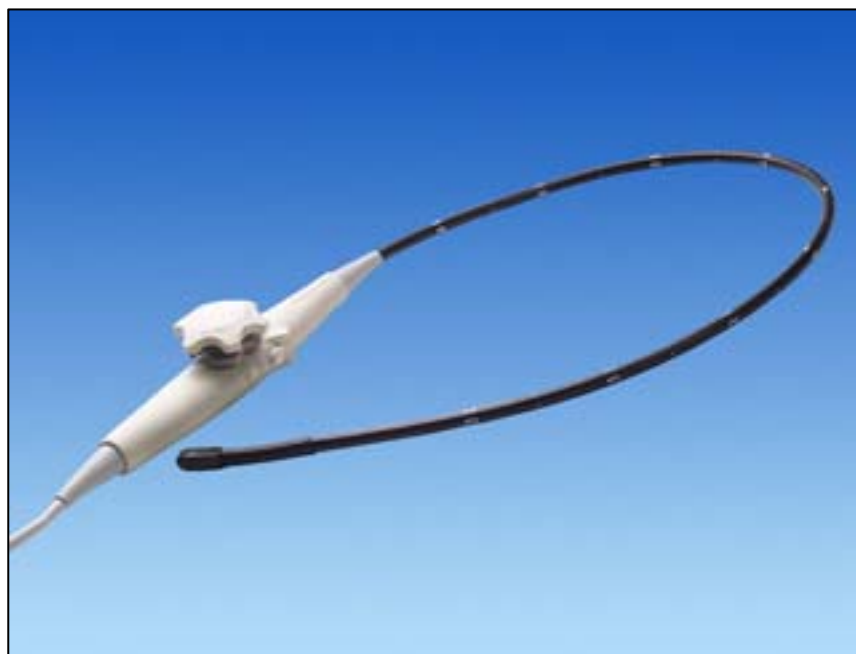

On the Proper Care of a Transesophageal (TE) Probe

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INTRODUCTION

Transesophageal echocardiography (TEE) has become the standard of care for various cardiac related clinical applications and is used in the echo laboratory, outpatient settings, as well as the operating room. The clinical dependence on the proper operation of these probes is increasing with expanding clinical utility and significant technological advancements in transducer design, specifically and recently with 2D matrix arrays that provide a 4D volumetric image. Transesophageal probes (TE) are often used in the most demanding clinical environments and are exposed to many different hazards that can result in damage to this important and expensive probe. In fact, the proper care and regular testing of TE probes are the key determinants relative to the overall level of operating expenses related to the ultrasound systems in the echo department. Empirically derived data over the last 10 years has shown that approximately 70% of ultrasound service calls turn out to be, in some manner, probe related. Multiple published studies have also shown that improperly functioning probes can negatively impact the clinical results of the ultrasound examination¹⁻³. However, almost all TE probe failures, when discovered early enough, can be repaired in a safe and efficacious manner, potentially saving the echocardiography department tens-of-thousands of dollars per year in operating expense. This white paper is designed to present the clinical end user, as well as those responsible for the care of the TE probes, with specifics on what steps are necessary to extend the maximum useable life of these very expensive and delicate probes, as well as to ensure the safety of both the patient and the user of the probe. Further, we will present examples of common TE probe problems and how to identify them in a timely manner, while cost effective repairs can still be made. To help with this process we have included in this white paper a flow chart sample that guides the TE probe from use, through disinfection, testing, and transportation of the probe. While it is clear that everyone involved with the maintenance of the echocardiographic devices in your department is responsible for providing the patient with a safe and efficacious echo study, the lead for ensuring this falls to the professional who handles the TE probe on a daily basis. The clinical end-user, by virtue of their work, should normally be the first to observe any changes in the ultrasound image, spot any obvious structural damage to the TE probe, and see any bite holes in the bending area of the probe, cracks in the case or tears in the cable, and probe articulation problems. Any of these signs

of failure should be reported to the Hospital Biomedical Engineer or Clinical Engineer as soon as they are discovered and use of the probe should be discontinued until the problem is resolved.

