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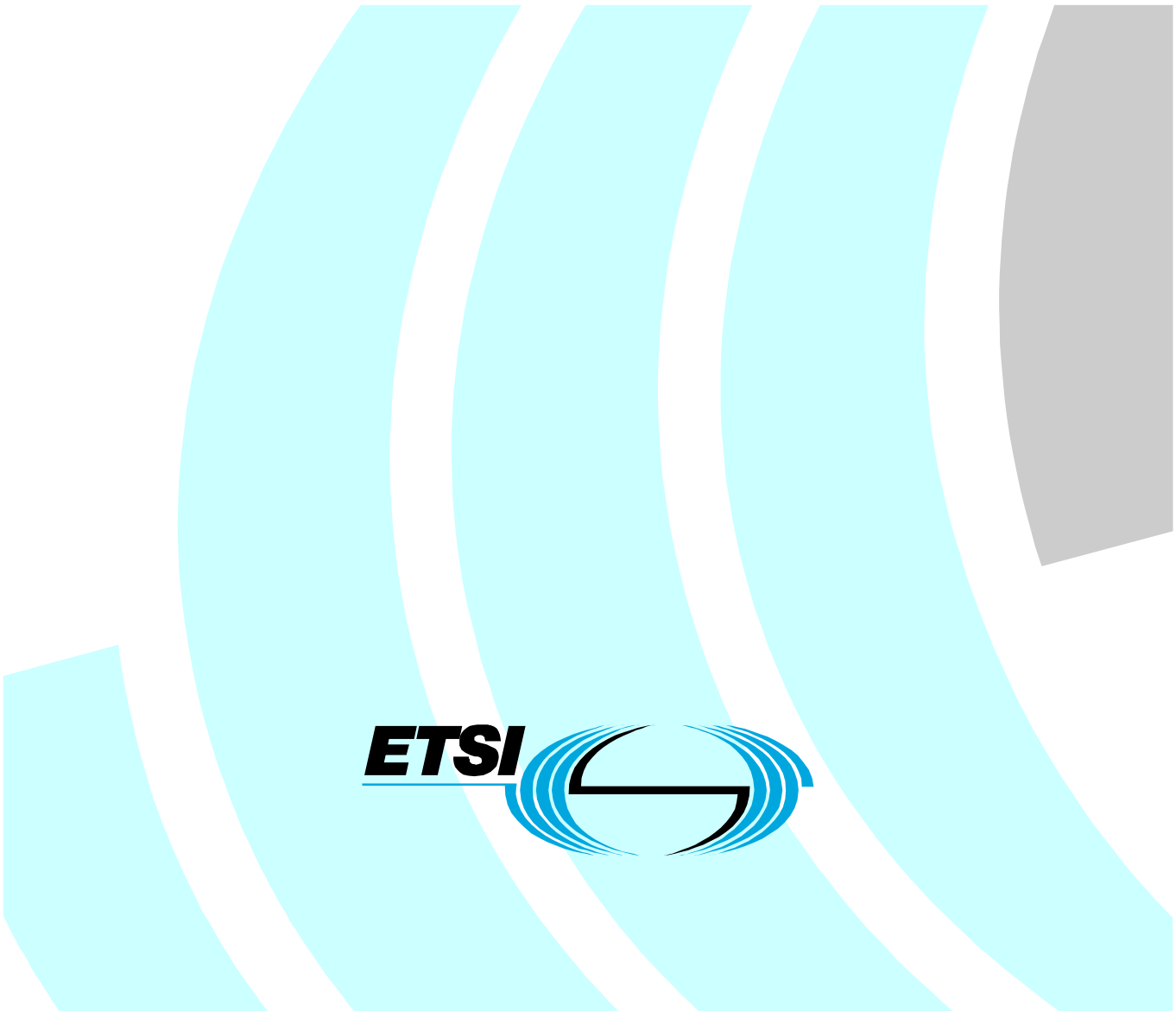
Technical Report

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



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Foreword

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

Directive 90/385/EC (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 for 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 this document are intended to be included as a normative annex in the EN 300 330-2 [3] or in a new European Harmonized Standard. 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], annex 12.

