Electronic Communications Committee (ECC)
within the European Conference of Postal and Telecommunications Administrations (CEPT)

ULTRA LOW POWER ACTIVE MEDICAL IMPLANT SYSTEMS (ULP-AMI)

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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 easy penetration of most materials encountered in medical environments including human body tissue, which is very desirable for medical applications. LF magnetic technology was first applied to medical implants for communications purposes in the early 1970's and is the current technology of choice for this application.

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.

Due to the advanced technology used in developing the implants, e.g. sharp filters and the particular mode of electromagnetic coupling used (magnetic head of implant programmer being placed directly onto patient's skin), it was considered that in most cases the implants were unlikely to suffer harmful interference. Therefore, this direction of interference has not been considered in this report.

MARKET BRIEFING

Heart failure affects about 22.5 million persons world-wide, 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 implantation of a pacemaker or defibrillator system 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 world-wide.

MARKET FORECAST

Based on the above, for the purpose of this study[1] it is assumed that the number of ULP-AMI devices will increase during the next 10 years up to:

ULP AMI patients with telemetry in Europe	15.000.000
Programmers with telemetry in Europe[2]	15.000

Table 0.1

[1] The number of ULP-AMI is chosen intentionally high to show the very low impact of such an application on the probability of interference.

[2] Currently the ULP-AMI devices are used almost exclusively within a hospital area. One might expect that in the near future more programmers for a so-called "home call" will be needed, but this number is expected to be very low relative to the clinical use of the equipment.

1 INTRODUCTION

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 mostly in a doctor/patient environment. Field strength levels for operation above 135 kHz are expected to be very low, so that they are below the ambient 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.

EC Directive 90/385/EEC [1] demands national provisions ensuring that the safety level of medical apparatus should be harmonised in order to guarantee the free movement of active implantable medical devices without lowering existing and justified levels of safety in the Member States.

The basis for a common regulation of the communications systems used by active medical implantable devices within the CEPT countries is CEPT/ERC/REC 70-03 [4].

To find a solution for the common regulation of the communications systems used by active implantable medical devices, studies were on the requested possible co-existence of ULP-AMI communications systems with the primary radio communications services within the frequency range from 9 kHz to 315 kHz, in which the ULP-AMI application shall be allocated.

Since application of inductive loop equipment was previously allowed [4] within the frequency range 9 kHz to 135 kHz, only the frequency range 135 kHz to 315 kHz needed to be studied.

Other radio communication services within this frequency range are:

Amateur Service	135.7 – 137.8 kHz
Broadcast	148.5 – 255 kHz, 255 – 283.5 kHz
Maritime mobile	130 – 148.5 kHz
Fixed stations	130 – 148.5 kHz (operating as "permitted service")
Radio navigation	255 – 315 kHz (Aeronautical and/or Maritime)

Table 1.1

The characteristics of these possible victim services are described in section 5.

Based on a proposal of the ULP-AMI medical community within the ETSI ERM/RP08RM committee and described in the draft TR 101 981 [3] studies were carried out to determine the interference probability for the following power [*)]output levels:

22 dB(µA/m)	as a minimum requirement
30 dB(µA/m)	as a margin for production inaccuracy

Table 1.2

The ULP-AMI applications are described in section 2, the ULP-AMI characteristics in section 3, the propagation model in section 6 and the interference calculation in section 7.

[*] *To avoid any misunderstanding relating to the term "power" the following definition was assumed for this study: The term „power" is understood as "the electro-magnetic energy, which produces at a distance of d [m] a magnetic field strength of H [A/m]".*

2 ULP-AMI APPLICATIONS

Ultra low power active medical implants (ULP-AMI), for purposes of this study, were defined as transmitters designed to transmit digital information in the frequency range 9 to 315 kHz for the purpose of providing a telemetry link between an active medical implant and an external programmer controller. Active medical implants are diagnostic or therapeutic devices containing a power source and designed to be implanted in a human body, or provide therapeutic treatment via internal delivery of therapy to a human body, that use the frequency band 9 kHz to 315 kHz for the purpose of providing a digital communications link between the implant and an external device.

ULP-AMI devices find wide acceptance for applications such as pacemakers, defibrillators, nerve stimulators, drug delivery among others. All active medical implants, such as pacemakers, defibrillators, nerve stimulators, combined pacemakers/defibrillators, and drug delivery pumps, have several very unique characteristics in common;

(a) typically, they are totally implanted within a human body,
(b) the function they perform in providing medical treatment to individuals cannot reasonably be provided for by any other means and
(c) they are expected to reliably perform their intended function for periods of time up to 10 years.