Replacing transducers is the highest cost component in the maintenance of ultrasound systems. The most expensive medical devices used with the echocardiography system, with the exception of the system itself, are the TE probes (also known as TE transducers). The cost of a new TE probe ranges from \$42,000 to \$80,000 depending on the type of TE probe, with the higher amount being the newer 2D Matrix Arrays. When a TE probe fails the cost of an exchange from the Original Equipment Manufacturer, or OEM, is generally in a range of \$21,000 to \$50,000. Even if the probe is under warranty or service contract, customer "abuse", or "avoidable transducer damage" determinations made by the OEM may result in the hospital paying for the exchange anyway.⁴

There are some very important, yet easy to implement and follow, preventive measures that not only extend the useful life of these expensive probes, but will also improve patient safety, ensure clinical efficacy, and reduce the overall operating costs for the facility. The most important of these preventive actions are:

- Electrical leakage testing at the beginning of every disinfection cycle;
- Proper and consistent use of bite guards;
- Following the manufacturer's recommended disinfection procedures;
- Regular testing of the probe's articulation mechanism;
- Regular visual inspection of the probe;
- Careful handling, transportation and storage of the probe.

Electrical Leakage Testing

For TE probes, almost all manufacturers' operator's manuals say that electrical leakage testing should be done before *every* patient exam. This instruction is given with good reason, since a TE probe that fails electrical leakage puts a potentially dangerous path to ground right behind the patient's heart. The more common patient safety risk is that of a hole or bite mark that breaches the coating or rubber insulation of the endoscopic shaft portion of the probe. This type of insulation compromise not only causes the TE probe to fail electrical leakage, but also causes an increased risk of cross-contamination and infection. Additionally, a TE probe that fails electrical

leakage generally has a puncture defect that allows fluid, such as the disinfectant that is used to clean the probe between patients, to migrate into the insertion tube of the probe. These disinfectants have been known to leak out of the probe while it is inserted into the patient, and have resulted in reports of burning of the patient's esophagus and illness following a TEE exam.⁵

The disinfecting solutions used with TE probes are both electrically conductive and highly corrosive. Once these fluids are inside the TE probe they can flow to other parts of the probe including the control housing and the transducer array inside the tip of the probe. Fluid infiltration sometimes cause an immediate failure of the probe, but even more serious damage will occur as a function of time as the disinfectant "eats away" at the vital components inside, such as the elements in the transducer array, any electronic components that may be in the tip of the probe, and the articulation wires (see photo to right for example of the corrosive effect). The articulation wires within the endoscope shaft of the TE probe connect the controls (usually knobs) located on the control housing to rings located between the bending neck rubber and the scanhead (tip), and are used to position the array in the scanhead so that the appropriate images can be obtained. If the articulation wires break, which can happen due to wear, force, or more commonly after a long period of exposure to disinfecting fluids, the probe will need to be repaired and the articulation wires replaced. If an articulation wire breaks while the TE probe is inserted into the patient, it may cause patient injury when the probe has to be extracted from the esophagus without being able to properly straighten the end of the insertion tube.



Most of the failures outlined above associated with fluid intrusion can be repaired, but if the corrosion damage is not caught early enough in the process the severity of the damage sometimes cannot be completely reversed and will eventually result in the necessity of replacing the TE probe. Therefore it is essential that after every TEE procedure the probe insertion tube be closely inspected for any compromise to the integrity of the insulation. If a hole, suspected hole, or cut is seen in the insertion tube area the probe should not be disinfected until electrical leakage and FirstCall⁶ testing is performed by the Biomedical Engineer. The electrical leakage testing can be

done with a device such as the iTest⁷ ultrasound leakage tester or the testing device provided with the TE probe by the OEM. The FirstCall device is used by the Biomedical Engineer to determine whether fluid infiltration of the TE probe has occurred. Electrical leakage testing should also be performed prior to or at the very beginning of the disinfection cycle, to avoid possible fluid infiltration into the TE probe. A probe that fails electrical leakage must be taken out of use immediately.