2 References

The following documents contain provisions which, through reference in this text, constitute provisions of the present document.

- References are either specific (identified by date of publication and/or edition number or version number) or non-specific.
- For a specific reference, subsequent revisions do not apply.
- For a non-specific reference, the latest version applies.

[1] ERC Report 44: "Sharing between inductive systems and radiocommunication systems in the band 9-135 kHz", Jan 97.

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

[3] 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 article 3.2 of the R&TTE Directive".

[4] EU/DGVI IDEA project overview from JRC/Ispra, Joint Research Centre of the EU Commission, Institute for Systems Informatics and Safety".

[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 (R&TTE Directive).

[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] ETSI ETR 028: "Radio Equipment and Systems (RES); Uncertainties in the measurement of mobile radio equipment characteristics".

[9] ETSI EN 300 330: "ElectroMagnetic Compatibility and Radio Spectrum Matters (ERM); Short Range Devices (SRD); Technical characteristics and test methods for radio equipment in the frequency range 9 kHz to 25 MHz and inductive loop systems in the frequency range 9 kHz to 30 MHz".

3 Definitions, symbols and abbreviations

3.1 Definitions

For the purposes of the present document, the following terms and 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

Ultra Low Power Active Medical Implant (ULP-AMI) 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:

Eo	reference electrical field strength, (see annex A)
f	frequency
H	magnetic field strength
Ho	reference magnetic field strength, (see annex A)
m	magnetic dipole moment
P	power
R	distance
Ro	Reference distance, (see annex A)
t	time

3.3 Abbreviations

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

IDEA	IDentification Electronique des Animaux
JRC	Joint Research Centre (of the EU Commission)
ULP-AMI	Ultra Low Power Active Medical Implant

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.

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 to 6 kbits/s generally 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, etc. 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 were 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 reception from the implant. Modulation type is generally pulse position encoded but other forms of modulation may occasionally 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 and FEC check codes coupled with a very limited instruction command set that is recognized by the implant. The above measures protect patient safety from data corruption due to ambient signals.

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 rare 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 [3]. 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 [3]. At 10 m, the implant levels are well below the existing ambient noise levels at these frequencies.

Current regulations

CEPT/ERC 70-03 specifies in annex 9 for inductive loop applications the following parameters.

	Frequency Band	Field Strength (table 2 of Rec 70-03)	Antenna (table 3 of Rec 70-03)	Channel spacing (table 4 of Rec 70-03)	Licensing requirement (table 5 of Rec 70-03)	Approvals (table 6 of Rec 70-03)	Duty cycle (table 7 of Rec 70-03)
aa	9 kHz to 59,750 kHz	3 (see note 2)	1, 2 or 3 (see note 3)	13	2	1, 2 or 4 (see note 4)	-
ab	59,750 kHz to 60,250 kHz	2	1, 2 or 3 (see note 3)	13	2	1, 2 or 4 (see note 4)	-
ac	60,250 kHz to 70 kHz	3 (see note 2)	1, 2 or 3 (see note 3)	13	2	1, 2 or 4 (see note 4)	-
b	70 kHz to 119 kHz	2	1, 2 or 3 (see note 3)	13	2	1, 2 or 4 (see note 4)	-
c	119 kHz to 135 kHz	3 (see note 2)	1, 2 or 3 (see note 3)	13	2	1, 2 or 4 (see note 4)	-

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 m^2 and 0,16 m^2, the field strength 3 is reduced by 10 × log (area/0,16 m^2); for an antenna area less than 0,05 m^2 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 [5].

These levels are accepted as a recommendation, CEPT/ERC/REC 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/REC 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 this equipment. The proposed field strength limits are below those provided for in clause 4.1.1.1 of EN 300 330-2 [3]. The average measured magnetic field strength at 10 m distance of the units was +22 dBuA/m. Measurements on production quantities showed a few units produced a level of +30 dBuA/m measured at 10 m distance.

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 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/REC 70-03 [2].

