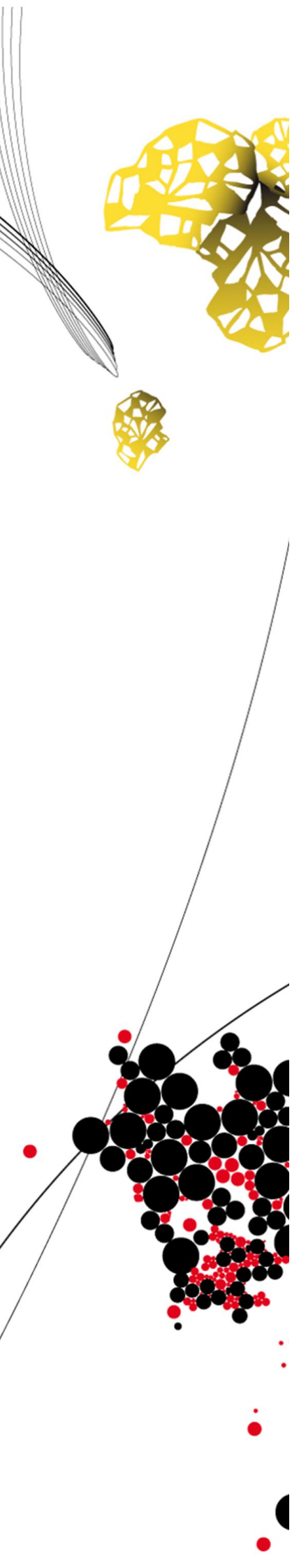

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Electromagnetic Sources in the Hospital Environment: Risks Analysis and Measures for Electro-Magnetic Compatibility (EMC)

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M.Sc. Thesis

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Summary

The introduction of new intentional emitters in the hospital environment have raised concerns about the electromagnetic compatibility (EMC). Electromagnetic interference (EMI) created by these emitters could disrupt the function of the surrounding ME equipment.

Electromagnetic compatible electrical devices operate adjacent to each other without disturbing the operation of each other. EMC is related to three factors: 1) The emission of the source. 2) The efficiency of the coupling path. 3) The immunity of the victim. There are four kinds of coupling paths: 1) Conductive 2) Inductive 3) Capacitive 4) Radiative. In this thesis the focus is only on the radiative coupling path. The severity of EMI is related to the function of the victim.

In the hospital environment a multiple of intentional emitters can be present. The devices identified are the portable radio, Walkie-Talkie, cell phone, computer, tablet and long-range RFID. The devices support a multiple of wireless communication techniques on a multiple of frequencies. The emissions created by these digital wireless communication techniques can be compared to a pulse modulated signal. The field strength of the emitted signal could be calculated by using the free space propagation with an additional factor for the reflection contribution.

The electromagnetic susceptibility (EMS) of medical electrical (ME) equipment is laid down in the ME EMC standard, IEC 60601-1-2. The standard has had several editions through the years. The last edition, which is not yet in force, has special immunity requirements for bands at which intentional radiators could be present. The one but last edition makes a distinction between life-supporting and non life-supporting ME equipment and requires higher immunity for the first. For several reasons the immunity of ME equipment can be different in practice.

To ensure EMC the manufacturers provide recommended separation distances for their ME equipment. These recommended separation distances do not allow emitters close by ME equipment. In practice, the use of certain emitters close by ME equipment have benefits for healthcare providers and it is difficult to ban certain emitters. Therefore these distances are mostly not followed. Separation distances can also be calculated by the information known about the emissions of the sources, the propagation characteristics and the immunity of the ME equipment.

Researchers also conducted empirical studies to find separation distances for the intentional emitters. Not for all emitters the researchers came to a consensus about a safe separation distance.

A more consistent and modern approach to EMC is risk based. A risk analysis method is proposed and applied to the neonatology and intensive care department of the Medisch Spectrum Twente. First the risk of EMI induced by a certain emitter to a certain victim is assessed. Of the source-victim pairs bearing a high theoretical risk after assessment, the experimental risk is determined. With the information of the risk analysis, a risk management policy is proposed to ensure EMC in these departments.

The experiments showed multiple instances of EMI on the ME equipment. The experiments also pointed out that the modulation of a signal and the combination of multiple signals could have a different interference effect.

Only an introductory study about the EMC of the hospital environment is done. At which only a limited number of medical instruments of a limited number of environments were tested. To have a better view on this subject, a more comprehensive and in-depth research is necessary.

Contents

List of acronyms

AM	amplitude modulation
CSMA	carrier-sense multiple access
CW	continuous wave
DMR	digital mobile radio
ECG	electrocardiogram
EEA	European Economic Area
EIRP	equivalent isotropic radiated power
EM	electromagnetic
EMC	electromagnetic compatibility
EMI	electromagnetic interference
EMS	electromagnetic susceptibility
EN	European norm
ERP	effective radiated power
EPC	Electronic Product Code
FCC	Federal Communications Commission
GSM	Global Systems for Mobile Communications
HF	high frequency
IC	intensive care
IEC	International Electrotechnical Commission
IEEE	Institute of Electrical and Electronics Engineers

ISM industrial, scientific and medical

ITU International Telecommunication Union

LAN local area network

LF low-frequency

LTE Long-Term Evolution

ME medical electrical

MST Medisch Spectrum Twente

OOK on-off keying

PAN personal area network

PIE pulse-interval encoding

PMR446 personal mobile radio, 446 MHz

RFID radio frequency identification

RMS root mean square

TDMA time-division multiple access

TETRA Terrestial Trunked Radio

UHF ultra high frequency

UMTS Universal Mobile Telecommunication System

TX transmitter

Chapter 1

Introduction

This graduation assignment is commissioned and has been performed by Nedap in collaboration with the Medisch Spectrum Twente (MST). First some background information on Nedap and MST is presented. Afterwards follow the problem definition and research question. At the end of organization of the report is discussed.

1.1 Nedap Identification Systems

The N.V. Nederlandsche Apparatenfabriek, in short Nedap, was established in 1929. In the course of time, it has grown to an international company which is specialised in the development and production of electrical and electronic products. Nedap formulated the mission: Moving markets with technology that matters. To achieve this mission Nedap has 9 business units, 11 offices and over 750 experts worldwide.

One of the business units is Nedap Identification Systems (IDEAS), which is the leading specialist in systems for long-range identification, wireless vehicle detection and city access control. Products of their portfolio provide solutions for convenient door access and long-range identification of vehicles, people and rolling stock. The products can provide access control for offices, hospitals, gated communities, campuses and industrial areas.

1.2 Medisch Spectrum Twente

MST is a Dutch hospital with its headquarters in Enschede. It offers almost all medical specialities in its headquarters, situated in the city centre of Enschede. A secondary location is present in Oldenzaal and outcare facilities in Losser and Haaksbergen. The MST belongs to the largest non-academic hospitals of the Netherlands.

1.3 Problem definition

In modern day hospitals, new technologies are introduced everyday. These technologies include wireless communication and radio frequency identification (RFID) systems, which intentionally emit electromagnetic (EM) radiation for its functioning. One of the RFID systems, which makes way through the hospital environment, are the long-range RFID systems of Nedap Identification Systems, the UPASS and TRANSIT. Although the benefits and convenience of the new technologies are clear, there is a possible drawback. The emission radiated could possibly cause electromagnetic interference (EMI) on the adjacent medical electrical (ME) equipment. EMI could as a consequence, disrupt the functioning of the ME device, which in turn could have disastrous, possible lethal consequences for the patient relying on the ME apparatus.

1.4 Research question

The research question concluding the problem definition is:
What is risk of electromagnetic compatibility issues, caused by intentional emitters, in the modern day hospital environment?

1.5 Report Organization

In chapter 2 the aspects of electromagnetic compatibility (EMC) will be regarded. In the following chapter, chapter 3, the emissions and its propagation in the hospital environment are treated. In chapter 4 the electromagnetic susceptibility (EMS) of the ME equipment is regarded. In the following two chapters, chapter 5 and 6, the EMC of the hospital environment is treated. The thesis is concluded by the conclusions and recommendations of chapter 7.

Chapter 2

Aspects of electromagnetic compatibility

In this chapter the aspects of EMC are treated introductory, to provide a better understanding of the concept and what is involved.

2.1 EMC in general

EMC is about compatibility of electrical devices to operate alongside each other in the same EM environment. Each electrical device generates EM energy, which is radiated or conducted in an EM field or wave. The electrical device generating EM energy is called the source or emitter. EM waves generated can reach other electrical devices via a coupling path, for example via a wire. The EM energy is received by the other electrical devices (the receiver, receptor or victim) in the same EM environment. The receptor can be affected in its operation by the received EM field. In case the receptor is affected, there are EMC problems between the source and receptor. In the other case, the normal operation of the receptor continues, the devices are EM compatible. For the analysis whether EMC occurs or not, three main aspects should be taken into account:

1. The strength of the emission.
2. The efficiency of the coupling path between source and receptor.
3. The susceptibility (immunity) of the receptor.

In general, there are three ways to mitigate the chance of or prevent EMI.

1. Decrease the emission generated by the source.
2. Decrease efficiency of the coupling path.
3. Increase the susceptibility of the victim.

2.2 Sources of EMI

EM energy can be created by a large variety of sources. Each creation of EM energy contributes to the EM environment, although in most cases, only a few sources are significant in their contribution. The main classification is between natural and man-made sources of EM energy. A well-known natural source is the geomagnetic field of earth. This source can be regarded as a large magnetic dipole with one pole near Ellesmere Island in Canada and the other at Antarctica. Both the strength of the field and the position are subject to variation. Another well-known natural source is lightning. Lightning is one of the most energetic natural EM phenomena. The moment before lightning strikes, the potential difference between the thunderclouds and earth is in the order of 100 MV. During a thunderstorm, 10^{10}J of EM energy is potentially in transit. These examples do not exhaust the list of all natural sources, terrestrial and extraterrestrial processes create even more.

The operation of man-made electrical devices contribute to the EM environment. These contributions may be further classified into intentional and unintentional emissions. A form of intentional man-made emissions are radio transmitters. Applications are found in wireless telecommunication services and radar. Examples of systems which utilise transmitters are Global Systems for Mobile Communications (GSM), Long-Term Evolution (LTE), Wi-Fi and Bluetooth. International regulatory bodies allocate fixed frequency bands to the emission of these applications. Another form of intentional emissions are the electro-heat applications. The microwave oven is an electro-heat application, which heats food by transmitting EM waves at 2.45 GHz.

An unintentional form of emissions are created by digital signal processing and transmission. Modern digital circuitry utilizes fast pulses to encode information. These pulses have low fall and rise (transition) times. The presence of these pulses on printed circuit boards can increase the radiation and coupling across (crosstalk) adjacent circuits. Another example is energy stored in the electrical field of a capacitor or the magnetic field of an inductor. A redistribution of this energy requires a minimum amount of time. During this redistribution large quantities of energy are in transit. The circuit is under transient conditions. At this state, overvoltage, overcurrent and fast pulses can occur, which can be a cause of EMC problems. The electricity grid is the source and victim of EMI. The signal of the electricity grid is not ideal. Due to presence of converter equipment, non-linear devices such as transformers and arc furnaces, higher harmonics voltages and currents are generated, which are a multiple of the fundamental frequency. These interferences propagate through the mains network to other electrical devices. In turn electrical devices connected to the mains, can feed interferences onto the electricity grid.

Another phenomenon, which can cause EMC problems is electrostatic discharge.

It happens when a body charged by either acquiring electrons or giving away electrons, discharges via a conductor. The human body can charge to a potential of 10 kV. Electrical ignition systems, which can be found in combustion-engine cars, use electrostatic discharge for ignition. A high-power EM pulse is produced by a nuclear detonation and the high intensity EM fields cause severe EMI. This phenomenon is studied by the military for defence and protection of civil infrastructure [1, Ch.5].

2.3 Coupling paths

A source and victim could have four coupling paths, as shown in Figure 2.1. Not every coupling path is present in every situation. This depends on the EM environment of the source and emitter. The conductive path is present, if there is a direct electrical contact between the source and the victim. For example, via transmission lines, wire, cable or PCB trace between source and victim.

A capacitive or inductive path may be present if the source and victim are a short distance apart (typically less than one wavelength of the EM wave). Depending on the orientation and separation between two adjacent conductors capacitive or inductive coupling occurs. Capacitive coupling is an interaction between the electric fields of two conductors. The conductors can be regarded as the plates of a typical capacitor. Inductive coupling is about the interaction of the magnetic fields between two conductors. A magnetic flux is produced when a current flows through a conductor. In the situation that a flow of current in one circuit is producing a flux in an other circuit, there is a mutual inductance. This is shown in the figure as an inductive coupling [2, Chap. 2].

Radiative coupling may be present when source and victim are separated by a large distance (typically more than one wavelength of the EM wave). The source and victim act like a radio antenna. The source radiates an EM-wave which propagates through space and is picked up by the victim.

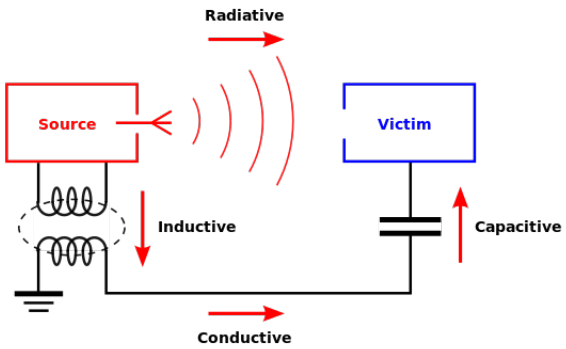


Figure 2.1: EMI coupling paths. Adopted from [3]

2.4 Consequences of EMC problems

There are numerous instances of effects caused by EMC problems. The effects range from almost none to life-threatening or catastrophic. In this section a few examples are treated [4, Sec. 1.3].

A common case of EMI is the concurrence of a buzz sound when a speaker system is close by a GSM cell phone. This effect only appears when the cell phone is close by and is mitigated by moving away the cell phone.

A certain manufacturer of trailer trucks with an electronic breaking system found out that keying a citizens band transmitter in a passing car nearby could cause the brakes of the truck to ”lock up”. It turned out that the transmitter signal coupled into the electronic circuitry of the braking system.

The U.S. army purchased an attack helicopter which was designated as the UH-60 Black Hawk. In November 1988, a number of news agencies reported that the Black Hawk was susceptible to EMI. The news agencies revealed evidence that most of the crashes of the Black Hawk, since 1982, which killed 22 people, were because of EMC issues. The EMS of the Black Hawks flight control systems to emissions close too radar and radio transmitters was suspected to have caused the crashes.

These occurrences of EMC problems show that the consequences can range from annoying to life-threatening situations. This is subject to how critical the function of the electrical system is.

2.5 Legislation

Alongside of the EMC requirements imposed by the product manufacturer, there are EMC requirements mandated by governmental agencies. These requirements, consisting of maximum emission levels and minimal levels of susceptibility for electrical devices, are legally binding to access the market. The EMC requirements of individual manufacturers may be stricter than legally necessary to increase the reliability and quality of the product. To ensure EMC, the legislation in most countries is based on the following essential requirements [5], [6]:

1. The product may not cause harmful interference

2. The product must accept any interference received without degradation of performance

Despite these requirements, EMC between electrical products is not guaranteed.

In European Union (EU) this legislation is covered by Directive 2014/30/EU. Fulfilling the harmonized standards (or European norms (ENs)) presumes conformity with the directive. Conformity with the directive is required for a manufacturer to be granted to sell its products in the European Economic Area (EEA). The standard prescribes the maximum emission and the minimal immunity of electrical equipment. Harmonized standards are taken from International Electrotechnical Commission (IEC). The IEC is an international organization, which develops electrotechnical standards for worldwide use. The IEC consists of members from national committees of every country. These committees are representatives of their national electrotechnical interests. The national committees appoint professionals from industry, government bodies and academia as their members [7].

In the United States (USA) the Federal Communications Commission (FCC) is charged with the regulation of radio and wire communications. A part of this responsibility is about the EMC of electrical devices. The FCC regulations differ significantly from the European EMC Directive, because the FCC does not require products to be tested for their immunity [4, Sec. 2.1]. However, the manufacture must demonstrate that its product can operate without degradation in its intended EM environment. A manner to demonstrate is by complying with the standards of the IEC. Other countries generally adopt the standards of the IEC with slight modifications [8].

2.6 EMC in hospitals

EMC problems are not uncommon in hospitals [9]. ME devices can provide critical functions to patients in the hospital, this implies that interference could cause minor to even lethal consequences for a patient. This is depending on the function of the ME device and the strength of the interference. Both intentional and unintentional emitters could cause this interference. In the last decades new wireless technologies have been introduced into the hospital rooms, increasing the number of intentional emitters in the hospital environment. Furthermore new medical equipment, like the introduction of electrosurgery, introduced new unintentional emitters in the hospital environment.

The IEC standard 60601-1-2 is about the general requirements for basic safety and essential performance of medical electrical equipment in the EMC domain. Fulfilling this standard is in most countries sufficient to be conform to the respective national directive [10]. The standard prescribes, among others, the minimal immunity of medical electrical equipment. Regularly, a new version of the standard is published to cover the development of the EM environment. Chapter 4 treats the immunity requirements in more details.

Chapter 3

Emissions in the hospital environment

In this chapter, the emitters, its emissions and the propagation of the emissions are treated. The focus is only on intentional radiative emitters, which could be present in the Dutch hospital environment. Diathermy and MRI are examples of unintentional emitters, which will not be treated in this study.

3.1 Intentional (radiating) emitters

The number of wireless devices in operation worldwide continues to grow [11]. A large share of these devices are in use for mobile applications. Since these applications are mobile, the devices for the application can be carried by healthcare providers and visitors into the hospital. As a result healthcare providers and visitors carry intentional emitters with them, which contribute to the EM environment of the hospital. On the other hand, RFID application can improve the healthcare, which also contribute to the EM environment. The following intentional emitter technologies have been identified as (maybe) present in the modern Dutch hospitals [12].

3.1.1 C2000

C2000 is the name of the closed communications network of the Dutch emergency and security services. C2000 is based on the international Terrestial Trunked Radio (TETRA) standard. TETRA is the standard for the mobile communications of the public order and security services. The hand-held devices of C2000 operate on the 380 MHz band and have a maximum emission power of 1.8 W effective radiated power (ERP) with power control. Power control means that only as much emission power is used as necessary to keep a stable connection. Inside the hospital only

the ambulance staff requires and bears C2000 hand-held devices.

3.1.2 Walkie-Talkie

Walkie-talkie uses the personal mobile radio, 446 MHz (PMR446) technique or digital mobile radio (DMR) to support communication between the hand-held devices. The maximum emission power is 0.5 W ERP for the PMR446 system and an emission power of 1 W ERP for the DMR system. The use of DMR is license-free inside the 446 - 446.2 MHz band, but also can operate in the 442 - 448 MHz and the 450 - 470 MHz band with a license. The exact implementation is dependent on the choices of the hospital. Walkie-talkies are in use by some members of staff in the hospital, but are not present in all hospital environments.

3.1.3 Cell phone

Cell phone is used to make or receive phone calls, send and receive messages and use other telecommunication services. In the recent years cell phone have become smaller and are able to offer more functions. The number of cell phone subscriptions continues to grow [11]. Hence, an increasing number of users are carrying their cell phones with them at all times. Cell phone uses a multiple of wireless technologies to provide its service. Supported standards are GSM and its extensions GPRS and EDGE, Universal Mobile Telecommunication System (UMTS) and its extension HSDPA (3G) and LTE and its extension LTE-advanced (4G). The emission power depends on the frequency and standard, but is typically up to 2 W ERP with power control. Frequencies of operation in the Netherlands are the 800, 900, 1800, 1900 and 2600 MHz bands [13], [14].

