Benefits of RFID for Medical Device OEMs

A PRACTICAL GUIDE

Introduction

In a hospital or practice, easy, accurate tracking of medical devices is absolutely critical. After all, in a medical environment, a single asset miscount, mislaid item or misidentification can result in a significant amount of wasted time, lost revenue … or much worse.

That's why today's innovative manufacturers are embedding RFID technology directly within their devices, increasing value to end users by allowing them to easily and cost-effectively gather accurate, real-time data on their medical devices and instruments.

This guide will examine why OEMs are increasingly turning to integrated RFID to add value to their products in an increasingly crowded marketplace, and provide key applications for RFID in the medical device field.

Why Integrate RFID into Medical Device Design?

Integrated RFID technology directly into medical device product design allows OEMs to enhance value at every stage of the supply and use chain. This creates distinct, real-world benefits – and tangible ROI.

- **Improved Product Traceability:** By embedding a durable, passive RFID tag directly into their products, OEMs can automate work-in-process tracking. With a unique RFID identifier built into the device at the start of the manufacturing process, an OEM can then automatically collect data about the drawing or revision level to which it was built, as well as lot numbers and configuration data for constituent parts.

- **Better Supply Chain Management:** Products containing integrated RFID technology can be easily and accurately tracked throughout the supply chain at the serial number level. This means the identity of the distributor and end customer for any individual product can be accessed immediately.

- **UID Compliance Backup:** Onboard RFID eliminates problems posed by missing or illegible UID tags. This simplifies both life cycle management (items can easily be identified for preventative maintenance or upgrades) and potential recalls. These factors are critical for patient safety and compliance with new FDA rules.

- **Real-Time Location:** In the hospital or practice setting, a properly deployed combination of onboard RFID and readers significantly reduces the risk of devices being lost or misplaced. This decreases unnecessary device replacement, cuts discretionary budget waste and all but eliminates staff hoarding.

- **Life Cycle Management:** A best practices asset tracking solution based on embedded RFID technology creates an additional layer of patient safety by ensuring that sunset devices or instruments are never accidentally put into use, and improving infection control and sterilization compliance.

- **Customer Inventory Management:** Similarly, better inventory control on consumables ultimately provides device manufacturers and their customers with improved usage data, helping them manage their inventory.

- **IP & Brand Protection:** With a properly implemented system, embedded RFID can protect OEMs against counterfeit and grey market devices, and help ensure that only properly certified consumables are employed in their devices.

And because the RFID tag is part of the device, rather than an aftermarket addition, it is guaranteed to work well in the particular use case for the entire lifespan of the product.

Embedded RFID: Enhancing Value & Improving Patient Safety

Embedding passive RFID tags directly into devices enhances security, traceability and trackability in a way that is both invisible to the end user and indelible over time.

For example, products that require tracking at the serial number level for chain of custody management or lifecycle management can be enhanced through the addition of embedded RFID. Rugged RFID tags can be molded into a plastic, rubber or composite element of the device – leaving them invisible to the user, but still "visible" to an RFID reader meters away.

Enhance durability

Unlike labels, embedded tags are inherently protected from impacts, chemical degradation, abrasion and other hazards of the environment and handling. They are not obscured by dirt or grime. They will not fall off because the adhesive becomes old and brittle. They will last for the life of the device, even if this is many decades. In addition, because they are passive devices, embedded RFID tags require zero maintenance. With embedded RFID, there is never a concern about being able to read the serial number of the device; the information is always there.

Enhance security

Because the tag is incorporated into the structure of the device, it is extremely difficult to remove, deface or counterfeit. It is virtually impossible to destroy the tag without destroying some element of the device. A properly encoded tag cannot be altered, and it is virtually impossible to counterfeit an RFID tag, since all have unique numbers that are programmed during the silicon fabrication process. This aids in the protection of valuable IP that is part of the device.

Enhance information access

An RFID tag containing a unique device identifier can also be used to store additional critical information about the device. Configuration, design or date code information can be programmed into the RFID tag. This can provide customer and service personnel with useful information without the need to connect to a network, shortening diagnostic and service cycles.

