

Embedded RFID for Medical Devices

Embedded RFID has become a game-changing technology



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JADAK White Paper

Executive Summary

Embedded RFID has become a game-changing technology that medical manufacturers and healthcare providers are using to satisfy some of their most pressing needs. This paper identifies key challenges facing manufacturers of medical devices and supplies and explains how embedded RFID technology is being leveraged to overcome those challenges in a way that enhances safety and reliability, increases revenue and brand equity, and reduces operating costs.

When integrated into medical device manufacturers' existing and new product lines, embedded RFID now enables medical and healthcare solutions to:

- **Protect against counterfeit consumables**: Ensure that genuine test solutions are used in laboratory procedures. Guarantee medical devices are used and tests administered as intended.
- **Easily manage controlled substances**: Match the correct medication, blood and other treatments to the patient. Optimize the patient experience and reduce costs of customized care.
- **Maintain inventory visibility**: Manage supply and medical inventories in real-time for direct purchase and consignment.
- **Automate surgical instrument tracking**: Tracking the usage of surgical instrumentation and adherence to sterilization guidelines for improved workflows and patient safety.

For each of the above challenges that medical device manufacturers and suppliers face, this paper identifies and further investigates the current problem, explains how embedded RFID can offer a solution, and presents case studies of a current JADAK customer who has benefited from embedded RFID.

By incorporating RFID as a feature into new and existing products, companies can gain the product differentiation and competitive advantage that RFID-enabled features and functions impart.

Protect Against Counterfeit Consumables

The Problem

Getting the right component – part, reagent, or sample – matched to the right system is critical not only to ensure manufacturing and testing integrity, but also to prevent companies from using the wrong items. RFID built into machinery, water analyzers, medical devices, and other systems can seamlessly identify correct and incorrect products.

Counterfeiting is a global issue that costs businesses billions of dollars in revenue each year. According to the Organization for Economic Cooperation and Development, trade in counterfeit goods [reached an estimated \\$250 billion in 2007](#), and the problem has only grown worse since then. Clearly, counterfeiting afflicts numerous items across many industries, and it is now a top concern for medical device manufacturers supplying chemical reagents and device consumables to hospitals and laboratories across the globe.

What the top medical Device Companies are saying about the counterfeiting epidemic:

- **Johnson & Johnson:** “[Counterfeiting of health care products is a serious issue](#), as it puts people’s health and lives at risk and undermines confidence in product safety and effectiveness.”
- **Cygnus Technologies:** “[Analytical reagents falsely represented as manufactured by Cygnus Technologies](#) may significantly compromise the intended quality control of a given analytical method.”
- **Sysmex:** “[Eliminating Counterfeit Reagents to Assure Reliability of Patients’ Test Results](#) - In order to assure accurate testing results, we ask our customers at medical institutions to use Sysmex-branded instruments and reagents together. In recent years, however, reagents disguised as Sysmex reagents have been found in circulation among such countries as China, the Philippines, and Indonesia. The use of such counterfeit reagents cannot guarantee the reliability of testing results and, in some cases, can be harmful to patients’ health. While calling users’ attention to these illegal reagents by publishing announcement ads in local newspapers and by other means, we seek cooperation from local governments and, when necessary, we bring cases to court.”

How Embedded RFID Can Help

As counterfeit proprietary substances become more prevalent, the need to authenticate original products becomes increasingly necessary. By embedding RFID directly into medical devices and healthcare delivery systems, manufacturers can foil counterfeiters and secure recurring revenue streams:

- **Reclaim lost revenue** – Permit only sanctioned disposables and stop counterfeits.
- **Protect brand integrity** – Thwart counterfeiting to neutralize negative brand association and market degradation.
- **Improve product safety** – Ensure that medical devices are assembled, configured and used in the manner intended by the manufacturer -- safely and securely.
- **Limit legal liability** – Eliminate counterfeiting and lesser quality substitutes in order to minimize liability. Prevent the use of assets with expired warranties or overdue service dates. Decrease chance of error involved with human interaction.
- **Enforce expiration dates** – Permit consumption of reagents within pre-defined expiration dates.

