Using FDA Documents for Vetting Suppliers

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MD EXPO

MDEXPO
SoCal • April 15-17, 2025

About the Speaker: G. Wayne Moore

- G. Wayne Moore is the Founder/Partner with Acertara Acoustic Laboratories an independent ultrasound acoustic testing laboratory and service organization located in Longmont, Colorado.
- Mr. Moore is the 2025 Chair of the Ultrasound Section of AdvaMed Imaging, as well as a Committee member on the AIUM Bioeffects Committee as well as liaison to the AIUM Technical Standards Committee.
- He is a fellow of the American Institute of Ultrasound in Medicine (AIUM) and a Fellow of the American Society of Echocardiography (ASE). He was the recipient of the Roentgen Award in 2022 for his contributions to the development of ultrasound technologies. He holds more than 25 US and International patents in the field of ultrasound devices.
- He earned a Bachelors degree in Engineering and Masters in Business Administration from the University of Denver – Daniels College of Business

Content

- Overview of FDA Guidance Documents
- How They Apply to HTMs and ISOs
- Points to Consider when Researching
- Why Vetting Matters
- Class II Medical Device Example
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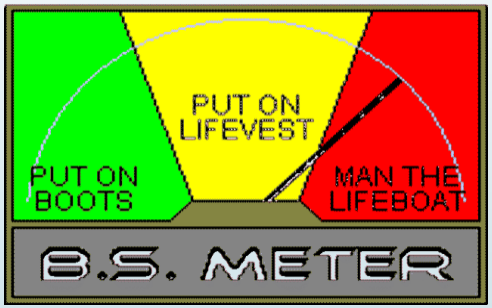
Medical Device FDA Classifications

Class I (Low Risk)	Devices are subject to general controls that are applicable to all classes of devices.
Class II (Medium Risk)	Devices for which general controls alone are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and are therefore subject to special controls to provide such assurance.
Class III (High Risk)	Devices for which general controls alone are insufficient and for which there is not enough information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device. Class III devices typically require premarket approval (PMA).

For example, ultrasound probes are classified as Class II finished medical devices

Separating Myth from Fact



Overview of FDA Guidance Documents

The FDA internally develops and legally reviews their guidance and regulatory documents. They are the sole interpreter of what those documents say, or don't say, and is responsible to enforce their interpretation. This approach is similar with what the IRS does with its "filing instructions" – they write, interpret, and enforce. The enforcement approach both agencies take is that you are presumed guilty, and you must prove your innocence. This point is essential when reading Agency documents as the word "should", for example, could instantly morph into "must" depending on the situation. When selecting 3rd Party service providers, HTMs should factor this reality into the vendor selection process and ask for objective evidence from service providers that show they are treating FDA "shoulds" as "musts".

Overview of FDA Guidance Documents

"*In general, FDA guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.*" For example, the recently released Remanufacturing of Medical Devices Guidance has 70 footnoted citations. So, the reader of the Guidance document must also read each of those 70 citations to ensure they do not contain applicable statutory requirements. "*The use of the word 'should' in Agency Guidance means that something is suggested, or recommended, but not required.*" The word "should", as used by the Agency has, therefore, no presumptive force of law.

Contains Nonbinding Recommendations

Remanufacturing of Medical Devices

Guidance for Industry, Entities That Perform Servicing or Remanufacturing, and Food and Drug Administration Staff

Document issued on May 10, 2024.

The draft of this document was issued on June 24, 2021.

For questions about this document regarding CDRH-regulated devices, contact the Regulation, Policy, and Guidance Staff at RPG@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010, or by email at ocod@fda.hhs.gov.

FDA U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

Reading the Documents

Determine what the Guidance is truly focused on, for example, is the activity being performed on a finished medical device simply routine servicing or remanufacturing? Look for language in the Guidance that says something like; *"Activities that are not intended to significantly change the performance or safety specifications, should still be evaluated to determine whether they actually do significantly change the devices' performance and safety specifications."* In this case even though the Agency uses the word "should" with the verification that no significant change occurred during the activity, there can exist in a cited reference that this must be done[1]

[1] "Deciding When to Submit a 510(k) for a Change to an Existing Device," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-changeexisting-device

Should Versus Required

Entities performing activities on devices should make a determination about whether each activity and the cumulative effects of such activities are remanufacturing and document their rationale. When deciding whether an activity is remanufacturing, entities should document the decision-making process and the basis for the determination. The documentation should be prepared in a way that clearly describes the rationale underlying the conclusion, such that it could be understood by an FDA investigator or a third party. For this, we recommend that the documentation include at a minimum, the following:

- Product name (including model and serial number, if applicable)
- Date of activities performed, assessment, and determination
- Description of device
- Description of activities to be performed, including documentation of components, parts materials involved
- Determination of whether the activity is remanufacturing (we recommend using the applicable sections of this guidance)
- Reference to related documents supporting the decision-making process

Repair Versus Remanufacturing

Note: The FDA does not have a definition for a “bad repair”, it only offers two scenarios: (1) repair is an activity that returns the device to OEM specs, or (2) if it doesn’t then the activity is defined by the FDA as remanufacturing. When reviewing FDA docs remember – words matter

How Does ISO Certification Differ from FDA Compliance?

