

Common Ultrasound Probe Failures

As Seen in Clinical Settings

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INTRODUCTION

The proper care and regular testing of diagnostic ultrasound probes substantially influences the level of operating expense related to the ultrasound systems in your department and across the hospital. In fact experience has shown that more than 70% of ultrasound service calls are in some fashion probe related. Published studies have also shown that improperly functioning probes can materially and negatively impact the results of an ultrasound examination. Probe failures, when discovered early enough, can more often than not be repaired and restored to a full operational condition, potentially saving the department tens-of-thousands of dollars per year in operating expense. This paper is designed to present the Sonographer with examples of common probe problems and how to spot them in a timely manner, while effective repairs can still be made. Further, probe testing suggestions are presented to insure optimal performance from the probe as well as obtaining the longest effective use of the product. While it is clear that everyone involved with the maintenance of the ultrasound devices in your department is responsible for providing the patient with a safe and efficacious study, the lead for ensuring this falls to the Sonographer, the professional who handles the probes on a daily basis. The Sonographer, by virtue of their work and skill, is normally the first to spot any changes in the ultrasound image, feel any slight electrical “tingles” from the probe, and see any holes in the lens, cracks in the case or tears in the cable. Any of these signs of failure should be reported to the Hospital Biomedical Engineer or Clinical Engineer for resolution as soon as they are discovered. Additional ultrasound QA documents are available to Sonographers and Biomedical Engineers free of charge on the Acertara website, www.acertaralabs.com.

A Suggested Probe Inspection Routine

Inspecting the Transducer (Probe)

- Cracks on the handle
- Cracks on the nose piece
- Cuts or gouges on the lens material
- Swelling of the lens material
- Condition of the bend relief(s)
- Cracks or other signs of damage to the connector
- Bent or damaged pins in the probe connector
- If using a “pin-less” connector (e.g., Siemens S2000, GE LE9, etc.) inspect the surface of the connector to insure it is clean and that the probe locks correctly
- Integrity and flexibility of the cable, as well as any cable discoloration
- Bite marks on the bending rubber (TEE probes) – also known as the insertion sleeve

What Can Hurt a Transducer?

- Gels that have perfume or other molecular changing substances
- Electro-static discharge on or around the lens of the probe, or the pins on the probe connector
- Rapid deceleration trauma (dropping the probe), or other blunt force trauma
- Using the wrong sterilizing agents, or using the correct ones in the wrong manner
- Improper storage and/or probe transport
- Not freezing the image before removing or connecting a probe to the system
- Improper or insufficient cleaning, or cleaning with wrong substance (e.g. alcohol-based wipes on the lens tends to dry the lens and make it detach from the probe)
- Not using bite guards when performing a TEE examination

What Preventative Measures Can I take?

- Inspect the probe on a daily basis – use a magnifying glass (Loupe 10x) to inspect the lens
- Follow the recommendations for use and cleaning in the probe manual
- Have the probe tested on a three-month basis, or if a problem is suspected
- Keep transducer cables off the floor
- Use the system probe holders when probe is not in use

What Else Should I Be Doing?

- Electrical leakage testing as recommended by the Original Equipment Manufacturer
- Involve your hospital Biomedical Engineer in regularly testing the probe elements
- Establish with your Biomedical Engineering Department a comprehensive ultrasound QA program that includes not only the probes, but the ultrasound system as well
- If you suspect a probe is compromised in some manner, don't use it until it is tested.

Common Probe Failures



Array housing separating at the seam normally occurs when the probe has been in use for some time, or if there is a manufacturing defect. Many OEMs use glue in the manufacturing process to seal the cap of the array housing to the body of the probe. This glue can deteriorate as a function of time as well as from exposure to harsh cleaning agents. A probe with this failure should not be used as it may present an electrical shock hazard to the patient and the sonographer. Further, if cleaning agents get inside the probe they will normally destroy the array. This type of failure can be repaired if caught early.

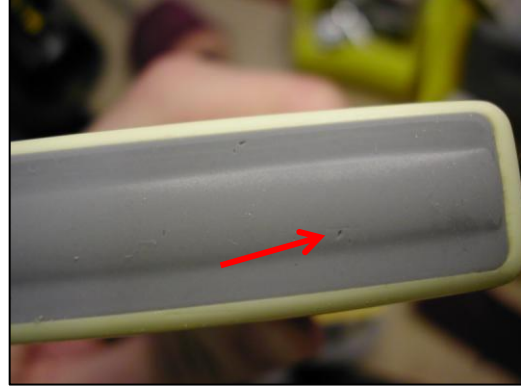


Seam line separating at the nose cone can become the site of fluid ingress. Less obvious than the example above, the probe to the left shows the beginning of the cap detachment. The compromise at the seam-line can be easily seen with the aid of a small magnifying glass (Loupe 10x). If the problem is found at this early stage, the probe is easily repairable.