Enhance functionality

Device manufacturers are using RFID to improve or simplify the functionality of their products by substituting radio frequency connections for wired connections. An RFID connection makes parent-child device pairing more reliable. RFID systems are entirely solid state and quality problems associated with bent or broken connectors, oxidized connection points, and improperly oriented connectors are eliminated. RFID also delivers more reliable and less costly automated configuration. If devices use multiple subsystems in different combinations, one RFID reader can identify all of the elements and enable rapid and accurate self -configuration. RFID can be used to enhance safety features and operational interlocks, as well. By using a tag and reader in place of a limit or proximity switch, interlocks can be made 'smarter' and more difficult to defeat because the reader needs to see exactly the right tag before the system will operate.

Validate consumable compatibility

By adding an RFID reader to their devices, OEMs are ensuring that the consumables used in their devices, like reagents, are compatible with the devices and the specific tests or procedures being performed. By having the consumables tagged with RFID, the device can automatically identify and validate that the product being used is the proper one for the device and the procedure. This also protects the OEM's brand by ensuring the best possible results are obtained using the device.

Enhance trackability

Embedded RFID makes real-time asset tracking and location a reality. For example, if a bedside diagnostic device were to become caught in bedsheets, an RFID reader portal at the laundry station could catch it before it went through a wash cycle. Likewise, accidental movement of devices between sections of the hospital (or out the door) could be essentially eliminated.

Other potential benefits

You could enhance the efficiency of your distribution chain by embedding RFID in your device, since your customers can take advantage of the embedded RFID tag to track the quantity and configuration of devices in their inventory. The same is true for end users, who would be able to quickly count inventory of parts. In the event of a product recall or major upgrade event, RFID enables the rapid and highly accurate identification of the unique devices requiring service. When hard wire interconnects are not realistic, RFID can be used to facilitate machine-to-machine communication and local data storage.

There are many potential benefits that should have many OEMs considering embedding passive RFID tags into their products. These benefits accrue to both the OEM and his customers, and endure for the life of the device.

RFID for Medical Devices: FAQs

How can RFID be integrated with medical device design?

Leading RFID technology providers offer products specifically designed to be embedded directly within devices, rather than affixed after manufacturing. Vizinex's ViziCore™ technology, for instance, utilizes a unique, patented tag design, which facilitates the rapid development of low-cost solutions that exactly meet the requirements of the OEM, its distribution system and its customers.

Can any RFID tag be integrated directly into a product?

No. Many off-the-shelf tags cannot stand up to the high temperatures, high pressure or aggressive chemistries associated with manufacturing processes like injection or compression molding, enamel curing, or lamination. In addition, an RFID device that meets the packaging requirements for incorporation into an OEM's device and also meets the RF performance requirements of their manufacturing operation, their distribution chain and end users is unlikely to be an off-the-shelf tag.

> **What is the difference between HF and UHF?**

HF (High Frequency) tags have short read ranges (less than one foot). These tags can be used to tag tissue samples, blood and other critical fluids. They work well in proximity to liquids and human tissue. Some HF devices are available with security features like encryption, and/or significant amounts of memory for storage of additional information about the tagged object.

UHF RFID products have longer read ranges, but unless they are properly engineered, can be detuned by proximity to tissue, fluids and metals. These RFID products are used to track and locate critical medical devices, manage inventories of medical items, and, sometimes for tracking and identifying patients.

The vast majority of both HF and UHF RFID tags are compliant with worldwide standards and are easily deployed, because of their compatibility with widely available and competitively priced RFID readers.

What is the difference between passive and active tags?

Simply put, passive tags require no internal power source; this makes them ideally suited for embedded applications when maintenance would be difficult or impossible. Active RFID tags require onboard batteries for continuous power. They are not recommended for integrated or embedded use cases.

About Vizinex RFID

Vizinex RFID, headquartered in Allentown, PA, designs and manufactures RFID tags for diverse asset tracking applications-from rugged environments in the oil industry, to medical devices requiring repeated sterilization, to long-range vehicle tracking. With prototyping and manufacturing located in the U.S., our time from concept to delivery is unmatched. Vizinex RFID maintains a tradition of innovation, superior functionality and outstanding customer support - allowing us to deliver RFID, the way you imagined.

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