“The ISO registrar is *auditing* for conformity to a standard, a service for which you voluntarily pay. FDA is *inspecting* for compliance to a regulation. There is a significant difference."

The basic message is that *conformity* to a standard does not equal *compliance* with a regulation. An auditor representing the registrar that issues your ISO certificate is trained to assess conformity of your QMS to the standard by employing a methodology that is different from that of an FDA inspector, and the consequences for nonconformance are different. Also, if you are out of compliance with a regulation the FDA Agent may shoot you, while in most cases the ISO auditor will not. Just kidding

How Does ISO Certification Differ from FDA Compliance?

Compliance ≠ Quality

"...one device manufacturer can meet FDA requirements
and *still* make a poor quality device whereas

a second manufacturer may not comply with all FDA requirements
and yet make a high-quality device"

Jeff Shuren, M.D., J.D.,
Director CDRH

What Applies to HTMs?

HTMs that are employed by the hospital as FTEs are not considered 3rd Party Servicers by the FDA. These HTMs can do what they are directed to do by the hospital relative to repair or modification of a device. However, those repairs or modifications should be evaluated against this document if they are going to be returned into Interstate commerce (i.e., sold or traded back into the market). The system may be classified by the Agency as adulterated based on the modifications or “repairs” that were performed.

What Applies to OEMs?

The considerations in this section apply to OEMs, third party servicers, and ISOs. The intent of this section is to provide additional insights for entities that may be less familiar with the FDA's medical device regulatory requirements

What Applies to ISOs?

Activities that are not *intended to* significantly change the performance or safety specifications, however, should still be evaluated to determine whether they *do* significantly change the finished device's performance and safety specifications. Multiple changes, when considered cumulatively, may significantly change the performance or safety specifications.

Essential Points

The Reman v Service guidance discusses whether activities performed by OEMs and third parties on such devices are likely remanufacturing – Page 3, Paragraph 2

Legal definition of a Third party - A person or entity who is not a principal party. Often refers to someone who is not party to a dispute or agreement.

FDA definition of Third-party servicers and Independent Service Organizations (ISOs): Entities, other than the OEM or healthcare delivery organizations

Irrespective of an entity's self-identified designation as a "servicer" or "remanufacturer," FDA focuses on the specific activities an entity performs on a particular device.

Make note of references listed and how they may apply to your organization – for example, "More information on the oversight and regulatory differences between ISOs and healthcare delivery organizations can be found, at https://www.fda.gov/media/113431/download. 24 21 CFR 820.3(w)."

Why Testing and Validation Matters

Guiding Principles

1. Assess whether there is a change to the intended use
2. Determine whether the activities, individually and cumulatively, significantly change the safety or performance specifications of a finished device
3. Evaluate whether any changes to a device require a new marketing submission
4. Assess component, part, or material dimensional and performance specifications
5. Employ a risk-based approach
6. Adequately document decision-making

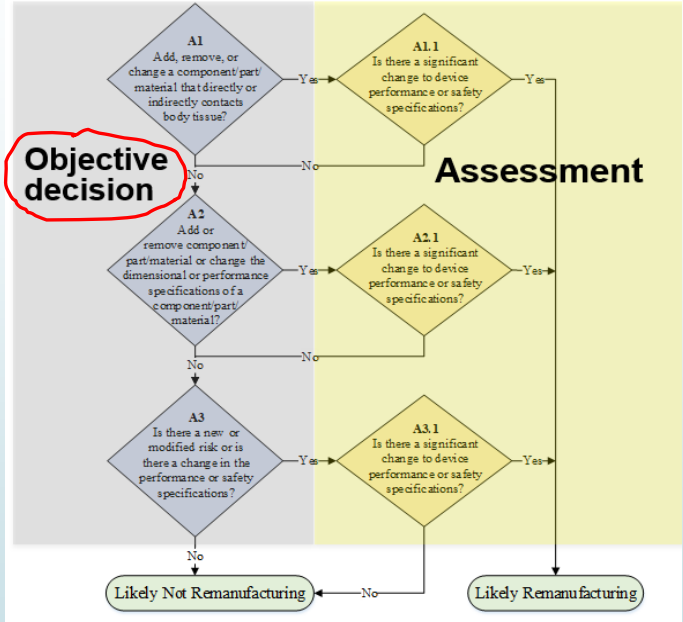
Applied Principles

"Activities that are not intended to significantly change the performance or safety specifications, however, should still be evaluated to determine whether they do significantly change the devices' performance and safety specifications."

