

Elements of Speed

No matter what's going on in the world around us, turn-around time will always be a critical issue for maintaining uptime, client satisfaction, and patient care for healthcare facilities of all sizes. But getting your ultrasound probes back in operation quickly is not always a good thing.

Speedy repairs, not backed by proven methodologies and qualified providers, can actually create serious liabilities in addition to downtime that disrupts patient care and bottom lines. Fast turn-around times and low-cost solutions only matter if your devices perform safely, accurately, and sustainably. Regardless of where you are in your imaging services career, it's important to know what constitutes a repair you can rely on for first-time accuracy and long-term use.

Following is a brief checklist of The Elements of Speed you should look for to assure your quick repair is safe, effective, and sustainable.

MEASUREMENT OF APPLIED TECHNOLOGY

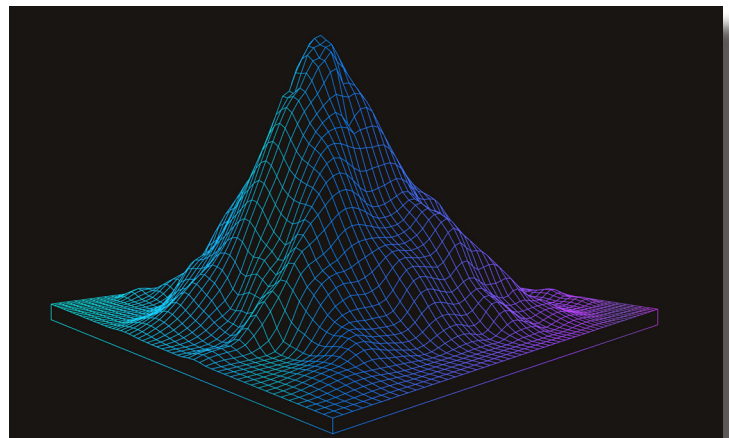
Many imaging professionals inherently trust repair providers and assume the technology behind their repaired and exchanged products has been authenticated, yet in many cases, it is not. The reality is that the quality of a repair is only as good as the quality of the technologies and methodologies used to execute the repair and the outcomes that document performance, efficacy, and safety.

A few methodologies that can be used are:

① Acoustic Power Measurement

Acoustic power measurement 3-dimensionally maps the acoustic pressure field of an ultrasound probe and helps define key safety factors such as mechanical index and thermal index.

Typically, acoustic power measurement is only performed by manufacturers as part of the regulatory process, but it is a performance metric that can degrade overtime or change as a result of damage.



② Radiation Force Balance

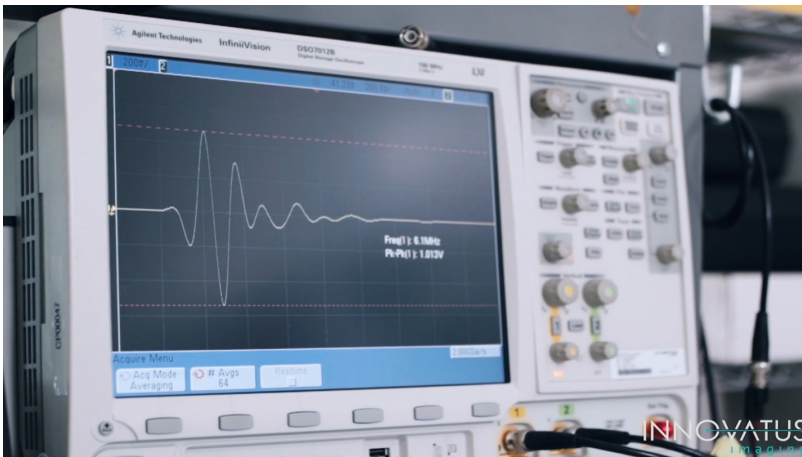
Although Acoustic Power Measurement helps to define key performance indicators and safety factors, Radiation Force Balance adds a critical component for characterizing safety parameters for new and repaired devices. Measurements based upon traditional acoustic power measurements have uncertainty levels of 20%. However, radiation force balance measurements can produce certainty levels of 90% or greater. This is a critical difference when it comes to safety, efficacy, and restoring a device's intended design. **While medical device manufacturers are required to document acoustic output power, repair providers are not.**

As a device manufacturer, Innovatus has invested in the tools, equipment, and talent to test these critical safety parameters and we are able to utilize this data to qualify components and processes used in repair

- 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 to affect patient diagnoses

③ Pulse Echo Testing

Pulse Echo Testing interrogates each element in the acoustic array and provides an element-to-element comparison of acoustic performance. Ideally, every acoustic element would perform consistently as the next throughout the array, but variances are acceptable based on design specifications. It's also possible that a percentage of non-functional elements may be acceptable, based upon design specifications.



Typically, Pulse Echo Testing is only performed by probe manufacturers to document acoustic performance.

Several off-the-shelf devices are commercially available to the layperson. However, cost is extremely high, and accuracy is very much dependent upon precise positioning, consistent test settings and a thorough understanding of acoustic science and how it relates to image formation.

The engineering teams at Innovatus have developed proprietary devices to perform pulse echo testing in our manufacturing environment as well as our repair facility.

4 Cable Flex Testing

It's only possible to predict failure if you know the thresholds across which performance is affected. Innovatus engineers test multiple aspects of a device to identify failures that could affect product performance and ultimately potentially affect a diagnosis. The Tick-Tock test is another one of our proprietary tests that helps characterize cable performance. Typically, wire continuity in a cable assembly becomes intermittent at or near a strain relief, where



much of the flexing occurs. The Cable Flex Test continuously twists and flexes the cables and strain reliefs of new and repaired probes to determine the point that performance is diminished.

