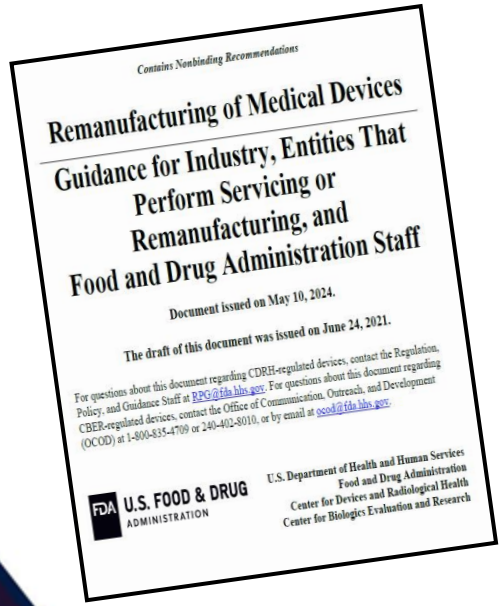
WHY TESTING MATTERS

By: G. Wayne Moore, B.Sc., MBA, FAIUM, FASE
Acertara Acoustic Laboratories



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.

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

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Why Testing Matters

- 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

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Why Testing Matters

- Overview
- How the FDA looks at it
- Reverse engineering
- Why ISO vetting matters
- Class II Medical Device Example
- Essential Takeaways
- Q&A

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Why Testing Matters

Question:

If you knew a piece of equipment was broken and produced questionable data, would you allow it to be used? Then why is it used without this knowledge?

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Why Testing Matters

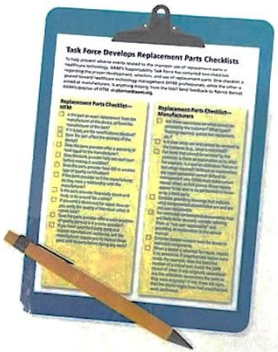
HTMs, the thin blue line protecting patients from defective devices

HOME> Products & Publications> AAMI News

AAMI News October 2015

AAMI's Supportability Task Force Creates Checklists

To help prevent adverse events related to the improper use of replacement parts in healthcare technology, AAMI's Supportability Task Force has compiled two checklists regarding the proper development, selection, and use of replacement parts. One checklist is geared toward healthcare technology management (HTM) professionals, while the other is aimed at manufacturers. Is anything missing from the lists? Send feedback to Patrick Bernat, AAMI's director of HTM, at pbernat@aami.org.



Replacement Parts Checklist—HTM

device, or from the manufacturer of the part?

- If it is not, are the specifications identical?
- Does the part affect the accuracy of the device?
- Does the parts provider offer a warranty at least equal to the manufacturer?
- Does the parts provider fully test each part before making it available?
- Does the parts provider have ISO or another type of quality certification?
- If the parts provider isn't the manufacturer, do they have a relationship with the manufacturer?
- Is the parts provider financially sound and likely to be around for a while?
- If you send a device out for repair, how do you verify the quality of the repair when it comes back?

If you send a device out for repair, how do you verify the quality of the repair when it comes back?

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How the FDA looks at it

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, and (2) if it doesn’t then the activity is defined as remanufacturing. Although the FDA does not categorize a bad repair, we all know that bad repairs are a reality in the medical device servicing industry. An old adage sums up what bad repairs cost; “The most expensive repair you will ever have is a bad repair.” Today we are going to see exactly what it takes to avoid bad repairs through objective testing both pre and post repair.

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How the FDA looks at it

"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."

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How the FDA looks at it

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, and 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

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Why Testing Matters

How the FDA looks at it

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).

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Why Testing Matters

How the FDA looks at it

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

FOOD AND DRUG ADMINISTRATION FDA

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Why Testing Matters

How the FDA looks at it

Risk-based Assessment

The individual residual risk of each hazardous situation is considered acceptable if the following criteria for acceptability have been met.