Irrespective of an entity's self-identified designation as a "servicer" or "remanufacturer," FDA focuses on the specific activities an entity performs on a particular device.

Objective Evidence

Objective evidence is data that supports the verification of something and is factual, measurable, and quantifiable. It can be obtained through observation, measurement, testing, or other methods. Objective evidence is not based on what someone says, but on factual documentation



Objective Evidence

The impact of component/part/material changes can be evaluated by comparison to the OEM components/parts/materials specifications and/or through verification and validation testing.

Deviations in component/part/material specifications from the OEM's legally marketed device may result in significant changes to the device's performance or safety specifications, and may necessitate closer evaluation, such as conducting an engineering analysis, verification and/or validation testing, or a risk-based assessment, and consideration of the regulatory criteria describing when a new marketing submission is required.

Example of Reading What Matters

Marketing Clearance of Diagnostic Ultrasound Systems and Transducers

Guidance for Industry and Food and Drug Administration Staff

Document issued on February 21, 2023.

Document originally issued on June 27, 2019.

This document supersedes "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" dated September 9, 2008.

Contains Nonbinding Recommendations

Table of Contents

Example of Reading What Matters

Appendix C Non-OEM Replacement Transducers and Remanufactured Transducers

Non-original equipment manufacturer (OEM) replacement transducers are generally those that are manufactured by a party other than the OEM and are intended to replace a transducer originally provided by the system manufacturer. Transducers may be remanufactured by the OEM, or entities other than the OEM. FDA considers transducers that are processed, conditioned, renovated, repackaged, restored, or subjected to any modification that significantly changes its performance or safety specifications, or intended use to be remanufactured.[29] Examples of actions that could be considered remanufacturing are changing the acoustic stack, electrical component, or patient-contact material.

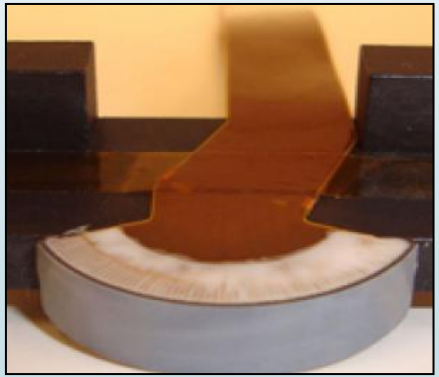
Like new OEM transducers, non-OEM replacement transducers and remanufactured transducers are new medical devices. As such, they are subject to the 510(k) premarket notification regulations (21 CFR 807.81). They are required to have a cleared 510(k) prior to being marketed.

In addition to the information recommended in the body of this guidance, we recommend the following in regard to acoustic output testing, biocompatibility testing, and labeling for diagnostic ultrasound replacement transducers:

1. In making the acoustic output comparison between the replacement and the OEM transducers, three or more transducers of each type should be used. The use of a single OEM generator may be appropriate if it operates within the OEM's specifications.
2. Acoustic output comparisons in the basic modes of M, B, and pulsed Doppler may be appropriate, but worst-case (i.e., maximum output) conditions should be identified and reported.
3. New acoustic output information (see Sections 5.2.7.2 and 5.2.8.2) should be provided in the transducer operator's manual whether or not you can demonstrate that the acoustic outputs of the replacement or remanufactured and OEM transducers agree within the limits of the measurement uncertainty. Moreover, if the outputs do not agree, the manufacturer should demonstrate that means have been incorporated into the replacement transducer to ensure the accuracy of the acoustic output real-time display indices, as well as the accuracy of any clinical measurement performed using the transducer. Furthermore, if the outputs do not agree, then the transducers should not be referred to as "replacement." Instead, the transducers should be referred to as "similar to" and the differences should be noted.
4. The acoustic output measurement methodology should be completely described following Section 5.2.4.1 of this guidance.

[29] 21 CFR 820.3(w).

Examples of actions that could be considered remanufacturing are changing the acoustic stack, electrical component, or patient-contact material.



