ETSI TR 102 655 V1.1.1 (2008-11)

Technical Report

**Electromagnetic compatibility
and Radio spectrum Matters (ERM);
System reference document;
Short Range Devices (SRD);
Low Power Active Medical Implants (LP-AMI) operating
in a 20 MHz band within 2 360 MHz to 3 400 MHz**

ETSI

Reference
DTR/ERM-RM-252

Keywords
health, SRD

ETSI

650 Route des Lucioles
F-06921 Sophia Antipolis Cedex - FRANCE

Tel.: +33 4 92 94 42 00   Fax: +33 4 93 65 47 16

Siret N° 348 623 562 00017 - NAF 742 C
Association à but non lucratif enregistrée à la
Sous-Préfecture de Grasse (06) N° 7803/88

Important notice

Individual copies of the present document can be downloaded from:
http://www.etsi.org

The present document may be made available in more than one electronic version or in print. In any case of existing or
perceived difference in contents between such versions, the reference version is the Portable Document Format (PDF).
In case of dispute, the reference shall be the printing on ETSI printers of the PDF version kept on a specific network drive
within ETSI Secretariat.

Users of the present document should be aware that the document may be subject to revision or change of status.
Information on the current status of this and other ETSI documents is available at
http://portal.etsi.org/tb/status/status.asp

If you find errors in the present document, please send your comment to one of the following services:
http://portal.etsi.org/chaircor/ETSI_support.asp

Copyright Notification

Contents

Intellectual Property Rights

IPRs essential or potentially essential to the present document may have been declared to ETSI. The information pertaining to these essential IPRs, if any, is publicly available for **ETSI members and non-members**, and can be found in ETSI SR 000 314: *"Intellectual Property Rights (IPRs); Essential, or potentially Essential, IPRs notified to ETSI in respect of ETSI standards"*, which is available from the ETSI Secretariat. Latest updates are available on the ETSI Web server (http://webapp.etsi.org/IPR/home.asp).

Pursuant to the ETSI IPR Policy, no investigation, including IPR searches, has been carried out by ETSI. No guarantee can be given as to the existence of other IPRs not referenced in ETSI SR 000 314 (or the updates on the ETSI Web server) which are, or may be, or may become, essential to the present document.

Foreword

This Technical Report (TR) has been produced by ETSI Technical Committee Electromagnetic compatibility and Radio spectrum Matters (ERM).

Introduction

CEPT/ERC Recommendation 70-03 [i.1], annex 12 and EC Decision "2006/771/EC [i.44] on harmonization of the radiospectrum for use by short range devices" define frequencies for wireless applications in healthcare, in parallel. ETSI has published several Harmonized European product Standards for wireless applications in healthcare.

Rapid developments within the active medical implant area are expected, requiring new applications and additional spectrum. To control and monitor these devices in hot-spot areas with many patients such as hospitals, clinics and assisted living facilities, require increased system capacity.Future medical applications may require significant higher data rates. The present document covers the spectrum request for these applications that may be possible due to the development of the semiconductor technology.

The purpose of producing the present document is to lay a foundation for industry to quickly bring innovative and useful products to the market while avoiding any harmful interference with other services and equipment. A license exempt regulation for this type of application is required.

The present document proposes to operate these devices in an approximately 20 MHz wide sub-band inside the 2 360 MHz to 3 400 MHz frequency range. It is realized that it may be difficult to obtain this goal below 2 GHz. It is mandatory to designate a world-wide frequency band due to travelling of patients with implants.

In 2005, 17 000 people worldwide had cochlear devices implanted. In the U.S. alone some 900 000 people are believed to be deaf or near deaf [i.30]. As cochlear implants need high duty cycle transmissions this application is not considered to be suitable for the frequency range 2 483,5 GHz to 2 500,0 GHz. Therefore, this need will addressed in a separate document at a later stage.

It is envisioned that the proposed radio systems may require a change of utilization of the present regulatory framework for the proposed band(s).

Status of pre-approval draft

The present document was developed by ERM/TG30 and approved for publication by ERM at its 36th meeting, November 2008. The information in the present document has undergone coordination by ERM. It contains final information.

Table 1: Current status of the present document

Target version	Pre-approval date version (see note)				
V1.1.1	**a**	**s**	**m**	**Date**	**Description**
0.0.1	0.0.3			22 January 2008	Draft for TG 30 review
0.0.1	0.0.4			30 May 2008	Draft for ERM-TG30 review
0.01	0.0.5			3 June 2008	ERM-TG30 approved subject to editorial
0.01	0.0.6			10 June	ERM-TG30 editorial comments
0.0.1	0.0.7			11 June	Version with BNetzA comments
1.1.1	0.0.9			27 June	ETSI mini enquiry Version
1.1.1	0.0.10			21 August	Final document including mini consultation comments
1.1.1	0.0.11			26 August	Minor editorials done
NOTE: See clause A.2 of EG 201 788 [i.45] (V1.2.1).					

1   Scope

The present document defines new requirements for radio frequency spectrum usage for low power, active medical implants and their peripheral radio control systems.

It is noted that the present document proposes a concept that should permit a harmonized regulatory framework for these systems and provides a basis for a licence exempt arrangement preferably on a secondary allocation.

The present document includes necessary information to support the co-operation between ETSI and the Electronic Communications Committee (ECC) of the European Conference of Post and Telecommunications Administrations (CEPT).

It includes:

- Detailed market information.

- Detailed technical information.

- Expected sharing and compatibility issues.

2   References

References are either specific (identified by date of publication and/or edition number or version number) or non-specific.

- For a specific reference, subsequent revisions do not apply.

- Non-specific reference may be made only to a complete document or a part thereof and only in the following cases:

  - if it is accepted that it will be possible to use all future changes of the referenced document for the purposes of the referring document;

  - for informative references.

Referenced documents which are not found to be publicly available in the expected location might be found at http://docbox.etsi.org/Reference.

For online referenced documents, information sufficient to identify and locate the source shall be provided. Preferably, the primary source of the referenced document should be cited, in order to ensure traceability. Furthermore, the reference should, as far as possible, remain valid for the expected life of the document. The reference shall include the method of access to the referenced document and the full network address, with the same punctuation and use of upper case and lower case letters.

NOTE: While any hyperlinks included in this clause were valid at the time of publication ETSI cannot guarantee their long term validity.

2.1   Normative references

The following referenced documents are indispensable for the application of the present document. For dated references, only the edition cited applies. For non-specific references, the latest edition of the referenced document (including any amendments) applies.

Not applicable.

2.2 Informative references

The following referenced documents are not essential to the use of the present document but they assist the user with regard to a particular subject area. For non-specific references, the latest version of the referenced document (including any amendments) applies.

[i.1] CEPT/ERC Recommendation 70-03: "Relating to the use of Short Range Devices (SRD)".

[i.2] Void.

[i.3] ITU-R Recommendation SA 1346: "Sharing between the Meteorological Aids Service and the Medical Implant Communications Systems (MICS) operating in the Mobile Service in the Frequency Band 401-406 MHz".

[i.4] CEPT/ERC Report 25: "The European Table of Frequency Allocations and Utilisations in the Frequency Range 9 kHz to 1000 GHz: Lisboa 02 - Dublin 03 - Kusadasi 04 - Copenhagen 04 - Nice 07".

[i.5] International Diabetes Federation.

NOTE: Available at http://www.idf.org/e-atlas/home/index.cfm?node=84.

[i.6] "Implanted Antennas inside a human body: simulations, designs and characterizations: J. Kim, Y. Rahmat-Samii.

NOTE: IEEE Transactions on Microwave Theory and Techniques, vol. 52, n 8, August 2004, pp. 1934-1943.

[i.7] "Design of implantable Microstrip Antenna for communication with medical implants": P. Soontornpipit, C.M. Furse Y.C. Chung.

NOTE: IEEE Transactions on Microwave Theory and Techniques, vol. 52, n°8, August 2004, pp. 1944-1951.

[i.8] "FDTD analysis of a coupled close-coupled 418 MHz radiating devices for human biotelemetry": Phys. Med. Biol., vol. 44, n 2, pp. 335-345, Feb. 1999. W.G. Scanlon, N.E. Evans, J.B. Burns.

[i.9] M.W.S., Computer System Technology (C.S.T.), GmbH, Darmstadt, Germany.

[i.10] "Antennas and propagation for body-centric wireless communications": Artech House Inc., 2006. P. S. Hall, Yang Hao.

[i.11] "Compilation of the dielectric properties of body tissues at RF and microwave frequencies": Armstrong Lab., CITY, STATE. C. Gabriel, S. Gabriel.

NOTE: Available at http://www.brooks.af.mil/AFRL/HED/hedr/reports/dielectric/home.html.

[i.12] ETSI EN 301 839-1 (V1.1.1): "Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Ultra Low Power Active Medical Implants (ULP-AMI) and Peripherals (ULP-AMI-P) operating in the frequency range 402 MHz to 405 MHz; Part 1: Technical characteristics and test methods".

[i.13] "Composition And Electrical Properties Of A Liquid That Has The Electrical Properties Of Tissue": Hartsgrove and Kraszewski 1984.

[i.14] USAFSAM-TR-85-73: RADIOFREQUENCY RADIATION DOSIMETRY HANDBOOK (Fourth Edition), in line document. Carl H. Durney, Ph.D., Habib Massoudi, Ph.D., Magdy F. lskander.

[i.15] Agilent: "85070E Dielectric Probe Kit, 200 Mhz to 50 Ghz.

[i.16] Void.

[i.17] "An internet resource for the calculation of the dielectric properties of body tissues", Institute for Applied Physics, Italian National Research Council.

NOTE: Available at http://niremf.ifac.cnr.it/tissprop/.

[i.18]   ETSI EN 301 839-2: "Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Ultra Low Power Active Medical Implants (ULP-AMI) and Peripherals (ULP-AMI-P) operating in the frequency range 402 MHz to 405 MHz; Part 2: Harmonized EN covering essential requirements of article 3.2 of the R&TTE Directive".

[i.19]   ETSI EN 301 489-27: "Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 27: Specific conditions for Ultra Low Power Active Medical Implants (ULP-AMI) and related peripheral devices (ULP-AMI-P)".

[i.20]   ETSI EN 301 489-29: "Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment operating in the 401 MHz to 402 MHz and 405 MHz to 406 MHz bands; Part 29: Requirements for Medical Data Service Devices (MEDS)".

[i.21]   ETSI EN 302 537-1: "Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Ultra Low Power Medical Data Service Systems operating in the frequency range 401 MHz to 402 MHz and 405 MHz to 406 MHz; Part 1: Technical characteristics and test methods".

[i.22]   ETSI EN 302 537-2: "Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Ultra Low Power Medical Data Service Systems operating in the frequency range 401 MHz to 402 MHz and 405 MHz to 406 MHz; Part 2: Harmonized EN covering essential requirements of article 3.2 of the R&TTE Directive".

[i.23]   Council recommendation 1995/519/EC of 12 July 1999 on the limitation of exposure of the general public to electromagnetic fields (0 Hz to 300 GHz).

[i.24]   CEPT/ERC Recommendation 74-01:" Unwanted emissions in the spurious domain".

[i.25]   Eurostat (year): The source of harmonized and comparable statistical information of the European Union.

NOTE: Available at http://ec.europa.eu/eurostat/.

[i.26]   "Heart Disease and Stroke Statistics, 2008 Update, Circulation 2008".

[i.27]   The Euro Heart Failure Survey Programme: "A Survey of the Quality of Care Among Patients with Heart Failure in Europe. Part 1: Patient Characteristics and Diagnosis". Eur Heart J 2003;24: 442-463 Cleland JG, Swedberg K, Follath F et al.

[i.28]   International Diabetes Federation, 2007: Diabetes Atlas, third edition.

[i.29]   The Neurotechnology Industry 2005: "Strategic Investment and Market Analysis Report of the Global Neurological Disease and Psychiatric Illness Market. San Francisco: NeuroInsights; 2006: Introduction".

[i.30]   http://www:businessweek.com/magazine/content/05-46/b3959101.htm.

[i.31]   The heart, arteries and veins: New York: McGraw-Hill, 1998:1081-1112. RC, Fuster V, eds.

[i.32]   Cardiac arrest and sudden cardiac death: In: Braunwald E, ed. Heart disease: a textbook of cardiovascular medicine. Philadelphia: WB Saunders, 1997:742-779. Myerburg RJ, Castellanos A.

[i.33]   Out-of-hospital cardiac arrest in the 1990s: a population-based study in the Maastricht area on incidence, characteristics and survival. J Am Coll Cardiol 1997;30:1500-1505. [PubMed] de Vreede-Swagemakers JJ, Gorgels AP, Dubois-Arbouw WI, et al.

[i.34]   Heart Failure Facts and Figures: OU Medical Centre.

NOTE: Available at www.oumedcenter.com [last accessed 26-09-05].

[i.35]   The Task Force for the diagnosis and treatment of CHF of the European Society of Cardiology. Eur Heart J 2005;26:1115-40; Swedberg k., Cleland J., Dargie H., et al.

NOTE: Full guidelines online at www.escardio.org/knowledge/guidelines/Chronic_heart_failure.htm.

[i.36]   Heart Disease and Stroke Statistics - 2005 Update, American Heart Association.

NOTE: Available at www.americanheart.org/downloadable/heart/1105390918119HDSStats2005Update.pdf [last accessed 22-09-05].

[i.37]   EUCOMED data: Pacemaker implant rates, 2007.

NOTE: Available at http://www.eucomed.org/press/~/media/5D7FDD75E5A84547945D1C83E8C8CDE3.ashx.

[i.38]   EUCOMED data: CRT-Defibrilator implant rates, 2007.

NOTE: Available at http://www.eucomed.org/press/~/media/F6FA04CF29564206B742ED19B87E0395.ashx.

[i.39]   EUCOMED data: CRT-Pacemaker implant rates, 2007.

NOTE: Available at http://www.eucomed.org/press/~/media/2CD88BC32C0E401AA874C0FF4AFE525F.ashx.

[i.40]   EUCOMED data: ICD implant rates, 2007.

NOTE: Available at http://www.eucomed.org/press/~/media/E60CE28CFAFE4E30AE3575BDE9AAFEB2.ashx.

[i.41]   EUCOMED data: Reference regarding the number of employee and turnover for medical devices in Europe.

NOTE: Available at http://www.eucomed.org/press/~/media/pdf/tl/2008/portal/aboutindustry/medtechbrief2007.ashx.

[i.42]   US FCC (United States Federal Communications Commission), DA 08-953: "Office of Engineering and Technology to treat ex parte comments of GE Healthcare as Petition for Rule Making and seeks comment".

[i.43]   ERC Decision ERC/DEC(97)03 of 30 June 1997 on the Harmonised Use of Spectrum for Satellite Personal Communication Services (S-PCS) operating within the bands 1 610 to 1 626,5 MHz, 2 483,5 to 2 500 MHz, 1 980 to 2 010 MHz and 2 170 to 2 200 MHz.

[i.44]   EC Decision 2006/771/EC on harmonization of the radiospectrum for use by short range devices.

[i.45]   ETSI EG 201 788: "Electromagnetic compatibility and Radio spectrum Matters (ERM); Guidance for drafting an ETSI System Reference Document".

[i.46]   ITU Radio Regulations.

[i.47]   Decision 2008/477/EC; Commission Decision of 13th June 2008 on the harmonisation of the 2500-2690MHz frequency band for terrestrial systems capable of providing electronic communications services in the Community.

[i.48]   ECC Decision ECC/DEC/(05)05 of 18 March 2005 on harmonised utilisation of spectrum for IMT-2000/UMTS systems operating within the band 2500 - 2690 MHz.

[i.49]   ETSI TS 125 104: "Universal Mobile Telecommunications System (UMTS); Base Station (BS) radio transmission and reception (FDD) (3GPP TS 25.104 version 8.1.0 Release 8)".

3 Definitions, symbols and abbreviations

3.1 Definitions

For the purposes of the present document, the following definitions apply:

Active Implantable Medical Device (AIMD): any active medical device (AMD) which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure

Active Medical Device (AMD): any medical device relying for its functioning on a source of electrical energy or any source of power

Medical Device (MD): any instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with any accessories or software for its proper functioning, intended by the manufacturer to be used for human beings in the:

- diagnosis, prevention, monitoring, treatment or alleviation of disease or injury and for prolongation of life;

- investigation, replacement or modification of the anatomy or of a physiological process;

- control of conception,

and which does not achieve its principal intended action by pharmacological, chemical, immunological or metabolic means, but which may be assisted in its function by such means

Ultra Low Power Active Medical Implant (ULP-AMI): ultra low power radio part of any active medical device (AMD), which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure

Low Power Active Medical Implant (LP-AMI): low power radio part of any active medical device (AMD), which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure

> NOTE: LP-AMI may communicate with another LP-AMI or with a LP-AMI-P, LP-BWD, LP-AMD and LP-AMD-P.