Lens Problems



Lens separating from housing
Common Cause: Over cleaning and use of inappropriate cleaning agents.



Multiple holes in the lens
Common Cause: Free-hand needle biopsy



Hole in Lens
Common Cause: Rough cleaning

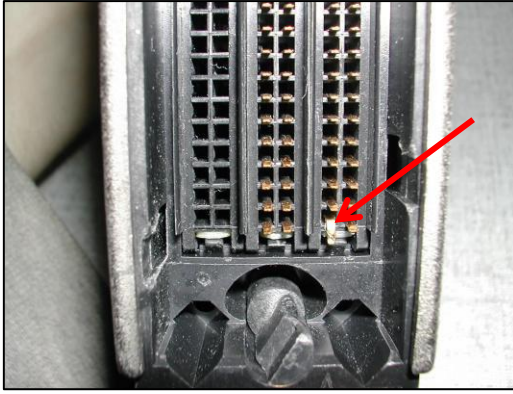


Swollen Lens
Common Cause: Manufacturing defect



Multiple punctures
Common Causes: Trauma, improper HLD, or biopsy needles

Various Structural Defects



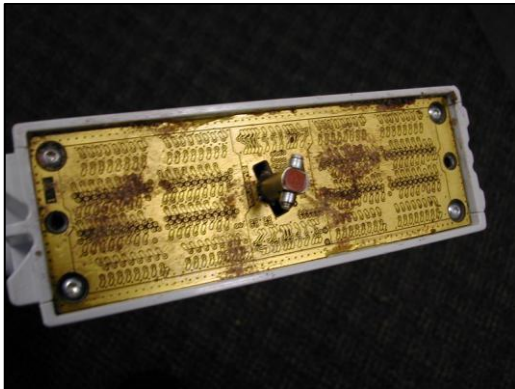
Bent pins in the connector

Common cause: Misalignment with system connector coupled with a hard shove



Dents in connector housing

Common cause: Rough use, trauma by dropping, or banging on a hard surface



Dirty pin-less connector

Common cause: Poor or no preventive maintenance



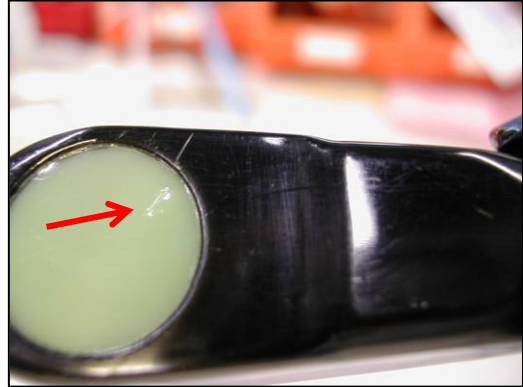
Crack in lens cap

Common cause: Dropping probe onto hard surface

TEE Probe Problems



Broken seal near head of TEE probe
Common cause: Rough handling, poor storage, or aggressive cleaning



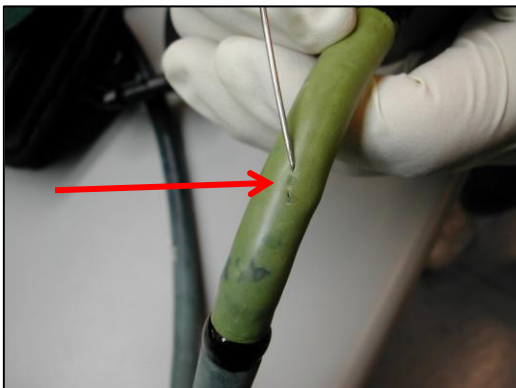
Scratch on TEE lens
Common cause: No bite guard, hard cleaning



Contaminated bending rubber
Common Cause: over-soaking in Cidex



Holes in bending rubber
Common cause: Bite guard not used



Stained bending rubber with hole
Common cause: Over-soaking and no bite guard



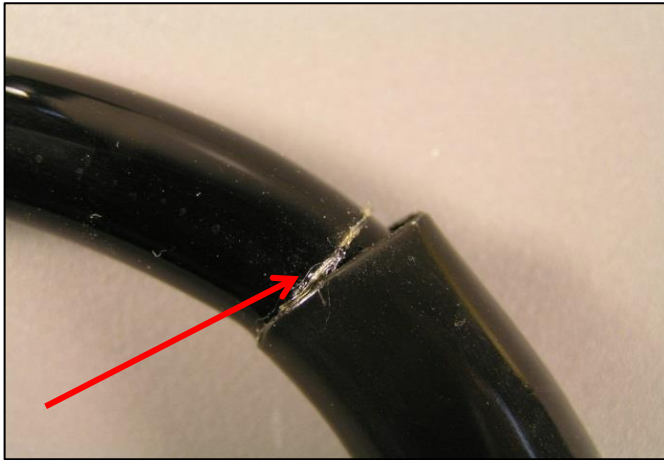
Bite mark in bending rubber
Common cause: Bite guard not used