- Transducers are finished medical devices manufactured to certain performance and safety consensus standards, for example…
  - ISO10993-1 (also see FDA 21 CFR, Part 58): Biocompatibility for patient contact materials (cytotoxicity, sensitization, and irritation), such as the lens, TEE insertion tube, and other parts
  - EC60601-1: Electrical leakage
  - IEC60601-2-37: Lens surface temperature maximum (43°C)
  - IEC60601-2-37: Acoustic output measurement and display standard for diagnostic ultrasound equipment
  - IEC60529: Degrees of protection provided by enclosure (IP Code): protection against fluid ingress into probes
- Materials and testing processes used in transducer repair should protect the finished devices performance specifications, safety specifications and intended use.

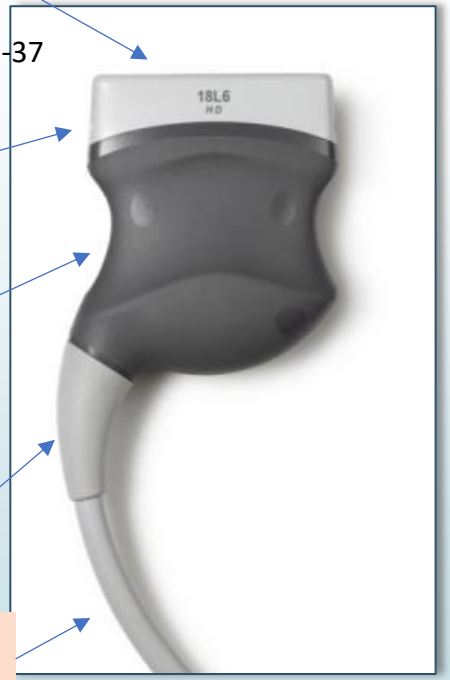
Lens
- IEC60601-1
- ISO10993-1
- IEC60529
- IEC60601-2-37

