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Foreword

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

Introduction

ECC/ERC Recommendation 70-03 [i.4], annex 12 and EC Decision "2006/771/EC [i.9] on harmonization of the radio spectrum for use by short range devices" lists frequency bands and legislative parameters for Active Medical Implants (AMI) and their associated peripherals. ETSI has published standards based on the legislative parameters specified in ECC/ERC Recommendation 70-03 for the bands that have been harmonized under the R&TTE Directive.

Rapid developments of new technologies and applications for active medical implants are occurring that require either modification of an existing spectrum allocation or a new allocation of spectrum for their operation. This document proposes to accommodate this evolving technology that is related to new very low power cochlear implant systems to allow their operation in the 2 483,5 MHz to 2 500 MHz band. Providing spectrum for this industry will allow product developers of these very low power cochlear implant systems to design, develop, and quickly bring new and innovative products to the market while avoiding any harmful interference to other services and equipment.

The present document proposes to operate these devices in the existing designation in ECC/ERC Recommendation 70-03 [i.4], annex 12 band (e) authorizing use of the 2 483,5 MHz to 2 500 MHz band for low power active medical implant (LP-AMI) devices. Currently, this allocation restricts devices that are peripheral to the implant to indoor operation only. However, as discussed later, for the application of cochlear implant system operation, outdoor operation of peripheral devices is required. It is the eventual goal to pursue designation of this band as a world-wide frequency band for LP-AMI, including cochlear implants and related peripheral devices, to allow patients with these implants to travel freely internationally.

The present document is being developed by ERM_TG30 and should ultimately be approved for publication by ERM at its 49th meeting, 2013.

1 Scope

The present document defines the necessary adaptation for radio frequency spectrum usage for low power active medical cochlear implants and related peripheral radio systems that will operate in the band 2 483,5 MHz to 2 500 MHz. The present document proposes to build on the existing regulations to permit cochlear implant systems in the above band under a harmonized regulatory framework on a license exempt arrangement.

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 specific references, only the cited version applies. For non-specific references, the latest version of the reference document (including any amendments) applies.

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

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 necessary for the application of the present document.

Not applicable.

2.2 Informative references

The following referenced documents are not necessary for the application of the present document but they assist the user with regard to a particular subject area.

[i.1] Cochlear Implants.

NOTE: Available at http://www.nidcd.nih.gov/health/hearing/coch.asp.

[i.2] Results of the yearly inquiry on implantations; European Association of Cochlear Implant Users; CIU 2010; Ruud van Hardeveld.

[i.3] Cochlear implants in deaf children; Report drawn up by Professor Gunilla Preisler; Department of Psychology; Stockholm University.

[i.4] ECC/ERC Recommendation 70-03: "Relating to the use of Short Range Devices (SRD)"; Annex 12 - Active Medical Implants and their associated peripherals - 7 May 2012.

[i.5] ERC Report 149 (September 2010): "Analysis on compatibility of Low Power-Active Medical Implant (LP-AMI) applications within the frequency range 2360-3400MHz in particular for the band 2483,5-2500 MHz with incumbent services".

[i.6] IEEE, G.A. Conway: "Low-profile microstrip patch antenna for over-body surface communication at 2.45 GHz".

NOTE: Available at http://www.4taconic.com/dielctrc/pdf/technicalarticles--patch_antenna_body_communication.pdf.

[i.7] 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.8] CEPT/ERC Recommendation 74-01:" Unwanted emissions in the spurious domain".

[i.9] EC Decision 2006/771/EC on harmonization of the radio spectrum for use by short range devices.

[i.10] Wireless link budget analysis (01/09/2012).

NOTE: Available at http://www.tranzeo.com/allowed/Tranzeo_Link_Budget_Whitepaper.pdf.

[i.11] Laurens Roelens, promoter Luc Martens, Ghent University: "Path loss model for wireless narrowband communication near biological tissue" (Sixt FirW PhD Symposium, Faculty of Engineering, paper nr. 120, 30 November 2005).

[i.12] J.Ryckaert, P. De Doncker, R. Meys, de Le Hoye and Stéphane Donnay: "Channel model for wireless communication around human body" (Electronic Letters, 29th April, 2004 Vol.40 No.9).