Embedded RFID can be added wherever a device requires a disposable. The following SkyeTek (*now part of JADAK*) customer example shows how IRIS Diagnostics uses RFID to authenticate a proprietary product to protect revenue streams and ensure patient safety.

Counterfeit Disposables Example: Iris Diagnostics

Iris Urinalysis, a division of Beckman Coulter, manufactures and sells urinalysis systems for use in hospitals and commercial laboratories worldwide. Based on patented and proprietary technology, their automated urinalysis system utilizes chemical reagents to detect the presence of molecules in urine samples. These systems are designed to provide faster and more complete results, plus labor savings over manual methods of performing microscopy, one of the most labor-intensive procedures in a clinical laboratory. The reagents used must be of the correct type, freshness, and authenticity in order to deliver the most accurate results.



Iris Urinalysis incorporated JADAK's RFID readers and SkyWare Security software to prevent reagent counterfeiting and secure a recurring revenue stream by guaranteeing only its reagents are used in the system. By embedding a JADAK RFID reader module directly in the machine itself and tagging its branded reagents with an encrypted unique ID, the manufacturer can assure that the machine will only operate if the consumable is valid and within expiration.

Patient and Medication Management

The Problem

Hospital administrators are constantly searching for ways to improve patient safety and provide a quality medical experience, while simultaneously managing costs.

How Embedded RFID Can Help

Embedded RFID provides the technology to recognize a patient and his or her relevant medical information to ensure the products and services to be delivered are both correct and acceptable to the patient.

- **Increase satisfaction** – Offer a highly personalized experience.
- **Align services with patient requirements** – Track patient activities and preferences in real-time.
- **Reduce patient complaints** – Automatically re-direct patient to shorter wait times.
- **Enhance provider integrity** – Provide consistency of service.
- **Minimize patient service costs** – Enable greater patient self-service.

Patient Management Example: Avancen's "Medication on Demand" (MOD) System

Avancen, a medical device company dedicated to improved patient care at the bedside, manufactures and sells the "Medication on Demand" (MOD®). The MOD® is a patient-controlled oral drug delivery system that provides hospitals, healthcare professionals and patients a better way to manage pain. The device is locked onto an IV pole, delivered to the patient's bedside and placed within easy reach of the patient. The patient wears an RFID wristband programmed into the device for the exclusive use by that patient only. When a pre-defined lockout interval has passed, the patient sees the bright green ready light on the MOD®. To request a dose of medication the patient follows these three steps:

The SkyeTek (*now part of JADAK*) M1-Mini RFID module is embedded behind the pain scale on the



1. Patient Records Pain Level



2. Patient Swipes Wristband



3. Patient Removes Pill

device and when the patient swipes his or her RFID wristband (or when a nurse swipes a registered nurse card), the M1-Mini collects the data and stores it to provide exclusive recognition of only that patient (wristband) and the registered nurse card.

The addition of JADAK RFID to the MOD increases medication security by ensuring that only the patient will be able to access the controlled pain medication prescribed for the patient, as well as offering a valuable data collection system that would otherwise have to be gathered manually.

Maintain Inventory Visibility

The Problem

Expired reagents, empty shelves, misplaced product, and missing inventory are significant challenges in any medical environment. The inability to track and manage individual items can mean inadequate care and lower patient satisfaction. Facilities and vendors need insight to the location and current state of inventory at the item-level.

How Embedded RFID Can Help

Embedded RFID allows customers to manage supply and medical inventories in real-time for direct purchase and consignment.

- **Real-time billing** – Bill immediately for products used.
- **Reduce excessive inventory and overstocks** – Minimize stock with just-in-time inventory and automated restocking. Reduce carrying costs. Eliminate stock-outs.
- **Assure product quality** – Remove expired products from circulation. Ease new product introduction by locating and replacing obsolete items.
- **Protect brand integrity** – Immediately enact product recalls to limit damage to customer and brand.
- **Instill accountability** – Know who, what, when and where about assets and inventory.

- **Right-time / Right-product** – Locate medical equipment quickly in highly populated or trafficked regions or where time-sensitivity is of the utmost concern such as Operating Rooms and ERs.

