



Reprocessing Sensor-Enabled Mapping Catheters

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In 2019, Innovative Health filed a lawsuit against Biosense Webster for monopolizing and restraining trade in the nationwide markets for the sale of high-density mapping catheters and ultrasound catheters – specifically sensor-enabled catheters. A California district court held an eight-day jury trial in May 2025, and on May 16, 2025, the jury returned a unanimous verdict in Innovative Health’s favor on all four counts presented at trial, finding that Biosense Webster violated federal and California antitrust laws. A permanent injunction issued August 27 ordered Biosense Webster to discontinue its practices designed to restrict the use of reprocessed devices.

The use of reprocessed sensor-enabled catheters was the subject of the trial. What are sensor-enabled catheters? What makes them unique? Can they be reprocessed? Are reprocessed sensor-enabled catheters dangerous? This whitepaper goes into technical detail with these questions.



1 Introduction and Background

Electrophysiology (EP) is a specialty within cardiology, focused on diagnosing and treating cardiac arrhythmias through targeted interventions such as catheter ablation. These procedures require precise localization of electrical signals and anatomical landmarks within the heart. Historically, physicians have relied on fluoroscopy for this precise targeting, which exposes both patients and clinical staff to ionizing radiation.

Over the past decade, the field has been shifting towards advanced 3D mapping systems to dramatically reduce reliance on fluoroscopy and radiation exposure. These systems allow physicians to visualize the heart's electrical activity and catheter position in real time, often enabling procedures to be performed with minimal or even zero fluoroscopy. This evolution has improved procedural safety, reduced radiation burden, and enhanced mapping accuracy.

1.1 Why Mapping Catheters Matter

Mapping catheters are the interface between the patient and the mapping system during an EP procedure. These catheters collect intracardiac electrical signals and transmit spatial data that allows the system to construct a dynamic electro-anatomical map. Sensor-enabled mapping catheters go a step further: they contain embedded location sensors that provide real-time positional feedback, enabling precise navigation without continuous fluoroscopic guidance.

These catheters are essential for:

- Reducing radiation exposure: By enabling real-time localization, sensor-enabled catheters minimize or eliminate the need for fluoroscopy.
- Improving procedural efficiency: High-density mapping and accurate localization reduce mapping time and increase ablation precision.
- Enhancing safety: Less radiation means lower risk of long-term complications for both patients and staff.
- Supporting Ambulatory Surgery Center (ASC) migration: As EP procedures move into Ambulatory Surgery Centers, minimizing radiation becomes even more critical due to infrastructure constraints.

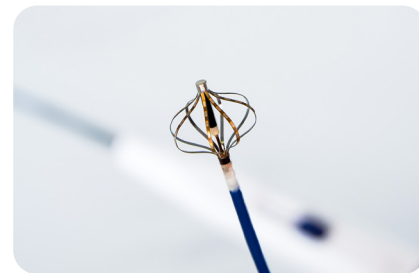


Image 1: Mapping Catheters

1.2 Hybrid Mapping Systems

Modern mapping platforms (such as CARTO 3, EnSite Precision etc.) use hybrid localization technologies that combine magnetic field triangulation with impedance-based tracking. This dual-modality approach enhances accuracy, supports cross-compatibility, and provides redundancy in signal acquisition.

Electrophysiology (EP) procedures rely on these precise anatomical and electrical mapping to diagnose and treat complex arrhythmias. At the center of this process are sensor-enabled catheters, devices embedded with location sensors that allow real-time spatial tracking within the heart.

Sensor-enabled catheters are not passive conduits. They are active components in the mapping ecosystem. Their embedded coils or electrodes generate electromagnetic signals that are interpreted by the mapping system to determine the catheter's position in three-dimensional space. This spatial data is layered with intracardiac electrical signals to construct actionable electro-anatomical maps that guide ablation therapy.

