MRsafe - Prototypical Development and Evaluation of a Mobile Application for Healthcare Professionals to Query the MR Compatibility of Cardiac Implantable Electronic Devices

Master Thesis

For attainment of the academic degree of
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Declaration

I declare that I have developed and written the enclosed master thesis completely by myself and have not used sources or means without declaration in the text. Any thoughts from others or literal quotations are clearly marked. This work was not used in the same or in a similar version to achieve an academic grading or is being published elsewhere.

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Place, Date	Signature

Preface

This master thesis is the culmination of an interesting and varied master programme. Without the support of some people, it would have been much more difficult to complete this master programme successfully. Therefore, I would like to take this opportunity to thank all those who have supported me during my studies and in writing this master thesis.

First, I would like to thank the entire Digital Healthcare team at the St. Pölten University of Applied Science for their support and motivation during my studies. Deep gratitude to FH-Prof. Jakob Doppler MSc, who supervised me during the writing of this master thesis. Thank you for your guidance, your valuable input, and your time. I would also like to thank my superiors and work colleagues, whose support made this part-time master programme possible. A big thank you is also due to all the participants of the interviews and the usability test, who provided important input to this master thesis during the user-centered design process. I would also like to thank Prof. Mag. Otto Ernest Gutmann for taking the time to proofread this master thesis.

Furthermore, I would like to thank all the companies and organisations that provided useful information for writing this master thesis. Thank you to the Austrian Institute of Public Health for providing data from the Diagnosis and Service Documentation System, to the Styrian Hospital Society m.b.h. (KAGes) for providing helpful barcodes and to MR:comp GmbH for providing the ASTM International standards and the ISO TS 10974. Additionally, I would also like to thank Koninklijke Philips N.V., Austrian Standards International and ASTM International for giving the permission to reproduce content in my master thesis. A copy of the complete ASTM standards may be obtained from '*www.astm.org*'.

Most of all, I would like to thank my family and friends for their moral support and encouragement during this part-time master programme. Finally, thanks to my fellow students, who I spent two exhausting but enjoyable and educational years of study with.

Abstract

Background: Patients with cardiac implanted electronic devices (CIEDs) still report difficulties in accessing MRI examinations worldwide, despite the first MR conditional pacemaker system become available in 2008 (EU) and 2011 (US). Reasons for this include safety concerns about patient risk.

Purpose: Development and evaluation of a prototypical app to help healthcare professionals find the necessary MRI safety information on CIEDs, so that MRI examinations can be performed safely on patients with cardiac implanted electronic devices.

Methods: In a user-centered design process literature research and expert interviews were conducted to identify and understand the user needs. The interviews also elicited the functional and technical requirements for the MRsafe app. After the prototypical development of the app, a quantitative usability test was performed to evaluate the usability of the app based on task completion rate *(%)* and task time *(min)*.

Results: The usability test shows that the completion rate without using the app has a mean value with a standard deviation of 79*,4% ± 32,7%*, whereas with using the app a completion rate of *99.2% ± 3.2%* was achieved. Similarly, the task time for clarifying the MR compatibility of the given CIEDs without the app was *20:00 min ± 12:55 min*, while with the app it was *00:43 min ± 00:14 min*.

Conclusion: The results of this master thesis suggest that the use of an app to query the MR compatibility of CIEDs can be a good alternative to already existing sources, as an improvement in both completion rate and task time was achieved. Further development of the prototype as well as a larger study could be aimed at.

Kurzfassung

Hintergrund: PatientInnen mit kardial implantierten elektronischen Geräten (CIEDs) berichten immer noch über Schwierigkeiten beim Zugang zu MRT-Untersuchungen weltweit und das, obwohl seit 2008 (EU) bzw. 2011 (US) die ersten MRT-geeigneten Herzschrittmachersysteme verfügbar sind. Ein Grund dafür sind Sicherheitsbedenken hinsichtlich des PatientInnenrisikos.

Ziel: Ziel war die Entwicklung und Evaluierung einer prototypischen App, die das medizinisches Fachpersonal dabei unterstützt, die erforderlichen MRT-Sicherheitsinformationen von CIEDs abzurufen, so dass MRT-Untersuchungen an PatientInnen mit kardial implantierten elektronischen Geräten sicher durchgeführt werden können.

Methode: Im Zuge eines User Centered Design Prozesses wurden sowohl Literaturrecherchen als auch Interviews mit Fachpersonen durchgeführt, um die Bedürfnisse der BenutzerInnen zu erkennen und zu verstehen. Die funktionalen und technischen Anforderungen an die MRsafe App wurden ebenfalls durch die Interviews erhoben. Nach der prototypischen Entwicklung der App wurde ein quantitativer Usability-Test mit Aufgabenszenarien durchgeführt, um die Benutzungsfreundlichkeit der App anhand der Abschlussquote *(%)* und der Bearbeitungszeit *(min)* zu evaluieren.

Ergebnisse: Der Usability-Test zeigt, dass die Abschlussquote ohne Nutzung der App einen Mittelwert mit einer Standardabweichung von *79,4% ± 32,7%* aufweist, während mit Nutzung der App eine Abschlussquote von *99,2% ± 3,2%* erreicht werden konnte. Aus dem Usability-Test geht ebenfalls hervor, dass die Bearbeitungszeit für die Abklärung der MRT-Tauglichkeit der vorgegebenen CIEDs ohne die App *20:00 min ± 12:55 min* beträgt, mit der App hingegen *00:43 min ± 00:14 min*.

Schlussfolgerung: Die Ergebnisse dieser Masterarbeit deuten darauf hin, dass die Verwendung einer App zur Abfrage der MRT-Tauglichkeit von CIEDs eine gute Alternative zu bereits bestehenden Quellen sein kann, da eine Verbesserung der Abschlussquote sowie der Bearbeitungszeit erreicht werden konnte. Eine Weiterentwicklung des Prototyps sowie eine weiterführende, größere Studie könnten angestrebt werden.

List of Abbreviations

AIMD	Active Implantable Medical Devices
app	Mobile Application
B_0	Main Magnetic Field
B_1	High Frequency Field
BPEG	British Pacing and Electrophysiology Group
CIED	Cardiac Implantable Electronic Devices
CRT	Cardiac Resynchronization Therapy
CRT-D	Cardiac Resynchronization Therapy Integrated in a Defibrillator
CRT-P	Cardiac Resynchronization Therapy Integrated in a Pacemaker
dB/dt	Gradient Field
DLD	Diagnosis and Service Documentation of Austrian Hospitals
ECG	Electrocardiogram
FDA	Food and Drug Administration
G	Gauss
GOEG	Austrian Institute of Public Health
G_x, G_y, G_z	Spatial Directions of Gradient Coils
HF	High Frequency
ICD	Implantable Cardioverter Defibrillator
ICM	Insertable Cardiac Monitor
ILR	Implantable Loop Recorder
IMD	Implantable Medical Devices
JSX	JavaScript XML
KAGes	Styrian Hospital Society m.b.h.
LM	Landmark
LV	Left Ventricle
MHz	Megahertz
min	Minutes

MR	Magnetic Resonance
MRI	Magnetic Resonance Imaging
NASPE	North American Society of Pacing and Electrophysiology
params	Parameters
PM	Pacemaker
prop	Property
RA	Right Atrium
res	Response
RF	Radiofrequency
RMS	Root-Mean-Square
RQ	Research Question
RV	Right Ventricle
Rx	Receive Coils
s	Seconds
SAR	Specific Absorption Rate
S-ICD	Subcutaneous Implantable Cardioverter Defibrillator
T	Tesla
Tx	Transmit Coils
UCD	User-Centered Design Process

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1 Introduction

Magnetic resonance imaging (MRI) is a preferred diagnostic imaging modality for many clinical conditions due to the high soft tissue contrast images that can be obtained with very little risk to the patient undergoing the MRI examination. In fact, MRI has a very positive safety profile for most of the general population and provides this diagnostic information using high intensity electric and magnetic fields rather than exposing patients to ionizing radiation and iodinated contrast agents [1]. Nevertheless challenges remain in the area of MRI safety, related to the increasingly rapid MR imaging workflow and time pressures, frequent shortages of radiographers, complex and evolving sources of information including electronic medical records, and complicated patients with an ever-increasing number of implanted devices [2]. Interactions between implantable medical devices (IMDs) and the MR environment can lead to serious injury, device malfunction or, in the worst case, even to the death of the patient. These interactions can be mechanical, such as displacement force and torque, or electromagnetic, such as heating and stimulation. Thus, to avoid such interactions, it is necessary to perform tests to characterize the behavior of medical implants in the MR environment. Simple visual icons and terms need to be provided based on the test results: MR safe, MR conditional, MR unsafe [3]. In particular, the presence of cardiac implantable electronic devices (CIEDs) has historically been considered as an absolute contraindication to MRI due to these potential interactions [4], [5]. In order to make these devices MR compatible, CIEDs have been redesigned and reengineered [6]. However, the transition from MR unsafe to MR conditional CIEDs has been slow, and confusion regarding safe MRI scans for these patients remains [7]. Although the first MR conditional pacemakers became available in 2008 (EU) and 2011 (US) [5], [8], patients with CIEDs still report difficulties in accessing MRI scans worldwide. The most commonly cited reasons are lack of support from cardiology or pacemaker clinics (64%), lack of monitoring equipment (51%), lack of training (45%), lack of scanning capacity (36%), and concerns about patient risk (35%) [9]. With up to 75% of patients with CIEDs expected to have an indication for MRI during their lifetime [7], [10], there is an increasing need to understand and minimize these safety concerns [1]. Therefore, aggregated MRI safety information needs to be provided to healthcare professionals to safely perform MRI examinations in patients with IMDs [11].

1.1 Motivation

In daily routine, when patients with an unclear MR compatible implant, such as CIEDs, show up for an MRI examination, healthcare professionals need to check the uniform labelling and consider whether the device is MR safe, MR conditional or MR unsafe. Although there are sources such as manufacturer information or dedicated websites to check the MR compatibility, this can often take a long time and interfere with the daily MR routine and workflow. Sometimes appointments even must be rescheduled because MR compatibility cannot be clarified in time. In addition, the MR compatibility assessment of CIEDs is extremely complex, as it requires interdepartmental consultation between the referring clinical department, radiology and cardiology, and specific conditions must be met for a safe MRI scan.

1.2 Aim

The aim of this master thesis is to develop and evaluate a prototypical mobile application (app) for healthcare professionals in Austria, especially radiographers, radiologists, and cardiologists, to easily query the MR compatibility of CIEDs, so that all necessary MRI safety information is provided, and MRI examinations can be performed safely in patients with CIEDs.

1.3 Pivotal Questions

Three research questions were posed to be answered in this master thesis, based on the problems stated above:

RQ 1: What kind of information from cardiac implantable electronic devices is necessary to ensure a safe MRI examination?

RQ 2: What are the functional and technical requirements for the mobile application to support healthcare professionals in determining the MR compatibility of cardiac implantable electronic devices?

RQ 3: What are the task completion rate and task time as usability metrics when testing a prototypical service for assessing the MR compatibility of cardiac implantable electronic devices?

1.4 Method

The method used for the prototypical development and evaluation was a user-centered design (UCD) process, a mixed method with qualitative and quantitative approaches *(Figure 1)*. The UCD method is about accurately assessing the needs of end users and designing systems that focus on meeting those needs [12].

First, a literature review was conducted to identify user needs by examining the state of the art in CIED construction, basic principles of MR imaging, general implant testing and labelling, and MRI safety regulations and logistics *(Chapter 2)*. Qualitative expert interviews were then conducted to define the requirements for the app and to ideate possible features. In addition, the expert interviews were used to confirm the user needs identified in the literature research *(Chapter 3)*. Next, a prototype was designed and developed, including an appropriate front-end visualization and a fitting back-end management. React Native was used for the front-end, Airtable as the database for the back-end management and the Fetch API for networking *(Chapter 3)*. Finally, a quantitative usability test with three task scenarios was performed to evaluate the prototype. In each task scenario, the healthcare professionals had to research the MR compatibility of a given CIED, in one case without using the app and in another case using the app *(Chapter 4)*.

The Ethics Committee of the Province of Lower Austria has stated that there is no requirement for this study to be submitted to an Ethics Committee.

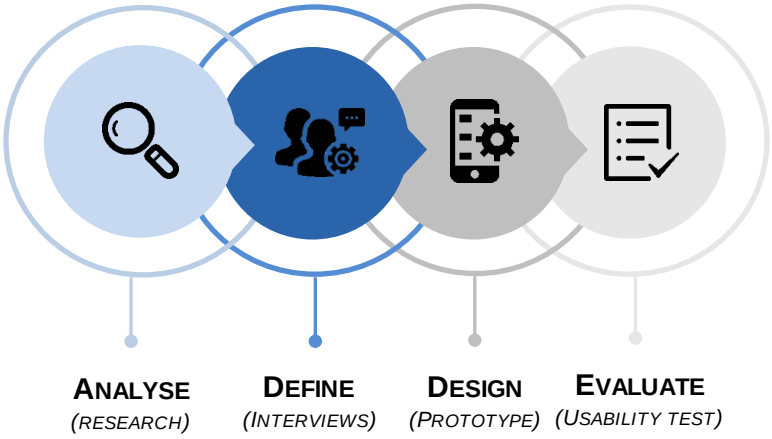

Figure 1: User-centered design method

2 Background of CIEDs and MRI

In the past, the presence of cardiac implantable electronic devices (CIEDs) was considered as an absolute contraindication to MRI examinations [4], [5], [8], [10], [13]. The reasons for this were the potential interactions between the CIED and the static magnetic field gradient, the radiofrequency fields and the gradient magnetic fields of the MRI [10]. However, manufacturers are increasingly aware that patients with CIEDs require the diagnostic power of MR imaging, and therefore design and testing for the MR environment is becoming a common practice in the development of novel active implanted medical devices (AIMDs) [4]. In 2008 (EU) and 2011 (US), the first MR conditional pacemaker system became available [5]. Thus, over a period of years, CIEDs have evolved from being a complete contraindication in the MR environment to no significant risks for MR conditional CIEDs in controlled situations [7]. Accurate identification of the CIED model is necessary to ensure that the most current conditions for safe MRI scanning are used [4].

2.1 Cardiac Implantable Electronic Devices

Cardiac implantable electronic devices (CIEDs) are active implantable medical devices (AIMDs) that are essential for the diagnosis and treatment of a variety of cardiac conditions [13], [14].

Diagnostic

The implantable loop recorder (ILR), also known as insertable cardiac monitor (ICM), is a minimally invasive CIED for non-therapeutic purposes [15], [16]. It is a device used to diagnose heart rhythm disorders and is implanted subcutaneously. These devices continuously monitor the heart rhythm and can record and store ECG snapshots in the event of brady- or tachyarrhythmias [16].

Treatment

CIEDs provide a lifesaving therapy for the treatment of bradyarrhythmias, tachyarrhythmias, and heart failure. There are generally three main classes [13]:

- Pacemakers (PM)
- Implantable cardioverter defibrillators (ICD)
- Cardiac resynchronization therapy devices (CRT)

A PM detects cardiac activity and delivers the necessary electrical impulses to the heart to regulate slow heart rates or irregular heart rhythms and is mostly used for symptomatic bradyarrhythmias. An ICD is a device that contains both pacing and defibrillation components. It can deliver a high-energy shock to treat life-threatening arrhythmias, most commonly ventricular tachyarrhythmias. CRT is an important treatment option for patients with systolic heart failure and is also known as biventricular pacing. It consists of simultaneous stimulation of the right and left ventricles and can be integrated into either a pacemaker (CRT-P) or an ICD (CRT-D) [8], [13], [17].

CIEDs used for treatment can have two different implementation systems: transvenous and epicardial. Transvenous systems are implanted percutaneously and are placed in the infraclavicular region of the anterior chest wall. Epicardial systems are placed in the upper part of the abdominal free wall and require invasive surgery. Thus, epicardial systems have mainly been replaced by transvenous systems and are only used when transvenous placement is not possible or contraindicated. In response to the limitations of these systems, novel systems have been developed that are more minimally invasive, such as leadless pacemakers and subcutaneous ICDs (S-ICD) [15], [17].

2.1.1 CIED Construction

The implantable loop recorder is a small, leadless box and has two self-contained electrodes [18]. All other conventional CIED systems consist of a pulse generator and one to three leads that transmit electrical impulses to the heart and receive cardiac signals [15], [17]. In addition, these CIEDs can be programmed in different modes to target a specific type of arrhythmia, depending on the patient's needs [7].

Pulse Generator

There are generally two types of pulse generators: pacemakers and defibrillators. The pulse generator contains a battery, a circuitry, a can, an antenna, a reed switch, and connectors. The circuitry has a microprocessor that controls the sensing, telemetry, output, and diagnostic circuits [17]. Reed switch sensors are only used in some MR unsafe CIEDs and have been replaced by hall sensors in the MR conditional CIEDs [7]. The connectors are used to connect the leads to the pulse generator and the antenna is used to communicate with the programmer. All components have a can that acts as a conductor and keeps out body fluids. Defibrillators have additional components, including high-voltage capacitors to store energy, a high-voltage transformer to convert the low battery voltage to high voltage, activity sensors, and audible alarms [17].

Leads

The leads are bi-directional wires that detect intrinsic cardiac activity and deliver electrical pulses to the heart. Transvenous leads have an active or passive fixation mechanism at the distal tip to anchor the leads to the myocardium and are connected to the pulse generator at the proximal end. Epicardial leads are surgically attached to the epicardial surface of the heart. ICD leads also have 1-2 shock coils integrated into the lead body to allow defibrillation [8], [13], [17].

The number of leads in a transvenous system depends on the type of CIED. Devices with a single lead are called single-chamber pacemakers or ICDs, and the lead is usually implanted in either the right ventricle (RV) or the right atrium (RA). Devices with two leads are called dual-chamber pacemakers or ICDs, and the leads are usually implanted in both the right ventricle (RV) and the right atrium (RA). CRT uses a third lead, usually implanted in a ventricular branch of the coronary sinus, to detect the left ventricular (LV) epicardium at the same time as the right ventricular (RV) activation, thereby improving the synchronization between right and left ventricular contractions. These triple-chamber devices are called CRT-P or CRT-D [8], [17].

Modes

There are specific codes to describe the basic functions of various implantable pacemakers and defibrillators:

- NBG: A five-letter code used for pacemakers
- NBD: A four-letter code used for defibrillators

In 1974, a three-letter code was first proposed by a combined task force of the American Heart Association and the American College of Cardiology and was subsequently revised by the North American Society of Pacing and Electrophysiology (NASPE) and the British Pacing and Electrophysiology Group (BPEG). The current codes were published in 1987 and updated in 2001. Each letter position represents a specific category, and each letter has a specific meaning *(Table 1, 2)* [17], [19].