Housing Cap
- IEC60601-1
- ISO10993-1
- IEC60529

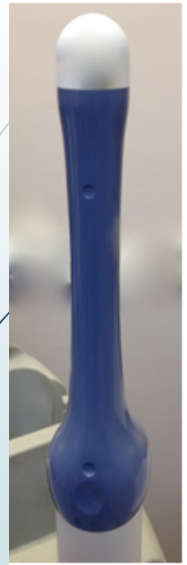
Housing
- IEC60601-1
- IEC60529

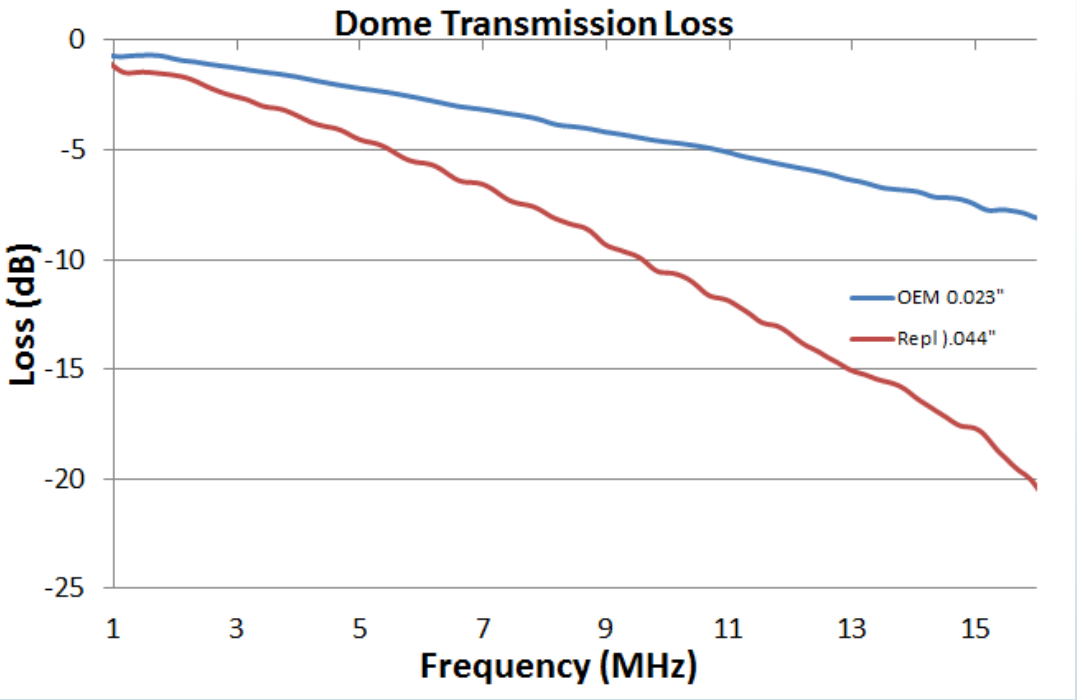
Strain Relief
- IEC60601-1
- IEC60529

Cable
- IEC60601-1



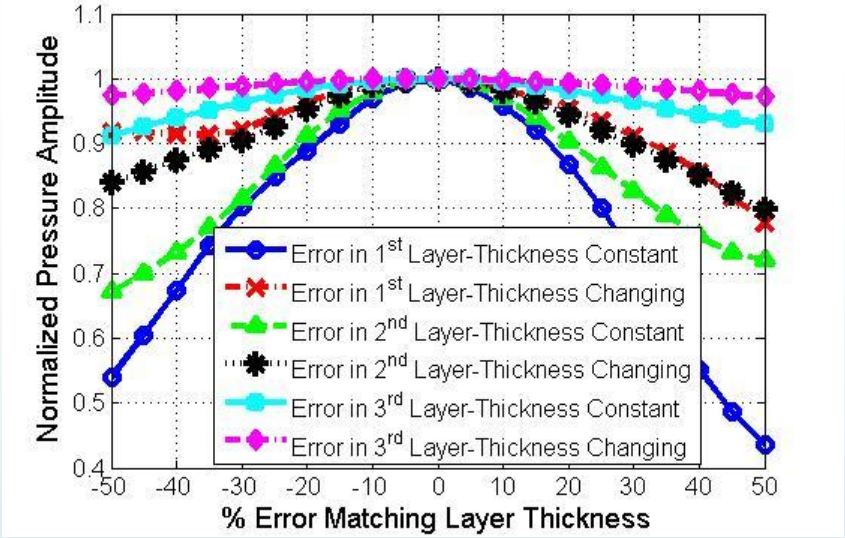
Example of Non-OEM Material – Substantive Change

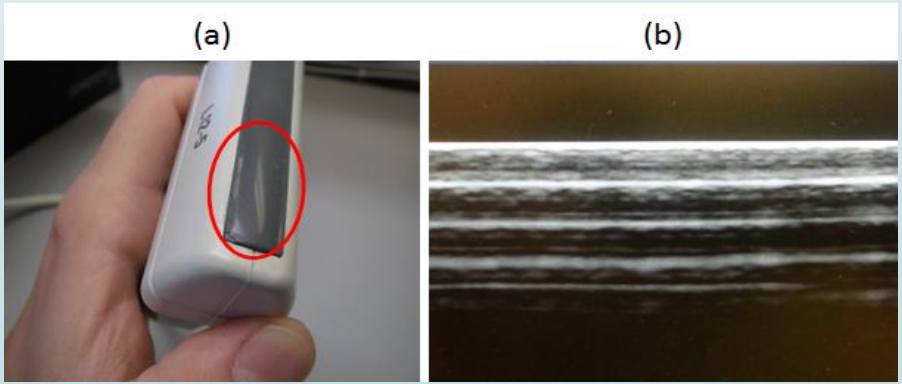




Dome Component Change

Normalized peak-peak pressure amplitude relative to the optimal case as a function of the error in the corresponding matching layer thickness. The results for both constant acoustic stack thickness and variable acoustic stack thickness are shown.





