Electronic Communications Committee (ECC)
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THE COEXISTENCE BETWEEN ULTRA LOW POWER - ANIMAL IMPLANT DEVICES (ULP-AID) OPERATING IN THE FREQUENCY BAND 12.5 – 20MHz AND EXISTING RADIOCOMMUNICATION SYSTEMS

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EXECUTIVE SUMMARY

Inductive loop active medical implant communication systems used in medically related scientific studies are biomedical telemetry systems that provide one-way communication capability between an external receiver and an implant placed inside an animal body that transmits physiological data to the external receiver. These transmitters, due to power consumption and size constraints, typically use pulse position modulation and have minimal filtering thus having relatively broad emissions.

Current medical studies typically involve individual animals that are independently housed in cages permitting separation of the animals in order to retrieve the data from each animal. However, there are European treaties that are in process of being adopted by the EU Member States that will effectively require social animals used in many of the studies to be housed in groups rather than individually resulting in an urgent need for additional frequencies to be made available. Without the additional frequencies, many studies will be significantly affected requiring longer durations for completion or even elimination.

The analysis presented in this report covers the existing radiocommunications services in the frequency band 12.5 ─ 20 MHz. Proliferation of units and locations of the facilities conducting these studies are discussed and analysed. Based on this analysis, it is concluded that due to their very low density, duty cycle of less than 10% and indoor-only usage no significant interference to the existing radiocommunications services will occur from Ultra Low Power Animal Implant Devices (ULP-AID) operating in the band 12.5 to 20 MHz with a limit of ─ 7 dBμA/m measured in 10 kHz at 10 m corresponding to a limit of – 9 dBμA/m measured in 10 kHz at 10 m when operating as intended (i.e. implanted).

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1 INTRODUCTION

The purpose of this report is to develop an analysis to determine the impact of Ultra Low Power Animal Implant Devices (ULP-AID) equipment on the existing radiocommunications services in the frequency band 12.5 to 20 MHz as a function of the proposed technical specifications for these devices. Included with the analysis is background information on market size and facility locations, etc., that are critical to the proposal and the final conclusions.

2 BACKGROUND INFORMATION

Animal implants consist of two sections, the physiological parameter sensor (or sensors) and the transmitter section to enable the telemetry function. The RF pulse drive circuit is typically integrated into a hybrid chip that drives an internal coil capacitor circuit. This coil is the radiating antenna for the implant and may range from about 4 cm in diameter to less than a cm. Generally the package is sealed in a suitable polymer case with sensor leads extending through the case. Animal medical implants for use in these animal studies are the only technology capable of providing continuous pulse coded data which is required due to the need for constant monitoring of the study subject. These studies ultimately serve to preserve and enhance the quality of life for millions of patients worldwide as physicians prescribe the various medications and/or utilize surgical techniques developed using this technology.

The subject devices, as described in ETSI TR 103 315 [1], are very low power animal implantable transmitters providing a simplex communications link to an associated nearby receiver. The implant and one or more of a series of different sensors is implanted in an animal being used in a laboratory to determine the efficacy of a drug product or medical technique. The data is transmitted using pulse position coding providing minimal battery drain to maximize the life of the implant. The associated receiver is located very near the cage containing the implanted animal (typically directly under the cage) to maximize coupling between the implant and receiver.

3 MARKET INFORMATION

Animal implants used world-wide in medically related studies total approximately 15000 units yearly. Of the 15000 units, there are about 5200 units in Europe. ULP-AID for use in pharmaceutical and surgically related animal studies is the only technology capable of providing continuous pulse coded data which is required due to the need for constant monitoring of the study subject.

Existing ULP-AID devices do not operate in the 12.5 – 20 MHz frequency band. Additional frequency bands may be required as a result of the proposed changes to the "European Convention for the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes" [2] [3]. The proposed technology builds on and utilises the current lower frequency technology with single or multiple physiological parameter sensors and transmitting using pulse position modulation coding to transmit the physiological parameter information to a separate receiver. Within the given band, the ability to select commonly available components for specific frequencies will permit cost reduction to the benefit of the industry and public.

4 ULP-AID TRANSMITTER MASK

The transmission mask of ULP-AID is defined as follows:

- 3dB bandwidth: 300 kHz;
- 10dB bandwidth: 800 kHz;
- 20dB bandwidth: 2 MHz.

5 CONSIDERATION ON THE POSSIBLE AFFECTED SERVICES

5.1 Identification of the possible affected Services

ERC Report 25 (often referred to as ECA, European table of Common frequency Allocations) [4] provides the current services allocated to use the considered frequency band.

