

## FAQs

### RFID Technology on Surgical Instruments

#### RFID Technology

**What is the difference between RFID and Datamatrix?**

RFID Technology	Datamatrix
Good readability in almost all environments	Difficult to read in poor lighting conditions, moisture, scratched surface
Built-in security code in the RFID tag	Easy duplication
Bulk reading is part of RFID technology	Readability of only one code/information at a time
Tag does not damage / change instrument and can be removed	No removal, change possible
RFID tag must be glued	Datamatrix must be glued or lasered

**Up to what distance can the RFID tags be read? Is there a difference to other technologies?**

All technologies based on barcodes / 3D matrix are based on the 'line of sight'. This means that the user must hold the information area so that the reader can see it. In addition, there must be sufficient (but not too much) light. RFID does not have this major disadvantage and can be read from a distance of up to approx. 4 metres in the case of surgical RFID tags (depending on size). For trays and trolleys, RFID tags can even be read from a distance of up to 20 metres. It is also important to note that RFID technology is not a chip that has to be read directly, but a chip that transmits its information on demand.

## Software

### **What does the RFID software do?**

The software solution includes the tracking of surgical instruments within the RUMED and the operating theatre.

### **How can it be accessed?**

It is preferably cloud-based but can also be offered 'on premise' by arrangement between us and the customer. The web application can be accessed from a PC, tablet or mobile phone.

### **What are the requirements for installing and operating the software?**

- PC with Windows operating system (version 7 or 10, preferably Windows 10)
- No firewall that denies access to SQL Server (check by user IT)
- At least Dot Net 4.6.1
- Access to MS SQL Server (installation by user IT)

### **In which languages is the software available?**

The software is currently available in English, German, French, Spanish, Czech, Polish and Portuguese.

### **How many instruments can be stored in an RFID system?**

All tags are coded with an electronic product code (EPC) under the guidance of GS1. We use the 96 bit coding standard. By using this standard, each hospital / customer can register more than one billion instruments with a unique EPC = UDI.

### **Can products that do not yet have an RFID tag be included in the digital packing lists?**

Yes, as we allow various options (RFID, data matrix, barcode, etc.), products without an RFID tag can also be included in the packing list.

### **Can the solution be integrated with existing solutions such as Instacount, T-Doc or other systems?**

We are generally open to integration with existing systems, but it is important to clarify whether the systems to be integrated allow this. Integration is possible via a so-called API or HL7 interface. Both are standardised procedures. However, this must be clarified from project to project.

### **Can the system be modified?**

Our system can be modified and integrated to existing systems, depending on certain requirements and specifications.

## Tagging

### **How does the application of the tags with the robot work in detail?**

To apply more than 10,000 tags, the hospital / customer needs a robotic system. The application process is patented and works as follows:

The robot applies the RFID tag to the instrument and then mats around it with the special adhesive and are then cured in the oven. The instruments with the RFID tags are then cooled, registered in the database and the data entered. The data includes, for example, the UDI number, the manufacturer's article number, the name of the clinical centre and the maintenance rules.

### **Can the RFID tags also be applied to existing items? Is there anything special to consider here?**

Yes, the RFID tags can also be applied to existing items using the patented robotic solution. It is important that the instruments are clean, corrosion-free, undamaged and free from oily residues.

### **What about new instruments purchased in the future? Does using the system limit purchasing options?**

No, there is no limit to tag new instruments. Some manufacturers are already offering RFID tags installed to new instruments when purchased. We are open to work with all surgical instrument manufacturers.

### **How many sterilization cycles will the tag on the instrument survive?**

Our glueing process is validated for 2500 sterilization cycles. Please be aware that the lifetime depends on the used chemicals and used procedures.

### **Can tagged instruments be washed in ultrasonic cleaners?**

Yes, our tags can also be washed in ultrasonic cleaners.

### **Can the tags be removed and re-applied?**

No, to remove a tag from an instrument, the tag would have to be damaged. It is also not allowed according to the legislation (MDR 2017/745) and the UDI (Unique Device Identification) requirements.

## **Safety and Standards**

### **Are the RFID products UDI / MDR compliant?**

We fully support the UDI / MDR - any new changes or additions by the FDA or EU will also be supported.

### **Which standards are taken into account?**

We work exclusively with recognized standards and products:

- RFID tag: ISO 18000-6 and the new ISO 18000-63
- RFID readers: Standard UHF frequencies such as 865 - 868 MHz (for Europe) and 915-920 MHz (e.g. Japan, USA, Brazil, Australia) ISO 18000-6 and the new ISO 18000-63
- Microsoft: Windows 7/10 and MSSQL

### **Is UHF safe for health?**

Yes, absolutely. The UHF RFID tags used is very safe and broadly used by many industries such as retail, agriculture, and supply chain.

### **How secure is system against attacks?**

The RFID system is coded with special software to prevent the system from being bypassed or hacked. What exactly is behind this is and remains a secret. This is to prevent any ideas from arising as to how the system could be circumvented.

### **Where is the data generated in the RFID system stored and who has access to the data?**

The solution is intended for the cloud and here we works together with AWS or Azure (Microsoft), for example. Here, each customer gets their 'private cloud' and only the customer has access to their data. The customer in turn can define which employee has access to what, e.g. via Microsoft directory.

### **Can the RFID tags be damaged by repair work?**

Yes, but there will be certified service partners who can guarantee a safe repair.