Lens Material Changes

Lens Material Changes…

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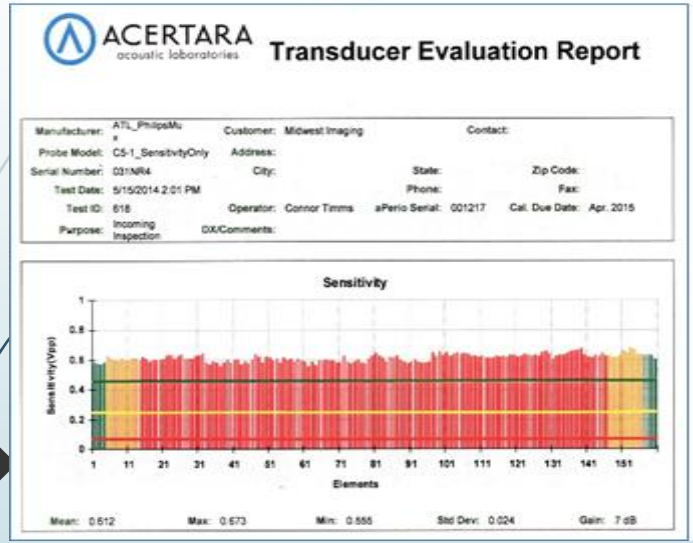
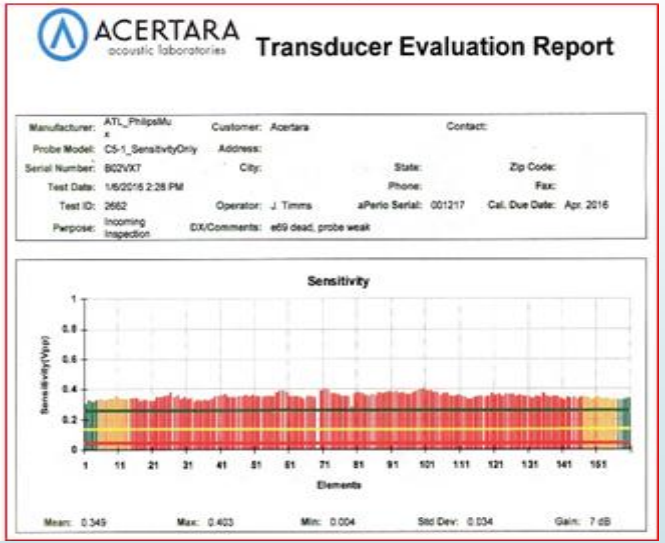
Example of Reading What Matters

(a)



(b)



Acoustic Stack (Component/Part) Changes…

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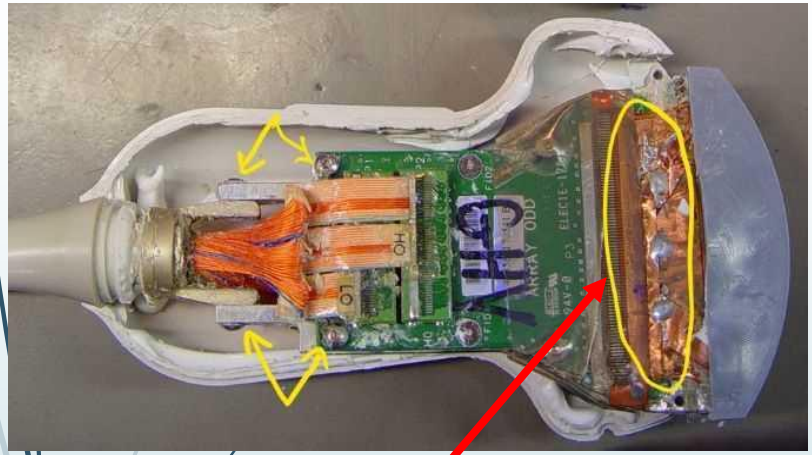
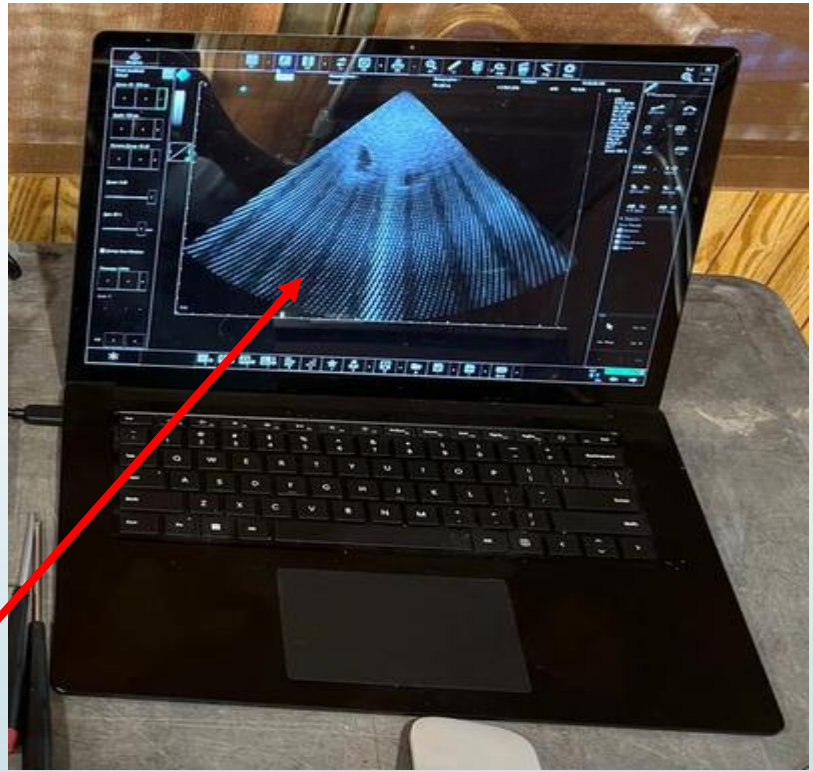
Material Changes…