TEE Probe Problems



Bending Neck Bead split (also referred to as insertion tube sleeve)

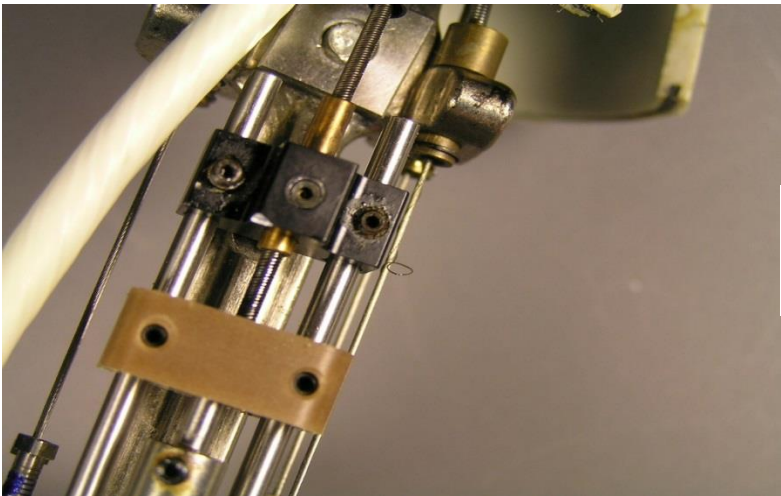
Common cause: Age and multiple HLD cleanings, also improper storage or transportation



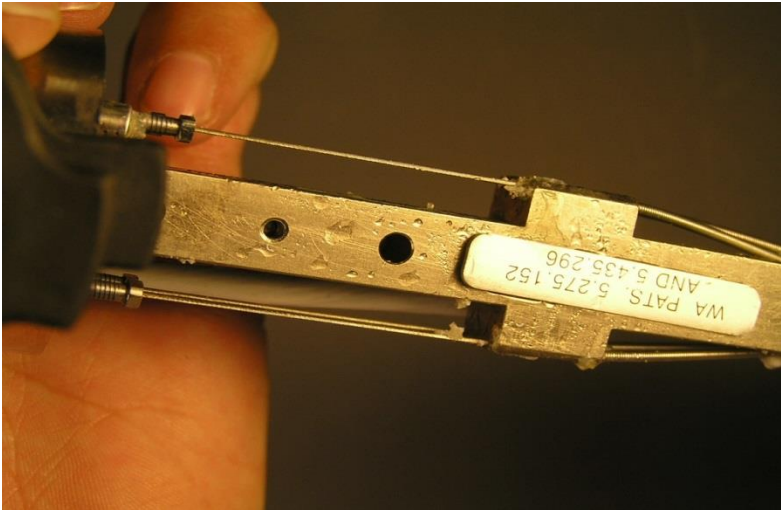
Damaged Insertion Tube (leads to fluid ingress and failing electrical leakage)

Common cause: Harsh cleaning over time, improper storage or transportation

TEE Articulation Wire Problems



Corrosion on cable mounts
Common cause: Fluid ingress



Frayed articulation wires
Common cause: Age and use



Corroded articulation wire
Common cause: Fluid ingress

Good articulation wire

Cable Problems



Cable pulled out from under strain
Common cause: Pulling the system by the probe



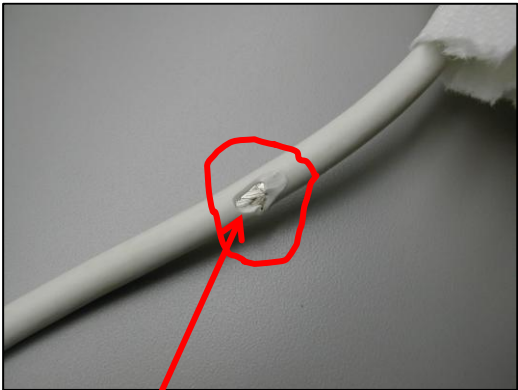
Strain relief pulling away from array housing

