

# MAKING PERFORMANCE CALLS ON CONTEMPORARY DIAGNOSTIC ULTRASOUND TRANSDUCERS

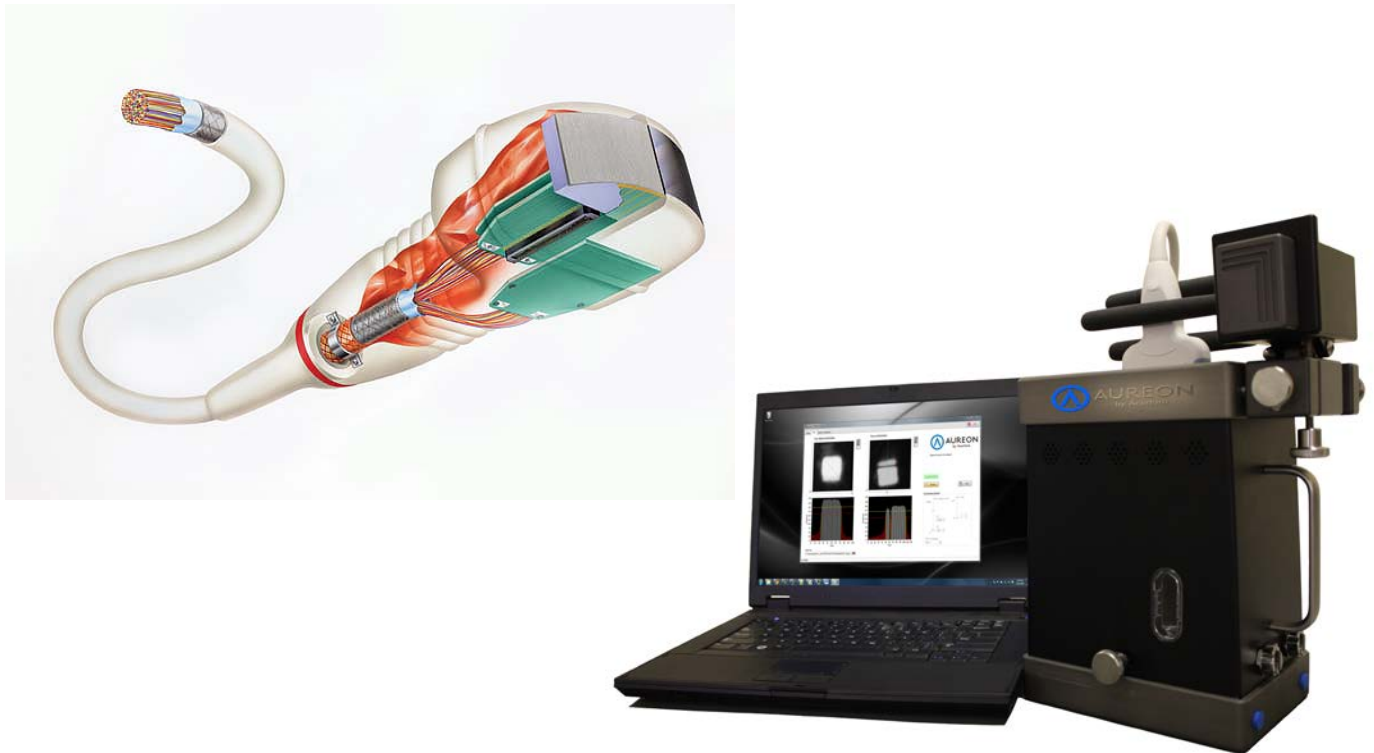
Guidance on establishing transducer performance acceptance criteria and when to consider replacing or repairing a diagnostic ultrasound probe using a modern probe analysis and performance testing system - Aureon™

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**About Acertara:** Founded by ultrasound industry pioneers G. Wayne Moore and Jim Gessert, Acertara was created to serve the acoustic testing and quality control product development needs of ultrasound engineering and service professionals worldwide. Acertara is an independent ISO/IEC 17025:2005 accredited acoustic measurement and testing laboratory providing advanced ultrasound testing products (we invented the probe tester known as FirstCall™) and measurement services, as well as advanced contract research & development engineering. Our engineering team, formerly the R&D group at Sonora Medical Systems, has been directly involved in the development and commercialization of more than twenty technologically intensive ultrasound systems ranging from specialty applications such as IVUS through fully-featured cart-based cardiology and radiology ultrasound systems. The Acertara team has authored and co-authored more than 40 United States patents and is highly published in both clinical and engineering journals. As an active member of the Medical Imaging Technology Alliance (MITA/NEMA), and AdvaMed, Acertara is intimately involved in the development of various domestic and international diagnostic ultrasound regulatory standards.

