ETSI TR 101 981 V1.1.1 (2001-07)

Technical Report

Electromagnetic compatibility

- and Radio spectrum Matters (ERM);
 - Short Range Devices (SRD);
- System Reference Document for Inductive Loop -
- Ultra Low Power Active Medical Implants (ULP-AMI) -
- systems operating in the frequency bands 9 kHz to 315 kHz



Reference DTR/ERM-RM-004

2

Keywords

Magnetic, power, radio

ETSI

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

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

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

Important notice

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

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

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

If you find errors in the present document, send your comment to: editor@etsi.fr

Copyright Notification

No part may be reproduced except as authorized by written permission. The copyright and the foregoing restriction extend to reproduction in all media.

> © European Telecommunications Standards Institute 2001. All rights reserved.

Contents

Intelle	ectual Property Rights4
Forew	/ord4
1	Scope4
2	References
3 3.1 3.2 3.3	Definitions, symbols and abbreviations
4	Executive summary
5	Main conclusions
Anne	x A: Detailed market information
A.1	Range of applications
A.2	Market size
A.3	Traffic evaluation
Anne	x B: Technical information12
B .1	Detailed technical description
B.1a	Magnetic field requirements for inductive systems
B.2 B.2.1 B.2.2 B.2.3	Technical justifications for spectrum 13 Power 13 Frequency 13 Transmission mask 13
B.3	Information on current version of relevant ETSI standard
Anne	x C: Expected compatibility issues
C.1	Coexistence studies (if any)
C.2	Current ITU allocations
C.3	Sharing issues
Histor	ry15

Intellectual Property Rights

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

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

Foreword

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

Directive 90/385/EC [6] (AIMD Directive) has established requirements for active implantable medical apparatus. This directive is used throughout Region 1 for insuring active medical implants and their accessories meet the standards that are necessary to insure the safety of these products as they are used in the medical community.

1 Scope

The present document applies to the radio sections of inductive loop Ultra Low Power Active Medical Implants in the field of Short Range Devices (SRDs) transmitters and receiver systems operating on various frequencies within the range of 9 kHz to 315 kHz.

The present document gives guidance on the definition of a transmitter mask for the operating frequencies, analyses and the spectrum requirements for transmission of power and data from/to stationary programmers or mobile neurostimulation systems (pain control) to/from active medical implants.

The present document considers the ERC Report 44, [1] and contains the technical characteristics for radio equipment as given in CEPT/ERC Recommendation 70-03 [2]. Therefore, the frequency range 9 kHz to 135 kHz is already sufficiently regulated inductive systems in CEPT/ERC Recommendation 70-03 [2]. The necessary operation for the frequency range 135 kHz to 315 kHz is not addressed in CEPT/ERC Recommendation 70-03 [2] and is addressed in the present document.

The spectrum parameters for inductive loop ULP-AMI devices that are the subject of the present document are intended to be included as a normative annex in the EN 300 330-2 [4]. They are submitted for consideration to CEPT/ERC WGSE for compliance studies and in WGFM/SRD MG for inclusion in the CEPT/ERC Recommendation 70-03 [2].

2 References

For the purposes of this Technical Report (TR) the following references apply:

- [1] ERC Report 44: "Sharing between inductive systems and radiocommunication systems in the band 9 135 kHz".
- [2] CEPT/ERC Recommendation 70-03: "Relating to the use of Short Range Devices (SRD)".
- [3] ETSI EN 300-330-1: "Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Radio equipment in the frequency range 9 kHz to 25 MHz and inductive loop systems in the frequency range 9 kHz to 30 MHz; Part 1: Technical characteristics and test methods".

[4]	ETSI EN 300 330-2 (V1.1.1): "Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Radio equipment in the frequency range 9 kHz to 25 MHz and inductive loop systems in the frequency range 9 kHz to 30 MHz; Part 2: Harmonized EN under the R&TTE Directive".
[5]	Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity.
[6]	Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices.
[7]	SE24 (95) 57R2 Helsinki: Calculation of interference probability between LF inductive devices and primary services.
[8]	EU/DGVI IDEA project overview from JRC/Ispra (Joint Research Centre of the EU Commission), Institute for Systems Informatics and Safety".

[9] IEC 60601-1: "Medical electrical equipment - Part 1: General requirements for safety".