Warning -- Be sure to read and follow the included instructions and the safety warnings specific to your particular ultrasound leakage analyzer.

Use of Bite Guards

The “gag reflex”, or an involuntary bite response, can be a potential patient safety risk during any TEE examination. A bite guard protects the patient from potential injury and protects the TE probe from avoidable damage. In Japan, for example, it is actually illegal to perform a TEE examination without using a bite guard. The OEM user manuals call for the use of a bite guard for every exam⁸, and if the probe is damaged as a result of not using a bite guard the OEM will generally not cover the probe under warranty (see respective OEM operator's manuals for warnings in this regard). Not using a bite guard can also result in what is referred to as "tooth drag" or pulling the insertion tube over a tooth that may have a sharp edge, resulting in a cut or tear in the insertion tube. These cuts, holes or tears create a potential entry point for fluids. Proper use of the bite guard means placing and securing it in the patient's mouth *prior* to insertion of the TE probe.

Proper Disinfection Procedures

The proper disinfectant is one that is listed as approved for use in the documentation provided by the OEM of the particular probe. This information is normally found in the TE probe operator's manual and many of the OEMs also list approved disinfectants on their respective Internet sites. The instructions on the disinfectant should be followed, and they include information such as how long the solution can be used once activated, how many minutes the transducer should be soaked, how to test the solution to ensure it is still effective and how to properly dispose of the solution. Using an unapproved disinfectant may result in voiding of the warranty on the probe, and may expose the probe to both premature failure and insertion tube discoloration or fading.

Because of the importance of the disinfecting process close attention should be given to the methods used by the personnel disinfecting the transducer and the training they receive. This will ensure that the disinfection is done properly, consistently, and in a manner that is least likely to result in accidental damage to the transducer, or cross-contamination. Some essential points to consider for the disinfection process are:

- Electrical leakage testing should be done just prior to or at the very beginning of the soak cycle.
- Soaking the TE probe for too long in a disinfectant will cause excessive wear and damage to the insertion tube.
- Proper ventilation is required to meet the OSHA Air Contaminants Standard (29 CFR 1910.1000).
- No disinfecting solution or rinsing water can be allowed beyond the end of the insertion tube, or liquids may potentially get into the probe or connector and cause failures.
- The transducer elements are located at the end of the insertion tube (tip) and are very fragile, so care needs to be taken to not have the tip impact any hard surface such as a table or the sink basin.

The use of a specially designed, FDA 510(k) cleared, automated TE probe disinfecting device such as the CS Medical model TD-100⁹ is recommended for safely and effectively disinfecting TE probes. This automated device mitigates many handling and cleaning issues that are primary causes for TE probe failures associated with handling and over-soaking.

Testing the Articulation Mechanism

The articulation mechanism is comprised of control knobs on the control housing of the TE probe, which connect to very thin cables that are routed through the insertion tube to the scanhead (tip). The articulation knobs are used to move the tip of the TE probe (along with the transducer array) into various positions and angles needed in order to obtain and maximize the desired scan image or Doppler signal. Over time and with frequency of use, this articulation mechanism will wear (e.g., loosen, or become "sloppy" and unresponsive), be damaged by fluid infiltration and the resultant corrosion, or be damaged by improper handling and use of the TE probe. As stated earlier in this paper, a failure of the articulation mechanism while the probe is inserted into the patient's esophagus presents a potential safety hazard. For this reason, daily testing of the

articulation mechanism is important to detect any changes in its performance of the mechanism so that repairs can be made early in the failure process. Personnel that use or clean the TE probe regularly should be trained to do this articulation testing and what to look for in terms of changes in performance or function. In-house biomedical engineering personnel, OEM personnel or an independent ultrasound field service engineer should also check the articulation performance during regularly scheduled preventive maintenance service calls. Depending upon frequency of use, it is recommended that this mechanical inspection be done once per day and any changes noted in an equipment log.