Risk Matrix		Severity of Harm				
		Negligible	Minor	Serious	Critical	Catastrophic
Probability of Harm	Frequent	Acceptable	Investigate	Unacceptable	Unacceptable	Unacceptable
	Probable	Acceptable	Investigate	Unacceptable	Unacceptable	Unacceptable
	Occasional	Acceptable	Investigate	Investigate	Unacceptable	Unacceptable
	Remote	Acceptable	Acceptable	Investigate	Investigate	Unacceptable
	Improbable	Acceptable	Acceptable	Investigate	Investigate	Investigate

Unacceptable Risk: Requires further risk reduction*

Investigate Risk: Requires investigation to determine if further risk reduction is *practicable**

Acceptable Risk: Risk is negligible, further risk reduction is NOT required

* If further risk reduction is NOT *practicable*, a *Benefit-Risk Analysis (BRA)* has been conducted and concludes that the individual residual risk with respect to all hazardous situations is acceptable when weighed against the benefits of the medical device in its intended use.

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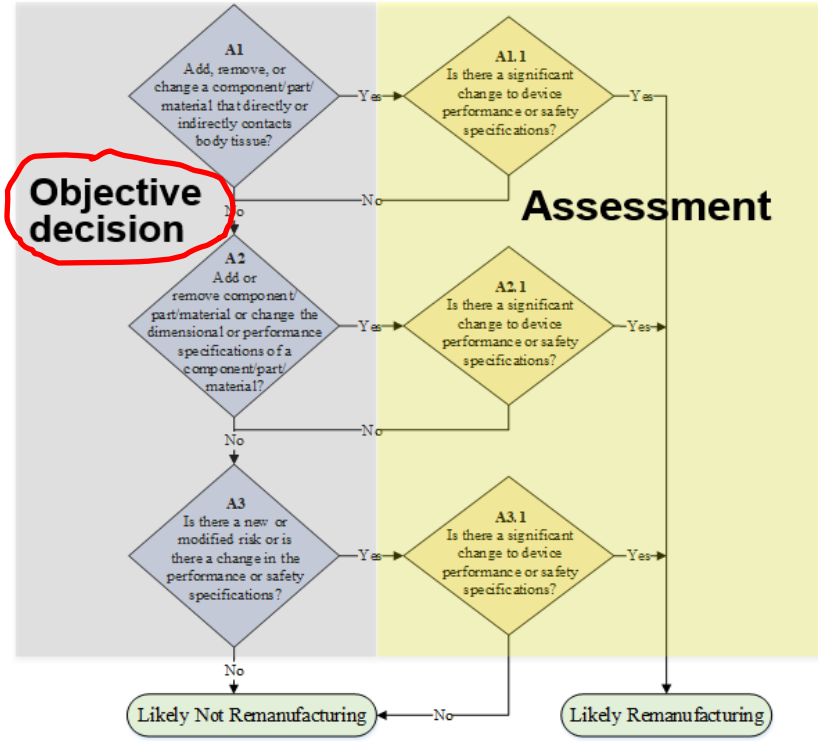
How the FDA looks at it

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.

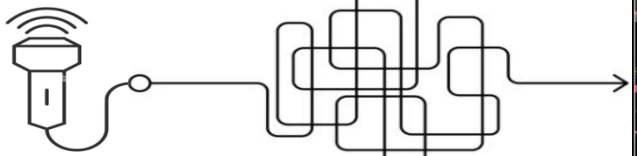


Why Precision Testing Matters

Reverse Engineering – the path to objective testing

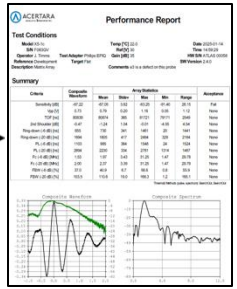
2D Matrix Array Probe

Reverse Engineer Probe ASIC



Load Transmit and Receive Code to Engage ASIC

Test Array Elements and Cable Wires for Failures



Objective Performance Data Acquired to Determine Repairability and to Establish Substantial Equivalence in Repair

Demonstrate Compliance with FDA Guidance

"Like new OEM transducers, non-OEM replacement 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 cleared 510(k) prior to being marketed. Examples of actions that could be considered remanufacturing are changing the acoustic stack (array), an electrical component, or patient contact material."