3.1.4 Wi-Fi

Wi-Fi is the common name for Institute of Electrical and Electronics Engineers (IEEE) 802.11 standard and uses the 2.4 GHz and 5.8 GHz industrial, scientific and medical (ISM) band to provide a high speed local area network (LAN). The technique can be found in cell phones, computers, tablets, etc. The typical maximum emission power is 100 mW equivalent isotropic radiated power (EIRP) with power control.

3.1.5 Bluetooth

Bluetooth is a wireless technology, which enables exchange of data over a short distance and the building of a personal area network (PAN). It operates on the 2.4

GHz ISM band with power control, the maximum emission power is 100 mW EIRP, but is typically 1 mW [15]. The Bluetooth technology can be found in cell phones, computers, tablets, etc.

3.1.6 Long-range RFID

RFID consists of multiple techniques to remotely identify and track a tag. In healthcare, RFID systems could be used to improve asset management (being able to locate mobile equipment at all times), patient care (being able to correctly identify a patient for treatment) and inventory management (being able to identify what you actually have in store). The most important criteria to differentiate RFID systems are the operating frequency, coupling method and range of the system. RFID systems with a range up to 1 centimetre are called close-coupling systems and can be operated on any desired frequency between direct current and 30 MHz. The systems are coupled by both electric and magnetic fields. RFID systems with a range up to 1 meter are known by the term remote coupling systems. Almost all of these systems operate based on inductive coupling. Common frequencies of operation are the 125-134 kHz (low-frequency (LF)) and 13.56 MHz (high frequency (HF)) frequencies. The RFID systems with a range of 1 meter and more, of focus here, are named long-range RFID systems. These systems operate using radiated waves on the ultra high frequency (UHF) at 868 MHz in Europe and the microwave frequencies of 2.45 GHz and 5.8 GHz [16, Sec. 2.3] [17]. Details on the operation of long-range RFID systems can be found in Appendix A. The UPASS and TRANSIT, developed by Nedap, are examples of long-range RFID systems.

UPASS

UPASS is the leading vehicle and people identification platform based on UHF technology. The reader is Electronic Product Code (EPC) generation II compliant and can therefore be operated with passive tags [18]. There are three readers in UPASS line-up: Target, Reach and Access. All readers in the line-up have a distinct field of application. The Target is for long-range vehicle identification, the Reach is the reader for parking access and the Access is a hands-free door access reader. The frequency band of operation is 865 to 868 MHz in Europe with a maximum emission power of 2 W ERP with pulse-interval encoding (PIE) and no power control. The tag utilizes the forward signal of the reader

Figure 3.1: UPASS Target

for its emission. Since this is the case, the emission of the tag can be regarded as negligible in comparison with the emission of the reader.

TRANSIT

TRANSIT is leading platform for automatic identification of vehicles and drivers, based on semi-active RFID technology. TRANSIT identifies vehicles and their drivers at a distance up to 10 meters, with a maximum travelling speed of 200 km/h. The line-up consists of the following readers: Ultimate, Standard and Entry. The Ultimate is the successor of the Standard and has objective to provide long-range vehicle identification. The Entry has hands-free door access as its purpose. All TRANSIT readers only operate on the 2.45 GHz band, except for the Ultimate which operates simultaneously on the 433 MHz band and 2.45 GHz band. On the 2.45 GHz band a (constant) continuous wave (CW) with a maximum power of 0.5 W EIRP is emitted. On the 433 MHz band, a self-radiating tag is in use, therefore the emissions of the tag at 433 MHz are considered. However the emission is strength on the 433 MHz band are very low, which are -5 dBm for the reader and -10 dBm EIRP for the tag.

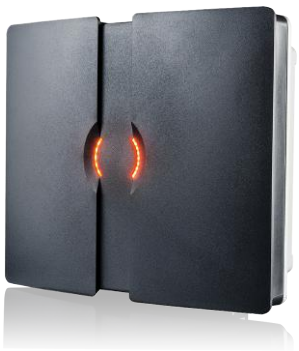


Figure 3.2: TRANSIT Ultimate

3.1.7 Summary

In Table 3.1 all emitters identified, as found in the Netherlands, are summarised. The abbreviation PC stands for power control, PIE for pulsed interval encoding and CW for continuous wave. The column '(Uplink) band' is about the frequency band of the emission. In case there is a two-way radio communication system with a base and mobile station and frequency domain duplexing is used only the uplink band is regarded. The table was checked by the radio communications agency of the Netherlands.

3.2 Air interface

Part of the emission analysis is on the properties of the emitted signals. All intentional emitters found in Table 3.1 are digital. A treatment of the details of the signals of the techniques would be too complex and time-consuming. Therefore in the standards [31]–[34], the properties of the emitted signal are simplified to a

Table 3.1: Intentional emitters of the hospital environment

Device	Technique	(Uplink) band (MHz)		ERP (W)	ERP (dBm)	Note	Ref.
C2000 hand-held	TETRA	380	390	1.80	32.5	PC	[19]
Walkie-talkie	PMR446	446	446.2	0.50	27.0		[20]
	DMR	442	448	1.00	30.0		[21]
		450	470	1.00	30.0		
Cell phone [22], [23]	GSM	880	915	2.00	33.0	PC	[24]
		1700	1785	1.00	30.0		
	UMTS	880	915	0.25	24.0	PC	[25], [26]
		1920	1980	0.25	24.0		
	LTE	832	862	0.20	23.0	PC	[27]
		880	915	0.20	23.0		
		1700	1785	0.20	23.0		
		2500	2615	0.20	23.0		
Cell phone, Computer, etc	Wi-Fi	2400	2483.5	0.06	17.9	PC	[28]
		5150	5350	0.12	20.9		[29], [30]
		5470	5725	0.12	20.9		
	Bluetooth	2400	2483.5	0.06	17.9	PC	[28]
Nedap RFID	UPASS (EPC gen II)	865	868	2.00	33.0	PIE	[18]
	TRANSIT	433	434	0.00	-7.2		
		2446	2453	0.31	24.9	CW	

pulse modulated signal. Several reasons are given as justification. Firstly, the most techniques employ time-division multiple access (TDMA) or carrier-sense multiple access (CSMA) as a multiple access scheme. Since TDMA and CSMA switches the emission between a signal and no signal, it can be regarded as a pulse modulated signal. TDMA and CSMA are not always employed, but is at most techniques allowed as one of the access schemes. Secondly, in case no pulsing occurs because of the access scheme, it could be caused by the duplexing. Time domain duplex could have the same effect, which is mostly an option for the service provider to employ. Thirdly, pulse modulated signals are known for a more severe interference effect in comparison with a CW or frequency swept signals. As a consequence, a pulse modulated signal can represent the worst case scenario of the digital wireless communication signals.

3.3 Propagation of EM waves

The EM energy of the emission will get distributed over the available space. The characteristics of space around the emitter affects this distribution. The distribution in free space is very straight forward, distribution by reflections, for example by incidence on objects, require a more complex evaluation.

3.3.1 Near and far field

The space around the antenna has a different field structure depending on the region. The regions are: reactive near field, radiating near field and far field [35, Chap. 2]. The near and far field is related to the kind of antenna. In this section a short dipole antenna is assumed, this and related kinds are widely in use. The region defined by the condition in equation 3.1, is the reactive near field. In this region the reactive field predominates.

$$r < \frac{\lambda}{\pi} \tag{3.1}$$

Where r is the distance from the antenna surface, D is the largest dimension of the antenna, and λ is the wavelength.

The region between the reactive near field and the far field is the radiating near field. The condition for the far field region is defined in equation 3.2. In the radiating near field the radiation fields predominate and the angular field distribution is dependent on the distance from the antenna.

$$r >> \frac{\lambda}{2\pi} \tag{3.2}$$

In the far field region, the angular field distribution is independent of r.

3.3.2 Free space propagation

In the most simple scenario the transmitter is in free space and radiates its energy isotropically. Since energy is conserved , the integral of the power density over any closed surface around the transmitter (TX) is equal to the transmitted power. This equation allows the calculation of EM energy at every point in the free space. If now the closed surface is a sphere with radius r, with the transmitter positioned at its centre, emitting isotropically, the power density at the surface of the sphere is [31, Chap. 4] [36], [37]:

$$P_d = \frac{P_{TX}}{4\pi r^2} \tag{3.3}$$

Poynting's theorem relates the power density to the E-field and H-field vectors as follows:

$$P_d = E \times H \tag{3.4}$$

The magnitude of the power density is:

$$|P_d| = EH = \frac{E^2}{120\pi} \tag{3.5}$$

Where 120π is the impedance of free space in far-field.
Now combining equation 3.3 and 3.5 gives the following expression for the E-field strength:

$$E = \frac{\sqrt{30 P_{TX}}}{r} \tag{3.6}$$

This equation is only applicable in the far-field of an isotropical antenna. In case the antenna is replaced for one with a gain, the E-field increases proportionally:

$$E = \frac{\sqrt{30 P_{TX} G_{TX}}}{r} \tag{3.7}$$

Note that $P_{TX}G_{TX}$ is equivalent to the power of the transmitter in EIRP.

3.3.3 Reflection and transmission

The equations for the power density and the E-field strength in previous section were derived for the free space environment. In practice, EM waves might incident on objects present around the transmitter. At incidence of the EM wave on an object reflection or transmission (penetration of the wave on and through the object) of the wave occurs, this section focuses on these mechanisms. The consequence of an incidence as depicted in Figure 3.3 is related to reflection and transmissions coefficients. The different reflection and transmission coefficients are shown in equations 3.8, 3.9, 3.10 and 3.11. The derivation of these equations can be found in Appendix B.
E-field reflection coefficient for TE polarisation:

$$R_{eTE} = \frac{E_r}{E_i} = \begin{cases} \frac{\sqrt{\eta_1}\cos\theta_1 - \sqrt{\eta_2}\cos\theta 2}{\sqrt{\eta_1}\cos\theta_1 + \sqrt{\eta_2}\cos\theta 2} & \sqrt{|\frac{\eta_1}{\eta_2}|}\sin\theta_1 < 1 \\ 1 & \sqrt{|\frac{\eta_1}{\eta_2}|}\sin\theta_1 \geq 1 \end{cases} \tag{3.8}$$

E-field reflection coefficient for TM polarisation:

$$R_{eTM} = \frac{E_r}{E_i} = \begin{cases} \frac{\sqrt{\eta_2}\cos\theta_1 - \sqrt{\eta_1}\cos\theta 2}{\sqrt{\eta_2}\cos\theta_1 + \sqrt{\eta_1}\cos\theta 2} & \sqrt{|\frac{\eta_1}{\eta_2}|}\sin\theta_1 < 1 \\ 1 & \sqrt{|\frac{\eta_1}{\eta_2}|}\sin\theta_1 \geq 1 \end{cases} \tag{3.9}$$

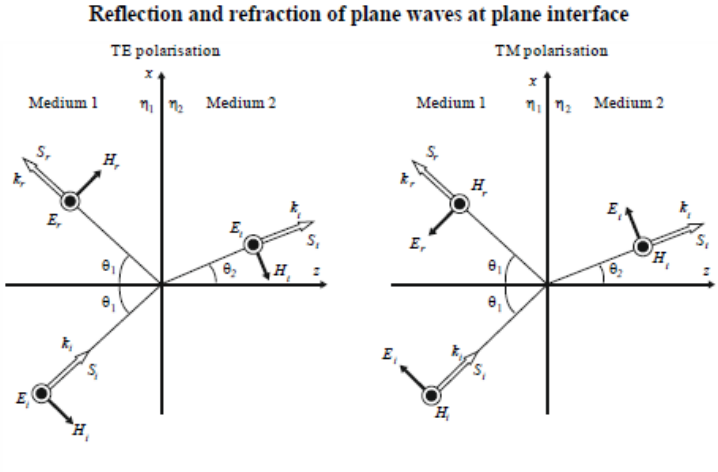


Figure 3.3: Reflection and transmission. Adopted from [38]

E-field transmission coefficient for TE polarisation:

$$T_{eTE} = \frac{E_t}{E_i} = \begin{cases} \frac{2\sqrt{\eta_1}\cos\theta_1}{\sqrt{\eta_1}\cos\theta_1 + \sqrt{\eta_2}\cos\theta 2} & \sqrt{|\frac{\eta_1}{\eta_2}|}\sin\theta_1 < 1 \\ 0 & \sqrt{|\frac{\eta_1}{\eta_2}|}\sin\theta_1 \geq 1 \end{cases} \tag{3.10}$$

E-field transmission coefficient for TM polarisation:

$$T_{eTM} = \frac{E_t}{E_i} = \begin{cases} \frac{2\sqrt{\eta_1}\cos\theta_1}{\sqrt{\eta_2}\cos\theta_1 + \sqrt{\eta_1}\cos\theta 2} & \sqrt{|\frac{\eta_1}{\eta_2}|}\sin\theta_1 < 1 \\ 0 & \sqrt{|\frac{\eta_1}{\eta_2}|}\sin\theta_1 \geq 1 \end{cases} \tag{3.11}$$

3.3.4 Effects of multi-path signals

With the equations given in section 3.3.3, the strength and phase of a reflection can be determined. Assume the situation as depicted in Figure 3.4, the reader emits two waves one direct and another one which is reflected via the ground.

At a certain distance from the reader the reflected wave will contribute to the field strength of the direct wave. This contribution could be destructive, if the direct and reflected wave are out of phase, or constructive, if the direct and reflected wave are in phase. Therefore the field strength at this point can be smaller or larger than the free space field strength of the direct wave.

Most emitters do not only emit a direct wave (to a tag), but also radiate to a range of other directions. In indoor environments, these waves are incident on walls, floor, ceiling and individual objects. As a consequence, many more reflected waves are created. The field strength of a point at a certain time in the indoor environment, would require a comprehensive analysis of the contribution of the direct wave and

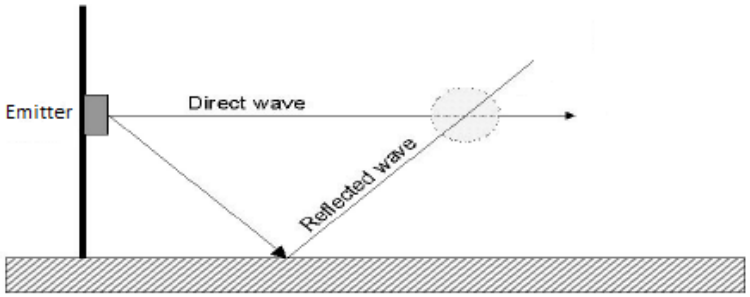


Figure 3.4: Multi-path signals. Adopted from [39]

all reflected waves. To simplify the analysis, the field strength at a point in the environment is often determined by calculating the field strength in free space and adding a factor for the contribution of the reflected waves.

The determination of this factor is often done by making an estimate of the order of increase (in EMC studies) in the worst-case scenario. In the standard [32, Annex E3] a statistical fluctuation by reflections in the order of 6 dB for indoors environments is assumed. In [40] an empirical study about the fluctuation for indoor environments was conducted and a worst-case value of 8 to 12 dB was found.

Outdoor environments are opposite to indoor environments more open (but with a ground plane), causing less reflections and therefore field strength contributed by reflections is less.

3.4 Multi-tone EMI

Instead of a single source, a multiple of EM sources can be present at the same time in the same area. This situation of multiple EM sources interfering a victim should be regarded to give a complete picture of possible EMC issues. The E-field strength at the victim is not a simple addition of the E-field strengths created by every source. In most case the E-field strength is less than the total of the addition. A few reasons can be given for this. Firstly, the most digital wireless communication techniques are not transmitting at all times, but have an on- and off-time, because of the utilised access scheme or duplex. When multiple sources are present, there is a small chance that the sources are transmitting at the same time. As a consequence, the victim will mostly not be exposed to multiple EM fields at the same time. Secondly, in case the sources emit an E-field that is received at the victim at the same time, an addition of the E-field strengths is not likely to occur. Only in the case that the received E-field signals are in phase, constructive addition occurs. In the other case, the addition is

mitigated or can even be destructive. The preceding treatment shows that in most cases the source, which has the largest contribution to the E-field strength at the victim, should be the source of focus in the EMC analysis.

3.5 In summary

The field strength at a certain position is dependent on the radiated power and the propagation characteristics of the dominant emitter. To give an expectation of the E-field strength induced by the emitters treated in section 3.1, Table 3.2 shows the values at 1 and 3 meter separation distance. In which the 'FS' is the field strength in the free space, i.e. with 0 dB reflection contribution, and the 6 and 12 dB reflection contributions are shown in the next columns.

Table 3.2: Field strength caused by emitters

					Field strength at 1 m			**Field strength at 3 m**		
Device	**Technique**	**(Uplink) band (MHz)**		**ERP (W)**	**FS (V/m)**	**6 dB (V/m)**	**12 dB (V/m)**	**FS (V/m)**	**6 dB (V/m)**	**12 dB (V/m)**
C2000 hand-held	TETRA	380	390	1.80	9.4	18.8	37.4	3.1	6.3	12.5
Walkie-talkie	PMR446	446	446.2	0.50	5	9.9	19.8	1.7	3.3	6.6
	DMR	442	448	1.00	7	14	27.9	2.3	5.4	9.3
		450	470	1.00						
Cell phone	GSM	880	915	2.00	9.9	19.8	39.5	3.3	6.6	13.2
		1700	1785	1.00	7	14	27.9	2.3	5.4	9.3
	UMTS	880	915	0.25	3.5	7	14	1.2	2.3	4.6
		1920	1980	0.25						
	LTE	832	862	0.20	3.1	6.3	12.5	1	2.1	4.2
		880	915	0.20						
		1700	1785	0.20						
		2500	2615	0.20						
Cell phone, Computer, etc	Wi-Fi	2400	2483.5	0.06	1.7	3.4	6.8	0.6	1.1	2.3
		5150	5350	0.12	2.4	4.8	9.6	0.8	1.6	3.2
		5470	5725	0.12						
	Bluetooth	2400	2483.5	0.06	1.7	3.4	6.8	0.6	1.1	2.3
Nedap RFID	UPASS (EPC gen II)	865	868	2.00	9.9	19.8	39.5	3.3	6.6	13.2
	TRANSIT	433	434	0.00	0.1	0.2	0.4	0	0.1	0.1
		2446	2453	0.31	3.9	7.8	15.5	1.3	2.6	5.2

Chapter 4

Electromagnetic susceptibility of medical equipment

The EMS of a ME device varies depending on its function, age and manufacturer's choices. The chapter of EMS can be divided into two main parts. The first part is about the minimal immunity of ME device prescribed by the standard (IEC 60601-1-2). In practice this immunity might be higher or lower, which is treated in the second part of this chapter.

In most countries immunity requirements are laid down in EMC standards. EMC standards provide a clear way to manufacturers to comply with the (inter)national directives on EMC. Manufacturers of electrical equipment are obligated to comply with the directive(s), to be permitted to sell their products in a certain jurisdiction. The most common way to comply is by implementing the applicable EMC standards. EMC standards applicable worldwide are issued by the IEC. As a consequence, the IEC standards for EMC are adopted by manufacturers worldwide (with slight deviations made if so desired by a jurisdiction). The date of adoption of a certain IEC EMC standard can be different for every jurisdiction in the world. The IEC 61000 series lays the foundation for the general conditions and rules necessary to achieve EMC. The particular standard IEC 60601 is a series of technical standards for the safety and effectiveness of medical electrical equipment. The collateral standard IEC 60601-1-2 is part of the series and is specifically about the EMC of ME equipment. The IEC 61000 series is used as basis for the IEC 60601-1-2. Since the IEC 60601-1-2 standard is about the EMC of ME, it defines the immunity of ME equipment.

4.1 IEC 60601-1-2

The international standard developed by the IEC for the EMC of medical electrical equipment is part 1-2 of the IEC 60601, titled: ”General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility”. Periodically a new version of the standard is issued to cover new developments in the EMC domain. The fourth and latest edition, was issued in 2014. Since ME equipment found in hospitals has different years of construction and thus can be issued in compliance with an older versions of the standard, the older versions have to be in the scope of the immunity analysis. The 1st edition was issued in 1993.