Low Power Active Medical Implant Peripheral (ULP-AMI-P) device: low power radio part of medical equipment outside the human body that communicates with another LP-AMI-P or with a LP-AMI, LP-AMD, LP-BWD

Low Power Active Medical Device (LP-AMD): low power radio part of any active medical device (AMD) outside the human body which has its radio antenna external to the body and is used to communicate with another LP-AMD or with a LP-AMD-P, LP-AMI, LP-BWD LP-AMI-P

Low Power Active Medical Device Peripheral (LP-AMD-P): low power radio part of medical equipment outside the human body that communicates with a LP-AMD, LP-BWD, LP-AMI or other LP-AMD-P

Low Power Body Worn Device (LP-BWD): low power radio part of a medical device, such as a physiological parameter sensor or handheld device, that is intended to operate in proximity to the human body (6 cm or less from the skin surface) which has its radio antenna external to the body and is used to communicate with another LP-BWD or LP-AMI, LP-AMD, LP-AMI-P, LP-AMD-P

3.2   Symbols

For the purposes of the present document, the following symbols apply:

dB	deciBel
dBi	deciBel relative to an isotropic radiator
f	Frequency
P	Power
R	Distance
t	Time

3.3   Abbreviations

For the purposes of the present document, the following abbreviations apply:

AFA   Adaptive Frequency Agility
AIMD   Active Implantable Medical Device
AMD   Active Medical Device
ARQ   Automatic Repeat reQuest
AV   Atrio-Ventricular
CEPT   Conference of European Postal and Telecommunications Administration
CHF   Congestive Heart Failure
CNS   Central Nervous System
CRC   Cyclic Redundancy Check
CRT   Cardiac Resynchronization Therapy
CST   Computer System Technology (GmbH) (DE)
ECA   European Common Allocation
ECC   Electronics Communications Committee
e.i.r.p.   effective isotropically radiated power
EMC   Electro Magnetic Compatibility
ESC   European Society of Cardiology
EUCOMED   EUropean Confederation Of MEDical suppliers association
FEC   Forward Error Correction
ICD   Implantable Cardioverter Defibrillators
LAN   Local area Network
LP - AMD - P   Low Power Active Medical Device Peripheral
LP - AMD   Low Power Active Medical Device
LP - AMI - P   Low Power Active Medical Implant Peripheral
LP - AMI   Low Power Active Medical Implant
LP-AMD   Low Power Active Medical Device
LP-AMD-P   Low Power Active Medical Device Peripheral
LP-AMI   Low Power Active Medical Implant
LP-AMI-P   Low Power Active Medical Implant Peripheral
LP-BWD   Low Power Body Worn device
MD   Medical Device
MICS   Medical Implant Communications Systems
MWS   Micro Wave Studio
NCHS   National Center for Health Statistics (USA)
NHANES   National Health And Nutrition Examination Survey (USA)
NHLBI   National Heart, Lung, and Blood Institute (USA)
R&TTE   Radio and Telecommunications Terminal Equipment
RF   Radio Frequency
SAR   Specific Absorption Rate
SCD   Sudden Cardiac Death
SRD   Short Range Device
ULP-AMI   Ultra Low Power Active Medical Implant

4   Comments on the System Reference Document

Comments from Vodafone, Deutsche Flugsicherung GmbH (DFS) and Ministry of Economic Affairs NL were received on during the ETSI ERM correspondence approval procedure. All comments have been accepted and included in the present document.

5   Executive summary

5.1   Background information

Europe is facing the challenge of delivering quality healthcare to all its citizens, at affordable cost. Prolonged medical care for the ageing society, the costs of managing chronic diseases, and the increasing demand by citizens for best quality healthcare are major factors. Healthcare expenditure in Europe is already significant (8,5 % of the GDP on average) and rising faster than overall economic growth itself. Personalized Monitoring is a way to address this issue.

Active Implantable Medical Devices (AIMD) are currently instrumental in saving or enhancing a significant number of the lives of patient inflicted with various kinds of heart conditions, nervous disorders and diseases, which otherwise would have resulted in death or disability and which devices can also significantly improve the quality of life.

The active medical implant system consists of devices that are implanted in the body. These devices can currently only communicate with an external peripheral radio device. Examples of these implanted devices are defibrillators, pacemakers, various types of nerve stimulators, sensors, implantable infusion pumps and cardiac resynchronization devices. Current systems are typically used in hospitals and/or doctor's office environments with increasing ambulatory remote monitoring in the patient's normal environment. Additionally, this development will include body-worn devices, patient peripherals for use both in- and outside hospitals and clinics.

Due to the rapid development and increased use of Active Implantable Medical Devices it is desirable to increase the range and system capacity significantly. Both higher data rates and sufficient memory are available technologically and are already provided by other non-medical systems, for example Bluetooth, Radio LAN. However, such systems use spectrum with high user density and, because of the protocols used, require several orders of magnitude higher current consumption than is practical for medical implant systems. Therefore, a new spectrum able to handle the increased demand is required. It is important to note that the spectrum should be worldwide to the maximum extent possible.

5.2   Market information

5.2.1   Cardiac market.

For further details on market information, see annex A.

In 2006, according to EUCOMED data, more than 400 000 implants were implanted within the European Community. This number will increase due to aging population. Within 10 years it expected to have more than 3 million European patients with implanted devices.

Heart failure incidence approaches a large population as expressed in figure 1. Source: "Heart Disease and Stroke Statistics_2008 Update, Circulation 2008", Chart 7-1 [i.26].
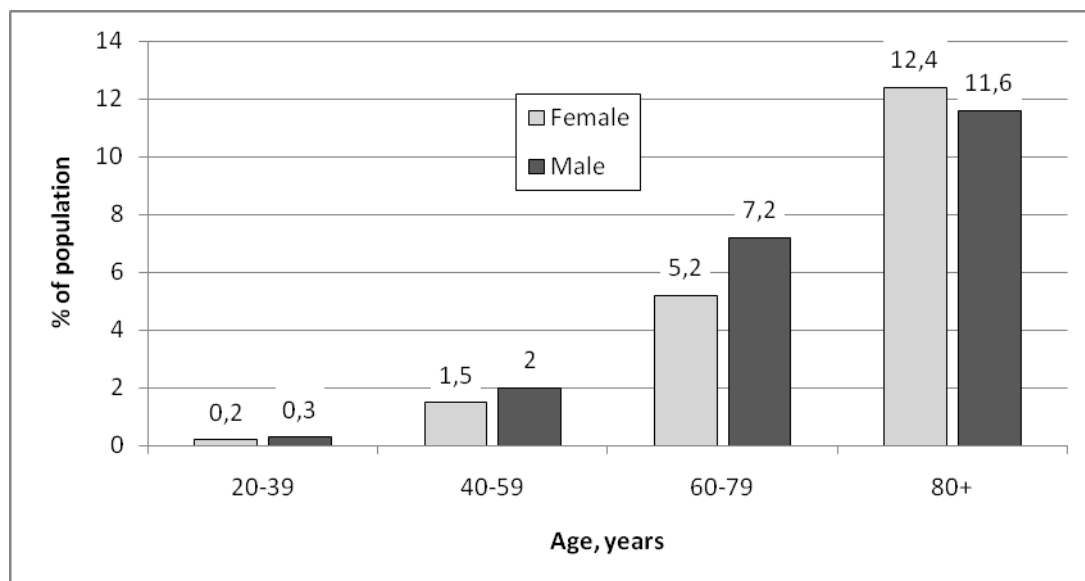
Sources: NCHS and NHLBI

Figure 1: Prevalence of heart failures by sex and age (NHANES: 1999 to 2004)

In 2015, the population of heart failure patients will be spread to 12 million people, according to table 2.

Table 2: European population of heart failures

Age	European Male population in 2015 (see note 1)	Male Heart Failures in 2015 (see note 2)	European Female population in 2015 (see note 1)	Female Heart Failures in 2015 (see note 2)
20 to 39	67 858 986	203 577	65 684 972	131 370
40 to 59	71 617 141	1 432 343	72 252 697	1 083 790
60 to 79	45 763 736	3 294 989	53 267 523	2 769 911
80+	9 333 440	1 082 679	16 979 589	2 105 469
Total	194 573 303	6 013 588	208 184 781	6 090 541

Sources:
NOTE 1: Eurostat (year):(http://ec.europa.eu/eurostat/ The source of harmonised and comparable statistical information of the European Union) [i.25].
NOTE 2: Heart Disease and Stroke Statistics, 2008 Update, Circulation 2008 [i.26].
Cleland JG, Swedberg K, Follath F et al.The EuroHeart Failure Survey Programme-
A Survey of the Quality of Care Among Patients with Heart Failure in Europe.
Part 1: Patient Characteristics and Diagnosis. Eur Heart J 2003;24:442-463 [i.27].

Of these 12 million, according to the European Society of Cardiology (ESC) approximately 40 %, 4,8 million patients are candidates for active implantable medical device implants, CRT.

5.2.2 Other implanted devices

There are several emerging therapies that will benefit from implanted devices. For example, nerve stimulation implants and drug delivery infusion pumps are finding success in controlling and/or treating various bodily functions and diseases such as urinary incontinence, uncontrollable muscular spasms, insulin injection, and delivery of pain medication to mention a few. Active implantable medical devices are the only technology capable of full time non-stop delivery of these types of necessary medical therapies that are required to preserve and enhance the quality of life for many in this group of patients. Further details on other implanted devices are given in clause A.1.

5.3   Radio spectrum requirement and justification

The advent of technology permitting implanted devices to communicate with external devices at distances of a few meters over extended periods of time has opened up a new era in medical treatment. Considerations of tissue loss, battery life, existing users, and ambient signal levels in the selected spectrum result in the selection of bands below 3 GHz as the most suitable for implant technology. Today, medical device manufacturers have developed applications for implant technology that will place much greater demands on the available spectrum due to increased proliferation of implanted devices and a need for much greater transmission speed. Additional frequency spectrum is required to handle the increased demand for transmission bandwidth.

There is not sufficient capacity in the existing band; a significantly increased bandwidth is required.

The use of wireless communications to implanted devices will increase dramatically over the next 10 years. Further details are given in clause 5.3.1.

5.3.1   Technical developments

The following important technical developments is to be noted:

- It is now feasible to support RF telemetry in most active implanted medical devices. Additionally, many traditionally non-active medical implants may become active like artificial hips, knees, grafts, stents and many others.

- There are on-going efforts to enable remote monitoring and programming by incorporating RF telemetry into applications such as implantable drug pumps, orthopaedics, artificial limbs, neurostimulators, functional electrical stimulations, implantable diagnostics, bladder stimulators, cochlear implants.

- Wireless remote monitoring of patients with active implanted medical devices will become the standard of care in hospitals, clinics, assisted living facilities (homes for the elderly), and their daily living environment.

Growth in telemetry range is driven by:

- The need for greater patient mobility. Physicians and patients will require Active Implantable Medical Devices to have increased ranges to allow patients greater mobility and patient convenience and compliance will continue to drive this.

Ranges in an order of magnitude larger than currently achieved will be needed to reliably monitor patients throughout their daily living environment.

Remote monitoring demand will continue to grow:

- As remote monitoring / programming becomes increasingly more adopted, physicians and patients will require more access points.

- Limits on allowable data latency will increase demands on the link availability.

Long-term wireless implantable medical application needs to include the following:

- World-wide available spectrum (sharing within already harmonized frequency band).

- Licence exempt.

  - LP-AMI has interference mitigation techniques to protect primary and secondary users.

  - LP-AMI has robust interference mitigation techniques to protect itself against interference from primary and secondary devices.

- LP-AMI (future) designated spectrum should have low density occupation by other users.

- Support for relatively high data rate at short range and decreased data rate at long range.

- Bidirectional communication modes:

  - Implant to external communication.

  - External to external communication in which an implant is present in the system.

  - Implant to implant communication.

Additional spectrum for medical systems with higher user density and data rate will permit the expansion of different types of communication links. This will permit downloading large amount of patient data from implant to mass storage facilities and from a peripheral device to a central communication system for further review and analysis. In addition, it is possible to extend these communications from programmer to central communication system using the same band if and or when the capacity allows.

An accumulation of a large database of retrieved data over time can be analysed by physicians to diagnose a patient's condition. This will improve the therapy delivered by the implant.

5.4 Regulations

5.4.1 Current regulations

Ultra Low Power Active Medical Implants (ULP-AMI) and peripherals are currently permitted to operate in the MICS band 402 MHz to 405 MHz as class 1 devices. These operate in compliance with spectrum regulatory requirements described in ITU-R Recommendation SA 1346 [i.3] and EC Decision [i.23]. Harmonized emissions and EMC standards have been adopted for these applications, EN 301 839-1 [i.12], EN 301 839-2 [i.18], and EN 301 489-27 [i.19].

In the bands 401 MHz to 402 MHz and 405 MHz to 406 MHz all in compliance with spectrum regulatory requirements as provided for in ERC/REC 70-03 [i.1], annex 12 bands (a), (a1) and (a2) [i.1]. Harmonized emissions and EMC standards have been adopted for these applications, EN 302 537-1 [i.21] and EN 302 537-2 [i.22] and EN 301 489-29 [i.20].

Some medical equipment are using 868 MHz to 869 MHz band, although this band is designated to Short Range Devices (SRDs). This usage of this band is high and therefore medical applications are limited.

There is currently no regulation for an additional spectrum for medical communication implant link allowing transmission at longer ranges and higher data rates.

5.4.2 Proposed regulation and justification

ECC is requested to adopt a 20 MHz wide band for active implantable medical device communications as a world wide designation:

- as a first choice the band: 2 483,5 MHz to 2 500 MHz;

- as a second choice, a 20 MHz segment inside the band: 2 700 MHz to 3 400 MHz. It is noted according to Deutsche Flugsicherung GmbH that sharing between LP-AMI and radars, particularly in the subband 2,7 GHz to 2,9 GHz may not be possible;

- as a third choice a 20 MHz segment inside the band 2 360 MHz to 2 400 MHz.

It is to be noted that the band under a) is already designated on the worldwide basis to "Global Star" mobile radio and it is expected that medical devices will be able to share the spectrum with this service by using LBT/APC/AFA or optional LDC. The band is only 16,5 MHz wide. This band is also under ERC/DEC(97)03 [i.43] for MS downlink.

Another condition for this band is ITU Radio Regulations [i.46] footnote 5.150 for ISM for the whole range 2 400 MHz to 2 500 MHz.

Additionally, there is an agenda item 1.18 of WRC-11 for extension of Radio Navigation Satellite Service (RNSS), which is supported by several European countries.

For the second choice band under b), especially in the sub-band 2 700 MHz to 2 900 MHz is to be considered. This band is allocated to flight navigation service, which is safety relevant. It is doubtful if this sub-band can be used as medical implants can be on-board aircraft. It is noted that sharing between LP-AMI and radars, particularly in the subband 2,7 GHz to 2,9 GHz may not be possible.

Both the 2 483,50 MHz to 2 500 MHz and 2 700 MHz to 2 900 MHz bands are adjacent to the 2,6 GHz mobile band. In accordance with Commission Decision 2008/477/EC [i.47], licences for mobile services will be awarded in the 2 500 MHz to 2 690 MHz band in all EU Member States within a few years. Any implantable medical devices for use in either band will need to have sufficient immunity to the transmissions expected in the 2,6 GHz band to ensure that their use does not compromise the clinical conditio n or the safety of patients (see clause C.2).

It is to be noted that for the band under c) there is a Petition for Rulemaking submitted by GE healthcare and under consideration by the US FCC (United States Federal Communications Commission, DA 08-953) [i.42] which currently does not include provisions for Active Implantable Medical Devices. Therefore, this band is useful for transfer of medical data in general. However, the band is already used in the US by wireless video links including other applications used by public safety organizations as it is already realized the existing capacity for the medical applications is insufficient for the future.

Additionally, WRC-07 identified the 2 300 MHz to 2 400 MHz band for IMT, and there are firm plans in several important countries in Asia to make this spectrum available, as well as discussions in some countries in Africa. It is expected that this band will be used for TDD, so terminals could transmit in any part. I noted the discussion in the SRDoc about the possibility of patients travelling. This seems especially relevant where the potential source of interference could be so close to the patient.

It is proposed for active implantable medical device communications to operate with the following specifications under a license-exempt regulation, see table 3.

Table 3: Proposed regulatory parameters

Candidate frequency bands GHz	Band edge mask width	Maximum radiated power e.i.r.p.	Listen Before Talk LBT)	Adaptive Power Control (APC)	Adaptive frequency selection (AFS)	Minimum number of channels
2,360 to 2,400	20 MHz	+10 dBm	Yes	Yes	Yes	20
2,4835 to 2,500	16,5 MHz	+10 dBm	Yes	Yes	Yes	16
2,700 to 3,400 (see note)	20 MHz	+10 dBm	Yes	Yes	Yes	20
NOTE: According to Deutsche Flugsichering GmbH the sharing between LP-AMI and radars, particularly in the subband 2,7 GHz to 2,9 GHz may not be possible.						

The occupied bandwidth of the equipment is determined by the lowest and highest frequencies occupied by the power envelope where the output power falls to -20 dB below the maximum power. For emissions in the spurious domain see clause B.2.1.2.

Measurements of RF attenuation in a body phantom containing 2,45 GHz equivalent body liquid based on scientific data given in the literature for further details see clause B.3.2.

The measurements are compared to simulations made with commercially available simulation software. All the simulations were performed using Microwave Studio (MWS) software made by Computer System Technology (CST), [i.9] for further details see clause B.3.5.

The proposed radiated power is based on link budget calculations which includes attenuation of the human body at an operation frequency of 2,45 GHz, for further details see clause B.3.4.

Additionally, an estimation of SAR exposure levels caused by a +10 dBm implanted loop transmitter has been carried out using the CST MWS human model Hugo, for further details see clause B.3.6.

6   Expected ETSI actions

The overall system specifics (power, bandwidth, etc.) related to a two-tier approach including:

   a)   High data rate with a range up to 10 m; and

   b)   Low data rate with a range up to 30 m.

will be further addressed during the ETSI standard development process.

It is expected that the relevant Harmonized ETSI standard will be available approximately one year after the completion of the required ECC studies.

7   Requested ECC actions

It is proposed that ECC considers the present document, which includes necessary information to support the co-operation under the MoU between ETSI and the Electronic Communications Committee (ECC) of the European Conference of Post and Telecommunications Administrations (CEPT) for amending the ERC Recommendation70-03 [i.1], annex 12.

ETSI believes that procedures for administrating and ensuring adherence to regulations should be kept minimal both for the regulator as well as for the users of Active Implantable Medical Device radio systems.

A regulation for license free operation for Active Implantable Medical Device radio systems in for example ERC Recommendation 70-03 [i.1], annex 12 is requested by late 2009.

It is requested that harmonised European conditions for the availability for use of the radio spectrum be developed.

Additionally, an inclusion in the technical annex of EC Decision 2006/771/EC [i.44] is requested for 2010 revision of the technical annex.

ECC is requested to promote the selected band on a world-wide basis considering the fact that the first choice band is already used on a world-wide basis by Globalstar application.

Once the specific band has been allocated products could be on market in less than 5 years and will be in use for at least 10 years.

Annex A:
Detailed market information

A.1   Range of applications

a) Cardiac devices
According to EUCOMED data, more than 400 000 active medical devices were implanted in European Union during 2006. The majority of these were cardiac devices. The number implanted devices will increase due to aging population. Within 10 years it expected to have more than 3 million European patients with implanted devices. In 2015, according to the European Society of Cardiology (ESC), is it expected 12 million Europeans will have a heart failure of which approximately 40 %, 4,8 million patients are candidates for active implantable medical device implants [i.27].

b) Insulin pumps
Diabetes currently affects 246 million people worldwide and is expected to affect 380 million by 2025. There are currently 32 million Europeans with diabetes [i.5] and [i.28].

c) Neurodevices
The market for neurodevices is relatively new and is growing rapidly currently 2,6 billion dollars per year. It is used for pain management, epilepsy, Parkinson and many other [i.29].

d) Cochlear implants
In 2005, 17 000 people worldwide had cochlear devices implanted. In the U.S alone some 900 000 people are believed to be deaf or near deaf [i.30].
(ERM/TG30 to investigate if cochlear implants need separate frequency spectrum. The proposed spectrum 2 483,5 MHz to 2 500,0 MHz is designated for "Global Star" a worldwide satellite based mobile radio system used for voice.)