First position Chamber(s) Paced	**Second Position** Chamber(s) Sensed	**Third Position** Response to Sensing	**Fourth Position** Rate Modulation	**Fifth Position** Multisite Pacing
0 = None	0 = None	0 = None	0 = None	0 = None
A = Atrium	A = Atrium	T = Triggered	R = Rate modulation	A = Atrium
V = Ventricle	V = Ventricle	I = Inhibited		V = Ventricle
D = Dual (A + V)	D = Dual (A + V)	D = Dual (T + I)		D = Dual (A + V)
S = Single (A or V)	S = Single (A or V)			

Table 1: NBG Pacemaker Codes, adapted from [19]

First position Shock Chamber(s)	**Second Position** Antitachycardia Pacing	**Third Position** Tachycardia Detection	**Fourth Position** Antibradycardia Pacing Chamber(s)
0 = None	0 = None	E = Electrogram	0 = None
A = Atrium	A = Atrium	A = Hemodynamic	A = Atrium
V = Ventricle	V = Ventricle		V = Ventricle
D = Dual (A+V)	D = Dual (A+V)		D = Dual (A+V)

Table 2: NBD Defibrillator Codes, adapted from [17]

MR conditional CIEDs have additional pacing modes that can be activated for an MRI scan. These modes are called MR modes and allow the CIED to pace at a controlled rate during the MRI scan [7]. MR modes for MR conditional CIEDs vary from device to device and the manufacturer's instructions should be followed, as there is no standard approach between the different CIEDs. In general, the modes relate to the modification of CIED settings to adapt to the MR environment, so that oversensing and inappropriate therapy is minimised and the restoration of pre-MRI programme states and values is facilitated [6].

2.1.2 Situation Analysis of CIEDs in Austria

The Austrian Institute of Public Health (Gesundheit Österreich GmbH, GOEG) is an institution that is responsible for researching and planning public health in Austria and a competence center for health promotion [20]. According to §45 of the Medical Devices Act, GÖG is authorized to keep a register of pacemakers, implantable defibrillators and loop recorders [21].

The Diagnosis and Service Documentation System (Diagnosen- und Leistungsdokumentationssystem, DLD) regulates the documentation of health-related data in intra- and extramural outpatient and inpatient care as well as the processing of patient and service provider data in pseudonymized form in Austria. The DLD is based on the Federal Act on Documentation in the Health Care System [22].

Data from the DLD on CIEDs were provided by the GOEG by email with the permission to use it in this master thesis [23]. The data cover following CIEDs:

- Cardiac monitors (ICM)
- Cardiac pacemakers (PM), single chamber system
- Cardiac pacemakers (PM), dual chamber system
- Systems for cardiac resynchronization therapy (CRT-P)
- Automatic cardioverter defibrillators (ICD)
- Automatic cardioverter defibrillators with cardiac resynchronization function (CRT-D)

Analysis of these data shows that the number of new CIED implantations in Austria was on average around 8,700 per year between 2010 and 2021, with an upward trend. The exception to this upward trend is the year 2020, which is due to the Covid 19 pandemic *(Figure 2)*. It is also evident that an increasing number of newly implanted CIEDs are MR conditional, while the number of newly implanted CIEDs that are MR unsafe is decreasing in Austria. In 2021 the ratio was approximately 3:1 *(Figure 3)*.

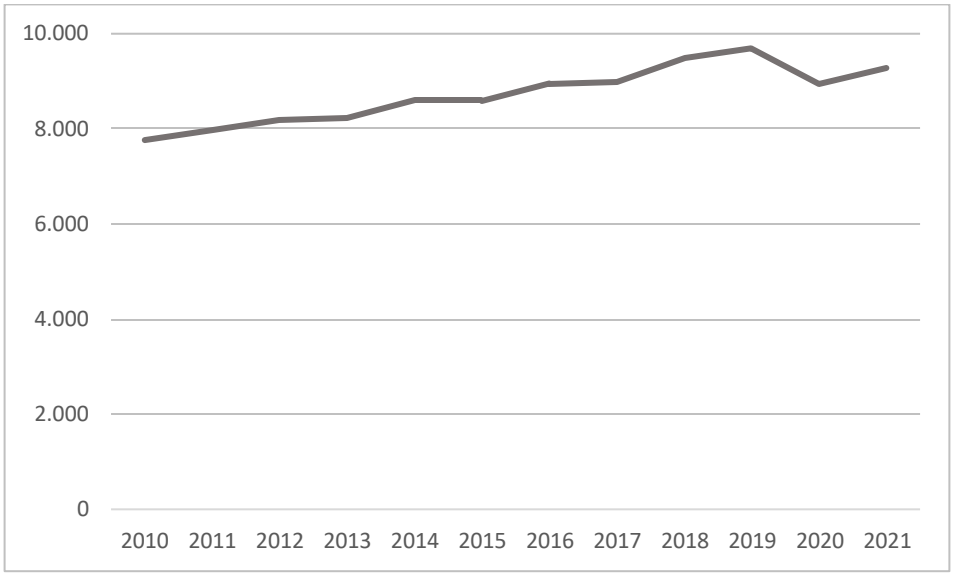

Figure 2: Trend in new implantations of CIEDs in Austria from 2010 to 2021

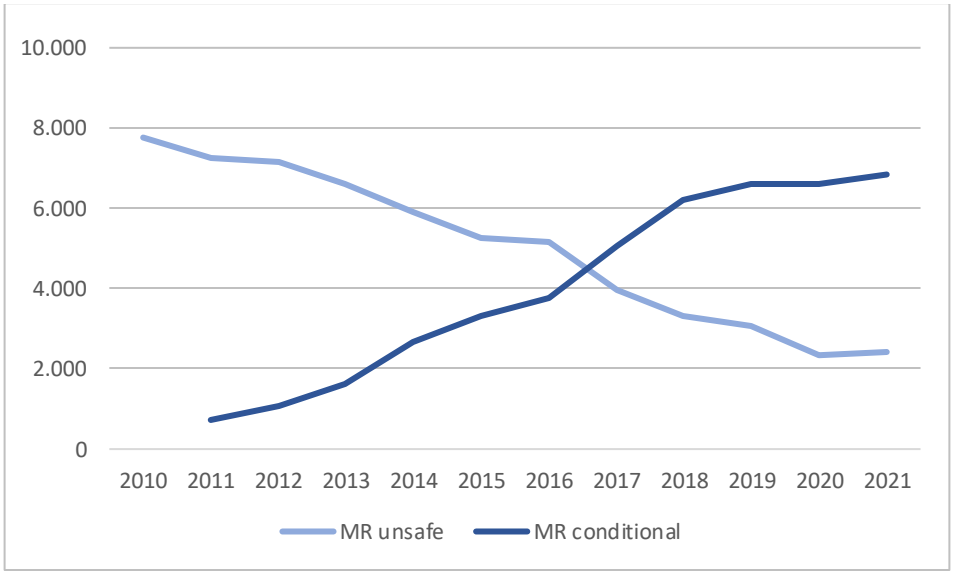

Figure 3: Course of new CIED implantations in Austria from 2010 to 2021 considering the MR compatibility of the CIEDs

The DLD data also show that the number of generator changes in Austria was on average around 2,750 per year between 2010 and 2021. There is no clear trend *(Figure 4)*. In 2020, there were almost as many generator changes for MR conditional CIEDs as for MR unsafe CIEDs. However, the trend in generator changes for MR conditional CIEDs is increasing, while the number of generator changes for MR unsafe CIEDs is decreasing *(Figure 5)*.

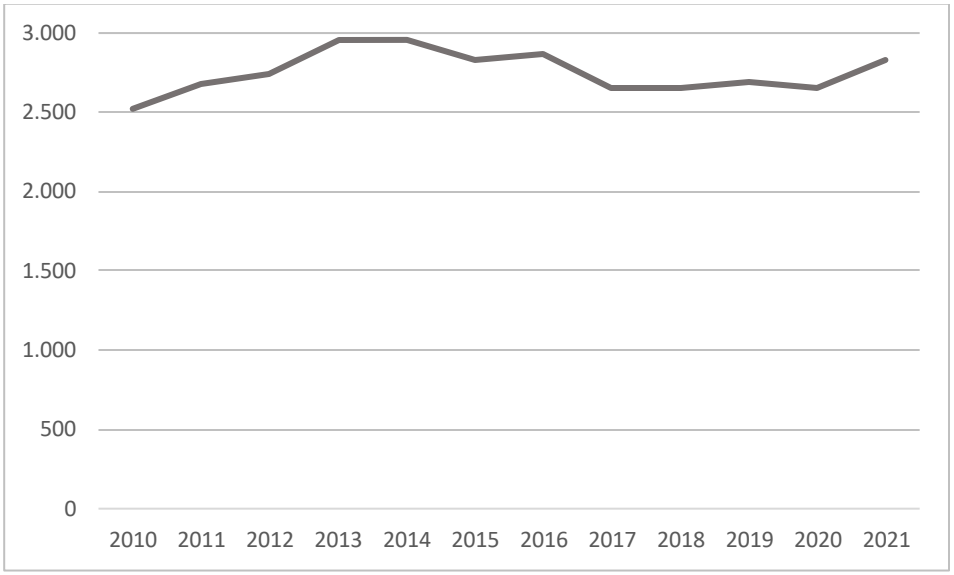

Figure 4: Trend in generator changes of CIEDs in Austria from 2010 to 2021

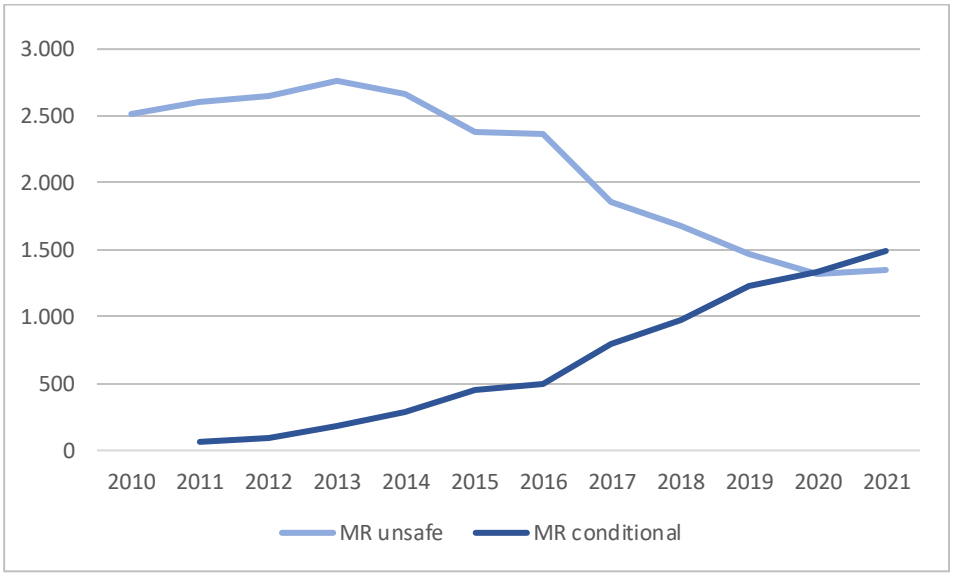

Figure 5: Course of CIED generator changes in Austria from 2010 to 2021 considering the MR compatibility of the CIEDs

2.2 Basic Principles of MR imaging

In general, MR imaging uses three different types of electromagnetic fields:

- Main magnetic field *(B_0)*
- Gradient magnetic field *(dB/dt)*
- Radiofrequency magnetic field *(B_1)*

CIEDs can interact with these fields during an MRI scan which can raise potential safety concerns related to CIED damage or patient risk *(Figure 7)* [7], [10], [24].

2.2.1 Main Magnetic Field (B_0)

The main magnetic field (B_0) is generated by a superconducting magnet in the MR system and is a static magnetic field that is always active. The B_0 strength is measured in units of Tesla (T) or Gauss (G), where 1T is equal to 10,000G. It is typically 1.5T or 3T for clinical MRI scanners [7], [25].

Physical forces, such as translational forces and torque, are the cause of adverse interactions between CIEDs and the B_0. These physical forces have the potential to cause movement or displacement of the CIED and may result in patient discomfort. Translational forces are proportional to the spatial gradient of the magnetic field (T/m), which is greatest near the opening of the bore. As moving closer to the center of the MR, the translational forces decrease and the torque increases *(Figure 6)*. The torque is greatest at the center of the MR and is related to the strength of the magnetic field. The main concerns regarding translational forces and torques relate to the components in the pulse generator. However, the tissue around the implanted pulse generator can help to hold the device in place [1], [7].

Another potential interaction between CIEDs and the B_0 are a device or reed switch malfunction [10]. Exposure of a CIED to the B_0 can result in a device reset, a reprogramming, a magnetic remanence, a battery drain, or a permanent damage [24]. Reed switch sensors are components inside of some MR unsafe CIEDs and allow the CIED to be programmed by placing a magnet over it [10]. Thus, the interaction between the CIED and the MRI scanner can lead to an erroneous activation of the sensor. This can lead to incorrect pacing or inhibition of therapy [7].

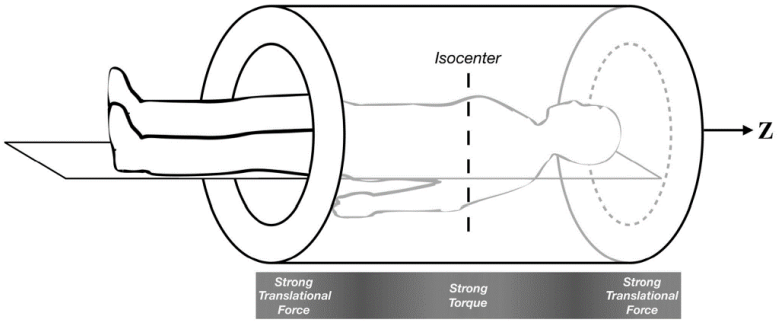

Figure 6: Physical forces exerted by the B_0 field within the scanner bore, reprinted [7]

2.2.2 Gradient Magnetic Field (dB/dt)

The gradient magnetic fields are time-varying and active during MR imaging. Gradient coils are used for spatial encoding of images (G_x, G_y, G_z) in MRI. The slew rate defines the speed at which a gradient can be switched on and ranges from 100 to 200 T/m/s [7], [24]–[26].

By rapidly turning the gradient magnetic field on and off, a time-varying electric field is generated that can induce electric currents. In leads, these currents can lead to peripheral nerve stimulation with or without the presence of a CIED [7]. The currents may also be induced in conductive enclosures and other conductive internal surfaces of a CIED, which can result in heating of the device. A time-varying magnetic moment that interacts with the static magnetic field (B_0) is also generated by the induced eddy currents. This interaction can lead to a vibration of the conductive surfaces and consequently to a vibration of the device. Potential harm to the patient results from possible breakage of the device, which may lead to compromised functionality or failure of the therapy [24], [27].

Exposure to the gradient magnetic field may also cause failure to deliver the intended therapy, inappropriate tracking, memory corruption, or temporary or permanent loss of device programmed settings [1], [24].

2.2.3 Radiofrequency magnetic field (B_1)

The radiofrequency (RF) field or high-frequency (HF) field is also a time-varying field and is used to generate the MRI signal by exciting the hydrogen protons. It has magnetic field strengths of approximately 64 MHz at 1.5T and 128 MHz at 3T. Radiofrequency coils are used to transmit RF pulses and receive the signal back from the patient's body and can be transmitter (Tx), receiver (Rx), or combined transmitter-receiver (Tx/Rx). The interactions between a CIED and the RF field of the MRI are the most complex and significant ones [7], [25], [26].

RF pulses used in MRI generate electric fields. In the setting of electromagnetic coupling with induced RF fields, significant heating can generally occur. Highly conductive and long components, such as CIED leads, may also act as antennas. Additionally, RF energy may be deposited in body tissues. This can lead to tissue damage at the heart to lead tissue interface. Such damage may alter the pacing threshold of a patient with a CIED, cause loss of capture or induce arrythmia. Especially fractured, epicardial and abandoned leads may be susceptible to heating. The amount of RF energy delivered is measured by the specific absorption rate (SAR) and is expressed in W/kg [1], [7]. Examinations at two SAR levels are approved by the Food and Drug Administration (FDA):

- Normal operating mode *(≤ 2 W/kg whole-body SAR)*
- First-level operating mode *(≤ 4 W/kg whole-body SAR)*

SAR, however, is dependent on the patient's height, weight, age, and gender. An alternative way of estimating the applied RF energy is the time-averaged (root-mean-square) RF magnetic field (B_{1+RMS}). This depends only on the MRI exam parameters and not on the patient-specific ones and is expressed in µT. Nevertheless, SAR and B_{1+RMS} are only a means of estimating the whole-body deposited RF energy and do not estimate the actual thermal energy at the lead-tip of the CIED [7].

RF exposure to CIEDs may also result in failure to deliver the intended therapy, reprogramming and resetting of the device, permanent damage, or stimulation of tissue caused by RF rectification [24].

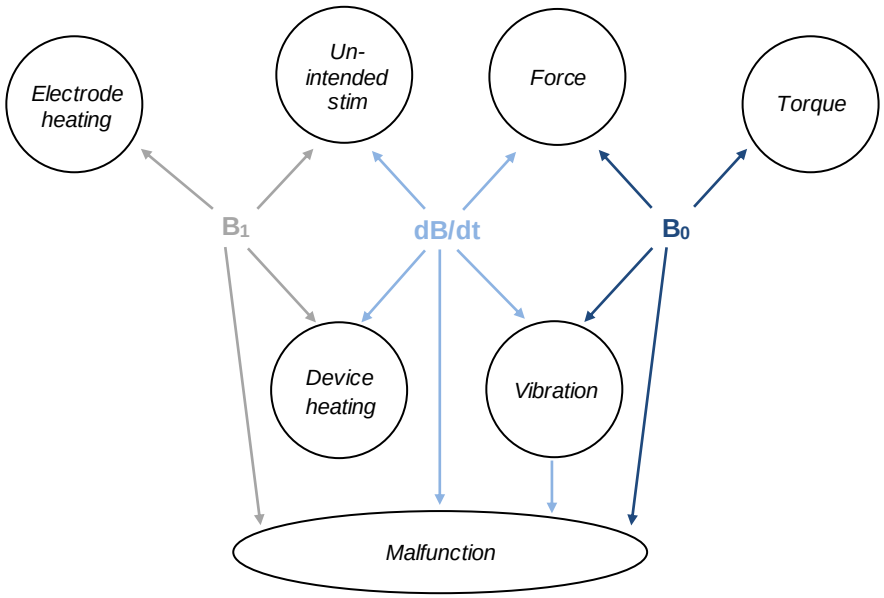

Figure 7: Potential interactions of CIEDs with magnetic field components of an MRI, adapted, with permission from [27]

2.3 MR Testing and Labeling

Magnetic resonance compatibility is an important issue for all medical active and passive implants [28]. Interactions of such implants with the MR environment can result in serious injuries or even in the death of patients or other individuals. These interactions can have direct (mechanical, electromagnetic, or acoustic) or indirect (malfunction of implants) causes. To avoid these interactions, it is necessary to perform tests to characterize the behaviour of a medical implant in the MR environment. These tests are performed according to the ASTM International standards and the ISO TS 10974 *(Table 4)*. Additionally, based on the results of the tests, simple visual icons and terms must be provided directly on the patient information card or in the labeling to prevent injuries and other mishaps. For this purpose, a uniform system for labeling conditions is specified: MR safe, MR conditional, and MR unsafe *(Table 3)* [3].