The immunity requirements in the IEC 60601-1-2 are specified on port-by-port basis [41, Chap. 8]. A port is defined as an access to a device or network where EM energy can be supplied or received or where the device or network variables can be observed or measured. Every ME device or systems can be seen for immunity testing as shown in Figure 4.1.

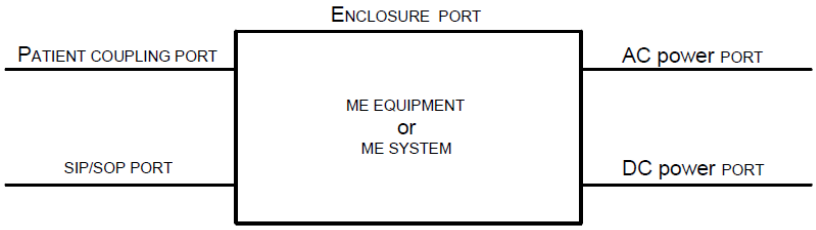


Figure 4.1: Ports of ME devices. Adopted from [41]

The emissions regarded in chapter 3, are radiated EM fields, which can impinge on the enclosure of a device. Therefore only the immunity of the enclosure port for radiated EM fields of the ME system is of importance.

The immunity is defined in maximum E-field strength which can be applied on the specified port. The field strength is given in V/m root mean square (RMS) of a CW signal. The frequency of the CW is incremented step-by-step in the range specified in the immunity test. The CW signal is amplitude modulated with a frequency of 1 KHz and a modulation depth of 80%. In Figure 4.2, the described modulation is applied to a CW with a RMS level of 1 V. Figure 4.2a shows that a 1 V RMS CW signal has a 2.8 V peak-to-peak value. The result of applying the modulation is shown in Figure 4.2b the Vp-p increase, and thereby the maximum Vrms value of the total signal.

Emitters of wireless communication systems use different types of modulation to encode information into a signal. The severity of the EMI of different modulation types is correlated with the maximum RMS value of the modulation. [32, Annex A] shows that significant differences between the effects of the different modulation

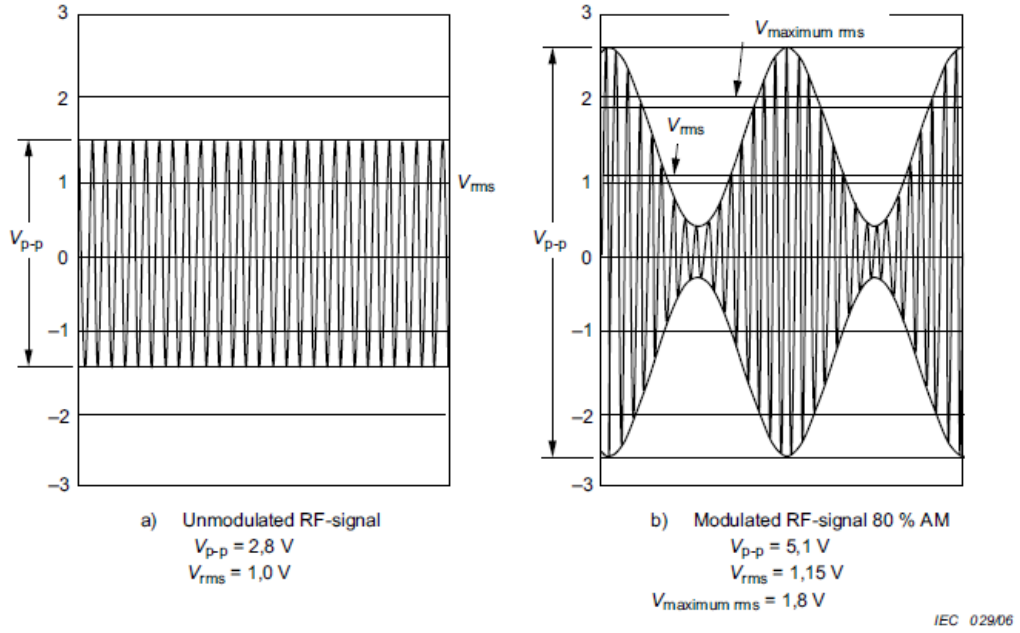


Figure 4.2: Test signal applied to enclosure port. Adopted from [32]

types exist, but in all cases amplitude modulation (AM) modulation has the most severe effect. In other words, AM modulation is always at least as severe as pulse modulation, which is utilized in many digital wireless communication systems, but may miss some failure mechanisms.

The immunity test levels required by the standard and other specifics differ per edition. The specifics of interest will be evaluated per version in the next sections.

4.1.1 4th edition

The fourth and most recent edition of the standard is published in February 2014. It categorises the hospital ME equipment into three environments of intended use: Professional healthcare facility environment, home healthcare environment and special environment. Examples of these environments can be found in Figure 4.3. For ME equipment intended for the use in the emergency medical service environment, such as in an ambulance, the home healthcare environment applies.

The immunity test levels in Table 4.1 have been specified for radiated RF EM fields. A ME device passes the test if no degradation of performance occurs when it is exposed to the test signal. For the special environment no immunity test levels are given, the manufacturer has to specify its own immunity test levels, a justification for the determined immunity test levels has to be provided.

Lower immunity test levels are allowed if mitigations are used, the manufacturer must include documentation explaining how it can be reasonably expected that the

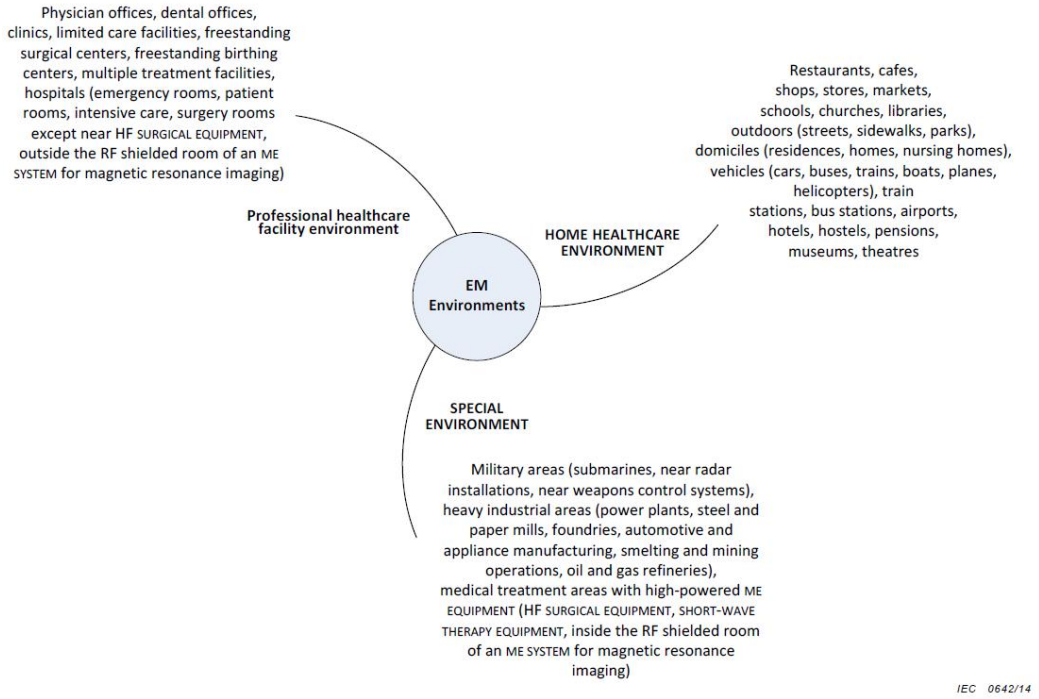


Figure 4.3: Examples ME EM environments. Adopted from [41]

Table 4.1: Immunity test levels of 4th edition

Professional healthcare facility environment	**Home healthcare environment**	**Special environment**
3 V/m 80 MHz - 2.7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz - 2.7 GHz 80 % AM at 1 kHz	- (not specified)

mitigations will continue to be effective over the expected service life in all locations in which the ME equipment is expected to be used.

Since the previous editions of the IEC 60601-1-2 (third edition) new digital wireless technologies have been introduced not only to hospitals, but also to the general public. In addition, existing technologies are being used in new ways, which were not known before. In light of these developments healthcare providers have specifically requested for new requirements so that wireless communications equipment can be used in closer proximity than recommended in the third edition of IEC 60601-1-2.

To cover the request of the healthcare providers, extra immunity requirements are asked for the bands in use by the new digital wireless technologies. These requirements are set-up by conducting an analysis on which and how the new digital wireless technologies are used and whether they pose a risk. The outcome is shown in Figure 4.4. As the figure shows in the column 'modulation' for most tests pulse modulation is used instead of 80% AM modulation, this is to represent the digital

encoding of the modern digital wireless communications. Moreover it also means, that the values of the column 'immunity test level' are also the maximum RMS values in contrast to the values of Table 4.1. The standard also states that the ME device should also be tested for immunity for other emitters which are not represented by the figure and can be expected to operate in any location of intended use.

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 –390	TETRA 400	Pulse modulation [b] 18 Hz	1,8	0,3	27
450	430 – 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0,3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0,2	0,3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0,3	28
870						
930						
1 720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0,3	28
1 845						
1 970						
2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0,3	28
5 240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0,2	0,3	9
5 500						
5 785						

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

[a] For some services, only the uplink frequencies are included.

[b] The carrier shall be modulated using a 50 % duty cycle square wave signal.

[c] As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Figure 4.4: Test specifications instated for close-by wireless communications equipment. Adopted from [41]

This edition suggests a minimum separation distance to ensure EMC which is calculated, as described in the standard, by the following equation:

$$d = \frac{6}{E}\sqrt{P} \tag{4.1}$$

Where P is the ERP in W, d is the minimum separation distance in m, and E is the immunity test level in V/m. Equation 4.1 is comparable to equation 3.7 from section

3.3.2. Converting equation 3.7 into the form of equation 4.1 yields a factor 7 instead of 6. Note that no reflection contribution is taken into account at both equations.

The immunity test levels of Figure 4.4 are determined by assuming a minimum separation distance of 30 cm between emitter and the EM device. From this can be concluded, that it is suggested for wireless communications equipment to keep a minimum separation distance to ME equipment (complying with this edition) of 30 cm.

4.1.2 3rd edition

The third edition of the standard is published in March 2007 [42]. It categorizes the ME equipment in a different way than the subsequent edition.

The categorization is done by life-supporting and non life-supporting ME equipment. Life-supporting ME equipment is defined as ME equipment that is intended to actively keep alive or resuscitate patients and the failure of which is likely to lead to serious injury or death of a patient. Both categories have different immunity test levels as can be seen in Table 4.2.

Table 4.2: Immunity test levels of the 3rd and 2nd edition

life-supporting	**Non life-supporting**
10 V/m	3 V/m
80 MHz - 2.5 GHz	80 MHz - 2.5 GHz
80 % AM at 1 kHz	80 % AM at 1 kHz

Instead of a minimum separation distance this edition provides a recommended separation distance. In the accompanying documents of the ME device a statement about the EMC and the recommended separation distance shall be given.

For the ME equipment the equations in Table 4.3 determine the recommended separation distance. Where P is the ERP in W, d is the recommended separation distance in m, and E is the immunity test level in V/m.

Table 4.3: Recommended separation distances

Band	**life-supporting**	**non life-supporting**
80 - 800 MHz	$d = \frac{12}{E}\sqrt{P}$	$d = \frac{3.5}{E}\sqrt{P}$
800 MHz - 2.5 GHz	$d = \frac{23}{E}\sqrt{P}$	$d = \frac{7}{E}\sqrt{P}$

Filling in the equations with the immunity test levels as shown in Table 4.2, provides almost the same result for the recommended separation distance for both the life-supporting as the non life-supporting case. Which means that for life-supporting

ME equipment a larger safety margin is retained. This edition does not recommend the use of wireless communication equipment in close proximity of ME equipment. Therefore the edition states that an additional factor of $\frac{10}{3}$ is incorporated into the equation of the recommended separation distance to decrease the likelihood of mobile wireless communications to cause interference. For example, the wireless communication equipment in the 800-960 MHz band allows a maximum power of 2 W [41], the corresponding recommended separation distance will be around 3.3 meter.

This edition allows the immunity test levels to be lowered, provided that there is sufficient justification based on physical, technological or physiological limits.

4.1.3 2nd edition

The second edition of the standard is published in November 2001 [43]. The edition endorses the same immunity test levels as its successor. The numbering and structure of the standard is different, but the content of interest is broadly the same.

4.1.4 1st edition

The first edition of the standard is published in April 1993 [44]. The immunity test levels are shown in Table 4.4. The ISM frequencies are bands reserved by the International Telecommunication Union (ITU) for industrial, scientific and medical purposes other than telecommunications.

Table 4.4: Immunity test levels of 1st edition

life-supporting	**Non life-supporting**
3 V/m	3 V/m
26 MHz - 1 GHz	Only at ISM frequencies within 26 MHz - 1 GHz
80 % AM at 1 kHz	80 % AM at 1 kHz

If lower immunity test levels are justified, the accompanying documents will contain the level, its justification and any action which will be taken by the user (as a consequence).

This edition does not mention a manner to determine separation distances.

4.1.5 In summary

The immunity test levels found in previous sections are summarised in Table 4.5 and 4.6. The exceptions mentioned in Table 4.6 can be found in Figure 4.4. The

immunity test levels are the (maximum) RMS value of the unmodulated CW signal, applying the prescribed modulation of 80% AM at 1 kHz will increase the maximum RMS value with a factor of 1.8. The 4th edition provides minimum separation distance depicted in equation 4.1. The 3rd and 2nd edition provide a recommended separation distance which can be found in Table 4.3.

Table 4.5: Immunity test levels of 1st, 2nd and 3rd edition

Edition		1	2	3
Year of publication		1993	2001	2007
Frequency range (MHz - GHz)		26 - 1	80 - 2.5	80 - 2.5
Category	Life-supporting (V/m)	3	10	10
	Non life-supporting (V/m)	-, 3 (only at ISM)	3	3

Table 4.6: Immunity test levels of 4th edition

Edition		4
Year of publication		2014
Frequency range (MHz - GHz)		80 - 2.7
Category	Professional (V/m)	3 (with exceptions)
	Home (V/m)	10 (with exceptions)
	Special (V/m)	- (not specified)

4.1.6 Adoption of the standard

Every jurisdiction set its own adoption dates for every edition of the standard. Albeit all jurisdiction members of the CB scheme of the IEC will after a period adopt the most recent version of the standard, the transition dates are not synchronised between the members. Member countries included are the EU, USA, China, India, Korea and Russia [45]. A major benefit of the CB scheme is that a test report made by a certification body of one of the members will be recognized by the certification bodies of other members.

The transition dates in the EEA by implementing the standard as an EN are shown in Figure 4.5. All devices sold in the EEA must comply with the EN, there is no grandfathering of legacy devices. As can be seen in the figure, at some dates there is an overlap, which means the manufacturer can opt for one or the other edition. The information is extracted from the European foreword of the respective edition.

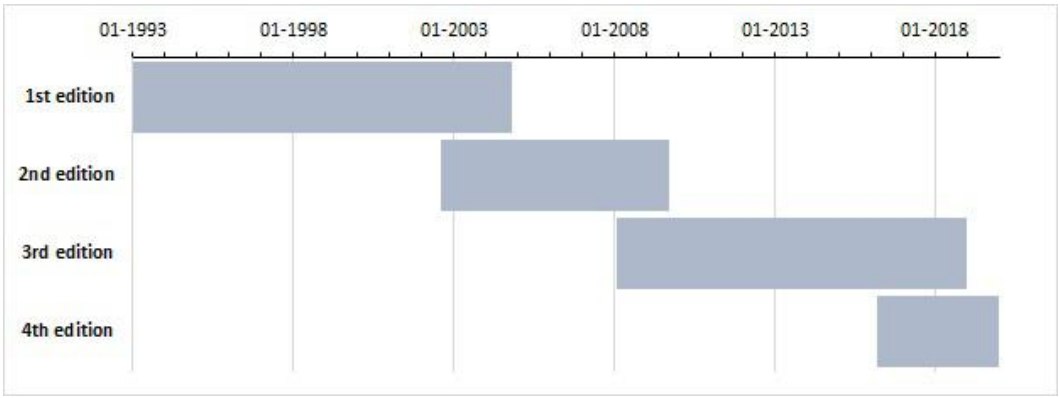


Figure 4.5: Necessary edition(s) of IEC 60601-1-2 to be compliant in EEA

4.2 Immunity in practice

In practice the immunity of the ME devices can differ from the expectation created by the standard. Firstly, manufacturers are allowed to use lower immunity test levels than prescribed, if they provide sufficient justification. Secondly, compliance with the standard is often done by testing one prototype. The production units can have slight variations in its EMC characteristics. Furthermore the EMC characteristics can change over time by servicing, design changing and ageing. Thirdly, for the immunity test the ME device is only exposed to a RF signal with the prescribed modulation. Exposure to a RF signal with a different modulation form could have a different (and even more severe) interference effect. Fourthly, most manufactures ensure a margin between the test level and the actual immunity of the ME device [33, Chap. 8].

Notice that the installed base of ME equipment in the hospital environment can differ in age and thereby immunity. ME equipment which complies to the first edition of the standard has almost none requirements for immunity, but still could be in use.

Chapter 5

Non risk-based EMC of hospital environment

In previous chapters the EM emissions of the sources and the immunity of the ME equipment was treated. With the aid of this information an EMC assessment can be done.

The most conventional way to assess the EMC of the hospital environment, is rule-based. At rule-based EMC, for every source a rule about the separation distance is formulated, which should be abided to ensure EMC. This separation distance is provided by the the EMC declaration of the ME device concerned, which is based on the standard. This chapter will also treat another way to draw EMC rules and provides a summary of results found in empirical studies. In next chapter a full risk-based EMC analysis is presented.

5.1 Rule-based EMC of hospital environment

Using the information of the standards, rules can be extracted to ensure EMC. The 4th, 3rd and 2nd editions provide a manner to determine EMC rules.

In the 4th edition the minimum separation distance is calculated by using Equation 4.1. The emitters identified as present are also listed in Figure 4.4, from this figure the minimum separation distance of 30 cm is found. The standard will not be required until 1 January 2019 in the EEA, which means that most ME equipment does not comply at this time to this recommendation.

In the 3rd and 2nd edition, another method is used for EMC. A recommended separation distance is given, which can be found in Table 4.3. Filling in the equations yield the results of table 5.1. The immunity test levels mentioned in the standard are used for the calculation, at life-supporting and non life-supporting the recommended separation distance is the same.

Table 5.1: Recommended separation distance

Emitter	ERP (W)	Band (MHz)	life-supporting (m)	non life-supporting (m)
Cell phone/UPASS	2	>800	3.3	
C2000 handheld	1.8	<800	1.6	
DMR portable radio	1	<800	1.2	
PMR446 portable radio	0.5	<800	0.8	
TRANSIT	0.31	>800	1.3	
Wi-Fi/Bluetooth	0.12	>800	0.8	

In practice, the use of cell phones have benefits for the healthcare providers and it is difficult to enforce rules on the use of cell phones to visitors of the hospital. Therefore the EMC rules of the table are not deemed valid in the hospital environment. Hospitals have developed their own set of regulations in the past years, which can be environment depended, in most cases not following the separation distances treated before.

5.2 EMC by field strength

Another way to draw rules about the EMC is by using the information of chapter 3 and the immunity levels of the standard. In Figure 5.1, the E-field strength is plotted against the separation distance. The E-field strength is calculated by Equation 3.6 and the addition of a reflection contribution. The red dotted lines are the immunity levels for life-supporting (the top one) and non life-supporting (the bottom one) ME equipment. These are the less conservative maximum RMS field strength test levels instead of the carrier field strength levels, which can be chosen according to [32, app. E]. The figure clearly shows that reflection contributions could have a severe effect on the needed separation distance and lower immunity levels require higher separation distances. Although non life-supporting equipment, requires a larger separation distance, it is of less importance. A disruption of non life-supporting equipment does not have lethal consequences (by definition).

