INNOVATUS imaging

Imaging Jeopardy

Lightning round to test your imaging IQ

MDEXPO
DALLAS, TEXAS
APRIL 16-17, 2021

- Learn important aspects of imaging device troubleshooting, repair, and maintenance
- Relative to Ultrasound, MRI, and Quality and Regulatory
- Fun, fast-paced, game show format session
- Participation is limited to ***ONLY*** hospital and service personnel. Vendors excluded

Rules

- The ***TOPIC*** will be displayed along the left-side of the screen
- The ***QUESTION*** or ***ANSWER*** will be displayed
- Use your knowledge, your phone, or laptop to ***FIND THE ANSWER***
- When you think you know the answer raise your ***HAND***
- But ***WAIT****, you better be sure*

Rules

- Are you willing to ***RISK*** it?
  - ***CORRECT*** answer wins an Amazon gift card
  - ***INCORRECT*** answer forfeits an Amazon gift card

- Final Question
  - ***DOUBLE JEOPARDY:*** Risk up to 2 cards to win up to 2 cards


READY?

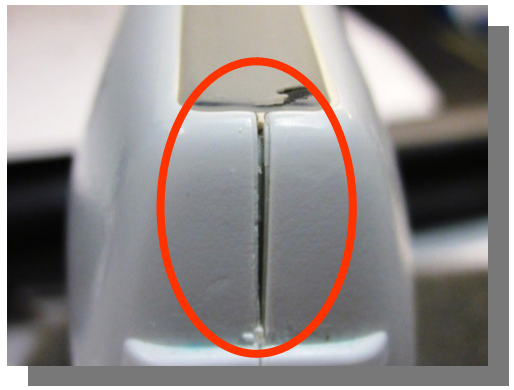
ULTRASOUND

Assuming ***ideal*** care and handling and omitting options for probe repair, ***what is the expected lifespan of an ultrasound probe?***

ANSWER

Omitting options for probe repair and assuming ideal care and handling, the lifespan of a standard probe is estimated to be ***5-7 years***

- Ideal care and handling seldom occur and options for probe repair greatly affect probe lifecycle.
- Our data shows that standard probes typically fail between ***2-3 years*** and TEE probes between ***1-2 years***



DISCUSSION

Did you know…

Two items that can greatly shorten probe lifecycle are:

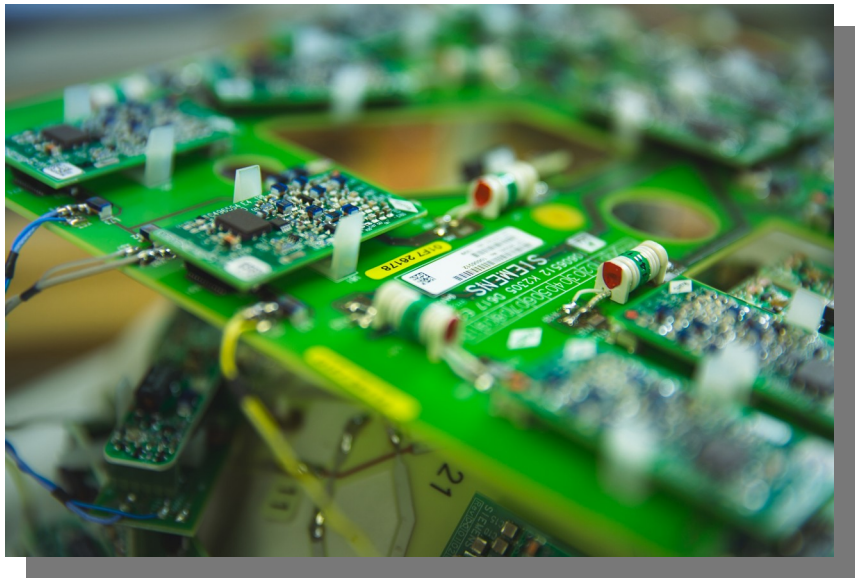
1. Using an ***unapproved*** chemical, or
2. Using an ***approved*** chemical ***improperly***
   - Even OEM approved chemicals can shorten lifecycles through over exposure or inadequate rinsing
   - Work with your customers to determine if they are using approved chemicals and following proper guidelines

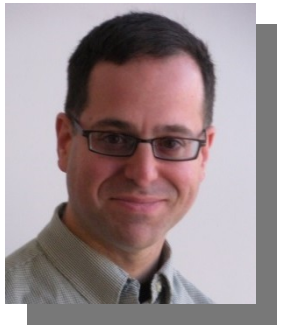
What is the ***function*** or ***purpose*** of an MRI coil?

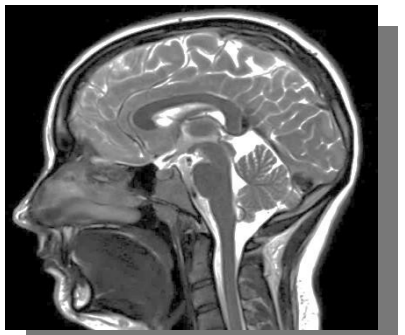
ANSWER

An MRI coil acts as an ***antenna*** to receive radio frequency signals emitted from the tissues in your body.

- The coil ***amplifies*** the signals and transmits them to a computer in the scanner which ***processes*** and ***generates*** images.
- No coil = No image







DISCUSSION

Coils come in various sizes and shapes based upon the anatomy to be imaged and can vary in complexity and cost

- New and replacement coils: $35,000 - >$150,000
- With a legacy in coil manufacturing and as an authorized service center for several large OEMs, Innovatus has a wealth of knowledge and experience in ***MRI coil repair***
- Full repair capabilities on over ***1000*** different coil models

QUALITY & REGULATORY

Answer in the form of a question (Jeopardy-style)

A written submission that demonstrates that a device to be marketed is as ***safe*** and ***effective***

ANSWER

What is a 510(k)?

A 510(k) submission is a type of regulatory submission made to the FDA called a Premarket Notification

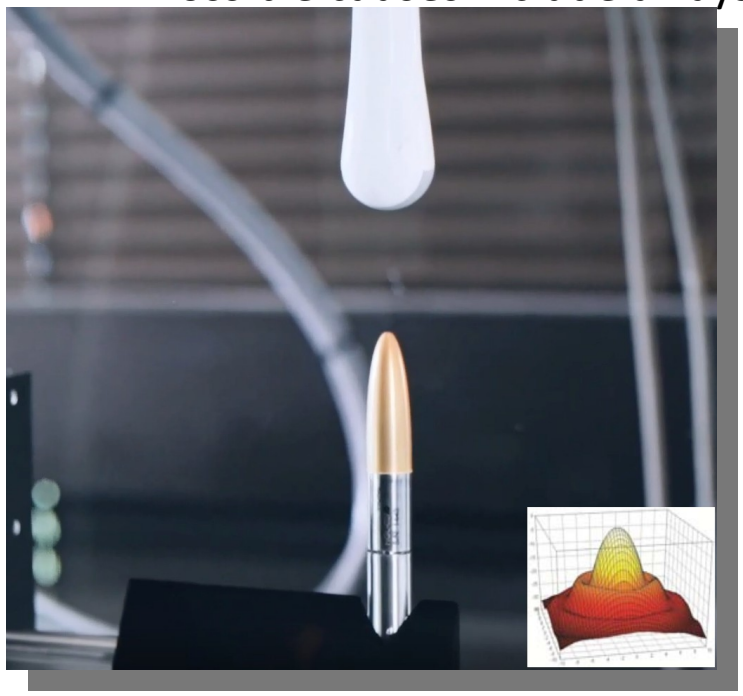
- In a 510(k), a medical device manufacturer must ***demonstrate*** that a device is safe and effective**, OR has** substantial equivalence to an already approved device