Inventory management is best exemplified through consigned inventory in a smart-cabinet. Take, for instance, an orthopedic implant manufacturer who has arranged to sell their implants on consignment at a hospital. Because they only get paid when the product is used and reported, they experience a significant lag between usage and revenue and high carrying costs. Compound this with lost revenue due to misplaced product and high stocking costs associated with manual inventory checking, and it is no surprise that most large distributors and manufacturers are looking for a way to obtain automated, real-time inventory & order placement.

Such a company would obtain a customized, secure cabinet embedded with an RFID reader responsible for storing and cataloging the implants. In addition to tracking what implants were used, the reader would also verify and record the identity of any individual accessing the unit. With an internet backhaul to the manufacturer's order and fulfillment system, the hospital is assured they will have the right product at the right time, while the manufacturer can bill immediately upon product retrieval. This scenario also works for Hospitals who own their own inventory such as surgical supplies and other consumables.

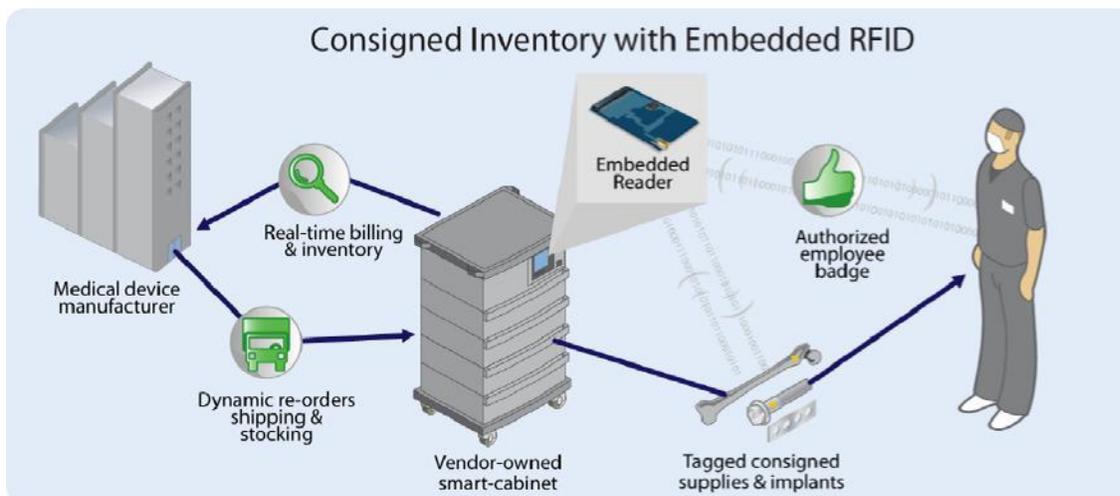


Figure 0-1: Consigned Inventory with Embedded RFID

Inventory Management Example: Medical Supplier Consigned Inventory

In cases such as surgical implants where doctors use highly specialized products, hospitals often chose to carry their supplies on consignment – that is, the manufacturing company is responsible for housing the products on hospital premises until they are used by the staff. This is also known as Vendor Managed Inventory.

Smaller hospitals will source their medical devices for a specific function from a single vendor or through a distributor. However, when they grow to a point where they have negotiating leverage with the vendors, they will typically try to shift the purchasing arrangement from a 'stocking' system to a 'consigned inventory' system. Although the hospital will typically have to pay higher list prices, they still benefit as they are no longer susceptible to inventory expiration or obsolescence. In short, vendors have to provide consigned inventory arrangements in order to stay competitive. Although consignment arrangements are made across all medical product categories, implantables (orthopedic, cardiology, and vascular implantables, specifically) tend to be under consignment more often.

Current Consignment Management Practices:

The tracking and management of consigned inventory is largely archaic. While some manufacturers and distributors have taken steps to provide automated controls over the inventory, in many situations a sales rep maintains stock with the use of a spreadsheet. In most instances the sales rep is limited to the frequency that they can stock/check the consigned inventory to once a month or longer.