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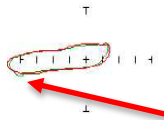
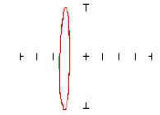
Why Precision Testing Matters

Reverse Engineering – the path to objective testing

Pin Name:	17	ID:	17	Pin Number:	17	Net Name:	
Shorts:							
Area:	42			Deviation:	7		
Range Information							
Range Number:	3	ID:	51				
Voltage:	3	Resistance:	50	Frequency:	60	Tolerance:	5
Com. Pin 1:	0	Com. Pin 2:	0	Prob. Com. 1:	0	Prob. Com. 2:	0
Capacitance:	0.000F			Ref. Capacitance:	0.000F		
Resistance:	0.000 Ohm			Ref. Resistance:	0.000 Ohm		
Power:	54mW			Ref. Power:	54mW		
Fwd. Brkdwn.:	0.000V			Ref. Fwd. Brkdwn.:	0.000V		
Rev. Brkdwn.:	0.000V			Ref. Rev. Brkdwn.:	0.000V		
Area:	42			Deviation:	7		
Stimulus	0			Ref. Serial Number:	F0CPQ8		
Status:				Ref. Scan Date/Time:	4/1/2025 8:39:32 AM		



Range Information							
Range Number:	2	ID:	50				
Voltage:	3	Resistance:	1K	Frequency:	200	Tolerance:	5
Com. Pin 1:	0	Com. Pin 2:	0	Prob. Com. 1:	0	Prob. Com. 2:	0
Capacitance:	0.000F			Ref. Capacitance:	0.000F		
Resistance:	700.000 Ohm			Ref. Resistance:	700.000 Ohm		
Power:	8.1mW			Ref. Power:	8.1mW		
Fwd. Brkdwn.:	0.000V			Ref. Fwd. Brkdwn.:	0.000V		
Rev. Brkdwn.:	0.000V			Ref. Rev. Brkdwn.:	0.000V		
Area:	0			Deviation:	-4		
Stimulus	0			Ref. Serial Number:	X8-2t GOLD		
Status:				Ref. Scan Date/Time:	3/28/2025 1:31:50 PM		



Range Information							
Range Number:	1	ID:	49				
Voltage:	3	Resistance:	50K	Frequency:	500	Tolerance:	5
Com. Pin 1:	0	Com. Pin 2:	0	Prob. Com. 1:	0	Prob. Com. 2:	0
Capacitance:	0.000F			Ref. Capacitance:	0.000F		
Resistance:	30K Ohm			Ref. Resistance:	30K Ohm		
Power:	162uW			Ref. Power:	162uW		
Fwd. Brkdwn.:	0.000V			Ref. Fwd. Brkdwn.:	0.000V		
Rev. Brkdwn.:	0.000V			Ref. Rev. Brkdwn.:	0.000V		
Area:	0			Deviation:	-5		
Stimulus	0			Ref. Serial Number:	X8-2t GOLD		
Status:				Ref. Scan Date/Time:	3/28/2025 1:31:50 PM		

Circuit analysis on X8-2t Probe demonstrated a small variant in a sensitivity loop. A preamp component in the probe connector was defective and replaced. This test saved the hospital from buying a replacement probe at $20k

