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Identification of instruments and implants with RFID and Data Matrix Codes for the use at the instrument table

***Abstract**. The number of instruments and implants increases the more complex surgeries get. Furthermore, sometimes the labeling is hard to read what takes more time to find the right piece. This research is about the development of a scanner for the identification of medical instruments and implants in an operating theatre. Identification takes place either with passive Radio Frequency Identification (RFID) transponders or Data Matrix barcodes. The data gets transmitted with a Bluetooth module to a connected which analyses the transmitted data and displays both information and a picture. The control of the scanner hardware takes place with a built-in microcontroller, which also connects the scanner with the Bluetooth module. The barcode scanner is able to read the smallest code size of 127 µm in a distance from 43 to 115 mm. RFID transponders placed on or in metal can be read in a distance up to 44 cm depending on the part structure.*

Streszczenie.** Wraz ze skomplikowaniem operacji chirurgicznych rośnie liczba wykorzystywanych w nich narzędzi i implantów. Szybka i poprawna identyfikacja tych narzędzi na podstawie jedynie etykiety nie zawsze jest możliwa. Artykuł prezentuje prototyp skanera służącego do identyfikacji instrumentarium oraz implantów w warunkach panujących na sali operacyjnej. Identyfikacja jest możliwa zarówno poprzez pasywne identyfikatory Radio Frequency Identification (RFID) jak i kody paskowe w formacie Data Matrix. Skaner działa pod kontrolą wbudowanego mikrokontrolera. Dane na temat zidentyfikowanych narzędzi są przesyłane za pomocą modułu Bluetooth do urządzenia mobilnego, gdzie są prezentowane w formie tekstowej i graficznej użytkownikowi. Odczyt kodów paskowych jest możliwy z odległości od 43 do 115 mm dla najmniejszych kodów o rozmiarze 127 µm. Zasięg odczytu identyfikatorów RFID, wbudowanych lub naklejanych, wynosi do 44 cm w zależności od struktury implantu lub narzędzia.* ***Identyfikacja instrumentów i implantów przy wykorzystaniu detektorów RFID

Keywords: instrument identification, RFID, Data Matrix, mobile scanner.
Słowa kluczowe: identyfikacja narzędzi, RFID, Data Matrix, skaner mobilny.

Introduction

This research is about the development of an instrument and implant scanner for the use at the instrument table in an operating theatre. The aim for this development is to support the surgical team in their daily work in the hospital. The more complex surgeries get the more different medical instruments and implants are necessary. Hereby the printed labeling can be hard to read because of its size or different impairments. To increase safety and decrease the identification of the printed label additional ways for identification should be used. Depending on the size and application of the implant or instrument either an autoclavable passive Radio Frequency Identification (RFID) transponder can be attached or a Data Matrix barcode can be printed on the parts. A scanner placed on or nearby the instrument table in an operating theatre can be used to readout both RFID and barcodes. To guarantee the mobility of the scanner a rechargeable battery should be used. Furthermore, it's important to ensure the use in the sterile working area in the operating theatre, so the surface has to be covered with a sterile adhesive foil. The scanned data should be transmitted to a device close to the user. Hereby additional information and an image of the part should be showed. Required for the use of Data Matrix barcodes is an optical scanner which can readout the smallest used code sizes of 5 mil (127 µm). For using the scanner close to the instrument table it's also important that it has a low profile for not disturbing the workflow during a surgery.

Material and Methods

After a first research of the state of the art, it was found out, most of the identification systems use a handheld scanner which either can detect RFID transponders or barcodes with a single device. The main disadvantages of those systems are the use of additional cables, the need of a handheld scanner and the ability to read just one identification method, which can be insufficient. Additionally, this scanner should be easy to use.

First it was necessary to determine the identification methods for the scanner. In modern healthcare it gets more and more important to implement additional information into the used devices. The amount of data stored in a printed label is very low. For that reason, an alternative method had to be found. Passive RFID transponders attached on or embedded in the parts allow us to store additional data about the object. Beside the serial number additional information about size, production and inspection date and number of sterilization cycles could be saved and edited. With a saved product ID more general data can be displayed by using an external database. Because of the different shapes and sizes of implants and instruments RFID transponders can't be used for every part. It's also not desired to use those electronic transponders for implantable products. Therefore, optical identification methods can be used. In medical technology this is the state of the art. Beside legal required data, also additional fixed information can be stored, for example the manufacturing date. For a high amount of information Data Matrix barcodes can be used. These binary codes can be printed with an element size of only 5 mil (127 µm). Therefore, the space needed on the object is very small – which is important because the amount of data depends on the size of the barcode [1,2].