Vendor Concerns with Consignment:

- Excessive Inventory/Overstock
- New Product Introductions
- Timeliness of Consumption Data
- Obsolete Products
- Carrying Cost

Hospital Concerns with Consignment:

- Out-of-stocks
- Accountability/Access Control
- Lost/Stolen Inventory
- Just-in-time Inventory

The Embedded RFID Solution

With embedded RFID, manufacturers and hospitals alike are able to streamline the management of consigned and stocked inventory. Much of the press has focused on Hospitals retrofitting their stocked inventory and back-office with RFID-enabled shelves capable of tracking cases and pallets while overlooking the value RFID brings to the manufacturers themselves. By embedding RFID into custom-built cabinets stocked with supplies and placed within hospitals, manufacturers now have a consignment inventory management option that offers:

Just-in-time inventory – Immediately reorder parts as they are removed from the cabinet. Keep inventory on hand at minimal levels while delivering highest availability.

- **Ease new product roll-out** – Locate all old products in order to replace with new items. Offer incentives to push through or recall obsolete parts.
- **Real-time reporting** – Know when and by whom a product is used. Predict future demand and improve upon process.
- **Real-time billing** – Bill immediately upon product usage instead of waiting for manual and periodic inventory counts.

Automate Surgical Equipment Tracking

The Problem

Surgical instruments contaminated with blood, tissue and other debris are showing up in hospitals at an alarming rate. A study from a recent issue of the Journal of Patient Safety says that between 210,000 and 440,000 patients each year who go to the hospital for care suffer some type of preventable harm that contributes to their death⁽¹⁾. According to the US Centers for Disease Control and Prevention (CDC), roughly 100,000 of these deaths can be attributed to hospital-acquired infections ⁽²⁾, transmitted from patient-to-patient via improperly cleansed surgical instruments or reusing equipment designed for single-use.

How Embedded RFID Can Help

Several procedures are employed by hospitals today to sterilize reusable medical tools. The most common sterilization method is the use of autoclaves, which kill harmful microorganisms with intense heat and pressure. Other forms of sterilization include chemical cleansing with ethylene oxide (EtO) gas, electron beam radiation, and gamma sterilization.

Whatever the method, it is imperative that sterile processing departments adhere to manufacturer recommended sterilization procedures and guidelines. Any given hospital must track and maintain

thousands of surgical instruments on a daily basis. In order to track such large volumes of instruments, technology-based tracking systems are becoming increasingly necessary to protect against unintentional human error.

By embedding RFID tags in to reusable instrumentation, sterilization teams can use RFID readers & writers to record that the instruments have been properly sterilized on a certain date and time. In the case of single-use equipment, embedded RFID can be used to prevent reuse of a device and adjust inventory levels accordingly. Operating Room teams can then operate with confidence that their surgical equipment is clean and safe for use, without fear of transmitting harmful (and potentially deadly) infections from patient-to-patient.

Another key advantage of RFID in the sterilization process is that unlike barcode, RFID does not require line of site. Therefore rather than tracking individual instruments, entire sets of OR equipment can be processed at once, while proving a full history from decontamination to its intended point of use. This effectively eliminates human error and vastly improves workflow and efficiency.

Conclusion

Once considered costly and complex to integrate, embedded RFID technology has matured to become a hard-to-ignore solution for hospitals and medical device OEMs alike. RFID solutions promise substantial improvements in patient safety, inventory visibility, and real-time tracking of medical instrumentation and equipment throughout the healthcare ecosystem. Medical device engineers looking to embed RFID technologies in to their equipment can benefit by employing experienced partners with deep RFID engineering expertise. Many suppliers can offer a wide variety of RFID products to choose from. Unlike most data collection manufacturers, JADAK has one of the broadest RFID product portfolios in the industry, backed by engineers with the resources and technical expertise to help OEMs implement solutions to meet their specific needs and requirements.

1. James, John T, PhD, "A New, Evidence-based Estimate of Patient Harms Associated with Hospital Care" Journal of Patient Safety, September 2013 – Volume 9 – Issue 3 – p 122–128. Accessed February 27, 2015
2. "Healthcare-Acquired Infections (HAIs)" PatientCareLink.org, Accessed March 2, 2015

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