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Electromagnetic compatibility and Radio spectrum Matters (ERM); System Reference Document (SRDoc); Short Range Devices; Low Power Cochlear Implant Systems (LP-CIS) operating in the band 2 483,5 MHz - 2 500 MHz

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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 ($\leq$ 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.

- LP-CIS uses robust interference mitigation techniques to prevent data loss or maintain data integrity (such as FEC, CRC) to protect itself against interference from the primary and secondary services.

- Support for data rate variability as a function of range.

- TDD communication mode:

  - External communication including control and program data to implant and vice versa between the LP-AMD-P and the CI.

  - External communication including control and program data to implant and vice versa between the LP-BWD and the CI.

  - LP-BWD to CI communication including stimulation data in which an implantable battery is present in the system.

  - Implant to implant communication.

Additional spectrum for these very limited deployment medical systems with low user density and moderate data rate requirements will permit controlling the LP-CIS and downloading patient data transferred from implants to storage facilities and from a peripheral device to a central processing system for further review and analysis.

The moderate data rate implies transfers with a typical symbol rate of 1 Mbps to 2 Mbps at low RF power and low duty cycles (0,1 % to 12,5 %) for indoor and outdoor operation.

The accumulation of a large database of retrieved data over time can be analysed by physicians and/or audiologist to best treat a patient's condition. This will improve the therapy delivered by the implant by tailoring its sound processing to the specific hearing capabilities and needs of each individual patient in lieu of the current empirical practice.

5.4.2 Current regulations in ERC/REC 70-03, annex 12 sub-band (e)

Table 1: Current regulations in ERC/Recommendation 70-03 [i.4], annex 12 sub-band (e)

Frequency Band MHz	Power	Spectrum Access and Mitigation Requirements	Channel Spacing	ECC/ERC Deliverable	Notes
2 483,5 MHz to 2 500 MHz	+10 dBm	LBT+AFA and ≤ 10 % duty cycle. Equipment to access the spectrum as described in the applicable harmonized standard or any other equivalent spectrum access mechanism	1 MHz	ECC Report 149 [i.5]	For Low Power Active Medical Implants and associated peripherals, covered by the applicable harmonised standard. Individual transmitters may combine adjacent channels on a dynamic basis for increased bandwidth higher than 1 MHz. Peripheral units are for indoor use only.

5.4.3 Proposed regulation and justification

The ECC is requested to modify the above provisions for low power active implantable medical devices to permit cochlear systems to operate outdoors as well as indoors at a power level of 0 dBm. This power level is comparable with current outdoor emission levels of 0 dBm that are emitted from operation of indoor devices under the current regulatory structure.

This band has been made available for indoor operation of implant systems at power levels up to 10 dBm with a duty cycle of $\leq$ 10 % for external peripherals. The interference analysis for operation of that system detailed in ECC Report 149 [i.5] concluded that taking a conservative 10 dB wall attenuation into account the radiated level of 0 dBm outdoor together with LBT+AFA and the duty cycle from the operation of the indoor device system would not pose a threat of interference to existing primary users. Based on the proposed similarity of technical parameters between cochlear systems and other implant systems, there is an expectation that cochlear systems with an EIRP of 0 dBm outdoor will not be a source of harmful interference.

It is proposed that cochlear implants and related active implantable medical device communications equipment be permitted to operate with the following specifications under a licence-exempt regulation, see table 2.

It is proposed to enable remote controlling and re-programming of the cochlear implant with the exclusion of audio communication and secondly to transfer stimulation data and/or control data from the external LP-CIS portion to the implantable portion in the near field.

Table 2: Proposed regulatory parameters

Candidate frequency bands	Band Edge Mask width	Maximum radiated power e.i.r.p.	Spectrum Access and Mitigation Requirements	Maximum Duty Cycle	Minimum Number of channels	Referred links See figure B.1.1.1
2 483,5 MHz to 2 500 MHz	16,5 MHz	0 dBm	LBT+AFA sFHSS	10 % 0,1 %	8	Any link between LP-AMD-P and CI (Link A)
2 483,5 MHz to 2 500 MHz	16,5 MHz	-27 dBm	Adaptive sFHSS	12,5 %	8	Link between LP-BWD and CI - whisper mode (Link B)

The proposed radiated power is based on link budget calculations which include attenuation of the human body at an operating frequency of 2 490 MHz, for further details see clause B.3.

The whisper mode is only to be used for transcutaneous communication in the near field between LP-BWD and CI and mainly targets transfers of stimulation data.

Implanted and body contact devices EIRP measurements are made using a suitable (head or body) phantom as specified in a harmonized standard containing tissue substitute material equivalent to the body tissue conductivity and dielectric constant in which the device will be implanted or located on the body at a frequency of 2 490 MHz. For further details see clause B.3.3. A deviation of ±10 % of the tissue parameters from nominal is acceptable.

With a possible maximum RF power level of 0 dBm (1 mW) implanted or otherwise portable transmitter, it is clear that it is not possible for these systems to cause an RF exposure level sufficient to exceed the accepted SAR levels specified by ICNIRP in Europe or ANSI in the US.

6 Expected ETSI actions

The overall system specifics (power, bandwidth, etc.) related to cochlear systems including:

a) relative data rate with a range up to 3 m; and

b) low Power specification for indoor and outdoor operation.

It is expected that the relevant Harmonized ETSI standard or modification of the existing 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 the 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 ECC/ERC Recommendation 70-03 [i.4], annex 12 band (e).

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 cochlear implant radio systems.

A regulation for license free operation for active cochlear medical radio systems ECC/ERC Recommendation 70-03 [i.4], annex 12 band (e) is requested as shown in table 3.