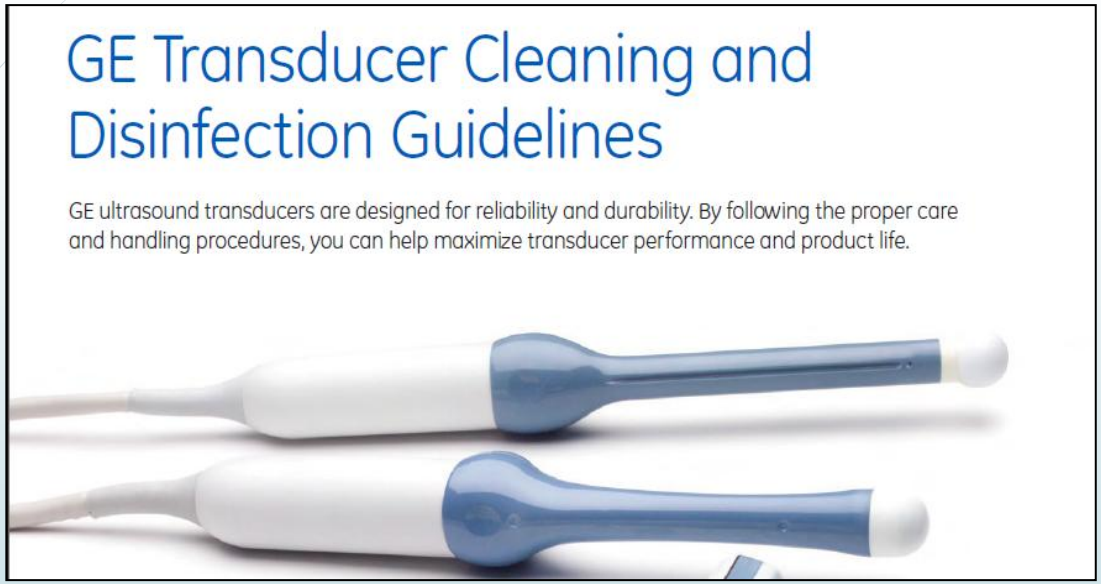


EMI shielding material was compromised from the distal side of the acoustic lens & grounding flaws.



Results in noise bars in the image

Example of Reading What Matters



Cleaning and Disinfecting Protocol Changes…

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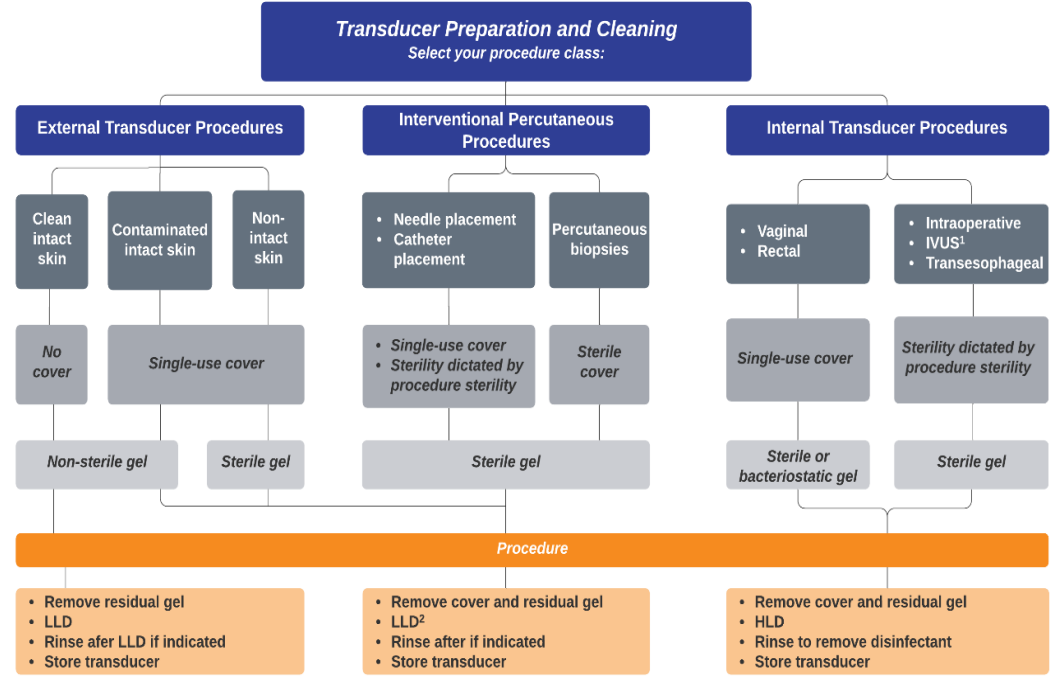
Example of Reading What Matters