The first step was to develop a first prototype of a portable scanner that includes two modules for capturing the targeted identification methods – RFID and barcodes. A Bluetooth module should be implemented to ensure an easy data transmission to different devices like smartphones, laptops or tablets. Because of the high power consumption of the readers it's non-essential to use a low energy module. Furthermore, it should be possible to change the operating mode of the scanner with implemented buttons. To ensure the mobility of the system a rechargeable battery can be used for powering the reader, so no external power unit is needed. By choosing the battery it's very important to ensure the use for a whole surgery – so the capacity needs to be as close as possible to the calculation of the maximum consumption. A low profile allows the use close to the instrument table without disturbing the workflow.

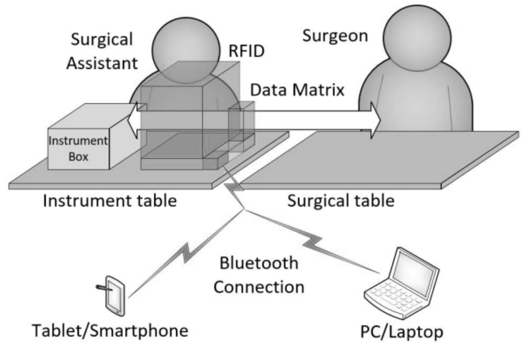

Fig.1. Concept of the scanner use in an operating theatre

Determination of the hardware

After setting the concept for the scanner system the hardware had to be selected. In case of the RFID module the ultra-high frequency band of 860-960 MHz (operating frequency band for Germany/EU: 865-868 MHz [3]) was chosen because of the high range, less interferences in the targeted environment and a faster detection of multiple transponders because of the higher effectiveness of the anti-collision algorithms. Therefore, a high frequency improves the reading of many RFID transponders in a small area – the so called bulk reading [4]. As shown in Fig. 1 the reading zone of the RFID scanner should be limited to a prismatic field. To limit the horizontal dispersion as good as possible, a high antenna gain was chosen. The gain is calculated from the efficiency and directivity of an antenna. To provide a larger area of capturing RFID transponders attached in or on different medical implants and instruments, also a large-area patch antenna array was chosen (Times-7 A5010) with a gain of 8.3 dBic. Beside the field direction the radius of the 3D reading area, the so called interrogation zone, is an important value of the reading system. Because of the changing transponder characteristics this value needs to be measured for different cases [5]. The concept of this scanner was to capture just single objects at once but the selected module also provides a bulk reading. This allows applying the developed scanner in many different areas.

Because of the major metallic surfaces of medical products particular transponders are needed. The chosen passive RFID transponders of the company “Xerafy®” are able to be attached on or even embedded in a metallic surface. For the attachment an autoclavable medical glue can be used. Additionally, the ability of being autoclavable is very important because otherwise the implants and instruments couldn’t be sterilized anymore. Further different disinfection methods like liquid chemicals, light or ultrasonic can be used to clean the transponders additionally. With a user memory size of 512 bit, 64 ASCII symbols can be stored in the RFID transponder. In addition to this memory a 96-bit identification number – the Electronic Product Code (EPC) - can be used to identify the unique instruments or implants [6].

Beside the hardware for the RFID system also a scan module for barcodes was needed to be chosen. In this case it’s very important to readout even the smallest code sizes of 5 mil in a distance between 43 and 115 mm. For limiting the transmitted data and the amount of conversions from the binary code to a readable text, the scan engine has a so called encoder board built-in which converts the scanned data to a text. So it’s not necessary to send the made image of the camera to the connected device and run a conversion algorithm. This is also very helpful for a mobile scanner without a connected device. So it wouldn’t be necessary to convert the images with the microcontroller of the scanner.

An Atmel® 32-bit AVR® microcontroller provides the connection between the scanning modules and the Bluetooth module. Thereby the Universal Asynchronous Receiver Transmitter (USART) interfaces can be set to connect two modules and transmit data from or to the connected device. Additionally, it’s possible to power up the scan modules with a single command.

To control the operating mode of the scanner, buttons are built into the housing. Capacitive buttons are selected to ensure a disinfection of the whole surface. These allow a fast switch of the operating mode without using the software provided by the connected device.