Table 3: Proposed regulatory parameters

Frequency band	EIRP Power	Spectrum Access and Mitigation Requirements	Channel Spacing	Notes
2 483,5 MHz to 2 500 MHz	0 dBm for the LP-AMD-P and the CI of the cochlear implant system.	LBT+AFA and ≤ 10 % duty cycle; or Adaptive sFHSS and ≤ 0,1 % duty cycle. Equipment to access the spectrum as described in the applicable harmonized standard or any other equivalent spectrum access mechanism.	1 MHz	For Low Power Active Medical Implant devices and associated peripherals, covered by the applicable harmonized standard. Individual transmitters may combine adjacent channels on a dynamic basis for increased bandwidth higher than 1 MHz. Peripheral units are for indoor use only except cochlear implant system devices may also operate outdoors.
	-27 dBm for the LP-BWD link towards the CI of the cochlear implant system (whisper mode).	FHSS and ≤ 12,5 % duty cycle. Equipment to access the spectrum as described in the applicable harmonized standard or any other equivalent spectrum access mechanism.		

Once the specific regulation for use of the band has been designated for cochlear systems, products for use by the profoundly deaf could be on market in about 2 years and will be in use for at least 10 - 15 years or longer.

Annex A:
Detailed market information

A.1 Range of applications

There are four types of hearing assistive implant technologies in the market today. Each of these technologies is described as middle ear implant, direct acoustic cochlear implant, cochlear implant and auditory brainstem implant. Of the four types, the cochlear implant is much more dominant in the marketplace. It is estimated that 78 000 of the total number of hearing assistive implants are of this type. It is characterized as having an external speech processor, an embedded electronics package that is inserted in a cavity made in the skull behind the ear, and a flexible lead consisting of a variable number of tiny wires and electrodes that are inserted in the cochlea of the patient. The electrodes are positioned in the cochlea such that they excite the aural nerve directly. Further information is found below.

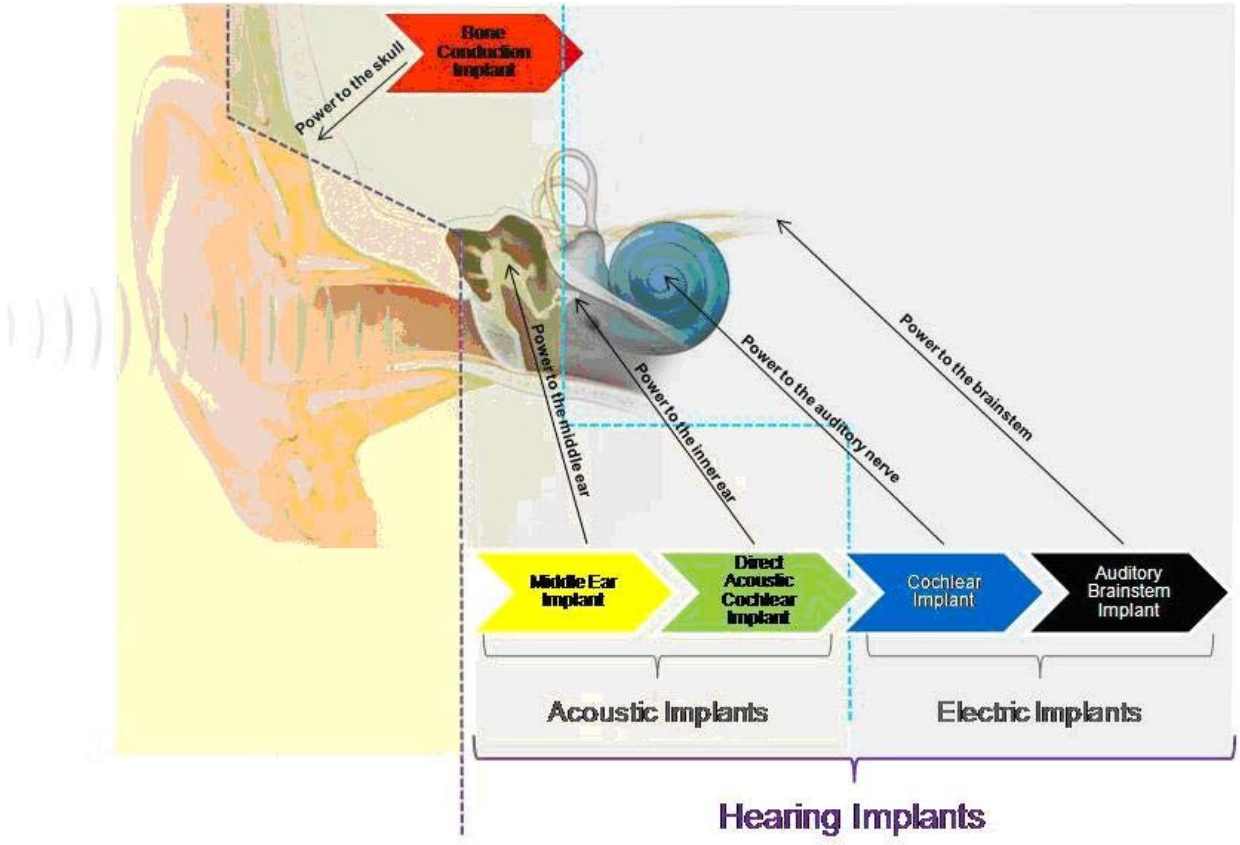
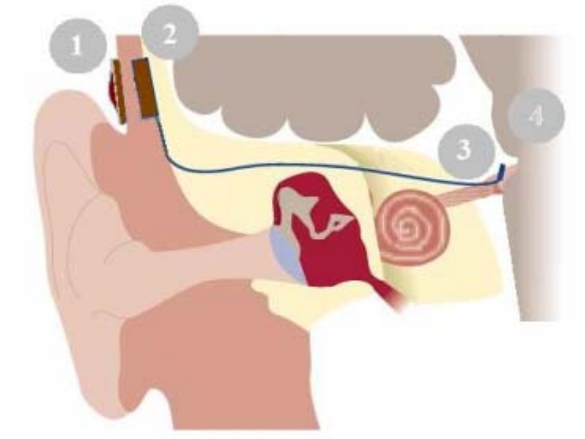


Figure A.1.1: Positioning of implantable hearing solutions

a) Auditory Brainstem Implant (ABI) system

The Auditory Brainstem Implant (ABI) is a small device that is surgically implanted in the brain of a deaf person who is lacking the auditory nerves that lead the sound signals from the ear to the brain. The implant enables otherwise deaf people to have a sensation of hearing.