[i.13] J. Keshvari, S. Lang: "Comparison of radio frequency energy absorption in ear and eye region of children and adults at 900, 1800 and 2450MHz" (Physics in Medicine and Biology 50 (2005) 4355-4369).

[i.14] ERC Report 150 (September 2010): "Compatibility studies between RDSS and other services in the band 2483,5-2500 MHz".

[i.15] ERC Report 165 (May 2011): "Compatibility study between MSS complementary study between complementary ground component operating in the bands 1610.0-1626.5 MHz and 2 483,5-2 500.0 MHz and other systems in the same bands or in adjacent bands".

3 Definitions, symbols and abbreviations

3.1 Definitions

For the purposes of the present document, the following terms and 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 including any accessories or software for its proper functioning

Cochlear Implant (CI): implantable portion of the LP-CIS or the surgically implanted active medical device that stimulates the auditory nerve directly by electrical pulses or indirectly by mechanical stimulation or vibration

Cochlear Implant System (CIS): active implantable medical system consisting of external peripheral device(s) together with a low power active medical implanted device that provides stimulation to the patient's cochlea

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.

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

Low Power Active Medical Device Peripheral (LP-AMD-P): low power radio part of medical equipment outside the human body that communicates with the CI

NOTE: LP-AMD-P may only communicate with the CI

Low Power Cochlear Implant System (LP-CIS): low power radio part of the cochlear implant system (CIS), which is intended to be totally or partially introduced, surgically or medically, into the human body, and which is intended to remain after the procedure

Low Power Body Worn Device (LP-BWD): external portion of the LP-CIS in close proximity (6 cm or less) to the CI and is used to communicate with the CI

3.2 Symbols

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

dB	deciBel
dBi	deciBel relative to an isotropic radiator
dBm	dB referred to 1mW
g	gram
f	frequency
mW	milliwatt
P	Power
R	radius, distance
t	time

3.3 Abbreviations

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

ABI	Auditory Brainstem Implant
AFA	Adaptive Frequency Agility
AIMD	Active Implantable Medical Device
AMI	Active Medical Implants
ANSI	American National Standards Institute
ASK	Amplitude Shift Keying
BER	Bit Error Rate
BPSK	Binary Phase Shift Keying
BTE	Behind-The-Ear
C/I	Carrier-to-interference ratio
CEPT	Conference of European Postal and Telecommunications Administration
CI	Cochlear Implant
CIS	Cochlear Implant System
CPFSK	Continuous Phase Frequency Shift Keying
CRC	Cyclic Redundancy Check
DACI	Direct Acoustic Cochlear Implant
DPSK	Differential Phase Shift Keying
e.i.r.p./EIRP	effective isotropic radiated power
e.r.p./ERP	effective radiated power
ECA	European Common Allocation Table
ECC	Electronics Communications Committee
ENG/OB	Electronic News Gathering/Outside Broadcasting
ERC	European Radiocommunications Committee
FDA	Food and Drug Administration
FEC	Forward Error Correction
FHSS	Frequency Hopping Spread Spectrum
FS	Fixed Service

FSK	Frequency Shift Keying
FSPL	Free Space Path Loss
GMSK	Gaussian Minimum Shift Keying
ICNIRP	International Commission on Non-Ionizing Radiation Protection
ISM	Industrial Scientific Medical applications
ITU	International Telecommunications Union
LBT	Listen Before Talk
LM	Land mobile
LNA	Low Noise Amplifier
LP-AMD-P	Low Power Active Medical Device Peripheral
LP-AMI	Low Power Active Medical Implant
LP-BWD	Low Power Body Worn Device
LP-CIS	Low Power Cochlear Implant System
MBANS	Medical Body Area Network System
MD	Medical Device
MEI	Middle Ear Implant
MSS	Mobile Satellite System
MTP	Monosyllable, Trochee, Polysyllable Test
OOK	On-Off Keying
QPSK	Quadrature Phase Shift Keying
R&TTE	Radio and Telecommunications Terminal Equipment
REC	RECommendation
RF	Radio Frequency
RX	Receive
SAP/SAB	Services Ancillary to Programme making/Services Ancillary to Broadcasting
SAR	Specific Absorption Rate
sFHSS	Slow Frequency Hopping Spread Spectrum
SRD	Short Range Device
TBCI	Transcutaneous Bone Conduction Implant
TDD	Time Domain Duplex
TTE	Telecommunications Terminal Equipment
TX	Transmit
US	United States

4 Comments on the System Reference Document

The opinion of the Netherlands and France administrations is that MBANS and all LP-AMI devices coexist in the band 2 483,5 MHz to 2 500 MHz on the basis of equal access to the spectrum. The compatibility issues if any will be addressed in the respective standards.

