EMBEDDED RFID FOR MEDICAL DEVICES
Introduction

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 the 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.

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 a case study of a current SkyeTek 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.
Embedded RFID for Medical Devices

Protect Against Counterfeit Disposables

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. Counterfeiting afflicts numerous items across many industries, including chemical reagents, device consumables, game tokens and chips, paper documents and certificates, removable media, and replaceable parts. In addition to counterfeit products, generics and substitutes cost companies revenue and often tarnish brand names.

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 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 Diagnostics, a division of Iris International, Inc. (NASDAQ: IRIS), 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 Diagnostics incorporated Skyetek’s RFID readers and SkyeWare 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 Skyetek 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.

Read the RFID Journal article about IRIS Diagnostics and its use of RFID
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:

1. **Patient Records Pain Level**
2. **Patient Swipes Wristband**
3. **Patient Removes Pill**

The Skyetek M1-Mini RFID module is embedded behind the pain scale on the 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 SkyeTek 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.

Read the RFID Journal article about Avancen and its use of RFID

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.
- **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.

**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.

### Conclusion

The primary objective with embedded RFID is top-line enhancement such as increased safety for providers and patients, new revenue, increased productivity, inventory visibility, and improved product security. Embedded RFID delivers security, inventory management, access control, and personalized patient experiences.

Unlike supply chain management solutions, embedded scenarios require intimate knowledge of the environment and use case in order to optimize the return on investment. Choosing a reader provider with a proven track record of integration is the key to succeeding with embedded RFID.

Medical OEMs and product designers have a timely opportunity to innovate with embedded RFID before it is saturated through all products. By incorporating RFID as a feature into new and existing products right now, companies can gain the product differentiation and competitive advantage that RFID-enabled features and functions impart.
How to get started

Visit our website at http://www.skyetek.com/ProductsServices/ to learn more about our complete offering of embedded RFID products, or contact SkyeTek directly at sales@skyetek.com or 720-328-3425 to learn more about how our embedded RFID readers can help you add RFID functionality to your medical device quickly and easily.

About SkyeTek

SkyeTek delivers stand-alone and embedded reader solutions that make RFID work easily, reliably, and economically for enterprises and OEMs. SkyeTek offers a complete line of both HF (High Frequency, 13.56 MHz) and UHF (Ultra High Frequency, 860 - 960 MHz) readers that can be used in a multitude of unique applications. Contact Sales today to see how we can make RFID work for your application. SkyeTek is a privately held, venture-backed company headquartered in Denver, Colorado, with sales operations in North America, Europe and Asia. For more information, visit www.skyetek.com.