Common cause for both: User abuse

Cable pulled away from strain relief

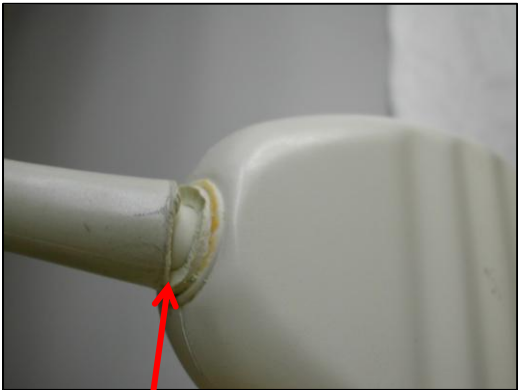


Common Tears and Scratches



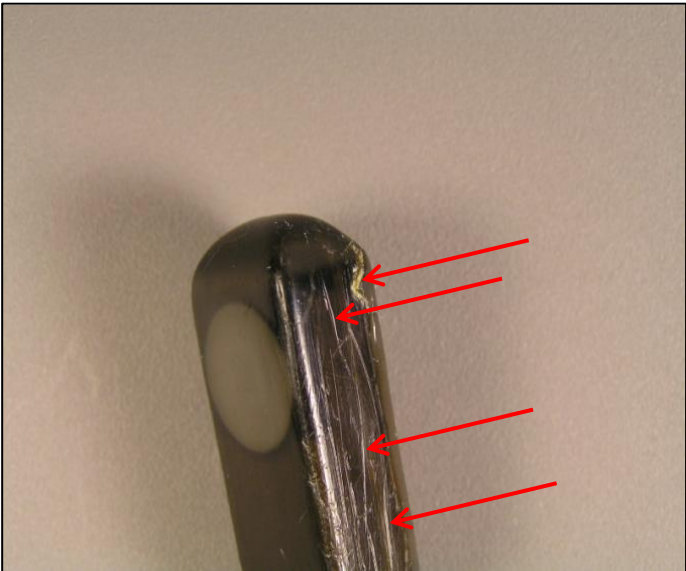
Cable Tear

Common cause: Cable catches in a doorway



Strain Relief Tear

Common cause: Exertion trauma and decomposition



TEE Array Housing Scratches

Common cause: Cleaning station process

TEE Re-coat and Re-Label



Before Re-label

After Re-label

One of the more common needs for repair on a TE probe is to re-coat and re-label the depth markers on the insertion tube. These marks fade over time as a function of use and through the disinfecting process. After the Acertara re-coat and re-label process the TE probe is fully restored to its original labeling and depth marker condition.

Probe Defects Found Most Often

General and Endocavitary Probes:

- Strain relief
 - 1) Stiffness, loss of pliability
 - 2) Torn or disintegrating
 - 3) Pulled away from scanhead housing, or connector
- Dead or weak elements
- Lens Delamination or air pockets below lens membrane
- Connector damage
- Broken wires or flex circuit termination disconnects
 - 1) Image dropout
 - 2) Poor or reduced resolution (axial and lateral)
 - 3) Noise in the CW (continuous wave) Doppler mode
 - 4) Multiplexer circuit failures in probe connector
 - 5) Transducer recognition failure
- Cable tears, holes, damage to wires, cable discoloration

Volumetric 3D Probes:

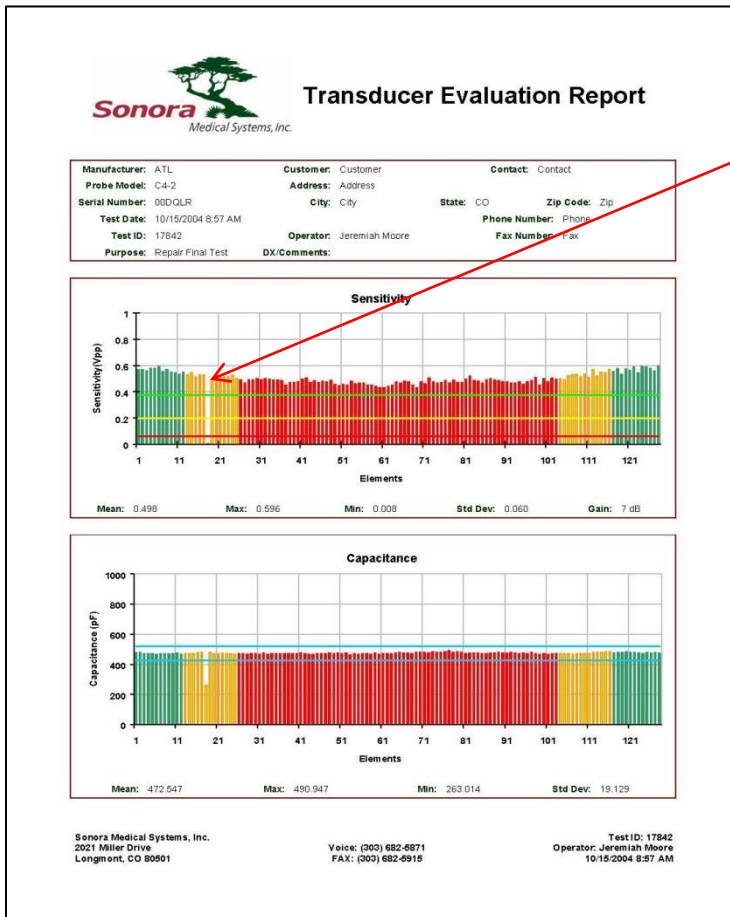
- Lens cap holes and cracks
- Bubbles in acoustic fluid
- Lens cap peeling
- Drive motor dis-functional
- Probe does not calibrate on system
- Strain reliefs
- Cable tears and other cable damage
- Dead elements

