

Frequently asked questions on RFID in Healthcare

1. ARE THERE ANY STANDARDS GOVERNING THE USE OF RFID FOR SURGICAL INSTRUMENT TRACKING?

There are no standards or regulations that require hospitals to track surgical instruments with RFID.

However, there are RFID standards that make it easier for hospitals, sterilization services and surgical device manufacturers to use the technology.

There are two things standards need to accomplish for this use case:

- 1) Provide a numbering system that ensures each instrument will be uniquely identified and its serial number or other identifier will never be duplicated. Unique identification is necessary to track the item throughout its lifecycle and associated actual utilization and sterilization records.
- 2) Support interoperability with all the RFID system components (e.g. tags, readers, software) needed for a complete solution. Using standardized equipment and software that supports it will give users the greatest choice of equipment options and prevent them from being locked into using a single vendor with proprietary technology, as has happened in some RTLS installations.

The GSI EPCglobal Gen 2 standard (which is often referred to as “Gen 2”) provides both unique item identification and interoperability. It is supported by an equivalent ISO standard, ISO 18000-6C. The Gen 2 standard is the most widely supported UHF RFID technology standard. Standard Gen 2 tags can be encoded with a Serialized Global Trade Item Number (SGTIN), which is a globally accepted numbering system used on billions of products worldwide.



The Unique Device Identifier (UDI) program was created by the U.S. Food & Drug Administration (FDA) to uniquely identify devices in the healthcare supply chain. Medical device manufacturers assign UDI numbers for every version of model of their devices. UDI numbers can be encoded into RFID tags (including Gen 2 tags) and must also appear in human-readable form. UDI is a standardized numbering system and does not include any RFID specifications.

The U.S. Department of Defense manages the Item Unique Identification (IUID) program that requires a unique, machine-readable identification mark on select items supplied to the U.S. military. The IUID program has its own requirements for serial numbers, and allows the use of RFID to encode them. IUID is a numbering system and does not provide RFID technical standards.



The Health Industry Business Communications Council (HIBCC) has developed the Health Industry Number (HIN) and maintains multiple unique numbering systems and resources for identifying healthcare products.



HIN, SGTIN, UDI and IUID numbers can all be encoded in standard RFID tags.

2. WHAT ARE THE ADVANTAGES OF USING RFID OVER BAR CODES?

RFID technology has two major advantages over bar coding for surgical item tracking plus several other important performance benefits. The major advantage RFID tags have in the surgical environment is their size – an RFID tag encoded with a serial number can be much smaller than a bar code marked with the same number.

That means less precious space on the instrument is devoted to carrying the identifier. The other major advantage is RFID tags do not have to be visible at all and can be embedded inside the instrument. Bar codes require direct line of sight between the symbol and the reader, and enough light for the reader to pick up the difference between dark and light elements. Bar codes can easily become unreadable if they fade or are obscured by stains or shadows. RFID tags and readers communicate by radio waves that penetrate the surface of a product (similar to the anti-shoplifting tags that are embedded inside consumer products sold at retail). RFID readers emit a wave that will detect and identify all tags in its path, unlike bar code readers, which must be aimed directly at the symbol to read it. RFID readers can process hundreds of tags simultaneously, unlike bar codes which must be read one-by-one. RFID readers have built-in algorithms that prevent the same tag from being read and recorded multiple times.



The way RFID tags are read provides several practical advantages for healthcare use cases. First, the small tags can be attached on instruments in different ways that are ergonomic. Second, it saves time because tagged items can be read and recorded quickly. RFID readers can process hundreds of tags simultaneously, and users don't have to spend any time locating bar codes and carefully aiming the scanner. In fact, no human intervention may be needed to read RFID tags at all. Unattended readers can be set to create a read zone that automatically and continually monitors the locations of tagged items, detect when they moved and can issue notification. Such systems have been used to increase security and to support automated asset management and inventory control systems.

RFID tags are also more durable than bar code labels. Xerafy has a family of tags that can survive thousands of autoclave sterilization cycles and remain functional for the entire life cycle of the tagged item. Bar codes may fade or become scratched over time, which causes them to fail.