A.2   Expected market size and value

The European medical technology industry invests some 3,8 billion euro in R&D and employs near to 435 000 highly skilled workers.

A.2.1   Cardiac rhythm management

The Cardiac Rhythm management market (8 billion euro) concerns implantable devices that control the heartbeat; cardiac pacing for Bradycardia, bi-ventricular pacing or cardiac resynchronization therapy (CRT) for heart failure, intracardiac defibrillation (ICD) for treatment of ventricular arrhythmias.

A.2.1.1   Bradycardia

The main causes for bradycardia are sinus node disease or sick sinus syndrome and AV-conduction disorders. These conditions are generally treated with a bradycardia pacemaker. Sick sinus syndrome is characterized by sinus node dysfunction with an atrial rate inappropriate for physiologic requirements. Although the condition is most common in the elderly, it can occur in persons of all ages, including neonates [i.33]. The mean age of patients with this condition is 68 years, and both sexes are affected approximately equally [i.34]. The syndrome occurs in one of every 600 cardiac patients older than 65 years and may account for 50 percent or more of permanent pacemaker placements in the United States [i.36].

Most of the other 50 percent of permanent pacemakers are placed for high-degree AV-nodal conduction disorders (AV-Block).

The pacemaker implant rates per million inhabitants for individual European countries are shown in figure A.1.

Pacemaker Implant Rates per Million Inhabitants
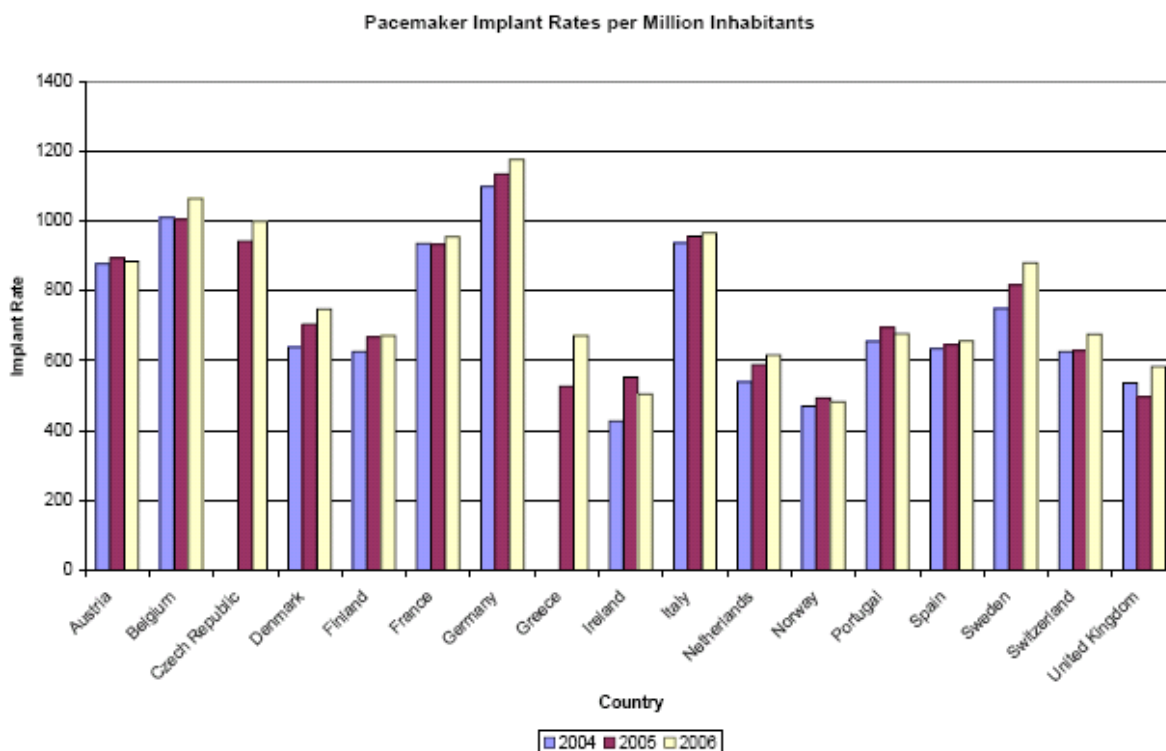
Source : EUCOMED 2007.

Figure A.1: Pacemaker implant rates per million inhabitants for Individual European countries

The total amount of pacemakers implanted during 2007 is given in table A.1.

**Table A.1: Total amount of pacemakers implanted during 2006**

	Population	Pacemakers implantation rates in per million	Pacemakers implanted in 2006
BE Belgium	10 656 209	1 100	11 722
CZ Czech Republic	10 345 927	1 000	10 346
DK Denmark	5 475 791	750	4 107
DE Germany	82 179 136	1 200	98 615
IE Ireland	4 414 798	500	2 207
GR Greece	11 216 711	700	7 852
ES Spain	45 283 259	650	29 434
FX France métropolitaine	61 875 822	950	58 782
IT Italy	59 528 974	950	56 553
NL Netherlands	16 404 282	600	9 843
AT Austria	8 334 325	900	7 501
PT Portugal	10 617 407	700	7 432
FI Finland	5 299 772	650	3 445
SE Sweden	7 918 292	900	7 126
UK United Kingdom	61 270 284	600	36 762
NO Norway	1 473 717	500	737
CH Switzerland	7 591 414	700	5 314
			357 777
Source: EUCOMED 2007 [i.37].			

A.2.1.2   Ventricular tachyarrhythmia

Ventricular tachyarrhythmia are defined as abnormal patterns of electrical activity originating within ventricular tissue. The most commonly encountered ventricular tachyarrhythmia of greatest clinical importance to clinicians are ventricular tachycardia and ventricular fibrillation. Ventricular fibrillation is characterized by irregular and chaotic electrical activity and ventricular contraction in which the heart immediately loses its ability to function as a pump. Pulseless ventricular tachycardia and ventricular fibrillation are the primary causes of Sudden Cardiac Death (SCD). The annual incidence of SCD is believed to approach 2/1 000 population but can vary depending on the prevalence of cardiovascular disease in the population [i.31]. It is estimated that 300 000 SCDs are recorded annually in the US, representing 50 % of all cardiovascular mortality in that country [i.32]. Data from Holter monitor studies suggest that about 85 % of SCDs are the result of ventricular tachycardia/ventricular fibrillation [i.33]. Implantable Cardioverter Defibrillators (ICDs) are devices that are designed to detect and treat ventricular tachyarrhythmia and thereby prevent SCD.

The defibrillator implant rates per million inhabitants for Individual European countries are shown in figure A.2.
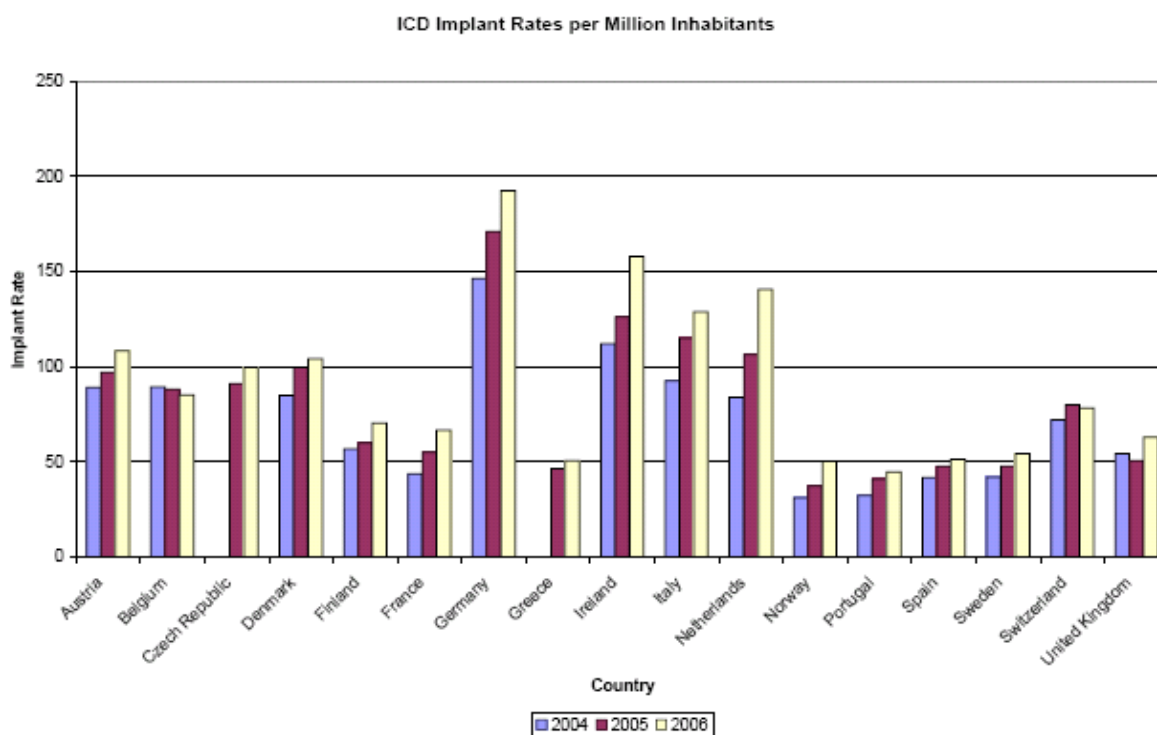
Source: EUCOMED [i.40].

Figure A.2: Defibrillator implant rates per million inhabitants for Individual European countries

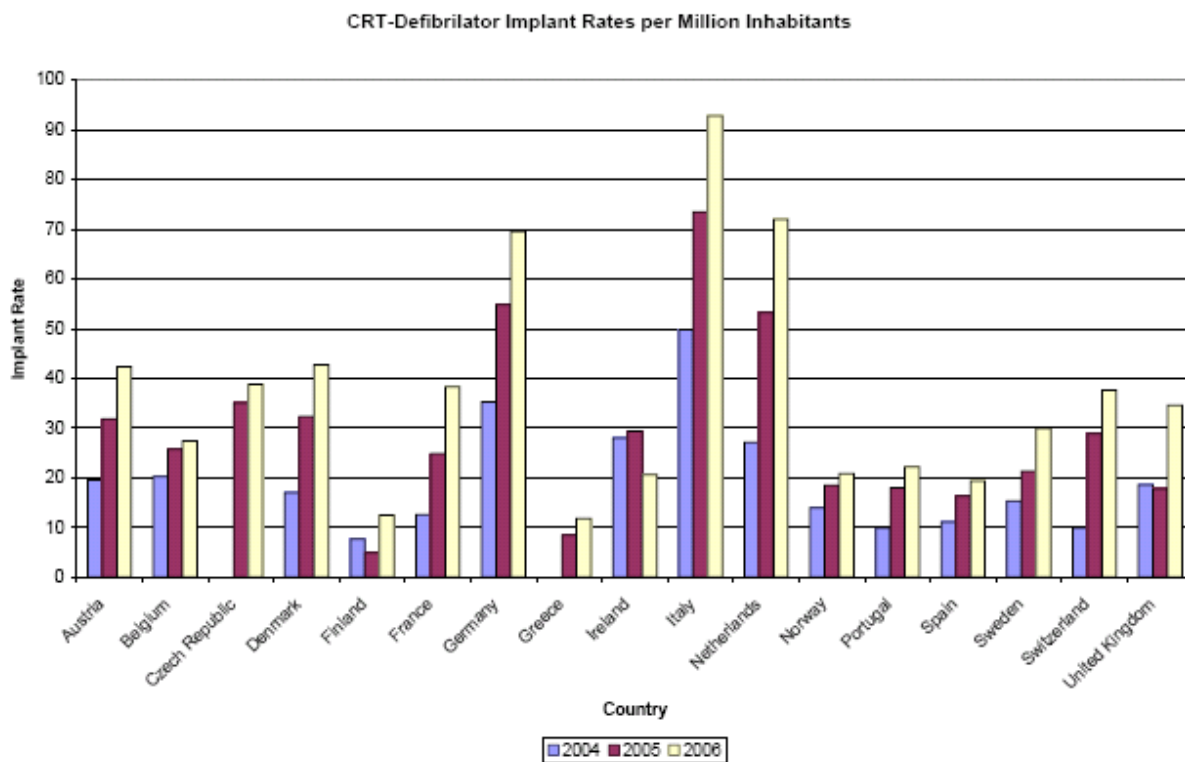The total amount of defibrillators implanted during 2007 is given in table A.2.

Table A.2. Total amount of defibrillators implanted during 2007

	Population	Defibrillators implantation rates in per million	Defibrillators implanted in 2007
BE Belgium	10 656 209	90	959
CZ Czech Republic	10 345 927	100	1 035
DK Denmark	5 475 791	100	548
DE Germany	82 179 136	140	11 505
IE Ireland	4 414 798	160	706
GR Greece	11 216 711	50	561
ES Spain	45 283 259	50	2 264
FR France	61 875 822	70	4 331
IT Italy	59 528 974	130	7 739
NL Netherlands	16 404 282	140	2 297
AT Austria	8 334 325	110	917
pPTPortugal	10 617 407	45	478
FI Finland	5 299 772	70	371
SE Sweden	7 918 292	55	436
UK United Kingdom	61 270 284	60	3 676
nNONorway	1 473 717	50	74
CH Switzerland	7 591 414	75	569
			38 465
Source: EUCOMED 2007 [i.40].			

A.2.1.3   Heart Failure

Heart failure is a major cardiac condition affecting 10 million Europeans [i.27] and more than 22 million people worldwide [i.34] and is expected to almost triple in 2020. According to the European Society of Cardiology (ESC) approximately 40 % of heart failure patients could benefit from cardiac resynchronization devices CRT-Ds and CRT-Ps, D stands for defibrillator, P stands for pacemaker [i.35]. Cardiac resynchronization therapy (CRT) aims at increasing cardiac pump efficiency by resynchronizing the contractions of the ventricles. CRT-D is indicated in heart failure patients who might be at risk for Sudden Cardiac Death (SCD) as it resynchronizes ventricular contractions and delivers defibrillation support when necessary. Sudden cardiac death is a sudden loss of heart function which is due most of the time to ventricular tachycardia (VT) or ventricular fibrillation (VF). According to American Heart Association (AHA) statistics [i.36]) a congestive heart failure in people, SCD occurs six to nine times more often than in the general population.

The CRT-defibrillator implant rates per million inhabitants for Individual European countries are shown in figure A.3.
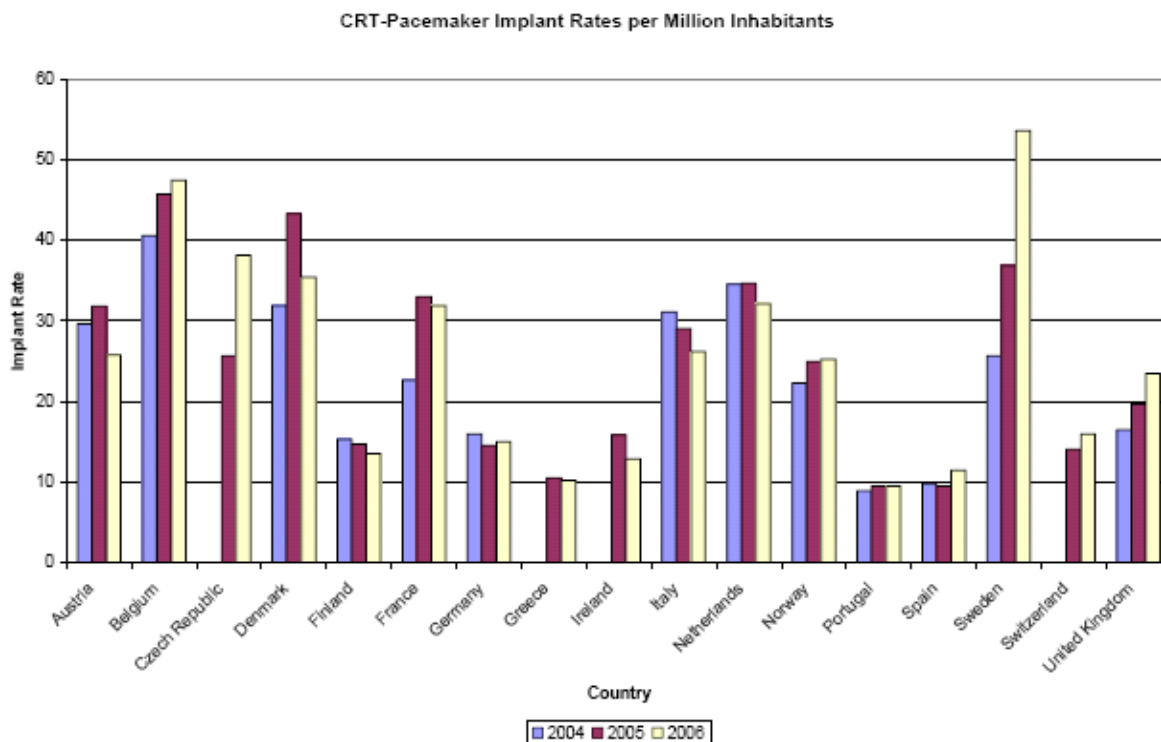
CRT-Defibrilator Implant Rates per Million Inhabitants

Source: EUCOMED 2007 [i.38].

Figure A.3: CRT-defibrillator implant rates per million inhabitants for Individual European countries

The CRT-pacemaker implant rates per million inhabitants for Individual European countries are shown in figure A.4.

CRT-Pacemaker Implant Rates per Million Inhabitants

Source: EUCOMED 2007 [i.39].

Figure A.4: CRT-pacemaker implant rates per million inhabitants for Individual European countries

The total amount of CRT implanted during 2007 is given in table A.3.