5.3 Literature about EMC in hospital environment

Many researchers performed empirical research about the EMI of intentional emitters, identified in section 3.1. Their findings and their recommended separation distances are evaluated in this section.

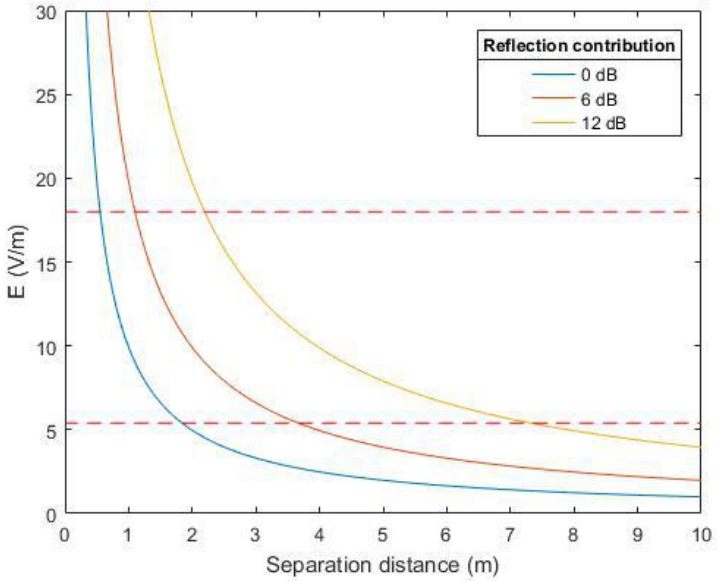


Figure 5.1: Cell phone/UPASS (2W ERP) emission to E-field strength with(out) reflection contribution

The disturbances found by the researchers, caused by (possible) EMI could be as severe as shown in Table 5.2. The table is adopted from [46], in which an empirical study about the EMI caused by Wi-Fi transmitters was conducted. The table gives an indication of the possible clinical consequences caused by the disturbances of EMI on medical equipment.

5.3.1 C2000

The risk of TETRA hand-held, and therefore C2000 hand-helds is about the same as the risk of the cell phone (GSM), if utilized with the same transmission power. The same precautions are recommended for its use. The studies about TETRA are not always comparable, since the transmission power is not set at the same level [12], [13]. The knowledge of section 3.3 could be applied to equalize the results.

5.3.2 Walkie-talkie

No literature can be found about the EMI caused by PMR446 or DMR walkie-talkie systems.

Classification of disturbance	**Example**
No	- Irrelevant noise or humble from speaker
Light	- Small interference on the video display of a medical apparatus, but no disturbance of its functioning - Relevant noise or humble from speaker
Significant	- Disturbance of functioning of apparatus, but no safety hazard for patient or user - Small spikes on ECG curves - Disturbance on display without hazard
Unsafe	- Defibrillator with spikes on ECG curves (synchronization error) - (correct) failure message without acoustical alarm - Disturbance or stopping of apparatus without (acoustical) alarm - Disturbing a process or an indication (e.g. a display) with a safety hazard aspect

Table 5.2: The severity of EMI on medical apparatuses

5.3.3 Cell phone

The literature describes multiple cases of EMI of cell phones on medical equipment [47], [48]. In the early days, due to the relative newness of the cell phone technology and the lack of advice about this problem, hospitals instated very strict and difficult to enforce rules on the use of wireless equipment [13], [49]. To gain more knowledge about the appearance of possible EMI, experimental studies were conducted. For example in [50], 22 medical devices were tested. This was done by exposing the medical device to a GSM and UMTS signal in the technical room of a hospital. The distance between the medical device and the signal was reduced gradually. During the reduction the medical device was checked for its functioning and possible disturbance were classified using Table 5.2. 10 out of 22 medical devices were influenced by the EMI of one of the cell phone techniques, this happened from a distance of 50 cm and smaller. In [51] the results of multiple empirical studies about the GSM 900 and 1800 MHz signal were summarised. In the total of all studies 45 out of 479 ME devices tested could be interfered by the 900 MHz GSM and 14 out of 457 ME devices by the 1800 MHz GSM signal. In [50] only one case of interference was found (of the total of 22 devices) by UMTS at a distance of 15 cm. Other researchers also found that UMTS threat was not significant in comparison with GSM [52]. The findings are consistent with observations by other studies which found a large portion of ME devices to be immune for the UMTS signal [52]. In [53] was concluded that LTE signals had almost the same interference characteristics as UMTS. Other researchers conducted similar research to gain insight about the

possible disturbance of cell phones. More recently, literature seems to have reached consensus about the advice to keep at least 1 meter distance to prevent cell phone interference [49], [51], [54], [55]. Hospitals have relaxed their regulations over time. The less strict regulations, allow caregivers to deploy mobile phones as a manner to support the further improvement of healthcare [56].

5.3.4 Wi-Fi

Similar empirical studies as at the cell phone were conducted for Wi-Fi. In [57] 45 ME devices only on the 2.4 GHz band were tested and in [46] 96 ME apparatuses on the 2.4 and 5.8 GHz band were tested. As a result, the researchers advocate a minimum separation of 10 cm between a ME device and Wi-Fi equipment on the 2.4 GHz and on the 5.8 GHz band a larger separation distance of 20 cm. At the advocated separation distances around 3% of the ME devices were interfered [46].

5.3.5 Bluetooth

In [15] an empirical study in which 44 different ME devices were exposed to Bluetooth emissions was conducted, none of the ME devices were interfered.

5.3.6 RFID

Scholars are ambiguous about the prerequisites to prevent EMI in the hospital environment from long-range RFID equipment, especially from UHF long-range RFID. Most researchers do express concerns about the RFID systems in hospitals from a EMC point of view and recommend on-site testing, before implementation of RFID systems [17]. For example, [58] conducted an empirical study, in which 41 ME devices were exposed to the emission of a UHF long-range RFID reader. The distance between the reader and the ME device was decreased until EMI occurred. 26 of the 41 ME devices were affected by EMI with a median distance of 30 cm and a range up to 600 cm. The findings of researchers are too diverse to draw general conclusions on the safe use of long-range RFID equipment [17], [59].

Chapter 6

Risk-based EMC of hospital environment

A more consistent and modern approach to achieve EMC is what is called risk-based EMC. At risk-based EMC the severity and probability of EMI are taken into account for the EMC analysis. Depending on the determined risks, measures can be taken to reduce the risk to an acceptable level. An important aspect of the risk analysis is its method, which is treated, before applying it in a case study, in the next section.

6.1 Risk assessment method

In section 5.1 a rule-based EMC analysis was conducted. A different perspective on EMC is risk-based. In this form, EMC is determined on the basis of risk. To know about the risk, a risk assessment has to be conducted. A risk assessment consists of a risk analysis and a risk evaluation. A step-by-step plan is proposed to conduct the risk assessment. The step-by-step plan is based on [60]–[62] and modifications were made to adept the risk assessment to the hospital environment. The proposed risk assessment method will only regard ME equipment as victim of EMI and intentional emitters as sources of EMI.

Step 1: Determine the EM environment of scope
Every hospital environment can be the scope of an EM environment. Examples of environments are the intensive care (IC) or the operation room. Only the ME equipment inside the demarcated physical environment will be regarded as (possible) victim of EMI. The mobile emitters can (possibly) affect the ME equipment from the outside of the demarcated physical environment. Mobile emitters which may have an influence are part of the EM environment of analysis.

Step 2: List all ME equipment (victims) in the EM environment
List all ME equipment in the demarcated EM environment. Every ME apparatus could be a possible victim of EMI. The outcome is a list as shown below.

- Victim 1
- Victim 2
- Victim 3

Step 3: List all (possible) sources of EM radiation
List all wireless emitters which are present or can be present in the EM environment:

- Source 1
- Source 2
- Source 3

Step 4: Assess the risk of every source-victim pairs
To have an overview, a table is drawn of all source-victim pairs. Every pair has its own risk (which should be assessed individually). In Table 6.1 a way to present all source-victim pairs is shown. Where, for example, R_{11} means the risk of EMI induced by source 1 into victim 1.

Table 6.1: Source-victim pairs

	Victim 1	Victim 2	Victim 3
Source 1	R_{11}	R_{12}	R_{13}
Source 2	R_{21}	R_{22}	R_{23}
Source 3	R_{31}	R_{32}	R_{33}

The concept of risk is a combination of two components. The probability of occurrence of harm and the severity of the consequence of that harm. For every source-victim pair, there is a (different and) certain risk. To assess the (expected) risk, the probability and severity have to be reviewed.

Probability
For the common wireless communication systems, researchers conducted experiments about the probability of EMI. The results can be part of the probability analysis. Moreover the three aspects mentioned below, can be used to estimate the probability. The evaluation of the probability will be done on qualitative scale with the levels shown in Table 6.3.

Emission of source
The emission of fixed and mobile transmitters has a severe influence on the probability of a mishap. The emissions of the transmitters can be quantified by the RMS strength, frequency and modulation of the electrical field.

Susceptibility of victim
The susceptibility of a device can be quantified by its accompanying EMC documents and the immunity levels of the followed standard. Other sources of interest are test reports and scientific literature.

Accessibility of victim
The accessibility describes the ability to get close to the ME equipment with an (intentional) emitter. Larger actual separation distances have a mitigating effect on the probability. The intentional emitters are categorized into zones with the victim in its centre. Three zones are distinguished on the basis on how close an emitter can approach the victim, see Table 6.2.

Table 6.2: Accessibility zones

Zone	**Range**
1	Closer by than 30 cm
2	Between 30 and 150 cm
3	Farther away than 150 cm

Table 6.3: Probability levels

Term	**Description**
Probable	Happens often or likely to happen
Moderate	Can happen occasionally
Minor	Negligible or unlikely to happen

Severity
Severity is about the result of the dis-functioning of the ME equipment (victim) on the patient relying on the ME equipment. The evaluation of the severity will be done on qualitative scale with levels shown in Table 6.4. The two aspects below can be used to estimate the severity.

Consequence
Consequence is about (possible) negative effect of the dis-functioning ME apparatus on the patient. The quantification can be done based on the severity of the conse-

quence and whether the consequence will be present instantaneously or require a longer period of time to appear.

Duration of dis-functioning
Duration is about how long a consequence is occurring on ME device. E.g. a ME device which samples every five minute to determine its action, is disturbed for five minutes, if one of its samples is interfered.

Visibility
Visibility is about the detectability of the consequence, a higher detectability will probably result in a shorter response time, which mitigates the total severity.

Table 6.4: Severity levels

Term	**Description**
Critical	Results in death, permanent impairment or life-threatening injury
Serious	Results in injury/impairment requiring medical intervention
Negligible	Results in inconvenience or injury/impairment not requiring medical intervention

Risk
After the evaluation of the probability and the severity, the risk is determined by placing every source-victim pair in Table 6.5. In which the cells with a red background have high risk, the yellow cells have a medium risk and green cells have a low risk. The risks of the example are placed arbitrary into the table.

Table 6.5: Risks of source-victim pairs assessed

		Severity		
		Critical	Serious	Negligible
Probability	Probable	R_{13}		R_{22}
	Moderate	R_{12},R_{23}		
	Minor	R_{33}	R_{21}	R_{11},R_{31},R_{32}

After the categorization, an overview of all risks can be given as in Table 6.6. Some source-victim pairs will show up bearing a high risk. These pairs are selected for further investigation. In the table these risks are R_{12},R_{13} and R_{23}.

Table 6.6: Source-victim pairs with assessed expected risk

	Victim 1	Victim 2	Victim 3
Source 1	R_{11}	R_{12}	R_{13}
Source 2	R_{21}	R_{22}	R_{23}
Source 3	R_{31}	R_{32}	R_{33}

Step 5: Further investigate the high risk source-victim pairs

From here on, all risks have been determined using theoretical analysis and the literature available. The further investigation focuses on collecting empirical data about the assessed risk. A representative experiment should be conducted to have an empirical based view of the chosen source-victim pair. The newly found risks can be used to improve the risk assessment. The result could be as in Table 6.7. As in the table can be seen, the risks R_{12}, R_{23} and R_{33} are improved by the empirical evidence. Only risk R_{13} is not mitigated by the empirical data.

Table 6.7: Source-victim pairs with assessed measured risk

	Victim 1	Victim 2	Victim 3
Source 1	R_{11}	R_{12}	R_{13}
Source 2	R_{21}	R_{22}	R_{23}
Source 3	R_{31}	R_{32}	R_{33}

Step 6: Draw conclusions and apply risk management

The final step is about how risk management should mitigate the non-acceptable risks still left after the last step. In case of the example, this is risk R_{13}. Examples of rules created by risk management are: setting rules for a minimal distance between source and victim, banning the use of certain wireless communication services (sources) in the EM environment and only allowing certain sources for certain applications, which have a medical benefit.

6.2 Case analysis

The risk assessment method will now be applied to a case. For this study, a collaboration is initiated with the Dutch hospital MST, located in Enschede. The case analysis assumes the situation and EM environment as it is in this hospital.

Figure 6.1: The neonatology environment and its ME equipment

Step 1: Determine the EM environment of scope

Two departments in the hospital hold some of the most critical and life-supporting ME equipment for patients: the neonatology and IC. In the neonatology department, medical care is given to newborn infants, especially to the ill or premature born infant. The intensive care department holds patients in life-threatening conditions requiring organ support and invasive monitoring.

In both departments only the patient room is of focus for the case analysis. Only the ME equipment present inside of the room is regarded as potential victim of EMI. The intentional emitters which can be present inside the room and one meter outside the room from the entrance are of focus in the case analysis. The pictures of the neonatology in Figure 6.1 and the IC in 6.2 depict the EM environment. The figures show circles around present victims.

Step 2: List all ME equipment (victims) in the EM environment

The MST provided a list of the ME equipment present in the patient rooms of the departments of neonatology and IC. The lists of both departments are shown in Tables 6.8 and 6.9. In Figures 6.1 and 6.2 the victims are circled and numbers are added, which correspond to the victim number in the relevant table. All victims are compliant with the IEC 60601-1-2 EMC standard. The immunity level tested for is shown in column 'EMC'. To which edition the device is compliant is not mentioned. The BIS (Bispectral index) and respiration function of the patient monitors are not utilised on the neonatology. On the IC, only the respiratory function is utilised.

A few things have to be noticed about the set-up of the ME equipment. A heated

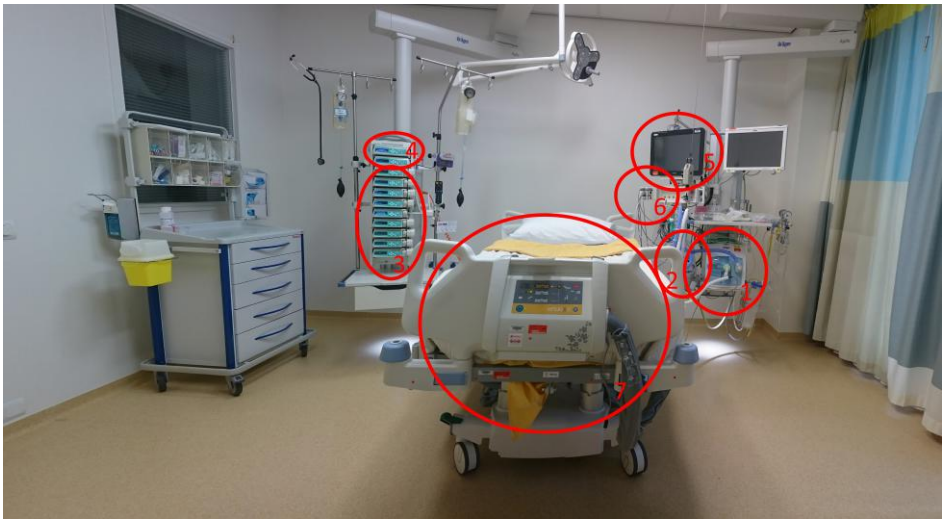


Figure 6.2: The IC environment and its ME equipment

air humidifier is never used in a stand-alone mode. It heats and humidifies the air coming from a ventilator or respiratory support device.

The patient monitors (Philips Intellivue MX800/MX500/MX450) cannot be used stand-alone. These monitors receive information to display from the Philips Intellivue X2. The X2 collects all sensor read-out values and does the processing of this data. The X2, in contrast to the other monitors, can be used in stand-alone mode.

Step 3: List all (possible) sources of EM radiation

Not all the emitters listed in section 3.1 are present in the IC or neonatology patient room. An exception is the C2000 handheld, an overview is provided in Table 6.10.

At the MST only DMR walkie-talkies (Motorola DP 3400), operating on the 460 MHz with an emission power of 1 W ERP are in use, from here on the walkie-talkies are assumed to have these characteristics.

Step 4: Assess the risk of every source-victim pairs

The sources and victims are numbered. For the sources the order is extracted from the Table 3.1. DMR with an band from 450 to 470 MHz is source 1. From source 1 down the other sources are incrementally numbered. Source 16 is the last source in the table, which is the TRANSIT with an uplink band from 2446 to 2453 MHz. The victims got the numbers as already shown in Table 6.8 and 6.9. An example of how the source-victim pairs are coded is the following. S2V6 means the risk of source 2 interfering on victim 6.

Table 6.8: Victims present in patient room of neonatology

No	Name	Function	EMC
1	Acutronic Fabian	Ventilator	10 V/m (80 MHz - 2.5 GHz)
2	Carefusion Infant Flow Sipap	Respiratory support	10 V/m (80 MHz - 2.5 GHz)
3	Wilamed Aircon Humidifier Heated	Heated air humidifier	3 V/m (80 MHz - 2.5 GHz)
4	Fisher & Paykel MP 850	Heated air humidifier	3 V/m (80 MHz - 2.5 GHz)
5	B.Braun Perfusor fm	Infusion pump	10 V/m (80 MHz - 2.5 GHz)
6	Philips Intellivue MX500	Patient Monitor	3 V/m (80 MHz - 2.5 GHz) (1 V/m for respiration and BIS)
7	Philips Intellivue MX450		
8	Philips Intellivue X2		
9	GE Giraffe Warmer incubator, infant, open/stationary	Neonatal incubator/ Infant radiant warmer	10 V/m (80 MHz - 2.5 GHz)
10	GE Giraffe Warmer Omnibed, infant, stationary		10 V/m (80 MHz - 2.5 GHz)

Table 6.9: Victims present in patient room of IC

No	Name	Function	EMC
1	Dräger Evita Infinity V500 Elite	Ventilator	10 V/m (80 MHz - 2.5 GHz)
2	Fisher & Paykel MP 850	Heated air humidifier	3 V/m (80 MHz - 2.5 GHz)
3	B.Braun Perfusor Space	Infusion pump	10 V/m (80 MHz - 2.5 GHz)
4	B.Braun Infusomat Space		
5	Philips Intellivue MX 800	Patient Monitor	3 V/m (80 MHz - 2.5 GHz) (1 V/m for respiration and BIS)
6	Philips Intellivue X2		
7	Wissner-Bosserhoff Multi-care	Bed	3 V/m (80 MHz - 2.5 GHz)

Risk analysis

Probability

One of the factors of risk is the probability. The probability is for the most part related to the source. As the discussion of section 5.3 shows the EMI analysis is mostly grafted on one source and its effect on a multiple of victims. The accessibility of the victim is mostly related to the sources, since the source are (mostly) mobile and the victims are mostly at a fixed location. The susceptibility of the victim is obviously related to the victim and by that related to the immunity level prescribed by the standard. None of the victims present comply with the 4th edition of the standard (The immunity levels are shown in Table 6.8 and 6.9). The sources can close-by create an electrical field in excess of the immunity levels of 10 and 3 V/m. In other words the recommended separation distances of section 5.1 and the minimum distances of section 5.2 will be broken. As a consequence the aspect 'Susceptibility of Victim' does not yield much importance for the probability analysis. The probability

Table 6.10: Sources present at the IC and neonatology

Device	Present	Reason
C2000 hand-held	No	The device is only used by the emergency services (outside of the hospital). At the MST, they are only present at the helideck and the ambulance station. Only firefighters could bring the device into hospital, when responding to a fire alarm, which only happens very incidentally.
Walkie-talkie	Yes	Stretcher-bearers (patient transport) and security personnel use the walkie-talkie system. They may enter the rooms of the IC and neonatology, which could be the case time to time.
Cell phone	Yes	All medical personnel bears a cell phone like system (Grip or Myco at MST) to access information and to be reachable at all times. Visitors of the hospital do also carry cell phones. For these reasons cell phones can be omnipresent.
Long-range RFID	Yes	At this time, long-range RFID is not present in the MST. However the presence of such systems is growing, therefore it is regarded as present.

analysis is only related to the properties of the source. The probability is assessed by passing the sources individually.