To check the articulation:

1. Hold the TE probe with the insertion tube in a position so that the scanhead end (tip) can move freely. The scanhead and bending neck sheath should be in line with the rest of the insertion tube.
2. Move the first articulation knob slowly in one direction. The scanhead should start to deflect (move) as soon as the knob is turned, and should move smoothly throughout the full deflection as the knob is turned. Then the knob should be turned so that the scanhead and bending neck are in line with the insertion tube again.
3. Move the first articulation knob slowly in the other direction; again checking to make sure the deflection of the scanhead is immediate and smooth.
4. Repeat the tests using the other articulation knob.
5. Any variances noted should be reported to the Biomedical Engineering for confirmation and the probe should be sent in for repair and articulation re-calibration.

Visual Inspection of the TE Probe

A TE probe should be visually inspected at least once per day, and many OEM user manuals call for this to be done prior to each patient examination. Sonora recommends using an off-the-shelf magnifying glass when scanning the length of the insertion tube up to the tip. Black insertion tubes often make it difficult to spot small holes or tears in the insulation material. This inspection is best done under a light so that any irregularities may be more easily identified. A few examples of problems to look for are shown in the following photos. The suggested checklist of things to look for is:

- Cuts, air bubbles or gouges on the lens material;
- Condition of the bend reliefs (connector and each side of the control housing);
- Cracks or other signs of damage to the connector;
- Cracks or other signs of damage to the control housing;
- Bent or damaged pins in the probe connector
 - (If using a “pin-less” connector, e.g., Siemens/Acuson Sequoia probes, inspect the surface of the connector to ensure it is clean);
- Integrity and flexibility of the cable;
- Bite marks on the bending neck rubber or lens.



Scratching on the Lens



Tooth Drag Marks

TE Re-coating and Re-Labeling



Before Re-label

After Re-label

One of the more common needs for repair on TE probes is to re-coat and re-label the depth markers. These marks fade as a function of use and through the disinfecting process, especially if the disinfecting process is a manual one where over-soaking can be a problem. After the Sonora re-coating and re-labeling process the depth markers and the outer protective coating of the TE probe insertion tube are fully restored to their original new condition. It should be noted that OEMs generally do not cover discoloration or fading under warranty¹⁰

A Suggested TE Probe Inspection Routine

Inspect Carefully for the Following

- Articulation changes (sloppiness, unresponsive, tight, etc.) in the tip deflection controls
- Discoloration of the insertion tube, or depth mark fading
- Cuts or gouges on the lens material
- Pinched endoscope shaft (insertion tube)
- Condition of the bend relief(s)
- Cracks or other signs of damage to the connector, or tip of the TE probe
- Bent or damaged pins in the probe connector
- If using a “pin-less” connector (e.g., Siemens/Acuson Sequoia probes) inspect the surface of the connector to ensure it is clean
- Integrity and flexibility of the cable
- Bite marks, holes or tears in the bending rubber

What Can Hurt a TE Probe

- Electro-static discharge on or around the lens of the probe, or the pins on the probe connector
- Not using bite guards on a consistent basis
- Rapid deceleration trauma (dropping the probe), or other blunt force trauma, especially during a manual cleaning process where the probe is handled
- Using the wrong disinfecting agents, or using the correct ones in the wrong manner
- Improper storage, handling and transportation
- Not freezing the image before removing or connecting a probe to the system
- Improper or insufficient cleaning