MEANING	ICON GEOMETRIC SHAPE AND APPEARANCE	
MR safe	*A square*	
MR conditional	*An equilateral triangle with radiused outer corners*	
MR unsafe	*A circle with diagonal bar*	

Table 3: MRI safety terminology, adapted, with permission from [3]

MR safe implants pose no known hazards resulting from exposure to an MR environment and are made of materials that are electrically non-conductive, non-metallic, and non-magnetic. MR conditional implants are safe in an MR environment if certain conditions are met, including conditions for the static magnetic field, the gradient fields, and the radiofrequency fields. MR unsafe implants, on the other hand, pose an unacceptable risk to the patient, healthcare professionals, or other persons in the MR environment [3].

Generally, testing for medical implants that may be placed in the MR environment should consider magnetically induced displacement force *(Test Method F2052)*, RF heating *(Test Method F2182)*, and magnetically induced torque *(Test Method F2213)* for passive implants. Active implants are tested according to *ISO TS 10974* [3]. All test methods use the SI units as the standard units. No other units of measurement are included [3], [29], [30].

POTENTIAL HAZARD	INTERACTION WITH FIELD COMPONENTS	TEST METHOD
Force	Static magnetic field (B_0)	*ASTM F2052*
Torque	Static magnetic field (B_0)	*ASTM F2213*
Heating	Radiofrequency field (B_1)	*ASTM F2182* *ISO TS 10974*
	Gradient field (dB/dt)	*ISO TS 10974*
Vibration	Gradient field (dB/dt)	*ISO TS 10974*
Unintended Stimulation	Gradient field (dB/dt) Radiofrequency field (B_1)	*ISO TS 10974*
Malfunction	Static magnetic field (B_0) Gradient field (dB/dt) Radiofrequency field (B_1) Combined field test	*ISO TS 10974*

Table 4: Potential hazards due to interaction with the field components and its associated test method, adapted from [24], [27]

2.3.1 ASTM F2052 – Magnetically Induced Displacement Force

This test method should be performed in a horizontal bore MR system with the static magnetic field horizontal and parallel to the bore of the MR system. It involves measuring the magnetically induced displacement force generated by the static magnetic field gradients on medical implants. For testing, a fixture consisting of a sturdy nonmagnetic structure containing a protractor with 1° graduated markings is used. A passive medical implant is suspended from a string attached to the 0° indicator on this fixture in an MR system near the entrance to the bore and on the bore axis *(Figure 8).* The weight of the string should be less than 1% of the weight of the medical implant. To increase the sensitivity of the measurement, it is important to choose the test location so that the spatial gradient of the field strength ∇B = dB/ds is within 20 percent of the maximum value of the spatial gradient on the axis of the bore. To obtain a result, the angular deflection of the string from the vertical is measured *(Figure 9)*. If the deflection α is less than 45°, the deflection force caused by the magnetic field of the MR system is less than the force applied to the device by gravity. Under this condition, it is assumed that the risk posed by the application of the magnetically induced force is not greater than the risk posed by normal daily activity in the Earth's gravitational field. The measurement should be repeated at least three times for each tested device. For devices with low mass, it could be useful to test multiple devices simultaneously to increase the mass of the test device. Implants that cannot be suspended from a string cannot be tested by this method [29].

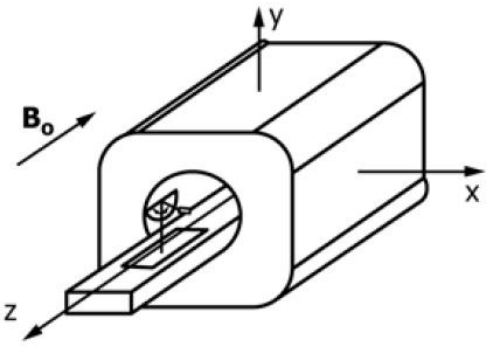

Figure 8: Displacement force test fixation on the patient table of an MRI scan, reprinted, with permission from [29]

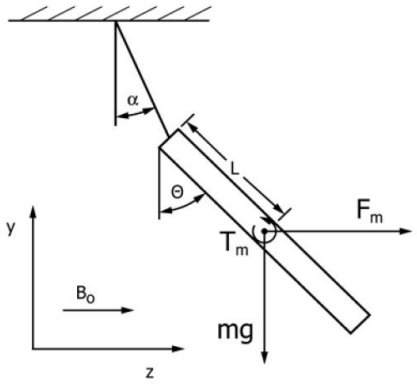

Figure 9: Displacement force test device in the magnetic field, reprinted, with permission from [29]

2.3.2 ASTM F2182 – Radiofrequency Induced Heating

This test method can be performed within an MR or several other RF exposure systems, including Volume RF transmit coils. The used RF exposure system must be properly characterized in terms of local background RF exposure. It involves measuring radiofrequency-induced heating at or near a passive medical implant in a phantom during magnetic resonance imaging. The amount of RF-induced temperature rise (ΔT) depends on the RF frequency. The RF frequency in turn depends on the static magnetic field strength of the MR system (1.5T or 3T). For testing, a passive medical implant is completely placed in a phantom filled with a suitable medium with RF physical properties corresponding to the average properties of the human body (e.g.: gelled saline). The medical implant should be placed in a location where the local background RF exposure is known. Three temperature probes should be placed where the maximum local ΔT is expected. In addition, a temperature reference probe should be placed at least 30cm away from the medical implant *(Figure 10).* Then the phantom is placed in an MR system or RF test system and subjected to a well-controlled RF exposure of sufficient strength and duration to establish a local RF background exposure in the testing location for the implant, measured with an appropriate sufficient signal-to-noise ratio. To get a result, the test procedure is divided into two steps: First, ΔT is measured at or near the medical implant at several locations using the three fibre-optic thermometry probes placed in the phantom. In addition, ΔT is also measured at the reference location. Secondly, the implant is removed and temperature measurements with the temperature probe or electric field measurements with the E-field probe are repeated at the same locations and under the same local background RF exposure as before. The temperature from

each temperature probe must be recorded at least once every 2s. After the RF exposure is turned off, the temperature monitoring and recording should be continued for at least two additional minutes to ensure that RF exposure is indeed the cause of the observed temperature rise *(Figure 11)* [30].

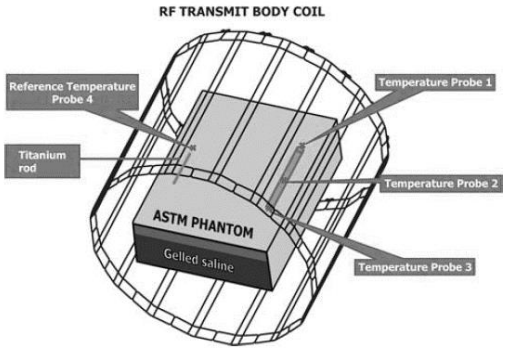

Figure 10: Example apparatus used for testing of RF-induced heating, reprinted, with permission from [30]

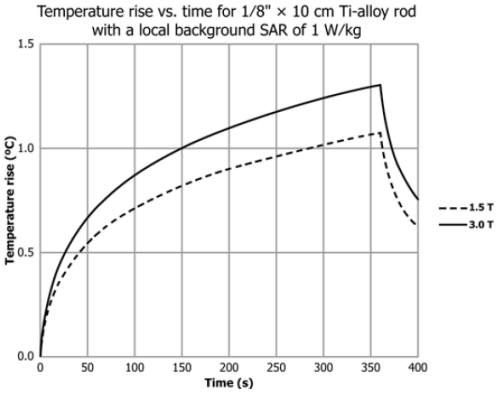

Figure 11: Calculated ΔT at temperature probes for RF-induced heating, reprinted, with permission from [30]

The method allows a characterization of the heating tendency of an implant rather than a prediction of heating during a particular MR procedure in a patient. The results can be used as input to a computational model for estimating ΔT due to the presence of the implant in a patient. The safety of the patient can then be assessed by combining the results of the test and the computational model. A medical implant the dimensions of which are less than 2cm in all directions may not need to be tested for RF-induced heating because it is expected to generate ΔT of less than 2°C during a 1-hour exposure to 1.5 T/64-MHz or 3 T/128-MHz frequencies [30].

2.3.3 ASTM F2213 – Magnetically Induced Torque

This test method is applicable to MR systems with a horizontal magnetic field. It considers the magneto-static torque generated by the interaction of the MRI static magnetic field (B_o) with the magnetization of the implant. The dynamic torque and the torque in lead wires are not addressed within this method. For testing, the medical implant should be sterilized, except sterilization is expected to affect the relevant properties of the medical implant. The test sample should be worst-case for the medical implant during the test. Mass, linear dimension and material magnetic susceptibility should also be considered for the testing. Testing should be performed with each principal axis of the test implant aligned parallel to the static magnetic field of the MR system except if there is a reason for a specific

worst-case orientation. This standard specifies five methods for measuring or evaluating the magnetically induced torque: the Torsional Spring Method, the Pulley Method, the Low Friction Surface Method, the Suspension Method, and the Calculation Based on the Measured Displacement Force Method [31].

The Torsional Spring Method: This method determines the magnetically induced torque using a torsion pendulum. The material of the apparatus for this test method should be non-ferromagnetic. It consists of a sturdy structure with a holding platform that is supported by a torsion spring and an angle measurement tool with 1° increments to measure the angle of rotation of the torsional spring *(Figure 12).* The test implant should be taped or otherwise attached to the holding platform and should be oriented with one of its principal axes in the vertical direction. The entire apparatus is placed in the center of the magnet of the MR system, where the magnetic field is uniform. To get a result, the deflection angle of the holder from its equilibrium position is measured. Therefore, the fixed base must be rotated, and the deflection of the implant must be measured concerning the base at 10° increments for angles between 0° and 360°. For angular values where the angular derivative of the torque changes sign, an abrupt change in deflection angle will occur as the test implant swings to the next equilibrium position. The deflection angle should then be measured as close as possible to this swing. Thus, the maximum magnetic torque can be determined and compared with the worst-case gravitational torque [31].

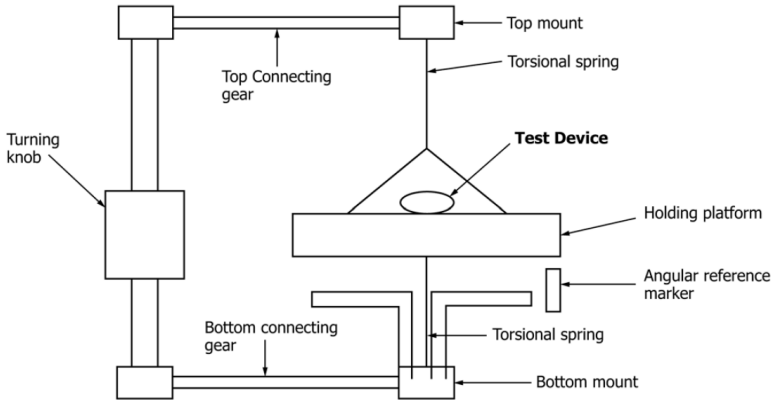

Figure 12: Diagram of a Torsion Spring Apparatus, reprinted, with permission from [31]

The Pulley Method: This method allows the determination of the maximum magnetically induced torque of a medical implant. A low-friction, non-metallic pulley mounted on a rotating platform is used. The medical implant should be fixed on this rotatable platform while positioning it as close as possible to the isocenter of the MR system, where the magnetic field is uniform. The material of the apparatus should be non-ferromagnetic. A lightweight string is attached to the

low-friction pulley and a force gauge with a sensitivity greater than 0.1 *(Figure 13)*. To obtain a result, the platform is rotated 360° by pulling the force gauge in a direct line away from the torque fixture along the z-axis. The maximum force measured during the 360° rotation should be recorded. Then the procedure should be repeated without the medical implant in place. The maximum force measured without the medical implant should be recorded again. This procedure should be repeated at least three times for each orientation of the tested implant. The maximum magnetically induced torque is then calculated by using: $\tau_{magnetic} = r\ x\ (F - F_f)$, where [31]:

$\tau_{magnetic}$ = maximum magnetically induced torque,
r = test fixture pulley radius,
F = maximum measured force with the device, and
F_f = fiction force of rotating platform measured without device

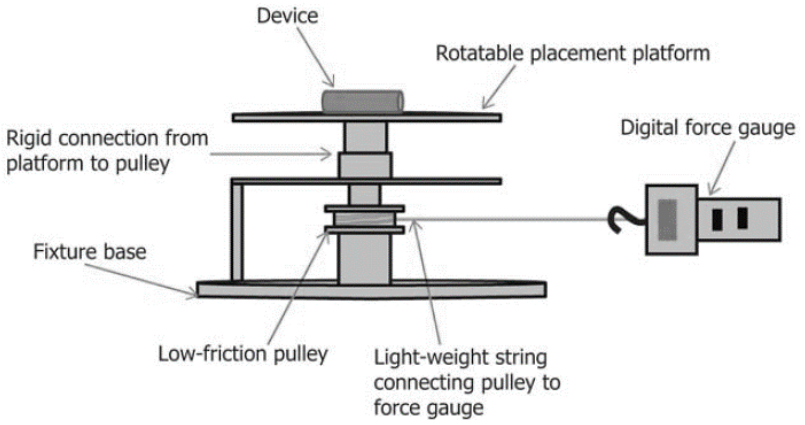

Figure 13: Diagram of a Pulley Torque Apparatus, reprinted, with permission from [31]

The Low Friction Surface Method: The apparatus for this test method consists of a low friction non-metallic and non-conductive surface. The Coefficient of Friction between the medical implant and the Low Friction Surface should be determined outside the MR environment by placing the test implant on the surface. The surface should be raised slowly until the angle of repose *Θ* (= angle at which the device is on the verge of sliding) is reached. With this angle, the coefficient of friction (μ) can be calculated by using $\mu = \tan\theta$ *(Figure 14)*. Afterwards, the test implant should be placed on the low friction surface so that it is positioned on the x-z plane as near as practical to the isocenter of the MR system. In addition, the test implant should be oriented so that one principal axis is aligned in the z-direction. To achieve a result, the test implant must be rotated in 45° increments about the isocenter on the x-z plane until a full 360° of rotation is completed. After each 45° rotation, the alignment or the rotation should be observed. Any motion of the test implant should be recorded. This procedure must be repeated two additional times for the other two principal axes of the test

implant. If a magnetically induced torque is observed and the implant rotates to align with the static magnetic field, then further testing according to the Torsional Spring Method or the Pulley Method should be conducted. For implants where the magnetically induced torque is expected to be greater than the gravitational torque, this method is not suitable [31].

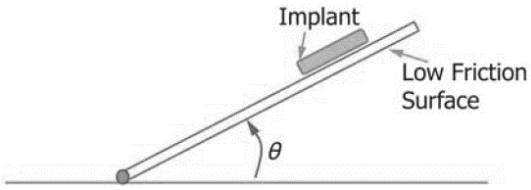

Figure 14: Diagram of the Angle of Repose (Θ), reprinted, with permission from [31]

The Suspension Method: The apparatus for this test method consists of a holding fixture with a lightweight string where the medical implant is suspended. The weight of the string should be less than 1% of the weight of the implant and capable of holding the implant without breaking. Suspension from two points is permitted if the geometry of the implant does not allow a suspension from a single point *(Figure 15).* The test implant must be positioned in a way so that its center of mass is as near as practical to the isocenter of the MR system. To get a result, the test implant is observed for any preferential orientation and is rotated slowly about the suspending spring in the x-z plane in 45° increments until a 360° rotation is completed. Thereby, the implant is moved by applying finger pressure or by twisting the suspension string. After each 45° rotation the procedure should be paused and the alignment or the rotation should be observed. It must be repeated a total of three times for each implant orientation tested. Any motion of the test implant to align with the static magnetic field of the MR system should be recorded. If magnetically induced torque is measured using the Suspension Method, the Low Friction Surface Method, the Torsional Spring Method, or the Pulley Method should be used in addition. This method is used for implants that are difficult to place on a low-friction surface and where the main axes are aligned with the z-axis of the MR system. It may also be used for medical implants where the magnetically induced torque is expected to be less than the torque due to gravity. This method is not suitable for implants where the magnetically induced torque is expected to be greater than the torque due to gravity [31].

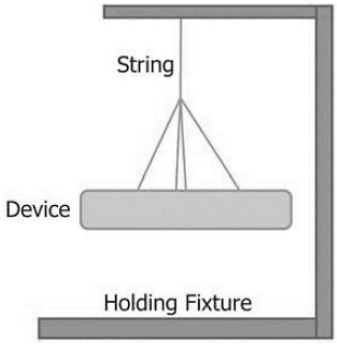

Figure 15: Example apparatus for the Suspension Method, reprinted, with permission from [31]

The Calculation Based on Measured Displacement Force Method: This method provides an upper bound for the magnetically induced torque based on measurements of the magnetically induced force measurements using test method F2052 and is used when the magnetic saturation of a medical implant material is not known. The upper bound of the maximum magnetically induced torque can be calculated based on the magnetically induced displacement force $\tau_{max} = \frac{M_s F_m}{4(\nabla B)}$, where [31]:

τ_{max} = maximum magnetically induced torque (N-m),
Ms = the magnetic saturation of implant (T),
Fm = the measured magnetic force according to Test Method F2052 (N), and
∇B = the spatial gradient magnetic field at the location of the measured magnetic force (T/m)

To calculate the maximum magnetically induced torque two conservative upper methods are given:

- *Method 1* uses the conservative magnetic saturation value of iron, which is (2.2T)[5] in place of M_s: $\tau'_{max} = \frac{2.2 F_m}{4(\nabla B)}$.
- *Method 2* uses the substitution of the largest magnetic saturation value of the material ($M_{s,\,max}$) within the implant in place of M_s: $\tau''_{max} = \frac{M_{s,max} F_m}{4(\nabla B)}$.

Does the upper bound for the magnetically induced torque calculated using Method 1 and/or Method 2 not meet the acceptance criterion, testing should be performed using one or more of the other standard test methods for measuring the magnetically induced torque of medical passive implants [31].

This method is most appropriate for implants which are composed of only one material. However, it can also be used for implants composed of multiple materials. For implants that contain magnets or ferromagnetic material this method is not appropriate [31].

2.3.4 ISO/TS 10974 – Active Implantable Medical Device

The ISO/TS 10974 covers assessment procedures for active implantable medical devices (AIMDs) in relation to vibration, malfunction, unintended stimulation, and heating hazards *(Table 4)*. However, AIMDs must also comply with the ASTM standards discussed earlier [27], [32]. Due to the complexity and scope, the individual assessments for AIMDs of the ISO/TS 10974 are only mentioned and not described in detail in this master thesis.

Heating: Heating can be caused by the RF field (B_1) or the Gradient field (dB/dt). The dB/dt field leads to generator heating, whereas B_1 field can lead to generator and lead electrode heating [24].