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## Introduction

The ultrasound literature is clear that even minimal variations in the performance of ultrasound probes can have a negative impact on the clinical efficacy of any given ultrasound examination. Published studies have shown that as few as two consecutive dead elements can lead to inaccurate data and potential misdiagnosis. Probes are subject to normal degradation in performance via use and subject to degradation via a myriad of other avenues such as improper cleaning and storage, dropping, banging, electro-static discharge, etc. There is no one single clinical use for an ultrasound probe or one single clinical environment in which any given probe is used that does not have the potential for damage occurring to the probe. Further, the manner in which the probe is constructed (form, fit and function) also plays a significant role into the determination of how frequently a probe should be performance and safety tested. For example tightly curved arrays, used in applications such as transvaginal and transrectal are very susceptible to damage at the apex of the array.

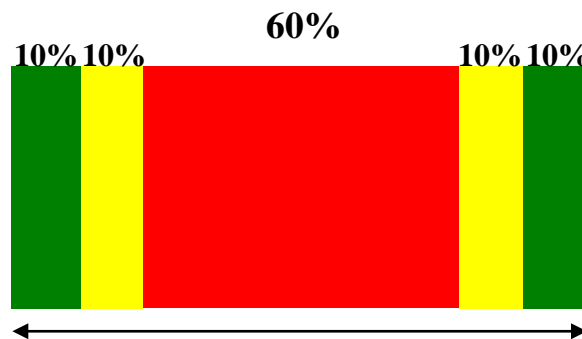
A matrix of all the probes in the institution should be developed that lists the type of probe, what it is being used for (clinical application) and in what department. Ultrasound systems and probes are used as both qualitative and quantitative testing devices in the clinical setting. If the system is being used as a quantitative tool then higher sensitivity needs to be paid to its clinical performance level. This determination should be made in partnership with the ultrasound lab within the hospital. When the use of the ultrasound systems under your care have been identified then a risk assessment can be made and a meaningful testing schedule developed for the probes. In addition to developing a routine testing schedule all newly purchased probes should also be tested and base-lined prior to being placed into clinical service. No newly purchased probes should be accepted if testing demonstrates performance flaws, e.g., dead elements. All probes should be tested regardless of their normal schedule if they have been dropped or otherwise harmed. Lastly, probes should be tested before they come out of initial warranty or off of a post-warranty service contract. Any of the covered probes found to have defects should then be replaced by the manufacturer prior to the expiration of the warranty.

The following page illustrates a more systematic way of making a determination of how many weak or dead elements you are willing to accept in any given probe type and is a recommended tool to use when discussing the subject with clinicians. This is of particular importance in any clinical study in which Doppler is being used, as it is both a quantitative mode and is the mode most susceptible to performance degradation as a function of dead and or weak elements. The clinical significance of this issue is explained in some detail on **Page 4**. Additionally when a high frequency probe is being used with a very shallow focal point, a smaller active aperture is used to create the image. Therefore any dead elements will compromise the beam profile and can negatively impact the B-mode image. This can present a significant problem in breast imaging where very small structures, such as micro-calcifications may be missed.