In normal operation, the auditory brainstem implant system functions as follows (referring to figure A.1.2).



1) Sound processor: External sound processor captures sound and converts it into digital signals. The processor transfers these digital signals to the internal implant by mains of a primary headpiece coil.

2) Implant: internal part capturing the digital signals from the sound processor by means of a secondary coil magnetically coupled to the primary coil.

3) Electrode array: array applying electrical pulses to the auditory brainstem.

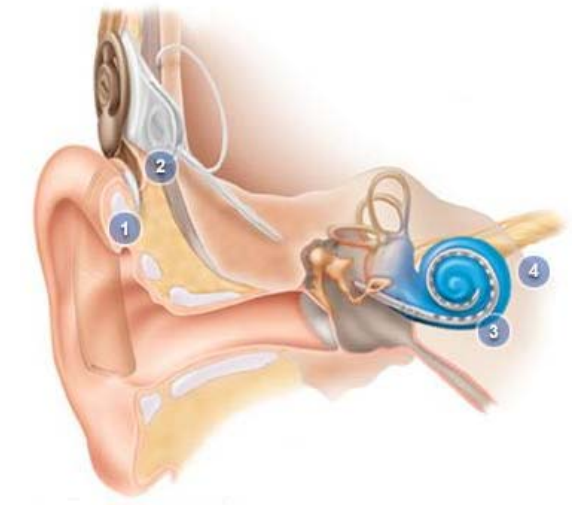
4) Auditory brainstem.

Figure A.1.2: Auditory Brainstem Implant system

b) Cochlear Implant (CI) system

A cochlear implant is a surgically implanted active medical device that electrically stimulates the auditory nerve, bypassing the non-functional inner ear of children and adults with profound-to-severe hearing loss. At a minimum, a cochlear implant system consists of a multichannel electrode array that is surgically implanted within the cochlea and an external sound processing unit, worn behind the ear, which controls the implant over a transcutaneous link. These two devices are illustrated in-situ in the figure A.1.3. Each cochlear implant system is configured to meet an individual's electric hearing needs, using specialized software.

In normal operation, the cochlear implant system functions as follows (referring to figure A.1.3).



1) The external sound processor captures and digitally processes sound.

2) The sound processor transmits power and the digital information to the internal implant.

3) The internal implant converts the digital information into electric pulses, and transmits the pulses via the electrodes placed within the cochlea.

4) The electric pulses stimulate the auditory nerve allowing the brain to perceive sound.

Figure A.1.3: Cochlear Implant system

c) Direct Acoustic Cochlear Implant (DACI) system

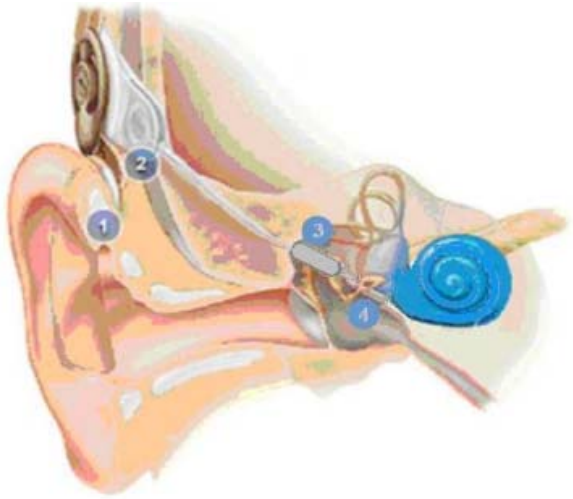
The Direct Acoustic Cochlear Implant is a surgically implanted active medical device intended to compensate for severe to profound mixed hearing loss (conductive and sensorineural) by direct acoustical stimulation of the cochlea. The operation is similar as the MEI system although the target group is different.

d) Middle Ear Implant (MEI) system

People with an obstruction of the outer or middle ear (conductive loss) mainly use middle ear implants. A significant residual hearing is still necessary. A Middle Ear Implant (MEI) is a small actuator that is inserted into the middle ear where it is physically coupled to the ossicles.

The implant transfers the sounds to the inner ear bones coming from a microphone that is placed on an external device behind the ear.

In normal operation, the Middle Ear Implant system functions as follows (referring to figure A.1.4).



1) Sound processor: External sound processor captures sound and converts it into digital signals. The processor transfers these digital signals to the internal implant by mains of a primary headpiece coil.

2) Implant: internal part capturing the digital signals of the sound processor by means of a secondary coil magnetically coupled to the primary coil.

3) Actuator: transducer, which directly vibrates the ossicles (bones in the middle ear).

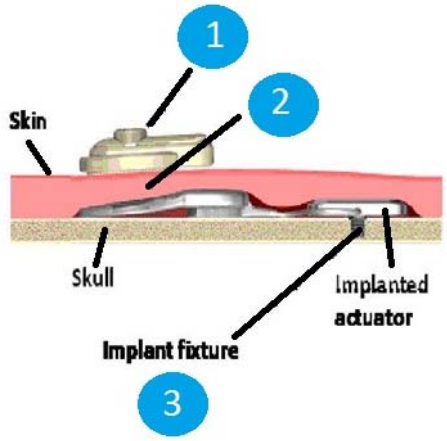
4) Ossicular chain or ossicles.

Figure A.1.4: Middle Ear Implant system

e) Transcutaneous Bone Conduction Implant (TBCI) system

The TBCI system is indicated to treat specific types of hearing loss, including conductive or mixed, as well as single sided deafness, where there is only one functioning cochlea. The TBCI system is an osseointegrated bone conduction implant system which utilizes direct bone conduction. This is where the bone acts as a pathway for sound to travel to the inner ear (cochlea), bypassing the outer and middle ear.

In normal operation, the Middle Ear Implant system functions as follows (referring to figure A.1.5).



