe performance the manufacturer should, at a minimum, test each element in each probe under contract and provide the customer with a report that shows the test results. These results establish a baseline of performance against which future tests can be compared. Furthermore, if two or more elements in the array are determined to be dead the manufacturer should replace the probe under the service contract. Additionally, the customer should be very direct with the manufacturer with regard to specifications claims in the manufacturer's printed materials. If a technical or performance claim is made, it is reasonable for the customer to insist that the claim be verifiable during warranty and post-warranty PM's.

When ultrasound became generally accepted as a viable, but limited diagnostic modality, systems and probes were not very complex. Systems contained mostly analog circuitry that tended to drift in performance as a function of time and wear. The first probes were either single crystal and mechanically steered, or very simple low-density linear arrays (16–32 elements). Tissue phantoms had a significant role in that era in determining many performance parameters of the system, including the accuracy of electronic calipers and analog scan conversion geometry accuracy. Basic gray scale in the early days of ultrasound was limited to either bi-stable or 16 'levels' of gray. The tissue phantoms were fairly good at distinguishing between these levels. From the probe side, it was fairly easy to see and measure the lateral and axial resolution performance using a tissue phantom. Doppler, if it was used at all, was a simple 'zero-crossing' detector and was not used to any meaningful degree as a quantitative modality. Modern ultrasound systems and their attendant probes bear little if any resemblance to those of the late 1970's and 1980's. Several orders of magnitude more complex, modern devices have long since surpassed the ability of a tissue phantom to detect subtle changes in system performance or early array failures. The majority of performance-inhibiting failures that occur with modern ultrasound systems are related to either the front-end analog components of the systems (claims by manufacturers of 'all digital front-ends' notwithstanding), e.g. transmitters, or more likely the probes themselves. The two most common probe problems that directly impact clinical studies are dead elements and acoustic lens delamination. In a non-scientific study we performed at the 2003 SDMS (Society of Diagnostic Medical Sonographers) meeting in the United States we had more than 60 sonographers visually inspect the lens of a typical linear array transducer and give us their opinion if the lens appeared to be intact. More than 90% could not see anything wrong with the lens and a small percentage would not give a definitive answer. Then, we gave them a $5 magnifying glass and asked them to look again. What they saw was a small hole in the lens where a biopsy needle had punctured it. The lens was compromised and would have resulted in greater probe failure if the probe were chemically sterilized.

Conclusion

Trying to develop a modern QA process, even a limited one, which has, at its core, a tissue phantom, will be a flawed process by design and should be viewed as a major step backward. Modern systems and transducers require test devices that will accurately portray the health of the system and probes, and provide the clinician with a reasonable expectation of performance. Visually inspecting a probe with the unaided eye is also problematic, given that some potential probe issues will be almost certainly missed. These can ultimately result in a catastrophic probe failure (chemical agents are very fond of eating piezoelectric materials and array backing materials). The need exists now and will only become more pronounced in the future for an evidence-based QA process for the modern ultrasound laboratory. Anything less should be viewed as an unjustifiable compromise. Diagnostic ultrasound is safe if, and only if, the data that it generates is accurate and leads to good patient management decisions. Furthermore, it is only a matter of time before there are medico-legal implications in running an ultrasound laboratory without a well-defined and accurate quality control process.

References

1. Technical Specifications for the iU22 Ultrasound System. Philips Medical Systems, 2005. [1]
2. Technical Specifications for the SONOS7500 Ultrasound System. Philips Medical Systems, 2005. [2]
3. Weigang B, Moore GW, Gessert J, Phillips WH, Schafer M. The methods and effects of transducer degradation on image quality and the clinical efficacy of diagnostic sonography. J Diagnost Med Sonogr 2002;19:3–13.
4. Powis R, Moore GW. The Silent Revolution: catching up with the contemporary composite transducer. J Diagnost Med Sonogr 2004;20:395–405.
5. Schafer ME, Lewin PA. The influence of front-end hardware on digital ultrasonic imaging. IEEE Trans Son Ultrason 1984;31: 295–306.
6. Guess J. Apodization and a clear gallbladder. Sono-Notes 1990;II(2). [3]
7. Ay T, Havaux X, *et al*. Destruction of contrast microbubbles by ultrasound. Am Heart Ass Circ 2001;104:461. [4]
8. FirstCall2000, Sonora Medical Systems, Inc. 2021 Miller Drive, Longmont, Colorado USA 80501. Available at: www.4sonora.com

Ultrasound ULT13.302.3d 21/6/05 18:51:15
The Charlesworth Group, Wakefield +44(0)1924 369598 - Rev 7.51n/W (Jan 20 2003)

Authors Queries

Journal: **Ultrasound**
Paper: **ULT65050**
Title: **The Need for Evidence-based Quality Assurance in the Modern Ultrasound Clinical Laboratory**

Dear Author
During the preparation of your manuscript for publication, the questions listed below have arisen. Please attend to these matters and return this form with your proof. Many thanks for your assistance

Query Reference	Query	Remarks
1	Author: Please give place of publication	
2	Author: Please give place of publication	
3	Author: Please give page nos	
4	Author: Please give all authors.	