A common solution to address intermittent wires is to cut-back a portion of an intermittent wiring harness and re-terminate to the scanhead which can result in cables that are shorter than the OEM intended design. Another solution is to harvest a used wiring harness to replace a damaged cable which can result in an already-worn cable being re-used again and again.

*Innovatus Imaging
manufactures over 80 different
wiring harnesses to meet OEM
form, fit, and function*

By comparing performance between new products and those from the field, we can identify the point at which cable assemblies should be replaced and offer quality replacements to our customers

5 Transducer Face Temperature Test

To minimize patient discomfort and potentially prevent patient injury, the face temperature of ultrasound probes must not exceed established regulatory limits. Maximum face temperature has been known to vary on probes used in the field as a result of sustaining physical damage or from contaminants (or fluid) gaining access to the probe. Face temperature is a parameter that is not commonly measured by probe repair providers. **As a probe manufacturer for several OEM's Innovatus, has the knowledge, equipment, and the expertise to perform this testing.**



ACCELERATION OF PROVEN PROCESSES

In automobile manufacturing, the processes that are performed at each step of the assembly line are the same. It's the quality of the skills and parts used during the execution that makes the difference in a Lexus versus a Kia. The same applies to repairing the various makes and models of ultrasound probes.

For nearly 40 years, the engineers at Innovatus Imaging have perfected the processes we apply to each repair we make, many of which have positioned us as pioneers in leading technological changes industrywide. We continuously research the efficacy of our processes and look for ways to execute faster and smarter, delivering higher levels of sustainability and efficiency to our customers and their patients. As a result, we are able to accelerate the speed of our execution without compromising the quality output.



Examples of Acceleration without Compromised Outcomes include:

⑥ Supply Chain

Much of the challenge in ultrasound probe repair comes from OEM's not selling replacement parts, not providing bills of materials, and not publishing specifications. Repair providers are on their own and typically have 2 options:

- Harvest broken probes for usable parts and components and/or,
- Developing a qualified supply chain (whether in-house or outsourced)

The former model can result in inconsistent repair offerings, delayed turn-around times, and/or unqualified replacement parts and materials.

***We've minimized the opportunity
for external factors to affect
our service offerings by
developing our own internal
supply chain***

Examples could include:

1. A probe model that is repairable today, but would need to be exchanged next week
2. A delayed repair due to having to wait for a donor probe and/or,
3. The use of worn, previously used, cables and other components



Similarly, to OEM manufacturing when needs arise, engineering and production teams produce required parts for assembly. Whether harvested from OEM probes, produced in-house, or procured through certified suppliers, by having qualified parts at our repair facility, we can expedite many repair procedures in ways other providers cannot.

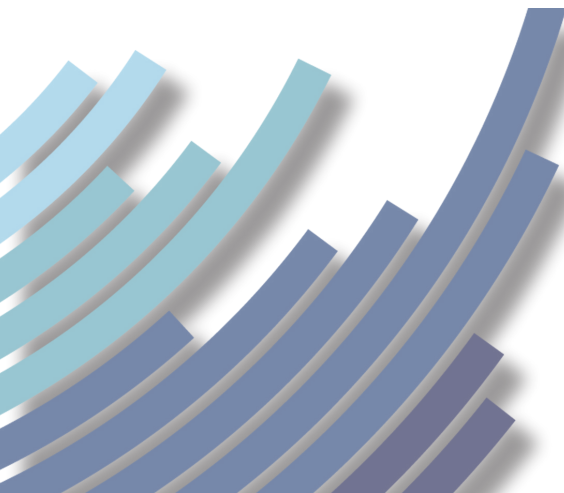
All parts used in our repairs are done so according to the intended form, fit, function and intended design by the OEM.

7 State-of-the-Art Assembly and Wiring Lines

Innovatus Imaging operates a 25,000 square foot Center of Excellence designed to address high volumes of repair with high levels of quality. Part of the unique distinction of this facility is the wiring line, where technicians meticulously perform wiring repairs and harness replacements.

Some of the most advanced probes contain over 192 individual micro-coaxial cables which must be laser-stripped to exact dimensions, positioned precisely and accurately, and terminated by hand, under considerable magnification.

These model-by-model procedures are guided by the methodologies established by our Design and Manufacturing Center of Excellence which operates in accordance with our ISO 13485:2016 certification.



8 Pre-Engineered Assembly Programs

Repair procedures are expedited when a damaged product arrives to a facility and is immediately assigned to a repair team equipped with all the parts and equipment to perform the repair. In many depot repair facilities across multiple industries, a device is diagnosed, is then sent to a technician, who then has to request the needed parts from the procurement team before that repair can begin. Sometimes, this act alone can add days to a repair.

By creating a pre-engineered repair program, technicians are equipped to start a repair as soon as the device is delivered to their station. It's like having your own pit-crew.

This ability is a direct result of having an internal supply chain which is a distinct value exclusive to Innovatus Imaging and is the direct result of the visionary leadership of our founders. We call this **RapidRepair**, and it's why we can deliver Philips X7-2t's and X8-2t's back to clients within 3 - 5 days.



By having all of the above Elements of Speed on your checklist each time you search for and select a partner for probe repair, your chances of securing a high first-time fix rate, sustainability for the functionality repaired, and longevity for your devices accelerates substantially.



For more information, please visit innovatusimaging.com or call us at 844-687-5100. You can also find a list of our capabilities and loaner inventory online.