3 Definitions, symbols and abbreviations

3.1 Definitions

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

assigned frequency band: frequency band within which the device is authorized to operate

conducted measurements: measurements that are made using a direct connection to the equipment under test

dedicated antenna: removable antenna supplied and tested with the radio equipment, designed as an indispensable part of the equipment

fixed station: equipment intended for use in a fixed location

H-field test antenna: electrically screened loop or equivalent antenna, with which the magnetic component of the field can be measured

full duplex: method of information exchange in which the information is communicated while the transceiver transmits the activation field

half duplex: method of information exchange in which the information is communicated after the transceiver has stopped transmitting the activation field

integral antenna: permanent fixed antenna, which may be built-in or designed as an indispensable part of the equipment

magnetic dipole moment: product of (Number of coil turns) × (coil area) × (coil current). (Air coils only)

portable station: equipment intended to be carried, attached or implanted

radiated measurements: measurements that involve the absolute measurement of a radiated field

ULP-AMI system: an ultra low power active medical implant system consists of a programmer/controller, used by a medical professional or by a patient, and an active medical implant that has been placed in the body of a patient

3.2 Symbols

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

f	Frequency
Н	Magnetic field strength
Но	Reference magnetic field strength, (see annex A)
m	Magnetic dipole moment
Р	Power
R	Distance
Ro	Reference distance, (see annex A)
t	Time

3.3 Abbreviations

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

f	Frequency
Н	Magnetic field strength
Но	Reference magnetic field strength, (see annex A)
IDEA	Identification Electronique des Animaux
JRC	Joint Research Centre (of the EU Commission)
LF	Low Frequency
m	Magnetic dipole moment
Р	Power
R	Distance
RF	Radio Frequency
Ro	Reference distance, (see annex A)
t	Time
ULP-AMI	Ultra Low Power Active Medical Implant
WGSE	Working Group Spectrum Engineering

4 Executive summary

Background

Ultra Low Power Active Medical Implant systems (ULP-AMI) using inductive loop techniques in the Low Frequency (LF) range have found wide acceptance and application for many medically related applications. LF magnetic field technology allows lossless penetration of most materials encountered in medical environments including human body tissue, which is very desirable for medical applications.

6

Today's inductive loop active medical implant communication system is a biomedical telemetry system that provides communication capability between an external programmer/controller and a therapeutic medical implant placed inside a human body. Typically, they use magnetically coupled coils operating at single fixed frequencies within the region of spectrum from 9 kHz to 315 kHz. Data rates vary according to manufacturer with typical rates of 2 kbits/s to 6 kbits/s using pulse position modulation. A magnetic sensing head associated with the programmer/controller must be placed and maintained in near perfect alignment directly over the implant during communications sessions with a separation distance of approximately 6 cm or less. This requirement is directly related to the extremely low magnetic fields the implants are capable of generating. Alignment requirements and physician time constraints limit typical communication sessions to reprogramming the implant and retrieval of reasonably small amounts of stored data with calculated duty cycles of less than 10 % averaged over one hour according to CEPT/ERC Recommendation 70-03 [2].

System operation and rationale

ULP-AMI systems use telemetry techniques based on low frequency inductive loops to control, programme and communicate with active implantable medical devices such as e.g. pacemakers, defibrillators, nerve stimulators, infusion pumps, ect. Implantable pulse generators were developed in the 1960's and used discrete components typical of most electrical apparatus of that period. In the mid-70's simplex communication from an external device (programmer) was introduced which allowed adjustment of the heart pacing parameters of the implant. In the late 70's, the first half-duplex communications systems were introduced using inductive loop radiators. These systems used pulse position modulation techniques to transmit information which coupled with careful design reduced power consumption from the internal battery to acceptable levels. Low frequency magnetic fields have little if any attenuation from passing through human body tissue and was thus ideal from the standpoint of frequency selection and power consumption. This is an extremely important consideration since typical active medical implants must operate reliably for periods from 7 to 10 years

Current ULP-AMI systems use external programmer/controllers incorporating tuned medium Q coil antennas to emit a modulated magnetic field for telemetry to and from the implant. Modulation type is generally pulse position encoded but other forms of modulation may be used. Implant transceiver circuitry is usually activated by placing a strong permanent magnet over the implant. Once activated the implant will "listen" for a signal from the programmer/controller RF head which is aligned directly over and within 6 cm of the implant. The programmer/controller and the active medical implant transmit signals which have been encoded with specific data which must agree before the implant will establish a link to permit either reprogramming of the implant or data retrieval from the implant by the programmer/controller. Implants generally use tiny coils that are part of the resonant circuit as antennas to radiate the pulsed magnetic field. Data integrity is insured by CRC check codes coupled with a very limited instruction command set that is recognized by the implant.