	Frequency Band	Field Strength[3] (table 2 of Rec 70-03)	Antenna (table 3 of Rec 70-03)	Channel spacing (table 4 of Rec 70-03)	Licensing requirement (table 5 of Rec 70-03)	Approvals (table 6 of Rec 70-03)	Duty cycle (table 7 of Rec 70-03)
a	9 kHz to 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]	-
c	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]	-
e	119 kHz to 135 kHz	3[1]	1, 2	13	2	1, 2 or 4[2]	-
f	135 kHz to 148,5 kHz	30 dBµA/m[4] at 10 m	1, 2	13	2	1, 2 or 4[2]	-
g	148.5 kHz to 255 kHz	30 dBµA/m[4] at 10 m	1, 2	13	2	1, 2 or 4[2]	-
h	255 kHz to 283,5 kHz	30 dBµA/m[4] at 10 m	1, 2	13	2	1, 2 or 4[2]	-
i	283,5 kHz to 315 kHz	30 dBµA/m[4] 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 m^2 and 0,16 m^2, the field strength 3 is reduced by 10 × log (area/0,16 m^2); for an antenna area less than 0,05 m^2 the field strength 3 is reduced by 10 dB.
NOTE 2: For countries which have implemented the R&TTE Directive.
NOTE 3: For measurement, a tolerance of ±6 dB (radiated) plus uncertainties as per by ETR 028 [8] is inclusive as specified in the EN 300 330 [9].
NOTE 4: The ULP-AMI industry will study the possibilities with a nominal level of +22 dBµA/m at 10 m if the WGSE/PT24 -sharing study results warrant this reduction.

Compatibility issues

Generally, in the band 9 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 to 148,5 kHz
- Fixed stations 130 kHz to 148,5 kHz (operating as "permitted service")
- Radionavigation 255 kHz to 315 kHz (Aeronautical and/or Maritime)

In the band 9 kHz to 135 kHz, inductive applications are already permitted in the CEPT countries for general usage or specific usage applications. For the frequency bands between 135 kHz and 315 kHz the ULP-AMI Industry has the opinion that compatibility issues do not exist, as the systems have been used for more than 10 years by this branch of the medical device industry without any disturbance complaints.

Nevertheless, the acceptance of +30 dBµA/m or alternatively +22 dBµA/m at 10 m in the frequency bands 135 kHz to 315 kHz must be verified by a sharing study in CEPT/ECC/WGSE/PT24. The ULP-AMI industry will actively collaborate in this sharing study.

Compatibility with the Amateur Radio Service

The Radio Amateur community has expressed concern that their experimental operations in the 135,7 kHz to 135,8 kHz may cause disturbance to ULP-AMI equipment. To address the concerns of the Radio Amateur community, the ULP-AMI industry wishes to present the following. Active medical implants and programmers only communicate in medical facilities under the direct supervision of a medical professional. Thus, there is no expectation that a communications session between an implant and a programmer would occur in a location where Radio Amateurs would be transmitting. Magnetic fields at these frequencies attenuate at a 60 dB per decade rate. Although the geographic separation between the services is expected to be large and the attenuation rate of the signals due to either service is very large, 60 dB/decade, there are additional factors that would preclude any possibility of interference either to the implant or radio amateur service. The implant transceiver circuitry cannot be activated except by some external means. A strong magnet placed directly over the implant is the typical stimulus that is required. Both programmers and implants use CRC and FEC techniques to protect the integrity of the data that is transmitted, thus, corrupted data is ignored. Further, there is a very limited instruction set that these systems are capable of recognizing. Thus, in order for an extraneous signal to cause interference to a medical implant system, the corrupted data would have to pass both an FEC and CRC check and then be in a pattern that would be compatible with an instruction format the system was capable of recognizing. Based on existing error analysis techniques used by the medical industry, the probability of this occurrence is of the order of 10^{-9} to 10^{-10}.