Based on the assumption of laboratory-only environment where ULP-AID systems will be located and their ultra low power and the limited duty cycle of less than 10%, most of the services listed in ERC Report 25 [4] can be generally excluded from consideration for potential interference from use of ULP-AID transmitters. For example, Amateur, Fixed, Maritime Mobile and Aeronautical Mobile services would be unaffected by ULP-AID operation due to the expected large physical separation of the services and persons using those devices. Users of these services would seldom, if ever, be co-located near pharmaceutical and medical laboratory facilities that are found in business and commercial environments. Further, Radio Astronomy facilities are generally located in isolated areas and would be unaffected by the very limited number of ULP-AID devices. Based on this exclusion, the remaining service that could theoretically need protection from ULP-AID operations is the Broadcasting Service.

Much of the following information was taken from the ECC Report 67 [5] for the general radiated limit for inductive applications in the frequency range 148.5 kHz – 30 MHz as it pertains to broadcast services below 30 MHz. The broadcast bands that are contained within the subject band are 13.57 – 13.87 MHz, 15.1 – 15.8 MHz, 17.48 – 17.9 MHz, and 18.9 – 19.02 MHz.

5.2 Broadcast systems description

Sound broadcasting consists of two system types in the bands allocated to the broadcast service below 30 MHz: analogue broadcasting (AM) and digital broadcasting (DRM: Digital Radio Mondiale).

Currently, there is an increasing requirement worldwide for suitable means of broadcasting high quality monophonic or stereophonic sound to mobile, portable and fixed receivers. The frequency bands below 30 MHz (LF, MF and HF bands) are very attractive because of their favourable propagation conditions particularly for wide area coverage capability. The amplitude modulated (AM) sound broadcast system, which has been operating in these bands for many years, will soon share them with the new digital sound broadcast system called DRM. In the medium term the DRM will replace the existing AM system in the LF, MF and HF bands.

The protection criteria of these two broadcast systems are quite different due to the difference in their minimum usable field strengths (40 dBµV/m for AM and 20/30 dBµV/m for DRM).

The commercial LF/MF/HF receivers are designed to operate in indoor and outdoor environments. They are quite small (portable) and are equipped with telescopic antennas measuring about 1 m and have a receiver bandwidth of 9/10 kHz. A wire antenna provided with the receiver can also be fixed on the telescopic antenna to match better to LF/MF/HF reception (extension possible up to 5.5m). In any case, in indoor use, the antenna is fixed to the receiver.

6 IMPACT ON THE BROADCAST SERVICES

6.1 Propagation of magnetic generated fields

From ERC Report 69 [6], it can be concluded that in the range of distances from 10 m to 100 metres from the magnetic field source, the roll-off rate is ─ 20 dB/decade for the frequencies of concern in this analyses. This roll-off rate will be used as appropriate in the following sections.

6.2 Background noise considerations

The ambient noise is dependent on the location of the equipment and pharmaceutical medical facilities are considered to be in an industrial or commercial environment. In these environments the ambient noise is very high whose main origins are the harmonics of different electric equipment, for example switch mode power supplies, personal computers, other medical equipment, ISM devices, fluorescent lights, electric distribution in general, etc.
In Recommendation ITU-R P.372-8 [7], the median ambient background noise levels based on use of a vertical monopole above a perfect ground can be calculated according to the following formula:

$$En\ (dB\mu V/m) = Fa + 20 \log (f) + B - 95.5 \qquad (1)$$

where:

Fa (dB): external noise factor
f (MHz): centre frequency
B (dB): $10\log_{10}(b)$
b (Hz): broadcast receiver bandwidth

6.3 Interference distance analysis

The following analysis is based on decay of the permitted signal to a level that is equivalent to the ambient noise level in the environment in which the equipment covered by this document is used. Thus, the protection distances calculated using this technique may vary from other techniques that do not use this approach such as the analysis covered in ECC Report 67 [5] for the generic limit below 30 MHz. The approach taken in this document is valid for the covered equipment and is intended to cover usage in facilities that are located in commercial/industrial environments.

The proposed level of ─ 7 dBµA/m would be measured in 10 kHz on an open field test site at a distance of 10 metres. It should be noted that these devices are only used when implanted within a laboratory animal and that the tissue absorption of RF energy at these frequencies is in the order of 2 dB. Therefore the actual field strength outside the body of the animal will be ─ 7 dBµA/m + (─ 2dB) = ─ 9 dBµA/m. The following compatibility analysis is based on a limit of ─ 9 dBµA/m measured in a 10 kHz bandwidth at 10 metres which is the actual power level of the device when in use.

At this distance at the frequencies under consideration, free space impedance (Z) can be used to convert the magnetic field level to an equivalent electric field level as follows; for Z = 377 ohms (120π) and H = ─ 9 dBµA/m.

$$E_{ULP\text{-}AID}\,(dB\mu V/m) = -9\ dB\mu A/m + 20\log_{10}(377) = 42.5\ dB\mu V/m \text{ at 10 metres} \quad (2)$$

The formulae given in the ERC/REP 69 have been used to calculate the distance (*d*) required for the ULP-AID transmitter signal to fade to or below the equivalent median ambient noise level.