B_1: RF-induced heating of the leads depends on the absolute temperature, duration of heating and individual implant considerations. Determining the rise in local tissue temperature due to the interaction of an AIMD with the B_1 of an MRI scanner is a complex process that depends on the design, location, and orientation of the AIMD as well as the MRI scanner technology, patient size, patient anatomy, patient position, and tissue properties. The assessment is sensitive to B_1 RMS and requires two stages to be carried out in a progressive manner:

- *Stage 1:* One of four-tiered approaches are used to estimate the RF power deposition around the AIMD. This approach is designed to accommodate the diversity of AIMDs, and the tiers are arranged in order of increasing complexity of the evaluation method and increasing accuracy of the estimate.
- *Stage 2:* Assessment of the tissue changes or damage due to the in vivo RF power deposition or resulting temperature rise.

There are some limitations to the use of the four-tiered approaches for determining RF power deposition around an AIMD exposed to incident MRI scanner RF fields. Tiers 1 and 2 can only be used for electrically short AIMDs due to phase effects, tiers 3 and 4 are applicable for any AIMD [24], [27].

dB/dt: Generator heating is sensitive to the average or root-mean square (RMS) gradient field amplitude $|dB/dt|$. The test method is measurement-based using an amplifier, a laboratory gradient coil, and a function generator that can simulate clinical gradient field exposure. As an alternative, testing can be performed using a clinical MRI scanner. Two tiers can be used for testing:

- *Tier 1:* Use of conservative waveform shape
- *Tier 2:* Use of clinically relevant waveform shape

All test parameters are set by the AIMD manufacturer to reflect conservative clinical conditions of use, apart from the test duration, which depends on the maximum allowable scan duration as specified on the AIMD label or 30 minutes. The dB/dt induced heating scales strongly with the device radius, so that larger devices heat more. It is not considered a high risk hazard for most AIMDs with extended leads [24], [27].

Vibration: The vibration is sensitive to the B_0 and the gradient dB/dt. The test concept is to subject the implant to prolonged vibration and then evaluate the AIMD performance, since most design failures are caused by fatigue failure of internal components. Testing is measured-based and there are two methods for testing the vibration of AIMD:

- *Method 1:* Use of an MRI scanner
- *Method 2:* Use of a shaker table

Method 1 provides a higher accuracy with an increased testing burden. Method 2 provides conservative approximations and allows reduced test burden after the initial calibration testing in an MRI scanner [24], [27].

The test duration represents the patient's cumulative scanning time over the lifetime of a typical AIMD for a given percentile of the patient population. Larger devices tend to vibrate more which causes a greater likelihood of device damage. For smaller and medium AIMDs as well as non-life-sustaining devices, vibration is not considered as a high-risk hazard. For AIMDs with extended leads that do not have planar conductive surfaces, there is no mechanism for MR-induced vibrations in the leads. Therefore, no MR-induced vibration assessment is required for these leads [24], [27].

Stimulation: Unintended stimulation can be caused by the RF field (B_1) or the Gradient field (dB/dt). In both assessments the device should pass the acceptance criterion established by the device manufacturer [24].

- *B_1:* The assessment for unintended stimulation from RF field-induced rectified lead voltage is similar to the lead electrode heating, but in contrast, it is sensitive to the B_1 peak [24].
- *dB/dt:* The assessment of unintended stimulation from gradient field-induced lead voltage is similar to that for RF field-induced rectified lead voltage but is sensitive to the dB/dt peak [24].

Malfunction: Malfunctions are due to interactions with B_0, B_1, dB/dt. The ISO/TS 10974 describes three methods for testing malfunctions, one method for each MR field:

- *B_0:* Devices are divided into three classes based on expected component behavior. The appropriate test is based on these classes.
- *B_1:* Field levels and induced voltages are determined by a combination of computer modelling and exposure testing. Testing includes radiated or injected RF exposure, depending on the type of the AIMD system.
- *dB/dt:* A combination of computer modelling, and exposure testing is used to determine field levels and induced voltages. The AIMD is tested by radiated field exposure and depending on the type of AIMD, by an additional injected voltage testing.

The acceptance criteria established by the device manufacturer based on the intended functionality should be met after exposure of the implant to each of the three fields [24], [27].

Combined field test: In addition, a combined field test provides an in vitro evaluation of AIMD function under simultaneous exposure to B_0, B_1 and dB/dt conditions. This test is performed in a scanner and exposes the AIMD to representative levels and temporal patterns of all three MR magnetic fields at the same time, in contrast to the maximum exposures normally required. The AIMD is positioned in a media phantom that simulates the tissue and placed in the scanner. Exposure to a series of MRI sequences is performed at different landmarks or simulated patient positions within the bore. Although this test is redundant to device malfunction testing, it is required to ensure that the device is tested in radiated environment under clinical conditions [24], [27].

2.4 MRI safety Regulations and Logistics

The feasibility of MRI in patients with CIEDs has been investigated in several studies. No clinically significant long-term adverse events have been reported, considering both MR conditional and MR unsafe CIEDs, if certain conditions are met. However, the safety of CIEDs in the MR has mostly been documented in 1.5T environments, especially for MR unsafe CIEDs. Further research is required to ensure the safety of both MR conditional and MR unsafe CIEDs in 3T MR environments [1], [5], [7], [10], [33]–[37]. Thus, the studies suggest that MRI can be performed by appropriately trained healthcare professionals with an acceptable risk-benefit ratio if a certain MRI protocol is followed, specific programming of the CIED device is performed, and both CIED parameters and patient symptoms are monitored. The MRI protocol depends on whether the patient has an MR unsafe or MR conditional CIED and should carefully consider safe procedures pre-MRI, during MRI, and post-MRI *(Figure 16, 17)* [7].

In general, the risks posed by MRI are significantly higher for ICD patients than for pacemaker patients, as ICDs have additional electrotechnical components, such as a capacitor to store the energy needed for shock delivery or a transformer to increase the battery voltage *(see chapter 2.1.1)* [26].

2.4.1 Pre-MRI

MRI scans in patients with a CIED require special attention from the referring clinical department as well as from the radiology and cardiology departments. The scan should have clear therapeutic or prognostic implications not available from other diagnostic modalities [37]. The cardiac outpatient department must perform the CIED interrogation to determine whether the pacemaker-specific conditions of use for MRI are fulfilled. Written documentation (checklist) by the attending cardiologist stating that the electrophysiological requirements for the use of the CIED have been met is recommended. The radiology performs verification of the MR-related conditions. Final written documentation (checklist) by the attending experienced radiologist that the MR-related conditions for use of the CIED have been met are recommended as well [26].

Before scheduling an examination of a patient with a CIED, it is necessary to verify whether the entire CIED system, including the pulse generator and the leads, is MR conditional or MR unsafe [5], [8], [26], [37]. Furthermore, there should be no additional leads or devices and no abandoned, epicardial, fractured or extended leads [38]. The patient's medical record, including the patient's implant card, should be available for consultation so that the CIED model and lead type can be identified, and the MR compatibility can be clarified thereby. Some devices or components may also be identified as MR conditional using radiography, as this can reveal radiopaque alphanumeric labels or symbols on the device. Many MR conditional leads, however, do not have such radiographically visible markings. Thus, radiography alone is not always sufficient to determine the MR compatibility or to identify a CIED model, but it may be helpful as a starting point. A recent chest radiography can also help to confirm the absence of broken epicardial and abandoned leads as well as lead extenders. The completeness of the entire CIED systems should be determined by consulting the manufacturer documentation [5], as leads and generators from different manufacturers cannot be mixed, as the MR conditional labeling is only valid for specific generator and lead combinations [1].

It is also important to note the limitations of MR conditional devices [1]. A radiographer should document the specific MRI conditions *(Table 5)* according to the manufacturer of the MR conditional system [37]. MRI safety information

regarding implantable medical devices (IMD) can be found on the device manufacturer's website, the Global Unique Device Identification Database, and the *'MRIsafety.com'* or *'MagResource'* websites. The last two websites are internationally known and very useful for checking the MR compatibility of IMDs. The *'MRIsafety.com'* website provides MRI safety information based on its own research. Its categories for MRI safety information differ from those of the ASTM International standards. *'MagResource'* complies with the ASTM International standards and provides MRI safety information based on the information published by the manufacturers [4], [11].

Patients with CIEDs must also wait for at least 6 weeks after the implantation before undergoing an MRI scan to reduce the effects of torque [6], [7], [10], [26].

Information about recent technical measurements must be available prior the MRI scan [37]. Therefore, pre-MRI battery voltage and threshold measurements must be performed [7], [26], [33]. Measurements should be within the normal range and devices should not be nearing the end of their battery life, as there is an opportunity to switch to a safe replacement mode during the scan [37].

Additionally, the device must be programmed into the MR mode before the MRI scan [1], [5]. This mode is easy to activate and can improve the safety during MRI scans, as the magnetic response of MR conditional CIEDs is automatically switched off when the MR mode is activated. It minimizes the susceptibility to electromagnetic interference and therefore avoids false signals [1], [10], [38].

2.4.2 During MRI

MRI can be performed safely in patients with CIEDs if the technical limitations of MRI scanning are taken into account [37]. These include, for example, lower magnetic field strength (1.5T over 3T), limited local gradient slew rate (< 200 T/m/s) and limited specific absorption rate (2-4 W/kg body weight) [10]. Therefore, radiographers must follow a specific scan protocol to meet the MRI conditions of the device [5]. All parameters and corresponding conditions with their units to be considered while scanning MR conditional devices are listed in *Table 5* [7]. There are additional manufacturer and model specific conditions of use for MR conditional systems to be considered, such as examination time (s or min), cumulative MRI examination time over the lifetime of the system, minimum patient height, exclusion of fever or impaired patient thermoregulation and patient position within the RF coil (LM) [26]. Certain CIED models, for example, cannot be scanned with the isocenter over the thorax. Newer models, however, have no zonal restriction [6].

PARAMETER	CONDITION	UNIT
Main magnetic field (B_0)	B_0 strength	T
	Local spatial magnetic field gradient	T/m
Gradient field (dB/dt)	Slew Rate	T/m/s
Radiofrequency field (B_1)	Specific absorption rate (SAR)	W/kg
	B_{1+RMS}	µT
Miscellaneous	Type of coils (Transmit, Receive)	Tx, Rx
	Imaging restrictions (Landmark)	LM
	Examination time	s or min

Table 5: Parameters and conditions to be followed when scanning MR conditional devices, adapted from [7]

Additionally, the patient must be monitored during the MRI scan by a clinician who is able to recognize and treat an abnormal rate or rhythm [5]. According to the manufacturer, monitoring must include pulse oximetry, ECG, or blood pressure measurement. The use of an MR conditional pulse oximeter is recommended, as ECG recordings are still often affected by significant artefacts and blood pressure measurements do not provide continuous monitoring of the patient [26], [38]. Furthermore, immediate access to resuscitation equipment, including an external defibrillator, must be available in the proximity of the MRI scanner, and the healthcare professionals must be trained in its use [5], [37], [38].

2.4.3 Post-MRI

After the MRI scan, the device should be reset to its pre-MRI settings and technical measurements should be taken. Particular attention should be paid to changes in electrode impedance, sensing, pacing thresholds and battery measurements. In case of significant changes, a longer observation period should be considered [26], [37].

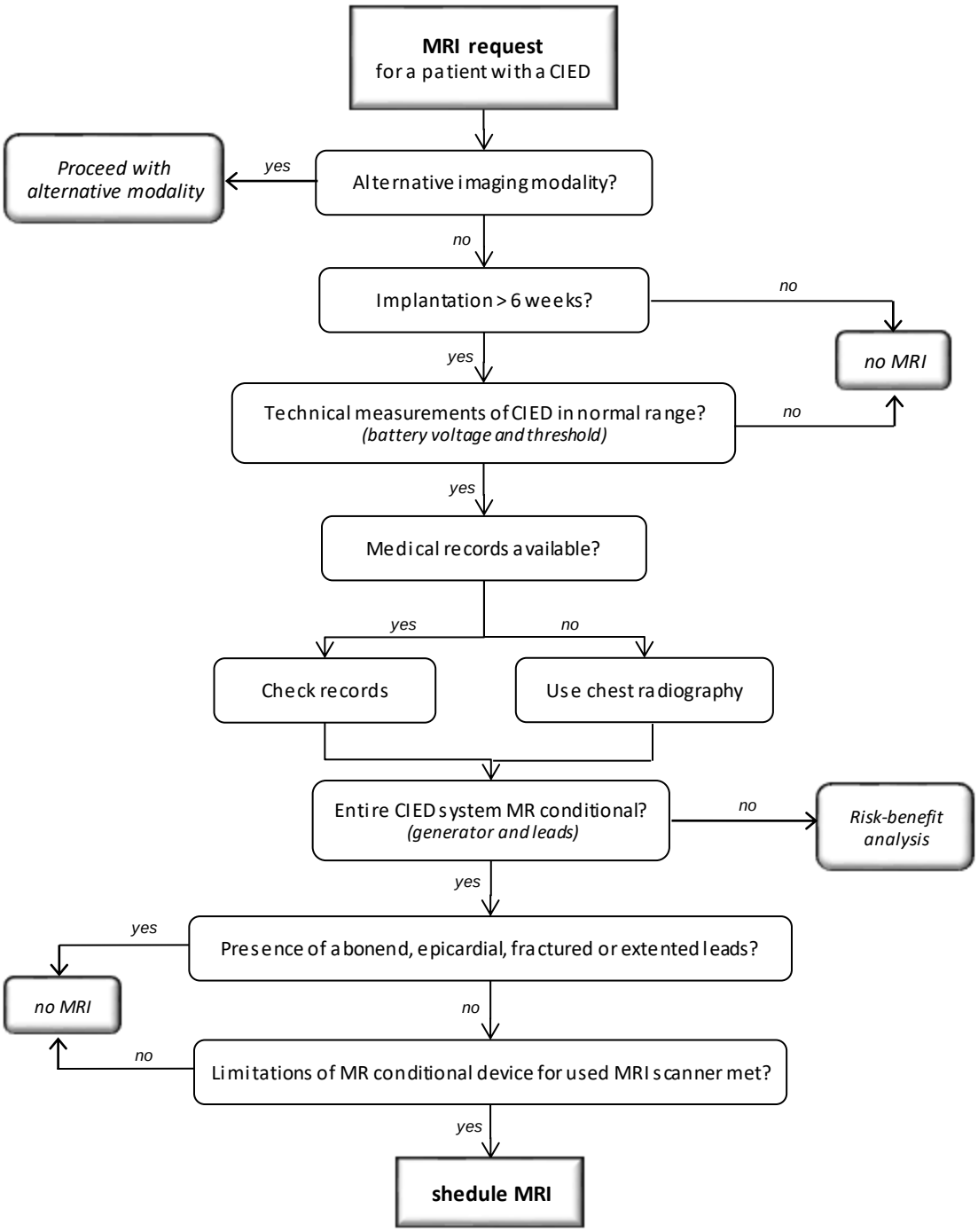

Figure 16: Pre-MRI workflow to assess MRI safety when an MRI for a patient with a CIED is requested

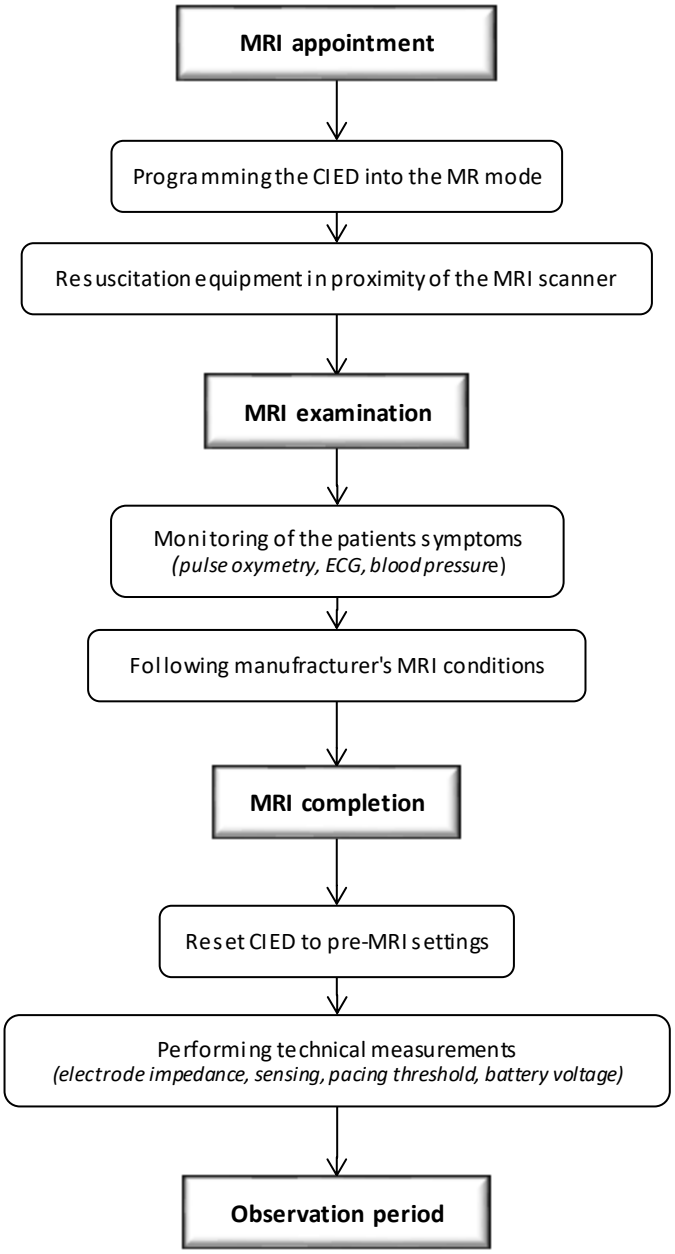

Figure 17: Workflow for performing safe MRI in patients with CIEDs and the post-MRI procedure

3 Development of the Prototypical Mobile Application MRsafe

After identifying and understanding the user needs through literature research, useful requirements, and features for the prototypical mobile application (app) were defined in a user-centered design (UCD) process with the help of experts. For this purpose, expert interviews were conducted. A prototype was then designed and developed using the previously defined requirements. MRsafe was considered as an appropriate name for the prototypical app as it should provide all necessary MRI safety information and should enable safe MRI examinations in patients with CIEDs.

3.1 Expert Interviews

Three semi-structured interviews were conducted in German language in December 2022 using a guideline *(see Appendix: Interview Guideline)* to define the requirements for the MRsafe app and to confirm the user needs identified in the literature research. They were conducted in person in a hospital environment (KAGes) and were recorded with the consent of the experts *(see Appendix: Declaration of Consent)*. A radiographer, a radiologist and a cardiologist were interviewed. All had a completed training and a professional experience of more than 20 years. The participation was voluntary.

To be interviewed, participants needed to meet the following criteria:

- Completed training as a radiographer or specialist in radiology or cardiology.
- At least 2 years of professional experience with MRI (radiology) or CIEDs (cardiology).