The opinion of the BMWi is that for MBANs and LP-AMI equipment operating in the band 2 483,5 MHz to 2 500 MHz an adequate spectrum sharing mechanism should be implemented to facilitate sharing between these technologies and applications and in case of congestion, to ensure equal access.

5 Executive summary

New very low power cochlear implant technologies offer solutions for profound hearing loss for moderate conductive or sensorineural hearing losses.

Currently, there is no spectrum, shared or otherwise which is designated for use by the cochlear implant industry in Europe.

The present document proposes to build on the existing regulations to permit cochlear implant systems in the 2 483,5 MHz to 2 500 MHz band under a harmonized regulatory framework on a license exempt arrangement.

Cochlear implant systems include low to moderate data rate transfers at 1 Mbps to 2 Mbps symbol rate between the different external devices and the implantable portion of the LP-CIS at low RF power and duty cycles (0,1 % to 12,5 %) for indoor and outdoor operation.

5.1 Background information

Europe is facing the challenge of delivering improved medical care to all its citizens including those afflicted with hearing loss. Worldwide hearing loss affects approximately 219 thousands of new individuals yearly and in Europe there are 80 thousands afflicted [i.2]. Modern technology can greatly improve the quality of life of individuals with hearing loss due to damage to any of several parts of the human hearing system such as the cochlea or aural nerve. These patients are, or will become, part of a growing mobile community of individuals implanted with some type of active medical implant to treat their hearing loss affliction. Individuals ranging in age from infants 1 year old to the elderly of any age with severe or profound hearing loss are candidates, as determined by medical authorities, for wireless active cochlear implant systems of one type or another. Suitable spectrum is required for the operation of these emerging wireless devices.

A wireless active medical implant system for hearing impaired patients is composed of devices that are implanted in the body communicating with related external support peripheral devices. These devices will require the capability for communications with each other on and as needed basis whether they are outdoors or indoors under the provisions currently implemented in ECC/ERC Recommendation 70-03, annex 12 band (e) [i.4], external LP-AMI peripheral units are only permitted to be used in indoor environments. This constraint limits the full utilization of the band by the medical industry supporting therapy for hearing impaired patients because it limits the availability of system applications and devices that can be deployed in the band. An example of a cochlear implant system that is basically precluded from use of the band are peripherals delivering commands to an implant for controlling, monitoring or programming the implant. Another exclusion is the transfer of stimulation data and/or control data from the external LP-CIS portion to the implantable portion in the near field allowing external hearing processing.

The full potential for the treatment and maximum achievement of the therapeutic value of cochlear implant systems require communications between external and implanted devices to be accommodated in the outdoor as well as the indoor environment.

Current cochlear implant devices are typically used in home environments with additional ambulatory usage in the patient's normal daily activity environment. Active medical implant device development for the profoundly deaf includes a communication link between devices such as hand held, body-worn, remote control, monitoring equipment and the fully implanted cochlear implant for patient use at home, both in- and outdoor. Devices intended for cochlear implant programming are mainly intended for indoor use.

All of the above rely on spectrum providing a high quality of service for wireless connectivity.

5.2 Market information

5.2.1 Cochlear implants

According to the U.S. Food and Drug Administration (FDA), as of December 2010, approximately 219 000 people worldwide have received cochlear implants [i.3] whereof 80 000 are European cochlear implant recipients [i.2]. As progress is made in development of hearing processing algorithms, these devices are seeing increased acceptance by hearing impaired people. In addition, very young children are now able to receive a cochlear implant which was previously not permitted. It is now realized that children born with significant hearing deficiencies have much better results when receiving implants as early as 1 year of age [i.3]. The number of new implants per year in Europe is of the order of 15 000 to 20 000 [i.2].

