

WHITE PAPER

Using RAIN RFID Technology to Fulfill the FDA's UDI Regulation and Improve the Healthcare Supply Chain

ABSTRACT

In 2013, in an effort to improve patient safety, the U.S. Food and Drug Administration (FDA) passed a regulation mandating the identification of medical devices using a Unique Device Identifier (UDI) labelling system (including such data as lot and serial number, and expiration date). Many in the healthcare industry initially reacted negatively to this UDI regulation, seeing it as a nuisance. But these views are now shifting, as both device manufacturers and hospitals are realizing the enormous benefits that are emerging from this mandate in the areas of patient safety, clinical outcomes, operational efficiencies, cost savings, and revenue capture. This paper will illustrate how one of the most effective ways of satisfying the UDI mandate and, in the process, transforming the healthcare supply chain, is through the use of RAIN RFID technology.

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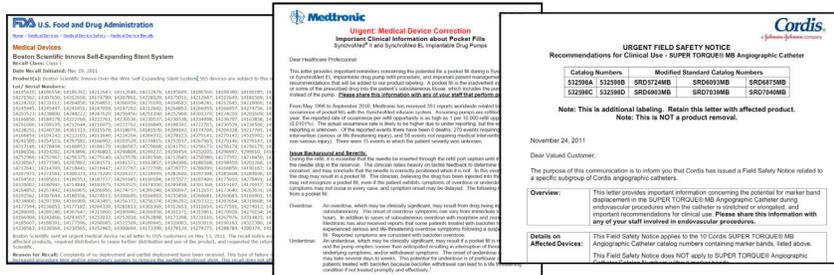
The Problem

The FDA's UDI regulation is critically important for patients because multiple medical devices and implants may be used in their care throughout their lifetimes. The main issue is that devices are often recalled, which can be a problem if they are not able to be tracked to specific patient records, in

which case they must be found manually, assuming it is even possible. Each year millions of units need to be tracked down, removed from the shelves, and identified as having been used in patient procedures so that affected patients can receive proper clinical follow-up.

Medical Device Recalls

- The number of medical device recalls has increased from 2,303 in FY2013 to 3,202 in FY2017, posing potentially serious health risks to patients (Source: Regulatory Affairs Professionals Society, 10 Jan 2018).

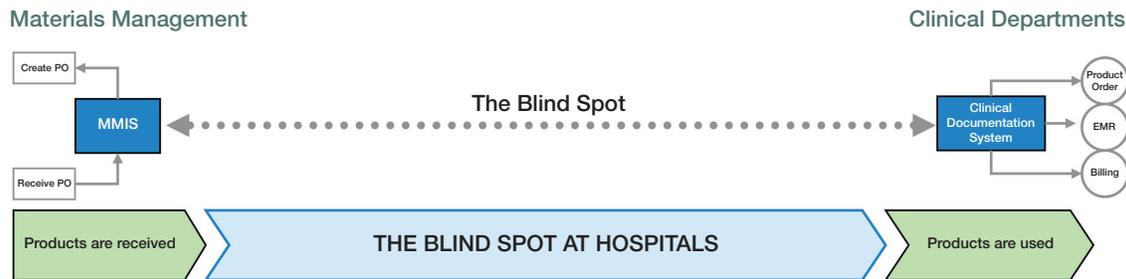


Currently, a major challenge for hospitals remains the fact that most of them are not using clinical inventory management technologies for tracking items throughout their lifecycle in the facility. We call this problem the “blind spot.” MMIS and clinical documentation systems are simply not designed to track and report on each product

throughout the hospital cycle. The blind spot primarily means that there is an inability to: (a) track each item from the point of entry into the hospital until it is used in a patient or removed from inventory; (b) track items precisely with lot/serial number and expiration date; and (c) find their exact location within the hospital.

Problem 1: The Blind Spot

MMIS and Clinical Systems are not designed to track and report on each product throughout the hospital cycle



- Inability to track each item from the point of entry into the hospital until it is used in a patient or removed from inventory.
- Inability to track items precisely with lot/serial number and expiration date, and to find their exact location within the hospital.

The lack of clinical inventory management technologies for tracking items also means that the documentation of items at the point of care is highly manual, duplicative, and error-prone. Poor and inaccurate

Benefits of the UDI Regulation

The UDI regulation creates a standard identification system for all medical devices, enabling “track & trace” from the point of origin of the device all the way to the patient in the procedure room. The regulation is designed to prevent errors and support recalls, and is expected to be fully implemented by 2020. The promise of the UDI rule is that no matter what procedure a device is used in, it can be

data capture at the point of care decreases patient safety (such as in the case of a recall), but also leads to inaccurate patient records and billing, among other problems.

easily and quickly identified, tracked, and analyzed. The UDI vision is that the operational, supply chain, and clinical and financial aspects of healthcare will all benefit from the regulation – not just with point-of-use data capture, but also with purchasing, reimbursement, inventory management, and recalls.

