

## RFID in Healthcare: Technology Meets Stringent Safety Regulations for use in Medical Devices





**RFID technology is used in a majority of industries today and not new in the medical and healthcare circles. What is new about RFID is the innovative uses, expanded features and capabilities, lowered costs and rich data streams.**

If one simply considers RFID's capability as a data carrier comparable to a bar code, the technology's dynamic features have been overlooked; features that are truly transformative to a process and potentially to entire business models. Indeed, RFID is an enabling technology, possessing qualities proven to bring about disruptive innovation to a current practice. Disruptive innovation creates new market and value chains.

The thing is, medical applications using RFID have a few – ok, a lot – more performance and regulatory hoops to jump through to reach compliance in the complex environments in which they operate, particularly with medical devices.

Just how more complex? Amended product safety requirements for medical electrical equipment updated in 2015 fall under ISO 60601 and include new and updated standards for:

- Risk management
- Essential performance
- Humidity
- Documentation
- Marking and Labeling
- Electrical hazards
- Temperature testing
- Programmable Electrical Medical Systems
- Construction

RFID is the leading technology being used today by medical device manufacturers to enable smart devices to deliver better quality of patient care.

ISO 60601 is the widely accepted benchmark for medical electrical equipment and compliance for the commercialization of electrical medical equipment globally, and many companies view compliance with IEC 60601 as a requirement for most markets.

Even with these updated standards, RFID is the leading technology being used today by medical device manufacturers to enable smart devices to deliver better quality of patient care. Common applications of RFID include:

- Delivery and tracking the right device for right patient
- Verification of proper sterilization
- Compliance issues for equipment maintenance and calibration
- Billing to link medical device use to patient
- Inventory management
- Reduction in staff time in tracking items and devices.

Operationally, RFID supplies low electromagnetic interference (EMI) properties, low cost, small size, low power and battery-less technology capabilities.

Add to that greater flexibility and extended usage of RFID tags. Advances in tag technology offer expanded memory capacity, enabling additional data to be stored on each tag, which helps to prevent counterfeiting and ensure product reliability. Data such as lot number, manufacturing date, expiration date, etc. can be written during the manufacturing process, while new information such as shipping date, date of sterilization or treatment history can be added throughout the product supply chain and lifecycle.

**Advances in tag technology offer expanded memory capacity, enabling additional data to be stored on each tag, which helps to prevent counterfeiting and ensure product reliability.**

Moreover, a distinctive anti-collision scheme allows RFID tags to be individually identified, enabling accurate reading and identification of tags even in large batches or inside packed boxes.

Of course, reliable identification is crucial when dealing with logistics and tracking systems for medical devices and instruments. This is particularly important for tracking biological samples in transit, or verification that a reusable piece of equipment has been sterilized. With the ability to withstand harsh sterilization conditions, RFID tags are ideal for verifying that instruments or devices have been properly sterilized, safeguarding against accidental cross-contamination with secure data that cannot be revised by unauthorized personnel.

In addition to ensuring proper device sterilization, RFID tags can be attached to disposable parts to ensure that authorized parts are properly attached to the right equipment, minimizing potential risk of misuse. Likewise, RFID technology can be used to ensure authorized access to controlled areas and cabinets for improved quality control.

But these are just a few examples of RFID being used for tracking and monitoring in healthcare, as the industry continues to adopt this versatile technology. Yet, as medical device manufacturers start designing RFID into their equipment, it's important to understand how to address testing and safety with RFID, and complying with the newer ISO standards and apply them to critical healthcare threats.

## Automated Tracking of Sterilized Products

Sterilization issues seemingly continue to plague hospitals and medical facilities. Problems with equipment and human error in protocols and training can make front-page news. In fact, there are companies whose sole mission is to fight infection in healthcare settings.