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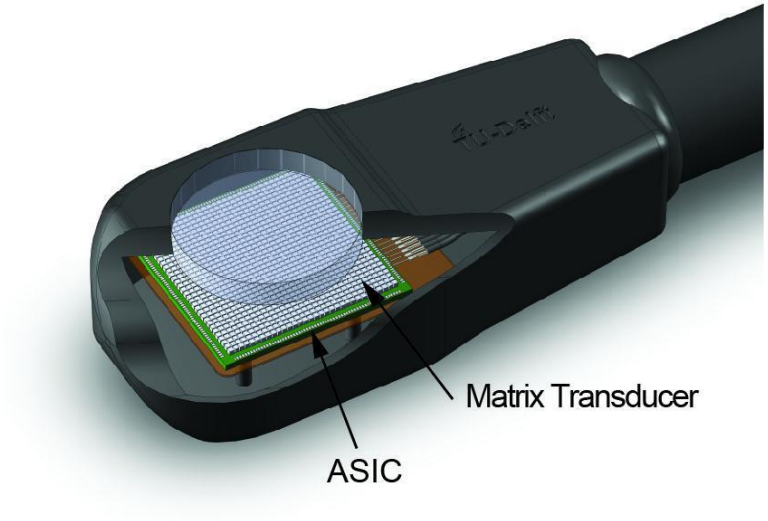
Example – Illustrating a General Rule
Let's look at an ultrasound probe



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Why Testing Matters

Reconciling FDA Guidance's

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.

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.

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Why Testing Matters

Contains Nonbinding Recommendations

Table of Contents

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.

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Why Testing Matters

3 Results

3.1 Acoustic output results

Table 3: Acoustic output reporting table: reportable mode 1 (Pulsed Wave Doppler)

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			5.94E-02	2.83E-02		3.87E-02		7.29E-02
Index component value				2.83E-02	2.29E-02	2.83E-02	3.87E-02	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	0.27					
	P	(mW)		0.29		0.29		0.29
	$P_{1\times1}$	(mW)		0.29		0.29		
	z_s	(cm)			0.15			
	z_b	(cm)					0.15	
	z_{MI}	(cm)	0.10					
	$z_{pii,\alpha}$	(cm)	0.17					
	f_{awf}	(MHz)	20.28	20.28		20.28		20.28
Other Information	prr	(Hz)	7.80E+04					
	srr	(Hz)	N/A					
	n_{pps}		1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm2)	1.1					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm2)	27.74					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm2)	35.43					
	p_r at z_{pii}	(MPa)	0.23					
Operating control conditions	20.0MHz-3.0mm-PW							

NOTE 1 Only one operating condition per index.
NOTE 2 Data should be entered for "at surface" and "below surface" both in the columns related to TIS or TIB.
NOTE 3 Information need not be provided regarding TIC for an TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.
NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.
NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.
NOTE 6 Unshaded cells should have a numerical value. The equipment setting related to the index has to be entered in the operating control section.
NOTE 7 The depths z_{pii} and $z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths z_{sii} and $z_{sii,\alpha}$ apply to SCANNING MODES.

Maximum FDA allowed Acoustic Output Power 720mW/cm^2. Testing objectively demonstrates substantial equivalence to the OEM output.

FDA Guidance: In addition to the information recommended in the body of this guidance, we recommend the following in regard to acoustic output testing for replacement arrays/transducers:

1) In making output comparisons between the replacement and the OEM transducers, three or more transducers of each type should be used…"
2) Worst case acoustic output comparisons should be identified and documented

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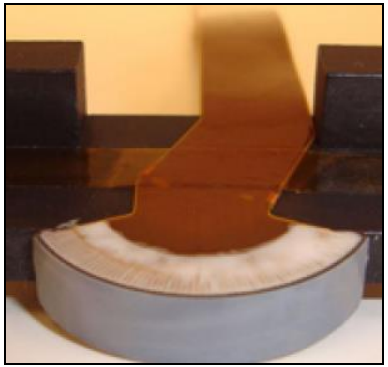
Why Testing Matters

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.

