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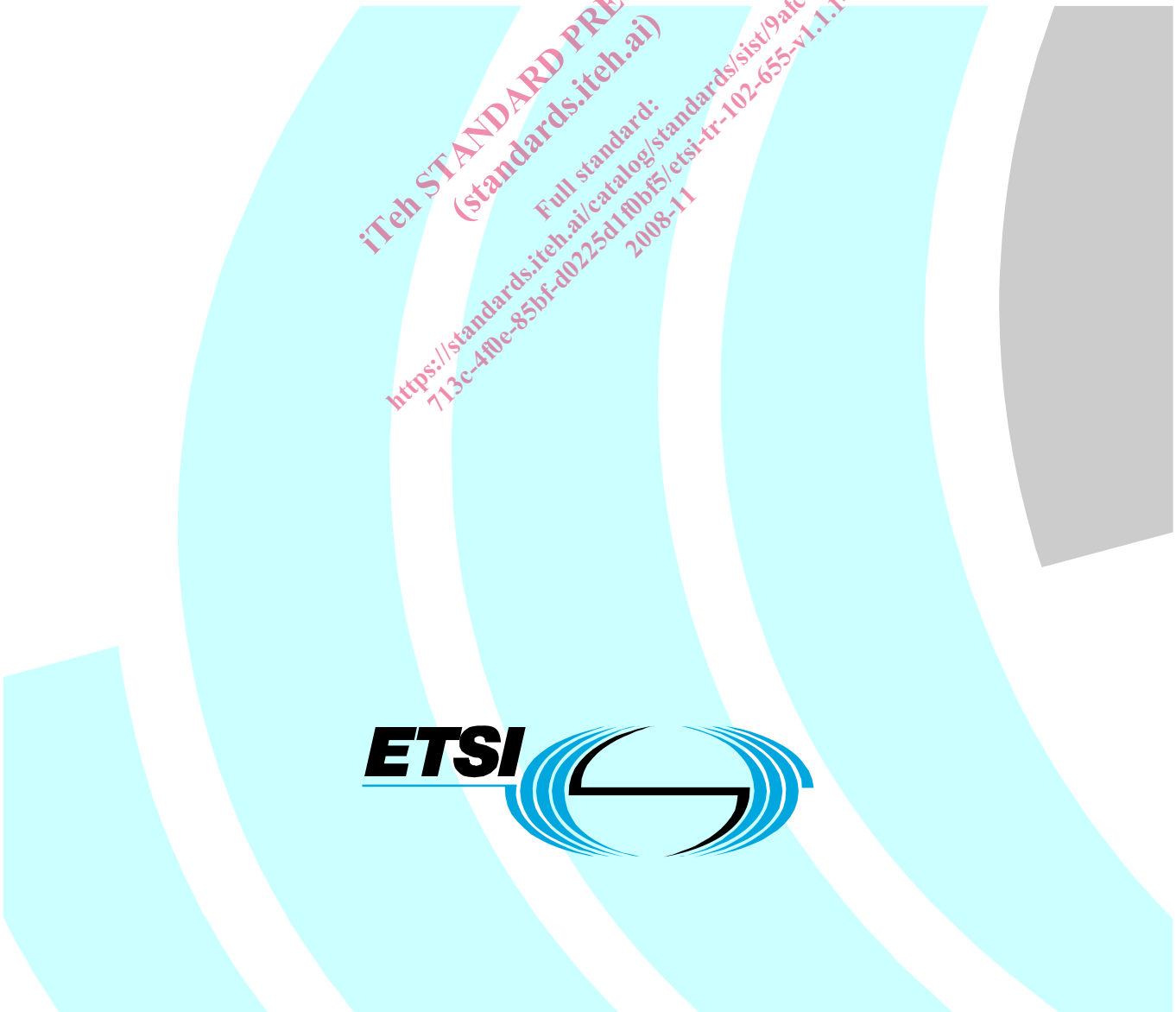
Technical Report

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



Reference

DTR/ERM-RM-252

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Contents

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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:
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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 Flugsichering 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].