## Making Performance Judgments on Ultrasound Probes – Establishing Acceptance Criteria

Radius of Curvature = ROC

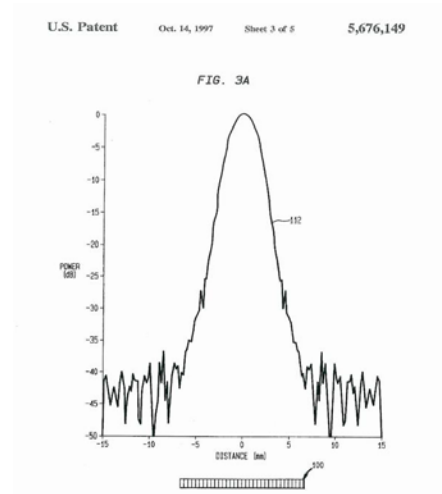
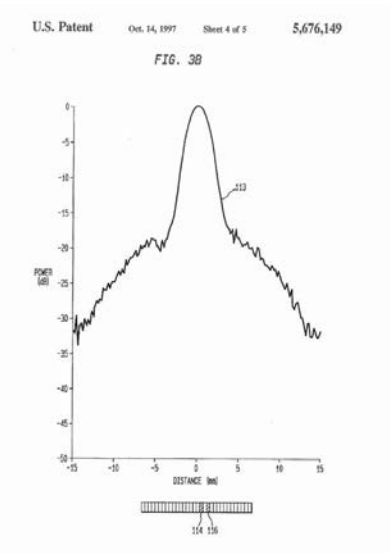
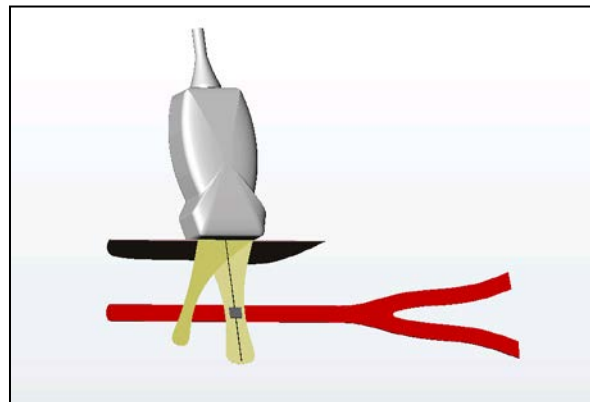
Number of Contiguous Dead Elements Allowed			
	Red Zone	Yellow Zone	Green Zone
	Aperture Size	Aperture Size	Aperture Size
Probe Type	60%	10% on either side	10% on either side
Curved Array			
ROC < 30mm	1	2	2
ROC > 30mm	1	2	2
Linear Array	1	2	2
Phased Array	2	3	3
Number of non-Contiguous Dead Elements Allowed			
	Red Zone	Yellow Zone	Green Zone
	Aperture Size	Aperture Size	Aperture Size
Probe Type	60%	10% on either side	10% on either side
Curved Array			
ROC < 30mm	2	3	4
ROC > 30mm	3	4	4
Linear Array	3	4	4
Phased Array	4	5	6