Source 1: DMR (450 - 470 MHz), Probability: Probable
Literature does not provide details on the EMI of this emitter. Nevertheless the probability could be compared to GSM (1700 - 1785 MHz), it has the same accessibility, which is zone 1 and the same emission power. The difference is in the frequency and the use of power control. There is no power control enabled, which increases the chance of EMI.
Source 2: GSM (880 - 915 MHz), Probability: Probable
The maximum emission strength is high. A cell phone (supporting GSM) can approach accessibility zone 1 of every victim. Therefore the probability level is probable. Literature describes many cases of EMI by the GSM signal at this frequency, as described in section 5.3.
Source 3: GSM (1700 - 1785 MHz), Probability: Probable
Although the emission strength at this frequency is lower than that of the previous regarded frequency, it still can be regarded as a high emission power. Literature describes multiple cases of EMI of this signal.

Source 4,5: UMTS (880 - 915 & 1920 - 1980 MHz), Probability: Moderate
As the literature describes UMTS is less likely to create EMI than the GSM signal. However an UMTS emitter can enter accessibility zone 1 of the victim and EMI could still occur, for this reason the 'Moderate' probability level is assigned.
Source 6,7,8,9: LTE (832 - 862, 880 - 915, 1700 - 1785 & 2500 - 2615 MHz), Probability: Moderate
LTE has almost the same chance to cause EMI as UMTS and can enter the same accessibility zone. Because of this the same probability is assigned.
Source 10,11,12: Wi-Fi (2400 - 2483.5, 5150 - 5350 MHz & 5470 - 5725 MHz), Probability: Minor
The low emission power mitigates the probability of EMI. A Wi-Fi emitter can enter accessibility zone 1. Studies only suggest a small minimal separation distance. However, all the victims passed the Wi-Fi test conducted by the MST, therefore no EMI incidences are expected.
Source 13: Bluetooth (2400 - 2483.5 MHz), Probability: Minor
In literature no cases of Bluetooth interference are described, Wi-Fi at the same band has a minor probability of EMI. Therefore EMI is not expected.
Source 14: UPASS (865 - 868 MHz), Probability: Probable
The emission strength of the source is high, no power control is enabled. The probability is mitigated by the larger separation distance between source and emitter, which is in accessibility zone 3, if the victim is at its fixed location. Nevertheless EMI could still occur according to the literature.
Source 15: TRANSIT (433 - 434 MHz), Probability: Minor
The emission strength is very low and the accessibility of the victim is in zone 3. As a result EMI is not expected.
Source 16: TRANSIT (2446 - 2453 MHz), Probability: Minor
The emission strength is higher than the Wi-Fi emissions on this band, but the accessibility is lower than Wi-Fi and the source only emits a CW signal, which interferes less in comparison than a Wi-Fi signal, thus the same probability is assigned.

Severity

When the factors for the severity are considered, it is noticed that these are only related to the individual ME device. In consultation with a nurse of the department concerned, the severity is estimated. The severity is assessed by passing the ME devices individually.

Neonatology

Victim 1: Acutronic Fabian, Severity: Critical
The Acutronic Fabian is a medical ventilator. It ensures a non-breathing (mostly se-

dated) patient to breath and prevents the patient to choke. A disruption of this device stops the breathing of the patient, which could have lethal consequence. The vitals of a patient in this state are (most likely) monitored, but even with monitoring the disruption can be life-threatening or could have consequences for the development of the patient.

Victim 2: Carefusion Infant Flow Sipap, Severity: Critical

The Carfustion Infant Flow Sipap provides breath support to the patient. In contrast to the Acutronic Fabian, this device is only used for breathing patients. The goal is to ease the breathing process of the patient. Nevertheless a disruption has direct consequences for the patient, the patient will have trouble breathing, and the alveoli may collapse, which could have severe consequences for the development of the patient.

Victim 3,4: Wilamed Aircon Humidifier Heated and Fisher & Paykel MP 850, Severity: Serious

The Wilamed Aircon Humidifier Heated and Fisher & Paykel MP 850 humidifies and heats the air coming from a medical ventilator, Sipap or low flow to the lungs of the patient. The heating and humidification is important aspect in keeping the patient on temperature in stable state. A short cease of function, will not have consequences, but a longer cease does. The temperature of the patient is monitored.

Victim 5: B.Braun Perfusor fm, Severity: Critical

The B.Braun Perfusor fm pumps a solution out of a syringe. Its function is to regulate the dose of (critical) medication given by the infusion to the patient. A disruption (a stop of alteration of the dose) could therefore have severe and even life-threatening results.

Victim 6,7,8: Philips Intellivue MX500/MX450/X2, Severity: Serious

The Philips Intellivue MX500/MX450/X2 monitors the vitals of the attached patient. A disruption will not change on itself the state of the patient, but the read-out values, which are constantly monitored, can trigger a medical intervention, and are used by healthcare providers to determine a treatment. Reliable read-out values are therefore necessary. Short disruptions will only trigger medical attention, longer disruptions could have consequences on the treatment of the patient. The chances on a longer term disruption are minimal, therefore the severity is determined as given.

Victim 9,10: GE Giraffe Warmer incubator/omnibed, Severity: Serious

The GE Giraffe Warmer has the function to keep the environment around the patient on the right temperature. A disruption (stop of the heating function) does not have direct consequence for the patient, as the incubator will gradually lose its heat to the environment. After a while, the temperature will be too low and harm could occur to the patient. In other words, a short cease of function does not have consequence, a longer cease does. The temperature of the patient is monitored.

IC

Victim 1: Dräger Evita Infinity V500 Elite, Severity: Critical

On the IC the severity is the same as the medical ventilator of the neonatology and the same reasoning applies.

Victim 2: Fisher & Paykel MP 850, Severity: Negligible

In contrast to the neonatology department, the air heating and humidification is of less importance at the IC. The patients are larger and have more body mass in comparison, turning off the ME device for a while only causes inconvenience to the patient, like a dry mouth.

Victim 3,4: B.Braun Perfusor Space & B.Braun Infusomat Space, Severity: Critical

On the IC the severity is the same as the infusion pump of the neonatology and the same reasoning applies.

Victim 5,6: Philips Intellivue MX800/X2, Severity: Serious

On the IC the severity is the same as the patient monitor of the neonatology and the same reasoning applies.

Victim 7: Wissner-Bosserhoff Multi-care, Severity: Negligible

The Wissner-Bosserhoff Multi-care is a hospital bed, particularly developed for the IC. The bed provides a place for the patient to lay down and an easy way to transport a patient. It supports a multiple of extra function, like adjustable softness of the mattress and rotational bed therapy. A disruption could cause the bed to ignore the input of the caregiver, causing possible inconvenience to the caregiver and/or patient.

Result

In Tables 6.11 and 6.12 the results of the risk analysis of the neonatology and the IC are summarised respectively. The source-victim pairs bearing a high risk (in red) will be evaluated with an experiment.

Table 6.11: Risks of source-victim pairs assessed at the Neonatology

		Severity		
		Critical	Serious	Negligible
Probability	Probable	S(1,2,3,14)V(1,2,5)	S(1,2,3,14)V(3,4,6-10)	
	Moderate	S(4-9)V(1,2,5)	S(4-9)V(3,4,6-10)	
	Minor	S(10-16)V(1,2,5)	S(10-16)V(3,4,6-10)	

Table 6.12: Risks of source-victim pairs assessed at the IC

		Severity		
		Critical	Serious	Negligible
Probability	Probable	S(1,2,3,14)V(1,3,4)	S(1,2,3,14)V(5,6)	S(1,2,3,14)V(2,7)
	Moderate	S(4-9)V(1,3,4)	S(4-9)V(5,6)	S(4-9)V(2,7)
	Minor	S(10-16)V(1,3,4)	S(10-16)V(5,6)	S(10-16)V(2,7)

Step 5: Further investigate the selected source-victim pairs

A systematic way to collect empirical data about the risk of EMI is to conduct an experiment. The method will be reviewed in the next section.

6.3 Experimental method

The source-victim pairs bearing a theoretical high risk of section 6.2 are evaluated. The evaluation is done by exposing the victim to a signal representative for the source and finding the constraints for EMC to occur in practice.

6.3.1 Set-up

The set-up is built-up as depicted in Figure 6.3. Depending whether the chosen source is available and can be set to the worst case scenario emission, the simulator of the actual source or the actual source is chosen. The victim is placed in line with the antenna, while in its operative mode.

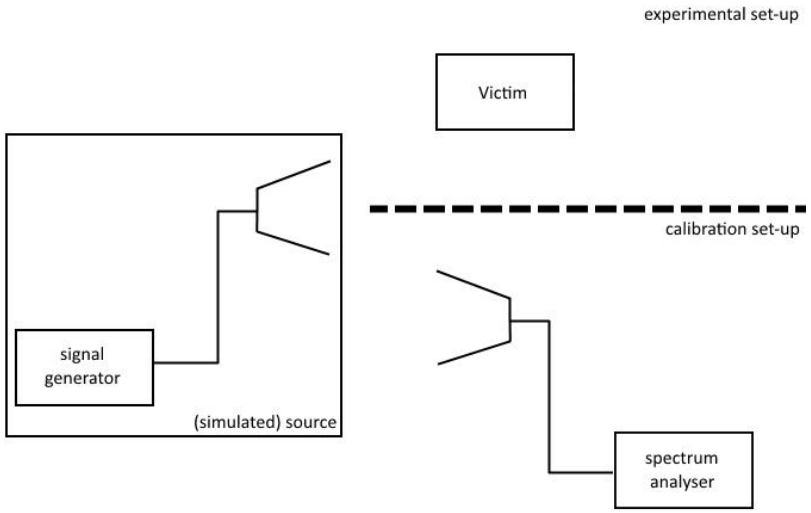


Figure 6.3: Experimental set-up

6.3.2 Sources and its representation

A multiple of sources have to be tested for this EMC study. All source will be simulated by the signal generator with a horn antenna attached, and if necessary an amplifier is utilised. Only for the walkie-talkie and the UPASS an exception is made, since it is possible to set both emitters to its maximum power mode. A horn antenna is used to radiate the generated signal [33], [34]. The benefits of a horn antenna are the large bandwidth and its mobility. A downside is the larger antenna dimension in comparison with the antennas in mobile emitters, which leads to different near and far field regions.

For every simulated source the signal generator needs to be set. The properties to set for the test signal are the frequency and the modulation.

Frequency: The centre frequency of every (uplink) band is chosen as the start test frequency of the test. [34] prescribes a step size of +1 or -1 % of the actual frequency, all frequencies found inside the band are tested. In this experiment, the test frequency is increased with a step size of approximately +2 or -2 % of the actual frequency, a larger stepsize is chosen to reduce the number of required experiments to a workable amount.

Modulation: [33] and [34] propose a pulse modulation to represent the digital wireless signals, but with different duty cycles (12.5% and 50% respectively) and slightly different modulation frequencies (200 Hz and 217 Hz). The bandwidth of the spectrum of EMI is mostly related by the slew rate of the pulsed signal (the sharpness of the edges) and less dependent on the duty cycle. A higher slew rate creates a broader spectrum. However a higher duty cycle can induce more energy into the victim, and as a consequence has a higher chance to induce EMI, which can be regarded as the worst-case scenario. A modulation frequency (or pulse repetition rate) around the 200 Hz is a representative manner, to simulate TDMA, CSMA and time domain duplex communication signals, which are present in the (digital wireless communication) sources. Because of these reasons, pulse modulation with a duty cycle of 50 % and a modulation frequency of 200 Hz is chosen. An exception is the TRANSIT in the band of 2446 to 2453 MHz, which emits a CW and will be represented by a CW.

6.3.3 Victims and settings

The ME apparatus has to be set to a test mode, at some devices the sensors should be stimulated to represent the real-world environment. This section will elaborate on the settings of the victims part of the experiment.

Medical ventilator: These require the flow sensor to be attached, the equipment will drain air from compressed air bottles, and at the inhaler the patient load is sim-

ulated with an artificial lung. Anomalies of the screen, alarms and irregular flow are regarded as signs of interference.

Respiratory support: No sensors are required for the functioning. The equipment will drain air from compressed air bottles, at the inhaler a neonate nose form will be attached. Anomalies of the screen, alarms and irregular flow are regarded as signs of interference.

Patient monitors: The patient monitor has a multiple of (electrical) sensors, which measure the electrocardiogram (ECG), temperature, saturation and respiration. These sensors are attached to a person during the testing. Another monitor is the Non-invasive Blood Pressure (NIBP), which is not tested, since the sensor is mechanical. Anomalies on the screen or in the graphs and alarms are signs of disruption.

Incubator: These have built-in sensors for the temperature and the humidity of the inside of the incubator. The sensors are part of a feedback system to hold the incubator at the desired temperature and humidity. Anomalies on the screen or in the read-outs of the sensors are signs of disruption.

Air humidifier: This device cannot be tested on its own, to provide a stable airflow, it will be tested with a ventilator or Sipap attached. It has two (electrical) temperature sensors. Anomalies on the screen or in the read-outs of the sensors are signs of disruption.

Infusion pump: The pump is tested in the constant flow mode. The output of the screen and alarms are used to detect anomalies.

6.3.4 Classification of disturbances

The disruption made by EMI differ in consequence and appearance. To provide an indication of the consequence, the anomalies created by the interference are noted down and classified. A (not comprehensive) list of anomalies are [33]:

- Cessation of function with(out) alarm
- Change in function
- Reboot or power down with(out) loss of data
- Change in measured and/or displayed data
- Distortion of displayed waveforms and display malfunction

The disruptions are not classified into categories for several reasons. Every disturbance of a medical apparatus is not acceptable during the treatment of a patient. Another reason is that the severity of the disturbance cannot always be estimated by the visible anomaly. Because of these reasons, the anomalies found during the experiment will be described, but no classification will be given.

6.3.5 List of materials

The following items are required for the set-up and experiment:

- Signal generator (Agilent ESG 4438C)
- Horn antenna (EMCO Gain Horn 3115)
- Amplifier (Tron-Tech P42GA-29) (with 10 dB attenuator on input)
- N-type/SMA cables
- UPASS TARGET
- Motorola DP 3400 mobile radio
- Victims
- Accessories required for functioning victim
- Ruler

6.3.6 Calibration of experimental set-up

For the calibration the victim of the experimental set-up is replaced by:

- Spectrum analyser (Rohde&Schwarz ZVL network analyzer or Rohde&Schwarz ESPI3 test receiver)
- Secondary horn antenna (EMCO Gain Horn 3115)

This set-up is built-up in the anechoic chamber of Nedap. The gains of the horn antennas are frequency dependent, the antenna factor and gains are for look up in a calibration table. At the receiving horn antenna a spectrum analyser is attached to measure the received power. By applying Friis transmission equation with cable losses, shown in equation 6.1, the transmission power of the horn antenna attached to the signal generator can be calculated and the ERP of the source. The maximum allowed ERP of every unique (uplink) band is checked at its centre frequency.

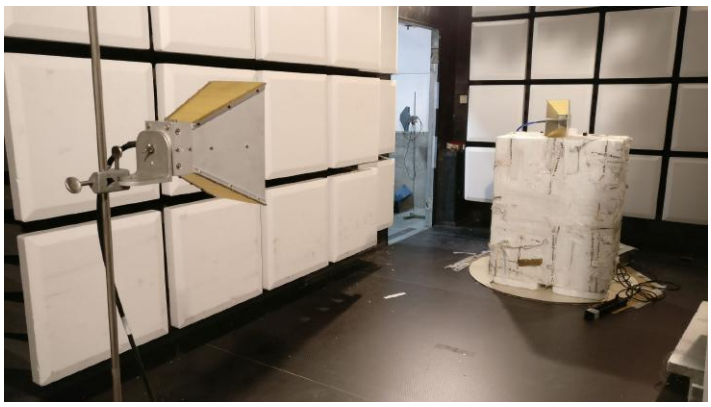
$$EIRP = P_t - L_{ct} + G_t = P_r + L_{cr} - G_r + 20log_{10}\left(\frac{4\pi df}{c}\right) \tag{6.1}$$

Where P_t and P_r are the transmitted and the received power in dBm, L_{ct} and L_{cr} are the losses of the cables at the transmitting and the receiver side, G_t and G_r are the gains of the transmitting and the receiving horn antenna in dBi respectively, c the speed of light, d the distance between transmitter and receiver and f the frequency of the signal.

6.3.7 Results of calibration

The utilised signal generator could not deliver enough power at some bands. Since the emission power is an important aspect for this study, an alternative solution is devised. The solution was to amplify the signal of the signal generator with an amplifier, for which bands an amplifier is used, can be found in Table 6.13. The horn antenna is designed and calibrated for a frequency of 1 GHz and up, which was a problem for the emission of the TRANSIT at 433 - 434 MHz. The gain of the horn antenna at this frequency is determined in the anechoic chamber, which is found to be -17 dBi, which is low, but still enough to represent the signal strength of the source. All frequency bands could be made with the desired signal power within a tolerance of 1 dB, except for the GSM (880 - 915 MHz) signal, which after amplification is still 2 dB lower than desired.

The calibration set-up was built-up as described earlier. In figure 6.4 a photograph of the anechoic chamber with set-up, and in figure 6.5 the slightly different set-up with amplifier is shown.

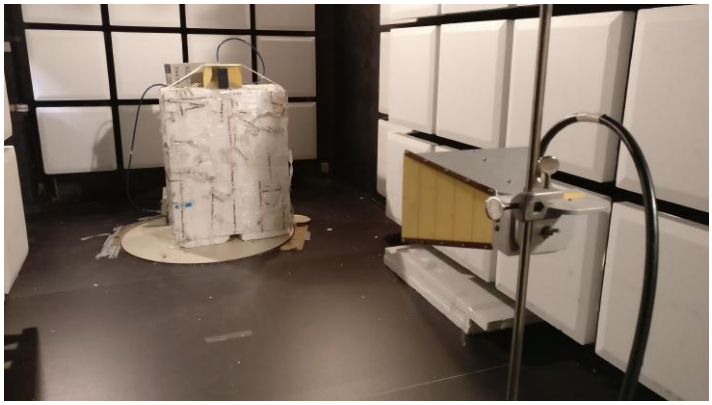


(a) The transmitting and receiveing antennas

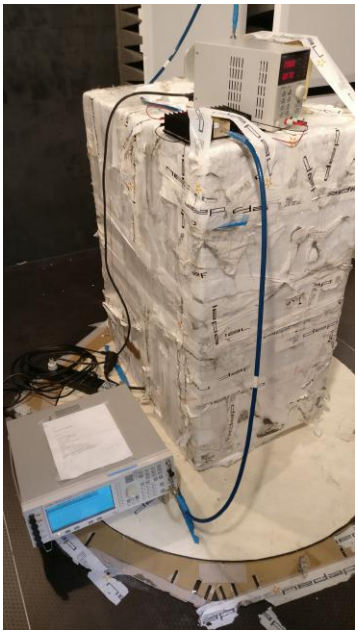
(b) signal generator attached to antenna

Figure 6.4: Anechoic chamber with standard set-up

The antennas were separated by a distance of 3 meter. The modulation of the signal generator was set to generate a pulse with a pulse period of 5 ms and a pulse width of 2.5 ms. At every unique band the test frequency was set and the power increased until the desired power was received. The frequency and power settings of the signal generator can be found in Table 6.13. The receiver cable



(a) The transmitting and receiveing antennas



(b) signal generator attached to amplifier before antenna

Figure 6.5: Anechoic chamber with amplifier set-up

loss was measured by attaching the signal generator to its input and the spectrum analyser at its output. The signal generator was set to generate a CW. For all the test frequencies the cable loss of the receiver side was determined. To ensure the reliability, an extra test is done. The signal generator was set to 1 GHz. At this frequency the gain of horn antennas are known from the calibration table. By composing the link budget, the cable losses of the transmitter and receiver side were determined to be 4.3 dB together. The losses of the individual cables were found to be 1.8 dB at the transmitting side and 2.5 dB at the receiving side, which add up nicely to 4.3 dB. In the almost the same way the gain of the horn antennas at 434 MHz were determined. In this instance, by composing the link budget, only the gains of the horn antennas are unknowns. The gain of the receiving antenna was found to be - 17 dBi.