Market briefing

Heart failure affects about 22,5 million persons worldwide, with about 2 million new cases diagnosed each year. About 6,6 million Europeans are victims, with approximately 590,000 new cases diagnosed each year. Of these approximately one half are candidates for heart implants. In addition, nerve stimulation implants and drug delivery infusion pumps are finding success in controlling various bodily functions such as urinary incontinence, uncontrollable muscular spasms, insulin injection, and delivery of pain medication to mention a few. Active medical implants are the only technology capable of full time non-stop delivery of medically necessary therapy that is required to preserve and enhance the quality of life for many for this category of patients worldwide.

Spectrum requirement and justifications

Frequencies currently used by LF ULP-AMI telemetry systems are within the range of 9 kHz to 315 kHz. Magnetic field strength levels from the external programmer/controllers used by medical professionals, or in some cases by patients, are typically of the order of a magnitude or more below the current ETSI magnetic field strength levels specified in clause 4.1.1.1 of EN 300 330-2 [4]. Magnetic field strength levels from the implants are so low that measurements must be made at distances of one meter or less. Using the theoretical inverse cube attenuation rate, to compare implant H field strength levels to the H field strength levels in clause 4.1.1.1, gives implant levels that are from 85 dB to 95 dB below the level in clause 4.1.1.1 of EN 300 330-2 [4]. At 10 meters, the implant levels are well below the existing ambient levels at these frequencies.

Current regulations

	Frequency Band	Field Strength (table 2 of [2])	Antenna (table 3 of [2])	Channel spacing (table 4 of [2])	Licensing requirement (table 5 of [2])	Approvals (table 6 of [2])	Duty cycle (table 7 of [2])
aa	9-59,750 kHz	3 ²	1, 2 or 3 ³	13	2	1, 2 or 4 ⁴	-
ab	59,750 kHz to 60,250 kHz	2	1, 2 or 3 ³	13	2	1, 2 or 4 ⁴	-
ac	60,250 kHz to 70 kHz	3 ²	1, 2 or 3 ³	13	2	1, 2 or 4 ⁴	-
b	70 kHz to 119 kHz	2	1, 2 or 3 ³	13	2	1, 2 or 4 ⁴	-
С	119 kHz to 135 kHz	3 ²	1, 2 or 3 ³	13	2	1, 2 or 4 ⁴	-

CEPT/ERC Recommendation 70-03 [2] specifies in annex 9 for inductive loop applications the following parameters:

7

- NOTE 1: Other types of anti-theft systems can be operated in accordance with other relevant annexes.
- NOTE 2: In the case of loop antennas type 1 and 2 with an area between 0,05 m² and 0,16 m², the field strength 3 is reduced by 10 dB × log (area/0,16 m²); for an antenna area less than 0,05 m² the field strength 3 is reduced by 10 dB.
- NOTE 3: In the case of type 3 antennas only loop coil antennas should be employed.

NOTE 4: For countries which have implemented the R&TTE Directive.

These levels are accepted as a recommendation CEPT/ERC Recommendation 70-03 [2] by 43 CEPT countries although some countries restrict the types of equipment permitted in these bands. There is currently a proposal under development that would change the status of these bands from a recommendation to a decision. If the status is changed to that of a decision, the above frequencies will be considered as harmonized frequencies within CEPT.

Finland and Sweden have no restrictions in this frequency range for inductive systems having low operating range as they are not considered to emit hertzian waves. Therefore, the use of the frequencies is of no concern to those countries.

Proposed regulation

It is proposed that CEPT adopt provisions in annex 12 of CEPT/ERC Recommendation 70-03 [2] for ULP-AMI equipment to permit operation of medical implants and their associated programmer/controllers in the frequency bands listed in the table below so as to regularize the current situation of these equipment. Incorporation of the additional frequencies in annex 12, specifically for ULP-AMI equipment, will provide that other SRD's will not proliferate in these frequency bands. The proposed field strength limits are below those provided for in clause 4.1.1.1 of EN 300 330-2 [4].

There have been concerns expressed over the use of the requested frequencies by some parties that currently provide services or otherwise use this spectrum. For example, the Radio Amateur community has expressed concern that experimental operations in the 135,7 kHz to 135,8 kHz could cause interference to ULP-AMI equipment. Other concerns have been expressed for requesting such a broad range of frequencies.