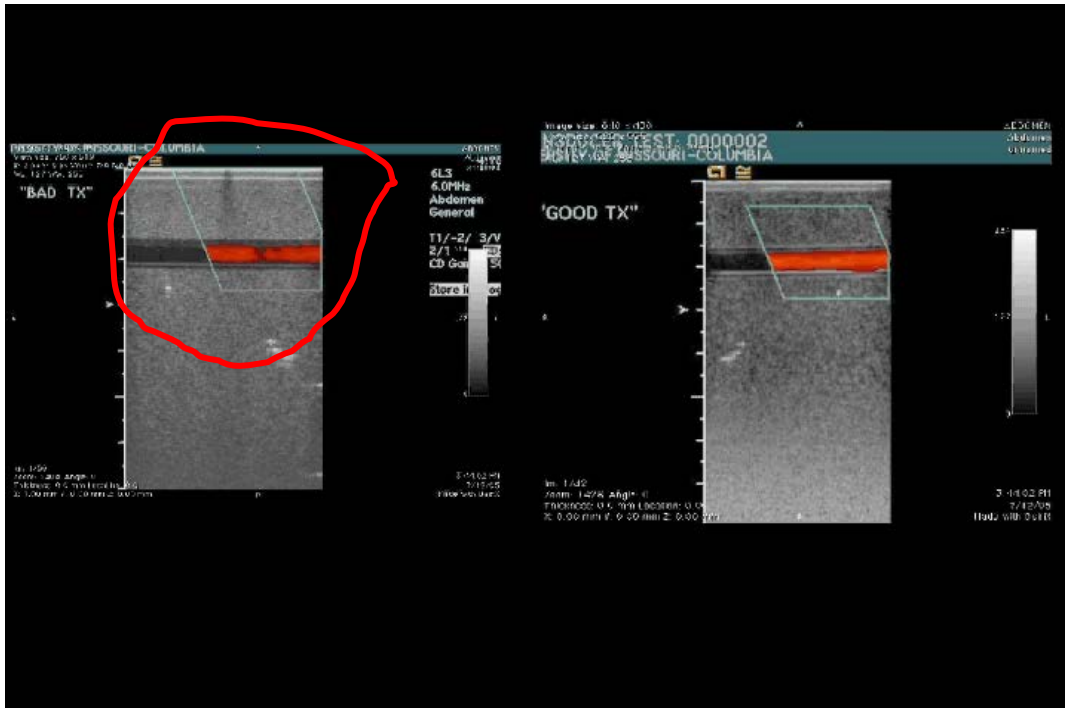
### Transducer Aperture

For example if the probe has 128 elements then the Green Zone is 13 elements wide on either side of the array, as is the Yellow Zone. The number of elements that make up any given aperture varies as a function of type and manufacturer. Tightly curved arrays (e.g., transvaginal probes) are susceptible to damage and should be checked at least one time per Quarter. Specialty probes, such as TEE or laparoscopic probes, should be tested on a monthly basis to insure any problems are detected early. Standard phased array and flat linear probes can be tested on an annual basis, and slightly curved arrays can be tested twice per year.

**Doppler:** If a probe is being used to obtain Doppler information then the number of dead or weak elements takes on an additional clinical efficacy concern. Doppler (and its derivative modes such as color flow) requires the most dynamic range of all imaging modalities. Also only a portion of the active aperture of an array is actually used during Doppler. Dead elements that fall within the active aperture space of the Doppler signal have a greater impact as a percentage of the active array. For example in a cardiac phased array the active element count may be 96 elements used to form an acoustic line. Therefore if you have 4 dead elements in that array it would represent 1/24<sup>th</sup> of the array. To form a pulsed Doppler signal, system designers will frequently use only 8 to 16 elements (referred to as a sub-aperture) of the entire array. So if there were 4 dead elements within that sub-aperture it would represent 1/4 to 1/2 of the active aperture. Complicating the issue further is that dead elements also give rise to unwanted Sidelobes, see Figure below. Sidelobes allow signals from off-axis flow targets to co-mingle with desired Mainlobe flow targets. In the color flow image shown on the following page one can see the results of element dropout on the flow profile as well as spectral broadening on the pulse Doppler waveform.

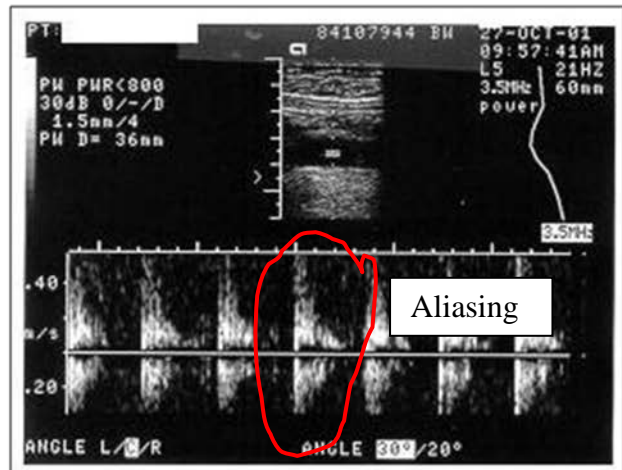
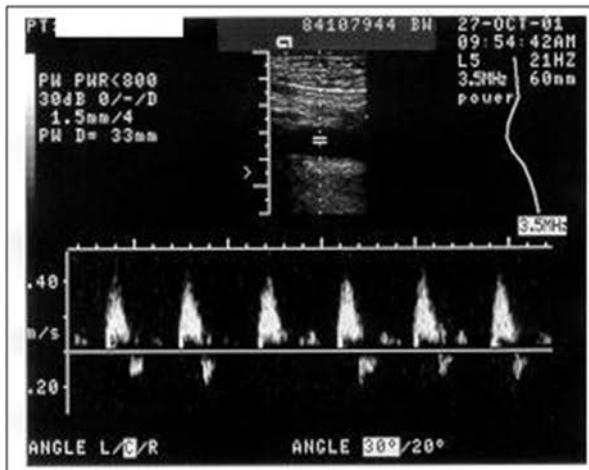