Transesophageal Probes:

- Holes, bite marks, tooth drag punctures, scratches
 - 1) Scratched housing tips
 - 2) Holes or dents in lens
 - 3) Holes, tears, dents, and scratches in the insertion tube sleeve
 - 4) Holes, tears, dents, and scratches to the insertion tube
 - 5) Cable discoloration
- Chemical damage
- Fluid ingress
- Failure to calibrate
- Articulation and/or motor problems in handle

Testing for Dead Elements

An example of a Sonora FirstCall Test Report, where each crystal within the array is tested, is shown below. In this example element number 19 is no longer functional (zero sensitivity). The FirstCall device was designed in the year 2000 and was introduced as a commercial product in 2001. FirstCall was designed by the current engineering team and Founders of Acertara. Although it remains a powerful tool for testing ultrasound probes, FirstCall requires an adaptor for each probe model (OEM). In 2014 there are so many different manufacturers and types of probes that a new type of probe tester was required. This new tester, Aureon, is shown on the following page. The color zones shown in the report relate to the level of importance of the elements within those zones being healthy. To understand the relationship between the numbers of elements within any given zone and the performance of the array please see the Acertara White Paper entitled “*Making Performance Calls on Contemporary Diagnostic Ultrasound Transducers*”

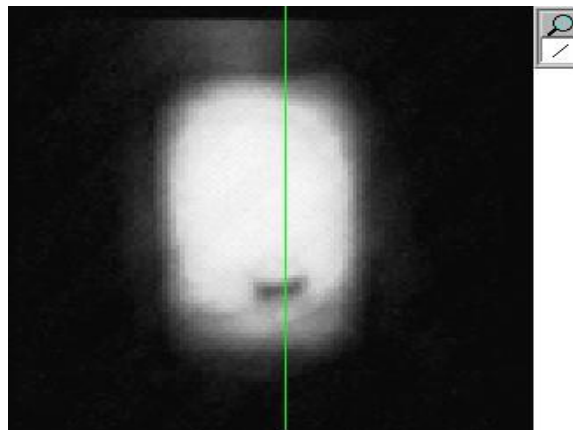
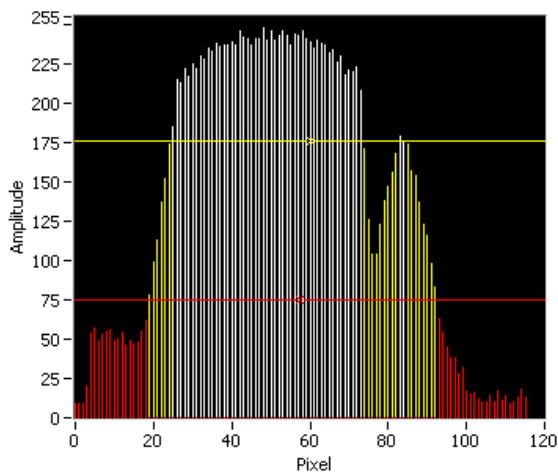
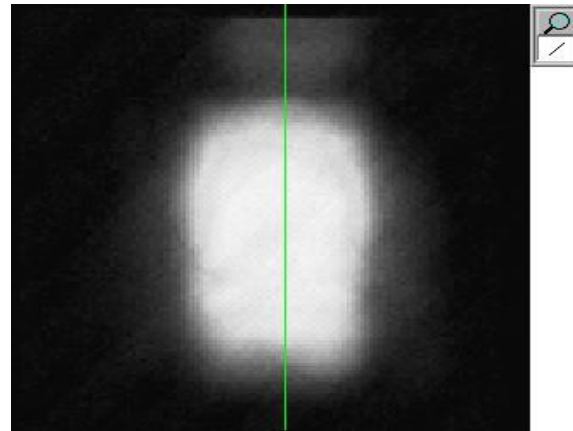
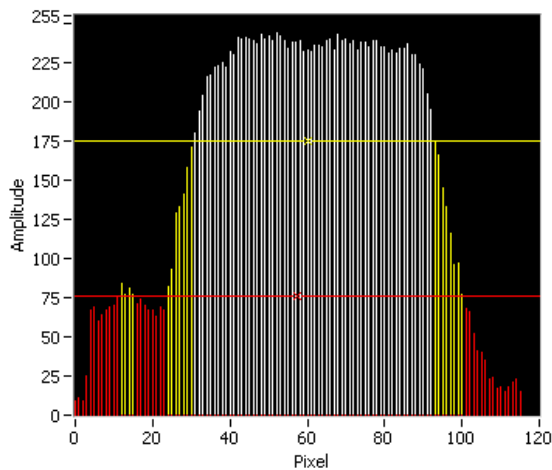