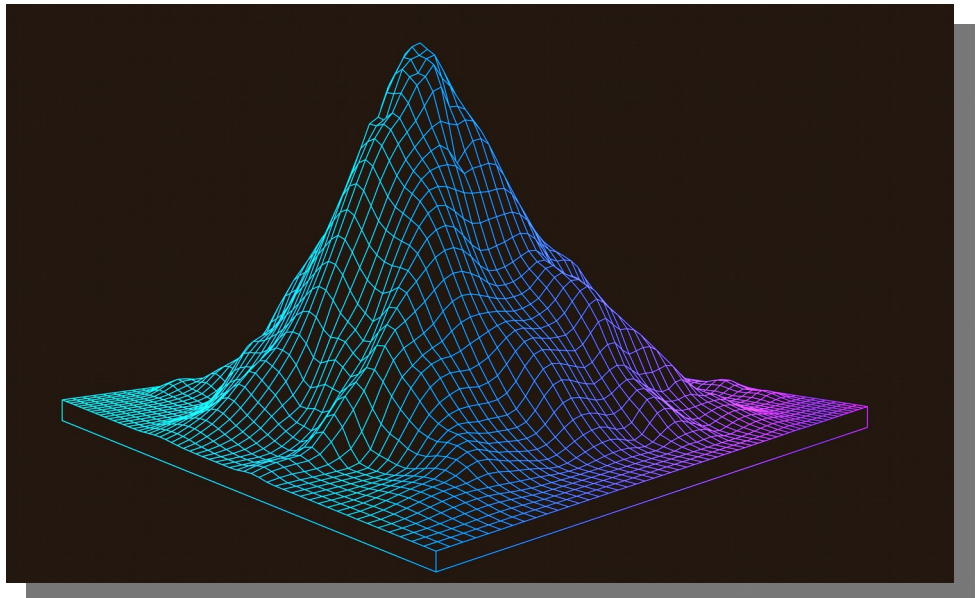
What is the name of the measurement device used to quantify the ***acoustic output*** of a probe?

ANSWER

Hydrophone or Acoustic Power Meter

- ***Excessive*** acoustic output power has the potential to induce thermal warming, patient burns, and/or cavitation
- ***Insufficient*** acoustic power can result in diminished image quality and sensitivity in all imaging modes, which has the potential affect patient diagnoses.
  - Possible causes include arrays and lenses





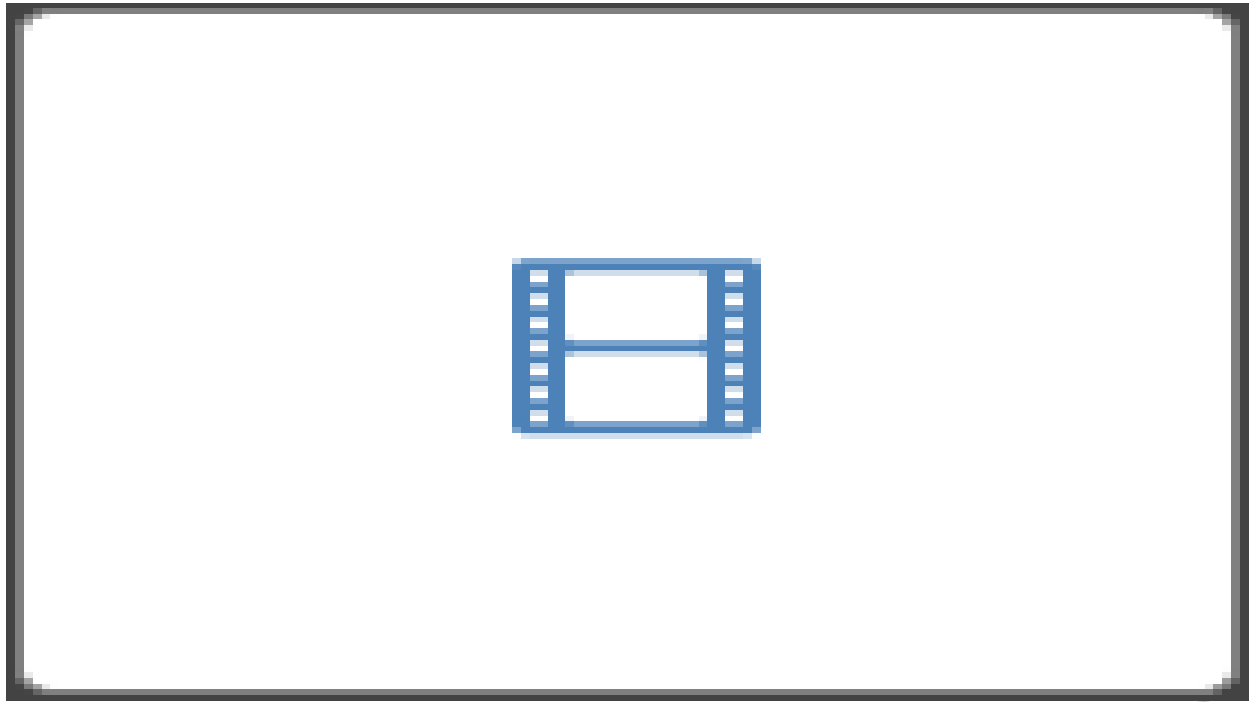
An MRI scanner is ***required*** to test the functionality of an MRI coil? ***True or False***

ANSWER

False

- MRI coils are built to meet design specifications.
- As part of the design process, a contract manufacturer will verify and validate the coil's design using a scanner
- Once the design has undergone V&V, its performance is proven

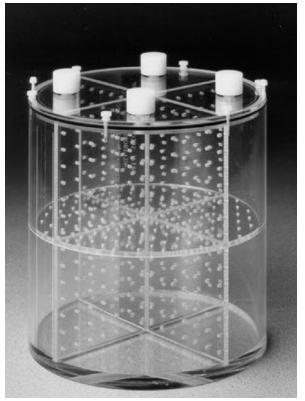
- Innovatus takes this approach for coil repair
  - Proprietary test fixtures emulate the magnet and verify coil performance based on known inputs and expected outputs

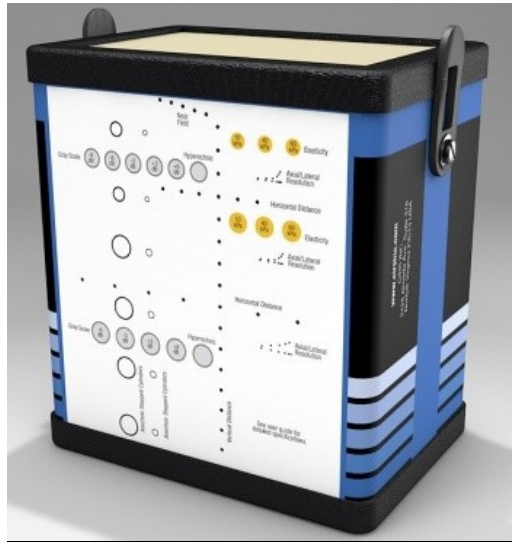


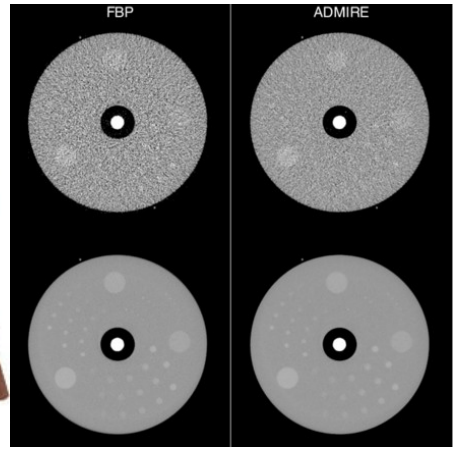
No matter the modality, a _____ should be used to assess image quality