For the standard set-up two screen-captures are shown in Figure 6.6. The figure clearly shows the properties of the pulse modulation. In Figure 6.7 the same is shown, but now for two bands were the signal was amplified by the amplifier. In Figure 6.8, the signal of the UPASS and the walkie-talkie is shown in its operative settings. In Figure 6.9 the signals which represent the TRANSIT emissions are shown.

Table 6.13: Results of the calibration

No.	max ERP (dBm)	Max EIRP (dBm)	Test frequency (MHz)	Power signal generator (dBm)	Amplifier	FSL at 3 m (dB)	Gain Receiving antenna (dBi)	Receiver cable loss (dBi)	Received power spectrum analyser (dBm)	Determined EIRP (dBm)	Notes
1	30	32.2	451	-	Motorola	35.1	-	-	25.2	33.3	Motorola DP3400
2	33	35.2	898	5	Yes	41.0	6.4	2.5	-4.3	32.8	2 dB lower, because of limitation amplifier
3	30	32.2	1743	1	Yes	46.8	8	3.5	-9.6	32.7	
4	24	26.2	898	-2	Yes	41.0	6.4	2.5	-10.3	26.8	
5	24	26.2	1950	25	No	47.8	9	3.7	-16.8	25.7	
6	23	25.2	847	2	Yes	40.5	6.4	2.5	-11.2	25.4	
7	23	25.2	898	-3	Yes	41.0	6.4	2.5	-11.5	25.6	
8	23	25.2	1743	18	No	46.8	8	3.5	-16.7	25.6	
9	23	25.2	2558	22	No	50.1	8	4.8	-21.1	25.8	
10	17.9	20.1	2442	10	No	49.7	8	4.4	-26.4	19.7	
11	20.9	23.1	5250	18	No	56.4	9.8	7	-30.8	22.8	
12	20.9	23.1	5598	18	No	56.9	9.5	7	-32.1	22.3	
13	17.9	20.1	2442	10	No	49.7	8	4.4	-26.4	19.7	
14	32.9	35.0	866	29.5	UPASS	40.7	6	2.5	-1.4	35.8	
15	-7.2	-5.1	434	18	No	34.7	-17	1.4	-57.4	-4.3	
16	24.9	27.1	2450	17	No	49.8	8	4.8	-19.3	27.3	

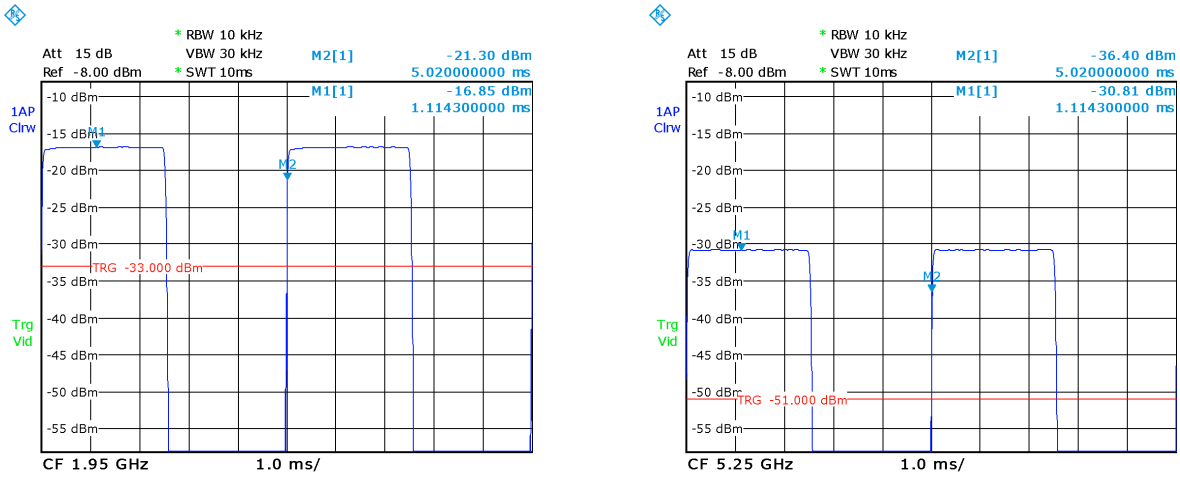
6.3.8 Comparison measurement

The MST also conducted a test, whereby medical equipment is exposed to the emissions of a GSM cell phone and Wi-Fi access-points. One of the ME devices, which is found by the MST to be interfered by the emissions, is also exposed to the emissions of the set-up of this study.

A cardiotocograph (Philips FM 30 avalon), also known as electronic fetal monitor (EFM) was exposed to the same transmitters radiation as at the MST test. A cardiotocograph has as purpose to measure the fetal heartbeat and the uterine contractions during pregnancy.

In the MST test, a GSM and a Wi-Fi access-point at 2400 MHz signal at a separation distance of 15 cm caused the EFM to show a heartbeat rate of 195 BPM (beats per minute).

The set-up and EFM was built-up in the anechoic chamber of Nedap, as shown in Figure 6.10a. The signal generator of the set-up was at first configured with the standard settings. The EFM was turned on and set to output found 'signals' to its speakers and the set-up was set to generate the GSM signal at 898 MHz. From a distance of 100 cm and smaller, a 200 Hz audio tone was audible from the EFM, which corresponds to the pulse repetition rate of the signal generator. To verify this correlation, the pulse repetition frequency (PRF) was reduced to a frequency of 3 Hz to find the BPM (200 BPM is the maximum value, which can be presented by the EFM). The EFM found a heartbeat rate of 180 BPM, which is the same as 3 times 60, as shown in Figure 6.10b. Lowering the PRF, reduced the BPM with the same proportion. The same situation occurred, at a different separation distance, at the



(a) UMTS at 1950 MHz

(b) Wi-Fi at 5250 MHz

Figure 6.6: Two representative emissions, made with the standard set-up

(a) GSM at 898 MHz

(b) GSM at 1743 MHz

Figure 6.7: Two representative GSM emissions, made with the amplifier set-up

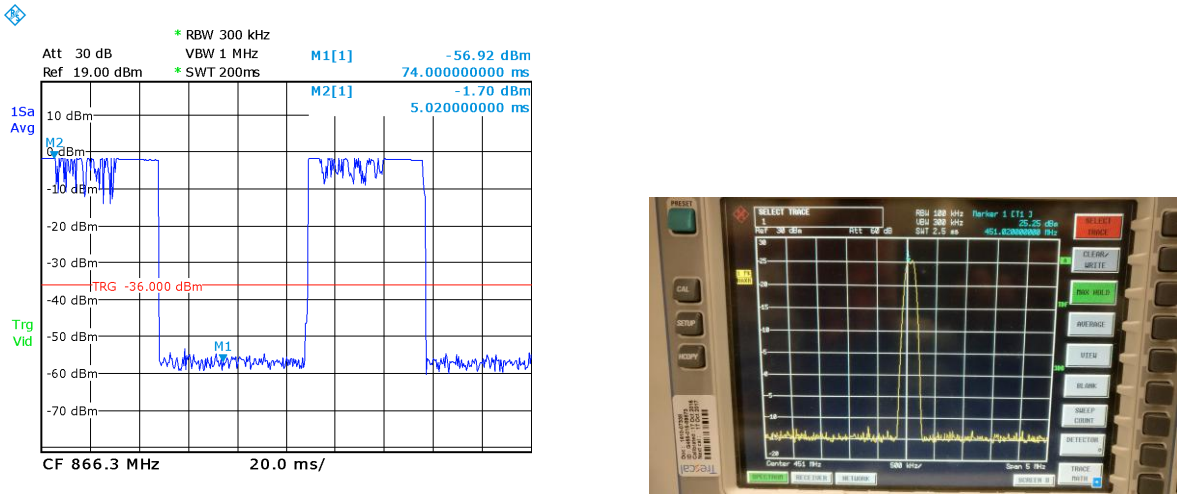
other GSM signal of 1743 MHz. The case of the Wi-Fi signal was slightly different, in this case the EFM detected a heart beat, but could not determine its BPM. The EFM will show a question mark on its screen. This detection occurred from a distance of 50 cm and smaller. In Table 6.14 the results are summarised.

Table 6.14: Summary of found results

Signal	Frequency (MHz)	EIRP (dBm)	Separation distance (cm)	E-field strength (V/m)	Notes
GSM	898	32.8	100	7.6	BPM related to PRF
	1743	32.7	64	11.7	BPM related to PRF
Wi-Fi	2442	19.7	50	3.34	Only detection, no BPM found

6.3.9 Test procedure

The steps of the test procedure are shown in the flowchart of Figure 6.11.



(a) UPASS Target

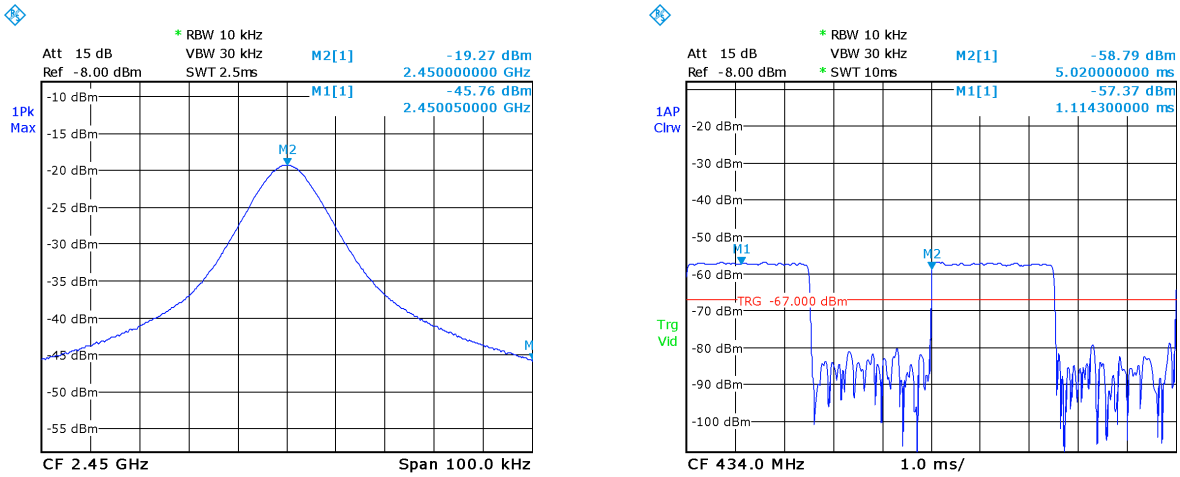
(b) Motorola DP3400 emission

Figure 6.8: UPASS and Motorola DP3400 emission

Due to circumstances the experiments could only be held on-site in a room at MST. There is no anechoic chamber available on-site and reflections will be present (as described in section 3.3.4). Because of this reason, the immunity test level cannot be determined exactly. Another problem for the determination is present at small separation distances. In this case the far field conditions are broken (as described in section 3.3.1). The E-field strength (and immunity level) cannot be calculated conveniently. Nevertheless the found minimum separation distances can be used as an indication for the probability of EMI.

The start separation distance is at 50 cm. The expectation is that the ME equipment will not be interfered at this distance. The choice to start at large distance and decrease it over time, and not the other way around, is made for an important reason. An emitter at a close-distance to ME equipment could (very unlikely) have permanent adverse effects on the ME device [33].

The ME device could have different EMC characteristics for every part and every incidence angle of the source signal of the victim. To ensure EMI cannot be induced into the victim, in case no EMI has occurred on a non-zero separation distance, the whole victim (including cables) will be scanned at the almost zero separation distance. Since polarisation properties could also influence the severity of the interference, the (horizontal or vertical polarised) horn antenna has been rotated 90 degrees and the victim has been scanned again. Only in this case, EM immunity for the reviewed source is drawn as conclusion.



(a) TRANSIT CW at 2450 MHz

(b) TRANSIT at 434 MHz

Figure 6.9: Representative TRANSIT emissions

(a) Set-up in the anechoic chamber

(b) The interferd EFM with PRF of 3 Hz

Figure 6.10: Anechoic chamber with amplifier set-up

6.4 Experimental results

In this section a summary of the results of the experiments are provided. The results are categorised on a department basis. Some more experiments are done about the UPASS interference signal, which can be found in its own section. In Figure 6.12, the infusion pumps during the test are shown.

6.4.1 Neonatology

As the risk assessment showed all ME devices present at the neonatology department had to be tested. An overview of the results ordered by emitter are shown in Table 6.15. Walkie-Talkie is abbreviated to 'W-T', Cell phone to 'CP', Computer and tablet to 'C,T' and the UPASS and TRANSIT to 'RFID'.

More details of the anomalies occurred can be found in Table 6.17 and 6.18. In column 1 the emitter is mentioned, column 2 the maximum distance of EMI is

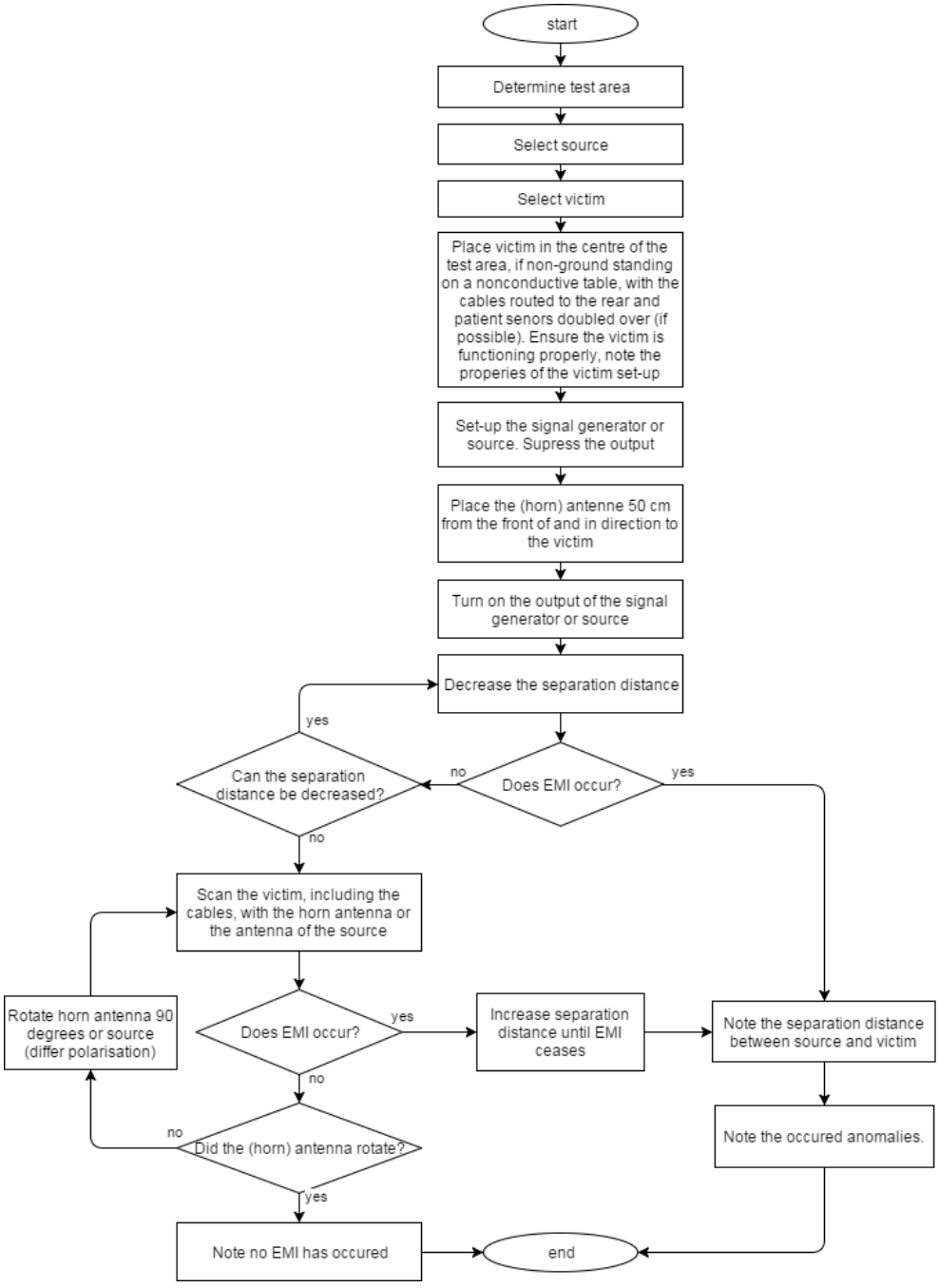
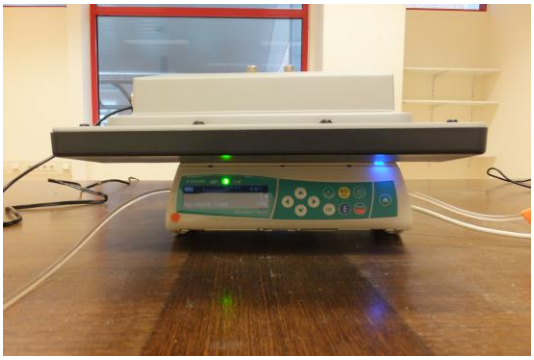


Figure 6.11: Flowchart of the test procedure

(a) BBraun perfusor exposed to radiation



(b) BBraun infusomat space exposed to UP-ASS radiation

Figure 6.12: Infusion pumps subject to the experiment

Table 6.15: EMI distances of victims on the neonatology

No	Medical Apparatus	EMI distance (cm)			
		W-T	CP	C,T	RFID
1	Acutronic Fabian	23	-	-	-
2	Carefusion Infant Flow Sipap	35	110	-	44
3	Wilamed Aircon Humidifier Heated	10	-	n	-
4	Fisher & Paykel MP 850	8	-	n	-
5	B.Braun Perfusor fm	-	-	-	-
6	Philips Intellivue MX500	-	-	n	300
7	Philips Intellivue MX450	-	-	n	300
8	Philips Intellivue X2	-	-	n	300
9	GE giraffe warmer incubator	60	-	n	-
10	GE giraffe warmer omnibed	-	-	n	-

given, column 3 describes the position at which the interference was found, column 4 is a description of the found anomalies and column 5 is a note about the found anomalies.

6.4.2 IC

On the IC other ME devices were present, an overview is provided by Table 6.16. Description of found anomalies are described in Table 6.18.