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Why Testing Matters

FDA Recognized Consensus Standards

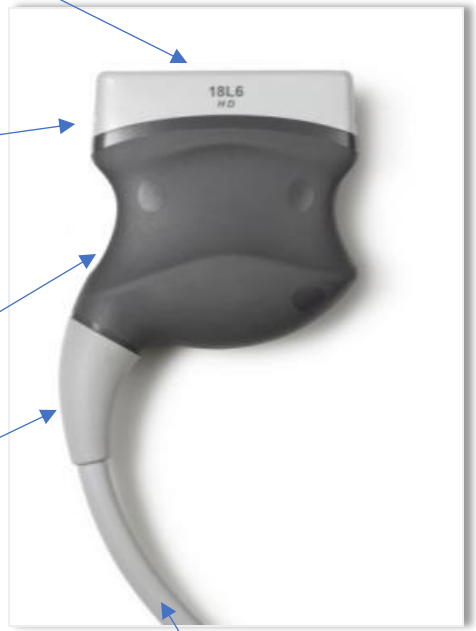
Lens
- IEC60601-1
- ISO10993-1
- IEC60529
- IEC60601-2-37

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

Housing
- IEC60601-1
- IEC60529

Strain Relief
- IEC60601-1
- IEC60529

Cable
- IEC60601-1



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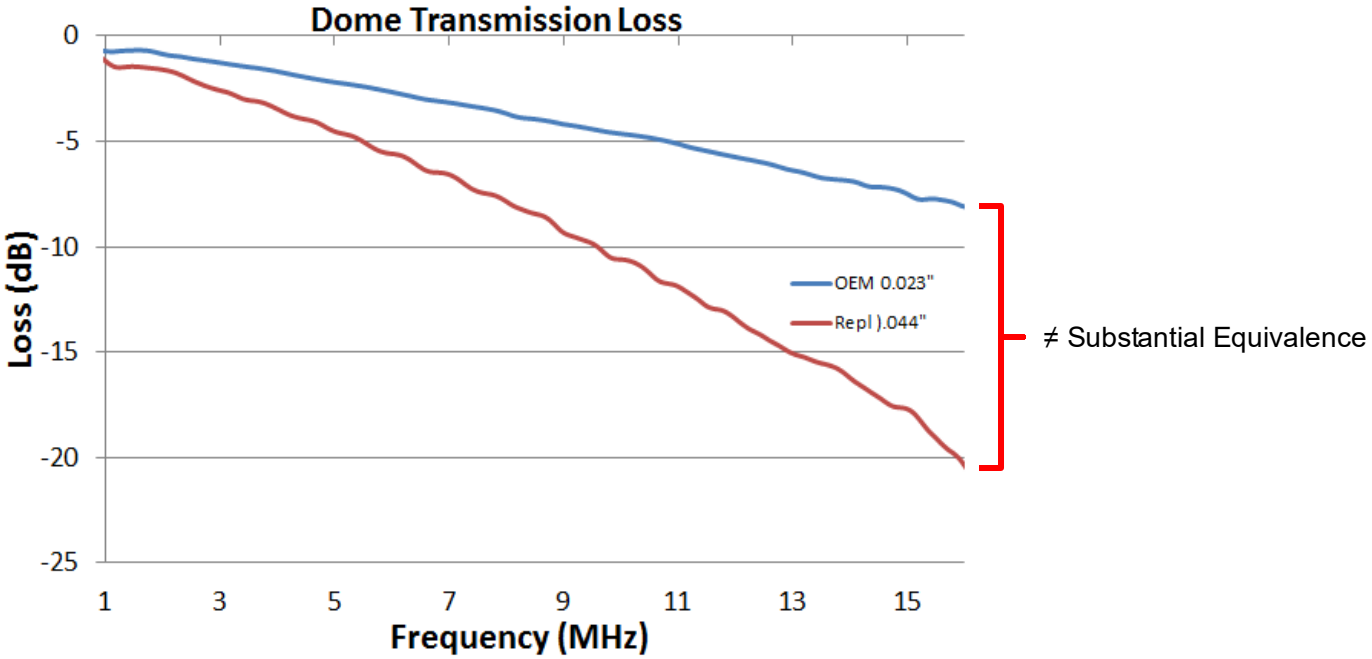
Why Testing Matters

