

THE OVERLOOKED RISK

Why Insulation Testing
in Surgical Instruments
Demands Greater Attention

How a near miss inspired a study on **insulation testing** and patient safety

Insulation testing of surgical instrumentation is not a new concept within the sterile processing field. Yet despite mounting evidence, updated standards, and published studies dating back to 2019 (highlighting its clinical significance), industry-wide awareness remains limited. Patients become more vulnerable to complications (both serious and preventable) when this gap in education and communication is unmet.

For Cheron Rojo, then a Clinical Education Specialist at Healthmark, this issue became personal in September 2020, when his eight-year-old daughter underwent a routine laparoscopic procedure. What should have been a straightforward recovery took an unexpected turn when, just a week later, she experienced serious complications.

As he searched for answers, he discovered that the facility had not been performing insulation testing. That moment, which thankfully had a happy ending, led to the launch of a study that would reveal just how widespread the gap in awareness and implementation is.

Recognizing the Gaps & Empowering Change

Stories like Rojo's daughter are, unfortunately, not isolated; however, they are preventable, and sterile processing department (SPD) professionals are uniquely positioned to lead that change.

The American National Standards Institute (ANSI) and the Association for the Advancement of Medical Instrumentation (AAMI) released an amendment in January 2021 to *ANSI/AAMI ST79:2017*¹, one of the industry's most foundational documents.

This amendment introduced practical, actionable guidance for insulation testing, including:

- **How often testing should be performed**
- **Key areas of focus during inspections**
- **Types of testers and accessories that should be used**
- **The need for ongoing staff education & competency**

While these guidelines are a step forward, many facilities haven't encountered them or haven't had the resources to fully adopt them. By bringing awareness to these standards and providing tools for implementation, we can support SPD professionals in continuing to do what they do best: protect patients.



Figure 1: Integrity failure in an insulated laparoscopic shaft.

Out of **416** instruments tested, **223** demonstrated insulation integrity failures.

2021–2022 Insulation Study Summary

For the full study, see: HSPA PROCESS. Rojo, C. (March/April, 2023). Findings from internal auditing study of insulation integrity practices to improve inspection, testing, and patient outcomes. Chicago, IL: Healthcare Sterile Processing Association.

The 12-month study, published in the March/April 2023 issue of HSPA PROCESS, was conducted from May of 2021–May of 2022 that consisted of 48 facilities showing that out of 416 instruments (i.e., insulated laparoscopic and bipolar forceps as well as monopolar cables) tested, 223 demonstrated insulation integrity failures.² (See Fig. 1). The instruments consisted of insulated laparoscopic and bipolar forceps, as well as monopolar cables. The highest integrity failures were the bipolar forceps with a 75%–100% failure rate out of 27 facilities (See Fig. 2).



Figure 2: Insulated bipolar forceps failures.

Adverse Events

A concurrent review was conducted using the U.S. Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE)³ database to identify patient adverse events associated with insulation integrity failures.

April 2021: An insulated laparoscopic instrument arced, resulting in a burn injury to a patient's liver.

July 2021: An insulated handle arced and caused blistering to the patient's skin.

March 2022: A monopolar cable exploded during a procedure and was subsequently found to have insulation integrity failures.

These incidents underscore the significant risks posed by inadequate insulation testing of surgical instruments.

Conclusion

Insulation testing plays an important role in keeping patients safe and ensuring quality care. While awareness of the standards is growing, it's critical that healthcare facilities focus on ongoing training, proper equipment, and a strong culture of careful inspection.

Sterile processing professionals are at the heart of this effort. Every day, they serve as the first line of defense in identifying potential risks and preventing harm.

Cheron Rojo's personal experience may have sparked the conversation, but it's the dedication of SPD teams that will carry it forward to ensure every patient, like his daughter, has the best chance at a safe and successful outcome.

Contributing Factors

Numerous contributing factors led to the identification of insulation integrity failures.

1. Inadequate and low-sensitivity insulation testers to catch smaller integrity failures (e.g., using a low-voltage battery) (Fig. 3) and the absence of appropriate accessories (e.g., testing cables) to test insulated instrumentation.
2. Incorrect technique and rushing through the insulation testing.
3. Insufficient repair service to identify or repair the integrity failure in the insulation.
4. Lack of education for front-line technicians to identify issues for inspection, testing techniques, and use of an insulation tester unit.
5. Pre- and post-operative care and handling, assembly, and storage.