Table A.3: Total amount of CRT implanted during 2007

	Population	CRT implantation rates in per million	CRT implanted In 2007
BE Belgium	10 656 209	80	852
CZ Czech Republic	10 345 927	80	828
DK Denmark	5 475 791	80	438
DE Germany	82 179 136	85	6 985
IE Ireland	4 414 798	35	155
GR Greece	11 216 711	20	224
ES Spain	45 283 259	30	1 358
FR France	61 875 822	70	4 331
IT Italy	59 528 974	115	6 846
NL Netherlands	16 404 282	100	1 640
AT Austria	8 334 325	70	583
PT Portuga	10 617 407	40	425
FI Finland	5 299 772	25	132
SE Sweden	7 918 292	85	673
UK United Kingdom	61 270 284	60	3 676
NO Norway	1 473 717	45	66
CH Switzerland	7 591 414	55	418
			29 632
Source: EUCOMED 2007.			

A.2.2 Homecare

Europe is currently undergoing radical demographic changes. Its population is growing evermore slowly and a Eurostat study projects that this growth will cease by 2025 [i.25], for details see table A.4.

Table A.4: European population estimates by Eurostat, 2005 (*1 000)

Year	EU 25	EU 15
1960	376 423,0	314 826,0
1965	393 266,4	328 644,7
1970	406 870,1	330 975,0
1975	417 468,9	348 644,3
1980	426 081,0	354 568,4
1985	432 107,2	358 472,3
1990	438 711,9	363 795,0
1995	446 390,2	371 187,6
2000	451 080,2	376 203,9
2004	457 188,9	383 047,2
2025	570 057,3	398 779,7
2050	449 831,2	384 356,2
Source: EUROSTAT [i.25].		

Due to this decline in population growth, Europe will be faced with an ever-growing ageing European population and a lower number of active people who can contribute to the financing of national healthcare systems.

This growing ageing population inevitably leads to an increase of care dependent people and to a modification of the pattern of disease, which results in chronic-degenerative diseases becoming more prevalent. Innovation in science and technology can improve the quality of life of disabled people, elderly people and children. Nevertheless, one of the major issues remains the scarcity of resources that governments have to respond to the increasing needs of the population.

Choosing for homecare, a collective name for different kinds of care and assistance delivered to the patient at home, is not an easy choice as it impacts the life of the patient, his environment and the care giver. It is a treatment intended for elderly people, patients with chronic illnesses, physical or mental handicaps.

Homecare has the potential to become a viable solution to alleviate resources constraint while keeping homecare services and patients' quality of life at least as effective as in institutional settings.

The World Health Organization defines homecare as follows:

"Homecare is defined as the provision of health services by formal and informal caregivers in the home in order to promote, restore and maintain a person's maximal level of comfort, function and health including care toward a dignified death. Homecare services can be classified into preventive-promotive, therapeutic, rehabilitative, long-term maintenance and palliative care categories."

In the field of medical devices, homecare services range from incontinence pads to telemedicine, from oxygen therapy to peritoneal dialysis.

Thanks to technological progress and innovation length of stay in hospitals can be reduced and the treatment can be continued at home. In addition, increasing numbers of patients can be treated at home thanks to medical technology - healthcare is brought to the patients' home.

In 1998, a study [i.33] found there were only few differences between in-hospital care and homecare when looking at the patient's health after treatment. Likewise, there were no discerning differences when looking at the patient's satisfaction. The cost of treatment thus becomes the defining indicator. These results were confirmed by a 2004 study in which 97 patients were followed who had undergone coronary artery bypass grafting (CABG), whereby one group remained in the hospital until complete recovery and another group was discharged early, followed by homecare treatment. Whereas the quality of life, re-admission rates and primary costs were similar for both groups, the costs during the 12-week follow-up period were higher in the conventional hospital treatment group.

By allowing routine monitoring and day-to-day care of patients with chronic illnesses to take place at home, scarce resources can be made available to patients for whom homecare is not an option to receive optimal treatment in hospitals, and less pressure is put on health budgets.

A.2.3   Neurostimulators

The neurodevices currently on the market or in clinical trials represent a new paradigm in patient care that is revolutionizing delivery of treatment for many neurologic disorders. Neurodevices comprise neurostimulators and drug infusion pumps delivering drugs or other therapies directly to disease targets. Neurostimulators deliver stimuli to spine for pain and also to brain for Parkinson or vagal nerve for depression.

These neurotechnologies generally take the form of battery-powered electronic devices. Designed to be surgically implanted in discrete areas of the body, the devices feature wire leads and electrodes that are routed through the body and emplaced in specific areas of the brain or nervous system to improve function and, in some cases, provide a complete restoration of a deficit.

"Given the rapid advances in neuroscience and clinical and biomedical engineering, neurotechnologies have tremendous potential to help people with neurologic diseases and injuries," said Leigh Hochberg, MD, PhD, associate neurologist at Brigham and Women's Hospital and an instructor in neurology at Harvard Medical School in Boston.

The study of neurodevices is still in its infancy, but the prospects are looking good, and the market is waiting. "The CNS and nervous system disorders represent the largest and fastest growing unmet medical market: 1.5 billion people worldwide," according to a market analysis and investment report [i.29]. According to the report, neurodevices already account for 2.6 billion dollars of the 110 billion dollar neurotechnology industry, which also includes neuropharmaceuticals and neurodiagnostics. Moreover, companies addressing CNS-related markets have "the greatest potential for major scientific discoveries, commercial success, and sustainable investment opportunities," according to the report.

"On a social scale, implants are becoming very commonplace if you consider all types of implants-intraocular lenses, orthopaedic implants, pacemakers, and defibrillators," observed Reese Terry, cofounder, chairman of the board, and executive vice president of Cyberonics, a medical device manufacturer based in Houston. "We are coming up on the 'bionic man' and the next frontier is neurologic implants."

The neurodevice market is really open territory in terms of the applications for this reversible and dynamically adjustable technology. We are right now in neuromodulation where cardiac pacings were 30 years ago.

A.3   Traffic and equipment density forecast

A.3.1   Spectrum use and efficiency:

Medical equipment covered in the present document is expected to emit electromagnetic radiation at a maximum power level of 10 milliwatts e.r.p in the 2 483,5 MHz to 2 500 MHz band. Transmission times will vary from brief intervals for some devices to almost continuous transmission by some active medical implants and an associated peripheral or peripherals.

The reasons for all of the above are:

- Power and transmission time frames are product specific. Cardiac systems tend to be accessed by a physician occasionally during office visits, however, home monitoring of these devices will increase the access of these systems to physicians and thus their transmission times and spectrum usage. Typically, implanted cardiac devices operate at lower power levels with wider bandwidths while the external programmers/controllers operate at or near the maximum permitted power level with lower bandwidths.

- Because implantable devices are battery driven, the communication use is a very small fraction of its life cycle.

- Insulin delivery systems and hemodynamic monitors will exhibit a much increased transmission time in order to provide a continuously updated physiological parameter measurement to the attendant or to a device delivering a drug such as insulin.

- Medical systems operating in the band employ a variety of interference mitigation techniques such as LBT, AFA and data integrity checks including CRC, FEC, ARQ and others.

Annex B:
Detailed technical information

B.1   Detailed technical description

B.1.1   System description

Medical systems proposed to be operated in the additional of spectrum consist of devices implanted within the body and external devices that support the operation of the implanted device. Implanted devices are placed in the body to deliver therapies and/or provide diagnostic data that is used by a physician to determine the condition of the implanted patient and develop appropriate therapies. External devices (peripherals) operating under the provisions of the present document support the operation of the implanted devices by providing a means for programming or altering the programming of the implanted device, retrieving diagnostic data from the implant, transferring data to a mass storage system and/or provide real time readout of physiological parameters.

External devices are also patient devices used at home for monitoring the health status of the patient, the electrotherapy and send alarms when necessary to a remote healthcare service centre.

In the Medical systems are also included autarkic (with autonomous power source) implantable sensors which communicate with others AIMD.

B.1.2   Applications

Currently, the 402 MHz to 405 MHz using MICS technology is the only band dedicated on shared basis to implants and it is utilized typically in implantable cardiac devices such as pacemakers that control the rhythm of heart contractions, defibrillators that recognize an abnormally high heart rate and deliver a high-energy pulse to restore a more natural rhythm, and combination devices that can do both of the above. Other medical implant devices that deliver drugs to the patient and devices that stimulate nerves to control pain are under development that exploit new sensor technology. For example, semi-permanent glucose sensors have been developed that permit blood glucose levels to be monitored over extended periods of time and transmitted to insulin pumps to adjust insulin levels "on demand". Significant advances in neural stimulation to control otherwise uncontrollable reflex muscular reactions from diseases such as Parkinson's and other brain disorders have been developed. Still other neural implant technologies are used to control incontinence and pain by applying an electrical stimulus to the human nervous system.

Within 5 years, the development within medical sensor technology and applications will require spectrum over and above that which is available today, see annex A.

B.2   Technical parameters and justifications for spectrum

B.2.1   Transmitter parameters

B.2.1.1   Radiated Power

B.2.1.1.1   Required transmitter parameters

See clause 5.4.2.

B.2.1.2   Emissions in the spurious domain

Table B.2 gives the emissions in the spurious domain.

Table B.2: Emissions in the spurious domain

Frequency State	47 MHz to 74 MHz 87,5 MHz to 118 MHz 174 MHz to 230 MHz 401 MHz to 406 MHz 470 MHz to 862 MHz	Other frequencies below 1 000 MHz	Frequencies above 1 000 MHz
Operating	4 nW e.r.p.	250 nW e.r.p.	1 µW e.r.p.
Standby	2 nW e.r.p.	2 nW e.r.p.	20 nW e.r.p.

Except for 401 MHz to 406 MHz, the table B2 spurious emissions is as in ERC REC 74-01 [i.24]. Similar requirements are to be considered for the selected band in the present document.

B.3   Link budget considerations

B.3.1   Introduction

Currently, existing studies on antennas used to build the communication links between implanted devices and exterior instrument for telemetry have not been widely reported.

The design of such an antenna is extremely challenging because of the impact of the human body on the antenna performances (significant reduction of antenna efficiency) and the application needs to down-size antenna dimensions. The design process is particularly original since experimentation in actual situation is critical and is limited to the use of models having properties similar to realistic in vivo tissues. Since experimentation allows limited analysis of antenna working mode in complex media such as human body, developments, studies and optimizations are generally carried out using electromagnetic simulation software [i.6], [i.7] and [i.8]. Consequently, it is necessary to validate the set-up of simulation tools in accordance with studied antennas parameters.

The in-situ electromagnetic propagation simulation tools used to study implanted antenna inside human body solve Maxwell's curl equation in taking into account physical and geometrical properties of three-dimension simulated structures. The solver technique consists in subdividing the studied structure into small elementary cells whose shape and dimensions are related both to the numerical method and the spatial resolution of the model. Specific conductivity, permittivity and permeability are assigned to each elementary cell. The study made in the present document is using the Micro Wave Studio (MWS) software made by Computer System Technology (CST) [i.9].

The study presented in the present document mainly focuses on the evaluation of the human body impact on implanted antenna impedance and radiation performances. To make this evaluation both measurements and simulations are made.

The study steps are the following:

   a)   Firstly, a body phantom model used for measurement is described.

   b)   Then, the experiment made on a canonical sleeve dipole is presented and the obtained results are discussed.

   c)   Finally, the simulations are compared with the measurement results. These simulations are made using two antennas: a sleeve dipole and a simplified pacemaker with a compact loop.

B.3.2 Body phantom

A phantom is used to perform radio wave propagation around or inside human body. As measurements are not easily possible within live human tissues, a phantom permits to conduct stable measurements with a controllable propagation environment [i.10],[i.13]. There are three types of phantoms which may be used:

a) liquid phantoms;

b) semisolid (gel) phantoms; and

c) solid phantoms.

For the performed measurements, a liquid phantom is used, see figure B.1. A similar requirement is included in standards for MICS-band (FCC, ETSI) [i.12] The phantom design consists of a Plexiglas cylinder containing a special liquid [i.12]. The fluid is made by a mixture of different components with specific proportion as indicated in [i.13] and [i.14]. The properties of the used fluid are reported on table B.3.
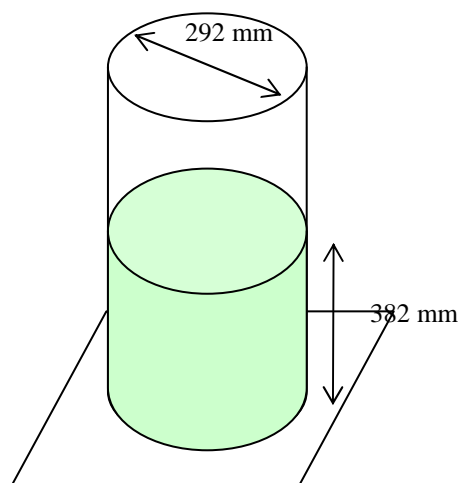
Figure B.1: A phantom model

The total volume of the phantom was limited to half of the height of the cylinder in order to limit the weight accordingly to the maximum mass allowed on the rotating antenna pedestal inside the anechoic chamber. The proportion of the phantom fluid is shown in table B.3.

Table B.3: Proportion of the phantom fluid components

Frequency	2,45 GHz	
Volume (l)	25,61	
Height (mm)	382	
density	1,15	
Total mass (kg)	29,41	
	Quantity (%)	Weight (kg)
H_2O	63,9	18,80
Sugar	34	10,00
NaCl	0	0
HEC (see note)	2	0,59
Bactericide	0,1	0,029
total	100	29,41
NOTE: Hydroxyethylcellulose.		

The phantom fluid properties have been measured using two kinds of probes (Agilent probe kit) [i.15]. Figure B.2 shows the real and imaginary parts of the relative permittivity obtained with both probes types.
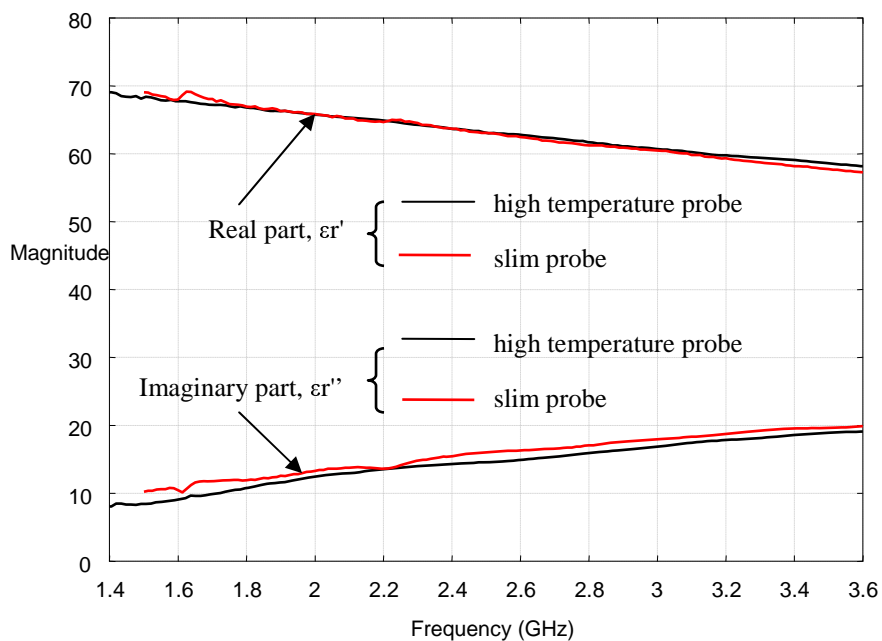
Figure B.2: Real and imaginary part of the phantom fluid permittivity

Table B.2 summarizes the dielectric properties of different components of a real human body at 2,45 GHz [i.17]. The dielectric properties $\varepsilon_r(\omega)$ of human tissue can also been obtained for any frequency using the 4-Cole-Cole following expression [i.10].

$$\varepsilon(\omega) = \varepsilon_\infty + \sum_{m=1}^{4} \frac{\Delta\varepsilon_m}{1 + (j\omega\tau_m)^{(1-\alpha_m)}} + \frac{\sigma_i}{j\omega\varepsilon_0}$$

In this expression, ε_∞ is the material permittivity at terahertz; ε_0 is the free space permittivity; σ_i is the ionic conductivity; and ε_m, τ_m and α_m are material parameters for each dispersion region.

According to table B.4 below, the dielectric properties of the fluid inserted in the phantom at 2,45 GHz [i.11] ($\varepsilon_r = 63.2 + j\ 16$) are relatively higher than classical human tissue such as muscle, fat, blood, bones and skin.

Table B.4: Dielectric properties of human body tissues at 2,45 GHz

Tissue Name	Relative permittivity ε'_r	Conductivity σ [S/m]	Tangent Loss $\tan\delta$	Penetration depth [cm]
Aorta	42,47	1,467	0,24837	2,3761
Bladder	17,975	0,69816	0,27927	3,2545
Blood	58,181	2,5878	0,31981	1,5842
Bone, Cancellous	18,491	0,82286	0,31996	2,8087
Bone, Cortical	11,352	0,40411	0,25597	4,4616
Brain, Gray Matter	48,83	1,843	0,27137	2,031
Breast Fat	5,137	0,14067	0,1969	8,5942
Cartilage	38,663	1,7949	0,3338	1,8638
Cerebro Spinal Fluid	66,168	3,5041	0,38078	1,2537
Cornea	51,533	2,3325	0,32544	1,6548
Eye Sclera	52,558	2,0702	0,28321	1,8773
Fat	5,2749	0,10672	0,14547	1,1455
Gall Bladder Bile	68,305	2,8447	0,29945	1,5592
Heart	54,711	2,2968	0,30185	1,7286
Kidney	52,63	2,4694	0,33736	1,5811
Liver	42,952	1,7198	0,2879	2,0434
Lung, Inflated	20,444	0,81828	0,28779	2,963
Muscle	52,668	1,773	0,24205	2,1886
Skin, Dry	37,952	1,4876	0,28184	2,2198
Skin, Wet	20,369	23,984	0,84665	1,0736
Small Intestine	54,324	3,2132	0,42529	1,2438
Stomach	62,078	2,2546	0,26114	1,8707
Testis	57,472	2,2084	0,27628	1,8394
Tongue	52,558	1,8396	0,25167	2,1083
Source: [i.11].				

B.3.3   Measurements

The lack of literature concerning the implanted antenna inside body operating at 2,45 GHz has justified measurements on the total propagation loss of an implanted antenna.

The aim of the measurement was to estimate the additional loss on the antenna performance at 2,45 GHz when implanted in the human body. A particular attention was paid to the calculation of the combination of the near-field and far-field in order to correctly design the overall link budget for the radio link.