Two dead elements in center of array



*"Sidelobes of the beam can also allow interference from flow outside the vessel under interrogation and may change the spectral mean velocity."*

Bjorn Angelsen, Doppler Ultrasound in Cardiology, 1985



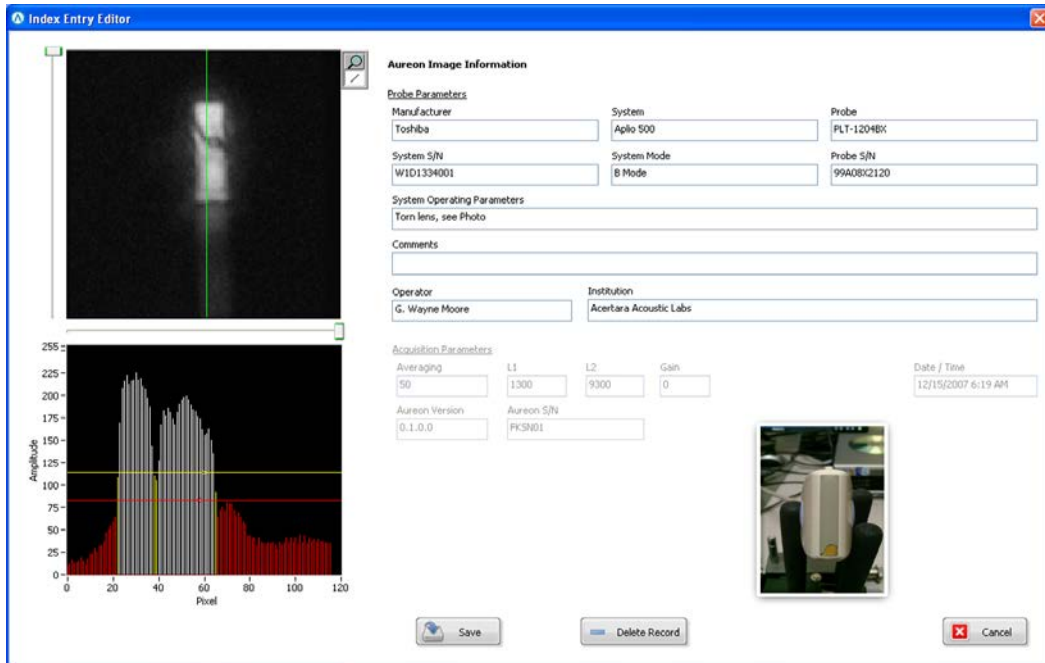
Acuson L5 two dead elements side by side (#'s 64 & 65)

Note above the spectral profile on the right demonstrates both spectral broadening and aliasing, an indication of non-laminar, or turbulent flow and increased velocity. In this case neither the spectral broadening nor the aliasing are related to any flow disturbance, rather they are caused by increased side lobe levels in the transducer beam detecting flow from two different directions and being superimposed one on the other.