1) Sound processor (e.g. a button shaped sound processor): external device receiving sound vibrations, as they would reach the ear.

2) Implant: internal part capturing the digital signals of the sound processor by means of a secondary coil magnetically coupled to the primary coil.

3) Titanium implanted actuator: fixation attached to the skull (mastoid) bone behind the ear where it bonds with the surrounding tissue through a process called osseointegration.

Figure A.1.5: Transcutaneous Bone Conduction Implant system

A.2 Expected market size and value

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 approximately 80 000 Europeans were cochlear implant recipients in total [i.2]. Current rates of implanting these devices in Europe are of the order of 15 000 - 20 000 per year.

The European medical technology industry related to hearing assistive implant systems and their related active medical implants invests approximately 300 million euro in R&D and employs near 15 000 highly skilled workers. Sales for the industry in Europe are approximately 1,5 billion euro based on 2010 sales figures.

A.3 Market growth and therapeutic value

Figure A.3.1 was obtained from Eucomed and contains unit sales information for several European countries. From this information it is clear that sales of these systems are very low compared to population density as would be expected. In absolute numbers for the year 2010, there were a total of 79 000 cochlear implants marketed in Europe.

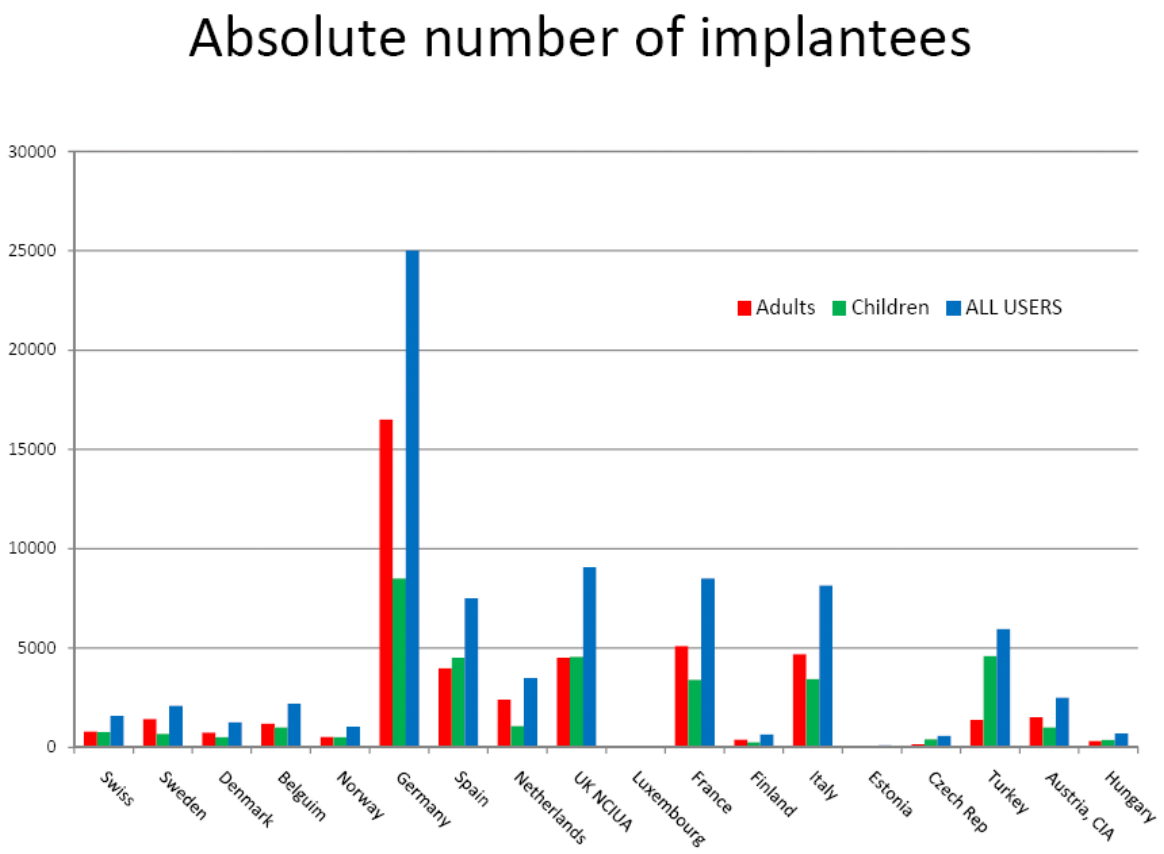


Figure A.3.1

Figure A.3.2 breaks down sales according to country on the basis of implantees per million population.