To evaluate the difference of link budget between the in-body to off-body configurations, the antennas radiation gain was measured in the two cases. The in-body measurements were performed using the phantom model described in clause B.3.2.

Finally, the measurements was also used to validate the theoretical results presented in clause B.3.3.4 concerning the simulated radiation properties of implanted antennas at 2,45 GHz.

B.3.3.1   Description test antenna

The test antenna to be used in the phantom is a half-wavelength dipole fed by a rigid coaxial cable (see figure B.3). The rigid coaxial also ensure a stable position of the antenna inside the phantom. The test dipole antenna is also called "sleeve antenna".

Figure B.3: Test antenna

The antenna used was built with a semi rigid cable in which the central part is bared to form one arm of the dipole. The other arm of the dipole was made by a metal sleeve soldered in the middle of the antenna to the outer screen of the coaxial cable. A cylindrical outer plastic radome was used to protect the radiating element (see figure B.4). Figure B.5 shows the antenna dimensions.

The antenna design is optimized to present an impedance of 50 Ohms at 2,45 GHz.

To ensure high performance the radome is made of a 3 mm thick plastic tube (Delrin) having a real part permittivity of 3,2 at 1 GHz together with a very low tangent loss.

Figure B.4: Dipole without the cylindrical radome
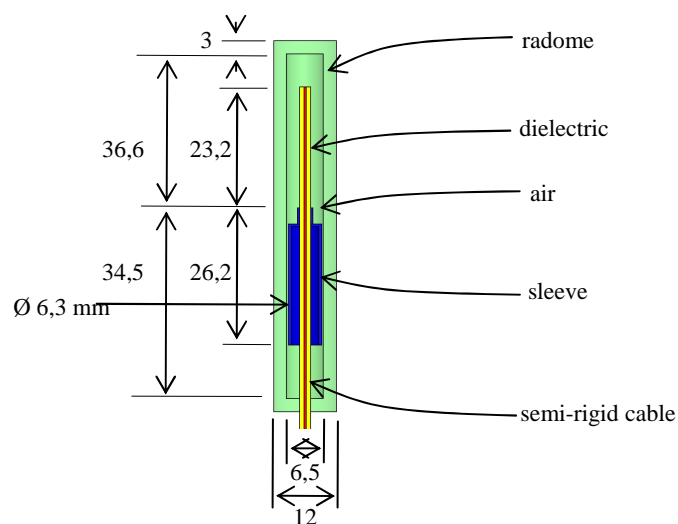
Figure B.5: Antenna design and main dimensions (mm)

B.3.3.2   Synthesis of measurements results

The experiment is made at the central frequency 2,45 GHz and over a bandwidth of 1 GHz around the central frequency. In the following clauses, the experimental details as well as the obtained results concerning the antenna impedance matching and the radiation gain are given.

B.3.3.3   Method of measurements

The goal of the measurements was to evaluate the impact on impedance and radiation of the fluid thickness between antenna and the phantom outer (inside the plexiglass container of the fluid).

During the tests, the dipole antenna was placed 3 cm from bottom of the radome to the bottom of the phantom as illustrated in figures B.6, B.7 and B.8. The various distances between the antenna and the inner wall of the phantom were determined by different circular plexiglass discs mounted on the antenna cable at each measurement. The entire set-up consisting of the phantom and the antenna was placed on a rotating mast in an anechoic chamber.

As the experiments are performed in an anechoic chamber, the results obtained are free from multipath and interferences effects.
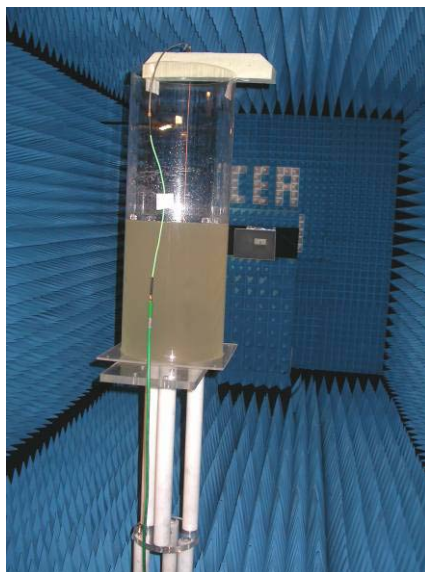
Figure B.6: View of test set-up
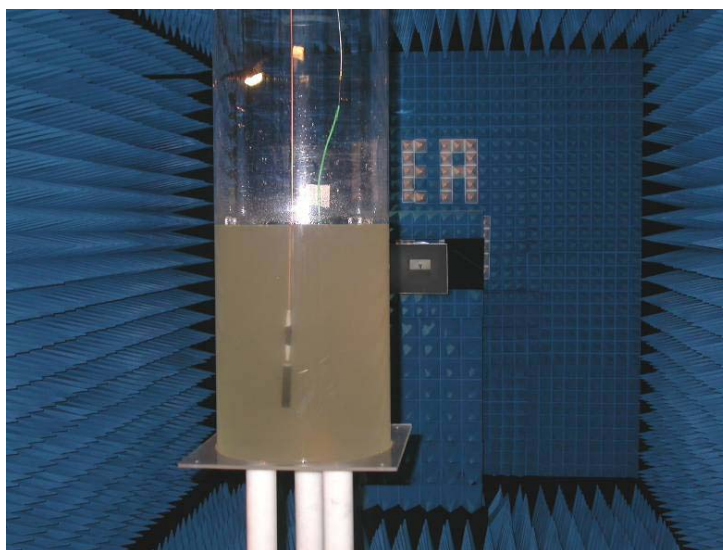
Figure B.7: Face view of the test antenna inside the phantom
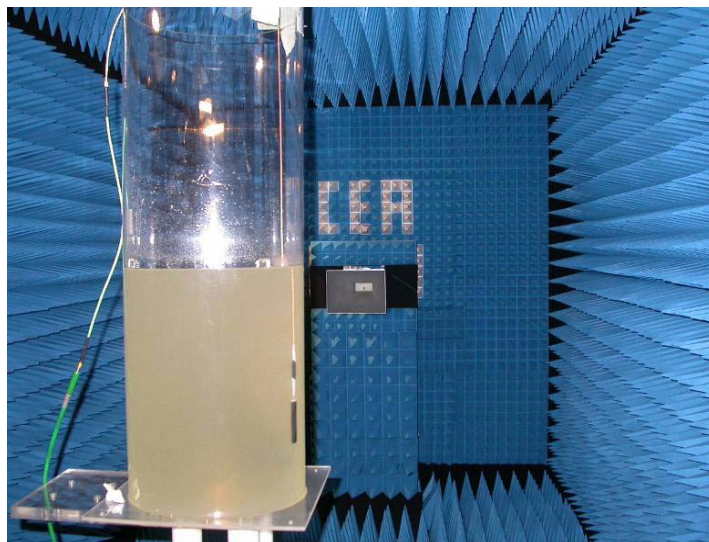
Figure B.8: Side view of the test antenna inside the phantom

B.3.3.4   Measurement results

B.3.3.4.1   Phantom influence on the impedance of the test antenna

The test antenna impedance measurements were performed in free-space and inside the phantom for three values of the fluid thickness between the test antenna and the phantom outer. Figure B.9 shows the return loss obtained for the four cases.

It is to be noted that the antenna impedance is not modified significantly by the insertion of test antenna into the phantom as the antenna is protected by the radome and therefore not directly in contact with the fluid.
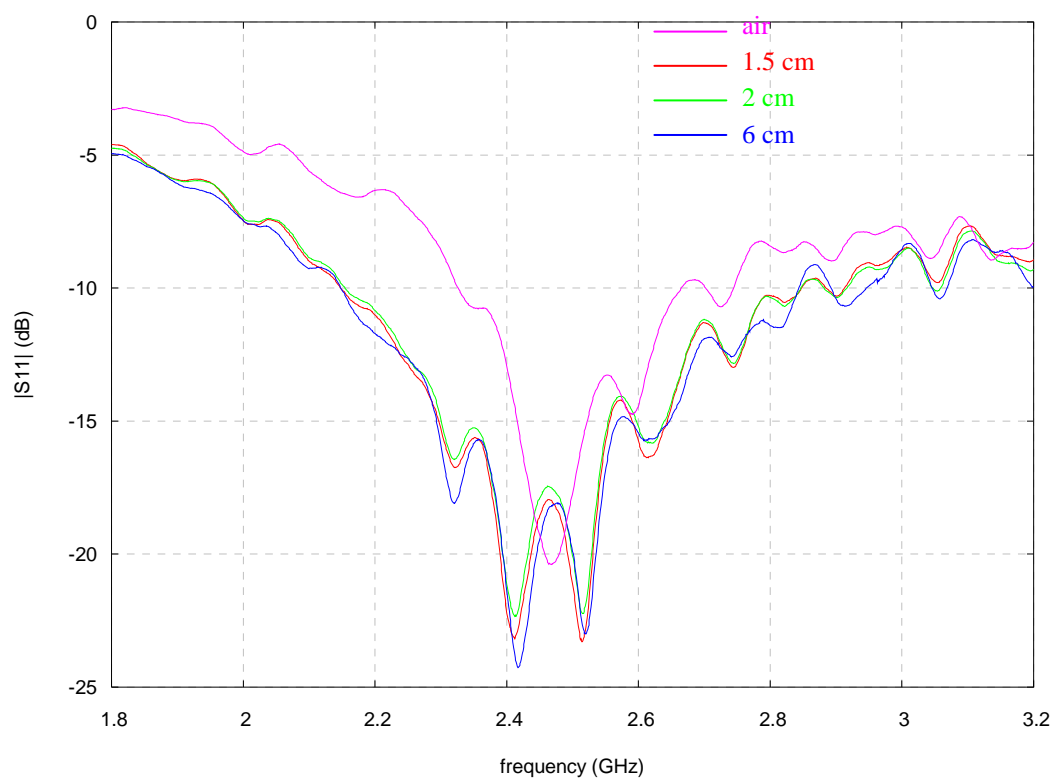
**Figure B.9: Measured return loss for the test antenna versus fluid thicknesses
between antenna and phantom outer**

B.3.3.4.2   Phantom influence on the test antenna efficiency

The antenna radiation gain inside the phantom was obtained from two different measurements.

   a)   The radiation pattern was measured over a full 360° rotation of the phantom at 2,5 GHz.

   b)   The second test was to measure the antenna gain versus frequency.

Figure B.10 shows the antenna pattern diagram for free space and two depths (thicknesses between antenna and phantom outside) inside the phantom plexiglass container.
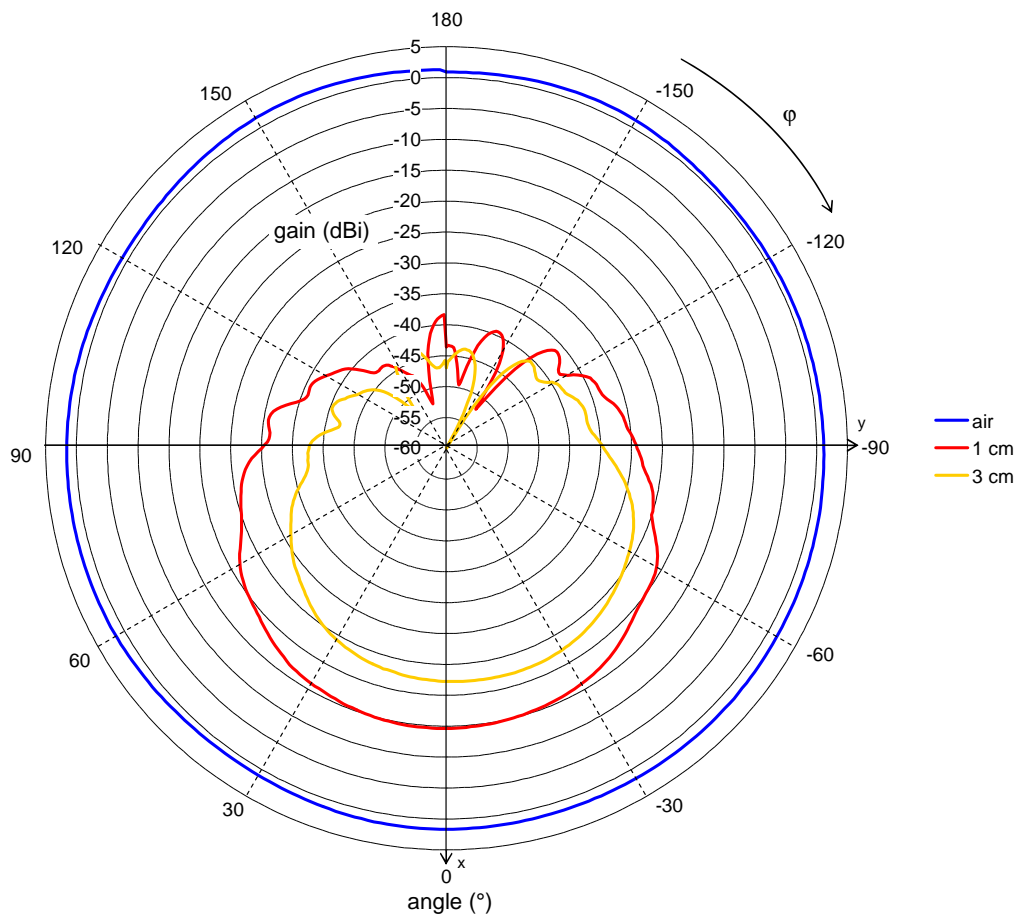
**Figure B.10: Measured gain and pattern at 2,5GHz for the test antenna
versus the depth in the phantom**

Figure B.11 shows the antenna maximum gain versus frequency for two depths inside the phantom. One can notice a variation of 5 dB to 10 dB over the 1 GHz bandwidth band considered.
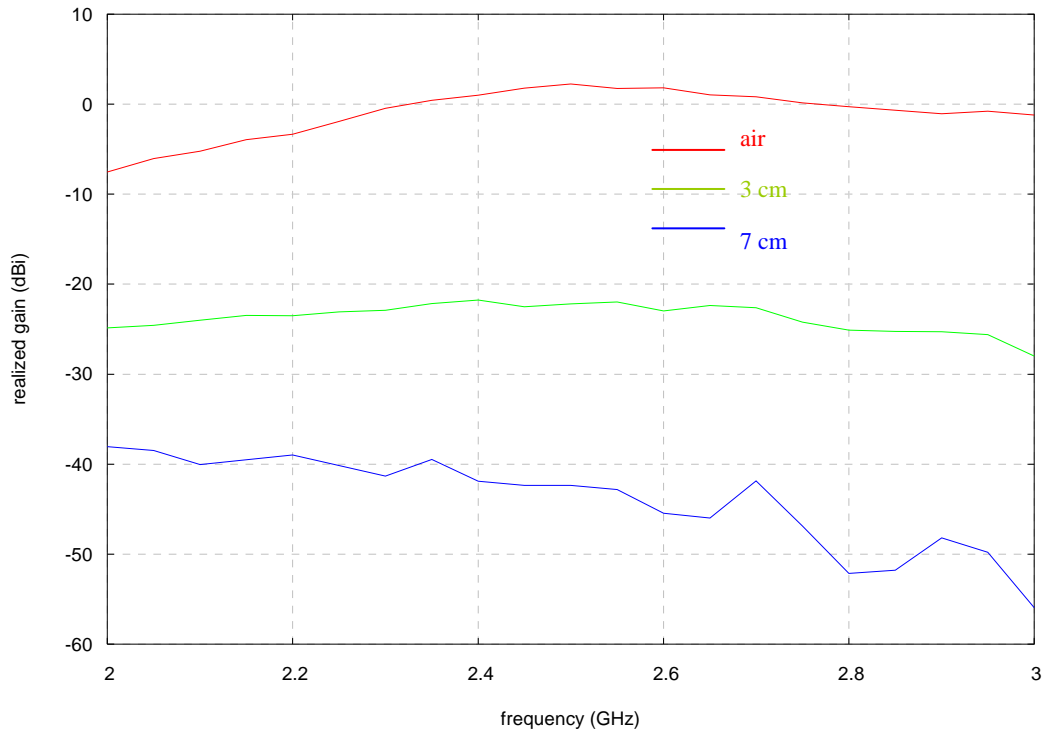
Figure B.11: Measured maximum gain for the test antenna versus frequency

Figure B.12 shows the gain (loss) according to the specific antenna depth inside the phantom. To obtain this plot, four measurements at 10 mm, 30 mm, 40 mm and 70 mm depths were made. By using these measurements points, a linear regression was performed in order to obtain the loss factor. The loss factor obtained is 4,65 dB/cm.

Considering a reference depth of 1 cm, it can be concluded that the antenna gain dependence of depth inside the phantom for the test antenna is the following relation where e refers to the phantom fluid thickness in cm.

$$G(dB) = G_{air}(dB) - 17,3 - 4,65 * (e - 1)$$
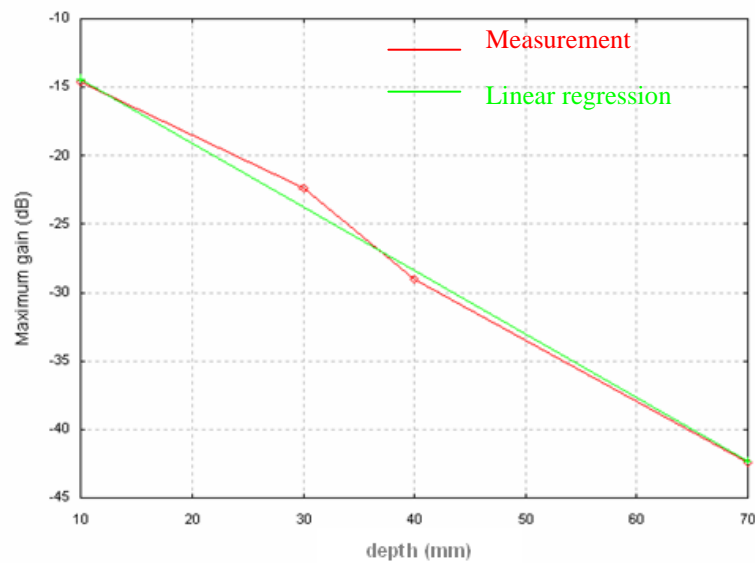
Figure B.12: Measured maximum gain versus depths of the test antenna

It is to be noted that the values of the gain in figure B.12 measured at 10 mm and 30 mm matches the values of figure B.10 at 0 degrees angle. Additionally, the value of the gain in figure B.12 measured at 70 mm matches the values of figure B.11.