Here's a categorized list of the most common electrophysiology catheters that incorporate location sensors, organized by manufacturer:

Biosense Webster (Johnson & Johnson) – CARTO System Compatible

- PentaRay NAV ECO Mapping Catheter, Multi-spine catheter with location sensor
- Lasso NAV ECO Circular Mapping Catheter, Sensor-enabled loop catheter
- SoundStar Ultrasound Catheter, Intracardiac echo catheter with location sensor
- DECANAV Diagnostic EP Mapping Catheter, Steerable catheter with location sensor

Abbott (St. Jude Medical) – EnSite™ System Compatible

- Advisor HD Grid Mapping Catheter, Sensor Enabled Grid-patterned catheter
- Advisor HD Grid X Mapping Catheter, Sensor Enabled Next-gen grid catheter
- Advisor FL Circular Mapping Catheter, Sensor Enabled Flexible loop catheter
- Advisor VL Circular Mapping Catheter, Sensor Enabled Variable loop catheter

Boston Scientific – RHYTHMIA HDx System Compatible

- INTELLAMAP ORION Mapping Catheter, high-resolution sensor-enabled



Image 2: INTELLAMAP ORION™ High-Resolution Mapping Catheter



Image 3: Advisor FL Circular Mapping Catheter, Sensor Enabled

These devices are essential for atrial fibrillation (AFib) procedures, which are increasingly performed in Hospitals and Ambulatory Surgery Centers (ASCs). With increased procedure volume and decreasing reimbursement rates, the need for cost-effective, high-performance devices becomes more urgent.

2 What are Location Sensors?

Location sensors are embedded components in mapping catheters that operate under Faraday's Law of Electromagnetic Induction. This principle states that a changing magnetic field within a closed loop induces an electromotive force (EMF), which can generate an electrical signal. The sensor-enabled catheters are engineered to deliver precise electrical signal through these embedded location sensors in the distal shaft. Location sensors interact with magnetic fields or impedance gradients generated by the respective mapping system to determine the catheter's exact position in three-dimensional space. The performance of these sensors is critical to the accuracy of electro-anatomical maps created by the catheter and the success of ablation procedures.

2.1 Sensor Basics

The location sensors embedded in mapping catheters are often copper wire loops positioned deep within the distal shaft. These coils function as passive electromagnetic transducers, generating current during movement in response to low-energy magnetic fields emitted by the mapping system's location pad.

- Material: Copper (chemically stable, non-reactive)
- Principle: Faraday's Law
- Placement: Embedded in adhesive or extruded within the catheter shaft
- Protection: Physically shielded from external exposure during use and reprocessing

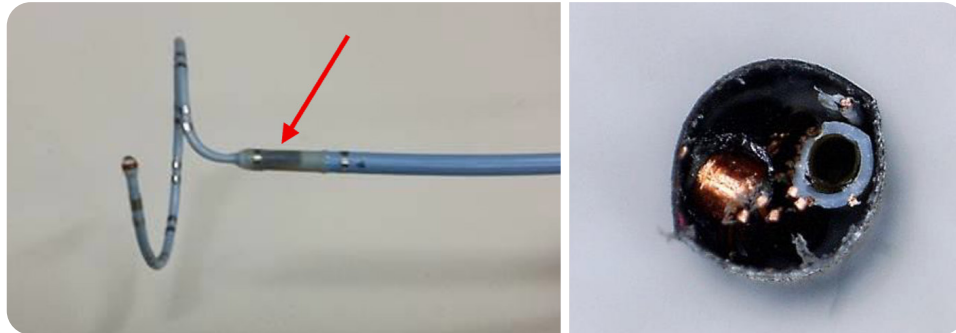


Image 4: Common sensor location in sensor-enabled mapping catheter, split view

These sensors are designed to be inert to heat, moisture, and chemical agents used during manufacturing or clinical use. Their physical and chemical stability ensures that they do not degrade, shift, or lose functionality during production, transit, sterilization etc.

2.2 Calibration Mechanism

During original manufacturing, each catheter's sensor response is characterized, analyzed and tested using their proprietary location sensor system. The results are used to generate a unique calibration file specific to that catheter, this file contains correction factors that account for coil geometry, signal amplitude, and spatial orientation. The data is stored in an EEPROM (Electrically Erasable Programmable Read-Only Memory) chip embedded within the catheter.

- EEPROM Function: Stores device-specific calibration data
- Calibration Data: Covers X, Y, and Z electromagnetic planes and correction factors
- Function: Provide the calibration specifics needed for effective structural mapping during catheter use

2.3 Procedural Calibration Safeguards

Prior to initiating a procedure, a new catheter needs to be "verified" with the mapping system in use. This is the "handshake" that determines the mapping system recognizes the catheter. Reference catheters are used to initiate the mapping catheter after the patient is fixed. When the catheter is plugged in, it verifies the catheter data within the EEPROM for accuracy and expiration.

