



How to Manage Failure Points During Custom EM Sensor Assembly

Dan Hanson, Product Development Engineer
Forj Medical

Custom electronic components – especially miniature electromagnetic (EM) sensors – present unique challenges for medical device OEMs. High-risk failure points can emerge at any stage of development, from prototyping to mechanization to scaling, and the stakes are high. Left unaddressed, these failure points can compromise patient safety, inflate costs, delay time to market, and jeopardize commercial viability – underscoring the importance of Failure Mode and Effects Analysis (FMEA) for medical devices.

While the types of failure points don't necessarily change across development and production stages, how they're managed must evolve throughout each phase to ensure success. Early detection is ideal, but even when issues are discovered during later stages, sound management practices can salvage projects and keep devices on track for success.

Here's how to recognize and manage failure points at every stage of custom EM sensor assembly, from initial prototypes to high-volume production.

High Stakes: The Cost of Poor Failure Point Management

Nearly every project has potential failure points. The key isn't to simply anticipate them – it's to identify them as early as possible, then properly manage and mitigate them. Poor management comes at a high cost, jeopardizing not only the project itself, but also patient safety and OEM reputation.

The real-world costs of failure point mismanagement include:

- **Financial Losses:** Rework, lost yield, and scrapped product quickly add up, especially when you're dealing with high-value components
- **Market Delays:** Delays in validation, regulatory testing, and production open the door for competitors to gain a foothold in the market
- **Clinical Risk:** Failure points that go unaddressed can lead to device malfunction, medical procedure complications, and compromised patient safety
- **Brand and Reputation Damage:** Clinical end users could lose trust in the product or brand, impacting future revenue and credibility in the market

Note that late-stage failures are exponentially more expensive and damaging than early-stage failures, underscoring the need for proactive failure point identification and management.

Common EM Sensor Assembly Failure Points

EM sensor failure points can lead to electrical opens and shorts that compromise accuracy and functionality in real-world medical applications. Some of the most common culprits include:

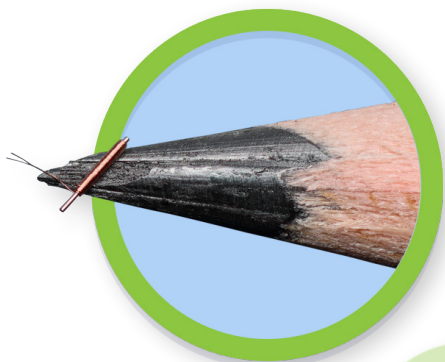
- **Fragile Wiring:** Fine-gauge wires used in high-performance EM sensors can be damaged during winding and routing
- **Connection Joints:** Critical junctions, especially where winding wires meet twisted pair leads, are high-risk areas for breakage
- **Sensor Placement:** Mispositioned EM sensors send false location data during procedures
- **Material Incompatibility:** Incompatible materials can cause failures during bonding and molding, and even compromise signal integrity, leading to functional failure. For example, the improper EMI shielding materials can allow EM signals to interfere with the main sensor signal, while the correct stainless steel reduces signal distortion and increases accuracy

- **Design-Induced Constraints:** Tight spaces, inflexibility, and poor attachment access can complicate EM sensor assembly and become failure points at various stages of development and production
- **Inconsistent Processes:** Process variability is a common culprit during prototyping and, later, the combination of manual and automated assembly at scale

Understanding Failure Points at Different Phases

In custom EM sensor assembly, failure points are often the same at each phase – from prototyping to mechanization to scaling – but how you manage them must evolve, as each phase introduces its own set of challenges and opportunities.

For example, fragile wiring and sensor placement are constant concerns, but the strategies to mitigate potential issues differ between manual assembly and full-scale automation. Once a failure point has been identified, it's crucial to plan to address it at each subsequent phase to assemble scalable, reliable EM sensor devices.



Prototyping

Early-stage development typically involves hand-assembling prototypes in a lab setting, but manual processes carry high variability and increased risk of quality issues, complicating the prototyping phase. Yet prototyping can provide the best opportunity to identify failure points when they're relatively easy and inexpensive to fix. The device is still evolving, and trial-and-error isn't just expected, it's critical to uncovering hidden failure points.

Of course, OEMs are seeking functional proof-of-concept during the prototyping phase, but that's not enough. It's one thing to know if a device can be made; it's another to know that it can be efficiently and profitably manufactured at scale.

However, Design for Manufacturability (DFM) is often an afterthought during prototyping, especially when OEMs are focused on proving functionality but not scalability. This can lead to fragile designs that are difficult, expensive, or even impossible to scale without significant redesign during later phases. Thus, a DFM approach should begin in the earliest stages to avoid significant setbacks and escalated costs later.

The best way to prevent these issues is to involve the EM sensor integration team early in the prototyping phase. EM sensor experts can help guide layout decisions, wiring strategies, and component selection to ensure the device is not only functional, but also scalable from the start.

Mechanization

After design freeze, the next step is to transition from hand-only assembly to mechanization using jigs, tools, and fixtures that improve consistency. The goal is to prevent manufacturing failures by minimizing variability in production inputs and processes.

However, this phase can also reveal disconnects between design and manufacturing – problems that weren't evident during prototyping but quickly become apparent when mechanization is introduced. In particular, poor planning around space constraints, tolerance stacks, and wiring routes can significantly increase the risk of field failure.

Let's say you're integrating an EM sensor into a flexing catheter. The device worked perfectly during the prototyping phase, when you relied on hand assembly to route the wiring.