Additional information on the current and actual use of the is 283,5 kHz to 315 kHz by ULP-AMI is needed to confirm the necessity of the identification of this band in the CEPT/ERC Recommendation 70-03 [2].

	Frequency Band	Field Strength (table 2 of [2])	Antenna (table 3 of [2])	Channel spacing (table 4 of [2])	Licensing requirement (table 5 of [2])	Approvals (table 6 of [2])	Duty cycle (table 7 of [2])
а	9-59,750 kHz	3 ¹	1, 2	13	2	1, 2 or 4 ²	-
b	59,750 kHz to 60,250 kHz	2	1, 2	13	2	1, 2 or 4 ²	-
С	60,250 kHz to 70 kHz	3 ¹	1, 2	13	2	1, 2 or 4 ²	-
d	70 kHz to 119 kHz	2	1, 2	13	2	1, 2 or 4 ²	-
е	119 kHz to 135 kHz	3 ¹	1, 2	13	2	1, 2 or 4 ²	-
f	135 kHz to 148,5 kHz	+22 dBµA/m at 10 m	1, 2	13	2	1, 2 or 4 ²	-
g	148,5 kHz to 255 kHz	+22 dBµA/m at 10 m	1, 2	13	2	1, 2 or 4 ²	-
h	255 kHz to 283,5 kHz	+22 dBµA/m at 10 m	1, 2	13	2	1, 2 or 4 ²	-
i	283,5 kHz to 315 kHz	+22 dBµA/m at 10 m	1,2	13	2	1, 2 or 4 ²	-

- NOTE 1: In the case of loop antennas type 1 and 2 with an area between 0,05 m² and 0,16 m², the field strength 3 is reduced by 10 x log (area/0,16 m²); for an antenna area less than 0,05 m² the field strength 3 is reduced by 10 dB.
- NOTE 2: For countries which have implemented the R&TTE Directive.

Above footnotes renumbered from previous table. New number 1 is old number 2 and new number 2 is old number 1.

Compatibility issues

Generally, in the band 14 kHz to 135 kHz, inductive applications are permitted in the CEPT countries for general usage or specific usage applications. Above 135 kHz the frequency bands of concern are the following:

Amateur Service	135,7 kHz to 137,8 kHz
Broadcast	148,5 kHz to 255 kHz, 255 kHz to 283,5 kHz
Maritime mobile	130 kHz to148,5kHz
Fixed stations	130 kHz to 148,5 kHz (operating as "permitted service")
Radionavigation	255 kHz to 315 kHz (Aeronautical and/or Maritime)

5 Main conclusions

Business, social, humanitarian, international manufacturing, trade and use considerations underline the importance and benefit for society in general, dependent patients in particular, and reduction in patient related medical cost justifies the request to permit ULP-AMI devices to use the LF spectrum in the range of 9 kHz to 315 kHz.

- Inductive LF ULP-AMI systems have been deployed by medical professionals worldwide for many years in applications where individual patient longevity and quality of life are dependent on them. These implants are used in a range of applications from heart pacing and defibrillation systems to pain control and drug delivery pumps.
- The magnetic field strength levels from ULP-AMI programmer/controllers are generally 10 dB to 15 dB below the H field levels specified in clause 4.1.1.1 and the levels from the implants are of the order of 85 dB to 95 dB below the levels in clause 4.1.1.1.
- Because of the extremely low magnetic fields from these systems, there is little probability of any potential for interference to existing services.
- Disruption of ULP-AMI systems by ambient signals has historically been addressed through the AIMD Directive. The AIMD directive requires compliance with the provisions of IEC 60601-1 [9] for EMC compatibility. The analysis required under the AIMD to address disruption of communication or disturbance by other radio signals is accepted within the medical community. The adequacy of this analysis is confirmed by the lack of any disturbance complaints over the last 10 to 12 years.
- Enforcement of radio interface and regulation compliance in applying the R&TTE [5] directive for "placing on the market" as well as "putting into service" may endanger the health and safety of millions of patients if the services in the requested band cannot share the band with ULP-AMI systems.
- Medical implant communications systems are used throughout the world to provide therapy to patients for a
 variety of medical conditions. These systems only radiate electromagnetic energy for brief intervals of time in a
 doctor/patient environment. Field strength levels for operation above 135 kHz are so low they are below the
 noise floor at distances of approximately 20 meters.