UDI Vision & Promise

- Point of use capture
- Shortages/substitutions
- Anti-counterfeiting/diversion
- Disaster/terror preparation
- Recalls/adverse event reporting
- Comparative effectiveness



- Purchasing
- Inventory management
- Logistics
- Demand planning
- Contract compliance
- Contract accuracy
- Billing
- Reimbursement

Why Use RAIN RFID Technology to Satisfy the UDI Regulation?

When the FDA established this UDI system, it did not specify whether manufacturers should use barcodes or RFID technology to identify medical implants, surgical instruments, and life-support devices. And while some device manufacturers are opting to use barcodes to comply with the mandate, thinking that this is the easier route to compliance, other companies are seeing this mandate as an opportunity to adopt RFID because it allows them simultaneously to improve their internal processes. RFID is beginning to be recognized as the way of the future for advancing the healthcare supply chain.

For those who are new to this technology, Radio Frequency Identification – or RFID – uses radio waves to read and capture information stored on a tag attached to an object. A tag can be read from up to several feet away and does not need to be within direct line-of-sight of the reader to be tracked. To be able to connect items to the internet, several components are required: (1) the endpoints (the items to which tags are attached); (2) the connectivity layer (the

readers that are collecting data from the tags); and (3) the software that delivers information about the identity, location, and authenticity of an item to the software application that puts it in context and makes that item intelligence useful to an end user.

RAIN RFID uses a single, global standard – UHF Gen 2 (ISO/IEC 18000-63) – and is a passive RFID system in which a reader sends a radio signal to a tag. The tag then uses the transmitted signal to power on and reflect energy back to the reader.

RAIN RFID hardware and data encoding are standards-based and lend themselves well to satisfying the FDA rule on UDI by using both approved device identifiers (DI) and production identifiers (PI) data structures such as Global Trade Item Number (GTIN) or Health Industry Bar Code (HIBC). With PI information such as lot or serial number and expiration date embedded in a RFID tag, far more granular and accurate traceability and control can be applied to medical devices.

UDI Data is Resident on the Tag Itself



UDI-encoding solution using GS1 EPC GEN2 UHF (RAIN) standards

- Device Identifier
- Production Identifier Data as applicable:
 - Lot Number
 - Batch Number
 - Serial Number
 - Expiration Date
 - Manufacture Date
 - HCT/P ID

The UDI-encoded RFID tag may be printed

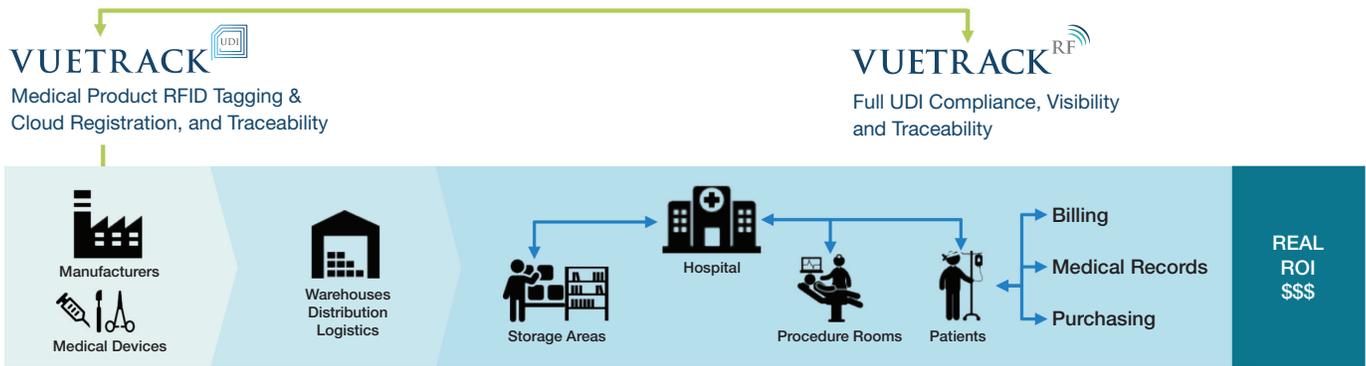


RAIN RFID technology is also highly flexible and scalable due to its ability to turn any space into an RFID-enabled area. And it achieves nearly perfect accuracy as well as precise location resolution from close range to up to 100 feet away, based on the specific objectives for the RFID application (e.g. monitoring a warehouse vs. a supplies closet) and with the support of a wide choice of RFID hardware.