The evaluation of the qualitative expert interviews is based on the Mayring method and involves the coding and categorization of the transcript *(see additional materials)*. Four categories were used: CIED specific information (grey background), functional and technical requirements (grey double underlined), other information (black single underlined), and profession (**bold**). Following information is necessary to ensure a safe MRI examination. For the sake of clarity, the results were divided into MR-specific and CIED-specific information.

MR-specific information:

- MR compatibility *(MR safe, MR conditional, MR unsafe)*
- Magnetic field strength *(Tesla)*
- Specific absorption rate *(W/kg)*
- Local spatial gradient *(T/m)*
- Scan mode *(Normal Mode, First Level)*
- Scan time limits
- Exclusion zone

CIED-specific information:

- Function and position of the generator
- Combination of generator and lead(s)
- Number of leads
- Implantation time
- Specific measurements (e.g.: stimulus threshold)

Functional and technical solutions that could be useful for the MRsafe app according to the interviews are listed below:

- Barcode scan
- Search box
- Links to MagResource or other sources
- Checklists (especially for smaller institutes and surgeries)
- MRI technical data sheet (especially if more than one MRI is used)

In general, the interviews also indicated that interdepartmental consultation is important. The experts stated that cardiologists are often responsible for clarifying the general MR compatibility, the CIED-specific information, and the programming of the CIEDs before and after the MRI scan. Radiologists need to carefully clarify the indication and consider alternative modalities. Requesting the specific parameters for the MRI scan is the responsibility of the radiographer.

The experts also mentioned that most of the MRI scans in patients with CIEDs are performed in outpatient clinics, as clarifying the MR compatibility can take up to one hour and should be done in advance. A chest radiography can also be done in advance, as this can help to identify the implanted CIED, as each CIED has a specific design, that can be identified very accurately on a chest radiography.

A special programming device is required to program the CIED into MR mode and back again. This programming is done directly before and after the MRI scan in the outpatient clinic and takes about 5-10 minutes each time.

The interviews also highlighted the need to clarify the general condition of the patient to be examined, as fever is a contraindication to such MRI examinations. To monitor the patient's condition during the examination, pulse oximetry must be monitored during the MRI scan.

3.2 Prototyping

The next step in the user-centered design process was the development of the MRsafe prototype. React Native was used for the front-end visualization and Airtable was used as the database to store the specific MRI safety information of the CIEDs. Data retrieval from the Airtable database to the MRsafe app was done using the Fetch API *(Figure 18)*. Barcodes were considered as a digital solution to determine the MR compatibility of different CIEDs. By scanning the CIED-specific barcode, not only relevant MRI safety information can be retrieved, but also checklists and helpful links can be found in the MRsafe app. As an alternative to scanning a barcode, a search function can be used to find a specific CIED by name, manufacturer, type, or serial number. Helpful information for prototyping was taken from *'W3 Schools'*, *'React Native Docs'*, '*React Navigation Docs', 'React Native Paper Components'* and *'Expo Docs'* [39]–[43]. The full code of the MRsafe app is available on GitHub *(https://github.com/stefaniepirzl/MRsafe)*.

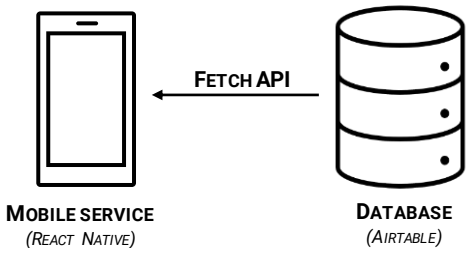

Figure 18: Technical concept for implementing the MRsafe app

The following system versions were used for the development:

- Operating system: *Microsoft Windows 11 Home Version 22H2*
- Code editor: *Visual Studio Code Version 1.78.2*
- Front-end: *React Native Version 0.70.8*
- Database: *Airtable Version ^0.11.6*
- Expo: *Expo Version ~47.0.12*

3.2.1 React Native

React Native is an open-source framework for developing mobile applications. It allows developers to build mobile user interfaces for iOS and Android using JavaScript and React, a web development framework. React Native components are typically written in JavaScript and JavaScript XML (JSX), a JavaScript extension that looks very similar to HTML. Properties and styles were added to customize the appearance of the components. The figure below gives an overview of the structure and hierarchy of the MRsafe app *(Figure 19)*.

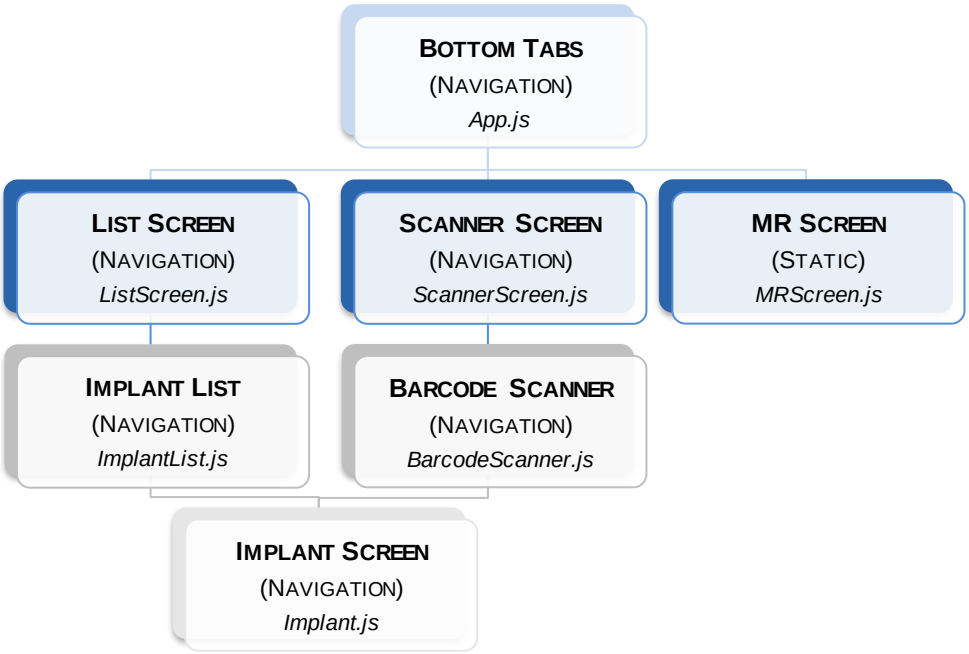

Figure 19: Structure and hierarchy of the MRsafe app in React Native

Bottom Tabs Navigation *(App.js)*

The MRsafe app has three bottom tabs that allow the user to switch between a list, a barcode scanner, and an MRI screen *(Figure 20)*. To implement the tabs, the component *'NavigationContainer'* from the library *'react-navigation/native'* and the *'createBottomTabNavigator'* function provided by *'react-navigation/bottom-tabs'* were installed, imported, and incorporated into the code. The *'NavigationContainer'* wraps all the components of the application that need to be navigated. Once the *'NavigationContainer'* was set up and the *'createBottomTabNavigator'* function was assigned to the variable *'Tab'*, other components from this library were used, such as *'Tab.Navigator'* or '*Tab.Screen'*. The *'Tab.Navigator'* component was used to define a tab navigation and contains in this case three '*Tab.Screen'* components. The screens to be navigated were defined in the '*Tab.Screen'* prop *'component'* and had to be imported at the top.

The unique tab name was defined by the '*Tab.Screen'* prop *'name' (Listing 1)*. To customize the tabs and headers, the '*Tab.Screen'* prop *'options'* was used to set the '*headerTitle'*, the '*headerTintColor'*, the '*backgroundColor'* of the header, the *'tabBarButton'* and the *'tabBarIcon' (Listing 2)*. The *'tabBarButton'* prop was set to *'CustomTabButton',* which was defined before the main function component of the *App.js* file *'export default function App() {}*' through a ternary operator to customize the upper border color when a tab is selected *(Listing 3)*. The icons for the bottom tabs were defined in the *'tabBarIcon'* prop, which is a function that returns an image component with a source *(Listing 2).* Each icon used was downloaded from the website *'www.flaticon.com'* and has been added to the *asset* file of the MRsafe app [44]. The icons were imported at the top and were assigned to a variable with the *'require()'* function, so that they could be used as the source of the image component *(Listing 1, 2)*.

Figure 20: MRsafe app navigation bar with three tabs

```
import 'react-native-gesture-handler';
import { View, Image, TouchableOpacity } from 'react-native';
import { NavigationContainer } from '@react-navigation/native';
import { createBottomTabNavigator } from '@react-navigation/bottom-
tabs';

import ListScreen from './src/ListScreen';
import ScannerScreen from './src/ScannerScreen';
import MRScreen from './src/MRScreen';

const Tab = createBottomTabNavigator();
const MRImage = require('./assets/MR.png');
const BarCodeImage = require('./assets/barcode.png');
const ListImage = require('./assets/list.png');

export default function App() {
 return (
  <NavigationContainer>
    <Tab.Navigator>
      <Tab.Screen name='List' component={ListScreen}/>
      <Tab.Screen name='BarCodeScan' component={ScannerScreen}/>
      <Tab.Screen name='MRI' component={MRScreen}/>
     </Tab.Navigator>
  </NavigationContainer>
)}
```

Listing 1: Bottom Tabs Navigation to switch between the three bottom tabs

```
<Tab.Screen name='List' component={ListScreen} options={{ headerTitle:
   'MRsafe', headerTintColor:'white', headerStyle: { backgroundColor:
   '#0E518D' },  tabBarButton: CustomTabButton, tabBarIcon: () => (
       <View>
          <Image source={ListImage} />
       </View>
)}} />
```

Listing 2: Detailed props of the 'Tab.Screen' component to customize the tabs and headers

```
const CustomTabButton = (props) => (
 <TouchableOpacity {...props}
   style={
    props.accessibilityState.selected
     ? [props.style, { borderTopColor: '#136cbb', borderTopWidth: 2 }]
     : props.style
    }/>
)
```

Listing 3: Declaration of the 'CustomTabButton' to customize the upper border color of an active tab

Screen Navigation *(ListScreen.js, ScannerScreen.js)*

A specific navigation had to be declared to navigate between the screens of the MRsafe app. This type of navigation was used in both the *ListScreen.js* and *ScannerScreen.js* files. For demonstration purposes, only the code from the *ListScreen.js* file is listed, as the basic structure of the code from the *ScannerScreen.js* file is the same. To allow a navigation between screens, the function *'createStackNavigator'* from the library *'react-navigation/stack'* and the library *'react-native-gesture-handler'* were installed, imported, and added to the top of the code. The function *'createStackNavigator()'* has been assigned to the variable *'Stack'* so that other components of this library could be used to complete the code, such as *'Stack.Navigator'* and *'Stack.Screen'*. The *'Stack.Navigator'* was used to create the stack-based navigation where each screen is placed on the top of a stack. The screens to navigate were defined in the *'StackScreen'* prop *'component'* and had to be imported at the top. The name of the tab was defined by the '*Stack.Screen'* prop *'name'* and is unique for each screen *(Listing 4)*. To customize the navigation, the '*Stack.Screen'* prop *'options'* was used to set the '*headerTitleStyle'*, the '*headerTintColor'* and the *'headerBackTitleStyle'* *(Listing 5)*.

In addition, the *'react-native-gesture-handler'* library had to be installed and imported at the top of the entry file *App.js* to prevent the app from crashing in production *(Listing 1)*.

```
import { createStackNavigator } from '@react-navigation/stack';
import 'react-native-gesture-handler';

import ImplantList from './ImplantList';
import Implant from './Implant';

const Stack = createStackNavigator();

export default function ListScreen() {
 return (
  <Stack.Navigator >
    <Stack.Screen name='All Implants' component={ImplantList} />
    <Stack.Screen name='Implant Details' component={Implant} />
  </Stack.Navigator>
)}
```

Listing 4: Screen Navigation between the Scanner Screen and the Implant Screen in the ListScreen.js file

```
<Stack.Screen name='All Implants' component={ImplantList} options={{
   headerTitleStyle: { fontSize: 16, color: '#0E518D', fontStyle:
   'italic' }, headerTintColor: 'grey', headerBackTitleStyle: {
   fontSize: 1 }} }
/>
```

Listing 5: Detailed props of the 'Stack.Screen' component to customize the stack navigation

Navigation/Routing

'Navigation' and *'Route'* are two important objects in *'React Navigation'* for managing the navigation between screens. They can be added as props to a function component *(Listing 6, 7)*. To implement the navigation logic the *'.navigate()'* method is used with the *'navigation'* object. The first parameter of this method is the *'RouteName'* of the screen to be navigated and the second one contains the *'params'* *(Listing 6)*. To read these *'params'* in the navigated screen the object *'route.params'* can be used *(Listing 7)*. These objects were used in the following files of the MRsafe app: *BarcodeScanner.js*, *ImplantList.js* and *Implant.js*.

```
export default function ImplantList({ navigation }) {
navigation.navigate('Implantat Details', {params});
```

Listing 6: Navigation object of 'React Navigation'

```
export default function Implant({ route }) {};
const { name } = route.params;
```

Listing 7: Route object of 'React Navigation'

List Screen

The List Screen has been implemented to allow the user to manually search for CIEDs, as there is not always a CIED-specific barcode given that can be scanned to query the MR compatibility *(Figure 21)*. The overall logic for the screen navigation was defined in the *ListScreen.js* file and explained in the *'Screen Navigation'* section. In addition, two files were created to define the screens to be navigated: *ImplantList.js, Implant.js*.

Implant List (ImplantList.js)

The Implant List contains a list of all the CIEDs in the Airtable database and a search bar at the top of the screen, where known information such as CIED name, manufacturer, series, label, serial number and CIED type can be entered. The data is filtered according to the information provided and only the CIEDs that match are displayed. The searched CIED can be clicked on, and the associated MRI safety information, checklists and helpful links are displayed on a new screen through the screen navigation.

For the implementation the *'React'* library and the *'useState'* hook were imported from *'react'*. The component *'Searchbar'* from the *'react-native-paper'* library was also installed, imported, and added to the code. In addition, a state variable *'searchInput'* and an update function *'setSearchInput()'* were declared. The *'searchInput'* variable is initialized with an empty string. The *'Searchbar'* component takes two props: *'value'* and *'onChangeText()'*. When the user types into the *'Searchbar'* component, the *'onChangeText()'* function is called with the new text as a parameter. This function updates the value of the *'searchInput'* state variable using the *'setSearchInput()'* function *(Listing 8)*.

```
import React, { useState } from 'react';
import { Searchbar } from 'react-native-paper';

export default function ImplantList() {
 const [searchInput, setSearchInput] = useState('');

 return (
  <View>
    <Searchbar
       value={searchInput}
       onChangeText={(text) => setSearchInput(text)}/>
   </View>
 )
}
```

Listing 8: Search bar to search for a specific CIED in the Implant List

The *'.filter()'* method has been used to filter the *'airtableData'* according to the search input. It loops over all *'implant'* objects of the *'airtableData'* and returns a new array, stored in the *'filteredData'* variable, including only the CIEDs that contain the *'searchInput'* value. The *'.toLowerCase()'* method is used to convert both the *'CIED'* prop and the *'searchInput'* value to lower case before comparing to ensure a case-insensitive search. For demonstration purposes, only the code to filter the *'airtableData'* according to the Airtable field *'CIED'* is listed *(Listing 9)*.

```
const filteredData = airtableData.filter(
  (implant) =>
    implant['fields']['CIED']
      .toLowerCase()
      .includes(searchInput.toLowerCase())
)
```

Listing 9: '.filter()' method to filter the 'airtableData' according to the 'searchInput' value

The *'.sort()'* method combined with the defined *'compare()'* function added as a parameter sorts the list of the CIED objects alphabetically and is assigned to the *'sortedData'* variable. The *'compare()'* function returns an integer that is used to determine the sort order by comparing the two inputs: *a, b*. It converts the names of the CIED objects *a* and *b* defined by *'a['fields']['Name']'* and *'b['fields']['Name']'* to lower case using the *'.toLowerCase()'* method and assigns them to the variables '*implantA'* and '*implantB'.* Then both variables are compared using conditional statements. If the comparison integer is greater than 0, '*implantB'* will appear before '*implantA'*. If it is less than 0, '*implantA'* will appear before '*implantB'*. If '*implantA'* and '*implantB'* are equal, the comparison value remains 0 *(Listing 10)*.

```
function compare(a, b) {
  const implantA = a['fields']['Name'].toLowerCase();
  const implantB = b['fields']['Name'].toLowerCase();

  let comparison = 0;
  if (implantA > implantB) {
    comparison = 1;
  } else if (implantA < implantB) {
    comparison = -1;
  }
  return comparison;
};

const sortedData = filteredData.sort(compare);
```

Listing 10: '.sort()' method combined with the 'compare()' function to sort the list of the CIED objects alphabetically

The *'.map()'* method takes the *'implant'* object as a parameter and was used to display each CIED as a list in a scrolling container using the component *'ScrollView'* from *'react native'* by iterating over the *'sortedData'* array. The CIED specific barcode is set as the *'key'* prop as a unique identifier for each implant in this list *(Listing 11)*. Additionally, each CIED is displayed as a *'TouchableOpacity'* component with some basic information (e.g.: name) and an image which is defined through the *'setImage()'* function. This function takes the *'implant'* object as a parameter. Conditional statements are used to determine which image to display based on the *'Label'* prop of the *'field'* object of this implant parameter. If the *'Label'* prop is *'MR safe'*, the *'setImage()'* function returns the image named *'MRsafe.png'*. If the *'Label'* prop is *'MR conditional'*, the *'setImage()'* function returns the image named *'MRconditional.png'*. And if the *'Label'* prop is *'MR unsafe'*, the *'setImage()'* function returns the image named *'MRunsafe.png'*. Each of these images has been added to the *asset* file of the MRsafe app and is loaded using the *'require()'* function *(Listing 12)*. The *'TouchableOpacity'* component has an *'onPress'* prop which is used to specify an anonymous function to be called when a user taps on a CIED in the list to display the specific MRI safety information. This function navigates to the screen called *'Implant Details'* using the *'navigation.navigate()'* method and passes parameters (e.g.: name) to the next screen *(Listing 11)*. This type of *Navigation/Routing* is explained in the *'Screen Navigation'* section.

```
export default function ImplantList({ navigation }) {
 return (
  <View>
   <ScrollView>
     {sortedData.map((implant) => (
       <View key={implant['fields']['Barcode']}>
         <TouchableOpacity
            onPress={() =>
              navigation.navigate('Implant Details', {
                name: implant['fields']['CIED'] })} >
            <Text> {implant['fields']['Name']} </Text>
            <Image source={setImage(implant)}> </Image>
         </TouchableOpacity>
       </View>
     ))}
   </ScrollView>
  </View>
 )
}
```

Listing 11: '.map()' method to display each CIED from the sorted Airtable data and 'navigation.navigate()' method to navigate to another screen

```
const setImage = (implant) => {
  if (implant['fields']['Label'] === 'MR safe') {
    const image = require('../assets/MRsafe.png');
    return image; }
  if (implant['fields'][ 'Label'] === 'MR conditional') {
    const image = require('../assets/MRconditional.png');
    return image; }
  if (implant['fields']['Label'] === 'MR unsafe') {
    const image = require('../assets/MRunsafe.png');
    return image; }
}
```

Listing 12: Conditional statements to set images based on the 'Label' prop

Scanner Screen

The Scanner Screen has been implemented to allow the user to scan a CIED-specific barcode to retrieve all necessary MRI safety information about it *(Figure 22)*. It uses a barcode scanner as a digital solution for determining the MR compatibility of different CIEDs. Relevant MRI safety information, checklists and helpful links can be accessed by scanning a CIED-specific barcode. This information is displayed on a new screen through the screen navigation after a barcode has been successfully scanned. The overall logic for the screen navigation was defined in the *ScannerScreen.js* file. In addition, two files were created to define the screens to be navigated: *BarcodeScanner.js*, *Implant.js*.