Table 6.16: EMI distances of victims on the IC

No	Medical apparatus	EMI distance (cm)			
		W-T	CP	C,T	RFID
1	Dräger Evita Infinity V500 Elite	-	-	-	-
2	Fisher & Paykel MP 850	8	-	n	-
3	B.Braun Perfusor Space	-	-	-	-
4	B.Braun Infusomat Space	10	-	-	-
5	Philips Intellivue MX 800	-	-	n	300
6	Philips Intellivue X2	-	-	n	300
7	Wissner-Bosserhoff Multi-care	n	n	n	n

Table 6.17: Detailed results of EMI (1/2)

Table: Description of EMI on neonatology

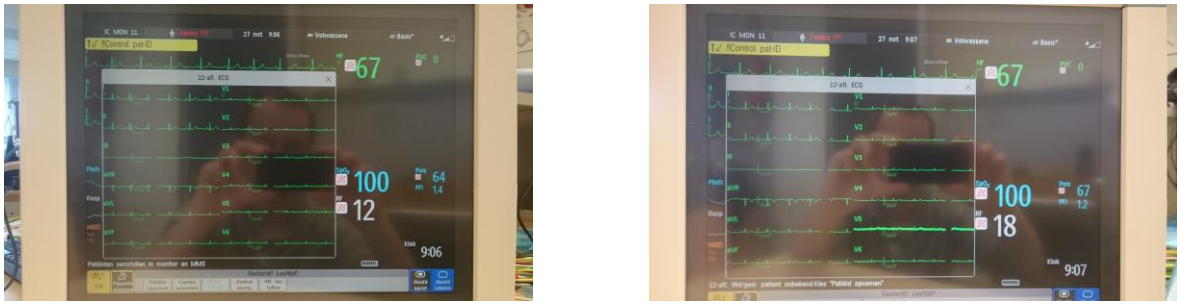
1. Acutronic Fabian: Medical ventilator				
W-T	23	Front, sides	DMR (1): Higher respiratory rate, trig flow alarm, irregular breathing artificial lung.	Disturbs the breathing pattern of the patient.
2. Carefusion Infant Flow Sipap: Respiratory support				
W-T	35	Front, right side	DMR (1): NCPAP read-out value increasing continuously, flickering screen.	The settings of the device are not disturbed. The disturbance during set-up decrease the reliability of the set values. It is not clear whether the increase of NCPAP value or oxygen level is relative or absolute.
CP	110	Front, right side	GSM (2): At 110 cm increase of 0.1 in NCPAP value (start value 4.5), maximum increase of 0.9 close by. Oxygen level (start value 21%) increased from 45 cm with a fluctuating 2 or 3 percent. GSM (3): At 100 cm increase of 0.1 in NCPAP value, maximum increase of 1.4 close by. No oxygen level change. UMTS (4): At 60 cm increase of 0.1 in NCPAP value, maximum increase of 0.2 close by. UMTS (5): At 27 cm increase of 0.1 in NCPAP value, maximum increase of 0.5 close by. LTE (6): At 78 cm increase of 0.1 in NCPAP value, maximum increase of 0.2 close by. LTE (7): At 43 cm and closer by increase of 0.1 in NCPAP value, maximum increase. LTE (8): At 49 cm increase of 0.1 in NCPAP value, maximum increase of 0.4 close by.	
RFID	44	Front, right side	UPASS (14): At 44 cm increase of 0.1 in NCPAP value and oxygen 2% increase, close by 0.5 and 5% respectively.	
3. Wilamed Aircon Humidifier Heated: Heated humidifier				
W-T	10	Front	DMR (1): Screen flickering.	No alteration of function observed/expected.
4. Fisher & Paykel MP 850: Heated humidifier				

Table 6.18: Detailed results of EMI (2/2)

W-T	8	Front, right	DMR (1): Drop of 8 degrees in read-out value of temperature at mouthpiece.	The temperature of the humidified air is feedback controlled, a disturbance alters the temperature.
6./7./8. Philips Intellivue MX500/MX450/X2: Patient monitor				
RFID	300	From sensors	UPASS (14): Noise on (one of) the ECG curves, broadening the ECG line. The distance of EMI can be drastically reduced (70 - 10 cm) by the utilised electrodes and a sanded skin. Connecting the electrodes to a phantom removes the EMI.	No reliable read-out of the ECG values is possible.
9. GE Giraffe Warmer Incubator: Incubator				
W-T	60	Front of screen, at sides	DMR (1): Sound audible, screen flickering.	No alteration of function observed/expected.

Table: Description of EMI on IC

4. Fisher & Paykel MP 850: Heated humidifier				
W-T	8	Front, right	DMR (1): Drop of 8 degrees in read-out value of temperature at mouthpiece.	The temperature of the humidified air is feedback controlled, a disturbance alters the temperature.
4. B.Braun Infusomat Space: Infusion pump				
W-T	10	Behind, high, low	DMR (1): Alarm 'te veel druppels' and alarm 'close roller clamp'. Not caused by the drop sensor.	The disturbance ceases the function of the device.
5./6. Philips Intellivue MX800/X2: Patient monitor				
RFID	300	From sensors	UPASS (14): Noise on (one of) the ECG curves, broadening the ECG line. The distance of EMI can be drastically reduced (70 - 10 cm) by the utilised electrodes and a sanded skin. Connecting the electrodes to a phantom removes the EMI.	No reliable read-out of the ECG values is possible.



(a) ECG curves without EMI

(b) ECG curves with UPASS EMI

Figure 6.13: Patient monitor without and with EMI

6.4.3 UPASS

As the Tables 6.15 and 6.16 show the interference of the UPASS was found to have an interfering effect on the patient monitors, in contrast to the GSM (1) signal, which is notable as the frequencies are only slightly different. The effect is depicted in Figure 6.13, the effect is not present on all ECG curves, but only on 'V5' and 'V6'. The signal generator was set to generate the frequency of the UPASS, with the modulation characteristics of the test signal. Exposing the electrodes of the patient monitor did not have an interfering effect. This implies that another tone or a multi-tone is causing the interference effect. To formulate an answer to what is causing the severe UPASS interference effect, a few experiments were conducted.

1. Pulse modulation frequency adjustment
   In this experiment the pulse repetition frequency of the pulse modulation was adjusted. It was reduced to 1 Hz and with steps 10 Hz increased to 1 kHz, it did not cause interference.

2. AM modulation 15%
   In next experiment, the modulation was changed to AM with a depth of 15%. The modulation frequency was adjusted from 1 Hz to 1 kHz, with steps of 10 Hz, from 1 kHz to 4 kHz, steps of 100 Hz were made. No interference effects were found.

3. Two-tone interference
   For this experiment a frequency mixer and extra signal generator was added to the set-up, making the overall set-up as shown in Figure 6.14. The first signal generator was set to create a test signal on the UPASS frequency (866.3 MHz). The second signal generator generates a CW with a power of -15 dBm, the frequency was increased step-by-step from 20 Hz to 4 kHz. The two-tone signal did not interfere on the patient monitor.

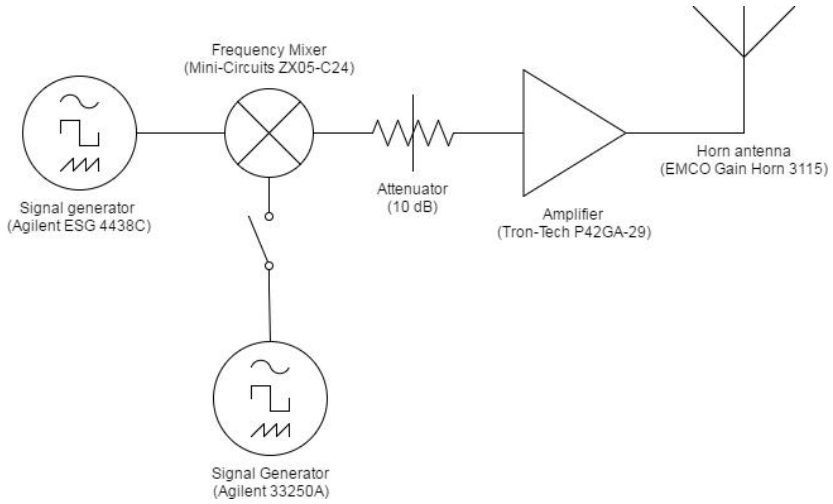


Figure 6.14: Two-tone set-up

The experiments did not answer the question what induced the interference. A possible method to find the signal causing the interference is by correlating the UP-ASS signal with the signal of the ECG. Because of time limitations, this was not done.

Step 6: Draw conclusions and apply risk management

Now the risk analysis is completed and the empirical data is collected. It is important to draw conclusion and formulate the risk management process, which is done in the next section.

6.5 Conclusion and risk management

Now the results of exposing ME equipment to EM signals are found. To manage the risk some precautions are required to be taken. The risk management policy should instate rules for every category of devices and is limited to the treated EM environments. Other environments might require different rules.

In the MST, the policy of 1.5 meter is in effect since 2007. Keeping this policy will reduce the risk of EMI to a minimum. Nevertheless, in most instances the policy can be relaxed. The recommendations are done on an emitter basis.

The Walkie-Talkie can be allowed in stand-by (receiving mode) at all places, it does not emit any excessive emissions in this state. Pushing the button to talk, switches on the emission. Only in this state possible EMI can occur. To prevent EMI a distance of 1 meter is advised.

The cell phone did in most cases not cause any interference. In the case of EMI

which was found, it did not influence the functioning of the ME device. Therefore the policy can be relaxed. Maintaining a distance of 50 cm between ME device and cell phone is still preferable as secondary modulation or multi-tone effects could cause interference, where the distance is taken from the 4th edition of the IEC 60601-1-2 standard with a margin.

Wi-Fi and Bluetooth enabled devices, these are commonly present in modern day hospitals, and sometimes integrated into newer ME devices. Because of the very low risk of EMI, no particular policy for the devices is needed. A Wi-Fi or Bluetooth enabled device could interfere if attached to a charger. This was not part of this study, but for the risk management policy it should be taken into account.

For Nedap RFID systems, in particular the UPASS, it is recommended to install the reader of the Nedap RFID systems at places, which hold a distance of 1 meter from the ME devices.

Another good practice, not related to the emitters, is to always use high-quality ECG electrodes, and sand the skin before applying (as described in the manual of the patient monitor [63]). It can drastically reduce the chance of EMI.

Even with this policy in place, it cannot be guaranteed that no EMC problems will occur. This policy will however drastically reduce the chances of such problems.

Chapter 7

Conclusions and recommendations

In this chapter the conclusions and recommendations of the conducted study are provided.

7.1 Conclusions

The combination of electrical devices in the hospital environment can pose the risk of EMC issues. ME devices could provide vital functions to a patient, therefore EMC issues could have critical consequences.

The identified intentional emitters are cell phones, computer, tablets, portable radio and RFID systems. These emitters consist of a multiple of wireless techniques with their own properties.

The minimum immunity requirements for ME devices are set by the international EMC standard IEC 60601-1-2. This standard describes, amongst others, the immunity test levels, to which a ME device has to comply. The latest edition, which will be in force on the 1st of January 2019 require higher immunity test levels for bands at which intentional emitters are expected. The previous editions do not distinguish this, but do make a distinction between life-supporting and non life-supporting ME devices, of which the first require higher immunity test levels. Although ME devices comply with minimum immunity requirements, the field strength, which are caused by the intentional emitters can be in excess, which as a consequence means that EMC issues cannot be ruled out.

To rule out EMC issues a few methods can be utilised. A first way is the rule-based manner by following the recommended separation distances, which are provided by the manufacturer. These distances are mostly not followed by hospitals, because of practical limitations. A second way, is by calculating the field strength around the emitter, and finding the distance at which the field strength is lower than the tested immunity level. A third way, is by following the recommendations

of scholars, which conducted empirical studies to determine when EMC problems occur. The conclusions of the scholars are not consistent for every emitter. The recommended separation distances are in general smaller than found with previous methods.

Another more consistent and modern approach is to perform risk-based EMC analysis. The departments of Neonatology and IC at the MST were in scope for this analysis. A method for the analysis is presented in this study. All source-victim pairs were classified into having a theoretical high, medium or low risk. The source-victim bearing a high theoretical risk, were tested with an experiment, to find the empirical risk. As a result a risk management policy is formulated to prevent EMC issues.

The experiments have also pointed to another conclusion. Not only the emission power and the modulation characteristics of the main source signal, could have a different interfering effect, but also the addition of an extra tone. Thereby creating a multi-tone signal.

7.2 Recommendations

In this thesis only an introductory study of the EMC in the hospital environment is done. A limited number of medical instruments were reviewed of a limited amount of environments. Variations in the immunity between ME devices of the same model were not studied. In other environments other emitters could be found like diathermy and magnetic resonance imaging (MRI). Spurious emissions and their effects on electrical devices were not regarded. The combined emissions of multiple sources and its interference effect was only touched upon.

Only a qualitative risk analysis is done for two hospital environments. The collection of more data about the risk and appearance of EMI could enhance the risk analysis. Taking into account factors like probability of the presence of a certain emitter and technique characteristics like power control and the characteristics of the emitted signal.

The interference effect depends on the applied signal. The standard prescribes certain signals for the immunity test. More research is necessary to know whether the utilised signal is a good representation for all digital wireless signals.

In the future new emitters could appear in the hospital environment, which alter the EM environment of the hospital. On the 1st of January 2019, the new edition of the standard will be in force, changing the immunity of ME equipment. The effects of these changes can be subject of study.

To have a well-reasoned view on this subject, a more comprehensive and in-depth research is required.

Bibliography

[1] C. Christopoulos, *Principles and techniques of electromagnetic compatibility*. CRC press, 2007.

[2] H. W. Ott, *Electromagnetic compatibility engineering*. John Wiley & Sons, 2011.

[3] Electromagnetic Compatibility. Accessed December 9, 2016. [Online]. Available: https://en.wikipedia.org/wiki/Electromagnetic_compatibility

[4] C. R. Paul, *Introduction to electromagnetic compatibility*. John Wiley & Sons, 2006, vol. 184.

[5] European Parliament and Council of the European Union, "Directive 2014/30/EU," Brussels, 2014.

[6] Federal Communications Commission. Quick labelling guide. Accessed December 1, 2016. [Online]. Available: https://apps.fcc.gov/kdb/GetAttachment.html?id=I2QqxFknp%2F39qNa3Mo4bOw%3D%3D&desc=784748%20D03%20Labelling%20Quick%20Guide%20V01&tracking_number=27980

[7] International Electrotechnical Commission (IEC). Who we are. Accessed December 5, 2016. [Online]. Available: http://www.iec.ch/about/profile/

[8] ——. Developing international standards. Accessed December 5, 2016. [Online]. Available: http://www.iec.ch/about/activities/standards.htm

[9] Food and Drug Administration (FDA). Manufacturer and User Facility Device Experience (MAUDE) - Reports of EMI. Accessed December 16, 2016. [Online]. Available: https://www.accessdata.fda.gov/

[10] F. Censi, G. Calcagnini, E. Mattei, M. Triventi, and P. Bartolini, "Rfid in healthcare environment: electromagnetic compatibility regulatory issues," in *2010 Annual International Conference of the IEEE Engineering in Medicine and Biology*. IEEE, 2010, pp. 352–355.

[11] A. Fehske, G. Fettweis, J. Malmodin, and G. Biczok, "The global footprint of mobile communications: The ecological and economic perspective," *IEEE Communications Magazine*, vol. 49, no. 8, pp. 55–62, 2011.

[12] Canadian Agency for Drugs and Technologies in Health, "Wireless device use and patient monitoring equipment in any healthcare delivery setting: A review of safety and guidelines," Canadian Agency for Drugs and Technologies in Health, Tech. Rep., 2014.

[13] J. Tikkanen, "Wireless electromagnetic interference (emi) in healthcare facilities," *Blackberry White Paper*, 2009.

[14] C.-K. Tang, K.-H. Chan, L.-C. Fung, and S.-W. Leung, "Electromagnetic interference immunity testing of medical equipment to second-and third-generation mobile phones," *IEEE Transactions on electromagnetic compatibility*, vol. 51, no. 3, pp. 659–664, 2009.

[15] M. K. Wallin and S. Wajntraub, "Evaluation of bluetooth as a replacement for cables in intensive care and surgery," *Anesthesia & Analgesia*, vol. 98, no. 3, pp. 763–767, 2004.

[16] K. Finkenzeller, *RFID handbook: Fundamentals and applications in contactless smart cards, radio frequency identification and near-field communication*. John Wiley & Sons, 2010.

[17] M. Fernández Chimeno and F. Silva Martínez, "Rfid systems in medical environment: Emc issues," in *9th International Symposium on EMC*, 2010.

[18] "Electromagnetic compatibility and Radio spectrum Matters (ERM); Radio Frequency Identification Equipment operating in the band 865 MHz to 868 MHz with power levels up to 2 W and in the band 915 MHz to 921 MHz with power levels up to 4 W; Part 1: Technical requirements and methods of measurement," European Telecommunications Standards Institute, Valbonne, France, International Standard, February 2015.

[19] " ETSI EN 300 392-2 v2.3.2 Terrestial Trunked Radio (TETRA); Voice plus Data (V+D); Part 2: Air Interface (AI)," European Telecommunications Standards Institute, Valbonne, France, International Standard, March 2001.

[20] Electronic Communications Commitee, "ECC Decision of 28 October 2005 on harmonised frequencies, technical characteristics, exemption from individual licensing and free carriage and use of digital PMR 446 applications operating in the frequency band 446.1-446.2 MHz,"

Tech. Rep., accessed February 10, 2017. [Online]. Available: http://www.erodocdb.dk/Docs/doc98/official/pdf/ECCDEC0512.PDF

[21] "ETSI TS 102 361-1 v2.2.1 Electromagnetic compatibility and Radio spectrum Matters (ERM); Digital Mobile Radio (DMR) Systems; Part 1: DMR Air Interface (AI) protocol," European Telecommunications Standards Institute, Valbonne, France, International Standard, February 2013.

[22] 4Gmasten.nl. Banden en frequenties. Accessed February 10, 2017. [Online]. Available: http://4gmasten.nl/achtergrond/lte-umts-gsm-banden-en-frequenties

[23] Agentschap Telecom. Techniek. Accessed February 10, 2017. [Online]. Available: https://www.antennebureau.nl/onderwerpen/techniek

[24] "GSM Digital cellular telecommunications system (Phase 2+); Radio transmission and reception (GSM 05.05)," European Telecommunications Standards Institute, Valbonne, France, International Standard, March 1996.

[25] "Universal Mobile Telecommunications System (UMTS); User Equipment (UE) radio transmission and reception (FDD) (3GPP TS 25.101 version 11.3.0 Release 11)," European Telecommunications Standards Institute, Valbonne, France, International Standard, November 2012.

[26] M. Reynolds, "PMSE Spectrum Usage Rights & Interference Analysis," Sagentia, Tech. Rep., accessed February 10, 2017. [Online]. Available: https://www.ofcom.org.uk/__data/assets/pdf_file/0019/33607/sagentia1.pdf

[27] "LTE; Evolved Universal Terrestial Radio Access (E-UTRA); User Equipment (UE) radio transmission and reception (3GPP TS 36.101 version 12.9.0 Release 12)," European Telecommunications Standards Institute, Valbonne, France, International Standard, October 2015.

[28] Agentschap Telecom, "Vergunningsvrije radiotoepassingen," Agentschap Telecom, Tech. Rep., accessed February 10, 2017. [Online]. Available: https://www.agentschaptelecom.nl/sites/default/files/brochure-vergunningsvrije-radiotoepassingen.pdf

[29] "5 GHz RLAN; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU," European Telecommunications Standards Institute, Valbonne, France, International Standard, November 2016.

[30] NTS. Dynamic frequency selection (dfs) in 5ghz unlicensed bands: an overview of worldwide regulatory requirements. Accessed March 20, 2017. [Online].

Available: https://www.nts.com/pdf/whitepapers/6_Dynamic%20Frequency%20Selection%20and%20the%205GHz%20Unlicensed%20Band.pdf

[31] A. F. Molisch, *Wireless communications*. John Wiley & Sons, 2011.

[32] "IEC 61000:2006(E) Electromagnetic compatibility (EMC) — Part 4-3: Testing and measurement techniques Radiated, radio-frequency, electromagnetic field immunity test," International Electrotechnical Commission, Geneva, Switzerland, International Standard, February 2006.