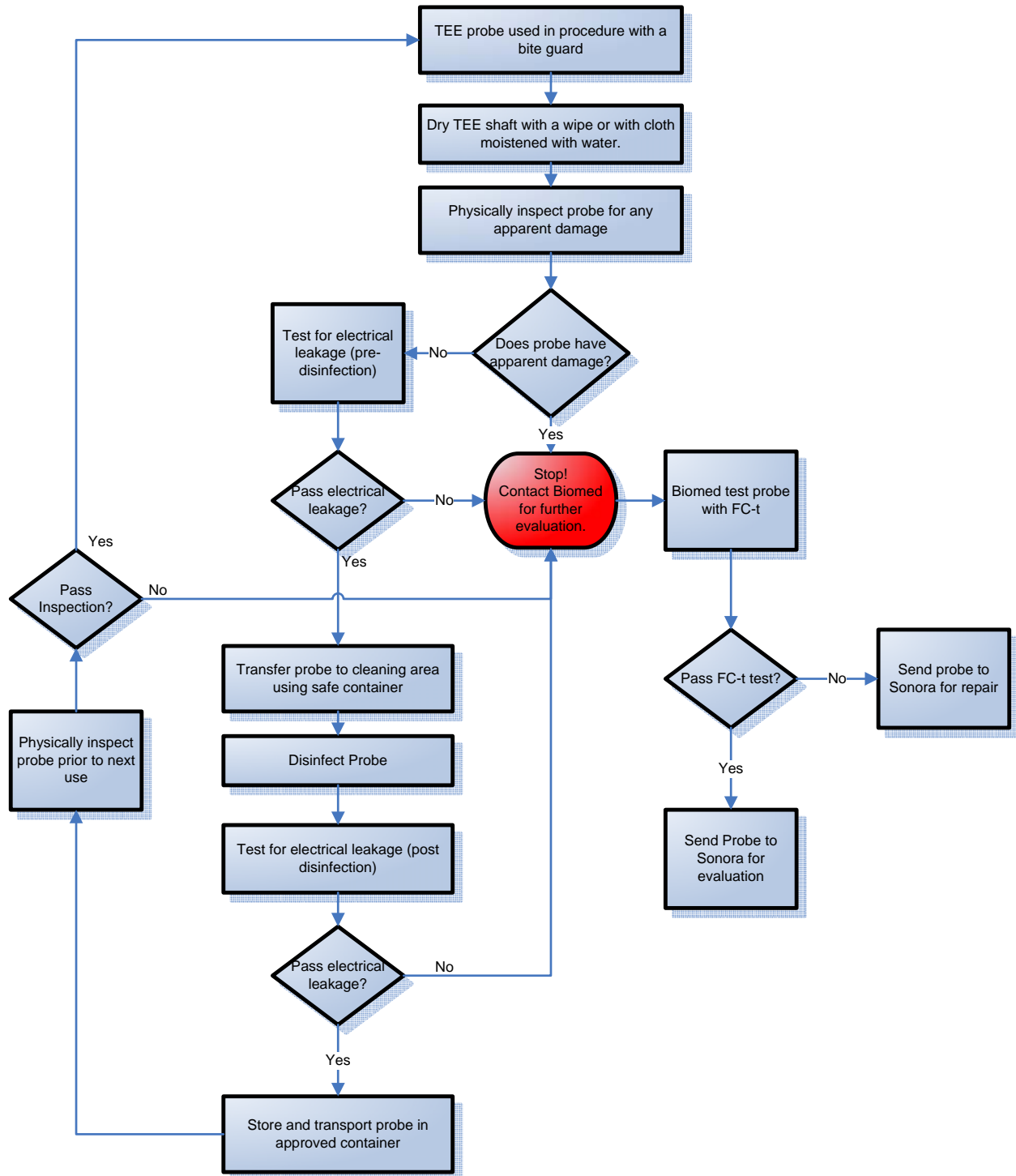
What Preventive Measures Can I take?

- Inspect the probe on a daily basis – use a magnifying glass to inspect the lens and insertion tube, pay special attention to the bending rubber area. Inspect under sufficient light
- Follow the recommendations for use and cleaning in the probe operator's manual
- Have the probe regularly tested on a daily basis, or if a problem is suspected. This is for both electrical and mechanical articulation evaluation.
- Keep transducer cables off the floor
- Use the TE probe storage rack or other suitable storage device when probe is not in use
- Keep a TE probe maintenance and inspection log

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 and the functionality and safety have been verified.

TEE Probe Care Cycle



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Careful Handling of TE Probes

It cannot be over emphasized that all the personnel using and disinfecting the probes need to be properly trained on how to test, inspect, transport, and handle TE probes. This includes the physicians, echocardiographers, the personnel in the OR, and the people that disinfect the probes. Dropping or banging the TE probe can cause serious damage. Even a slight impact can seriously damage the acoustic array, which is made of piezoelectric crystals as fragile as glass. The people that disinfect the TE probes may not even realize what part of the probe is the most vulnerable to damage without proper training. Physicians also need to be informed and reminded from time-to-time about the proper use of bite guards and the safe handling of the probes.