Regarding the possibility of interference to the Radio Amateurs, the ULP-AMI industry would again like to raise the issue of geographic separation of the two services. From the previous section, the average magnetic field strength of +22 dBuA/m measured at 10 m from the programmers will be reduced by 18 dB to a level of +4 dBuA/m at a 20 m distance. The magnetic field strength of implants is more that 60 dB below this level. Thus, the only potential source of interference to the Radio Amateur Service is from the programmers and the numbers of programmers are relatively very low. Further, the emission levels from the limited number of programmers is well below the expected existing ambient at these frequencies in the clinical settings this equipment is operated in. Thus, path loss between the services will reduce the signal from these medical systems very quickly to levels below the existing ambient with the result that any possibility of interference to the Amateur community is negligible. Further, the very narrow bandwidth of the Radio Amateur receivers will provide approximately 10 dB of additional interference protection to the Amateur receivers. Based on the above, the ULP-AMI industry sees no need for any further study of the ability of these systems to share this limited portion of the electromagnetic spectrum and considers there is no realistic possibility of any interference between the two services.

Option

However, if there remains any concern on the part of the Amateur Radio community, we suggest that this band could be excluded. Exclusion of this band would prevent ULP-AMI equipment from using a frequency within the band as its fundamental frequency. It is, however, the opinion of the ULP-AMI industry, that the amateur equipment will not cause disturbance to the ULP-AMI equipment and ULP-AMI equipment will not disturb the amateur equipment under any reasonable usage scenario.

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.

- The ability of ULP-AMI systems to share the band 9 kHz to 315 kHz 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 or clinical 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 these clinical settings.

- 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.

CEPT/ECC and ETSI actions

- Liaison statement from ETSI to ERC WGSE/PT24 and WGFM.

- WGSE/PT24: to verify compatibility with Maritime mobile, Radionavigation, Broadcast and fixed stations as needed. (Field test, absolute measurements, modelling analysis). The acceptance of the + 30 dBµA/m at 10 metre will fully depend on the outcome of this study. Alternatively, + 22 dBµA/m at 10 metre will be studied if the higher level is unacceptable.

- ERC/REC 70-03: modification of annex 12 as appropriate.

- The spectrum parameters for inductive loop ULP-AMI devices that are the subject of this document are intended to be included as an annex in the EN 300 330-2 [3] or in a new European Harmonized Standard.

- CEPR/ECC Decision on the Harmonization of the radio interface for ULP-AMI in the frequency bands 135 kHz to 315 kHz.

Annex A (informative): 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 commercialization 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	8 000
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
Programmer duty cycle based active transmission time/hr	> 1% < 10%

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 field strength 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 in EN 300 330-2 [3].

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 and pose interference threat to existing services.

Annex B (informative): 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.

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 cc 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.

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 average measured H field was +22 dBuA/m and minimum H field was -21,5 dBuA/m with a production unit measuring +30 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 [3].

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 [3]. 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 m using the procedure specified in annex J of EN 300-330-1. The extrapolated levels so obtained are expected be no greater than 70 dB below the levels specified in clause 4.1.1.1 of EN 300 330-2 [3].

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 clinical environments the ambient noise is typically much higher than the average ambients measured outside the clinical environment. The main noise sources are the harmonics of different electric equipment, for example switch mode power supplies, PC`s, monitors, other medical equipment, ISM devices, fluorescent lights, electric distribution in general, etc. According to ERC Report 44, the noise level in this type of environment, measured in a 1 kHz bandwidth, is expected to vary in the range 5 dBµA/m to 30 dBµA/m at 50 kHz. A typical level is 13 dBµA/m at 50 kHz. The noise level falls at a 3,5 dB/octave and it is typically -13 dBµA/m at 8 MHz.

B.2 Technical justifications for spectrum

B.2.1 Power

The maximum carrier level of + 30 dBuA/m measured at 10m distance is below the CEPT/ERC Recommendation 70-03 [2] annex 9 limits and is below the levels specified in clause 4.1.1.1 of EN 300 330-2 [3].

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 9 kHz 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 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 contains a sharing analysis between other inductive systems and existing users in the 9 kHz 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, lower than the H-field levels considered in ERC Report 44, from ULP-AMI systems.

B.2.3 Transmission mask

Emissions are measured in accordance with EN 300 330-2 [3].

B.3 Information on current version of relevant ETSI standard

The current ETSI standard is EN 300 330- 2 [3].

Annex C (informative): Expected compatibility issues

C.1 Coexistence studies (if any)

See ERC Report [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
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