Barcode Scanner (ImplantList.js)

The *'Camera'* component from the library *'expo-camera'* was installed, imported, and used as barcode scanner. The *'useState'* hook was also imported and is used to create an update function called *'setScanned()'* and a state variable called *'scanned'*, which is initially set to *'false'*. If *'airtableData'* is available, the *'handleBarCodeScanned()'* function is defined, accepting an object containing the '*type'* and *'data'* of the scanned barcode. This function sets the *'scanned'* variable to *'true'* using the *'setScanned()'* function after a barcode has been scanned to prevent the function from being called again until the *'scanned'* variable is reset to *'false'*. To check if the scanned barcode matches any of the barcodes in the array, the '*airtabledata'* array is iterated over using the *'.map()'* method, which takes the *'implant'* object as a parameter. If there is a match, the *'navigation.navigate()'* method is called to navigate to the *'Implant Details'* screen, passing parameters (e.g.: name) to the next screen, which is explained in more detail in the *'Screen Navigation'* section. The *'onBarCodeScanned'* prop of the *'Camera'* component is a callback that is invoked when a barcode has been successfully scanned by the device's camera. The result of this callback is an

object where the *'type'* and the *'data'* of the scanned barcode can be assessed. This prop uses a ternary operator to define the action to be taken after a successful scan. If the state variable is currently *'false'*, the '*handleBarCodeScanned()'* function is called. If this variable is *'true'*, a *'Scan again?'* button is displayed, which, when pressed, sets the *'scanned'* variable back to *'false'*. This allows the user to scan another barcode *(Listing 13)*.

```
import React, { useState, useEffect } from 'react';
import { Camera } from 'expo-camera';

export default function BarcodeScanner({ navigation }) {
 const [scanned, setScanned] = useState(false);

 if (airtableData) {
  const handleBarCodeScanned = ({ type, data }) => {
   setScanned(true);

   airtableData.map((implant) => {
    if (data == implant['fields']['Barcode']) {
     navigation.navigate('Implant Details', {
      name: implant['fields']['CIED'] }) } })
  };

  return (
   <View>
    <View>
     <Camera
       onBarCodeScanned={scanned ? undefined : handleBarCodeScanned}/>
    </View>

    {scanned && (
     <View>
      <Button title={'Scan again?'} onPress={()=>setScanned(false)}/>
     </View>
    )}
   </View>
)}}
```

Listing 13: Barcode scanner as a digital solution for determining the MR compatibility

When the Scanner Screen is opened for the first time the user is also asked for permission to use the camera. Therefore, the state variable *'hasPermission'* and the update function *'setHasPermission()'* were implemented using the *'useState'* hook again. The *'hasPermission'* variable was set to *'null'* initially. The function *'askForCameraPermission()'* is used to request the camera permission using the *'Camera.requestCameraPermissionsAsync()'* method and was defined with an async/await syntax. The asynchronous function returns a promise, and the *'await'*

keyword waits for the promise to be resolved or rejected. Within this function the *'Camera.requestCameraPermissionsAsync()'* method is called. This method returns a *'status'* object, which is either *'granted'* or *'denied'*. The *'hasPermission'* variable is then set to '*true'* if the *'status'* object is *'granted'*. The asynchronous function is followed by *'()'*, which invokes the function immediately, so that the code inside of the function is executed as soon as it is defined. To only call the *'askForCameraPermission()'* function on the initial render, the '*useEffect'* hook is used. It takes two arguments: a function and an array of dependencies. In this case, the array of dependencies is empty, so that the function is only called on the first render. Conditional statements are used to handle the *'hasPermission'* state variable. If the 'hasPermission' variable is *'null'* a message is displayed that a camera permission is being requested. If it is *'false'*, a no access message is displayed and an *'Allow camera'* button is provided which, when pressed, calls the *'askForCameraPermission()'* function *(Listing 14)*. Once the camera permission is granted, the camera view is rendered.

```
const [hasPermission, setHasPermission] = useState(null);

const askForCameraPermission = () => {
 (async () => {
   const { status } = await Camera.requestCameraPermissionsAsync();
   setHasPermission(status === 'granted');
 })();
};

useEffect(() => {
  askForCameraPermission();
}, []);

if (hasPermission === null) {
 return (
  <View>
   <Text>Requesting for camera permission</Text>
  </View>
)}

if (hasPermission === false) {
 return (
  <View>
   <Text>No access to camera</Text>
     <Button title = {'Allow camera'}
       onPress = {() => askForCameraPermission()}/>
  </View>
)}
```

Listing 14: Camera permission with async/await syntax, 'useEffect' hook and conditional statements

Implant Screen

The Implant Screen displays the detailed information about the specific CIED selected by the user by tapping on the CIED in the list or by scanning a barcode. In addition to the MR-specific parameters, links to the manufacturer's website and to a CIED-specific checklist are available *(Figure 23)*. Routing was used to obtain the correct information about the specific CIED selected and to navigate between the defined screens. The *'route'* object was passed as a prop to the function component *'Implant'* and the *'route.params'* object was used to pass data between the screens (e.g.: name) (*Listing 15)*. Each parameter of the CIED was defined in the function component *'Parameter'*, which has two props: *'parameter'* and *'value'*. This component was defined in the '*Parameter.js'* file (*Listing 16)* and imported into the *Implant.js* file. Linking was used to open external URLs. Thus, it was imported from *'react-native'* and the '*Linking.openURL()'* method was added to the code. The required URLs were defined using the *'setLinkChecklist()'* and *'setLinkSeries()'* functions and passed as parameters to this method. The image component was used to implement an image, which is defined by the *'setImage()'* function *(Listing 15)*. Each of these functions has used conditional statements to determine the image, the link, or the checklist *(Listing 12)*.

```
import Parameter from './Parameter';
import { Linking } from 'react-native';

export default function Implant({ route }) {

 const { name } = route.params;
 const { slewRate } = route.params;

 return (
  <View>
    <Text>{name}</Text>
    <Image source={setImage()}></Image>
    <Parameter parameter='Slew Rate:' value={slewRate}></Parameter>

    <TouchableOpacity onPress={() =>
      Linking.openURL(setLinkSeries())}>
      <Text>Checklist</Text>
    </TouchableOpacity>

    <TouchableOpacity onPress={() =>
      Linking.openURL(setLinkChecklist())}>
      <Text>Checklist</Text>
     </TouchableOpacity>
   </View>
)}
```

Listing 15: Linking to open external URLs to manufacturer's websites and *checklists*

```
export default function Parameter(props) {
 return (
  <View>
    <Text>{props.parameter}{' '}</Text>
    <Text>{props.value}</Text>
  </View>
)}
```

Listing 16: Initialization of the function component 'Parameter' which has two props defined: 'parameter' and 'value'

MR Screen

The MR Screen is a simple static screen with two images of the local spatial gradient of the Philips Ingenia 3.0T MR, showing the vertical and horizontal sections of the local spatial gradient *(Figure 24).* The images were provided by Koninklijke Philips N.V. via email with the permission to use them in this master thesis [45]. The images have been added to the *asset* file of the MRsafe app and are loaded using the *'require()'* function *(Listing 17).* The purpose of this screen is to view these sections after determining the MR compatibility and allowable local spatial gradient of a CIED and to verify that the examination can be safely performed on that MR.

```
const MRScanner1 = require('../assets/MRScanner1.jpeg');
const MRScanner2 = require('../assets/MRScanner2.jpeg');

export default function MRScreen() {
 return (
  <View>
    <Text>Philips Ingenia 3.0T</Text>
     <Text>Vertical section: Spatial gradient of the static magnetic
           field Bo</Text>
     <Image source={MRScanner1}></Image>
     <Text>Horizontal section: Spatial gradient of the static magnetic
           field Bo</Text>
     <Image source={MRScanner2}></Image>
  </View>
 );
}
```

Listing 17: Static screen with images loaded using the 'require()' function

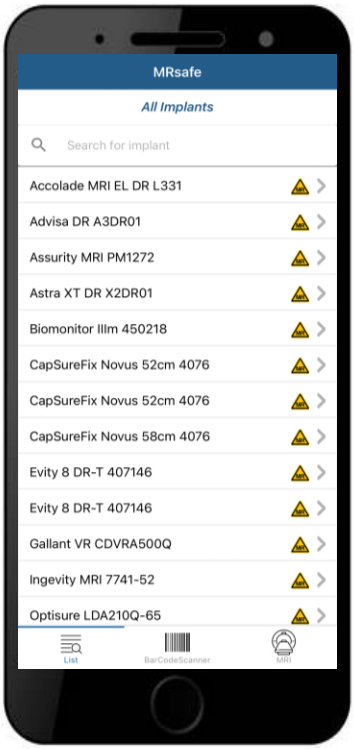

Figure 21: List Screen

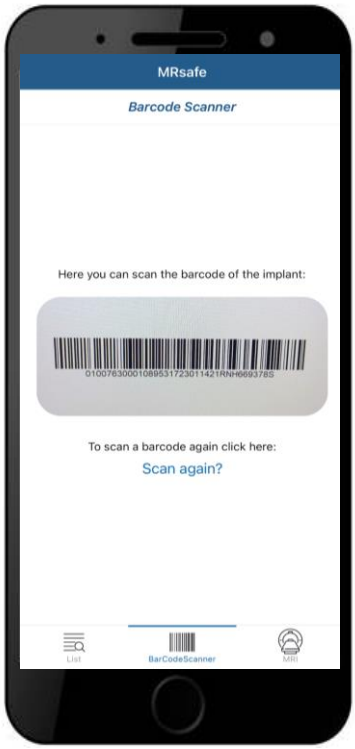

Figure 22: Scanner Screen

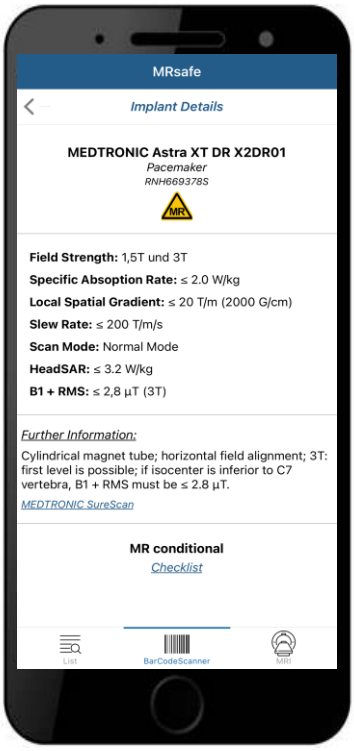

Figure 23: Implant Screen

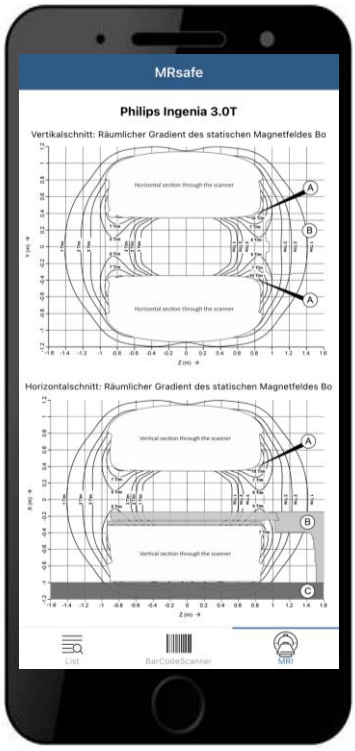

Figure 24: MR Screen

3.2.2 Airtable

Airtable was used to create and manage a database with 18 CIEDs for demonstration purposes. For authentication, each Airtable user has its personal API key that allows access to all the data in each Airtable bases *(= Account key)*. In addition, each base, each table, and each field within a table has its own ID. The base used for the MRsafe app is called *'CIEDregister'* and contains a table that is called *'CIEDlist'*. This *'CIEDlist'* has 18 records *(Figure 25),* and each record contains 18 fields of the type*: text, long text, and formula*. Each type can contain strings and numbers. The fields used in the *'CIEDlist'* are listed below in alphabetical order and have been chosen with reference to the previous results of the literature research and interviews:

- B_{1+RMS} *(text, string)*
- Barcode *(long text, string)*
- Checklist *(text, string)*
- CIED *(formula, number/string)*
- Field Strength *(text, string)*
- Further Information *(long text, string)*
- Head SAR *(string)*
- Label *(string)*
- Local Spatial Gradient *(string)*
- Manufacturer *(string)*
- Modell *(string)*
- Name *(long text, string)*
- SAR *(string)*
- Scan Mode *(string)*
- Serial Number *(string)*
- Series *(string)*
- Slew Rate *(string)*
- Type *(string)*

The information for each CIED was researched on the manufacturers' websites or provided by email with permission to use and added to the *'CIEDlist'*. The types of CIED that were stored in the Airtable database included:

- Pacemakers
- Defibrillators (ICD)
- Cardiac Monitors (ICM)
- Leads

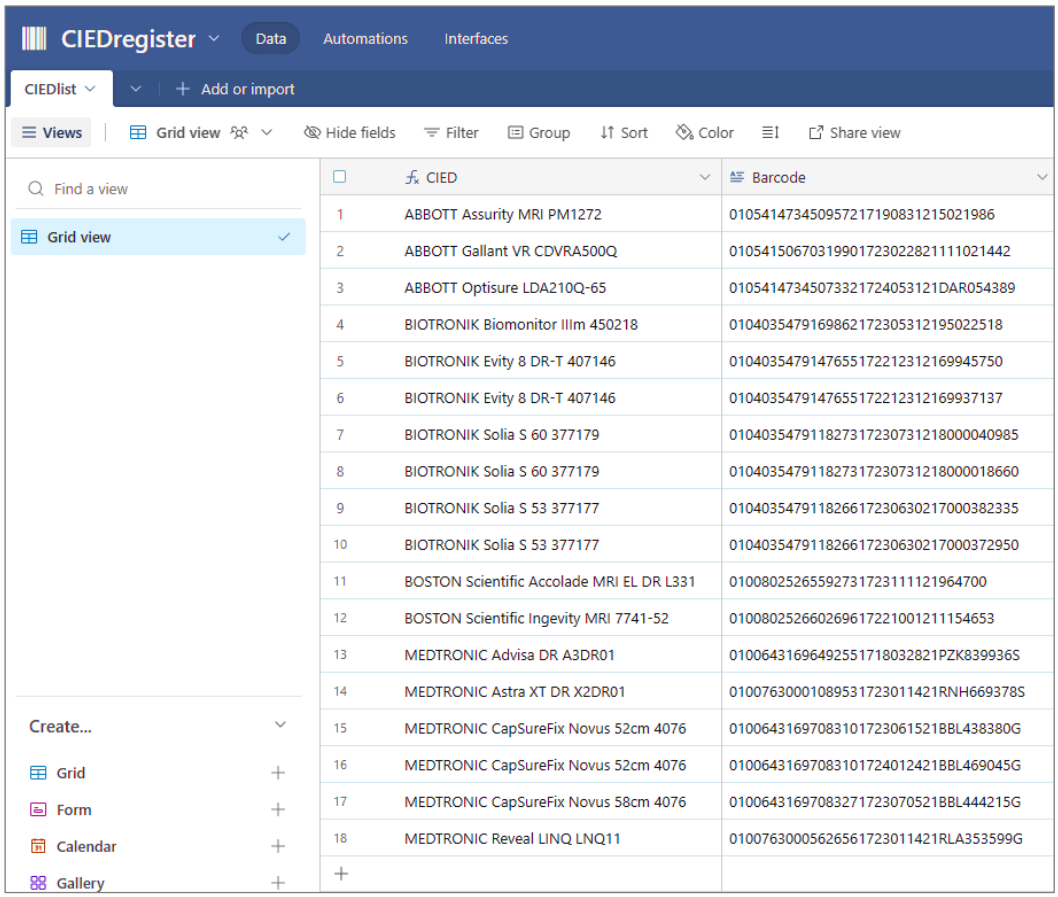

Figure 25: Part of the 'CIEDlist' in Airtable including the 18 records and the two fields: 'CIED' and 'Barcode'

3.2.3 Fetch API

The Fetch API is used for networking between React Native and Airtable and provides the *'fetch()'* method. This allows data to be retrieved asynchronously from the Airtable in the MRsafe app. State variables were used to store the data. Therefore the *'React'* library and the *'useState'* hook were imported from *'react'*. Three different state variables were declared: *'isLoading'*, *'error'* and *'airtabledata'*. Each variable can be updated using a defined function: *'setIsLoading'*, *'setError'* and *'setAirtableData'*. The *'isLoading'* variable is initialized to *'false'* and is used to keep track of whether a data is currently being loaded. It is updated to *'true'* when data fetching begins and to *'false'* again when data fetching has finished. The *'error'* and *'airtableData'* variables are initialized to an empty string. Errors that occur are stored in the *'error'* variable and the fetched data is stored in the *'airtableData'* variable once it has been successfully retrieved from Airtable. The *'fetch()'* method takes a URL as a parameter and returns a promise. An optional second parameter has been added to the *'fetch'* method to

define the authorization in the header. The keyword *'Bearer'* with the personal *'Account Key'* from Airtable was used for the authentication *(Listing 18)*. For security reasons, the base ID, the record ID, and the account key have been removed from the *Listing 18* and *Listing 20* and were replaced with the placeholders *'baseID'*, *'recordID'* and *'YOUR_SECRET_API_TOKEN'*. The promise returned by the *'fetch()'* method is handled by the *'.then()'* method. The first *'.then()'* method takes the response (res) as an argument and converts the response to JSON data using the *'.json()'* method. A formatted JSON data from a sample CIED is shown in *Listing 20*. The second *'.then()'* method takes the parsed *'jsonData'* as an argument, assigns the *'records'* prop of this object to the variable *'data'* and stores it in the state variable *'airtableData'* with the function *'setAirtableData(data)'*. Both *'.then()'* methods take callback functions as arguments. The *'.catch()'* method is used to catch an error and updates the *'error'* variable with the *'message'* prop of this object with *'setError(error.message)'*. The *'finally()'* method sets the *'isLoading'* state back to *'false'* after being set to 'true' at the beginning of the *'fetchData'* function and is called at the end of the fetch-request, regardless of whether the promise is fulfilled or rejected *(Listing 18)*.

```
import React, { useState } from 'react';

const airtableURL = 'https://api.airtable.com/v0/baseID/CIEDlist';

export default function ImplantList() {
  const [isLoading, setIsLoading] = useState(false);
  const [error, setError] = useState('');
  const [airtableData, setAirtableData] = useState('');

  const fetchData = () => {
    setIsLoading(true);

    fetch(airtableURL, {
      headers: { Authorization: 'Bearer YOUR_SECRET_API_TOKEN' }
    })
      .then((res) => res.json())
      .then((jsonData) => {
        const data = jsonData.records;
        setAirtableData(data); })
      .catch((error) => {
        setError(error.message); })
      .finally(() => {
        setIsLoading(false); });
  };
}
```