In addition, mapping systems like CARTO perform baseline location calibration after patient prep. This procedural safeguard ensures mapping accuracy regardless of device origin.

However, our internal testing ensures that such calibration is not compensating for device variability, it's confirming that the device is already within spec.

This dual-layer validation, internal testing plus procedural handshake, provides EP physicians with confidence that reprocessed sensor-enabled catheters are safe, accurate, and clinically effective.

3 Can Mapping Catheters be reprocessed safely?

Yes, sensor-enabled mapping catheters can be safely reprocessed without compromising their safety profile or performance, provided the reprocessor follows FDA-cleared protocols and rigorous engineering standards. Reprocessing sensor-enabled mapping catheters is a scientifically validated, FDA-cleared process grounded in real-world clinical testing.

What about the advanced sensors within these catheters, can they be reused?

Yes, the location sensors and associated electrical components are embedded deep within the catheter shaft, physically isolated from bodily fluids during use and shielded during reprocessing. These components are not exposed, accessed, or altered at any stage of the cleaning or sterilization process. Their integrity is preserved by design, and their function is verified through proprietary sensor testing systems that replicate the electromagnetic environment of clinical mapping platforms. This ensures that reprocessed sensor-enabled catheters maintain the same spatial accuracy, safety, and clinical reliability as their Original Manufacturer (OM) counterparts.



Image 5: Reprocessing Operations

At Innovative Health, we validate the performance of our reprocessed devices using the same capital equipment, mapping systems, and procedural workflows found in electrophysiology labs across the country. Our validation studies are designed to demonstrate substantial equivalence to the OM device in every critical attribute: dimensional, sensor performance, electrical functionality, structural integrity, and clinical utility. These studies form the structure of our regulatory submissions to provide regulators and subject matter experts with the assurance that reprocessed devices perform as intended.

4 Is Reprocessing Regulated?

Medical Device Reprocessing is a regulated, validated, and FDA-cleared and routinely audited manufacturing process. At Innovative Health, we operate under a robust quality management system that aligns with FDA regulations, ISO 13485 standards, and best practices in the industry. Our reprocessing of sensor-enabled mapping catheters is scientifically validated to ensure safety, performance, and substantial equivalence to the original device.

4.1 Regulatory Framework

Our reprocessing program is governed by a comprehensive regulatory framework that includes but is not limited to:

- 21 CFR Part 820 (Quality System Regulation):
Our quality system complies with FDA requirements for medical device manufacturers, including design controls, process validation, and corrective/preventive actions.
- ISO 13485:2016 Certification:
Our facilities are certified to the international standard for medical device quality management systems, ensuring traceability, documentation, and risk management.
- ANSI/AAMI ST98 Compliance:
Our cleaning and sterilization protocols for micro-lumened and sensor-enabled devices are validated in accordance with the latest AAMI standards for single-use device reprocessing.
- Device Master Records (DMRs):
Each reprocessed device is traceable to a complete DMR, including cleaning, inspection, testing, and release documentation.



Image 6: Mapping Catheters

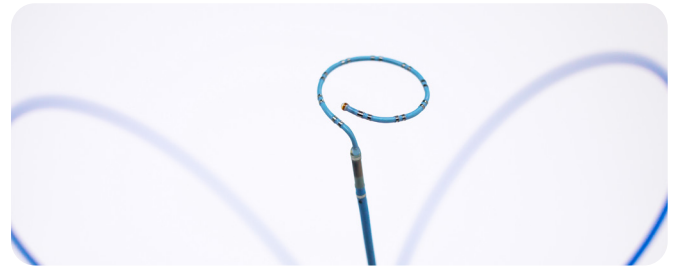


Image 7: Lasso Circular Mapping Diagnostic EP Catheter

4.2 FDA Clearance and Substantial Equivalence

Innovative Health has received FDA 510(k) clearance to reprocess sensor enabled mapping catheters. This clearance confirms that the reprocessed devices are substantially equivalent to the original manufactured device in terms of:

- Intended use
- Technological characteristics
- Performance and safety profile
- Materials and biocompatibility
- Functional integrity, including sensor accuracy

The predicate devices used in our 510(k) submissions are the actual original manufactured catheters, not similar or generic models to just represent the device design. This ensured that our validation and testing are benchmarked against the highest possible standard: the original device itself.