Single Dead Element

Common cause: Manufacturing process

Testing for Dead Elements

Shown in the Photo to the right is the new Aureon probe testing device from Acertara. This device is designed to be used with any probe and with any ultrasound system, without the need for an adaptor. Aureon captures, in real-time, the acoustic energy being emitted from the surface (aperture) of the probe under test. If there are any dead or weak elements the intensity of the image will either be subdued (weak element), or missing (dead element). This is demonstrated in the images below. The test shown is being performed on a Philips X6-1 matrix array probe that has more than 9,000 elements. A fully functional probe is shown in the top image and a less than functional probe, with two dead "zones" shown in the bottom image. The sonographer using the defective probe was complaining about a "strange" looking B-mode image, but could not determine what was causing it. The Aureon test revealed the two dead zones and the probe was taken out of service and returned to the OEM and replaced under warranty.

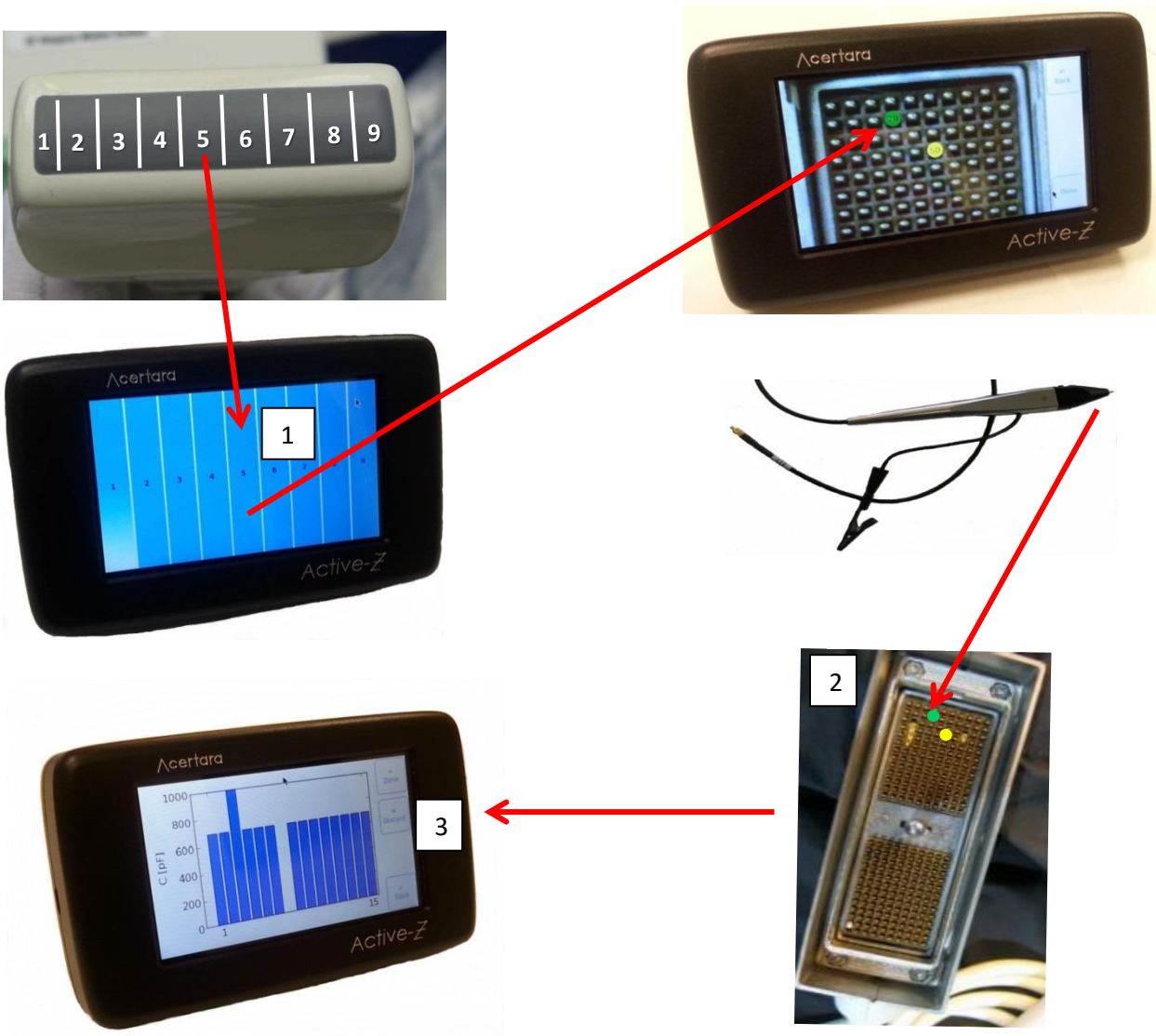


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Testing for Dead Elements

Active-Z™ is the industry standard for quantitatively testing the performance of diagnostic ultrasound transducers (probes). It is designed to be both easy to use and provide accurate and repeatable results concerning the health of the array, the cable, and the connector by measuring complex impedance. This low-cost, light-weight, point-of-test device features a rugged industrial design, long rechargeable battery life, USB connector for computer interface and report generation, and a high resolution LCD display. To use, simply touch the area of the probe's aperture, shown on the LCD display, where you suspect a problem may exist (1), use the Impedance probe to touch the corresponding pin in the connector (2), get immediate test results (3). There are normally ~ 15 elements per sub-aperture. The test below show element number 7 is dead, and a capacitive short in element number 3



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Dead Elements

Dead elements appear to be relatively common in probes in clinical use with various published data showing that 20 to 30% of probes in use having some form of clinically relevant performance problem. The Table below was part of an ultrasound quality assurance presentation given at the American Association of Physicists in Medicine (2005) and demonstrates the high percentage of probes found in clinical use with dead elements. In this study the probes were tested with the Sonora FirstCall probe tester. Since this presentation multiple international studies have been performed with defective probe findings at as high as 39% in some clinical facilities. Dead elements are generally defined as any element that is -6dB below the mean sensitivity. This definition would also include so-called weak elements.