In many cases, the frequencies available for this service are not common amongst the numerous countries. Yet, implanted patients are mobile, travel for business or pleasure reasons to foreign countries, and may require emergency medical assistance while they are in a foreign country. These patients should have assistance available at the closest medical facility regardless of the individual country. It is the responsibility of government authorities to provide for a maximum availability of medical services to active medical implant patients in order to cover emergency medical situations that may occur during their visit to a particular country. For this, government authorities should eliminate administrative barriers such as "their National Frequency Allocations table does not allow the use of these ULP-AMI systems."

Expected timing for products to market

- Products for use by the medical community are in volume production.
- There are currently approximately 15 manufactures worldwide that supply millions of LF ULP-AMI equipment.

ERC and ETSI actions

- Liaison statement from ETSI to ERC WGSE/SE24 and WGFM/SRDMG.
- SE24: verify compatibility with Maritime mobile, Radionavigation, Broadcast and fixed stations as needed. (Field test, absolute measurements, modelling analysis).
- CEPT/ERC Recommendation 70-03 [2]: modification of annex 9 or annex 12 as appropriate.
- The spectrum parameters for inductive loop ULP-AMI devices that are the subject of the present document are intended to be included as an annex in the EN 300 330-2 [4].
- National Administrations: issuance of radio interfaces for LF ULP-AMI equipment.

Annex A: Detailed market information

A.1 Range of applications

Heart pacemakers, defibrillators, cardioverter defibrillators, insertable loop recorders, nerve stimulators for pain control, muscular control, urinary control, with research developing additional applications.

A.2 Market size

Such programmable devices have been on the market since around 15 years and no obstacles to their commercialisation have been made. The following estimates indicate that there is a substantial installed base.

ULP AMI patients with telemetry in the world	3 000 000
ULP AMI patients with telemetry in Europe	1 500 000
Programmers with telemetry in the world	20 000
Programmers with telemetry in Europe	10 000
Estimated total of ULP AMI devices produced in Europe	300 000
Estimated total of people employed in Europe by the ULP AMI industry	1000
Estimated number of programming session per patient per year	2 to 4
Estimated transmission time per session	5 to 10 min.

The market and technology is supported by governmental organizations, the medical community and consumer groups.

A.3 Traffic evaluation

Spectrum use and efficiency:

- The emission of magnetic fieldstrength and the actual frequency usage is very low.

The reasons are that:

- a) The millions of implant transceivers are only occasionally activated and then only one at a time in a physician's office. Over the life of an implant (7 to 10 years), it is estimated that the telemetry function is typically activated less than 0,01 %;
- b) Transceivers are only activated on demand;
- c) Programmer/controller radiated levels are much lower (10 dB to 15 dB) than the maximum permitted H field;
- d) Implant levels are of the order of 85 dB to 95 dB below the maximum permitted levels.
- Due to the low duty cycle, the very low power, inductive loop active medical implant systems provide a high degree of frequency reuse within the service.

Annex B: Technical information

B.1 Detailed technical description

ULP-AMI System description

These devices are Active Implantable Medical Devices and accessories with an intermittent telemetry function. Programmer/controllers (RF heads and activators) are used externally by either physicians or patients to effect a medical therapy in implantable devices. A physician, via the RF head, transmits the programming information that selects the therapy to be delivered to the patient. The RF head is a small hand held device containing a coil of approximately 6 cm to 10 cm diameter, used as the antenna, with the associated RF drive electronics and is connected to a programming station via cable. Power and data are delivered to the RF electronics via the cable from the programming station. Activators are small battery powered devices containing minimal programming capability together with a transceiver using a small internal coil, which serves as a loop antenna.

12

Implants consist of two sections, the implant programmable pulse generator and the transceiver circuit to enable the telemetry function. The RF pulse drive circuit is integrated into a hybrid chip that drives an external coil capacitor circuit. This coil is the radiating antenna for the implant. Implant sizes vary from roughly 25 to 90 cc in total volume and house the pulse and transceiver systems together with the battery. The entire package is sealed in a titanium case with output from the pulse generator available through a header. Implant leads for therapy delivery are attached to the header. All leads are by passed at the point of entry into the implant case to prevent ambient interference from coupling into the system.

B.1a Magnetic field requirements for inductive systems

Transmitter field – External equipment

These systems use a variety of coil configurations using iron cores or in some instances air cores. Maximum antenna size is approximately 10-cm diameter with a 50-turn coil. Due to the varied construction used in the external devices, a number of units were tested. For external devices the maximum H field measured was 22 dBuA/m (14 dB below the limit) and minimum H field was –21,5 dBuA/m. It is reasonable that H field levels for external devices comply with the levels specified in clause 4.1.1.1 of EN 300 330-2 [4].