[33] "American National Standard Recommended practice for an on-site, ad hoc test method for estimating EMS fo medical devices to radiated RF emissions form RF transmitters," IEEE, New York, USA, American national standard, May 2014.

[34] "IEC 61000:2006(E) PRV Electromagnetic compatibility (EMC) — Part 4-39: Testing and measurement techniques Radiated fields in close proximity - immunity test," International Electrotechnical Commission, Geneva, Switzerland, International Standard, December 2016.

[35] C. A. Balanis, *Antenna theory analysis and design*, 2005.

[36] Semtech, "Tn1200.04 calculating radiated power and field strength for conducted power measurements," Semtech Advanced Comms & Sensing, Tech. Rep., accessed December 13, 2016. [Online]. Available: https://www.semtech.com/images/promo/Semtech_ACS_Rad_Pwr_Field_Strength.pdf

[37] Radiocommunication Sector of ITU, "Recommendation ITU-R P.525-3: Calculation of free-space attenuation," International Telecommunication Union, Geneva, Switzerland, Recommendation, September 2016.

[38] ——, "Recommendation ITU-R P.2040-1: Effects of building materials and structures on radiowave propagation above about 100 MHz," International Telecommunication Union, Geneva, Switzerland, Recommendation, July 2015.

[39] A. F. Forums, "Draft paper on the characteristics of rfid systems," *AIM FF*, vol. 1, 2000.

[40] R. Vogt-Ardatjew, S. van de Beek, and F. Leferink, "Influence of reverberation chamber loading on extreme field strength," in *Electromagnetic Compatibility, Tokyo (EMC'14/Tokyo), 2014 International Symposium on*. IEEE, 2014, pp. 685–688.

[41] "IEC 60601:2014(E) Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances – Requirements and tests," International Electrotechnical Commission, Geneva, Switzerland, International Standard, February 2014.

[42] "IEC 60601:2007(E) Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances – Requirements and tests," International Electrotechnical Commission, Geneva, Switzerland, International Standard, March 2007.

[43] "IEC 60601:2004(E) Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances – Requirements and tests," International Electrotechnical Commission, Geneva, Switzerland, International Standard, November 2001.

[44] "IEC 60601:1993(E) Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances – Requirements and tests," International Electrotechnical Commission, Geneva, Switzerland, International Standard, April 1993.

[45] International Electrotechnical Commission (IEC). Taking conformity assessment further. Accessed January 5, 2017. [Online]. Available: http://www.iec.ch/about/brochures/pdf/conformity_assessment/IECEE_brochure_LR.pdf

[46] R. Hensbroek, *96 Medical Apparatuses tested for interference by WLAN/WiFi signals*. Leiden: TNO, 2007.

[47] I.-H. Hahn, D. Schnadower, R. J. Dakin, and L. S. Nelson, "Cellular phone interference as a cause of acute epinephrine poisoning," *Annals of emergency medicine*, vol. 46, no. 3, pp. 298–299, 2005.

[48] A. Klein and G. Djaiani, "Mobile phones in the hospital–past, present and future," *Anaesthesia*, vol. 58, no. 4, pp. 353–357, 2003.

[49] S. Ettelt, E. Nolte, M. McKee, O. A. Haugen, I. Karlberg, N. Klazinga, W. Ricciardi, and J. Teperi, "Evidence-based policy? the use of mobile phones in hospital," *Journal of public health*, vol. 28, no. 4, pp. 299–303, 2006.

[50] R. Hensbroek, *Influence of Mobile Terminals for GSM, GPRS and UMTS on 22 Medical Apparatuses*. Leiden: TNO, 2009.

[51] N. Lawrentschuk and D. M. Bolton, “Mobile phone interference with medical equipment and its clinical relevance: a systematic review,” *Medical journal of Australia*, vol. 181, no. 3, pp. 145–149, 2004.

[52] S. Iskra, B. W. Thomas, R. McKenzie, and J. Rowley, “Potential gprs 900/180-mhz and wcdma 1900-mhz interference to medical devices,” *IEEE Transactions on Biomedical Engineering*, vol. 54, no. 10, pp. 1858–1866, 2007.

[53] S. Ishihara, J. Higashiyama, T. Onishi, Y. Tarusawa, and K. Nagase, “Electromagnetic interference with medical devices from third generation mobile phone including lte,” in *Electromagnetic Compatibility, Tokyo (EMC’14/Tokyo), 2014 International Symposium on*. IEEE, 2014, pp. 214–217.

[54] E. J. Van Lieshout, S. N. Van der Veer, R. Hensbroek, J. C. Korevaar, M. B. Vroom, and M. J. Schultz, “Interference by new-generation mobile phones on critical care medical equipment,” *Critical Care*, vol. 11, no. 5, p. 1, 2007.

[55] A. M. Pashazadeh, M. Aghajani, I. Nabipour, and M. Assadi, “An update on mobile phones interference with medical devices,” *Radiation protection dosimetry*, vol. 156, no. 4, pp. 401–406, 2013.

[56] R. G. Soto, L. F. Chu, J. M. Goldman, I. J. Rampil, and K. J. Ruskin, “Communication in critical care environments: mobile telephones improve patient care,” *Anesthesia & Analgesia*, vol. 102, no. 2, pp. 535–541, 2006.

[57] G. Calcagnini, E. Mattei, F. Censi, M. Triventi, R. L. Sterzo, E. Marchetta, and P. Bartolini, “Electromagnetic compatibility of wlan adapters with life-supporting medical devices,” *Health physics*, vol. 100, no. 5, pp. 497–501, 2011.

[58] R. Van Der Togt, E. J. van Lieshout, R. Hensbroek, E. Beinat, J. M. Binnekade, and P. Bakker, “Electromagnetic interference from radio frequency identification inducing potentially hazardous incidents in critical care medical equipment,” *Jama*, vol. 299, no. 24, pp. 2884–2890, 2008.

[59] B. Houliston, D. Parry, C. S. Webster, and A. F. Merry, “Interference with the operation of medical devices resulting from the use of radio frequency identification technology,” 2009.

[60] “Department of Defense Standard Practice — System safety,” Department of Defense — United States of America, Military Standard, May 2012.

[61] “ISO 14971:2007(E) (Corr. 2012-07) Medical devices — Application of risk management to medical devices,” International Organization for Standardization, Geneva, Switzerland, International Standard, March 2007.

[62] D. Mansson, R. Thottappillil, and M. Backstrom, “Methodology for classifying facilities with respect to intentional emi,” *IEEE Transactions on electromagnetic compatibility*, vol. 51, no. 1, pp. 46–52, 2009.

[63] “IntelliVue Multi-Measurement Module X2 - Versie K met softwareversie K.2x.xx Patientbewaking,” Philips, User manual, June 2014.

[64] Nedap Identification Systems. Understanding the confusing world of rfid tags and readers in access control. Accessed December 9, 2016. [Online]. Available: http://www.nedapidentification.com/news/insights/understanding-the-confusing-world-of-rfid-tags-and-readers-in-access-control.html

[65] Z. Fan, S. Qiao, J. T. Huang-Fu, and L.-X. Ran, “Signal descriptions and formulations for long range uhf rfid readers,” *Progress In Electromagnetics Research*, vol. 71, pp. 109–127, 2007.

[66] D. Dobkin, “The rf in rfid passive uhf in practice,” *United States of America, Newness*, 2008.

Appendix A

Operation of long-range RFID systems

In this appendix the operation principle of long-range RFID systems is treated. In the next section an overview is provided, the follow-up sections provide more detail.

A.1 The operation principle

A RFID system consists of a reader and one or multiple tags (or transponders). The tags carry identification information, which can be requested by the reader. Once the information is collected by the reader, it is fed back to a third party system, which uses this information to trigger (an) event(s) [64].

Long-range RFID systems, also known as backscatter, microwave or UHF RFID, are RFID systems that use the backscatter mechanism to remotely identify a tag, as shown in Figure A.1. This mechanism consists of the following steps. The reader emits a signal with a certain amount of power via its antenna, the forward signal. The forward signal propagates through space, until it reaches the antenna of a tag. The power of the signal, incident on the antenna of the tag, is used to power up the transponder chip and excessive power is re-radiated (or reflected). Before the excessive power is reflected, it is modulated with the tag's information by the transponder chip. The now modulated, reflected power, which is the backscatter signal, propagates back to the reader. The reader receives and demodulates the backscatter signal. After demodulation, the information of the tag is known to the reader. The reader feeds this information into a third-party system, which, for example, identifies the tag as legit and grants access or triggers another action [16, Sec. 8.1] [65].

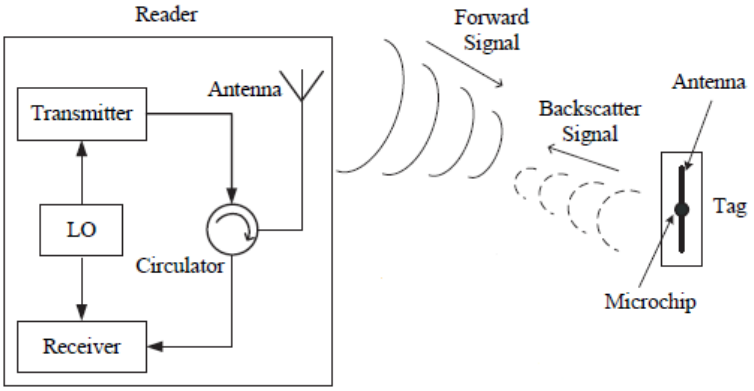


Figure A.1: Long-range RFID principle of operation. Adopted from [65]

A.1.1 Reader's emission

The emissions of a long-range RFID systems consist of two parts: The emissions generated by the reader and those by the tag. First the reader's emissions are treated, the tag's emissions follow.

Coding and modulation

A periodic signal, without change in amplitude, frequency or phase, persisting indefinitely, is a CW signal. This is for example the forward signal of the TRANSIT reader on the 2.45 GHz. This signal cannot carry any information. In some RFID systems, like the UPASS, two-way communication between reader and tag is required. For these systems, the forward signal of the reader is modulated to add information to the signal of the reader. Signals in RFID are generally digitally modulated. The simplest form of digital modulation is on-off keying (OOK). In OOK, depending on the transmitted symbol, the power of the signal is turned on or off for one symbol time. In Figure A.2 OOK is applied to datasequence, a binary '1' turns the power on, a binary '0' does the opposite.

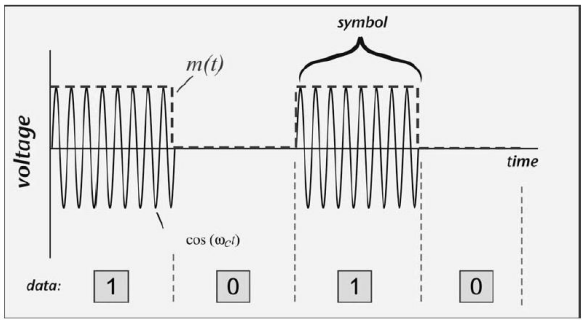


Figure A.2: OOK signal. Adopted from [66, Chap. 3]

As described in section A.1, the tag needs the power of forward signal to function. The downside of OOK modulation is the interruption of power when a zero symbol is transmitted. A few interruptions of power can be overcome by the tag. However a situation could occur in which the data consists of multiple of zeroes or many zeroes in a row, the power will be omitted for a too long duration and therefore the tag will not function. The dependence of the tag's functioning on the datastream of the forward signal is undesirable. A common solution to the power problem is by applying PIE to the data before modulation. Applying this encoding, a binary '1' is represented as long full-power interval with a short power-off pulse, a binary '0' is represented as a shorter full-power interval with the same short power-off pulse, shown in Figure A.3. The benefit is that a least 50% of the maximum power is delivered to the tag, for a random data sequence with equally mixed binary data around 63% of the maximum power is delivered. These numbers were 0% and 50%, respectively, without PIE. This coding scheme is in use for EPC Class-1 Generation-2 UHF RFID devices standard, other passive RFID standards can use slightly different encoding schemes, but all generally have the purpose to keep the reader power on as much as possible [66, Chap. 3].

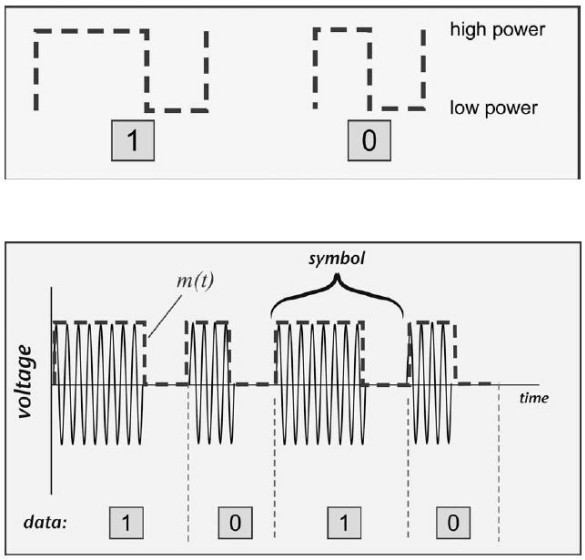


Figure A.3: PIE OOK signal. Adopted from [66, Chap. 3]

Emission power

For the radiated power, the gain of an antenna is mostly not of direct importance, legal limits of maximal radiation are set in EIRP. EIRP is related to transmitter power and gain as follows:

$$EIRP(dBm) = P_{TX}(dBm) + G_{TX}(dBi) \tag{A.1}$$

In practice, most RFID readers will be operated at the legal limit.

Polarisation

EM fields can be polarised in two ways, namely linear and circular. Since the tag mostly consist of a wire antenna, which is only sensitive for an E-field oriented along its wires, the polarisation is a factor of influence on the range of the RFID system. Circular polarisation has the benefit that it shifts the direction of the E-field over time, a circular wave incident on a tag wit a linear antenna will therefore always induce a power in the tag. Because of this property, circular polarisation is often chosen for the forward signal. The disadvantage is that the only the half of the maximum forward signal power is induced in the tag's antenna.

A.1.2 Tag's emission

The other part of the emission of a long-range RFID are the tag's emission, which is treated in the next sections.

Power source

Tags are differentiated by the power source of the transponder chip into two categories, namely passive and active (or semi-passive). Tags of both categories need the power of the forward signal (which is backscattered) to transmit data. The difference between the two is in the power supply of the transponder chip. In an active tag the transponder chip is powered by a battery, in the passive tag the forward signal delivers the power needed for the transponder chip [16, Sec. 2.4]. A modern tag integrated circuit consumes around 10-30 μW. Since the power from the antenna is alternating, a rectifying circuit is required to convert the power to DC. This conversion has an efficiency of about 30%. A conservative estimation of the threshold power and power use of the tag is 100 μW. This power will be extracted from the incident signal in a passive tag. At an active tag, the integrated circuit of the transponder is powered by a battery. As a consequence the passive tag only transmits its information, if sufficient power is received to power up the integrated circuit of the tag. An active tag is not dependent on the incident power to enable the integrated circuit of the tag to function. Therefore it requires less incident power to function, which has the benefit of a longer detection range [66, Chap. 3].

Coding and modulation

The integrated circuit of the tag modulates the backscatter with its data by altering the load of its antenna. By doing this the reflection characteristics of the antenna change. The amplitude of the reflected power will alter accordingly. Therefore the modulation scheme can be regarded as OOK.

Emission power and polarisation

The emission power of any tag is at most the incident power. Only the active tag can emit a backscatter signal with this power. For a passive tag the power required to enable the integrated circuit to function must be subtracted.

To keep the tag simple and small, most tags are equipped with a linearly polarised wire antenna.

Appendix B

Derivation of reflection and transmission coefficients

Assume a wave that is incident on a smooth, large (compared with the wavelength), non-ionized and non-magnetic material. Therefore the free charge density (ρ_f) is zero and the permeability of the material (μ) is similar to the free space permeability (μ_0). The fundamental variable of influence on the reflection and transmission mechanism is the velocity of the wave in the two media, which is related to the electric permittivity (ϵ) and the conductivity (σ) of the media [38] [31, Chap. 4].

The wave equation derived from the Maxwell's equations is the starting point. If taken into account all of the above assumptions, the wave equation for the E-field becomes:

$$\nabla^2 \vec{E} - \epsilon\mu_0 \frac{\delta^2 \vec{E}}{\delta t^2} = \mu_0 \frac{\delta \vec{J_f}}{\delta t} \tag{B.1}$$

Where $\vec{E}$ is the E-field intensity, J_f is current density of the free charges, ϵ the dielectric permittivity and μ_0 the permeability of free space. By Ohm's law $\vec{J_f}$ and $\vec{E}$ are related:

$$\vec{J_f} = \sigma \vec{E} \tag{B.2}$$

where σ is the conductivity. Filling in equation B.2 into B.1 has the result:

$$\nabla^2 \vec{E} - \epsilon\mu_0 \frac{\delta^2 \vec{E}}{\delta t^2} = \mu_0 \sigma \frac{\delta \vec{E}}{\delta t} \tag{B.3}$$

Now converting the $\vec{E}$ to the exponential notation, results in:

$$\vec{E} = \vec{E_0} e^{j(\omega t - \vec{k}\vec{r})} \tag{B.4}$$

Where $\vec{E_0}$ is the value of $\vec{E}$ when t and $\vec{r}$ are zero, $\vec{k}$ is the wavenumber, ω is the angular frequency and $\vec{r}$ is the spatial distance. Substituting equation B.4 in B.3 gives:

$$k^2 - \epsilon\mu_0\omega^2 + j\omega\mu_0\sigma = 0 \tag{B.5}$$

Where k is the magnitude of $\vec{k}$ and equals $2\pi/\lambda$,where λ is the wavelength.

In the situation of an non-conducting electric $\sigma = 0$ the field is not attenuated and the velocity of the propagation is:

$$v = \frac{\omega}{k} = \frac{1}{\sqrt{\epsilon\mu_0}} \tag{B.6}$$

Where ϵ can be written in terms of relative and free space permittivity:

$$\epsilon = \eta\epsilon_0 \tag{B.7}$$

Where η is relative permittivity of the medium and ϵ_0 is the dielectric permittivity of free space.

In the situation of a conducting dielectric $\sigma \neq 0$, the field attenuates as it propagates. It is convenient to define a complex relative permittivity (or dielectric constant). This can be done by substituting $c^2 = \frac{1}{\epsilon_0\mu_0}$ into equation B.5:

$$\frac{c^2}{v^2} = \eta - j\frac{\sigma}{\epsilon_0\omega} \tag{B.8}$$

Subsequently, because $\frac{c^2}{v^2} = \eta$, this can be regarded as a complex dielectric constant given by:

$$\eta = \eta' - j\frac{\sigma}{\epsilon_0\omega} \tag{B.9}$$

Relative permittivity can be written in the form:

$$\eta = \eta' - j\eta'' \tag{B.10}$$

Where η' and η'' are the real and imaginary parts respectively. From equation B.8 the imaginary part is extracted:

$$\eta'' = \frac{\sigma}{\epsilon_0\omega} \tag{B.11}$$

The plane wave is incident on a halfspace with angle θ_1, which is defined as the angle between the wave vector k and the vector that is orthogonal to the dielectric boundary. The TE case, where the E-field component is parallel to the boundary between the two dielectrics, and the TM case, where H-field component is parallel to the boundary between the two dielectrics, have different characteristics. The polarisations and angles are shown in Figure 3.3. The reflection and transmission coefficients can now be determined using the relative permittivities (η_1 and η_2) of the two mediums. Values for the η can be calculated from the real part of the permittivity (η') and conductivity (σ) using the equations B.10 and B.11. For the geometrical aspect of the reflection and transmission the following theorems apply:

- The angle of incidence equals the angle of reflection
- Snell's law relates the angle of incidence to the angle of refraction as in equation B.12.

$$\sqrt{\eta_1} \sin \theta_1 = \sqrt{\eta_2} \sin \theta_2 \tag{B.12}$$

Where θ_1 is the angle of incidence, and θ_2 is the refraction angle.

Using these properties yields into equations 3.8, 3.9, 3.10 and 3.11.