57 Probes from the UW-Hospital Department of Radiology were tested

Scanner	# of probes tested	>2 “bad” elements	>5 “bad” elements
ACUSON Sequoia (2 systems)	18	7	3
ATL HDI 5000 (3 systems)	18	4	2
Philips iU-22 (4 systems)	15	3	2
GE Logic 9	6	0	0

Courtesy of Dr. James Zagzebski, University of Wisconsin - Madison

Counterfeit Probes



Another growing concern for ultrasound departments has been the illegal introduction of both counterfeit and misbranded probes into the after-market, general from over-sea manufacturers. These probes are made to appear like they are built by the Original Equipment Manufacturer (OEM), but have identifying marks that an observant sonographer can spot. As shown above the two probes are very similar in appearance. The probe on the left is the counterfeit as is distinguished by the different font color in the number 4, as well as the absence of the name of the manufacturer, in this case Acuson. There is a potential safety concern if using this probe relative to both the level of acoustic power being transmitted by the counterfeit as well as electrical leakage and material biocompatibility. There are now methods of testing these probes in the hospital to determine the authenticity of the probe. For example, if the hospital has an Aureon probe-testing device, it will also reveal acoustic performance variance between the counterfeit probe and an actual OEM probe. The Active-Z device will reveal electrical variances (e.g., changes in capacitance values) in performance between an OEM probe and a counterfeit.

Detailed Testing and Use/Don't Use Example

Transducer testing always starts with a thorough visual inspection of the probe patient contact points or wear-surface (e.g., lens, housing and cable). 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 illuminated 10x magnifying glass (Loupe) is required for this inspection. Transesophageal (TE) probes are especially susceptible to damage in and around the insertion tube sleeve and should receive close inspection for any bite or tooth drag marks (see Photo at right). Holes in the insertion tube sleeve will allow fluid ingress into the TE probe and can compromise patient safety and significantly damage the probe. Further, IAC (Intersocietal Accreditation Commission) requirements beginning in 2016 will mandate that a TE probe must have an electrical leakage test prior to every use.