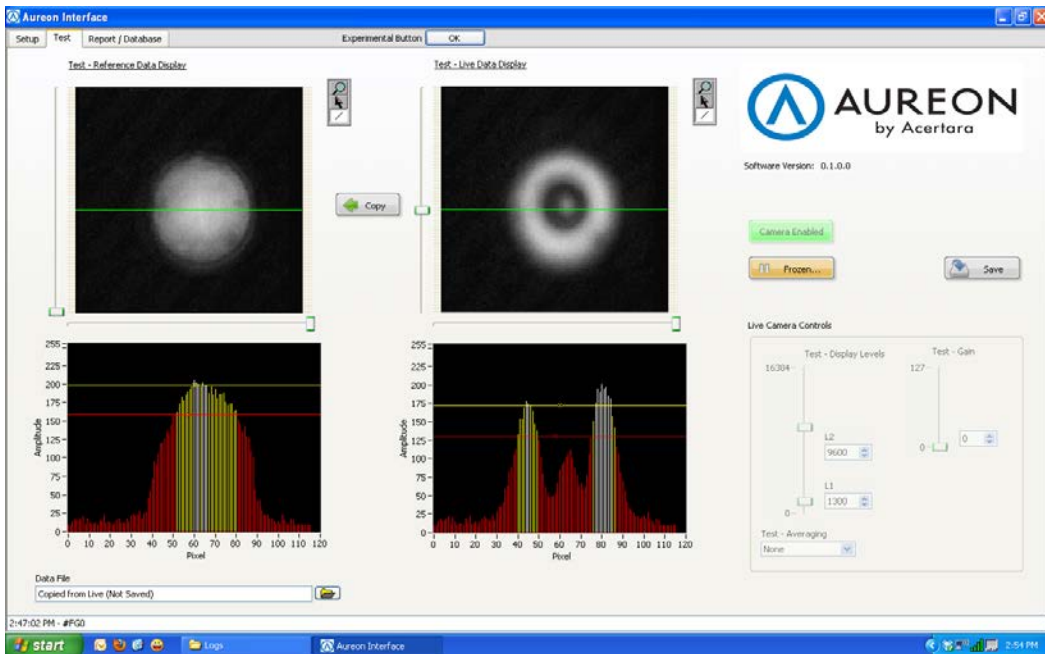
The image shown below is the Aureon™ probe analysis system from Acertara Acoustic Laboratories. On the following page are images of the energy content being emitted from the aperture of the array under test. Note the compromised elements in the area of the torn lens in the first image, and an air bubble under the lens in the second image.