Checklists should be used by the different people using and handling the TE probes, to ensure that they are testing and inspecting them regularly and to document the electrical leakage tests, any mechanical issues or changes with probe articulation, and the proper use of bite guards. These checklists will aid in determining causes of damage, detect failures earlier in the process when they can still be safely and effectively repaired, and provide objective evidence for inspectors and auditors of regulatory or accrediting agencies that an effective QA process is in place. Audits of the maintenance and inspection records on an ongoing and regular basis will help ensure that procedures are being followed and also help identify areas for improvement. The high risk and expense associated with these probes makes these efforts worthwhile, and cost effective.

Sonora Medical Systems has published a white paper entitled *Common Ultrasound Probe Failures* that is an excellent tool to use in training people on inspection of ultrasound probes. It is available free for downloading from our website (www.4sonora.com). Our regional sales managers in the United States are also available to give presentations on testing and inspection of TE probes, and to provide in-service training for BMETs, Clinical Engineers or end users of the equipment. They can also provide the training material that the Biomed or Clinical Engineering department can use to provide training to the hospital personnel. To request these presentations please email your request to sales@4sonora.com.

Conclusion

The TE probe is the most sensitive and most often damaged link in the ultrasound image quality chain. Because TE probes are handled by various hospital personnel, tested, cleaned, and transported within the hospital they are susceptible to all manner of physical damage resulting from accidental dropping, aggressive cleaning methods, or other traumatic occurrences such as banging. In our experience, high-use TE probes used in a facility without an effective QA program generally display some form of performance compromising anomaly within 6 to 14 months after being placed into service. During the ten-year (120 months) operational life span of a premium quality ultrasound system, a TE probe could potentially be replaced up to five times, simply due to “normal” use. Without an adequate TE QA process in place probes could be replaced as often as every 6 to 9 months. At an average cost of ~ \$21,000 per TE probe replacement, the financial impact of replacing transducers to the hospital or clinic becomes quite apparent.

An active and comprehensive ultrasound EBQA (evidence-based quality assurance) program can substantially lower costs for hospitals by identifying TE probes **early** enough in the failure process that they can be repaired rather than replaced. For example, a new transesophageal probe can cost \$50,000 or more and a replacement (meaning the damaged one is exchanged for another one) TE probe normally costs as much as \$30,000 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. Over the ten-year lifespan of the ultrasound system in this scenario it could mean the difference between as much as \$300,000 in replacement costs versus less than \$75,000 in repair costs, or less because an effective EBQA program will also drive down the number of failure occurrences. Even more important is the assurance of user and patient safety and the optimal clinical efficacy of the TEE examination.

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About Sonora Medical Systems

The dramatic cost containment health care environment in the United States 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 Sonora to provide hospitals 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 imaging capital assets for longer periods of time, and in many cases obviating the need for expensive OEM service contracts. From service training, to parts and industry leading advanced probe repair, Sonora provides a turnkey cost-effective solution for the hospital contemplating maintenance of its own ultrasound systems and probes. Sonora's team members have a combined 200 + years of experience in diagnostic imaging to put to use for our valued customers. Sonora is an active member of NEMA (National Electrical Manufacturers Association) – Medical Imaging Technology Alliance (www.nema.org), has a quality system that is ISO 9001 and ISO 13485 certified, and has established probe repair facilities in cooperation with international partners in seven countries around the world. Sonora has been voted in the Top Ten of the Reader's Choice Awards and is cited in the DotMed Top 100 Medical Companies. The President of Sonora Medical Systems, G. Wayne Moore, is a Fellow of the American Society of Echocardiography.

At Sonora we test and repair more than 3,500 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, and other after-market services go to www.4sonora.com, or call us at 303.682.5871. We look forward to serving you.



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