B.3.4 Conclusion for propagation model

The radiation characterization of antennas implanted in human body is made by means of a body phantom. Most often, scientists consider a homogeneous fluid phantom for this purpose. The dielectric properties of the phantom are assumed to have mean values representing the average properties of the human tissue.

A test antenna placed inside a fluid phantom needs to be protected by a radome. In this condition the impedance of the sleeve test antenna is only slightly modified when inserted in the fluid.

However, the radiation pattern of antennas is changed significantly when inserted in the phantom fluid. The direction of the maximum radiation is oriented in the front side of the body phantom where the equivalent tissue thickness is the thinnest. When the radiated far-field is measured outside the phantom there is a linear decrease in dB of the radiated power level versus the thickness of the phantom fluid.

From the measurements it is determined that the antenna gain versus the mounting depth, *e*, inside the phantom can be expressed by:

$$G(dB) = G_{air}(dB) - 17{,}3 - 4{,}65*(e-1)$$

where e is in cm and is to be higher than 1cm. This equation was derived based on measurements at 2,5 GHz.

It is to be noted that this relation is in concordance with the attenuation law obtained considering wave propagation in a lossy media with the same dielectric properties as the phantom fluid.

The applicable frequency range the propagation formula above may be judged by considering the gain variation versus frequency in figure B.11.

B.3.5 Simulation

Two simulations have been conducted on two types of antennas inserted inside a human body phantom. The two antennas considered for these simulations were the test antenna (sleeve dipole), (see figure B.5) and a simplified pacemaker mounted together with the compact loop antenna. Figure B.13 shows the pacemaker housing with a loop antenna on the side of the housing together with the positions of the loop wire connections.

This clause describes the simulation configurations and discusses the obtained results on the impedance, the radiation and SAR for both antennas.
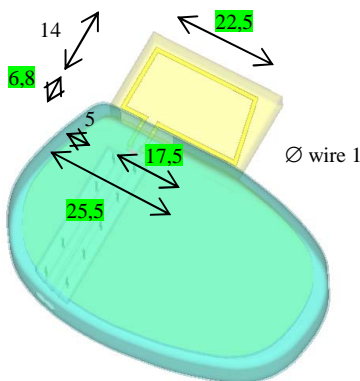

Figure B.13: Simplified pacemaker with a compact loop antenna (dimensions in mm)

B.3.5.1   Description of simulation

All the simulations were performed using the commercially available CST MWS software [i.9]. The two simulated structures are shown in figure B.14.
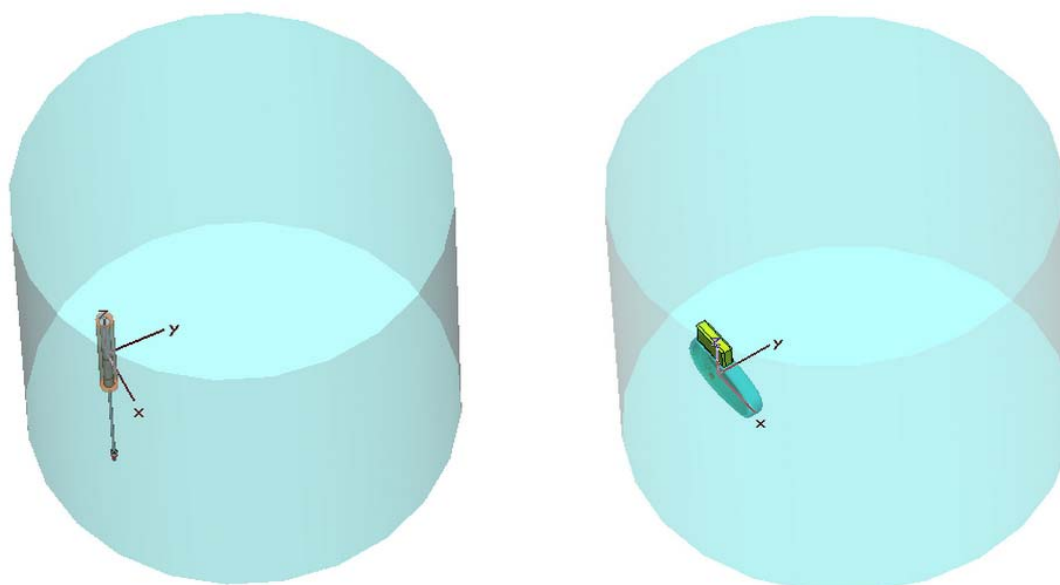

Figure B.14a. The sleeve dipole test antenna inside the phantom   **Figure B.14b. compact loop inside simplified pacemaker**

Figure B.14: Simulated structure set-up with CST MWS

The conducted simulations were using the same phantom configurations as for the measurements. The antennas were placed inside a human body phantom. The dielectric property of the phantom fluid close to muscle. At 2,45 GHz the data is:

- $\varepsilon'_r = 52,7$ and $\tan \delta = 0,24$.

These values leads to $\varepsilon_r = 52,7 + j\ 12,64$. It is difficult to match the theoretical values exactly in the phantom and it is to be noted that the values of the dielectric permittivity considered for simulations are slightly lower than those available for the measurement. However, the results in clause 3.5.4 show almost identical performance for measured and theoretical simulations in spite of the slight difference in dielectric property.

The three following clauses, B.3.5.2, B.3.5.3, B.3.5.4 and B.3.5.5, show the results obtained concerning the evolution of antennas impedance and radiation pattern versus the increase of fluid thickness between antenna and free space.

The human exposure limit, SAR, is calculated in clause B.3.5.6 with the heterogeneous human model of CST MWS named Hugo.

B.3.5.2   Results of the antenna impedance simulation

Simulations were made to determine the variation of the antenna impedance matching for four values of the fluid thickness between antenna and phantom outer. The results in figures B.15 and B.16 show the return loss obtained for both antennas respectively.
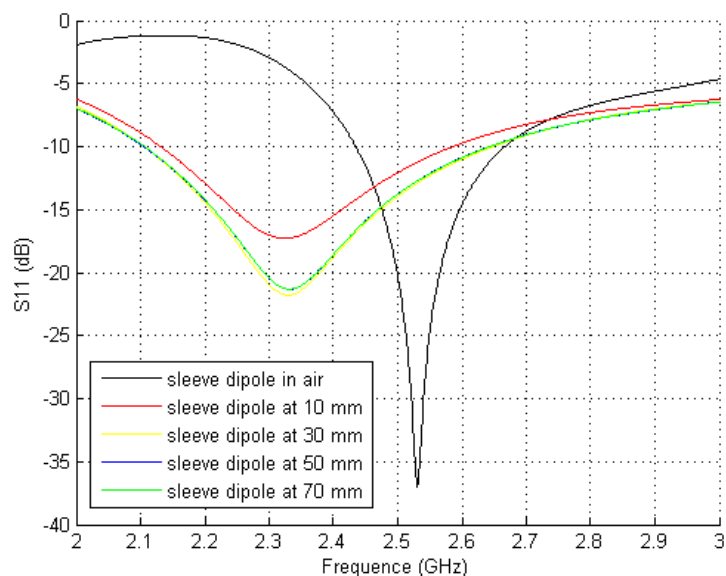
Figure B.15: Simulated return loss for the sleeve dipole test antenna versus fluid thicknesses between antenna and phantom outer
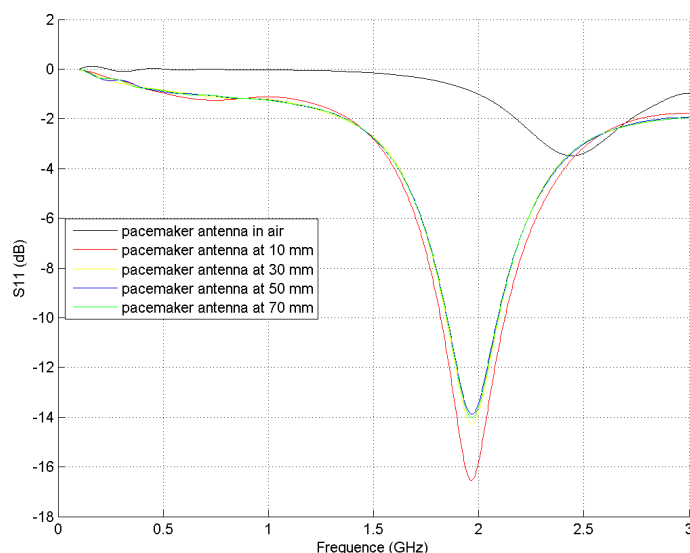

Figure B.16: Simulated return loss of simplified pacemaker with magnetic loop versus fluid thicknesses between antenna and phantom outer

The result shown in figure B.15 shows that the insertion of both antennas into the phantom slightly shifted the matching toward lower frequencies. The shift of impedance matching of the test sleeve antenna does not strongly affect the performances as the matching (return loss) is kept at -10 dB for the frequency of 2,45 GHz.

For the simplified pacemaker with magnetic loop, figure B.16 shows that the insertion in the phantom improves the matching. This is due to the fact that the used antenna structure is optimized for the considered application (implanted inside the human body).

B.3.5.3   Simulation results of antenna radiation efficiency

The results on the radiation efficiency obtained from simulation at 2,5 GHz are shown for both the test sleeve dipole and loop antennas.

Figures B.17 and B.18 show the radiation pattern of total field at 2,5 GHz for the sleeve dipole and the magnetic loop in the two planes.

The simulated horizontal plane corresponds quite accurately to the measurement in clause B.3.3.4.2, figure B.10.

Figure B.17 shows the simulated test antenna (sleeve dipole) gain pattern for four depths of 10 mm, 30 mm, 50 mm and 70 mm inside the phantom. One can notice that:

- There is important attenuation of the antenna maximum gain due to the increase of the antenna depth inside the phantom.

- The radiation pattern is modified by the antenna insertion inside the phantom for both vertical and horizontal planes. The phantom fluid besides the antenna acts as an absorbing medium. Therefore, the antenna pattern is maximum where the fluid thickness between antenna and the phantom outer is lowest.
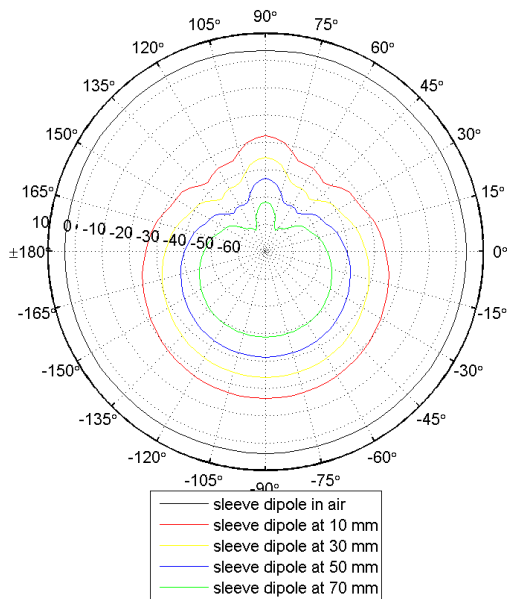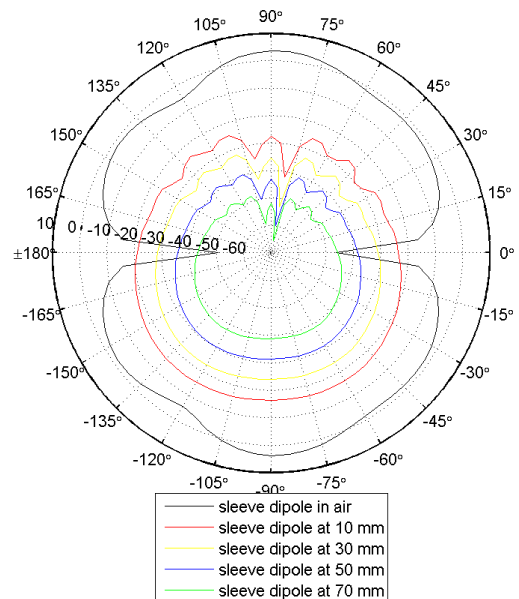

Figure B.17a horizontal plane

Figure B.17b vertical plane

**Figure B.17: Simulated sleeve dipole gain diagrams versus fluid thicknesses
between antenna and phantom outer**

Figure B.18 shows the gain pattern of the simplified pacemaker with magnetic loop simulated for four depths of 10 mm, 30 mm, 50 mm and 70 inside the phantom. One can notice that:

- There is also important attenuation of the antenna maximum gain due to the increase of the antenna depth inside the phantom compared to the test antenna (sleeve dipole).

- The omnidirectional structure of the radiation diagram starts to be strongly modified when the thickness is higher than 10 mm mainly in the vertical plane.
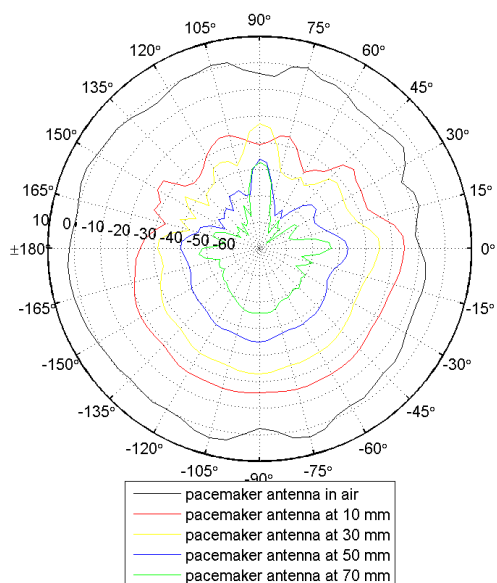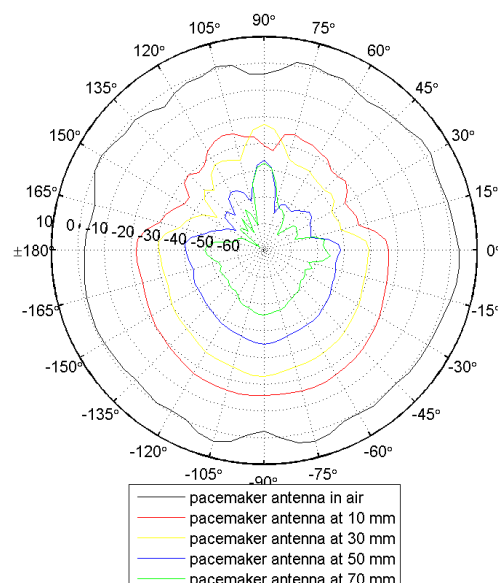
Figure B.18a horizontal plane

Figure B.18b vertical plane

Figure B.18: Gain diagrams of simplified pacemaker with magnetic dipole versus fluid thicknesses between antenna and phantom outer

Figures B.19 and B.20 show the dependence of the additional simulated gain loss versus the thickness of the fluid between antenna and phantom outer for both the test sleeve dipole and simplified pacemaker with magnetic loop. For the measurements, only the four depths values were considered. Using the simulated points, a linear regression was made in order to determine the loss factor. The loss factor obtained is 3,69 dB/cm and 3,92 dB/cm for test sleeve dipole and the simplified pacemaker with magnetic loop respectively. These values are in accordance with the theoretical loss factor (about 3,84 dB/cm) related to a propagation inside a loss medium with ε_r = 52,7 + j 12,64.

Using these loss factors, the two following expressions for maximum gain can be used at 2,5 GHz to model the loss for both considered antennas respectively where e is in cm. (e is to be higher than 1 cm).

$$G(dB) = G_{air}(dB) - 19,4 - 3,69 * (e - 1) \text{ (test sleeve dipole antenna)}$$

$$G(dB) = G_{air}(dB) - 19,2 - 3,92 * (e - 1) \text{ (Simplified pacemaker with magnetic loop antenna)}$$

These equations were derived based on simulations in the horizontal plane refer to figures B.18a and B.17a. It is to be noted that the propagation models for both antennas are relatively similar. This can make us conclude that the results obtained in measurement for the test sleeve dipole will probably be similar if we consider the simplified pacemaker with magnetic dipole. Moreover, as simulations are made with a phantom with a lower value of dielectric permittivity and losses, the simulation loss factor is thus less important than the measurement one.
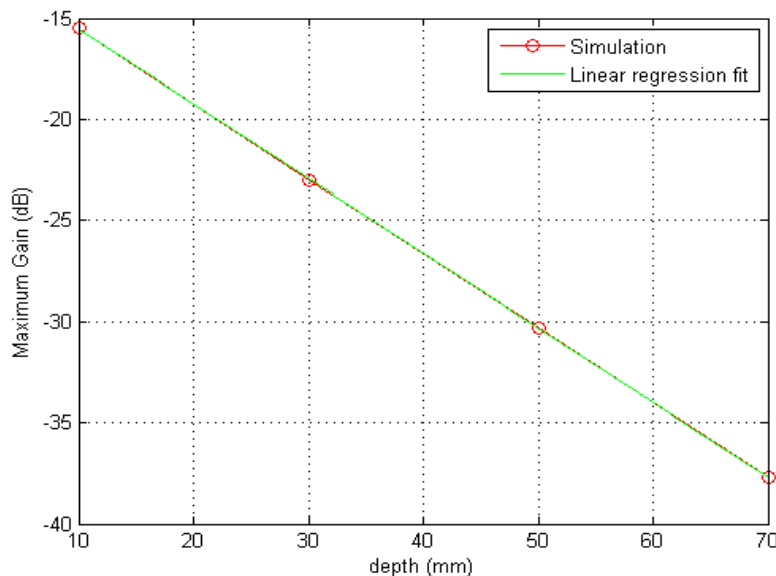
**Figure B.19: Simulated test sleeve dipole maximum gain versus fluid
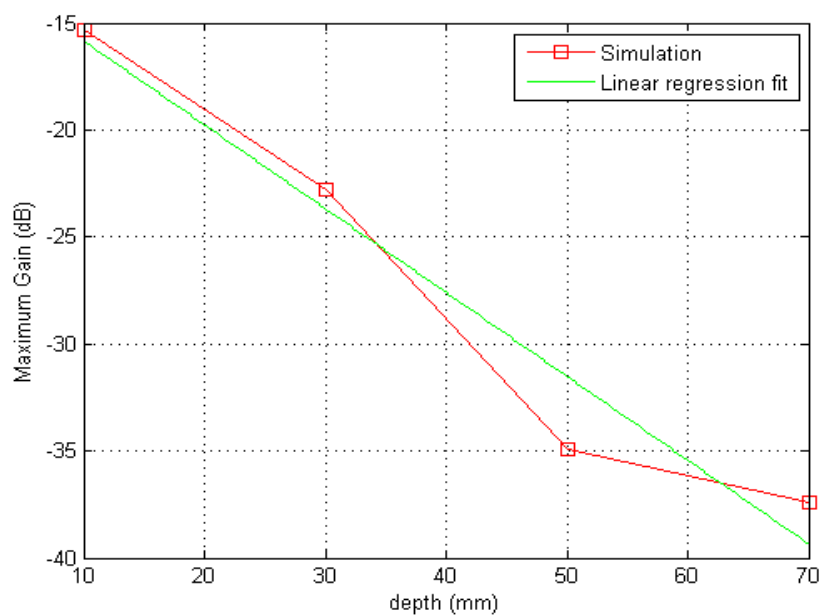thicknesses between antenna and phantom outer**

**Figure B.20: Simulated pacemaker with maximum magnetic loop gain versus fluid
thicknesses between antenna and phantom outer**

When the antenna is inserted inside the phantom, the decrease of the maximum antenna gain is mainly induced by the decrease of the efficiency due to losses in human tissue. The formula which links gain to efficiency is given below:

$$G(\theta,\phi,f) = \eta(f)\left(1 - \left|S_{11}(f)\right|^2\right)D(\theta,\phi,f)$$

where $\eta(f)$ is the efficiency, $S_{11}(f)$ is the return loss, and $D(\theta,\phi,f)$ is the directivity. Table B.5 shows the radiation efficiency of both antennas for various antenna depths. These values confirm the fact that the radiation efficiency of the antenna strongly decreases when it is inserted inside the phantom.