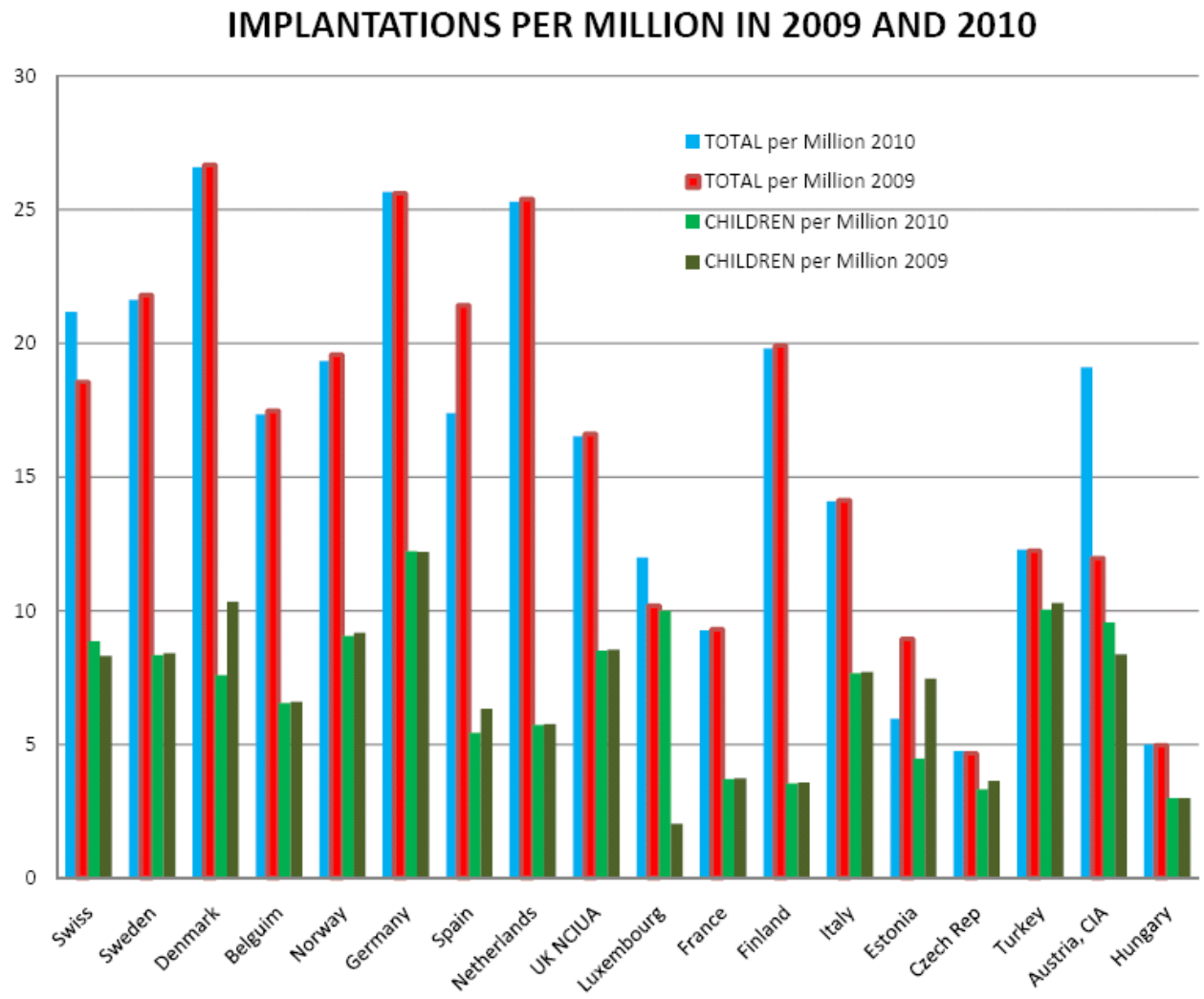


Figure A.3.2

Figure A.3.3 is based on test results of language capabilities of implantees after the operation and language therapy provided as part of the implantation process. Seventy-five percent of the patients with cochlear implants achieved excellent to good results. This result is remarkable considering essentially all of the patients were profoundly deaf before implantation.

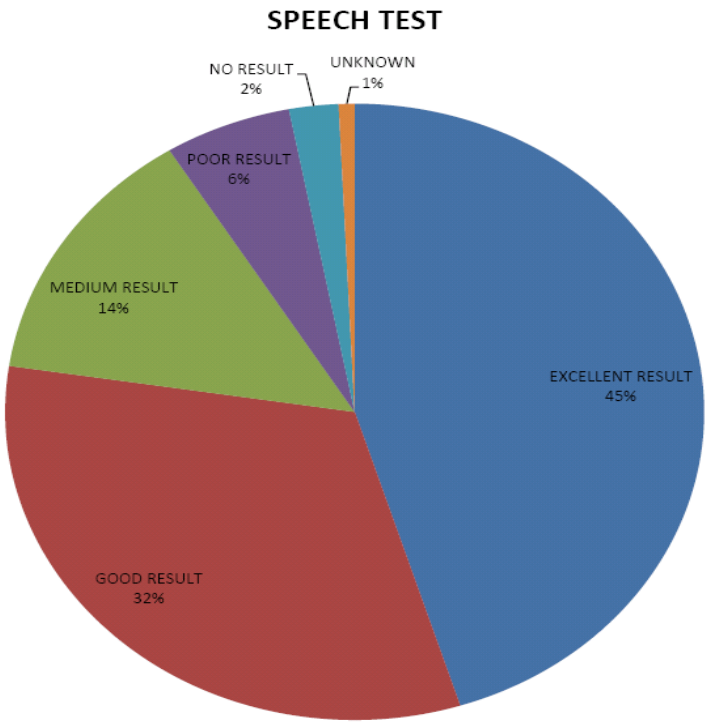


Figure A.3.3

A study of implanted children concluded the following:

"Particularly noteworthy are the language test results in children closed test format without lip-reading (MTP: Monosyllable, Trochee, Polysyllable Test) and in the open word comprehension test (Open Word Test). More than four fifths of the tested children achieve in the MTP test, a discrimination between 80 % and 100 %. In the MAIS-test (Meaningful Auditory Integration Scale) 82 % of the children reached a result in between 60 %-100 %.
The test conditions for children were in a common CI-Working group of all hospitals in Switzerland set so that with increasing number of Implantations, other factors can be analyzed".

A.4 Spectrum use and efficiency

The devices covered in the present document are expected to emit electromagnetic radiation at a maximum power level of 0 dBm e.i.r.p. in the 2 483,5 MHz to 2 500 MHz band. Transmission times will vary from brief intervals for some devices to rates approaching 10 % for other devices. In all cases the transmission time will be related to the functioning of the device and will not exceed 10 % duty cycle for 0 dBm e.i.r.p. and 12,5 % duty cycle for -27 dBm e.i.r.p..

The reasons for the above are:

- Transmission time frames are product specific. Physician or audiologist related Cochlear Implant (CI) programming and checking will likely be the heaviest usage of the spectrum whether it is in a hospital clinical environment or a session initiated by a therapist and patient over the internet. Other uses would include such devices as a remote control to facilitate patient adjustment of the device such as volume, tone, channel and program type switching to reduce noise in high ambient environments. The LP-BWD may only communicate with the implantable portion of the LP-CIS inside the 2 483,5 MHz to 2 500 MHz band.