Following FDA clearance, the validated reprocessing protocol is transferred into full-scale production under our ISO 13485 certified quality system, ensuring consistent, compliant, and clinically equivalent output across every reprocessed device.

5 Implementation of the Manufacturing Process after FDA Clearance

Reprocessing sensor-enabled mapping catheters is a tightly controlled, multi-stage manufacturing process governed by engineering discipline, regulatory compliance, and clinical accountability. At Innovative Health, our quality control framework is designed to ensure that every device released for clinical use is reprocessed using a validated process, and meets the performance, safety, and reliability standards equivalent to a new OM catheter.

This framework integrates visual inspection, functional testing, documentation, traceability, and batch-level analytics. It is built to detect non-conformances and to ensure product quality.

5.1 Multi-Stage Quality Control Process

Each catheter undergoes a structured sequence of quality control checkpoints. These checkpoints are designed to isolate failure modes, verify performance, and ensure consistency across reprocessed inventory.

The process includes:

Pre-Cleaning Inspection

- Visual assessment for gross contamination, mechanical damage, or structural compromise
- Identification of devices unsuitable for reprocessing before any resources are committed Post-Cleaning Verification
- Confirmation of cleaning efficacy using validated protocols
- Inspection for residual debris, fluid retention, or lumen blockage (especially in micro-lumened catheters)

Functional Testing

- Electrical continuity and impedance testing across all electrodes
- Location sensor testing across X, Y, and Z electromagnetic planes using proprietary test systems
- Comparison to OM defined performance envelope

Final Release Check

- Review of all inspection and test data
- Batch-level traceability and documentation
- Release authorization by trained quality personnel

Each step is documented in the Device History Record (DHR), which serves as the permanent record for that device's reprocessing lifecycle.

5.2 Electrical Performance

Electrical functionality is essential for signal acquisition and ablation guidance. Each electrode is tested for electrical continuity and resistance using calibrated diagnostic equipment.

Testing parameters include:

- Open circuit detection
- Short circuit detection
- Impedance measurement across all electrodes
- Signal transmission verification
- Location Sensor Performance

Platinum electrodes are chemically stable and resistant to degradation, but any deviation from expected electrical parameters results in rejection.

5.2.1 Location Sensor Calibration Integrity

The most critical component of a sensor-enabled catheter is its location sensor. Innovative Health does not recalibrate sensor-enabled catheters because the original calibration data that is stored in a read-only EEPROM chip remains intact and valid after reprocessing. The embedded copper coil sensors are chemically stable and physically protected, meaning their performance does not degrade with a single use.

To validate sensor performance, Innovative Health developed a proprietary location sensor tester. This system was reverse engineered to replicate the electromagnetic environment of the CARTO mapping system and is used exclusively for quality assurance. To establish the baseline location sensor performance, a statistically controlled pool of new, unused OM catheters was tested and evaluated. These devices were tested across all three electromagnetic planes (X, Y, Z), and their responses were modeled using advanced statistical techniques to establish the strict acceptance range across all metrics. Any deviation from the established performance requirement results in rejection.