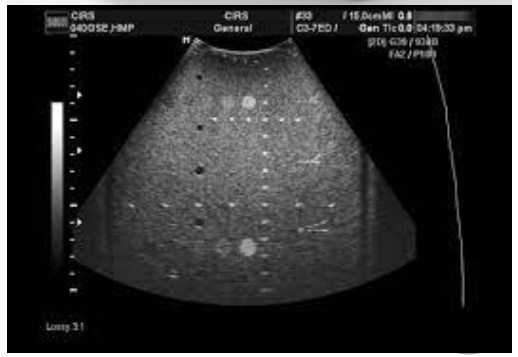
ANSWER

A phantom (or other device) that offers consistent results







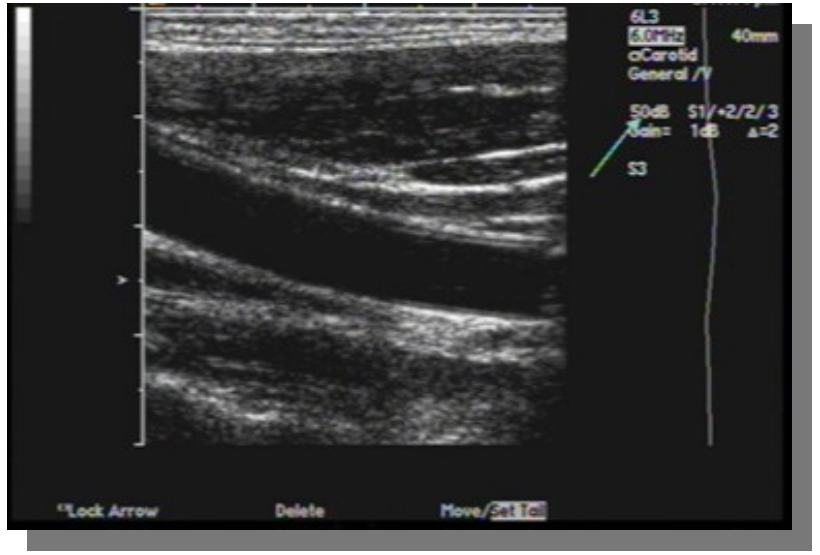


DISCUSSION

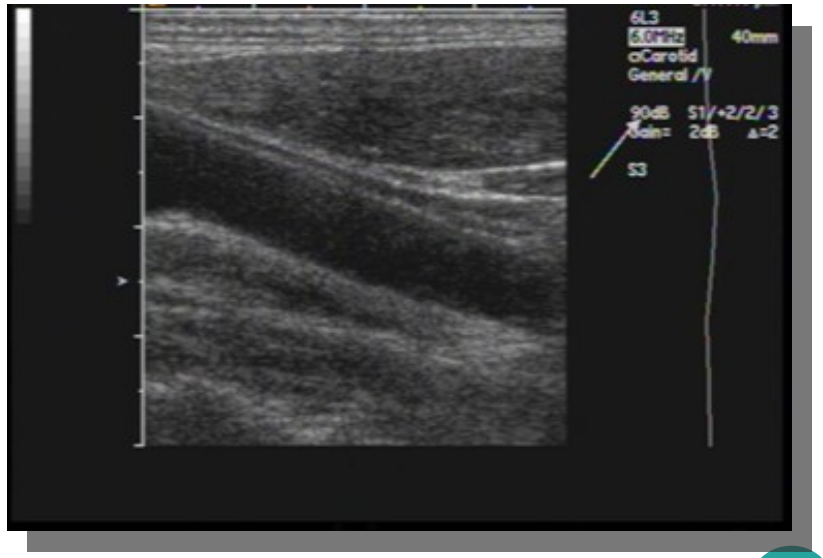
Best Practice…

Service engineers should ***never*** purely rely upon clinical images to assess image quality.

- Variables in human physiology and system setups have the potential to greatly affect the variability between two like systems
- Furthermore, the same system settings should be used to assess like systems, probes, coils, etc. as to not affect image variations



Same Probe, Same Scanner
Different Preset



ULTRASOUND

Answer in the form of a question (Jeopardy-style)

1540 meters/second

ANSWER

What is the average speed of sound in the human body?

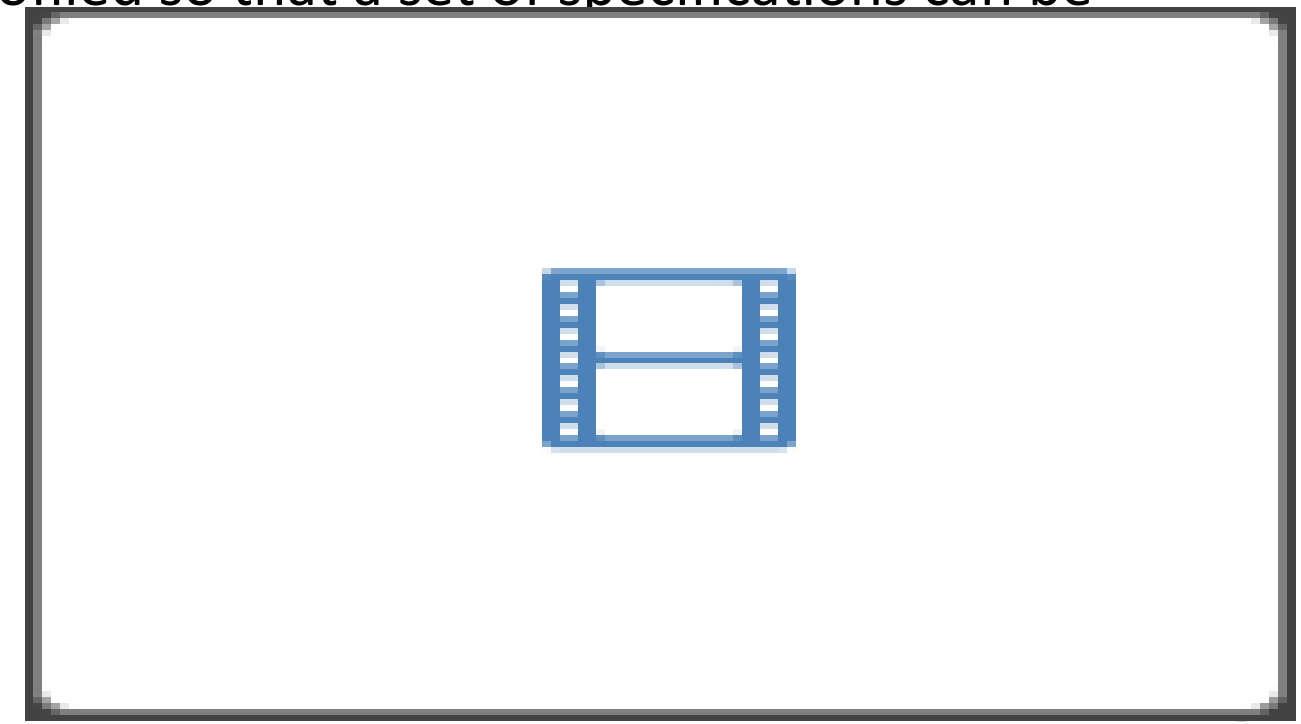
- Although the speed of sound varies in each tissue, the average speed of sound in the human body is 1540 m/s

Material	Air	Lung	Fat	Brain	Soft Tissue	Liver	Kidney	Muscle	Bone	Steel
Speed (M/ Sec)	330	500	1450	1520	1540	1550	1560	1580	4000	6000

DISCUSSION

Best Practice…

- Pulse echo testing, True Source and other devices are used to test, validate, and verify processes for new product manufacturing
  - Used to benchmark products for which we develop comprehensive repair capabilities
  - Each probe model is profiled so that a set of specifications can be developed



Answer in the form of a question (Jeopardy-style)

It’s one of the most ***frequently failed*** items on an MRI coil

ANSWER

What is the system cable?