Test Materials Used



≠ Substantial Equivalence

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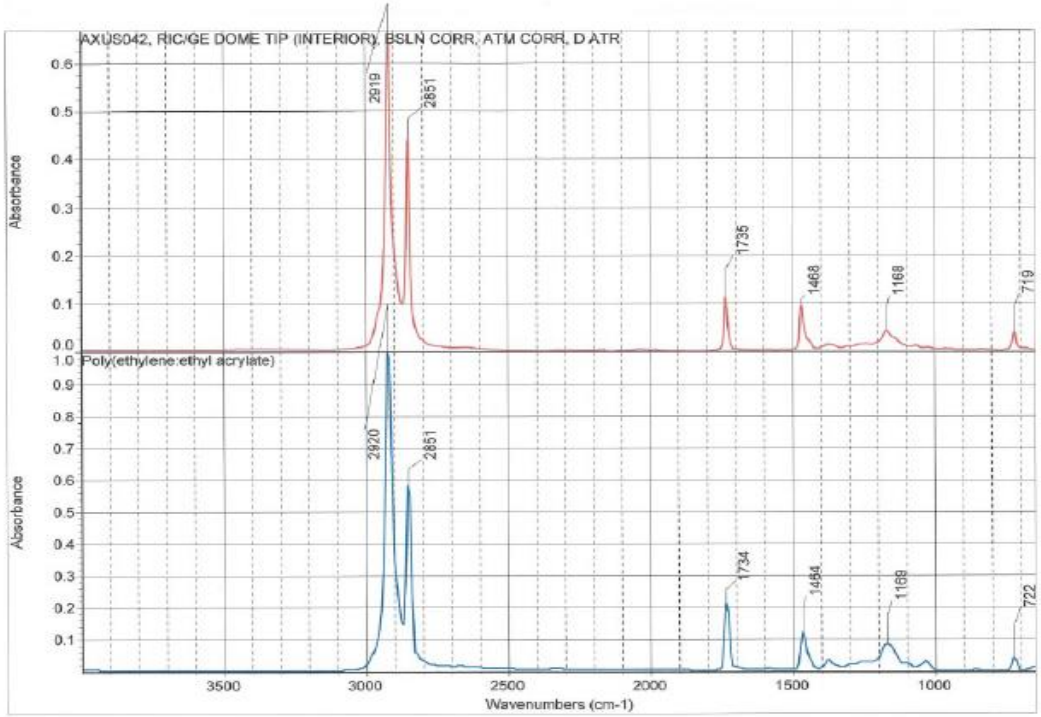
Why Testing Matters

Test Candidate Materials - FTIR

Figure 1 – IR Spectrum of "RIC/GE OEM Dome Tip" Interior Surface and Selected Reference