Why use automation to track medical supplies and devices? VUEMED's RAIN RFID technology provides many benefits:

- Reduce or eliminate accidental loss/shrinkage, manual inventory processes, excess inventory, and waste due to expirations;
- Track recalled and expiring devices instantly;
- Obtain optimal par levels due to better predictive analysis;
- Enhance billing accuracy and increase charge capture;
- Attain near perfect inventory tracking and patient records;
- Achieve UDI compliance.

Using RAIN RFID for Supply Automation and UDI Compliance from Manufacturer to the Patient



VUEMED's RAIN RFID solutions are achieved by installing a light fixed infrastructure. There's no need to remodel or replace existing storage solutions.

24/7 Visibility with Light UHF RFID Infrastructure



- UHF RFID Solutions—from Tag to Cloud
- Global Standards Interoperability of VUEMED's GS1



UHF RFID Tags

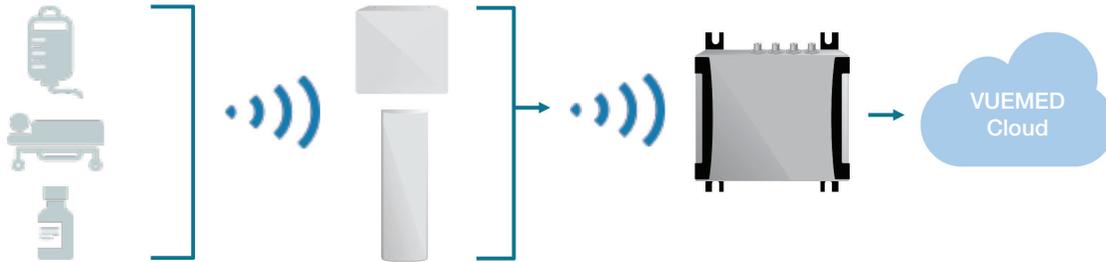
- For clinical products
- For assets and SPD
- For people

UHF RFID Antennas

- For ceilings/walls/shelves
- Inside or outside cabinets
- Excite and read tags

UHF RFID Readers & Hubs

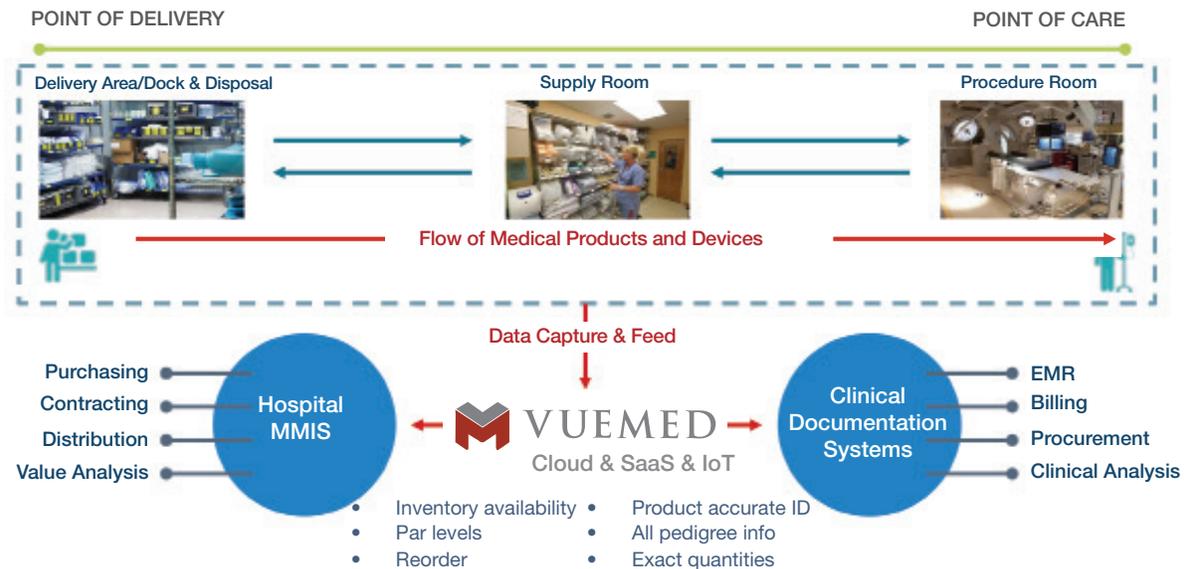
- Hidden in ceilings
- Power the antennas
- Route data to VUEMED Cloud



Another major advantage of VUEMED's RAIN RFID technology is its ability to track anything with a tag continuously and automatically: all products' movements – from delivery at the hospital to storage in the supply room to use in a patient procedure to disposal – are recorded and fed into other relevant systems, such as purchasing

and clinical documentation. Standards-based encoding allows us to incorporate the full UDI information onto the tag itself (including lot, serial, expiration date, etc.) so that the data can be picked up by any RAIN RFID reader wherever the item is moving.