Table B.5: Radiation efficiency of sleeve dipole and magnetic loop for various antenna depths

Implant depth	Sleeve dipole		Magnetic loop	
	linear	dB	linear	dB
In air	0,996	-0,02	0,9567	-0,2
10 mm	8,36e-3	-20,8	8,12e-3	-20,9
30 mm	1,48e-3	-28,3	9,49e-4	-30,2
50 mm	2,78e-4	-35,6	5,68e-5	-42,5
70 mm	5,14e-5	-42,5	5,12e-6	-52,9

The efficiency decrease confirms the dependence of maximum gain. Simulated (and measured) maximum gain levels are slightly higher than those directly predicted considering efficiency losses due to antennas directivity changes introduce by dielectric loading of phantom (see formula above).

B.3.5.4   Comparison between measured and simulated radiation pattern

Comparison between the simulated and measured radiation pattern for the test dipole (sleeve dipole) and the simplified pacemaker with a loop antenna are shown in figure B.21 and figure B.22 respectively. The simulated and measured values are shown as dotted lines and solid lines respectively. The following can be noted.

In open air, the pacemaker loop antenna is approximately 2-3 dB less efficient than the dipole test antenna.
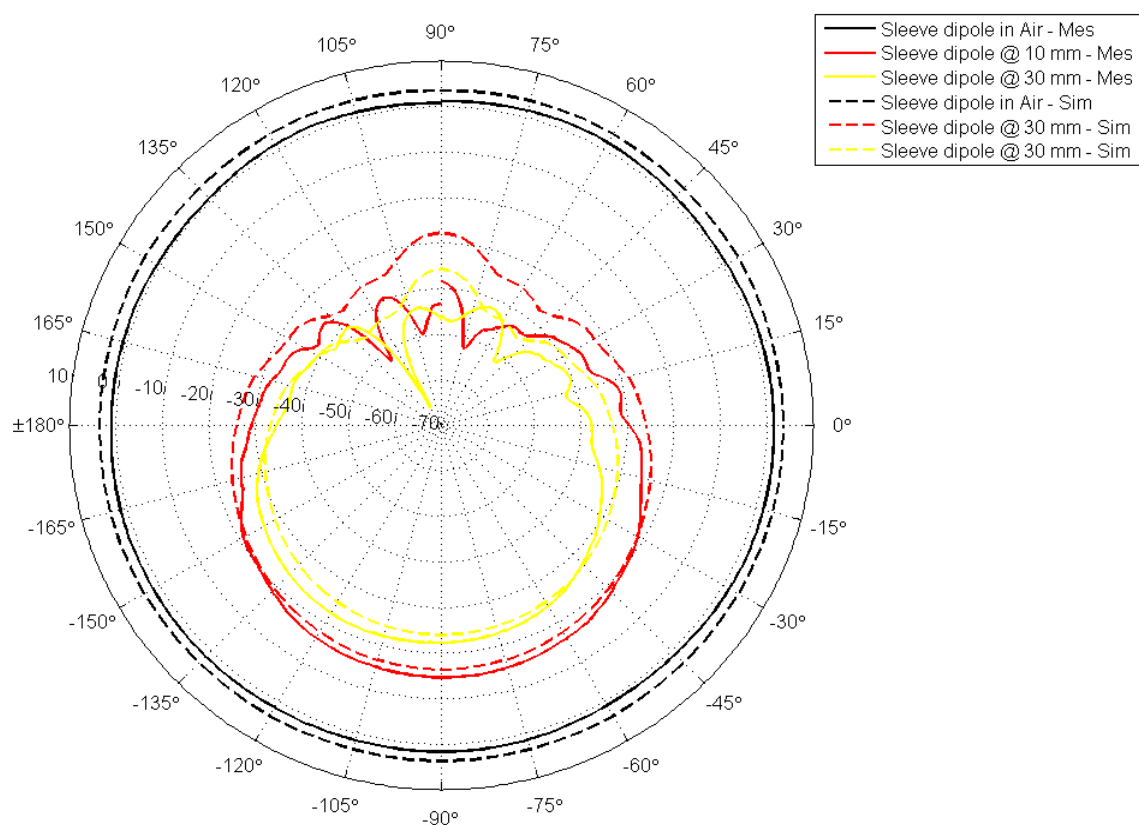

**Figure B.21: Horizontal plane measured and simulated antenna patterns for
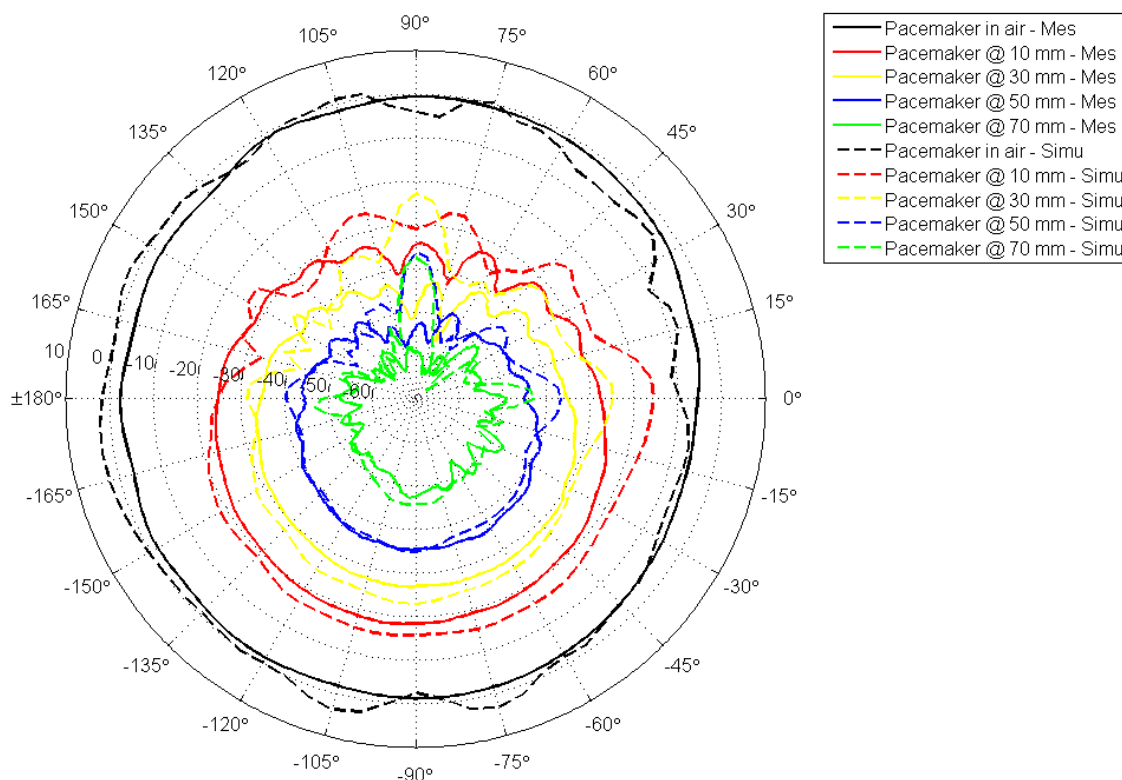a test antenna (sleeve dipole)**

**Figure B.22: Horizontal plane measured and simulated antenna patterns
for a pacemaker loop antenna**

B.3.6 Results on the SAR evaluation

An estimation of SAR levels has been carried out using the CST MWS human model Hugo. To accurately compute the level of absorbed power around the antenna structure, an accurate heterogeneous model is recommended. Taking into account the high attenuation of human tissues at 2,5 GHz, the volume of simulated human model was limited as illustrated in figure B.23 (limitation of computing time). To be closer to real application condition, SAR levels are estimated using the simplified loop antenna mounted onto a pacemaker.
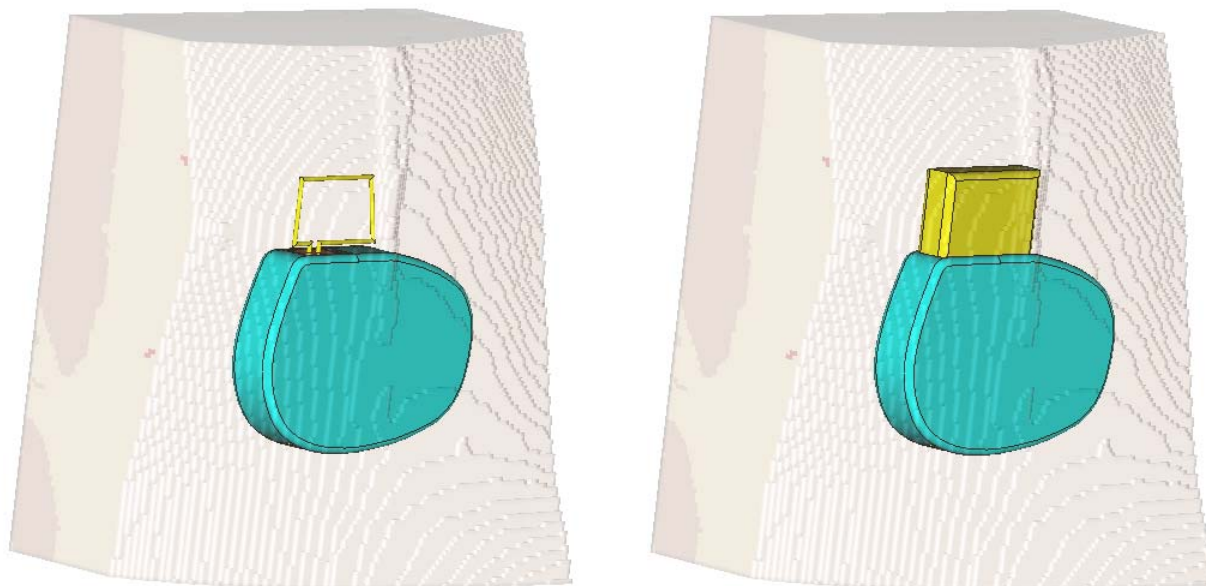
Figure B.23: View of the simplified pacemaker inside the CST human model Hugo

Figure B.24 shows the return loss of the magnetic dipole in the simplified pacemaker inserted inside the human model Hugo. It should be noted that the value of the return loss at 2,48 GHz is roughly -4,12 dB. This implies that if an input power of 1 W from a transmitter with an optimum load impedance of 50 Ohms is injected at the antenna port, it is not completely radiated. The real amount of input power to be considered to compute the SAR is 0,61 W if the input conducted power is 1 W.
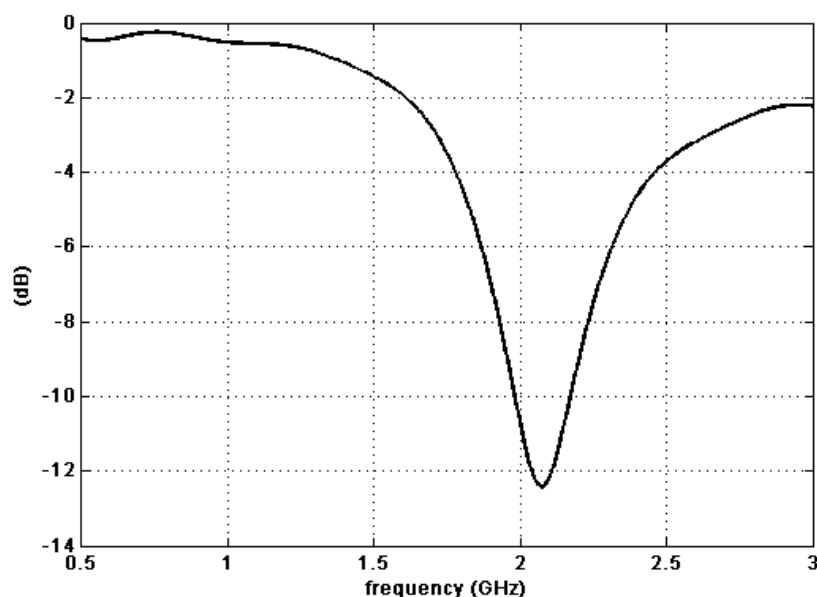

Figure B.24: Return loss of the magnetic dipole placed in the simplified pacemaker inside the CST human model Hugo

Table B.6 synthesizes the values of the maximum SAR obtained accordingly to two average tissue masses. These values of SAR have been obtained for an antenna depth of 15 mm under phantom skin.

Table B.6: Maximum SAR for two averaged tissue mass of 1 g and 10 g for a radiated power of 1 W

Reference input power (W)	$1*\left(1-\left|S_{11}\right|^2\right) \approx 0,61$		1	
Average tissue mass (g)	1	10	1	10
Max SAR (W/Kg)	21,7	5,1	35,47	6,72

The measurement of the SAR makes it possible to evaluate if a system complies with the regulation limitations. For example, concerning mobile phone, 1999/519/EC [i.23] the recommendation limit for an average mass of 1g is 1,6 W/Kg for a reference radiated input power, for a Pir = 2mW.

For a value of input power *Pir* less than 1 W, (the influence of 1W is simulated in table B.6), the level of maximum SAR is to be linearly weighted following the equation:

$$MaxSAR\big|_{Pir} = \frac{Pir}{1W} \cdot MaxSAR\big|_{1W}$$

Inserting MaxSAR for 1W reference power from table B.6 and Pir = 2 mW in the equation above yields:

$$MaxSAR\big|_{Pir} = \frac{0,002}{1} \, x \, 35,47 = 0,0709 \quad W/Kg$$

The SAR levels associated to the envisaged system and the RF power level available seems to be in accordance with EC Recommendation 1999/519/EC [i.23] as if *Pir* = 2 mW, then $MaxSAR_{1g}$ ~0,0709 W/Kg.

The allowed radiated $P_{allowed}$ is calculated as:

$$P_{allowed} = \frac{SAR_{LIMIT}}{MaxSAR_{1g}} \, x \, Pir = \frac{1,6}{0,0709} \, x \, 0,002 = 45,1 \, mW$$

In other words, to reach the EC Recommendation SAR limit of 1,6 W/Kg, the antenna reference input power is to be below 45,1 mW (+16,5 dBm). The intended power to the loop antenna is 10 mW.

A worst case SAR simulation is made with continuous power. It should be noted that power of the planned implantable applications will not have continuous transmit duty cycle and therefore the SAR has to be averaged over a six minute period. This gives an additional substantial margin.

The pictures in the figure B.25 are the SAR distribution around the simplified pacemaker with magnetic dipole inside the human model Hugo for 3 orthogonal planes. On these pictures, one can notice that the maximum SAR is actually concentrated in the vicinity of the magnetic dipole of the simplified pacemaker. All simulations are made for a transmitter conducted power of 1 W and therefore were the results above scaled to the used input power.

Cut plane YZ
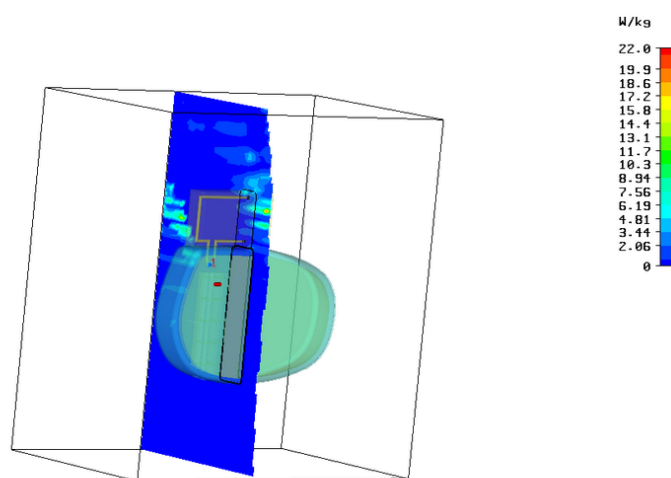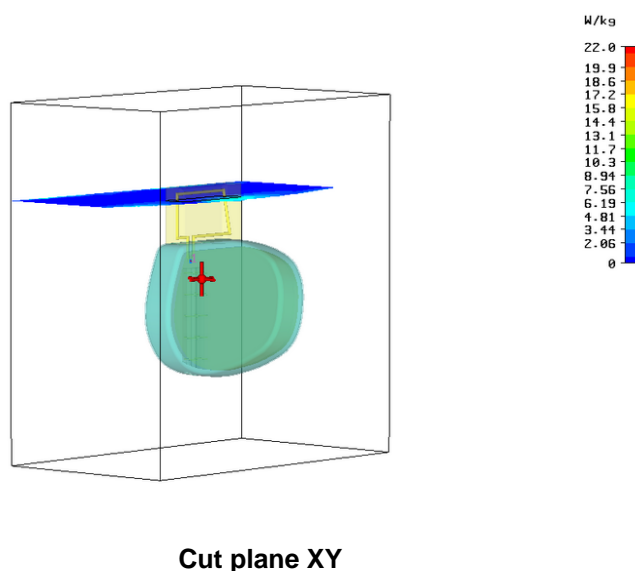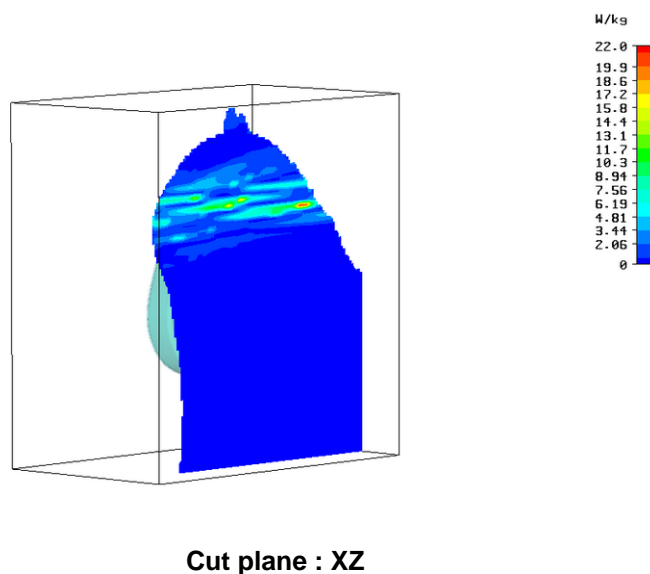
Cut plane : XZ

Cut plane XY

**Figure B.25: SAR distribution around the simplified pacemaker with magnetic loop
for 3 orthogonal cut planes (simulated with antenna input power = 1W)**

B.3.7   Conclusions

The propogation simulation was conducted with an antenna immersed in a fluid phantom.

