Data-Driven Repair and Your Bottom Line

Introduction to Data Driven Repairs and Why it Matters for Performance and Patients

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In an industry with much at stake, quick fixes are simply not enough. Imaging device repairs need to be backed up by “evidence” not just personal experience as to what will work fast and hold up for at least a little while.

Relying on scientifically-valid evidence and data-driven analytics to guide repair procedures for ultrasound probes and MRI coils is critical for results that enable devices to perform as originally intended while positively impacting operational and financial goals.

At Innovatus Imaging, we call this Data-Driven Repair (DDR). DDR represents methodologies developed over 25 years of proprietary research, testing and experience which guide our manufacturing and repair of probes and coils. It also integrates insights and methodologies from scientific studies, quality management systems, globally-recognized performance standards, and exclusive analytics from more than 160,000 successful repairs for just probes alone.

Our DDR processes are developed by our Design and Manufacturing Center of Excellence in Denver, Colorado lead by Chief Technology Officer, Mike LaBree, a renowned leader in technology development, device design and manufacturing processes. Primary components of DDR which are proven to extend performance quality and life of probes and coils include the following:

1 Medical device manufacturing and risk-based Quality System:

ISO certification matters. Companies that adhere to globally accepted 13485:2016 standards and understand medical device manufacturing will by design produce outcomes containing many key elements necessary for safe and reliable repairs. These processes are backed by substantial amounts of valid data that are much more reliable as an indicator of long-term repair performance than individual experience with no documented outcomes. A risk-based system ensures processes and parts which relate to patient safety are properly qualified before being utilized in a repaired device.

Providers without current certified quality systems, or those just using ISO 9001, may not be able to implement the stringent controls and risk-based analysis required to provide consistent, sustainable medical device repairs and/or service. Relying on DDR further ensures safe, effective repair outcomes.

2 Years of historical repair analysis:

Long-term experience creates substantial amounts of valuable data which can drive highly-effective results. Following are examples of how the insights we've gained through our DDR practices can benefit our customers:

- The number of cycles the bending rubber on TEE probes can endure before starting to degrade. Knowing thresholds like this can preempt replacement of a bending rubber avoiding a subsequent field failure.
- Even a tiny hole in a bending rubber can lead to fluid invasion and many potential latent failures of a TEE probe. Our substantial repair history tells us what to look for on a model-by-model basis to ensure customers don't experience latent failures resulting from a 'fix it and forget it' approach to replacing a bending rubber.
- A failed strain relief on some probe models means only physical damage to a strain relief, yet on other models is highly indicative of intermittent cable failures. Our extensive knowledge of long-term failure modes and failure trends enables us to look for hidden damage others may not see.

3 Acceptance criteria based on elevated science and industry standards:

Without OEM specifications, many providers do not address product requirements in their repair processes or they rely upon arbitrary criteria which are not specified by OEM's or related standards. Both can impact performance and patient safety. DDR involves careful measurements and analysis of OEM products to establish objective criteria for key performance parameters and consistency with standards and guidance OEM's must comply with such as IEC60601 and ISO10993. Our in-depth analysis of OEM products provides a Gold Standard Benchmark to which other evidence is applied, further enhancing our processes and outcomes.

As an original equipment manufacturer for probes and coils, and an industry-leading repair provider, Innovatus Imaging is thoroughly familiar with relevant standards for the equipment we service as we maintain significant capabilities for testing and measuring OEM products to establish acceptance criteria for ensuring safe, effective, and sustainable repairs.

For in-depth information about our Data-Driven Repair processes and outcomes, testing, and measurement capabilities, please visit our Resources Page at InnovatusImaging.com, call us at 844-687-5100 or email our Clinical Experience Specialist at TedL@innovatusimaging.com.

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