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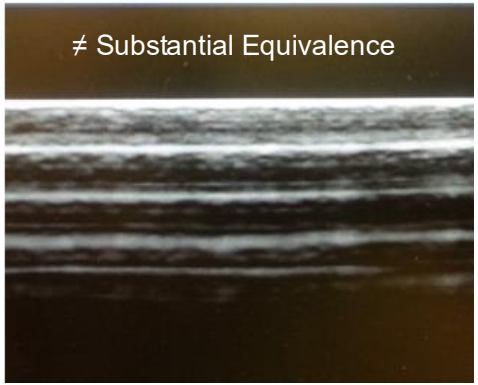
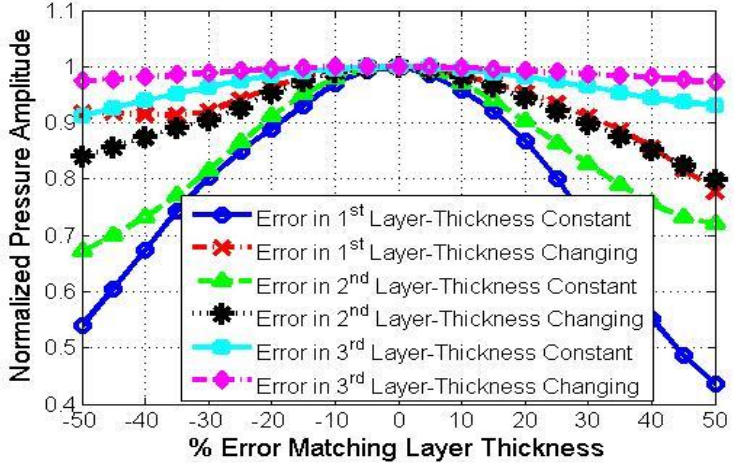
Why Testing Matters

Test Candidate Materials – in addition to performance – also test biocompatibility and Shore A hardness of the material





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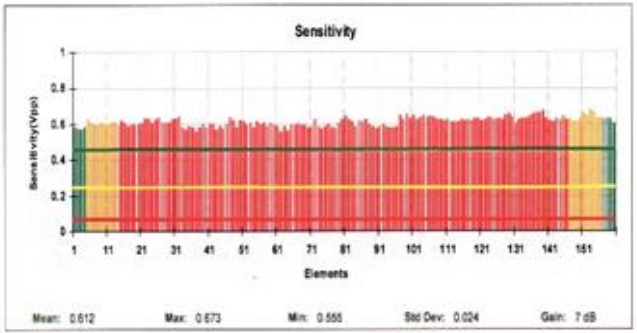
Why Testing Matters

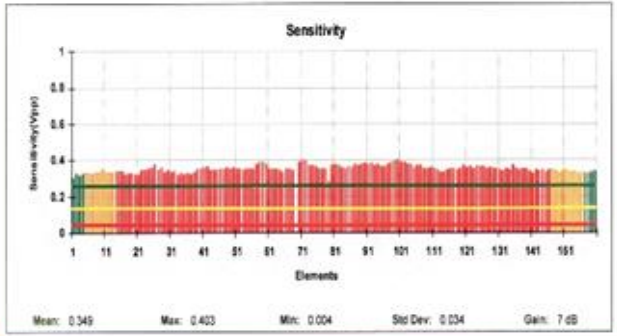
OEM Array Sensitivity

Manufacturer:	ATL_PhilipsMux	Customer:	Midwest Imaging	Contact:	
Probe Model:	C5-1_SensitivityOnly	Address:			
Serial Number:	031NR4	City:		State:	Zip Code:
Test Date:	5/15/2014 2:01 PM			Phone:	Fax:
Test ID:	618	Operator:	Connor Timms	aPerio Serial: 001217	Cal. Due Date: Apr. 2015
Purpose:	Incoming Inspection	DX/Comments:			



non-OEM Array Sensitivity

Manufacturer:	ATL_PhilipsMux	Customer:	Acertara	Contact:	
Probe Model:	C5-1_SensitivityOnly	Address:			
Serial Number:	B02VX7	City:		State:	Zip Code:
Test Date:	1/6/2016 2:28 PM			Phone:	Fax:
Test ID:	2662	Operator:	J. Timms	aPerio Serial: 001217	Cal. Due Date: Apr. 2016
Purpose:	Incoming Inspection	DX/Comments:	e69 dead, probe weak		