- Cochlear implant systems operating in the band will employ a variety of interference mitigation techniques such as LBT and AFA or equivalent interference mitigation techniques to ensure they are not sources of interference to the primary and secondary services of the band or other SRDs using the band.

Annex B:
Detailed technical information

B.1 Cochlear implant system

B.1.1 CIS description

The Cochlear implant system (CIS) proposed to be operated in the 2 483,5 MHz to 2 500 MHz band consist of a low power active medical implant (CI) and the external devices (LP-BWD or LP-AMD-P) in one form or another to support the operation of the implanted device. The CI is placed in the body to stimulate the cochlea or to deliver electrical pulses to the nerves or brain in order to facilitate a greater degree of hearing than the implanted patient otherwise has. External devices operating under the provisions of the present document support the operation of the CI device by:

- Providing a means for controlling or altering the programming of the implanted device, retrieving programming data from the implant, and transferring patient specific data to a mass storage system and/or provide real time readout of patient physiological parameters such as impedance variations of each electrical conductor contact point with the aural nerve. This is represented by Link A.
- Providing a means for transferring stimulation data to the CI. This is represented by Link B.

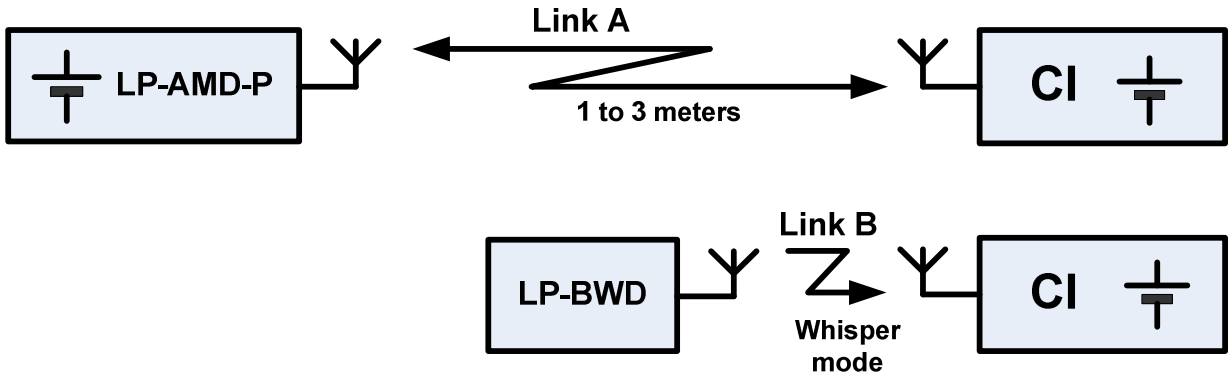


Figure B.1.1.1: The Cochlear Implant System (CIS)

B.1.2 Applications

Currently, there is no spectrum, shared or otherwise which is designated for use by the cochlear implant industry in Europe. The service this industry provides requires designated spectrum to be made available to it in order to develop systems that patients need. Digital signal processors and memory chips for data storage are capable of extremely low current drain allowing for very small size speech processors to store and recall multiple programming therapies that the patient can select based on their performance in different environments. Sizes are so small that in order to select different programming and control other functions, a remote transmitter should be used.

B.1.3 CIS data communication requirements

Table B.1.3.1 illustrates the type of the data transfers for the wireless links between the different devices and implant. Reference is made to figure B.1.1.1.

Table B.1.3.1: Overview of the data categories referred to the type of data communication link

Devices (see figure B.1.1.1)	Link (see figure B.1.1.1)	Data category	EIRP Power	Spectrum Access and Mitigation Requirements
Between LP-AMD-P and CI	Link A	Programming data (parameters and mass storage)	0 dBm	LBT+AFA and ≤ 10 % duty cycle
		Control data (parameters) Implant telemetry	0 dBm	Adaptive sFHSS and ≤ 0,1 % duty cycle
Between LP-BWD and CI	Link B	Stimulation data Control data (settings) Implant telemetry	-27 dBm	FHSS and ≤ 12,5 % duty cycle

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.2.1.1.2 Emissions in the spurious domain

Table B.2.1.1 gives the emission limits in the spurious domain.

Table B.2.1.1: Emission limits 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.i.r.p.
Standby	2 nW e.r.p.	2 nW e.r.p.	20 nW e.i.r.p.

Except for the 401 MHz to 406 MHz band, the table above defines spurious emission limits defined in ERC/Recommendation 74-01 [i.8].

B.3 Link budget

Digital radio system performance is related to the noise density ratio requirement Eb/No at the receiver for a certain probability of error, fading losses and interference levels.

Eb/No is determined by the type of modulation and the signal-to-noise ration S/N inside the channel.

When M is the number of alternative modulation symbols for a certain type of modulation (e.g. for BPSK and FSK M=2, for QPSK M=4, etc.) then the relationship between bit rate and symbol rate is $R_b = R_s.\log_2 M$.

If E_s is the energy per symbol we could write:

$$\frac{E_s}{N_0} = \frac{E_b}{N_0}\log_2 M$$

The relationship between S/N and E_s/N_0 is as follows:

$$\frac{E_s}{N_0} = \frac{S}{N}\frac{B_{RF}}{R_s}$$

wherein:

- R_b: bit rate [bps].
- R_s: symbol rate [sps].
- E_b: energy (average or peak) per bit [J/bit].
- E_s : energy (average or peak) per symbol [J/symbol].
- N_0 : single sideband spectral density of white Gaussian noise [J/Hz].
- S: Power of the signal [W or dBm].
- N: Power of the noise floor inside the channel [W or dBm].
- B_{RF}: RF bandwidth occupied by the modulated RF signal [Hz].