Transmitter field – Internal devices

In most applications, implants must be as small as possible. This, coupled with the battery power constraints, makes the radiated field very low. Approximately 25 different models of implants were measured in order to determine the magnetic field strength of these devices. At 1 m distance the measured levels were of the order of 80 dB to 90 dB or more below the maximum level specified in clause 4.1.1.1 of EN 300 330-2 [4]. For implanted devices it is proposed that due to the extremely low H field levels that measurements be made at 1 meter and that the level be extrapolated to 10 meters using the procedure specified in annex J of EN 300-330-1 [3]. The extrapolated levels so obtained are expected be no greater than 40 dB below the levels specified in clause 4.1.1.1 of EN 300 330-2 [4].

The ambient noise level

The ambient noise is dependent on the location of the equipment. Medical facilities can be considered an industrial or commercial environment. In these environments the ambient noise, especially below 135 kHz, is very high. The main noise sources are the harmonics of different electric equipment, for example switch mode power supplies, PC's, other medical equipment, ISM devices, fluorescent lights, electric distribution in general, etc. According to ERC Report 44 [1], the noise level in this type of environment, measured in a 1 kHz bandwidth, is expected to vary in the range 5 dB μ A/m to 30 dB μ A/m at 50 kHz. A typical level is 13 dB μ A/m at 50 kHz. The noise level falls at a 3,5 dB/octave and it is typically -13 dB μ A/m at 8 MHz.

B.2 Technical justifications for spectrum

B.2.1 Power

The maximum carrier level of +22 dBuA/m measured at 10 m distance is well below the CEPT/ERC Recommendation 70-03 [2] annex 9 limits and is 14 dB below the levels specified in clause 4.1.1.1 of EN 300 330-2 [4].

B.2.2 Frequency

The band from 9 kHz to135 kHz is generally recognized within the CEPT countries for inductive applications. The manmade contribution to the ambient noise in the band is gradually increasing as the proliferation of noise sources continues to increase. Further, the numbers of SRD's in the 9kHz to 135 kHz band is proliferating as new applications are developed. Because this band is a general use band, it is expected that the proliferation of applications will continue within this band. This proliferation of applications in this band could potentially raise the ambient levels to the point where ULP-AMI systems could no longer communicate, even at the 6 cm distances they are designed to communicate over.

Carrier frequencies of ULP-AMI systems vary within the range of 9 kHz to 315 kHz on a global basis. Due to the extremely low power capability of ULP-AMI devices, additional frequencies are required for operation as the effective noise in the 9 kHz to 135 kHz band continues to increase. The additional bands above 135 kHz up to 315 kHz are needed to accommodate system designs that were deployed by the medical community. Many of these implant systems were deployed by the medical community in the early to mid-1990's and are currently providing the intended therapy to the implanted patients.

Due to the very low power levels from this equipment, there is no expectation of interference to existing services. ERC Report 44 [1] contains a sharing analysis between other inductive systems and existing users in the 9 to 135 kHz band. This report concluded the risk of interference was low. This low probability is even lower because of the very low H-field levels from ULP-AMI systems.

B.2.3 Transmission mask

Emissions are measured in accordance with EN 300 330-2 [4].

B.3 Information on current version of relevant ETSI standard

The current ETSI standard is the draft EN 300 330-2 [4].

13

Annex C: Expected compatibility issues

C.1 Coexistence studies (if any)

See reference [1], Sharing between inductive systems and radiocommunication systems in the band 9 kHz to 135 kHz

C.2 Current ITU allocations

The radio regulations lists in region 1

9 kHz to 14 kHz	"Radionavigation"
14 kHz to 70 kHz	"Maritime Mobile, Fixed"
70 kHz to 130 kHz	"Radionavigation, Maritime Mobile, Fixed"
130 kHz to 148,8 kHz	"Maritime Mobile, /fixed/ as permitted service".
148,5 kHz to 255 kHz	"Broadcasting"
255 kHz to 283,5 kHz	"Broadcasting, /Aeronautical Radionavigation/ as permitted service"
283,5 kHz to 315 kHz	"Maritime Radionavigation, /Aeronautical Radionavigation/as permitted service"

C.3 Sharing issues

Sharing with existing services is anticipated due the to the low probability of co-location, the very low magnetic field radiated by ULP-AMI equipment and the high roll-off propagation characteristics of the equipment.

History

Document history				
V1.1.1	July 2001	Publication		

15