To insure that the scanner can operate during a full surgery the battery needs to last at least for 5 hours with both scan modules operating.

Regarding to the antennas dimensions it’s possible to place the antenna directly below the upper part of the housing. Thereby the rest of the hardware is arranged below the antenna, except for the user buttons and the barcode scanner.

The schematic arrangement of the instrument and implant scanner is shown below in Fig. 2. By designing the housing of the scanner it’s necessary to determine the optimal position for the barcode reader. On the one hand the scan field needs to be easy accessible but on the other hand the user needs to be protected from the strong LEDs of the device.

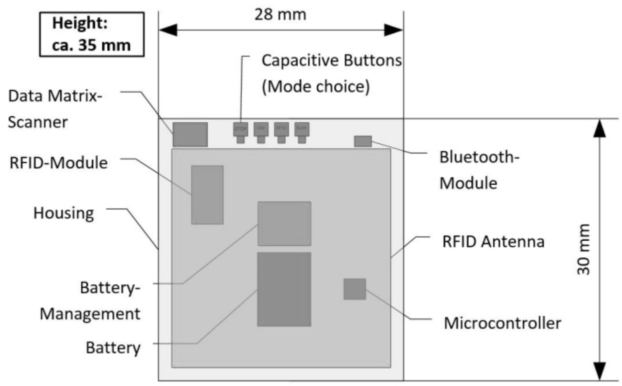

Fig.2. Schematic arrangement of the instrument and implant scanner

Development of the software

The development of the software is split in two parts – the program for the microcontroller and for a connected device. To limit the necessary operations by the controller most of the tasks are done by the more powerful device connected to the Bluetooth module. Therefore, the microcontroller is involved in four different tasks:

- **USART - Communication:** changing the connection between the three USART interfaces to connect either the RFID module or the barcode scanner with the Bluetooth module.
- **Readout of commands:** analyzing incoming commands and execute the corresponding method.
- **Readout of the capacitive buttons:** changing the operating mode depending on the pressed button. Waiting for a specific time interval for a double pressed button.
- **Control of additional hardware:** activation of LEDs for signaling the current operating mode or control similar indicators.

Because of the better performance the connected device is responsible for converting the received data and control of the scanner.

- **Initialization of the RFID module:** to use the RFID module several settings need to be set. It's also possible to change the operating parameters of the module with simple commands.
- **Choice of the operating mode:** for providing a flexible and efficient use of the scanner, different operating modes are set. Hereby one or both modules can be activated for a single or continuous scan. Furthermore, it's possible to write on captured RFID transponder to update their information.
- **Commands for the microcontroller:** to use the additional methods of the build-in microcontroller, several commands can be transmitted. Hereby the whole system can be reset or single modules can be turned off or on.
- **Display of the scanned data:** the received data first needs to be converted and analyzed. Afterwards the information is displayed on the user interface and an image of the scanned object can be added to prevent errors.

First tests of the system

Before setting up the whole system, the single modules had to be tested.

First the RFID module was tested for different medical instruments and implants. In Fig. 3 and Fig. 4 two different medical instruments are shown with in-metal and on-metal RFID transponders using an operational frequency of 902-928 MHz (US) and 866-868 MHz (EU) [6]. For embedding the transponders in the metallic instruments, a cavity of minimum 2.6 mm depth was cut into the surface. For the first tests an epoxy resin was used to fix the RFID transponders. Hereby it was important to choose a non-critical part of the instruments and implants to ensure a realistic positioning. Additionally, the resin needs to fill the whole cavity around the transponder to avoid gaps which would be very difficult to clean. An even surface above the transponder can be achieved by covering it completely with the epoxy resin or a medical glue. The on-metal transponders need no cavity, therefore the placement just needs to ensure, not to influence the correct use of the part [7].