Derived from previous equations:

$$\frac{E_b}{N_0} = \frac{E_s}{N_0}\frac{1}{\log_2 M} = \frac{S}{N}\frac{B_{RF}}{R_s}\frac{1}{\log_2 M} = \frac{S}{N}\frac{B_{RF}}{.R_b}$$

Table B.3.1: Summarized comparison table for different modulation types

Type of modulation	Min 3dB Tx bandwidth ($B_{RF,-3dB}$)	E_b/N_0 at BER 10^{-3}	Demodulationmethod
OOK (2-ASK)	~= R_b	10,8	Non-coherent
OOK (2-ASK)	~= R_b	9,8	Coherent
BPSK	~= R_b	8,1	Non-coherent
BPSK	~= R_b	6,8	Coherent
DPSK	~= R_b	8,1	Non-coherent
DPSK	~= R_b	7,2	Coherent
FSK (h=1) (CPFSK)	~= R_b	11,5	Non-coherent
FSK (h=1) (CPFSK)	~= R_b	9,8	Coherent
QPSK	~=0,5 R_b	9,2 (E_s/N_0 =12,2)	Non-coherent
QPSK	~=0,5 R_b	6,8 (E_s/N_0 =9,8)	Coherent
MSK(h=0,5)	~= 0,7 R_b	7	Coherent
GMSK (h=0,5)	~= 0,7 R_b	7	Coherent

The following link budget shows the requirements for successful communications between the external peripheral (LP-AMD-P) and the Cochlear Implant (CI) - link A; and the body worn portion of the LP-CIS (LP-BWD) and the Cochlear implant (CI) - link B. It is based on state-of-the-art transmitter and receiver specifications for implantable medical devices.

Table B.3.2: Transmitter specification

Description	Value	Units	Remarks
Transmitter power	0/-20	dBm	Worst case outdoor Tolerance +1 dB/-3 dB
Transmitter feeder losses	1	dB	By design
Total - TX power	***-1/-21***	***dBm***	Tolerance +1 dB/-3 dB

Table B.3.3: Demodulator specification

Description	Value	Units	Remarks
Bit rate Rb	1 000	kbps	
Symbol Rate Rs	1 000	ksps	(e.g. FSK)
E_b/N_0 at BER 10^{-3}	***11,5***	***dB***	Worst case (e.g. FSK non-coherent)

Table B.3.4: Receiver specification

Description	Value	Units	Remarks
Absolute noise floor	-174	dBm/Hz	
Receiver bandwidth (3 dB)	61,8	dB Hz	10 log (1,5 MHz) Offset of 60ppm represents ±150 kHz
Receiver feeder losses	1	dB	
Receiver noise	13	dB	LNA, 1/f flicker noise
E_b/N_0 at BER 10^{-3}	11,5	dB	
Total - RX sensitivity	***-86,7***	***dBm***	

Table B.3.5: TX and RX antenna loss specification

Description	Value	Units	Remarks
CI implantable antenna loss	15	dB	By design
LP-BWD/LP-AMD-P antenna loss	3	dB	By design
LP-BWD body antenna loss (BTE)	6	dB	By design

Table B.3.6: Path loss over-air

Description	Value	Units	Remarks
Path loss 1m range	40,2	dB	Free space path loss (FSPL)/Line of sight/Walfish-Ikegami model for d < 20 m/Friis
Rayleigh fading outdoor Link probability 90 %/99 %	8/18	dB	See [i.10]
Directivity loss	12	dB	Pointing errors not accounted for
Total RF path loss1m range:	***60,2/70,2***	***dB***	Probability 90 %/99 %

Table B.3.7: Near field coupling loss

Description	Value	Units	Remarks
Near field coupling loss 10 cm range	30	dB	By design See [i.6]

Table B.3.8: Tissue loss

Description	Value	Units	Remarks
Penetration loss for 1,25 cm tissue thickness (2 490 MHz)	5	dB	See [i.11], [i.12] and [i.13]

To determine the actual performance of the system, the following equations are used to define the link budget surplus or link margin:

EIRP [dBm] = TX power at antenna [dBm] - TX antenna loss [dB]

Link-budget surplus [dB] = EIRP [dBm] - Path loss over-air [dB] - Tissue loss [dB] - RX antenna loss [dB] - RX sensitivity [dBm]

Table B.3.9: Link Performance

System Configuration	EIRP	Losses	RX sensitivity for BER 10^{-3} (FSK)	Link Budget Surplus (excl. C/I)
LP-AMD-P and CI at 90 % link reliability	-4 dBm (=-1 dBm - 3 dB)	-80,2 dB (=- 60,2 dB -15-5 dB)	-86,7 dBm	+2,5 dB
LP-BWD and CI Near field coupling	-27 dBm (=-21 dBm - 6 dB)	-50 dB (=-30 dB -15-5 dB)	-86,7 dBm	+9,7 dB

The link budget results show that for a system meeting the specified design criteria the link requires a transmitter output power of 0 dBm (far field) or -20 dBm (near-field) in view of the use of designs based on using the same transceiver semiconductor in all system devices.

Another contributor to the link budget is the carrier-to-interference ratio which in this case are covered by the link budget surplus. See clause B.3.2.

B.3 Link budget considerations

B.3.1 Introduction

Currently, existing studies on antennas used to build the communication link in the 2 483,5 MHz to 2 500 MHz band between implanted devices and exterior instrument can leverage the antenna design work performed for the myriads of devices in the 2 400 MHz to 2 483,5 MHz band. Typical gain of miniature antennas in close proximity to the human body are expected to be of the order of -6 dBi. As for implanted devices where the radio system and antenna is internal to the body, there is a growing body of work available from studies performed for implanted devices at institutions such as Lund University in Sweden. Such antennas can be expected to be of the order of -15 dBi for cochlear systems. In addition the tissue penetration loss adds 5 dB loss for 1,25 cm tissue thickness. For implanted cochlear equipment the shallow depth of implantation would allow a higher gain antenna compared to other implantable devices more profound inside the human body.

B.3.2 C/I robustness of the receiver

Another contributor to the link budget is the carrier-to-interference (C/I) ratio.

The carrier-to-interference ratio is expressing the robustness of the receiver at a defined S/N to resist an interference signal without falling under a predefined BER threshold level. The spectrum of this interference signal could reside in the same frequency channel (co-channel), the adjacent channel, the adjacent frequency band or spread over a wide frequency band. The interferer may be noticeable as a continuous or as a temporary event and block the receiver. These effects are accounted for by minimal receiver selectivity performance and the margin on the link budget.