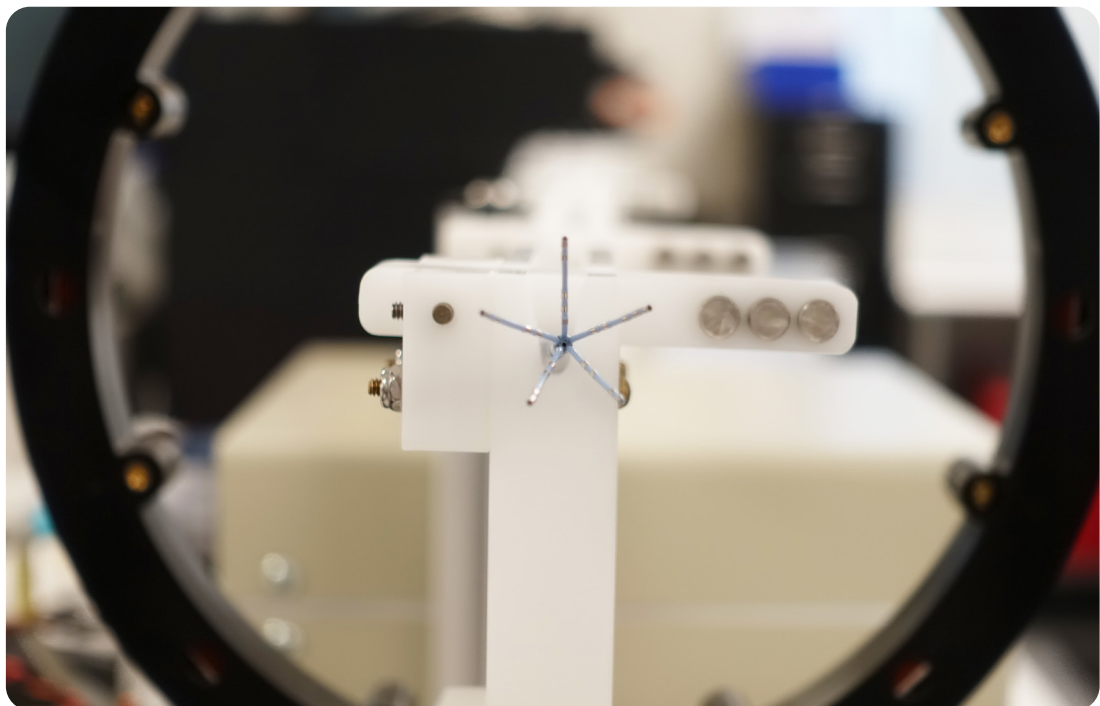


Image 8: Location Sensor Testing

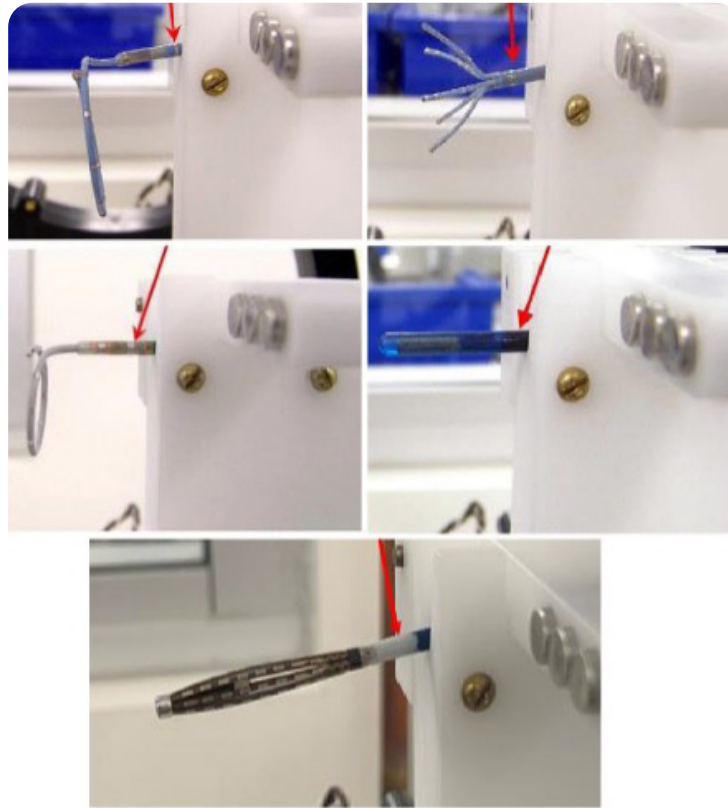


Image 9: Reprocessed Mapping Catheters being tested on Innovative Health's Location Sensor Tester. The embedded location sensor (arrow pointing to the embedded sensor within the catheter) performance across all three electromagnetic planes (X, Y, Z) are evaluated using this system