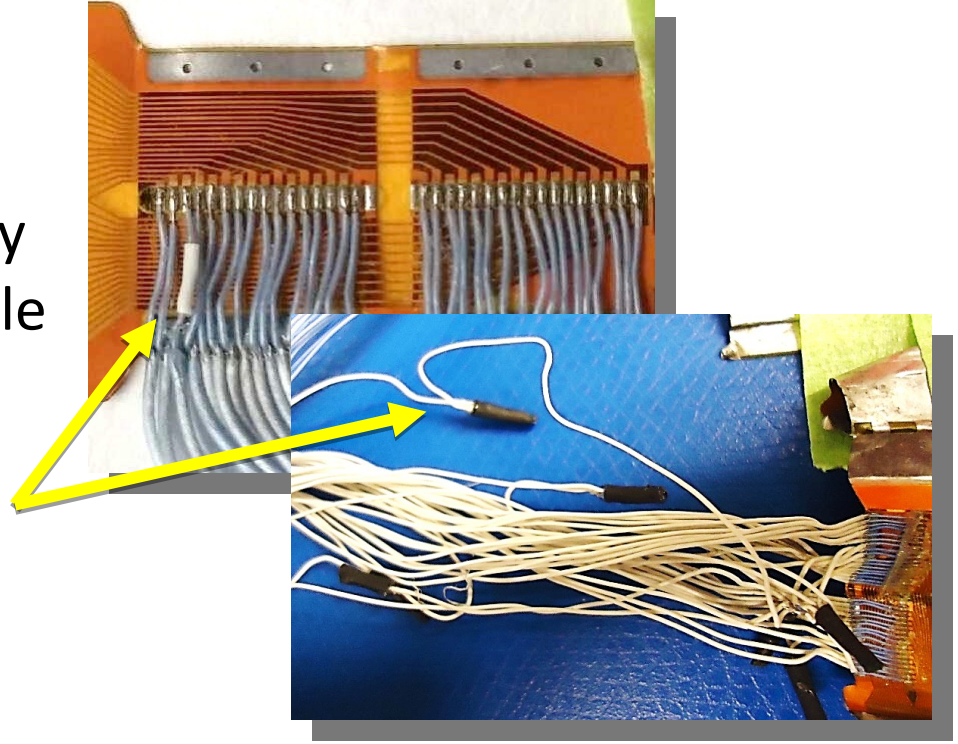
Like almost all cables, due to continued flexing they are a common point of failure

- Some OEMs do sell replacement cables for select coil models
- Cost may be between $5,000-$12,000

DISCUSSION

Did you know…

- A common approach in the repair industry to address cable failures is to ***splice*** a single broken or intermittent wire
  - Addressing only select wires in the harness leaves you open to latent failures



- Innovatus has the ability to ***fully repair*** almost any cable configuration at a fraction of the cost of replacement

QUALITY & REGULATORY

There's been a lot of industry buzz about ISO certification lately

What's the ***main*** difference between ISO 9001 and 13485

ANSWER

ISO 9001 is ***general*** quality model for continuous quality improvement

ISO 13485 is a quality model ***specific to medical devices*** and includes components associated with ***risk management***

DISCUSSION

Compare and Contrast

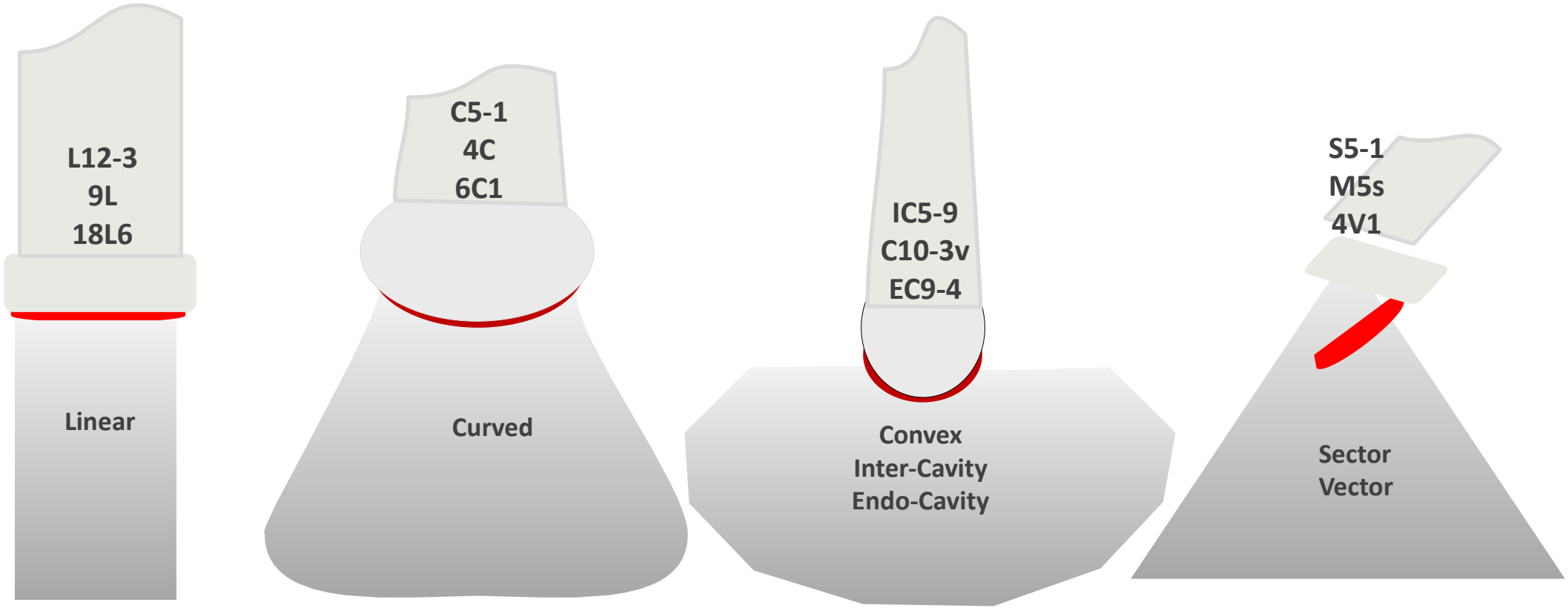
	21CFR:820	13485	9001
Maintain continuous quality improvement through a quality management system (QMS)	***Yes***	***Yes***	***Yes***
Continued suitability and ***effectiveness*** of the quality management system	***Yes***	***Yes***	***No***
Industry ***specific***	***Yes***	***Yes***	***No***
Embraces 21CFR:820 and FDA's cGMP and ***incorporates design controls***	***Yes***	***Yes***	***No***
Compliance with ***federal regulations*** where applicable, ***maintenance*** of documentation, and ***traceability***	***Yes***	***Yes***	***No***
Adopts a ***risk management*** approach: Identify & estimate risk, uses risk controls and techniques throughout product ***lifecycle***	***Yes***	***Yes***	***No***
Number of areas which require documentation or procedures		23	7

What ***details*** can be determined based on a probe's model number being ***L12-3***

ANSWER

Details such as…

- The probe's footprint and the image's shape are ***linear***
- The transmit and receive ***frequencies*** range from 3-12 Mhz