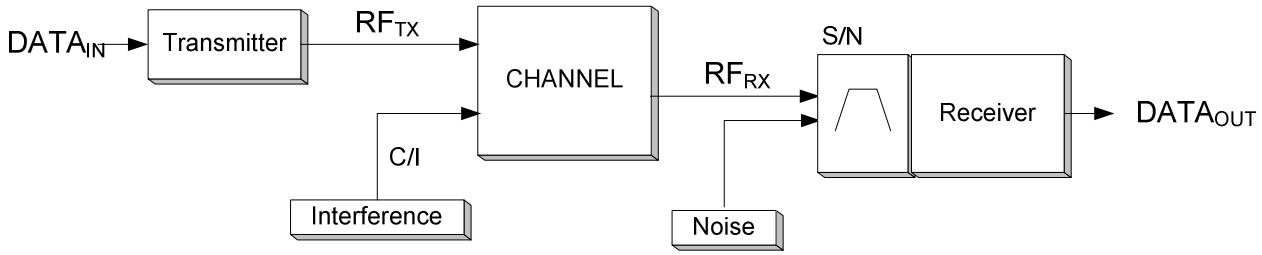


Figure B.3.2.1: The channel model of a radio system

B.3.3 Body phantom

As with other types of implants it is contemplated that use of a body phantom is required in order to have reproducible results. Such a phantom for this application will be developed as part of a Harmonized Standard for these products.

B.3.4 RF Exposure

The maximum proposed power for cochlear system indoor and outdoor devices is 0dBm. Based on levels specified in 1995/519/EC of 12 July 1999 [i.7], a device with a maximum output power of 1 mW would produce RF exposure levels well below the RF exposure threshold applicable in Europe or the US, 2,0 mW/gr and 1,6 mW/gr respectively. In the case of this equipment, there is no concern for exceeding the RF exposure limit specified by the authorities since the maximum power is limited to 1 mW.

B.4 Information on relevant standard(s)

There is no current ETSI standard that covers the operational characteristics of the cochlear system proposed for this band. 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

Table C.1.1 lists the current primary and secondary services in the 2 483,5 MHz to 2 500 MHz band. Of these services it is expected that the principle compatibility issue is sharing the band with the MSS space to earth services.

In case of a 10 % duty cycle at 1mW the cochlear LP-CIS system will mitigate against interference to the other primary and secondary services in the band by using an LBT and AFA spectrum access protocol to avoid frequencies in use.

In case of a 0,1 % duty cycle at 1mW the cochlear LP-CIS system will mitigate against interference to the other primary and secondary services in the band by using adaptive sFHSS avoiding channels which have higher usage.

In case of a 12,5 % duty cycle the power at the LP-BWD is heavily reduced at 2µW and FHSS is used for an efficient spectrum use.

Since cochlear systems are considered to be SRD's and do not transfer time-critical patient data, interference to them is not considered to be a critical compatibility issue.

C.1 Current ITU and European Common Allocations

The European Common Allocation Table (ECA) shows the following band allocation information.

Table C.1.1: European Common Allocation Table

Frequency band	Allocations	Applications
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

Additional information may be found in ERC Reports 149 [i.5], 150 [i.14] and 165 [i.15].

C.2 Sharing and compatibility studies to other in-band radio communication services

The following sharing and compatibility issues are foreseen.

Table C.2.1: Existing services 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 LM: I/N = 0 dB MSS: -10 dB ENG/OB: -10 dB	
NOTE: *ISM is not a radio communications service and no compatibility issue is foreseen.				

It should be noted that the ECC has made provision in ERC/Recommendation 70-03 [i.4] for medical implantable devices and their associated peripherals to share the 2 483,5 MHz to 2 500 MHz band. That system operates indoor only with a maximum permitted power of 10 mW e.i.r.p. and uses LBT and AFA below 10 % of duty cycle to mitigate causing or receiving interference.

Cochlear systems containing a LP-AMD-P will use the same or similar techniques to share the spectrum with primary or secondary radio services.

The near-field links between the LP-BWD (external portion of the LP-CIS) and the CI (implantable portion of the LP-CIS) are limited to a maximum e.i.r.p. of 2 uW (-27 dBm). In the most pessimistic coexistence use case the victim receiver would see an interferer of -87 dBm at 10 m distance (Friis equation) or -123 dBm at 640 m distance when operating outdoor assuming that the main antenna lobe is pointing towards a 0 dBi victim RX antenna. The line-of-sight approximation is very unlikely to become applicable in rural and urban areas.

In addition a 12,5 % duty cycle and FHSS scheme over a minimum of 8 channels to mitigate interference towards existing services is applied reducing the risk of co-channel interference even more.

It is contemplated that a new sharing study will be needed for cochlear implant systems. In particular, in band interference to the MSS service is expected to be the worst case scenario from outdoor operation of cochlear implant systems. For this analysis it is proposed to use the CEPT SEAMCAT simulation tool as the basis for a statistical sharing study. It was noted that interference to MSS service from outdoor operation of implant systems, based on statistical analysis, had a somewhat higher probability.

C.2.1 Compatibility with services in neighboring bands

Implantable cochlear devices intended for operation in the 2 483,4 MHz to 2 500 MHz band may need to employ band pass filtering in order to preclude interference from services in the adjacent bands above and below its band of operation. In this case they may need to specify system guard bands to preclude interference to the cochlear system. Obviously, this results in some loss of operating spectrum, but this is a decision for the system designer. The information transfer of a cochlear system is not foreseen as time-critical and therefore patient safety would not be compromised by any interruption.

C.3 Sharing with other SRD (Intra-sharing)

The sharing with other LP-AMI devices and Medical Body Area networks (MBANS) needs to be investigated and ensured in this frequency range.

Annex D: Bibliography

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NOTE: Available at http://www.cs.unt.edu/~rakl/ATL06.pdf.

History

Document history		
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