Listing 18: Fetch API for networking between React Native and the Airtable database

The *'useEffect'* hook has been implemented to fetch the Airtable data on the first render only. It takes two arguments: a function and an array of dependencies. The function is executed whenever one of the dependencies changes. In this case, the array of dependencies is empty, so that the function is only executed on the first render. This is used to initialize the Airtable data *(Listing 19)*.

```
React.useEffect(() => {
  fetchData();
}, []);
```

Listing 19: 'useEffect' hook to initialize the Airtable data on the first render only

```
{
  'createdTime': '2022-12-11T18:53:18.000Z',
  'id': 'recordID',
  'fields': {
    'B1+RMS': '≤ 2,8 µT (3T)',
    'Barcode': '01007630001089531723011421RNH669378S',
    'CIED': 'MEDTRONIC Astra XT DR X2DR01',
    'Checklist': 'yes',
    'FieldStrength': '1,5T und 3T',
    'FurtherInformation': 'Cylindrical magnet tube; horizontal field
       alignment; 3T: first level is possible; if isocenter is
       inferior to C7 vertebra, B1 + RMS must be ≤ 2.8 µT. ',
    'HeadSAR': '≤ 3.2 W/kg',
    'Label': 'MR conditional',
    'LocalSpatialGradient': '≤ 20 T/m (2000 G/cm) ',
    'Manufracturer': 'MEDTRONIC',
    'Modell': 'X2DR01',
    'Name': 'Astra XT DR',
    'SAR': '≤ 2.0 W/kg',
    'ScanMode': 'Normal Mode',
    'Serial Number': 'RNH669378S',
    'Series': 'SureScan',
    'SlewRate': '≤ 200 T/m/s',
    'Type': 'Pacemaker'
  },
}
```

Listing 20: Formatted JSON airtableData from a sample CIED

4 Evaluation of the Prototype

The last step of the user-centered design process was the evaluation of the MRsafe prototype. Thus, a quantitative usability test was conducted on three days in February 2023 in a hospital environment (KAGes) and included three task scenarios to assess the usability of the prototype. Five healthcare professionals participated in this usability test, which was conducted in German. Although the number of participants (n = 5) is not statistically significant, it has been kept small because, according to Jakob Nielsen, the best results are achieved by testing no more than five users and by conducting as many small tests as possible [46]. All participants were radiographers who had completed their training and agreed to participate *(see Appendix: Declaration of Consent)*. Three of them had a professional experience of 2-10 years and two had a professional experience of 10-20 years.

The following inclusion criteria had to be met to participate in the usability test:

- Completed training as a radiographer or specialist in radiology or cardiology.
- At least 2 years of professional experience with MRI (radiology) or CIEDs (cardiology).

4.1 Task Scenarios

In each task scenario, the health professionals had to research the MR compatibility of a given pacemaker, in one case without using the MRsafe app and in another case with this app. Therefore, the participants were given three implant passes created for the purpose of this usability test. Each implant pass contained an MR conditional pacemaker that was randomly selected and is mentioned below. The manufacturer, name, model, serial number, and specific barcode of the pacemaker were listed in the implant pass. In addition, information about the associated leads was provided, as some manufacturers' websites only allow the clarification of the entire CIED system. All these characteristics were taken from the manufacturer-specific information on the packaging of the individual pacemakers and leads. In addition, barcodes were provided by the Styrian Hospital Society m.b.h. (KAGes) [47] and reproduced using an online barcode generator *(https://barcode.tec-it.com/)* so that the quality was good enough for the usability test *(Figure 26-31)*. Each participant had to find out the specific allowable MRI safety information of the CIEDs during the usability test,

including MR compatibility, magnetic field strength, specific absorption rate, head specific absorption rate, slew rate, local spatial gradient, scan mode and B_{1+rms}. The individual MR parameters depended on the CIED, as different parameters are specified by the manufacturers. Test implant 1 had 8 parameters, test implant 2 had 7 parameters and test implant 3 had 5 parameters which are specified by the manufacturers *(Tables 6-8)*. The task scenarios were completed when the participants considered the MRI safety information to be complete or when the research took more than 45 minutes. The results had to be documented by the participants themselves on a predefined paper *(see Appendix: Usability Test)*. The time taken to complete the task was also documented. Each participant could decide for themselves which sources to use and whether to query the entire CIED system or just the pacemaker itself. This had to be documented on the paper as well. The links used were emailed to the project manager to verify and trace the MRI safety information provided, except when MagResource was used, as a password is required to access the information *(see additional materials)*.

4.1.1 CIED 1 – Medtronic

Pacemaker: Astra™ XT DR MRI SureScan™ X2DR01, SN: RNH669378S

Figure 26: Reproduced barcode of CIED 1 to obtain the necessary MRI safety information via barcode scan

Leads: CapSureFix Novus MRI SureScan™ 4076 - 58cm, SN: BBL444215G

Figure 27: Reproduced barcode of CIED 1 leads to obtain the necessary MRI safety information via barcode scan

MR Compatibility	Field Strength	SAR	Head SAR	Slew Rate
☐ MR safe ☒ MR conditional ☐ MR unsafe	☐ ≤ 1.5 T ☒ ≤ 3.0 T	☒ ≤ 2.0 W/kg ☐ ≤ 4.0 W/kg	☒ ≤ 3.2 W/kg	☒ ≤ 200 T/m/s
Local Spatial Gradient	**Scan Mode**	**B_{1+RMS}**	**Time needed**	
☒ ≤ 20 T/m ☐ ≤ 25 T/m ☐ ≤ 30 T/m ☐ ≤ 50 T/m	☒ Normal ☒ First Level (3T: ≤ 2,8 µT)	☒ ≤ 2.8 µT		

Table 6: Correct MR parameters of test implant 1 to evaluate the usability test

4.1.2 CIED 2 – Boston Scientific

Pacemaker: Accolade™ MRI EL DR L331, SN: 964700

Figure 28: Reproduced barcode of CIED 2 to obtain the necessary MRI safety information via barcode scan

Leads: Ingevity™ MRI 7741 52cm, SN: 1154653

Figure 29: Reproduced barcode of CIED 2 leads to obtain the necessary MRI safety information via barcode scan

MR Compatibility	Field Strength	SAR	Head SAR	Slew Rate
☐ MR safe ☒ MR conditional ☐ MR unsafe	☐ ≤ 1.5 T ☒ ≤ 3.0 T	☒ ≤ 2.0 W/kg ☒ ≤ 4.0 W/kg (Ingevity)	☒ ≤ 3.2 W/kg	☒ ≤ 200 T/m/s
Local Spatial Gradient	**Scan Mode**	**B_{1+RMS}**	**Time needed**	
☐ ≤ 20 T/m ☐ ≤ 25 T/m ☐ ≤ 30 T/m ☒ ≤ 50 T/m	☒ Normal ☒ First Level (Ingevity)	☐ ≤ 2.8 µT		

Table 7: *Correct MR parameters of test implant 2 to evaluate the usability test*

4.1.3 CIED 3 – Biotronik

Pacemaker: Evity 8 DR-T 407146, SN: 69945750

Figure 30: Reproduced barcode of CIED 3 to obtain the necessary MRI safety information via barcode scan

Leads: Solia S 60 377179, SN: 8000018660

Figure 31: Reproduced barcode of CIED 3 leads to obtain the necessary MRI safety information via barcode scan

MR Compatibility	Field Strength	SAR	Head SAR	Slew Rate
☐ MR safe ☒ MR conditional ☐ MR unsafe	☐ ≤ 1.5 T ☒ ≤ 3.0 T	☒ ≤ 2.0 W/kg ☒ ≤ 4.0 W/kg (Solia S)	☒ ≤ 3.2 W/kg	☒ ≤ 200 T/m/s
Local Spatial Gradient	**Scan Mode**	**B_{1+RMS}**	**Time needed**	
☐ ≤ 20 T/m ☐ ≤ 25 T/m ☐ ≤ 30 T/m ☐ ≤ 50 T/m	☐ Normal ☐ First Level	☐ ≤ 2.8 µT		

Table 8: Correct MR parameters of test implant 3 to evaluate the usability test

4.2 Results

The evaluation of the usability test is based on descriptive statistics and considers the task completion rate *(%)* and task time *(min)* as metrics. To evaluate each participant, a table was created in MS Excel *(Microsoft® Excel® for Microsoft 365 MSO Version 2302 Build 16.0.16130.20186 64 Bit)* and the data from each paper of the usability test was submitted *(Table 9)*. Graphs were created for better visualization considering the use of the MRsafe app, the queried CIED and the participants *(Figures 33, 34)*.

Task Completion Rate		*without App*	*with App*	**Task Time**	*without App*	*with App*
Participant 1	*CIED 1*	**25,0%**	**100,0%**	*CIED 1*	**10:26**	**00:48**
	CIED 2	**57,1%**	**100,0%**	*CIED 2*	**12:54**	**00:43**
	CIED 3	**100,0%**	**100,0%**	*CIED 3*	**32:19**	**01:08**
Participant 2	*CIED 1*	**0,0%**	**87,5%**	*CIED 1*	**09:54**	**00:47**
	CIED 2	**42,9%**	**100,0%**	*CIED 2*	**40:38**	**00:31**
	CIED 3	**80,0%**	**100,0%**	*CIED 3*	**20:56**	**00:50**
Participant 3	*CIED 1*	**100,0%**	**100,0%**	*CIED 1*	**26:44**	**00:39**
	CIED 2	**100,0%**	**100,0%**	*CIED 2*	**21:42**	**00:29**
	CIED 3	**100,0%**	**100,0%**	*CIED 3*	**14:50**	**00:23**
Participant 4	*CIED 1*	**100,0%**	**100,0%**	*CIED 1*	**26:38**	**00:51**
	CIED 2	**85,7%**	**100,0%**	*CIED 2*	**44:18**	**00:46**
	CIED 3	**100,0%**	**100,0%**	*CIED 3*	**26:27**	**00:45**
Participant 5	*CIED 1*	**100,0%**	**100,0%**	*CIED 1*	**03:59**	**01:06**
	CIED 2	**100,0%**	**100,0%**	*CIED 2*	**04:16**	**00:25**
	CIED 3	**100,0%**	**100,0%**	*CIED 3*	**03:59**	**00:28**

Table 9: Detailed task completion rate and task time data for each participant and CIED from the usability test

4.2.1 Sources Used in the Usability Test

The sources that were used in the task scenarios when the MRsafe app was not used are listed in the following table for each participant and CIED *(Table 10)*. The frequency of each source was assessed based on this table. Manufacturer information (11) was the most frequently used source, followed by MRI Safety (4), MagResource (3) and the Internet/Other (2) *(Figure 32)*.

PARTICIPANT 1		
CIED 1	*CIED 2*	*CIED 3*
Manufacturer	Manufacturer	Manufacturer
PARTICIPANT 2		
CIED 1	*CIED 2*	*CIED 3*
Manufacturer MRI Safety	Manufacturer Internet/Other	Internet/Other
PARTICIPANT 3		
CIED 1	*CIED 2*	*CIED 3*
Manufacturer MRI Safety	Manufacturer MRI Safety	Manufacturer MRI Safety
PARTICIPANT 4		
CIED 1	*CIED 2*	*CIED 3*
Manufacturer	Manufacturer	Manufacturer
PARTICIPANT 5		
CIED 1	*CIED 2*	*CIED 3*
MagResource	MagResource	MagResource

Table 10: Information about the sources used in the usability test considering each participant and each CIED queried

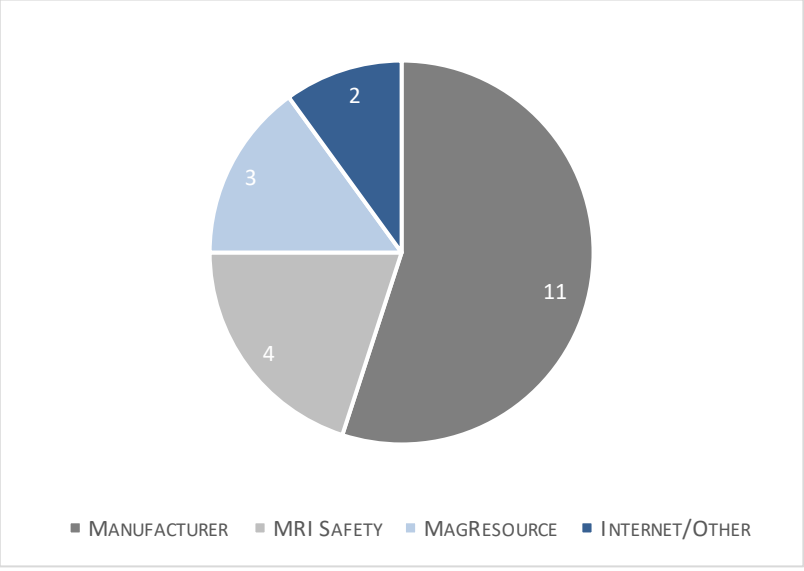

Figure 32: Frequency of the sources used in the usability test to query the MR compatibility of the CIEDs without the MRsafe app

4.2.2 Task Completion Rate

The mean value and the standard deviation were calculated using the =STABW() and =AVERAGE() formulas in MS Excel for the evaluation of the task completion rate. The result shows that the completion rate without using the app has a mean value with a standard deviation of 79,4% ± 32,7%, while with using the app, a completion rate of 99.2% ± 3.2% was achieved *(Table 11)*.

MEAN VALUE ± STANDARD DEVIATION (%)

WITHOUT APP	*WITH APP*
79.4 ± 32.7	*99.2 ± 3.2*

Table 11: Mean value ± standard deviation of the task completion rate from the evaluated usability test

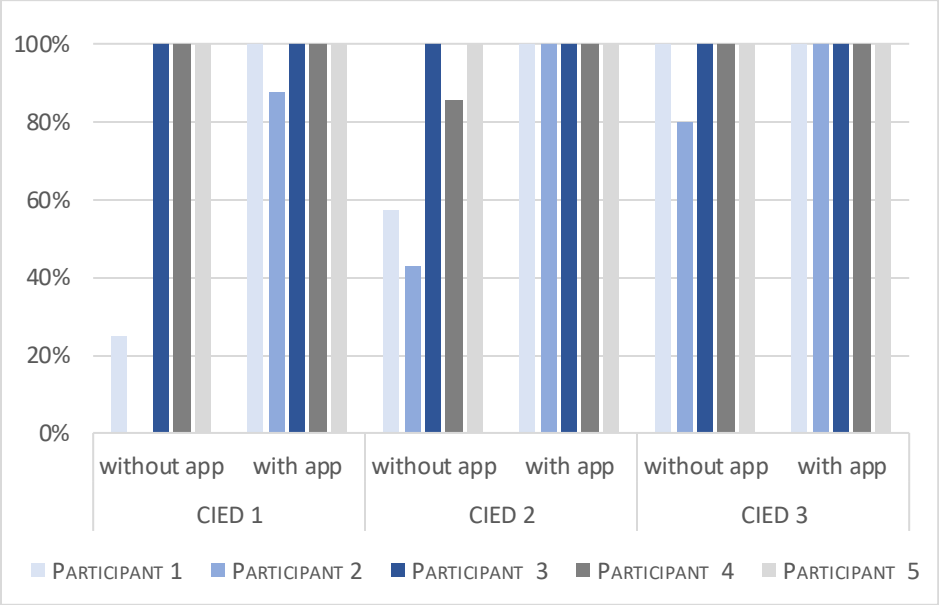

Figure 33: Visualization of evaluation results of the task completion rate considering the use of the MRsafe app, the queried CIED and the participants

4.2.3 Task Time

For the evaluation of the task time, the mean value and the standard deviation were calculated with the data from the usability test using the =STABW() and =AVERAGE() formulas in MS Excel. The result shows that the task time for clarifying the MR compatibility of the given CIEDs without the app was 20:00 min ± 12:55 min, while with the app it was 00:43 min ± 00:14 min *(Table 12)*.

MEAN VALUE ± STANDARD DEVIATION (*MIN*)	
WITHOUT APP	*WITH APP*
20:00 ± 12:55	*00:43 ± 00:14*

Table 12: Mean value ± standard deviation of the task time from the evaluated usability test

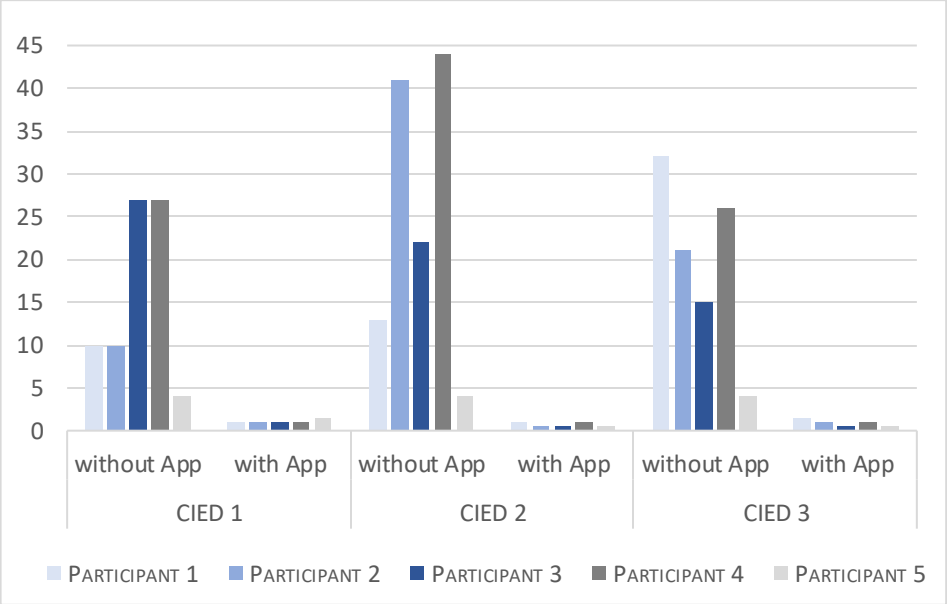

Figure 34: Visualization of evaluation results of the task time considering the use of the MRsafe app, the queried CIED and the participants

4.3 Feedback and Improvement Suggestions

The overall feedback was positive, all participants considered the app to be a good solution for querying the MR compatibility of CIEDs. Suggestions for improvement made during this usability test were as follows:

- Creation of a start menu where CIED and electrodes can be filled in.
- Improvement of the *'Scan again'* button: Scanner should not be visible after scanning a barcode, but only after pressing the *'Scan again'* button.
- Improvement of the search query regarding the spelling (CIED 2).