However, your tooling might place wires where they could kink or break. In this example, you have the same failure point – fragile wiring – but it must be addressed in a different way.

It's easy to see how poor DFM decisions – or complete lack of DFM consideration – can begin to catch up with you during the mechanization stage. If the assembly cannot be reliably replicated through mechanization, the device will never be scalable beyond the prototyping stage. That's why it's so critical to consider how to assemble the device in a high-volume production setting from the very beginning.

Scaling

Once the EM sensor is successfully integrated and the design is finalized, the next step is scaling production – and by now, most failure points should have been uncovered or addressed. Still, it's possible for new challenges to present themselves as you ramp up production, so be prepared to manage any failure points that emerge.

Scaling can follow two distinct paths: manual or automation, and the decision typically comes down to volume forecasts and quality control. Automation is economical for high-volume production and often necessary when a device has micro components and simply cannot be built by hand; manual is the practical choice when projects aren't cost effective to automate. Each route comes with its own considerations for managing failure points at scale.

Manual Scaling

Manual scaling is often the best approach when automation is cost-prohibitive, assembly is relatively easy, and you have low-to-moderate production volumes. The most common failure point here is human error, as operator technique, fatigue, and mishandling can turn known failure points such as fragile wiring, joint connections, and sensor placement into recurring quality issues.

To mitigate these risks for manual scaling:

- Develop standardized assembly instructions
- Invest in operator training
- Mechanize manual assembly with jigs, tools, and fixtures

Automation

Automation offers significant advantages for high-volume production and when precision is required for quality control. However, automation also introduces its own challenges.

For example:

- Automated pick-and-place systems and winding tools could put too much stress on fragile wires or connection joints
- Over time, tools can drift, causing inaccurate sensor placement, component misalignment, or imprecise routing
- Exposure to heat, pressure, or chemicals could degrade materials during curing and/or bonding processes
- Lack of human oversight can cause defective devices to go undetected, resulting in expensive scrap
- Assembly processes that work in a U.S. lab might fail in high-volume offshore facilities

With automation, even if your design is complete, you need to anticipate potential failure points and be prepared to rapidly respond.

Mitigate potential failure points in automation with:

- A DFM approach, instituted during the prototyping phase. Remember: just because a prototype works doesn't mean it's ready to scale. Build with scalability in mind from the start
- Robust process development and validation to test processes under real-world conditions before scaling to full production

- Monitoring and feedback, including real-time quality checks to detect issues early
- Routine maintenance and calibration to ensure equipment maintains the tight tolerances and precision required for reliable EM sensor assembly

Best Practices to Prevent or Minimize Failure Points

The following practices can help OEMs prevent failures points and minimize their impact.

- 1. Source Quality Components**
Implement strong quality control processes to ensure sourced components don't become unexpected failure points. Take time to vet vendors who can consistently deliver reliable, high-performance parts that support your success rather than introduce new risks. Keep in mind that an experienced manufacturing partner can assist with sourcing and vetting to help you avoid costly surprises.
- 2. Design for Manufacturability – Not Just Prototype Performance**
Manufacturability is often overlooked during prototyping, putting the entire project at risk. Though a single prototype might work great, if it can't be economically assembled at scale, it's destined to fail in the market. Prioritizing manufacturability at the outset helps prevent future failure points and fosters long-term commercial success.

3. Collaborate Early Across Disciplines

Collaborating with cross-disciplinary experts early in the process can prevent a bevy of failures down the road. Understand what you know, acknowledge what you don't, and consult a team of specialists across molding, electronics, assembly, and process development to take a holistic approach that gives your device the best chance at market success. The easiest way to access cross-disciplinary expertise is to choose a vertically integrated manufacturing partner that can manage everything under one roof.

4. Adopt a "Fail Fast" Mindset

Be willing to fail early and often. It's the quickest way to uncover weaknesses, iterate, and improve. Failing fast is especially critical in the early stages of development, when design flexibility is greatest. The sooner you identify and address potential failure points, the smoother subsequent phases will go.

5. Work with an Experienced Partner

Involve an experienced EM sensor manufacturing partner early in the development process. Look for one with a proven track record in sensor integration across all stages – from initial design through high-volume production – and a history of solving complex custom assembly challenges. The ideal partner can combine manual and automated assembly, including custom automation tailored to miniature and smart medical devices.

The right partner will collaborate with you early in the design phase, not just production, to ensure your device is designed for manufacturability. Choose a vendor that offers proactive communication, cross-functional support, and the flexibility to adapt to your project's evolving needs.

- Be transparent and proactive: Don't sit on bad news. Instead, immediately inform stakeholders
- Collaborate: Collaborate quickly to identify the root cause and determine corrective actions
- Adjust: Adjust specs, tolerances, or processes to recover without derailing your timeline

Remember: failure is expected. How you respond to it either erodes or builds trust.

For OEMs without deep in-house expertise in EM sensor assembly, the best path forward is partnering with a medical-focused manufacturer that has a longstanding legacy of micromedical innovation, integrated engineering, and robust quality control. With the right partner and proper planning, you can confidently scale from a fragile lab prototype to high-volume production and a commercially viable EM sensor device.

Managing the Inevitable: What to Do When Failures Happen

Complex medical devices do not forgive poor planning or siloed design processes. When it comes to custom EM sensor assembly, success isn't about eliminating failure points; it's about recognizing them and managing them.