3. WHAT IS THE ADVANTAGE OF USING UHF INSTEAD OF OTHER RFID TECHNOLOGIES?

There are multiple RFID technologies — and no single one is best for all uses cases. RFID interoperability has been a problem for some medical facilities that wanted to change their RTLS systems, because RTLS isn't standardized and multiple wireless technologies are used, including Wi-Fi. Many RTLS systems are inappropriate for surgical item tracking because of the size of their tags. For surgical instrument and other small-item tracking most organizations use ultrahigh frequency (UHF) technology, but high frequency (HF) is also an option.

The biggest difference between UHF and HF RFID systems is their range and data speed. HF technology read range is typically about 10 centimeters or 4 inches. UHF systems can operate at short range, but can also be configured to read items from more than 60 feet away. Due to the fast data speed, UHF technology enables quick bulk reading, and a tray of instruments can be read in seconds instead of a typical count and verification time of around 15 minutes. Also, a person using a handheld reader can quickly take inventory of all the items in a stock room, including those stacked on high shelves, without having to walk through the entire room. Unattended readers can monitor shelves, cabinets and portals to automatically record the locations of trays, carts and individual instruments and can issue alerts if items are missing (such as immediately after a surgery).

HF technology operates at 13.56 MHz while the frequency band for UHF technology is approximately 860-928 MHz. Both technologies are allowed for use around wireless and other medical devices and are supported by multiple international standards.

4. IS PASSIVE OR ACTIVE TECHNOLOGY BETTER FOR SURGICAL INSTRUMENT TRACKING?

Active RFID tags have a battery that powers the tag to transmit its data to the reader. Passive tags do not have a battery. They are powered (or “woken up”) when they receive a radio wave from the reader, and transmit their data via return wave. Because passive tags require no battery they can be much smaller than active tags. Most active tags are expensive and can’t conveniently fit on a surgical instrument, and thus passive is overwhelmingly the RFID technology of choice for tracking surgical instrument and other small items.



5. WHAT INFORMATION CAN BE ENCODED ON AN RFID TAG?

Anything that can be digitized can be encoded, including schematics. The amount of digital information that an RFID can carry is limited only by the tag memory. Most medical devices are only encoded with a unique serial number (such as one of those described in Question 1) and almost all tags on the market have enough memory to support common serialization numbers. There are also high-memory tags that can be used to encode information about an item’s attributes (e.g. configuration) and life cycle history (e.g. date of last service) so users can get important information about the item when there is no access to a records database.

6. DOES RFID UHF TECHNOLOGY IMPACT EQUIPMENT, INSTRUMENTS OR IMPLANTABLE DEVICES?

No. UHF RFID technology has been thoroughly tested and approved for use in hospitals, surgical theaters and in proximity to electronic medical devices.

7. WHAT TYPES OF READERS ARE COMPATIBLE WITH AND RECOMMENDED FOR XERAFY TAGS?

Xerafy manufactures tags that comply with the ISO 18000-6C/GS1 EPCglobal Gen 2 standard. That automatically makes them compatible with all readers that conform to the same standard, which is the most widely supported HF standard in the world. Xerafy can support custom designed reader and antennas for specific use cases, please consult your local sales rep regarding your requirement.

8. HOW ARE RFID TAGS ATTACHED TO SURGICAL INSTRUMENTS?

There are several options for reliably attaching RFID tags to surgical instruments to ensure the tag can withstand the sterilization cycles and not impact the use or balance of the instruments. The optimal attachment method depends on the size and shape of the item and the preferred location to place the tag to support user convenience. The most common approach is to have the RFID tags epoxied to the surface of an item. Larger instruments offer more placement options and tags can even be secured by rivets as long as it is not a bioburden.

In some cases, it may be possible to embed the tag into an item by drilling or carving a small recess and applying epoxy, or weld a carrier to the instrument by an authorized service provider or instrument company. It is important to consider how the instrument is used and its balance when determining the best placement and attachment option. Xerafy's autoclavable RFID tags attached to instruments can survive more than 1000 sterilization cycles.



Dash XXS attached on a scissors