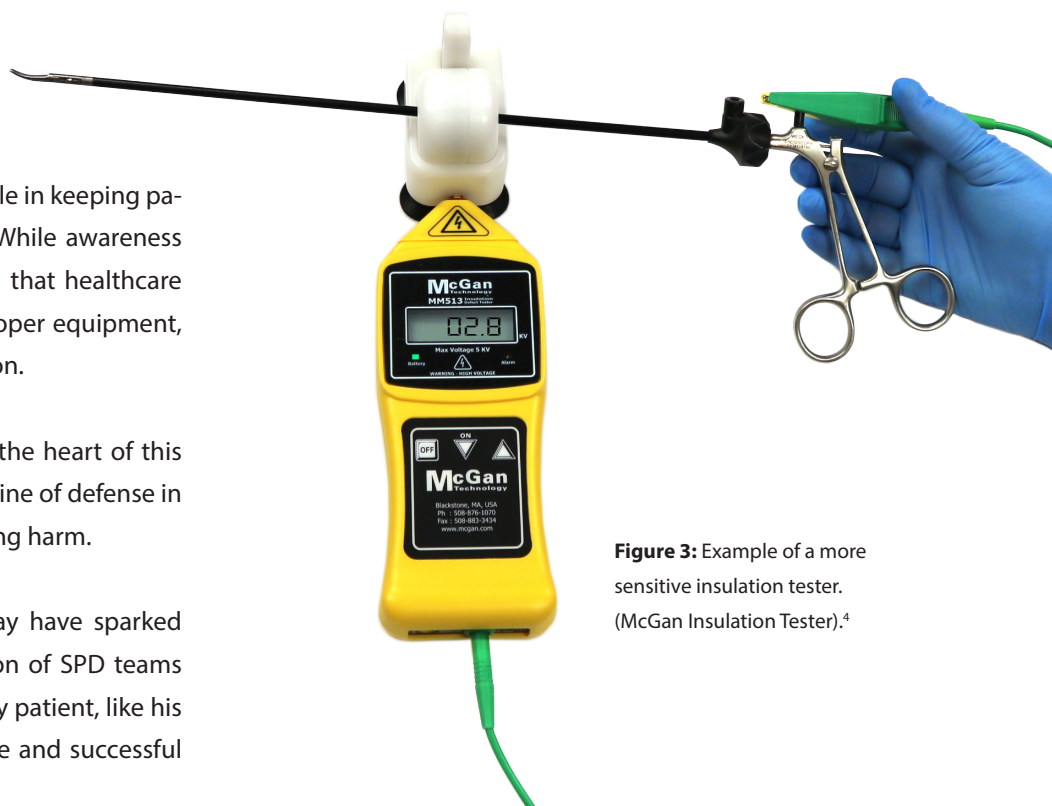


Figure 3: Example of a more sensitive insulation tester. (McGan Insulation Tester).⁴



Ready to Take Action?

Support your SPD team with the tools they need to confidently detect insulation failures before they reach the OR.

The McGan Insulation Tester, available from Healthmark, helps identify damage invisible to the naked eye — so your team can catch potential issues early and ensure the highest level of patient safety.

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Meet the Educator



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Cheron Rojo is the Senior Manager of Clinical Education at Healthmark, a Getinge company. He has authored multiple studies on topics including insulation testing, arthroscopic shaver cleaning, and rigid endoscope care.

Outside of his work educating Sterile Processing Departments, Cheron enjoys home décor projects and is a self-described foodie who loves discovering new culinary experiences. He lives in Las Vegas, Nevada, with his husband, Jose, and their daughter, Antoinette- now 13 years old, happy, and healthy.

References

1. AAMI. (2020). ANSI/AAMI ST79: Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities, Amendment A.2. Arlington, VA: Association for the Advancement of Medical Instrumentation.
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3. MAUDE - Manufacturer and User Facility Device Experience. (2024). U.S. Food and Drug Administration (FDA). <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm>
4. Healthmark. (Dec 2024). McGan Insulation Tester. Healthmark, A Getinge company. <https://www.hmark.com/product/insulation-tester/>