Distances *d* calculated for various degradation levels of N_{env} are given in Table 1:

Distances *d* calculated for various degradation levels of N_{env} in business environment						
Frequency range	**$E_{ULP\text{-}AID}$ at 10 m**	**N_{env}**	***d* for 3dB degradation (I/N_{env}=0)**	***d* for 2dB degradation (I/N_{env}=-2.3)**	***d* for 1dB degradation (I/N_{env}=-5.9)**	***d* for 0.5dB degradation (I/N_{env}=-9.1)**
MHz	dBµV/m	dBµV/m	m	M	m	m
13.57 – 13.87	42.5	12.5	273	313	383	461
15.10 –15.80	42.5	12.1	262	298	366	441
17.48 – 17.90	42.5	11.7	246	281	346	416
18.90 – 19.02	42.5	11.5	238	271	334	401

Table 1

One can also calculate the minimum separation distance (d_{min}) between interfering ULP-AID and victim broadcasting receiver by taking into account its minimum usable field strength levels in terms of dBµV/m and the required C/I in terms of dB.

The minimum separation distances d_{min} calculated for AM and DRM are given in Table 2:

d_{min} required to provide adequate protection to broadcasting service AM and DRM in the presence of an interfering ULP-AID in the HF band (Protection criterion used : C/I=C/N ⇒ I/N=0 dB)					
$E_{ULP-AID}$ at 10 m (dBµV/m)	**A_{wall}** (dB)	**E_{min}(AM)*** (dBµV/m)	**C/N(AM)**** (dB)	**I_{max}** (dBµV/m)	**d_{min}** (m)
42.5	5	40	30	10	236
		E_{min}(DRM)* (dBµV/m)	**C/N(DRM)**** (dB)	**I_{max}** (dBµV/m)	**d_{min}** (m)
		30	25	5	315
		20	17	3	354
*Values come from Rec. ITU-R BS.560 and BS.1615. **Values come from Rec. ITU-R BS.1615.					

Table 2

To provide adequate protection to broadcasting services in the presence of emissions from generic SRDs (see ECC Report 67 [5]), the above distances are quite large. Nevertheless, due to the very low density and indoor-only usage of ULP-AID operating in the band 12.5-20 MHz with a limit of -7 dBµA/m measured in 10 kHz at10 m, it is concluded that no significant interference to the existing broadcasting services will occur.

7 CONCLUSIONS

Based on the laboratory-only environment in which ULP-AID systems will be used and their ultra low power and the limited duty cycle of less than 10%, most of the services using the frequency range 12.5 – 20 MHz can be generally excluded from consideration for potential interference from ULP-AID transmitters. For example, Amateur, Fixed, Maritime Mobile and Aeronautical Mobile services would not be affected by ULP-AID operation due to the expected large physical separation of the services and persons using the UPL-AID systems. Users of these services would seldom, if ever, be co-located near pharmaceutical and medical laboratory facilities that are found only in business and commercial environments.

Further, Radio Astronomy facilities are generally located in isolated areas and therefore they would expected to be unaffected by the very limited number of ULP-AID devices.

Based on this exclusion, the remaining service that could theoretically require protection from ULP-AID operations is the Broadcasting Service. The impact of ULP-AID on broadcast systems is analysed in section 6. Based on this analysis and taking into account the fact that the ULP-AID applications are limited to indoor use only, and at a limited number of research centres/scientific/medical laboratories it is considered that the probability of any interference to the broadcast services is extremely low.

It can be concluded that the probability of interference occurring to radiocommunications services in the frequency band 12.5 ─ 20 MHz from ULP-AID devices with a limit of – 7 dBµA/m measured in 10 kHz at 10 m, corresponding to a limit of – 9 dBµA/m measured in 10 kHz at 10 m when operating as intended (i.e. implanted) is low.

REFERENCE DOCUMENTS

[1] ETSI TR 102 315: "Ultra Low Power Animal Implant Devices operating in the 12.5-20 MHz band"

[2] European Treaty Series (ET 123): "European Convention for the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes."

[3] European Treaty Series (ET 170): "Protocol of Amendment to the European Convention for the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes."

[4] ERC Report 25: "The European table of frequency allocations and utilisations covering the frequency range 9 kHz to 275 GHz."

[5] ECC Report 67: "Compatibility Study For Generic Limits for the Emissions Levels of Inductive SRDs below 30 MHz."

[6] ERC Report 69: "Propagation model and interference range calculation for inductive systems 10 kHz - 30 MHz."

[7] Recommendation ITU-R P.372-8: "Radio Noise."