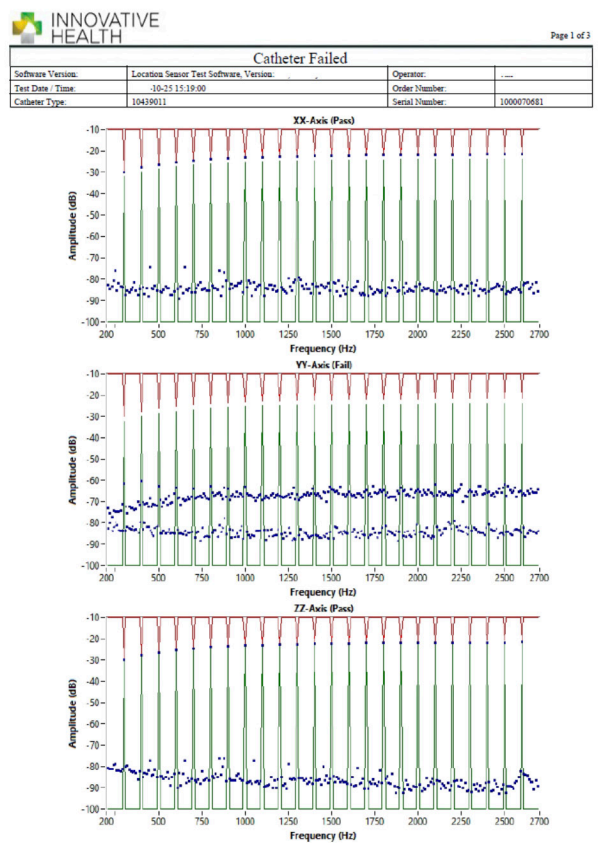
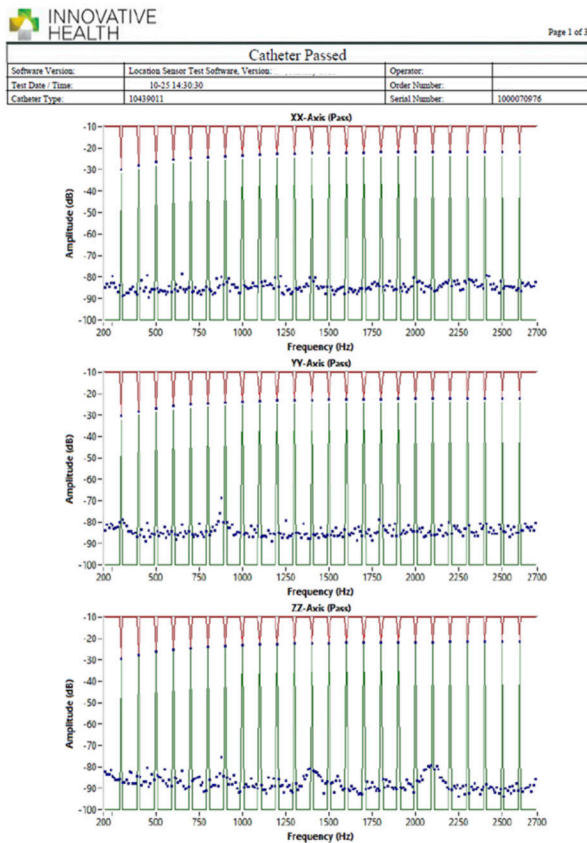


Image 10: Location Sensor Performance summary generated after testing. Device passed (left), device failed (right)

Unlike reprocessors who recalibrate sensors post-reprocessing to accommodate performance drift in the location sensor coils, Innovative Health rejects any device that does not meet the original calibration envelope.

We do not move the goalposts. We preserve them.

- EEPROM chips remain untouched.
- Calibration data is preserved.
- Sensor performance is verified, not redefined.

This policy reinforces clinical confidence. Physicians know that reprocessed devices have not been “tuned” to pass, they have been tested to ensure calibration files are intact and sensors are accurate.

5.3 Traceability and Documentation

Every reprocessed catheter is assigned a unique identifier that links it to its full reprocessing history.

This includes:

- Cleaning and sterilization records
- Inspection and test results
- Batch-level analytics
- Release authorization

All data is stored in compliance with FDA 21 CFR Part 820 and ISO 13485:2016 standards. This ensures full traceability for audits, recalls, and regulatory review.

5.4 Rejection Protocols

Innovative Health maintains a zero-tolerance policy for performance deviation. Devices are rejected if they fail any of the following:

- Visual inspection
- Cleaning requirements
- Electrical performance
- Sensor performance
- Packaging integrity
- Sterility assurance

Rejection is not negotiable.