≠ Substantial Equivalence

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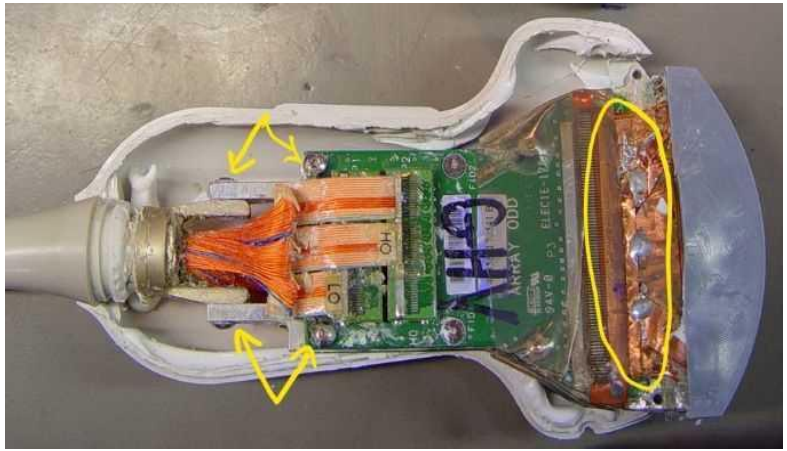
Why Testing Matters



EMI shielding material was compromised from the distal side of the acoustic lens to the grounds.

≠ Substantial Equivalence

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Why Testing Matters

Confirming a substitute material(s) can survive the OEM instructions for HLD.

GE Transducer Cleaning and Disinfection Guidelines

GE ultrasound transducers are designed for reliability and durability. By following the proper care and handling procedures, you can help maximize transducer performance and product life.

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Why Testing Matters

Transducer Preparation and Cleaning

Select your procedure class:

External Transducer Procedures

- Clean intact skin → *No cover* → *Non-sterile gel*
- Contaminated intact skin → *Single-use cover* → *Sterile gel*
- Non-intact skin → *Single-use cover* → *Sterile gel*

Interventional Percutaneous Procedures

- Needle placement; Catheter placement → *Single-use cover; Sterility dictated by procedure sterility* → *Sterile gel*
- Percutaneous biopsies → *Sterile cover* → *Sterile gel*

Internal Transducer Procedures

- Vaginal; Rectal → *Single-use cover* → *Sterile or bacteriostatic gel*
- Intraoperative; IVUS[1]; Transesophageal → *Sterility dictated by procedure sterility* → *Sterile gel*

Procedure

- Remove residual gel
- LLD
- Rinse afer LLD if indicated
- Store transducer

- Remove cover and residual gel
- LLD[2]
- Rinse after if indicated
- Store transducer

- Remove cover and residual gel
- HLD
- Rinse to remove disinfectant
- Store transducer

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Why Testing Matters

Shore A Hardness	Left (element one side)	Middle	Right
Top	88	90	91
Middle	87	87	88
Bottom	87	88	90

Shore A hardness strength was

≠ substantial equivalent

Replacement material had a
Shore A hardness strength of 52

Why Testing Matters

Essential Takeaways

- Use Vendors who can readily show they know and understand the testing requirements of the FDA
- Ask for objective evidence (documentation) 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 relevant testing and to perform adequate and traceable validation
- At a minimum use only vendors who are currently ISO13485:2016 Registered – for the correct activity

Introduction

0.1 General

This International Standard specifies requirements for a quality management system that can be used by an organization involved in one or more stages of the life-cycle of a medical device, including design and development, production, storage and distribution, installation, servicing and final decommissioning and disposal of medical devices, and design and development, or provision of associated activities (e.g. technical support). The requirements in this International Standard can also be used by suppliers or other external parties providing product (e.g. raw materials, components, subassemblies, medical devices, sterilization services, calibration services, distribution services, maintenance services) to such organizations. The supplier or external party can voluntarily choose to conform to the requirements of this International Standard or can be required by contract to conform.

Why Testing Matters

Hospitals and Advocates such as AIUM are pushing for this

“All repair entities of ultrasound probes should be held to the same regulatory and compliance standards as applied to the original equipment manufacturers (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

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Why Testing Matters

Vetting Template

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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Why Testing Matters

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