DISCUSSION

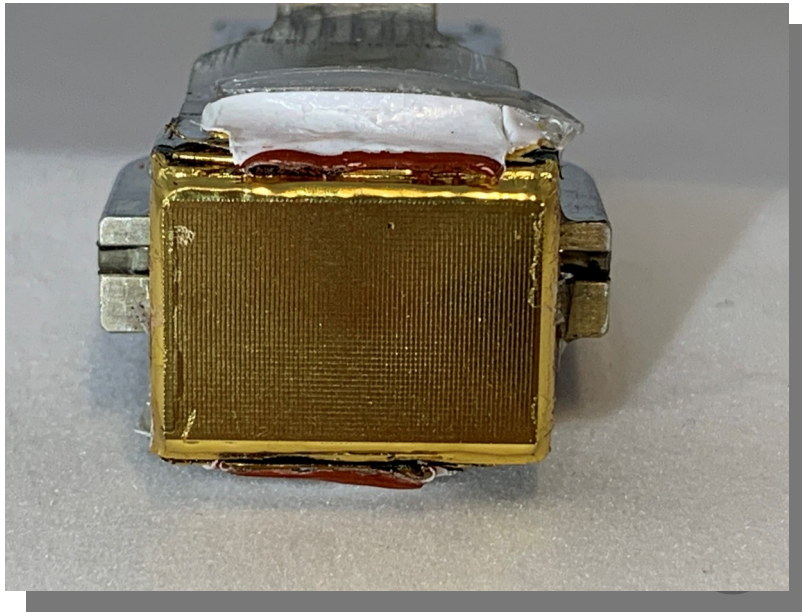
Additional Information…

- Philips X-Matrix and other Live 3D-Volumetric probes use X, V and Z
  - Contain thousands of acoustic elements

- Comprehensive repair capabilities on over 350 probe models including X-matrix probes

- Success rates over 75% on restoring safe and effective performance on the Philips X5-1, X7-2t, X8-2t and GE 6VT-D (even if fluid invaded)

Philips: X5-1, X7-2t, X8-2t
GE: 4V, 6VT-D
Siemens: 4Z1c, Z6M



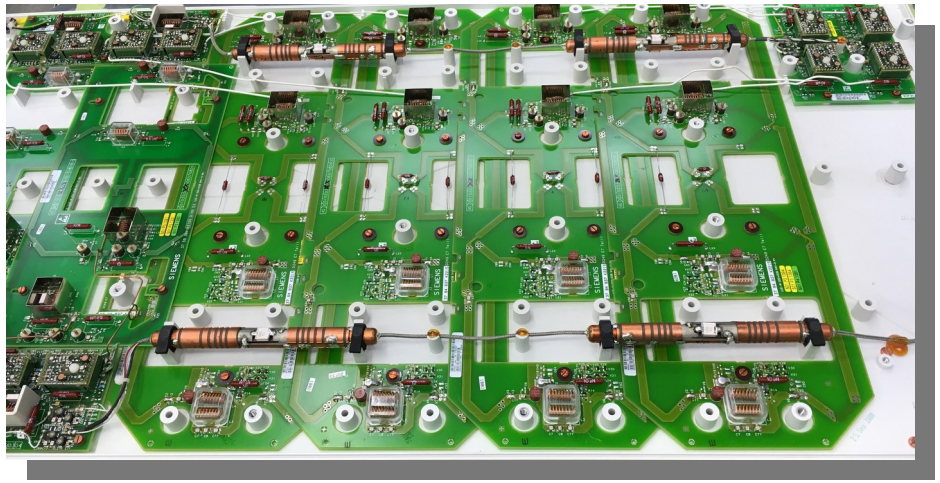
MRI

Although MRI technologists perform frequent QC checks on MRI coils, ***should coils be included in a comprehensive PM program?***

ANSWER

Yes

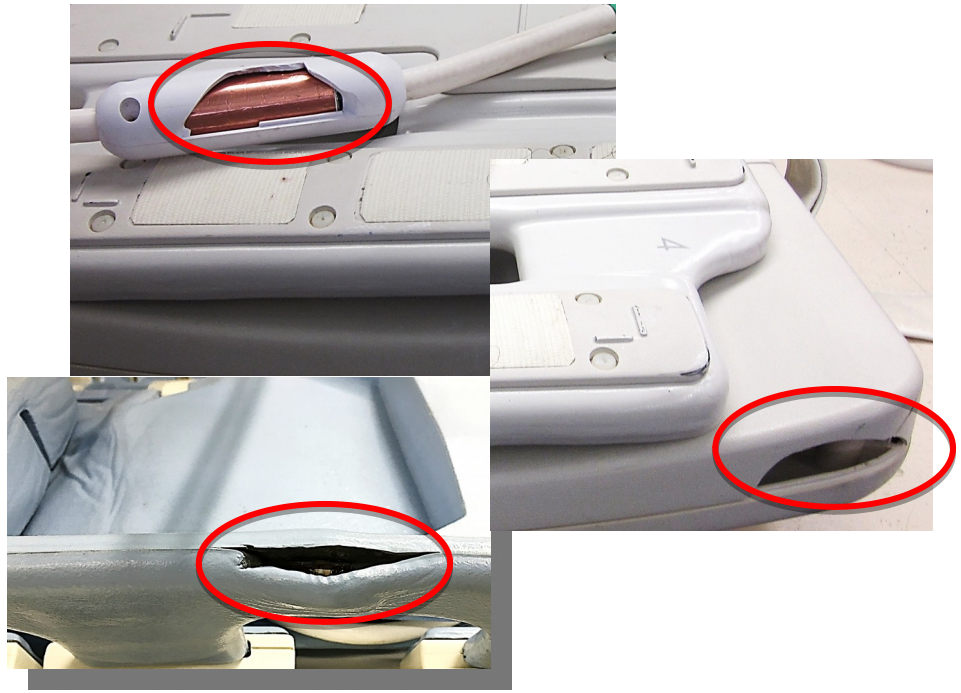
- Coils are still very ***analog*** in design
- Can ***drift out of tune*** over time
- Performance ***deteriorates*** as a result of intermittent component connectivity, wiring, and flex-circuits

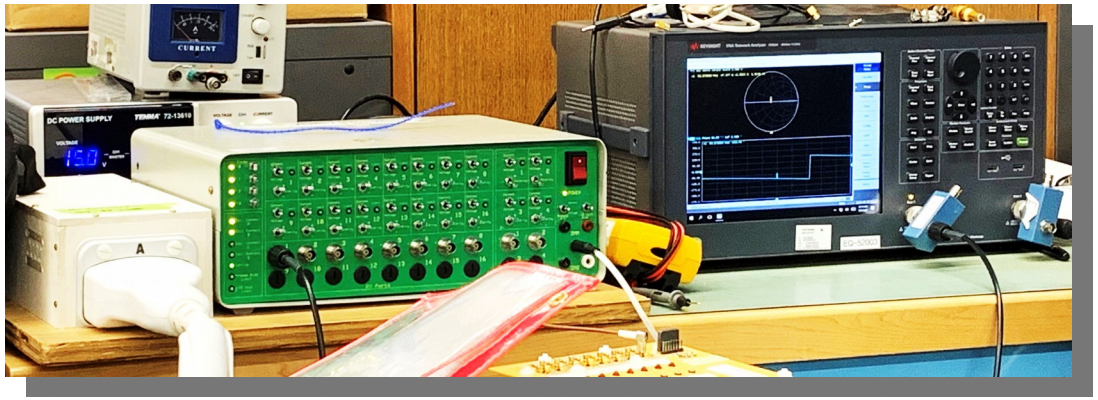


DISCUSSION

Recommendations…

- Add MRI coils to a comprehensive PM program
  - In-house: Thorough ***visual inspections*** by the service engineer
  - Outsource: Have the coil's performance assessed as part of the PM process
    - Quick, ***1-day turn around***