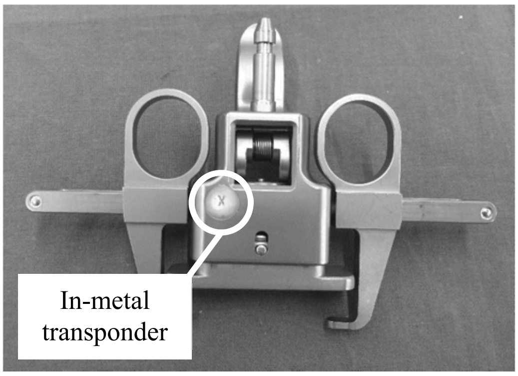

Fig.3. Medical instrument with in-metal transponder

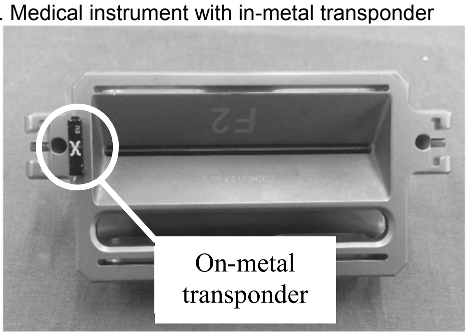

Fig.4. Medical instrument with on-metal transponder

It was important to use different structured objects for testing the worst and the best case. In particular, very small parts were difficult to capture. For massive parts the position of the transponder was very important. In some cases, the implemented transponders couldn't be captured. The maximum system reading distance was measured by lifting the parts vertical with different orientations and positions up above the antenna till no signal was received anymore. The output power of the RFID module was set to 26 dBm (approx. 398 mW) with a circular polarized antenna. Testing the ranges of the whole interrogation zone need to follow with different shaped objects.

For testing the barcode scanner different Data Matrix codes were printed out and the capturing range was measured. Further a medical screw, shown in Fig. 5, with a 5 mil Data Matrix code was tested with the scanner. This was important because of the metallic surface of the implant which could lead to errors in the capturing of the code pattern.

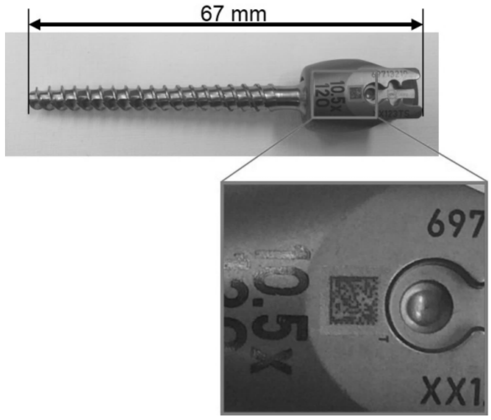

Fig.5. Medical screw with 5 mil Data Matrix code

The capacitive buttons and the additional electronics were tested in a simple test circuit. While testing, the resistance for the buttons could be set to adjust the range of activation. By changing this resistance, the buttons can be activated in a distance of approximately 2 cm or by touching the surface of the scanner. To provide a false activation or the possible activation of the nearby button a very small range of max. 2 mm was chosen.

Results

While testing the RFID module the read distance of the scanner highly depended on the part structure. Additionally, there's a significant difference between embedded and surface mounted transponders. In the following Table 1 some exemplary results of the measurements of the maximum system range were shown. Hereby different orientations of the part and several positions in the antenna field were tested.

Table 1. Maximum system ranges

	Object	Min. Distance	Max. Distance
On-Metal Transponder	Screwdriver	35 cm	39 cm
	Frame	37 cm	44 cm
In-Metal Transponder	Trial tibia plateau	19 cm	23 cm
	Alignment block	27 cm	29 cm
	Trial femur	34 cm	39 cm

The maximum range of the tested parts is between 19 and 44 cm. Thereby it matches the required distance of minimum 10 cm. To enlarge the interrogation zone, it would be possible either to deliver more power to the system or using more antennas with the help of a multiplexer [8]. The difference of the ranges occurs because of the circular polarized antenna and its nearly helical electromagnetic field. Therefore, the horizontal position of the transponder changes the range of detection. In some cases, it happened that no signal could be detected – this was caused by the solid structures of some instruments. In these cases, the part needed to be turned by a few degrees.

By testing the barcode scanner there was no significant deviations from the given values. The range of capturing 5 mil Data Matrix codes was between 43 and 115 mm. For a 10 mil code a range of almost 180 mm was measured. This enables a wide range detection of different barcodes for the scanner.

Also the tests of the additional electronic modules showed no problem with the single modules.