During this time as the therapeutic treatment needs change, these devices can be reprogrammed to meet those needs. Implants are also capable of storing valuable patient information and later relaying that information to the physician during patient follow up sessions.

Other emerging applications of active medical implants are for fertility monitoring, cochlear implants for the hearing impaired, experimental trials for controlling Parkinson's palsy, photographing and transmitting pictorial data in the gastro-intestinal tract, and optical nerve stimulators for the blind. With the rapid pace of technological development permitting the micro-miniaturisation of electronic circuitry, there is likely to be an ever-expanding list of applications where active medical implants will drastically improve the quality of life for affected patients.

3 ULP-AMI CHARACTERISTICS

Data links currently used between implants and programmers use low frequency magnetic field coupling systems operating in the range of 9 kHz to 315 kHz using TDD techniques and pulse position modulation. These communications links are essentially only established in a clinical setting such as a hospital or other doctor-patient medical facility setting.

In order to establish a communications link between the programmer and implant, it may be necessary to apply some type of external stimulus to the implant such as a strong steady magnetic field to activate its transmit function. This technique insures the implant only transmits when asked to do so thus conserving its battery power.

Other power saving features are the extremely low field levels produced by the implants which are typically in the order of 60 to 80 dB or more below the fields produced by the programmer and the low duty cycle of the active transmission, which is in the order of 1 % to 10 % with typical applications tending to be close to the 1% figure for programmer/controllers.

Note:
Since this duty cycle is valid for each current session, which takes approximately 20 minutes, for the purpose of this study duty cycles of 0.1%, 1% and 10% were considered.

Owing to the very low field of the implants, communication between the implant and the programmer typically requires the external programmer's magnetic head to have contact with the skin of the patient directly over the implant. Patients are usually in a prone position, thus during the activation period of the communications system the fields from the programmer and the implant are orthogonal to the fields that would be associated with signals from any primary radiocommunications services in the band. This provides an additional measure of protection from interference to or from the primary services in the band.

Transmitter
Due to the much higher power of the external programming devices, only they were considered for the sharing analysis. As previously stated the implants radiate fields that are much lower than those of the programming devices.

Programming devices typically use tuned medium Q coil antennas to emit a modulated magnetic field providing telemetry to an implant. They typically operate at single fixed frequencies within the region of spectrum from 9 kHz to 315 kHz.

These systems use a variety of coil configurations with iron cores or in some instances air cores. Maximum antenna size is approximately 10 cm in diameter with a 50-turn coil.

Data rates vary according to manufacturer with typical rates of 2 to 32 kb using e.g. pulse position modulation.

For external devices the maximum H field measured was 22 dB(µA/m) (approximately 14 dB below the permissible levels specified in EN 300 330 [2]) and the minimum H field from a small hand-held programming device was –21.5 dB(µA/m), measured at 10 m.

Communications with the implant requires the programmer loop antenna to be placed directly over the implant, normally in contact patient's skin.

During the session, the programmer will typically transmit information to change the implant program setting for 1 to 5 functions. Typical transmission time for the data stream to re-programme each function is in order of 2 ms.

Once the commands are entered and transmitted, the programmer only transmits a brief acknowledgement to the implant that it has received and correctly decoded data from the implant. Thus, programmer's transmit time is limited by the number of functions the physician determines need to be changed and the need to send a brief acknowledgement of receipt of a data packet from the implant. Based on a typical session as described, the duty cycle for the active time of transmission by the higher power programmer will normally be between 1% and 10%. The typical duty cycle of the programmer is normally expected to be of the order of 1%.

4 VICTIM RECEIVER APPLICATIONS

The following radio communication applications were considered:

- Broadcasting Service (analogue);
- Broadcasting Service (digital);
- Aeronautical Radio communication and Radio navigation Systems;
- Radio Amateur Service[1];
- Applications within an hospital area[2] ;
- European Long Wave Tele Switching[3];

[1] Because the Radio Amateur Service is allocated in the frequency range from 135.7 kHz to 137.8 kHz and the probability of interference is covered by the ECC Report 1 "Compatibility between LF and HF RFID Transponders and Other Radio Communication Systems in the frequency ranges 135 – 148.5 kHz, 4.78 – 8.78 MHz and 11.56 – 15.56 MHz" [6] the study of any impact on these caused by ULP-AMI was not performed.

[2] Within the frequency range, covered by this study, normally no radio communication applications are used in hospital areas. Therefore the study of any impact on these was not performed. Additionally these applications are covered by the EC Directive 90/385/EEC [1], Article 3, ANNEX 1, which demands that "their use does not compromise the clinical condition or the safety of patients".