QUALITY & REGULATORY

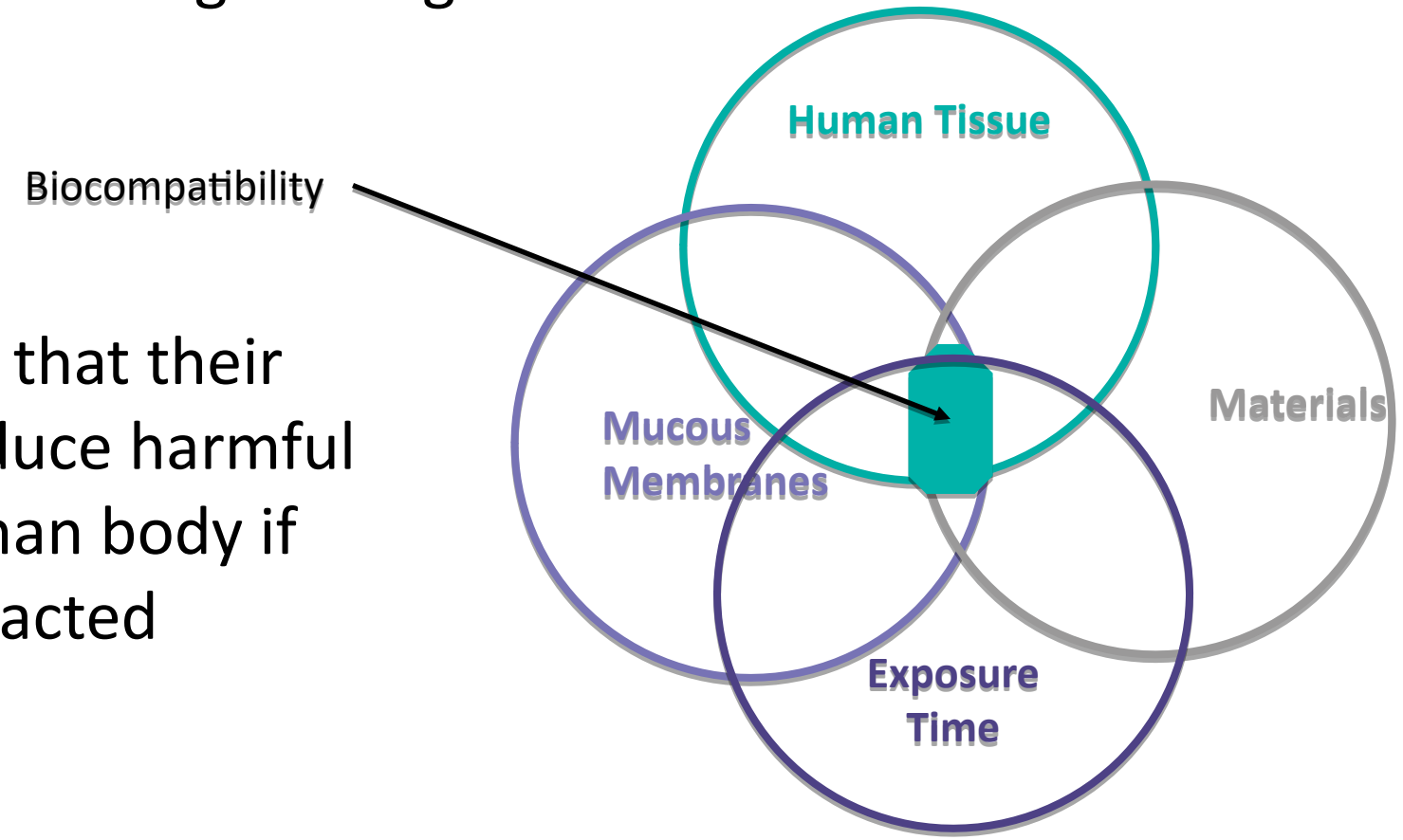
Answer in the form of a question (Jeopardy-style)

An ISO quality standard for assuring ***biocompatibility***

ANSWER

What is ISO 10993?

- Series of standards for evaluating the biocompatibility of medical devices to manage biological risk



- OEMs must prove that their devices do not induce harmful effects to the human body if implanted or contacted

DISCUSSION

Did you know…

- Currently, third-party repair providers are not required to use ISO 10993 certified materials in their repairs

- ***Ensure*** that your provider performs this testing as part of their repair offering

There are several methods used by repair providers to replace the acoustic lens on an ultrasound probe.

What could be the result of incorrect transducer lens dimensions (shape, thickness, and materials)?

ANSWER

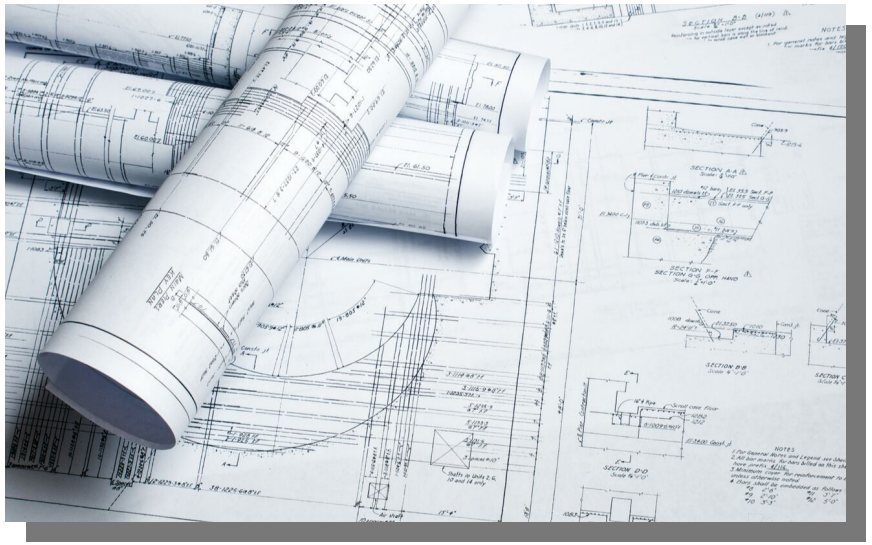
Possibilities are…

- Poor image quality
- Poor image focus
- Incorrect measurements
- Excessive/inadequate acoustic power

DISCUSSION

OEMs spend considerable efforts choosing the correct materials, shape, and dimension of the acoustic lens

- Material analysis
- Chemical testing
- Biocompatibility
- Precision Molding
- Power testing
- Image testing



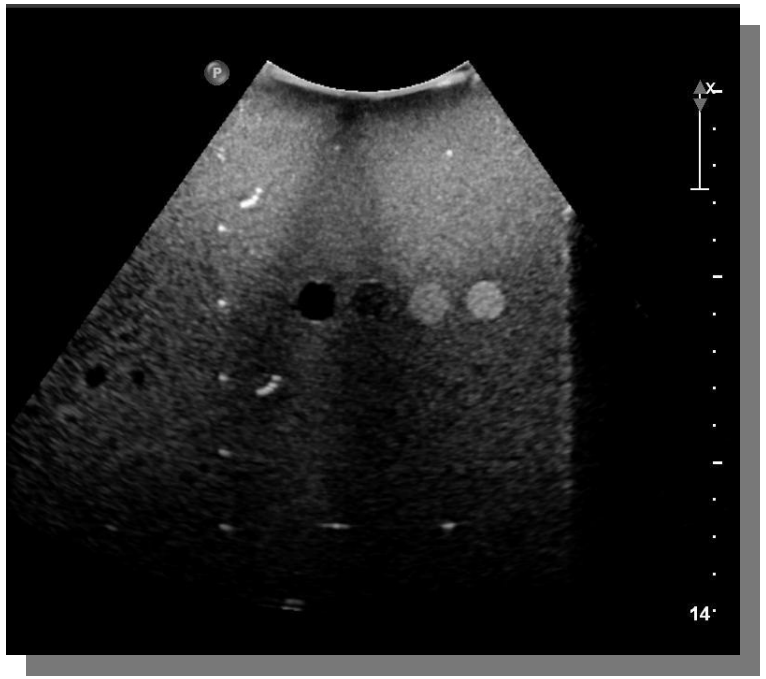
As an FDA registered manufacturer for ultrasound probes, Innovatus has the talent, tools, and experience to assure form, fit, and function of replacement lenses.