5 Conclusion

Assessing the MR compatibility of cardiac implantable electronic devices (CIEDs) can be complex and time consuming. Although many CIEDs are labelled as MR conditional nowadays, there are still implantations and generator changes of MR unsafe CIEDs. These devices may interact with the MR environment. Therefore, it is important to determine the label of the CIED and verify that the entire CIED system is MR conditional or not. No additional leads or devices should be present. Patient cards and radiography are helpful for this determination. If these are not available, the assessment of the MR compatibility is more difficult and takes longer. Furthermore, the approvals of implants for MRI may differ from country to country. To finally ensure a safe MRI scan in patients with CIEDs, many parameters and conditions need to be considered before, during and after the MRI. Thus, a mobile application (app) was developed and evaluated using a user-centered design (UCD) process. The aim of the MRsafe app is to provide healthcare professionals in Austria with adequate MRI safety information about CIEDs so that MRI examinations can be performed safely.

All posed research questions (RQ) could have been answered in this master thesis (*see chapter 1.3)*. At the beginning of the UCD process, the user needs were methodically collected through literature research and confirmed through expert interviews (**RQ1**). A lot of information is needed to ensure a safe MRI scan in patients with CIEDs, which can be divided into MR-specific and CIED-specific information. MRI parameters and conditions that need to be clarified are the MR compatibility of the CIED, the highest permitted magnetic field strength, the maximum allowable specific absorption rate (SAR), the maximum local spatial gradient, the scan mode, scan time limits and potential exclusion zones. For CIEDs, the information to be clarified includes the function and position of the generator, the combination of generator and lead(s), the number of leads, the implantation time, and specific measurements (e.g.: stimulus threshold). The expert interviews made it also possible to define the functional and technical requirements for the MRsafe app (**RQ2**). A barcode scan, a search box, links to sources, checklists and the technical data sheet of the MR were considered as helpful by the experts when querying the MR compatibility of CIEDs. After the prototypical development of the MRsafe app, considering the needed information of CIEDs and the stated requirements for the app, a usability test has provided information on the task completion rate and the task time of the task scenarios performed with and without using the app (**RQ3**). The results show that the

completion rate without using the app has a mean value with a standard deviation of 79*,4% ± 32,7%*, whereas with using the app, a completion rate of *99.2% ± 3.2%* was achieved. Similarly, the task time for clarifying the MR compatibility of the given CIEDs without the app was *20:00 min ± 12:55 min*, while with the app it was *00:43 min ± 00:14 min*. Furthermore, this usability test shows that manufacturer information was the most frequently used method to clarify MR compatibility without using the app, followed by MRI Safety, MagResource and Internet/Other.

In conclusion, the results of this master thesis suggest that the use of an app to query the MR compatibility of CIEDs can be a good alternative to already existing sources, as an improvement in both the completion rate and the task time was achieved. The MRsafe prototype allows healthcare professionals to quickly access aggregated MRI safety information of CIEDs, specified in this master thesis, by scanning a CIED-specific barcode or by manually searching for the CIED. Helpful links and checklists are also included in this app. Thus, a further development of the MRsafe prototype could be pursued.

However, there are also some limitations to this master thesis that need to be mentioned. As only radiographers participated in this usability test, various healthcare professionals faced with clarifying the MR compatibility of CIEDs could be recruited in further usability tests or studies. In addition, the ratio of sources used for the evaluation without the app could also be in the same dimension, as the task time of the different sources used differed from each other. Another limitation, encountered during the usability test, was that the access to one manufacturer's website was blocked by the employer (KAGes) as it was identified as a risky connection, which may have affected the task time and task completion rate (CIED 2). Furthermore, some manufacturers' websites only allow the clarification of an entire CIED system, as it is generally necessary to verify the entire CIED system to ensure a safe MRI examination. For reasons of time management, only the clarification of the pacemaker itself was requested in this master thesis. Information on the associated leads was included in the implant passes though, to allow the clarification of an entire CIED system, if requested by the websites. This had to be documented for traceability.

Questions raised during the writing of this master thesis are: How can the correctness of MRI safety information be guaranteed? What happens if someone is harmed by incorrect information? Is the MRsafe app a medical device under the Medical Devices Act? And what specifications would be required for the MRsafe app to be a medical device? Are healthcare professionals willing to use their personal mobile phones to check the MR compatibility for work purposes?

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Appendix

A. Declaration of Consent

Einwilligungserklärung

Ich (Name, Adresse, Geb.) _____
stimme ausdrücklich zu, dass meine personenbezogenen Daten, in Form von

- ☐ Bildverarbeitungen (sowohl in Form von Videos als auch Fotos)
- ☐ Tonaufnahmen
- ☐ Fragebögen
- ☐ Sonstige: _____

und *(von der Projektleiterin auszufüllen)*

- ☐ Daten besonderer Kategorien personenbezogener Daten (= sensible Daten, wie rassische/ethnische Herkunft, politische Meinung, religiöse oder weltanschauliche Überzeugungen, Gewerkschaftszugehörigkeit, genetische Daten, biometrische Daten, Gesundheitsdaten, oder Daten zum Sexualleben oder der sexuellen Orientierung)

- ☐ keine Daten besonderer Kategorien personenbezogener Daten

im Rahmen der Masterarbeit „**MRsafe - prototypische Entwicklung und Evaluierung eines Dienstes für medizinisches Fachpersonal zur Abfrage der MR-Tauglichkeit von kardial implantierbaren elektronischen Geräten unter Verwendung eines user-centered-design Prozesses.**“ zu Zwecken der Evaluierung des MRsafe-Dienstes verarbeitet werden.

In wissenschaftlichen Veröffentlichungen werden keine personenbezogenen Daten bekannt gegeben, um gegenüber Dritten sicherzustellen, dass es nicht zu einer Identifizierung der Person führen kann. Auch wird sichergestellt, dass die Daten nicht an unberechtigte Dritte gelangen, und die Speicherung auf sicheren, verschlüsselten Servern bzw. in versperrten Bereichen erfolgt. Sollte eine Datenverarbeitung in externen Cloud-Systemen (Dropbox, Dropbox for Business, Tresorit, Google Drive, …) unumgänglich sein, wird sichergestellt, dass diese Daten durch eine separate Verschlüsselung von unberechtigten Zugriffen Dritter geschützt werden.

Es gelten die nationalen und internationalen datenschutzrechtlichen Bestimmungen.

Nach Beendigung der Masterarbeit werden die Daten („Rohdaten“) zum Nachweis der Richtigkeit der Ergebnisse 10 Jahre aufbewahrt und danach einer Löschung/Anonymisierung zugeführt.

_____
Datum, Unterschrift der/des Teilnehmenden

Weiters stimme ich folgenden weiteren Nutzungen meiner Aufnahmen und Daten zu:

☐ Ich stimme zu, dass Tonaufnahmen im Rahmen der Masterarbeit von mir angefertigt werden dürfen, und im Rahmen der Masterarbeit für wissenschaftliche Zwecke verwendet werden dürfen.

☐ Ich stimme zu, dass meine Aufnahmen und Daten für weitere folgende Forschungsprojekte („Sekundärforschung") im Bereich der MR-Sicherheit von der Projektleiterin verwendet werden dürfen.

_____

Datum, Unterschrift der/des Teilnehmenden

Meine Einwilligung stellt die rechtliche Grundlage für die Verarbeitung der personenbezogenen Daten dar. Diese Einwilligungserklärungen können jederzeit, auch separat voneinander, von mir bei der unten genannten Adresse widerrufen werden, ohne dass dadurch die Rechtmäßigkeit der Verarbeitung bis zum Widerruf berührt wird. In diesem Fall werden die von mir erhobenen persönlichen Daten und Gesprächsaufzeichnungen umgehend gelöscht.

Ich bin berechtigt, bei der Projektleiterin eine umfangreiche Auskunftserteilung zu den zu meiner Person gespeicherten Daten zu ersuchen. Weiters kann ich die Berichtigung, Löschung, die Datenübertragung und Einschränkung der Verbreitung verlangen, und habe ein Beschwerderecht bei der österreichischen Datenschutzbehörde, welche bei dieser als zuständige Aufsichtsbehörde einzubringen ist.

B. Interview Guideline

LEITFADEN INTERVIEW

MRSAFE APP

Liebe TeilnehmerInnen,

mein Name ist Stefanie Pirzl und ich bin Radiologietechnologin am LKH Leoben und Studentin des Masterstudienganges „Digital Healthcare" an der FH St. Pölten. Im Zuge meiner Masterarbeit „MRsafe - prototypische Entwicklung und Evaluierung eines Dienstes für medizinisches Fachpersonal zur Abfrage der MR-Tauglichkeit von kardial implantierbaren elektronischen Geräten" möchte ich mit Hilfe eines user-center-design Prozesses eine prototypische App entwickeln, die das medizinische Fachpersonal bei der Abfrage aller erforderlichen MR-Sicherheitsinformationen von kardial implantierbaren elektronischen Geräten (CIEDs) unterstützen sollte. Als digitale Lösung zur Abfrage wird das Scannen des Implantat-spezifischen Barcodes am Handy in Betracht gezogen. Die Interviews mit Fachpersonen werden zu Beginn des User Centered Design Prozesses geführt, um herauszufinden, welche Informationen über CIEDs notwendig sind, um eine sichere MR-Untersuchung zu gewährleisten und welche funktionalen und technischen Anforderungen benötigt werden, um das medizinische Fachpersonal bei der Abfrage der MR-Tauglichkeit von CIEDs zu unterstützen. Die Datenerfassung und Datenbearbeitung erfolgt mittels kommerzieller Software, alle gewonnenen Daten werden in Computerdateien gespeichert, nur das Studienteam hat Zugang zu diesen Daten. Um die Anonymisierung der Daten sicherzustellen, wird beim Erfassen von personenbezogenen Daten der Name durch eine Kodierung ersetzt. Mit Ihrer mündlichen Einverständniserklärung wird das Interview aufgezeichnet um dieses anschließend transkribieren zu können.

Ich möchte mich recht herzlich bei Ihnen für Ihre Teilnahme und Unterstützung bedanken!

1) Welcher Berufsgruppe gehören Sie an?
2) Wie lange sind Sie bereits in diesem Berufsfeld tätig?
3) Welche Informationen müssen vor einer MR-Untersuchung abgeklärt werden, um PatientInnen mit einem kardial implantierbaren elektronischen Gerät eine sichere MR-Untersuchung garantieren zu können?
4) Gibt es etwas, dass bei der Abfrage der MR-Kompatibilität nicht übersehen werden darf bzw. besonders zu berücksichtigen ist?
5) Welche Schwierigkeiten bzw. Herausforderungen gibt es Ihrer Erfahrung nach bei der Abfrage der MR-Kompatibilität von kardial implantierbaren elektronischen Geräten?
6) Würden vorgegebene Checklisten hilfreich sein, um, vor allem unerfahrenem Personal, eine korrekte Abklärung zu ermöglichen?
7) Soweit Sie das beurteilen können, wäre es Ihrer Einschätzung nach sinnvoll, wenn das medizinische Fachpersonal das technische Datenblatt des eigenen Magnetresonanztomographen in der App abspeichern könnte, um dieses direkt mit dem Ergebnis der Suche vergleichen zu können?
8) Gibt es zusätzliche Features für die App, die ihrer Meinung nach bei der Abfrage der MR-Kompatibilität von Vorteil wären?

C. Usability Test

USABILITY TEST

MRSAFE APP

Liebe TeilnehmerInnen,

mein Name ist Stefanie Pirzl und ich bin Radiologietechnologin am LKH Leoben und Studentin des Masterstudienganges „Digital Healthcare“ an der FH St. Pölten. Im Zuge meiner Masterarbeit „MRsafe - prototypische Entwicklung und Evaluierung einer App für medizinisches Fachpersonal zur Abfrage der MR-Tauglichkeit von kardial implantierbaren elektronischen Geräten“ habe ich mit Hilfe eines User Centered Design Prozesses eine prototypische App entwickelt, die medizinisches Fachpersonal bei der Abfrage der MR-Tauglichkeit von kardial implantierbaren elektronischen Geräten unterstützen sollte. Durch Scannen des Implantat-spezifischen Barcodes werden die benötigten Informationen abgefragt. Mit der Teilnahme an diesem Usability Test sind Sie Teil des Evaluierungsprozesses dieses User Center Design Prozesses und nehmen an einer Pilotstudie teil. Dies ist eine kleinere Untersuchung an wenigen ProbandInnen mit dem Zweck, Methoden und Abläufen für eine spätere, größere Studie einschätzen zu können. Um repräsentative Ergebnisse über die Usability der MRsafe App, einschließlich der Abschlussquote und der Bearbeitungszeit zu erhalten, würde ich Sie daher bitten anhand von drei Testszenarien gewisse Informationen über bestimmte kardial implantierbare elektronische Geräte zu erheben und diese in dem angefügten Abschnitt zu dokumentieren. Bei jedem dieser Testszenarien bekommen Sie einen Implantatausweis von mir vorgelegt und müssen zuerst ohne Verwendung der MRsafe App die MR-Kompatibilität und ggf. die vorgegebenen Informationen dieses Implantates in Erfahrung bringen. Anschließend müssen Sie bitte dasselbe mit Verwendung der MRsafe App durchführen und die Ergebnisse dokumentieren.

DURCHFÜHRUNG
FEBRUAR 2023 | KAGES

Teilnehmer-ID: ___

Beruf ☐ RadiologietechnologIn ☐ RadiologIn ☐ KardiologIn
Berufserfahrung ☐ < 2 Jahre ☐ 2-10 Jahre ☐ 10-20 Jahre ☐ > 20 Jahre

Implantat		MR-Kompatibilität	Feldstärke	SAR	Head SAR	Anstiegsrate
#1	**ohne App**	☐ MR sicher ☐ MR bedingt ☐ MR unsicher	☐ ≤ 1,5 T ☐ ≤ 3,0 T	☐ ≤ 2,0 W/kg ☐ ≤ 4,0 W/kg	☐ ≤ 3.2 W/kg	☐ ≤ 200 T/m/s
		Räumlicher Gradient	**Scan Modus**	**B_{1+RMS}**	**Verwendete Quelle**	**Benötigte Zeit**
		☐ ≤ 20 T/m ☐ ≤ 25 T/m ☐ ≤ 30 T/m ☐ ≤ 50 T/m	☐ Normal Mode ☐ First Level	☐ ≤ 2,8 µT	☐ Hersteller ☐ MagResource ☐ MRI safety ☐ Internet/Sonstiges	Angabe in Minuten:
	mit App	**MR-Kompatibilität**	**Feldstärke**	**SAR**	**Head SAR**	**Anstiegsrate**
		☐ MR sicher ☐ MR bedingt ☐ MR unsicher	☐ ≤ 1,5 T ☐ ≤ 3,0 T	☐ ≤ 2,0 W/kg ☐ ≤ 4,0 W/kg	☐ ≤ 3.2 W/kg	☐ ≤ 200 T/m/s
		Räumlicher Gradient	**Scan Modus**	**B_{1+RMS}**	**Benötigte Zeit**	
		☐ ≤ 20 T/m ☐ ≤ 25 T/m ☐ ≤ 30 T/m ☐ ≤ 50 T/m	☐ Normal Mode ☐ First Level	☐ ≤ 2,8 µT	Angabe in Minuten:	

Implantat		MR-Kompatibilität	Feldstärke	SAR	Head SAR	Anstiegsrate
#2	**ohne App**	☐ MR sicher ☐ MR bedingt ☐ MR unsicher	☐ ≤ 1,5 T ☐ ≤ 3,0 T	☐ ≤ 2,0 W/kg ☐ ≤ 4,0 W/kg	☐ ≤ 3.2 W/kg	☐ ≤ 200 T/m/s
		Räumlicher Gradient	**Scan Modus**	**B_{1+RMS}**	**Verwendete Quelle**	**Benötigte Zeit**
		☐ ≤ 20 T/m ☐ ≤ 25 T/m ☐ ≤ 30 T/m ☐ ≤ 50 T/m	☐ Normal Mode ☐ First Level	☐ ≤ 2,8 µT	☐ Hersteller ☐ MagResource ☐ MRI safety ☐ Internet/Sonstiges	Angabe in Minuten:
	mit App	**MR-Kompatibilität**	**Feldstärke**	**SAR**	**Head SAR**	**Anstiegsrate**
		☐ MR sicher ☐ MR bedingt ☐ MR unsicher	☐ ≤ 1,5 T ☐ ≤ 3,0 T	☐ ≤ 2,0 W/kg ☐ ≤ 4,0 W/kg	☐ ≤ 3.2 W/kg	☐ ≤ 200 T/m/s
		Räumlicher Gradient	**Scan Modus**	**B_{1+RMS}**	**Benötigte Zeit**	
		☐ ≤ 20 T/m ☐ ≤ 25 T/m ☐ ≤ 30 T/m ☐ ≤ 50 T/m	☐ Normal Mode ☐ First Level	☐ ≤ 2,8 µT	Angabe in Minuten:	

Teilnehmer-ID: ___

Implantat		MR-Kompatibilität	Feldstärke	SAR	Head SAR	Anstiegsrate
#3	**ohne App**	☐ MR sicher ☐ MR bedingt ☐ MR unsicher	☐ ≤ 1,5 T ☐ ≤ 3,0 T	☐ ≤ 2,0 W/kg ☐ ≤ 4,0 W/kg	☐ ≤ 3.2 W/kg	☐ ≤ 200 T/m/s
		Räumlicher Gradient	**Scan Modus**	**B_{1+RMS}**	**Verwendete Quelle**	**Benötigte Zeit**
		☐ ≤ 20 T/m ☐ ≤ 25 T/m ☐ ≤ 30 T/m ☐ ≤ 50 T/m	☐ Normal Mode ☐ First Level	☐ ≤ 2,8 µT	☐ Hersteller ☐ MagResource ☐ MRI safety ☐ Internet/Sonstiges	Angabe in Minuten:
	mit App	**MR-Kompatibilität**	**Feldstärke**	**SAR**	**Head SAR**	**Anstiegsrate**
		☐ MR sicher ☐ MR bedingt ☐ MR unsicher	☐ ≤ 1,5 T ☐ ≤ 3,0 T	☐ ≤ 2,0 W/kg ☐ ≤ 4,0 W/kg	☐ ≤ 3.2 W/kg	☐ ≤ 200 T/m/s
		Räumlicher Gradient	**Scan Modus**	**B_{1+RMS}**	**Benötigte Zeit**	
		☐ ≤ 20 T/m ☐ ≤ 25 T/m ☐ ≤ 30 T/m ☐ ≤ 50 T/m	☐ Normal Mode ☐ First Level	☐ ≤ 2,8 µT	Angabe in Minuten:	

Feedback & Verbesserungsvorschläge

Ich möchte mich recht herzlich bei Ihnen für Ihre Teilnahme und Unterstützung bedanken!