Devices that fall outside the defined acceptance criteria are permanently removed from circulation. This includes:

- Minor sensor drift
- Electrode impedance anomalies
- Cosmetic damage that could affect handling or insertion
- Location Sensor Calibration mismatch relative to baseline models

Rejected devices are logged, analyzed, and used to refine future inspection protocols. This feedback loop ensures continuous improvement and risk mitigation. This closed-loop feedback system enables continuous improvement, enhances risk mitigation, and strengthens our quality assurance framework.

Each rejection provides actionable data that informs sensor testing thresholds, visual inspection criteria, and process control parameters. Once logged and analyzed, rejected catheters are disassembled and reduced to their base materials through controlled recycling processes. This ensures environmental responsibility while maintaining regulatory compliance and operational efficiency.

5.5 Quality System Oversight

Innovative Health's quality control framework is overseen by a dedicated team of engineers, quality assurance specialists, and regulatory professionals.

The system is subject to:

- Internal audits
- External audits (FDA, ISO and MDSAP)
- Continuous improvement initiatives
- CAPA (Corrective and Preventive Action) protocols

This oversight ensures that our reprocessing program remains aligned with evolving regulatory expectations and clinical needs.



Image 11: Reprocessing Techniques

6 Addressing Market Misconceptions

Despite FDA clearance, rigorous validation, and proven clinical performance, sensor-enabled reprocessed catheters continue to face skepticism in the market. Much of this skepticism is rooted in outdated assumptions, competitive positioning, or a lack of understanding of the engineering and regulatory rigor behind the reprocessing process. Below, we address the most common myths surrounding reprocessed sensor-enabled mapping catheters and provide clear, evidence-based responses.

6.1 Myth: "Reprocessing affects sensor calibration."

Reality: Calibration data is stored in an EEPROM chip embedded in the catheter. This information remains untouched during reprocessing. The location sensors themselves are chemically stable, physically shielded, and unaffected by cleaning agents, heat, or moisture. Our internal testing confirms that sensor response remains within OM defined tolerances across all three electromagnetic planes (X, Y, Z). If a device deviates from this range, it is rejected.

No recalibration is performed, and no compromise is accepted.

6.2 Myth: "OM recalibrates, so Reprocessor must too."

Reality: Recalibration is a choice, not a requirement. OM may recalibrate to expand their acceptance criteria and accommodate sensor drift. At Innovative Health, we take the opposite approach: we reject any device that does not meet the original calibration envelope. This preserves the integrity of the performance standard and ensures that every released device matches the OM baseline.

6.3 Myth: "Sensor variability makes mapping unreliable."

Reality: Our proprietary sensor testing system was reverse engineered to replicate the electromagnetic environment of magnetic mapping systems such as CARTO, Ensite X, etc. It evaluates sensor response across X, Y, and Z planes using statistical modeling and real-time signal analysis. Devices must fall within a tightly defined acceptance range based on new, unused OM catheters. Any deviation results in automatic rejection.

Furthermore, the CARTO system itself performs a baseline location validation prior to each procedure, ensuring consistent spatial accuracy regardless of device origin. If sensor variability were a legitimate threat to procedural integrity, it would affect OM catheters just as much as reprocessed ones.

6.4 Myth: "OM does not know how Reprocessor test the sensors."

Reality: Our sensor testing protocols were reviewed by the FDA as part of our 510(k) submissions. They include worst-case models, simulated-use testing, and real-world validation in clinical settings using OM CARTO systems. These protocols are proprietary, but they are grounded in engineering discipline and regulatory compliance. OM representatives may not be familiar with our internal testing systems and capabilities, but that does not diminish the rigor or reliability of our validated and independently verified reprocessing and testing capabilities.

In addition, our device usage history and complaint rates reflect consistent clinical success. Several leading teaching hospitals continue to use our reprocessed mapping catheters with strong procedural outcomes and no evidence of sensor-related compromise. The data speaks for itself: our reprocessing methods deliver safe, effective, and clinically equivalent devices.

7 Conclusion

Innovative Health's approach to reprocessing sensor-enabled catheters is grounded in engineering discipline, scientific rigor, and quality and regulatory compliance. Through uncompromising quality control, multi-axis sensor testing, and preservation of calibration data, we ensure that every device released for clinical use performs to the same standards as a new OM catheter.

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