Advanced Sterilization Products (ASP), a Johnson & Johnson company, is a global developer of innovative infection prevention solutions and educational programs. To help battle infection and maintain sterile environments, ASP developed the Sterrad 100NX, a hydrogen peroxide, low-temperature sterilization chamber for hospitals and medical facilities. In order to provide complete confidence that medical objects are fully sterilized in the chamber, ASP began using RFID technology to ensure automated compliance on cleaning and reprocessing protocols.

ASP outfitted the Sterrad 100NX with a high-frequency (13.56MHz) RFID reader module, and each hydrogen peroxide cassette is embedded with a HF RFID tag. RFID tagging of the cassettes enables detection and alerts for errors, as well as ensuring that the cassettes comply with ANSI/AAMI/ISO standard 14937:2009.



The system provides multiple benefits:

- Secure identification of connected components
- Secure identification of commodities, e.g. cleaning processes
- Identification of samples in a centrifuge
- Staff authentication for secure access to machines and devices.

As a result, the STERRAD 100NX offers the most comprehensive system monitoring for sterility assurance, improving quality control and providing healthcare workers with confidence that the sterilization process has been properly completed.

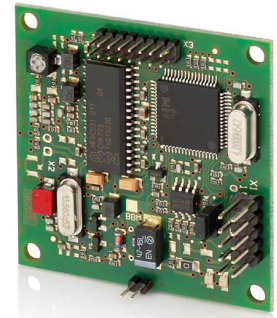
# Barriers to RFID in Medical Devices Continue Falling

Although companies like ASP have adopted RFID technology, even with the advanced ISO requirements, there are still obstacles.

For example, some in the industry are concerned that electromagnetic emissions from RFID could interfere with medical devices. The good news is the US Food & Drug Administration has stated it has not observed any adverse effects from the use of RFID.

Additionally, an Indiana University - Purdue University Indianapolis (IUPUI) research team recently concluded that a properly configured RFID system is safe to use around medical equipment.

While the risks are considered to minimal, medical device manufacturers and system integrators should conduct their own EMI assessments in a safe environment to ensure compliance.



Customized FEIG HF Proximity Reader Moz Module

**Medical facilities and the industry will demand greater capabilities and operating safeguards from equipment and device manufacturers. The greater the capabilities now and to come, medical staff can concentrate on the job that matters most -- delivery of quality patient care.**

## Raising RFID Standards

As demonstrated by the ASP STERRAD 100NX example, RFID delivers significant benefits for improved quality assurance through secure identification of cleaning processes and staff authentications. With the use of RFID technology, smart medical devices can be even smarter.

That's just one example of how progressive RFID manufacturers supply FCC-certified RFID read/ write modules, antennas, and enclosed readers supporting temperature and moisture-sensing applications.

The operating end of RFID systems is the reader. The new benchmark is ISO 60601 certified readers. Coupled with hands-free data capture and no required line of sight, readers can continuously and automatically search for RFID tags entering their field for enhanced tracking. Some are even enabled with an HID key code interface for access control.

Medical facilities and the industry will demand greater capabilities and operating safeguards from equipment and device manufacturers. The greater the capabilities now and to come, medical staff can concentrate on the job that matters most -- delivery of quality patient care.

### About FEIG ELECTRONICS, Inc.

FEIG ELECTRONICS provides a wide range of state-of-the-art RFID technology solutions ideally suited to healthcare applications. FEIG is a trusted provider of reliable, easy-to-use RFID readers based on more than 30 years of RFID design experience, offering 99.99% reliability, free technical support, and the best software development tools. A common application-programming interface is compatible with all FEIG ELECTRONICS readers for ease of integration.

**FEIG**  
ELECTRONICS  
[www.feig-electronics.com](http://www.feig-electronics.com)

FEIG ELECTRONICS Inc.

2220 Northmont Parkway, Suite 250  
Duluth, GA 30096  
USA

Phone: +1 770 491 8060

Fax: +1 687 417 6273

E-mail: [info@feig-electronics.com](mailto:info@feig-electronics.com)