Conclusion

The first tests of the developed modules already provide positive results. Further tests for of the finished prototype need to be executed. It's also important to match the legal requirements for electrical systems in an operating theatre to prevent possible influences on other devices. Past studies of the Food and Drug Administration (FDA) [9,10,11] show that frequencies in lower bands like 134 kHz or 13.56 MHz can cause serious errors in implanted and external medical devices. For the used frequency of 868 MHz several errors in peripheral devices like pumps and defibrillators occurred. For that reason, a much higher frequency should be used. Thereby the influence to the surrounding environment would be minimized. By using higher frequencies, the size of the transponders could be decreased significant. In that way RFID transponders could be also used for small devices. One approach is to use a frequency of 5.8 GHz. This would also enable a transponder reading out of a sterile container which isn't possible with the current used frequencies because of the too large wave lengths.

The electronic identification method with RFID may provide the highest amount of data but it's not desired to be used in non-trial implants or small parts which would be influenced by the mounting. Furthermore, it is very important to use a sterile adhesive foil to cover the scanner without influencing the barcode scanner in a significant way. Alternative an additional sterile housing could be designed which could be autoclaved after a surgery. Because of the high costs and time consumption the concept of covering the scanner with a foil is more practicable.

In general, the development of an instrument and implant scanner for medical use can increase the safety in the daily routine of a hospital and decrease the time of choosing the right part. Furthermore, additional product information can support the traceability and allow an easy overview for maintenance intervals.

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REFERENCES

[1] GS1, GS1 DataMatrix Guideline, Overview and technical introduction to the use of GS1 DataMatrix, Version 2.3, p. 8-40. http://www.gs1.org/docs/barcodes/GS1_DataMatrix_Guideline.pdf, Last checked on 23.06.2016.

[2] GS1 UK, Department of Health, Application package: Surgical Instrument Traceability, Version 6, p. 8-20, https://www.gs1uk.org/~/media/documents/marketing-documents/surgical_instrument_traceability_guidelines.pdf?la=en, Last checked on 23.06.2016.

[3] Bundesnetzagentur für Elektrizität, Gas, Telekommunikation, Post und Eisenbahnen. Frequenzplan, April 2016, Entry 251006. http://www.bundesnetzagentur.de/SharedDocs/Downloads/DE/Sachgebiete/Telekommunikation/Unternehmen_Institutionen/Frequenzen/Frequenzplan.pdf?__blob=publicationFile&v=9. Last checked on 23.06.2016. .

[4] Finkenzeller, Klaus. RFID-Handbuch. Grundlagen und praktische Anwendungen von Transpondern, kontaktlosen Chipkarten und NFC. 7-th Ed., München. Hanser. 2015, p. 250-271.

[5] Jankowski-Mihułowicz, Piotr; Kawalec, Damian; Węglarski, Mariusz. The Idea of Enhancing Directional Energy Radiation by a Phased Antenna Array in UHF RFID System. International Journal of Electronics and Telecommunications. Vol. 62. No. 2. 2016, p. 115-120.

[6] Xerafy, Dot XS-Autoclavable version, Version 03.04.16, http://www.xerafy.com/userfiles/uploads/datasheets/Autoclavable%20Dot%20XS%20Datasheet.pdf, Last checked on 23.06.2016.

[7] Xerafy, XS Series User Guide, Version 10.12.15, http://www.xerafy.com/userfiles/misc/resources/whitepapers/XS%20User%20Guide_EN%20update%2010.12.15.pdf, Last checked on 23.06.2016.

[8] Jankowski-Mihułowicz, Piotr; Węglarski, Mariusz. Interrogation zone determination in HF RFID systems with multiplexed antennas*. Archives of Electrical Engineering. Vol. 64. No. 3. 2015, p. 459-470.

[9] S. J. Seidman, R. Brockman, B. M. Lewis, J. Guag, M. J. Shein, W. J. Clement, J. Kippola, D. Digby, C. Barber, and D. Huntwork, "In vitro tests reveal sample radiofrequency identification readers inducing clinically significant electromagnetic interference to implantable pacemakers and implantable cardioverter-defibrillators," Heart Rhythm, vol. 7, no. 1, 2010, pp. 99–107.

[10] O. S. Pantchenko, S. J. Seidman, J. W. Guag, D. M. Witters, and C. L. Sponberg, "Electromagnetic compatibility of implantable neurostimulators to RFID emitters", BioMed Eng OnLine, vol.10, no.1, 2011, p.50.

[11] S. J. Seidman, J. W. Guag, "Adhoc electromagnetic compatibility testing of non-implantable medical devices and radio frequency identification," BioMed Eng OnLine, vol. 12, no. 1, 2013, p. 71. 50.