If there is no obvious physical damage revealed during the visual inspection, and if the probe passes electrical leakage testing, then it is prudent on at least a Quarterly basis to test the probe for performance using one of three currently available objective probe-testing devices: FirstCall, Aureon, and/or Active-Z. Observe and document the health of the individual elements in the array and note any areas in the aperture where there may be suspected sub-par performance. Remember elements can become weak as a function of use. In addition to detecting dead and weak elements, the devices mentioned above can also inform the user of broken wires in the transducer cable or connector. Further, these devices can determine if the acoustic lens is either performing properly, or if it is becoming delaminated.

Multiple published papers have suggested great care in using probes with multiple dead elements. In our experience, after reviewing both clinical and acoustic lab generated data, we suggest that probes with three or more consecutive dead elements in the main portion of the aperture (see Acertara White Paper: *“Making Performance Calls on Contemporary Diagnostic Ultrasound Transducers”*), should not be used for a clinical examination. Further, we recommend that if a lens is becoming delaminated (i.e., separated from the acoustic stack) the probe should not be used clinically, but should be sent out for repair. We do not recommend using a tissue mimicking phantom (TMP) as the sole device for evaluating the performance of the transducer as certain imaging processing algorithms in the ultrasound system itself can “mask” subtle imaging issues. Further TMP’s cannot be used to evaluate Doppler performance.

Conclusion

Because the transducer is the most sensitive and most often damaged link in the ultrasound image quality chain, and because it is always in contact with the patient while being used, great care must be taken on a disciplined and consistent basis to ensure its proper performance from both an imaging perspective as well as an electrical safety perspective. The push by the Intersocietal Accreditation Commission to mandate electrical leakage testing for Transesophageal echocardiography probes prior to every use underscores the growing awareness of the risks to patients associated with using these devices. As we researched for this White Paper, we discovered a lack of consistency in various ultrasound User manuals, and test device User manuals, relative to electrical leakage testing processes, tools, and even common language describing how to perform a test and how to interpret results with respect to the IEC Standards. In order for any test to be widely accepted standards regarding that test, as well as guidance on how to perform the test, must be provided to ensure the test is done properly and the subsequent results informative. This type of structure will ensure that each ultrasound laboratory, or HTM professional, conducting the testing will arrive at the same result as every other laboratory.

Electrical leakage testing is intended to test exactly what the name implies; electrical leakage. This then is a measure of current expressed in Amperes, or in the case of ultrasound probes, micro-amperes. It is not a simple pass-fail test using a red and green LED, as this does not inform the user of any trending from test-to-test nor does it tell the user how close to being over the limit it actually is. It is not an Ohmic measurement designed to detect a fluid ingress into a probe, which, although a useful measurement, does not address the IEC standards. It is a test to ensure that patient leakage current is less than the IEC standards proscribe, expressed in micro-amps.

The intent and goal of this paper was to shine a light on the current state-of-the-test for electrical leakage testing of ultrasound probes and to provide the reader with additional informative data that will provide further context around the why's and how's of this testing - a *"Thinker's Guide."*

About Acertara Acoustic Laboratories

The dramatic cost containment health care environment in the United States, coupled with the rapid industry consolidation of diagnostic ultrasound device manufacturing into the hands of four major companies (General Electric, Philips, Siemens, and Toshiba) has put tremendous pressure on hospitals to seek new and innovative ways to not only maintain profitability, but to survive. It is the driving purpose of Acertara to provide hospitals and other healthcare providers with a comprehensive portfolio of after-market products and services designed to allow our customers to dramatically reduce the costs associated with managing and maintaining their diagnostic ultrasound capital assets for longer periods of time, and in many cases obviating the need for expensive OEM service contracts. This cost savings is coupled with our desire to create products that not only reduce costs, but assure positive outcomes-based performance from the ultrasound devices. From regulatory testing of OEM ultrasound systems and probes, designing state-of-the-art probes testing devices, and offering industry leading advanced probe repair services, Acertara provides a turnkey cost-effective solution for the hospital contemplating maintenance of its own ultrasound systems and probes. Acertara is an active member of NEMA (National Electrical Manufacturers Association) – Ultrasound Section, the Medical Imaging Technology Alliance, or MITA, (www.mita.org), is ISO 13485:2016 certified to the Medical Device Directive, and has established probe repair facilities in cooperation with international partners in seven countries around the world. Supporting our repair and validation activities Acertara is also an ISO17025:2017 accredited ultrasound power testing and calibration laboratory.

At Acertara we currently test and repair more than 2,000 probes per year, saving the health care system in the United States alone more than \$25 million per year in unnecessary probe replacement costs. For more information on our probe repair services or our probes test devices go to www.acertaralabs.com, or call us at 303.834.8413. We look forward to serving you.





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