Continuous and Automatic Tracking of Items, Movements, Locations and Events



The key advantages of RAIN RFID technology are that it's standards-based, easy-to-scale, and enables transparency and the full chain of custody with little required infrastructure and little to no human intervention. VUEMED uses this technology to see and report on each item from the moment it's tagged at the manufacturer (or "born"), through each step in its lifecycle, all the way to the patient at the point of care. We now have the Internet of Things (IoT) for medical devices: from the application of the tag to the point of care, each individual product is recorded in the cloud, as well as every event and location associated with it.

Manufacturers (e.g. Cook, J&J, Boston Scientific, Medtronic, Terumo) are embracing RAIN RFID as well, since they are looking for ways to streamline their own operations while being able to offer more value-added services to their hospital customers. Both goals require good, reliable data about how their products are moving or being utilized. With this technology, there is never any doubt as to which products are on the shelves; inventory management is automated, hands-free and in real time. This signifies a huge improvement for the medical device industry which is now equipped with a powerful tool to do meaningful demand planning and inventory control.

Manufacturers Choose RAIN RFID

- Meet FDA UDI requirements for all medical devices and other supplies
- Produce, read, and process any GS1 EPC Global RFID tag (GTIN and SGTIN)
- Track consignment stocks and trunk stocks
- Provide exciting VMI programs



How Does RAIN RFID Technology Achieve UDI Implementation?

In short, here are the many ways that RAIN RFID enables manufacturers and providers to satisfy the UDI regulation:

- The UDI data (manufacturer name, batch, serial number, and expiration date) are encoded onto the RFID tag and can be read by any UHF standards-compliant reader or device;
- Medical devices are given a standards-based identity that can

be accessed and used throughout their lifecycle;

- Manufacturers and hospitals can immediately engage the UDI data to track medical devices from deep within the manufacturer's supply chain all the way to the point of care; and
- With the UDI data, devices can be tracked to hospitals' clinical, billing, and ERP systems, as well as to the EHR.

Financial Benefits and Savings from Using UDI-Compliant RAIN RFID Technology

There are many sources of savings to be gained when one adopts a RAIN RFID system for managing the supply chain and fulfilling the UDI mandate, such as the elimination of expirations, the achievement of a

lean inventory, a reduction in product purchases, and increased billed revenue capture, among many other benefits.

Conclusion

RAIN RFID isn't new - the adoption of RAIN RFID is broad and deep, spreading across many industries around the globe. It is new to healthcare, however, and we are seeing a growing level of interest in this set of capabilities as providers are looking for ways they can gain more visibility and control over their operations in a world where they are continuously under pressure to control costs while simultaneously delivering high quality patient care.

Although the FDA's UDI rule is aimed at device manufacturers and at ensuring product safety, it has broad implications for the healthcare supply chain as a whole. UDI adoption, in combination with RAIN RFID technology, offers numerous benefits for improving the supply chain and workflow efficiencies, data accuracy and management, complete inventory visibility, and significant enhancements in trading

partner relationships across the industry. Together, they hold the promise of preventing billions of dollars of waste worldwide for both manufacturers and hospitals, reversing long-standing constraints, and preparing the healthcare supply chain for the challenges to come.

Additionally, UDI-compliant RAIN RFID technology not only produces greater compliance, visibility, and traceability, it also vastly improves patient safety due to its ability to track both recalled and expiring items with near perfect accuracy. Hospitals and manufacturers can now identify the exact location and usage of all medical supplies and products at all times, thereby dramatically improving patient outcomes, clinical documentation, and integration of key supply data into other systems.

About VUEMED

VUEMED is a SaaS and Cloud-based healthcare IT company working to transform the healthcare supply chain through the most innovative RFID and barcode scanning technologies available today. VUEMED's mission is to solve acute inventory management, supply chain, and

product usage documentation problems at hospitals with tools that promote transparency and provide comprehensive and accurate data. Our goals are to improve the quality and delivery of patient care, achieve efficiency and savings, and increase revenue capture.

References

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2. <https://www.raps.org/regulatory-focus%E2%84%A2/news-articles/2018/1/device-recalls-in-2017-making-sense-of-the-numbers>