These simulations were conducted using CST MWS software (HUGO) using the dielectric properties of a fluid phantom with properties close to that of muscle tissue. Two types of antennas were used:

- a test antenna (sleeve dipole); and

- a magnetic balanced loop mounted onto a simplified pacemaker housing.

Simulation of the antenna immersed in the phantom fluid shows a shift of the optimum matched impedance frequency towards lower values. This conclusion has been already validated by the measurements results.

The simulation of the radiation efficiency and pattern show a reasonable degree of correlation with the measured results.

From simulations, it is also noted that a linear decrease in dB of the antenna maximum radiation level is in the far field region. For both antennas, we have expressed the evolution of the maximum antenna gain in a horizontal plane according to the immersion depth in the phantom by the following:

$$G(dB) = G_{air}(dB) - 19,4 - 3,69 * (e - 1) \text{(Sleeve dipole, test antenna)}$$

$$G(dB) = G_{air}(dB) - 19,2 - 3,92 * (e - 1) \text{ (Simplified pacemaker with magnetic loop)}$$

Additionally, the SAR was simulated inside the heterogeneous model of CST MWS called Hugo. The simulations have been conducted only in one part of the model namely the shoulder.

The results obtained concerning the SAR have confirmed that the radiated energy is mainly confined around the magnetic dipole placed in the simplified pacemaker. The SAR values obtained show that using such antenna, the maximum SAR level obtained is in accordance with the EC Recommendation 1999/519/EC [i.23] limit concerning the mobile phone SAR.

B.3.8   Conclusion on Link budget model and SAR

The present document has determined the antennas performances in terms of impedances matching, radiation gain pattern and the SAR level at 2,48 GHz when inserted in human body. A fluid phantom was used to simulate human body tissues.

Two types of antennas were considered:

   a)   Test antenna (sleeve dipole) protected by a radome, and

   b)   Realistic simplified pacemaker with a magnetic loop.

This study was carried out using both EM simulations and measurements.

A reasonable agreement was obtained between measurement and simulations results in spite of different dielectric properties of the fluid phantom: $\varepsilon_r = 52,7 + j\ 12,64$ (for simulation) and $\varepsilon_r = 63,2 + j\ 16,1$ (for measurement).

Tests and simulations have determined the dependence of the effective antenna gain versus the mounting depth inside the phantom (exponential law). Due to the agreement between simulations and measurements, it is possible to use the obtained simulation results for the magnetic loop mounted onto the simplified pacemaker to perform link budget for the implantable device application of interest.

The expression of the antenna gain versus the immersion depth inside the phantom is determined as the following:

$$G(dB) = G_{air}(dB) - 19,2 - 3,92 * (e - 1) \text{ (simulation with the magnetic loop)}.$$

By using this equation the total link budget versus the antenna immersion depth "e" inside the phantom can be determined.
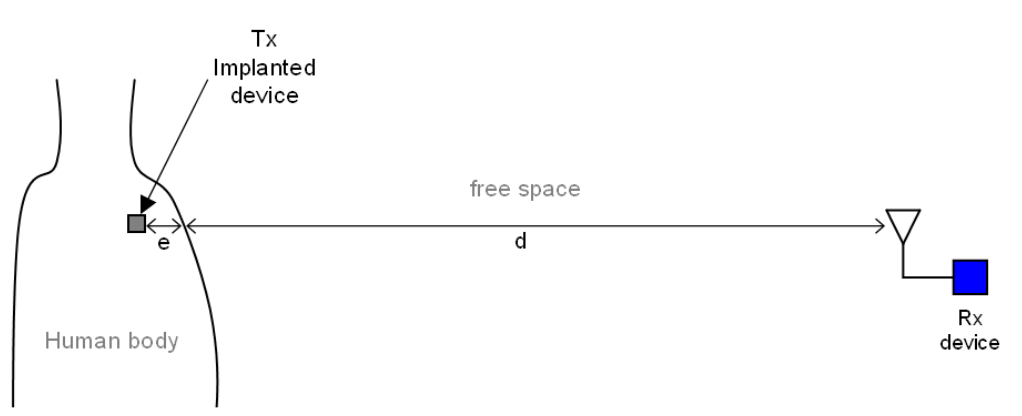

Figure B.26: Illustration of an in-body to off-body communication link

Figure B.26 illustrates an in-body to off-body communication link. Using this configuration, the present document proposes a link budget equation below.

In table B.7, the values reported in green, blue and red colours, are obtained using this formula with $n = 2$ (LOS), $m = -3,92$ and $L_G = -19,2\, dB$.

$$P_{Rx} = P_{Tx} + G_{Rx} + G_{air} + L_G + m*(e-1) + 20*\log 10(\lambda/4\pi) - n*10\log 10(d)$$

with:

- P_{Rx} : the received power (dBm);

- P_{Tx} : the conducted transmit power (dBm);

- G_{Rx} : the antenna gain at the receiver side (dB);

- $G_{Tx,air}$: the antenna gain at the receiver side consider to be measured in free space (dB);

- L_G : the transmitting antenna gain loss introduced by the insertion inside the human body at 1cm (dB). For the simplified pacemaker with magnetic dipole, it is -19,2 dB;

- m : the loss factor representing the increase of transmitting antenna gain loss with the immersion depth. For the simplified pacemaker with magnetic dipole, it is -3,92 dB;

- e : the antenna hiding depth inside the human body (cm);

- $\lambda = C/f$: the wavelength of the propagating wave in free space (m) where C is the propagation velocity in the air (3.10^8 m/s) and f is the frequency (Hz);

- n : the loss factor representing the path loss with the distance. If we consider a LOS link with one path, it will consider the value of 2;

- d : the free space propagation distance (m).

Table B.7: Summary of received power in dBm according to free space propagation loss and antenna gain loss introduced by the human body at 2,5 GHz

$G_{Tx,air}$		0								
G_{Rx}		2								
Free space Loss (dB)		-40,2251 @ d=1m			-46,2457 @ d=2 m			-60,.2251 @ d=10 m		
$L_G + m*(e-1)$ (dB)		-19,2 @ e=1cm	-23,12 @ e=2 cm	-27,04 @ e=3cm	-19,2 @ e=1cm	-23,12 @ e=2 cm	-27,04 @ e=3cm	-19,2 @ e=1cm	-23,12 @ e=2 cm	-27,04 @ e=3cm
P_{Tx} (dBm)	0	-57,42	-61,34	-65,26	-63,44	-67,36	-71,28	-77,42	-81,34	-85,26
	10	-47,42	-51,34	-55,26	-53,44	-57,36	-61,28	-67,42	-71,34	-75,26

According to table B.7, it can be seen that at 2,5 GHz and for a free space LOS propagation of 2 m, the mean expected received power is roughly -67 dBm and -57 dBm for conducted transmit powers of 0 dBm and 10 dBm respectively. This table assumes maximum antenna gain and does not take into account body positioning, polarization or multipath fading losses.

A similar analysis could be performed for the external to implantable device communication link.

B.3.9 Receiver parameters and maximum range

The following receiver parameters are assumed in the link budget, see table B.8.

Table B.8: Receiver parameters and maximum communication range

Bandwidth	100 kHz	1 MHz
KTB	-123,9 dBm	-113,9 dBm
NF	10 dB	10 dB
S/N ratio	12 dB	12 dB
Receiver sensitivity	-101,9 dBm	-91,9 dBm
Received signal @ 10m (from table B.7)	-75,3 dBm	-75,3 dBm
Margin at a range of 10 m	26,6 dB	16,6 dB
Maximum range at a roll-off of 35 * log (d/10)	57,5 m	28,7 m

The received signal at 10m from table B.7 assumes 3cm implant depth.

It should be noted that the maximum range for a conducted power of 10 dBm is calculated based on the margin at 10m and a roll-off of 35 x log (d/10) beyond 10 m.

B.3.10 Channel access parameters

The proposed medical implant system using the band 2,4835 GHz to 2,5000 GHz may require LBT and AFA for efficient operation and compatibility with other services.

The prime users of the band 2,4835 GHz to 2,5000 GHz are "GlobalStar" and "Iridium", which are satellite communication systems with mobile subscriber radios, with a small Europe customers base.

Global Star is using the widest system bandwidth of 16,5 MHz. Iridium is using a lower bandwidth of 10,5 MHz.

Global Star frequencies:

  a)   Mobile transmit channels (uplink) are in the band 1,610 GHz to 1,6265 GHz.

  b)   Mobile receive channels (down link) are in the band 2,4835 GHz to 2,5000 GHz.

Consequently, the duplex spacing for Global Star is D_s = 2 500 - 1 626,5 = 873,5 MHz.

Iridium is using the same duplex spacing.

As both are two frequency duplex systems, a special technique may be required if it is considered that LBT is needed to protect these primary services.

The received signal from the satellite at the higher frequency may not be possible to detect particularly for an indoor medical receiver system. In this case the transmitted signal from earth can be detected at the lower frequency band.

Figure B.1 shows an example of a receiver with simultaneous dual band LBT capability. The key here is to use a 1st IF frequency of ½ * D_s. For a duplex spacing D_s of 873,5 MHz the resulting IF frequency is 436,75 MHz and the entire IF amplifier and detector system can be implemented by a off- the shelf integrated circuit intended for SRDs.

The Receiver Signal Strength Indicator (RSSI) is determining the received field strength. The data detector is determining the type of signal received either Global Star, Iridium of medical equipment.
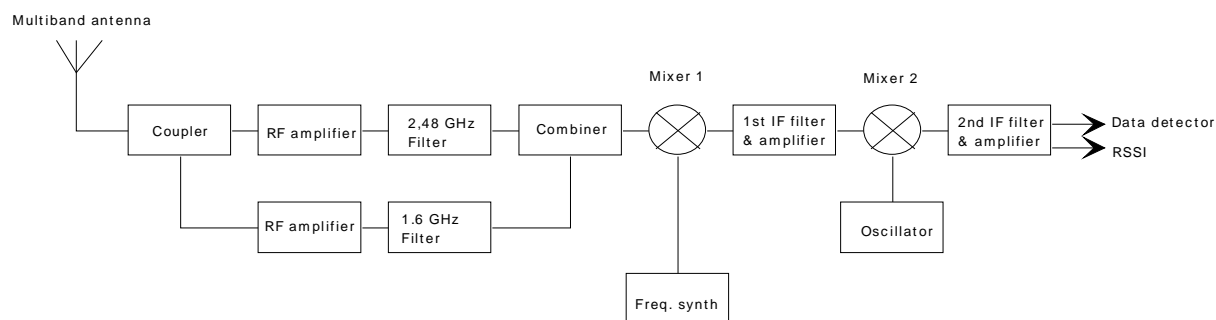
Figure B.27: Block diagram for receiver with dual band LBT capability

Alternatively to the one receiver implementation shown in figure B.27, two separate receivers can be used but at a higher cost.

B.4   Information on relevant standard(s)

There is no current ETSI standard that covers the operational characteristics proposed for these bands. ERM - TG30 will undertake development of standards to cover the operation of the devices described in the present document.

Annex C:
Expected sharing and compatibility issues

It is proposed to obtain sharing with Global Star and Iridium by using LBT and AFA access protocol on the satellite downlink. As Global Star and Iridium are using duplex communication it also possible to listen to the satellite uplink if the downlink does not provide the protection.

C.1   Current ITU and European Common Allocations

The European Common Allocation Table (ECA) shows the following information:

Table C.1: European Common Allocation Table

FREQUENCY BAND	ALLOCATIONS	APPLICATIONS
A. 2 300,0 MHz to 2 400,0 MHz	FIXED MOBILE Amateur Radiolocation	Aeronautical telemetry Land mobile SAP/SAB and ENG/OB Amateur (2 300,0 MHz to 2 450,0 MHz)
B. 2 483,5 MHz to 2 500,0 MHz	FIXED MOBILE MOBILE-SATELLITE (space-to-Earth)	Fixed links ISM Land mobile MSS Earth stations SAP/SAB and ENG/OB
C. 2 700,0 MHz to 2 900,0 MHz	AERONAUTICAL RADIONAVIGATION Radiolocation	Aeronautical navigation Radiolocation (civil) Radiolocation (military) Weather radar
D. 2 900,0 MHz to 3 100,0 MHz	RADIOLOCATION RADIONAVIGATION	Aeronautical navigation Radiolocation (civil) Radiolocation (military) (2 900,0 MHz to 3 500,0 MHz)
E. 3 100,0 MHz to 3 300,0 MHz	RADIOLOCATION Earth Exploration-Satellite (active) Space Research (active)	Radiolocation (military) (2 900,0 MHz to 3 500,0 MHz) Active sensors (satellite)
F. 3 300,0 MHz to 3 400,0 MHz	RADIOLOCATION	Radiolocation (military) (2 900,0 MHz to 3 500,0 MHz)

Additional information is given in CEPT/ERC Report 25 [i.4].

C.2   Sharing and compatibility studies (if any)

The following sharing and compatibility issues are foreseen.

Table C.2: Existing applications and the related interference criteria

Frequency band alternatives	Allocation	Application	Interference criteria for victim	Comments
A. 2 483,5 MHz to 2 500,0 MHz	FIXED MOBILE MOBILE-SATELLITE (space-to-Earth)	Fixed links ISM Land mobile MSS Earth stations SAP/SAB and ENG/OB	FS: I/N = -20 dB ISM: I/N = 0dB LM: I/N = 0 dB MSS: -10 dB ENG/OB: -10 dB	
B. 2 700,0 MHz to 2 900,0 MHz	AERONAUTICAL RADIONAVIGATION Radiolocation	Aeronautical navigation Radiolocation (civil) Radiolocation (military) Weather radar	AN: -20dB RN: -6dB RN:- 6dB WR: -6dB	
C. 2 900,0 MHz to 3 100,0 MHz	RADIOLOCATION RADIONAVIGATION	Aeronautical navigation Radiolocation (civil) Radiolocation (military) (2 900,0 MHz to 3 500,0 MHz)	AN: -20dB RN: -6dB RN: - 6dB	
D. 3 100,0 MHz to 3 300,0 MHz	RADIOLOCATION Earth Exploration-Satellite (active) Space Research (active)	Radiolocation (military) (2 900,0 MHz to 3 500,0 MHz) Active sensors (satellite)	RN: -6dB AS: -10dB	
E. 3 300,0 MHz to 3 400,0 MHz	RADIOLOCATION	Radiolocation (military) (2 900,0 MHz to 3 500,0 MHz)	RN: -6dB	

C.2.1   Compatibility with services in neighbouring bands

Commission Decision 2008/477/EC [i.47] requires Member States to designate and make available the 2 500 MHz to 2 690 MHz band for terrestrial systems capable of providing electronic communications services. ECC Decision (05) 05 [i.48] defines a bandplan with the frequency range 2 500 MHz to 2 570 MHz used for uplink.

TS 125 104 [i.49] defines two power classes for WCDMA terminals operating in the 2,6 GHz band, with nominal output powers of +21dBm and +24 dBm. Other terminals that are likely to be used in this band have similar transmit powers.

The traffic on 2,6 GHz band is expected to comprise a large amount of data as well as speech calls. Therefore, a terminal used by a patient could transmit when adjacent to the head or any part of the body (in a pocket, for example). For non-real-time data services, the user may not be aware when it transmits. For some services, the period of transmission could be extended (effectively continuous from the perspective of interference). Terminals can also be used by other users in the proximity of the patient.

Any implantable medical device intended for operation in these bands will need to have sufficient immunity to transmissions within the 2 500 MHz to 2 690 MHz band that the clinical condition or the safety of patients is not compromised. In the case of the 2 483,5 MHz to 2 500 MHz band, it is not possible to use a filter to achieve this, because there is no separation between the two bands.

Annex D:
Bibliography

- C.H. Durney, M.F. Iskander: " antenna handbook", in Antennas for medical applications, New york, Van Nostrand, 1988, Ch. 24.

- A. Rosen, M.A. Stuchly, A.V. Vorst: "Applications of RF/microwaves in medicine", IEEE Trans. Microwave Theory techniques, vol. 50, pp. 963-974, March 2002.

- H.F.S.S.: Ansoft corporation, Boulder, U.S.A.

- Peter Monk: "Finite element methods for Maxwell's equations"*,* Numerical Mathematics and Scientific Computation, Oxford University Press, New York, 2003.

- T. Weiland: "Maxwell's grid equation", Frequenz, vol. 44, n°1, 1990, pp. 9-19.

- J.D. Kraus, R.J. Marhefka: "Antennas for All applications", third edition, Mc graw-Hill, 2002.

- Koichi Ito: "Recent antenna technology for medical applications", EUCAP 2007, Edinburgh (Scotland), Nov. 2007.

History

Document history		
V1.1.1	November 2008	Publication