*AIUM Guidelines Chart – www.aium.org

Cleaning and Disinfecting Protocol Changes…

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Example of Reading What Matters

Cleaning and Disinfecting Protocol
Material Changes…

Essential Takeaways

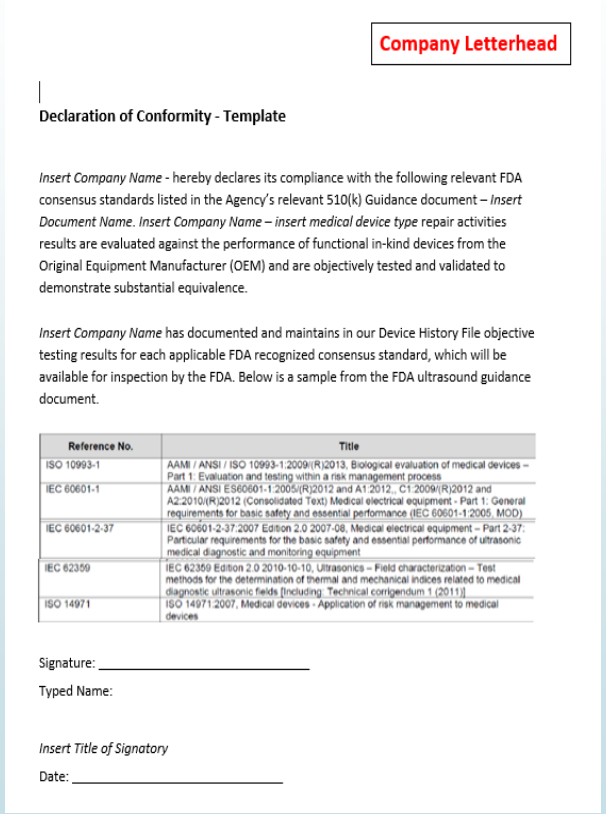
- Use vendors who know and understand the ways of the FDA
- Ask for objective evidence that demonstrates the vendor is validating parts, materials, and components that return the repaired device to substantial equivalence to the OEM for safety, efficacy, and intended use
- Ensure vendor has the subject matter expertise and technology to perform testing to perform adequate and traceable validation
- Use only vendors who are ISO13485:2016 Registered – for the right thing

Essential Takeaways

"All repair entities of ultrasound probes should be held to the same regulatory and compliance standards as applied to the original equipment. This means that 3rd party transducer repair facilities should be held to the same regulatory and compliance standards as OEMs. Repair processes, materials used, and components such as acoustic arrays, should be tested and validated to demonstrate substantial equivalence to the OEM probe. This testing should be documented and provided to the clinic upon return of the "repaired" probe. If a "repaired" probe does not meet the imaging standards of the original OEM probe, then the probe should be regarded as not repaired. Paying for a repair that was not properly done only lowers the quality of the medical care while raising the cost."

Timothy A Bigelow, PhD
Iowa State University, Ames, IA
Recommendations when Acquiring and Using Repaired Ultrasound Transducers
AIUM 2019

Essential Takeaways



Company Letterhead

Declaration of Conformity - Template

Insert Company Name - hereby declares its compliance with the following relevant FDA consensus standards listed in the Agency's relevant 510(k) Guidance document – *Insert Document Name*. *Insert Company Name – insert medical device type* repair activities results are evaluated against the performance of functional in-kind devices from the Original Equipment Manufacturer (OEM) and are objectively tested and validated to demonstrate substantial equivalence.

Insert Company Name has documented and maintains in our Device History File objective testing results for each applicable FDA recognized consensus standard, which will be available for inspection by the FDA. Below is a sample from the FDA ultrasound guidance document.

Reference No.	Title
ISO 10993-1	AAMI / ANSI / ISO 10993-1:2009/(R)2013, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
IEC 60601-1	AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012,, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
IEC 60601-2-37	IEC 60601-2-37:2007 Edition 2.0 2007-08, Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
IEC 62359	IEC 62359 Edition 2.0 2010-10-10, Ultrasonics – Field characterization – Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields [Including: Technical corrigendum 1 (2011)]
ISO 14971	ISO 14971:2007, Medical devices - Application of risk management to medical devices

Signature: _____

Typed Name:

Insert Title of Signatory

Date: _____

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