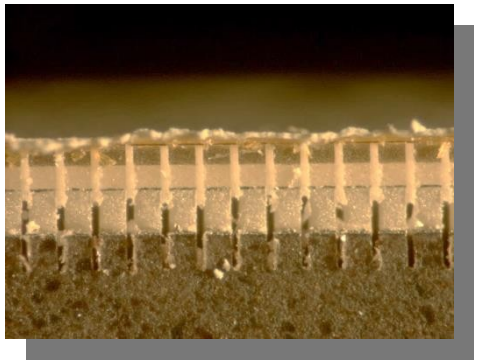
What is the ***single component*** within an ultrasound probe, that if damaged, greatly affects the probe's repairability?

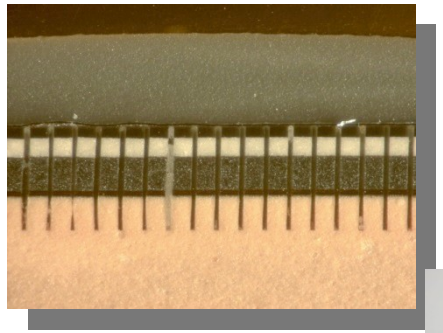
ANSWER

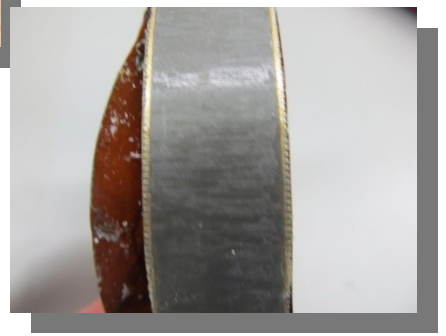
Acoustic Array

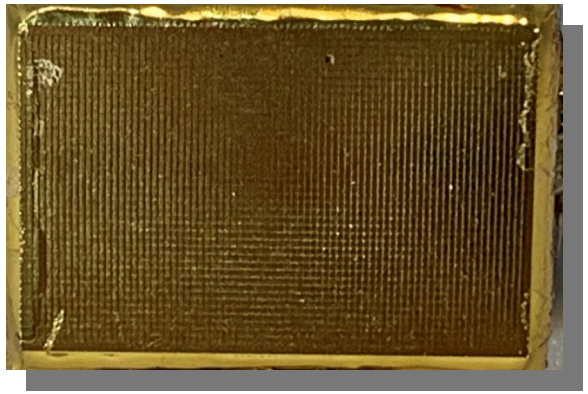
- Design and structure are similar to quartz and ceramic
- Some still refer to it as “the crystals”
- Damage results in image dropout











DISCUSSION

Did you know…

- Innovatus Imaging manufactures replacement arrays in our FDA registered Acoustic lab in Denver Colorado
  - Innovatus has expertise in array design and has strong relationships with array manufacturers.
  - Repair solutions consist of:
    - Purchasing replacement arrays from qualified suppliers
    - Surgically repairing the array
    - Manufacturing the array in-house
- ***Full repair capabilities*** on over 100 probe models which can eliminate high-cost replacements

MRI

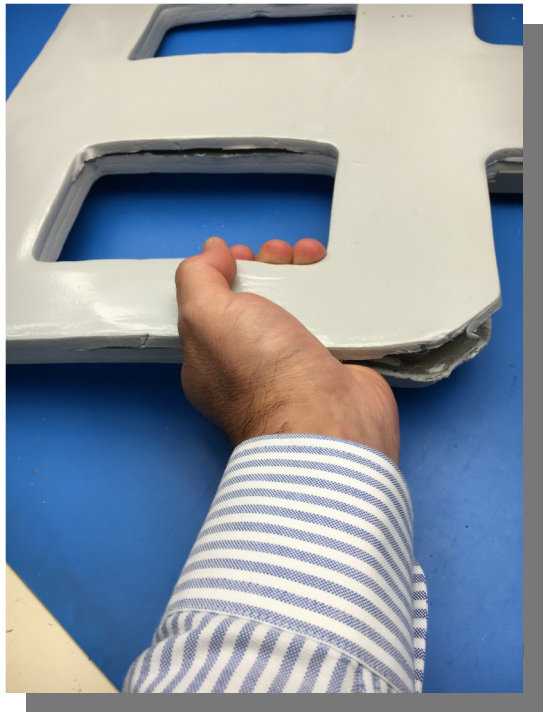
Flex coils should never be picked up, moved, or transported by the _____

ANSWER

Flexible foam section

- Although convenient, a coil should ***never be moved*** using the flexible section

- Easily ***damages*** the foam, the flex-circuit and its traces as well as the solder connections for the components.



DISCUSSION

Did you know…

- Common approaches to repairing damaged foam and flex circuits include ***patching*** and ***splicing*** damaged flex circuitry and then using ***adhesive*** to seal cuts and tears in the foam.
  - This often results in ***quick***, ***inexpensive***, ***temporary*** fixes

- On the most popular flex coil models, Innovatus can not only repair, but replace the entire flex-circuit as well as the foam covering
  - The result is ***like-new performance*** with little chance of a latent failure

What is the ***typical length*** of a cable of an ultrasound probe?

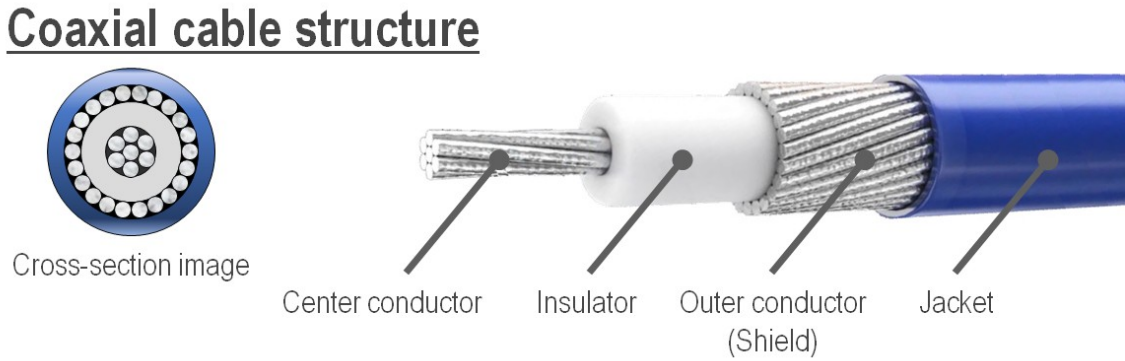
ANSWER

6 - 8 feet

- Actually, is model dependent
- OEMs design cables and wiring harnesses to meet specific design specifications of a particular probe model

Wire Properties

Length
Outside diameter
Jacket material
Inside diameter
Dielectric insulator type
Solid or stranded core
Magnetic permeability
Capacitance
Inductance
Resistance