**Aureon™ Probe Analysis System**

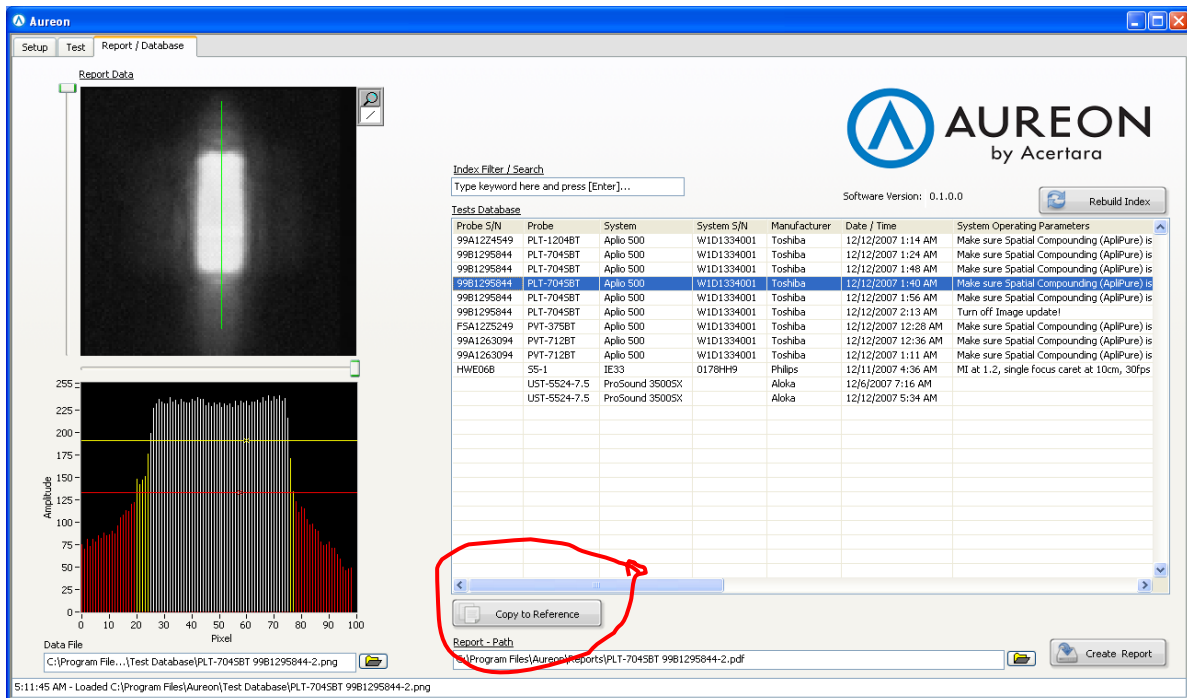


**Torn Lens and Damaged Elements**

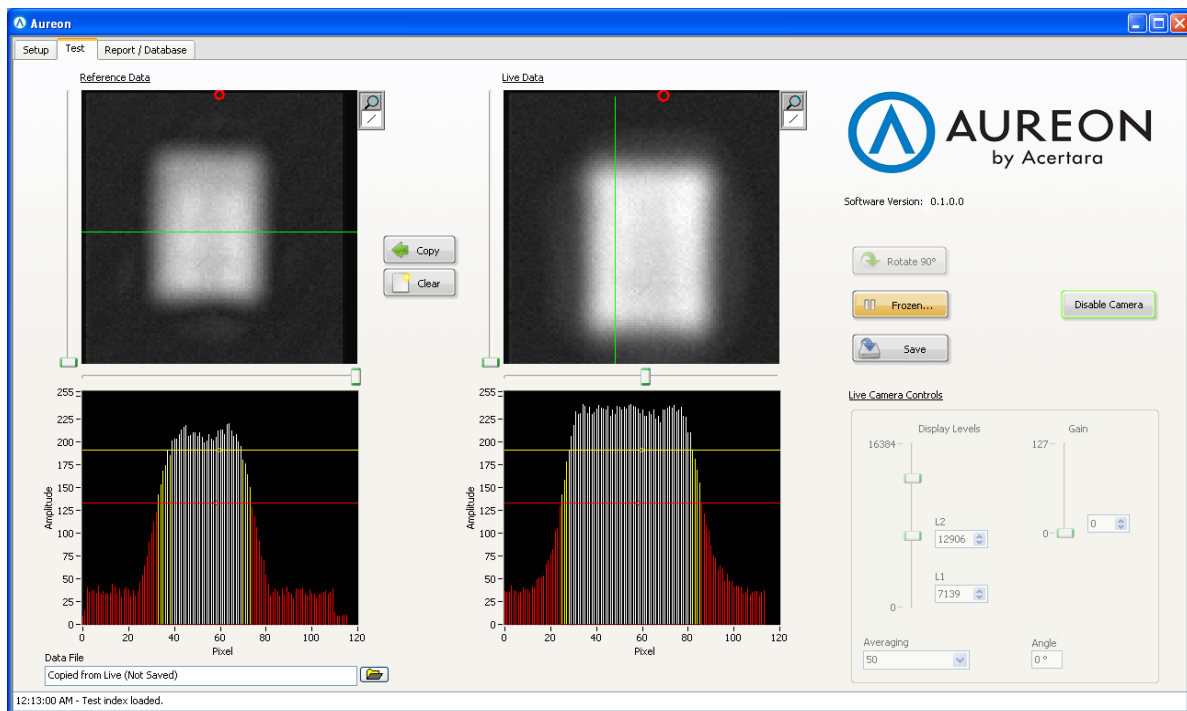


**Normal Output Shown on Left, Air Bubble under Lens Shown on Right**





The Aureon™ database screen shown above allows the operator to select a previous study performed on the same transducer and compare the probe’s previous performance level with the current test. This is done by selecting the “Copy to Reference” button outlined in red. This action moves the previous study to the current test screen shown below for comparison.



**Conclusion:** Ultrasound probes used to acquire quantitative flow information or very high resolution B-mode images should be tested at least on a semi-annual basis, or anytime when the performance of the probe may be suspect; for example, if the probe is accidentally dropped, or inadvertently banged on the side of the system or other hard surface, or if subjected to a static electricity discharge. Proper care and regular testing of ultrasound probes will ensure safe and efficacious ultrasound examinations. This type of testing will also lower the costs to the hospital for life-cycle maintenance of these expensive probes. 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 affect 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.

## General References

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Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment , NEMA UD2-2004

*“Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers”*. United States Food and Drug Administration, September 9, 2008

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Guidance on the Interpretation of TI and MI to be used to inform the Operator, Annex HH, BS EN 60601-2-37