Cochlear implants consist of a device that is typically inserted in an area behind the ear at a depth that precludes the appearance of a protrusion under the skin. The implant depth is typical 15 mm measured from skin to the centre of the implant body. This device has a very thin cable attached to it that is about 15 cm to 20 cm long containing up to 23 wires with electrodes attached to the end of each wire. This cable is inserted into the cochlea with a special tool such that the various electrodes attached to the wires are in contact with the aural nerve in the cochlea. These electrodes are stimulated in various ways as a function of proprietary software that is developed by each manufacturer. To date there are at least 3 selectable programs based on differing algorithms for unique applications as a function of the environment the patient is in. For example, a noisy environment will have a program that reduces the impact on understanding that results from the noise. Other programs have been developed that conduct information sequentially in serial fashion to stimulate the aural nerve while others conduct information simultaneously in a parallel fashion for stimulating the aural nerve. Currently a body worn speech processor stores multiple programs, selectable by the patient, for various types of environments that are tailored to the requirements of the individual patient. Due to its very small size, these speech processors are controlled by a hand held device that can select the operating channel, switch program types, adjust relative volume level among other things.

There are several emerging technologies for use by the profoundly deaf that will benefit from anywhere, anytime communications capabilities. For example in addition to conventional cochlear implants, brain stem stimulation, direct acoustic cochlear and transcutaneous bone conducting implant devices are emerging in the marketplace. Each has a unique capability to treat hearing disorder related to neural damage and conductive disorders that are not treatable by any other medical technology. Active implantable cochlear devices are the only technology capable of providing beneficial therapies that are uniquely required to preserve and enhance the quality of life for patients in this group. Further details on implanted devices are given in clause A.1.

5.3 Radio spectrum requirement

5.3.1 Justification

The advent of technology permitting implanted devices to communicate with external devices at distances of a few meters over extended periods of time is opening a new era in medical treatment for hearing impaired patients. Considerations of tissue loss, implant battery life, antenna design existing technology, and ambient signal levels in the selected spectrum resulted in the selection of the band 2 483,5 MHz to 2 500 MHz as very suitable for implant technology. This suitability was recognized by CEPT resulting in designating the band for use indoor by implant technology. The existing designation of the band for use by implant devices can be leveraged to permit cochlear implants to access the spectrum at a very low power (≤ 1 mW) and low duty cycle on a mobile patient basis. By making the band available for cochlear implants and related peripheral device, the industry can leverage the existing digital technology developed for the 2 400 MHz to 2 483,5 MHz consumer market to provide cost benefits to the patient, the medical insurance industry and government reimbursement/insurance programs. There is no intention to request for external to external communication inside the band 2 483,5 MHz to 2 500 MHz.

5.3.2 Technical developments

The ability to remotely monitor and optimize the operation of a patients system will become the standard of care for patients as they go about in their daily environments. There are on-going development efforts aimed at enabling remote control and re-programming of cochlear implant and related active medical implants by incorporating RF telemetry into applications that support them. In point of fact, as the physical size of cochlear implants and associated devices continue to evolve to smaller and smaller size, remote control is increasingly necessary. Remote monitoring demand will continue to grow with connectivity to the internet interacting with an on-line audiologist. Such techniques will allow hearing impaired patients to contact professional help anytime and anywhere.

As remote monitoring/programming becomes increasingly available, patients will require systems that allow them to interact with the system by wireless communication with the implanted device. This capability will also allow the collection of data from the implant that can be used by the audiologist to improve the ability of the individual patient to recognize speech. The evolution of this technology including parametric control and monitoring of the cochlear implant operating conditions does however, depend on the availability of suitable spectrum permitting outdoor as well as indoor connectivity.

Totally implantable or mostly implantable cochlear implant systems contain an implanted battery however the latter does not contain an implantable microphone and advanced means for processing towards the necessary stimulation data. This creates the need of a near-field communication link operating inside the band 2 483,5 MHz to 2 500 MHz between the closely allocated LP-AMD-P and the LP-CIS.

5.4 Regulations

5.4.1 Long-term regulations

Long-term regulations for LP-CIS (cochlear implant system) in wireless implantable medical applications need to include the following:

- Licence exemption.
  - LP-CIS has interference mitigation techniques (such as LBT, AFA and others) to protect primary and secondary users.