DISCUSSION

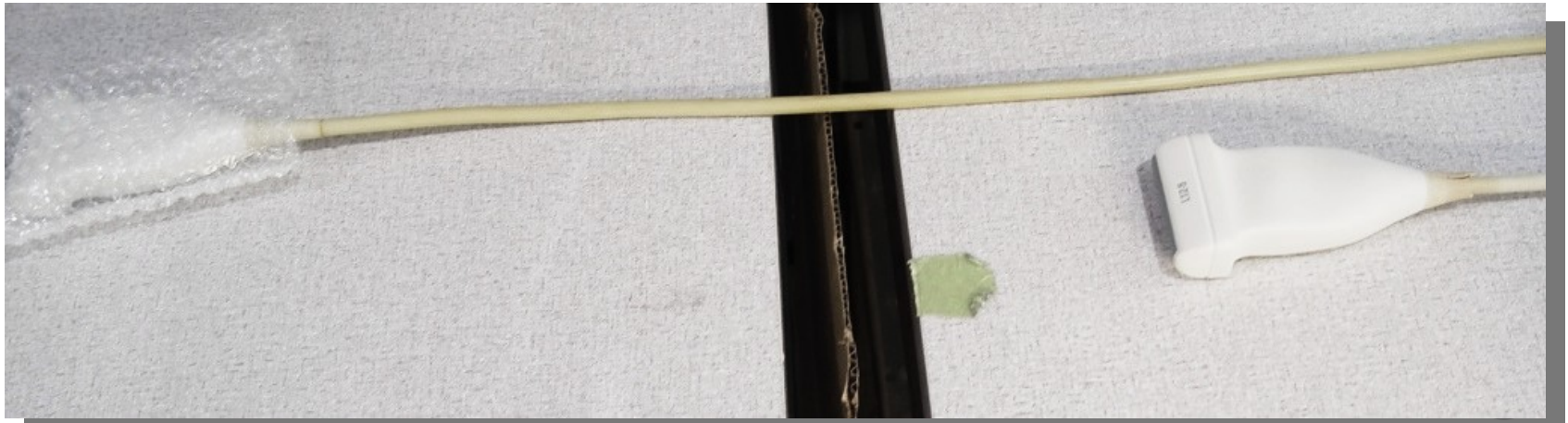
Did you know…

Common approaches to cable repair:

- Harvest a cable from another probe
- Cut-back the cable past the damaged point
- Splice individual wires

Robust, holistic solution

- ***Repair the entire cable harness***
- Innovatus has over 80 different types of full-cable repair solutions



Free For All: No risk of losing a card

Closest guess wins

How many flexes do you believe this cable withstood before beginning to deteriorate?

ANSWER

Well over 100,000

- The cable is a common point of wear on most products
- Cable is flexed 180 and rotated 360degrees

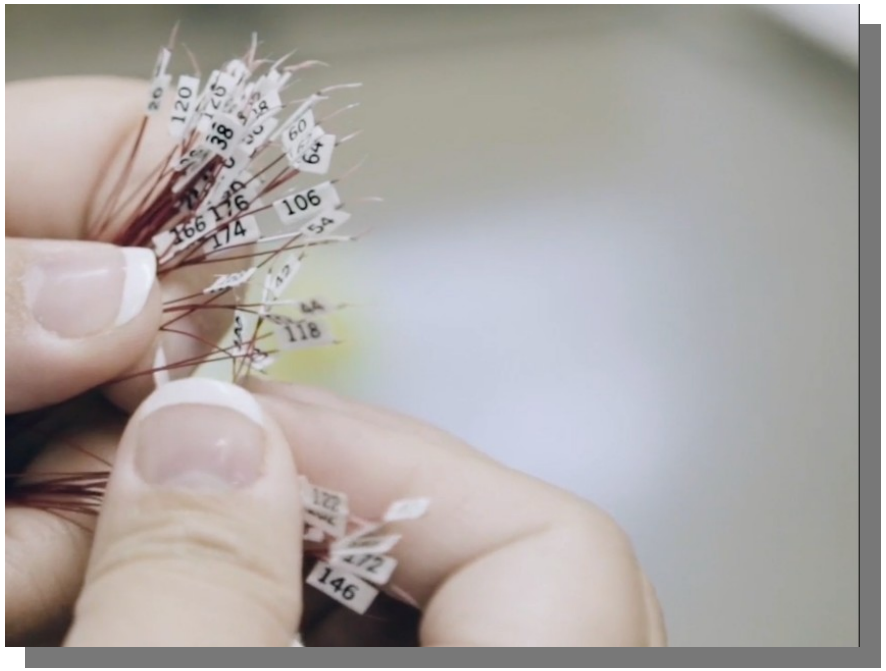
Free For All: No risk of losing a card

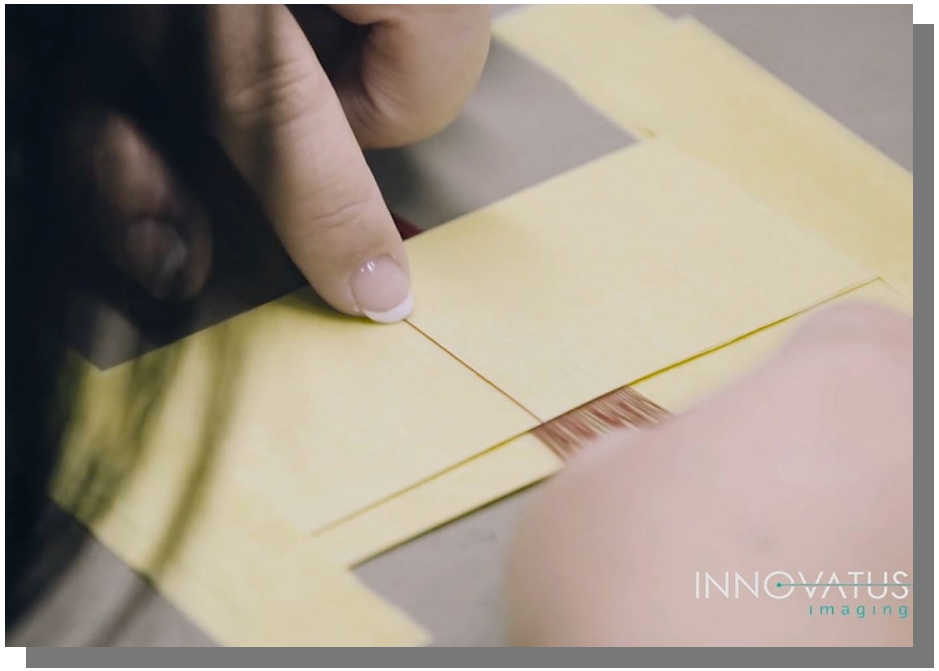
What is the typical ***wire gauge*** in a transducer cable?

ANSWER

42 – 44 gauge

- The center conductor on cable TV coaxial cable(RG-6) is 18 gauge
- Transducer cables can contain up to 256 micro-coaxial wires





Are third-parties required to repair medical devices to meet ***OEM specifications***?

ANSWER

No

- Typically, OEMs ***do not*** provide detailed specifications, material lists, or bills-of-materials to any third-party.
- Third parties usually ***are not*** privy to OEM acceptance criteria
- Currently, third parties have the freedom to ***choose their own*** materials, methods of repair, and acceptance criteria.

DISCUSSION

Best Practice…

- Develop specifications and acceptance criteria based on benchmarking OEM devices acoustically, mechanically, electrically, chemically and referencing published OEM manuals

- Results from all tests should be thoroughly documented in an ISO 13485 certified QMS for reference by governing bodies and client audits

FINAL QUESTION

DOUBLE JEOPARDY: Risk up to 2 cards to win up to 2 cards

FINAL QUESTION

How many ultrasound probes and MRI coils has Innovatus repaired throughout our lineage / history?

FINAL QUESTION

Ultrasound Probe Repair

30+ years of best-in-class processes for reliable, sustainable probe repairs with more than 160,000 probes repaired

MRI Coil Repair

A legacy in MRI coil manufacturing and a service provider since mid-1980's with over 35,000 coils repaired

Who Is The Winner?

Thanks For Playing Imaging Jeopardy!