[3] A German company (Europaeische Funkrundsteuerung EFR) uses frequencies at 129.1 kHz and 139 kHz for tariff-switching applications and load management as well as for the control of street lighting for example.

5 VICTIM RECEIVER CHARACTERISTICS

The victim receiver characteristics of the selected radio communication applications are shown in Table 5.1

Service	BW[a)] [kHz]	Signal to be protected [dB(µV/m)][b)]	C/I [dB][b)]	Permissible interference level [dB(µV/m)]	Permissible interference level [dB(µA/m)]
BC (analogue)	9	70	37	33	-18.5
BC (digital)	9	63	17	46	-5.5
Navigation	2	37	15	22	-29.5
Teleswitching	0.2	60	20	40	-15.5

Table 5.1: Victim receiver characteristics

a) For the purpose of this study an interferer bandwidth of 9 kHz is assumed.
Note:
According to the EN 300 330 [2] the bandwidth of the measurement receiver is 200Hz for frequencies below 150 kHz, and 9 kHz for frequencies from 150 kHz up to 30 MHz. These bandwidths must be used when the maximum permitted output level (carrier and spurious emissions) are to be measured.

Because the frequency range up to 148.5 kHz is covered by the ECC Report 1 [6] it is assumed that for a frequency range of less than 150 kHz (150 kHz – 148.5 kHz) the possible calculated error is negligible.

No bandwidth corrections factors were considered. The reasons are:

- *In cases where the emission bandwidth of the interferer is smaller than the receiver bandwidth of the victim no bandwidth correction factor applies.*
- *In cases where the emission bandwidth of the interferer is larger than the receiver bandwidth of the victim a correction factor can be used ($10*\log(BW_i/BW_v)$), which would increase the permissible interference level.*

b) The values for the levels of the Signal to be protected and the C/I are derived from the ITU (Final acts of the Regional Administrative LF/MF Broadcasting Conference (Regions 1 and 3) Geneva, 1975), the technical specifications (Navigation) and manufacturers/service providers instructions (Teleswitching), respectively.

6 PROPAGATION MODEL

For the purpose of this study the "near-field"propagation model, based on the ERC Report 69 [5] was used.

The reasons for model relection:
- the frequency ranges for the applications are below or equal to 315 kHz;
- on these frequencies there is no impact caused by walls or by environment;
- the surface of antenna loop is very small relative to the interference distance to be taken into account (the interference distance $d \ll \lambda/2\pi$).

The equation for the calculation of the magnetic field strength is;

$$H = \frac{n*I*A}{2*\pi*r^3} \quad (1)$$

with:
- H – magnetic field strength [A/m];
- I – current within the antenna loop [A];
- A – surface of the antenna loop [m²];
- r – measurement distance [m];
- n – number of coil's turns within the antenna loop (set to 1).

Note:
Normally, the far-field condition should be used for interference distances $d > \lambda/2\pi$. However,. since the pre-calculated interference distances were less than 200 m, it was assumed that the error within the calculation is negligible (see section 7).

To be independent of the unknown current within the antenna loop and its surface, constants K (i) = n*I*A (equal to the magnetic dipole moment [Am^2]) were introduced as a substitute of the magnetic field strength H_0 (i) of 22 dB (µA/m) and 30 dB (µA/m) measured at a distance of r = 10 m.

$$H_0 := \begin{bmatrix} 22 \\ 30 \end{bmatrix} \quad dB\left(\frac{\mu A}{m}\right)$$

$$K(i) := 2\cdot\pi\cdot r^3\cdot 10^{\frac{H_0(i)}{20}} \quad \mu Am^2$$

The constants K(i) are shown in **Table 6.1 below**

Magnetic field strength [dB(µA/m)]	K(i) [µAm^2]
22	7.91*10^4
30	1.987*10^5

Table 6.1

The resulting field strength as a function of the interferer distance *d* is calculated by:

$$H_{int.lin}(i,d) := \frac{K(i)}{2\pi d^3} \quad \left(\frac{\mu A}{m}\right)$$

as a linear function, and:

$$H_{int.log}(i,d) := 20\cdot\log\left(H_{int.lin}(i,d)\right) \quad dB\left(\frac{\mu A}{m}\right)$$

as a logarithmic function;

with:

$H_{int.lin}$	–	magnetic field strength of the interferer [µA/m];
$H_{int.log}$	–	magnetic field strength of the interferer [dB(µA/m)];
i	–	index ;
d	–	distance between interferer and victim;
K(i)	–	constants as a substitute for the radiated power as described above

The results are shown in **Figure 6.1** as a linear function and in **Figure 6.2** as a logarithmic function.

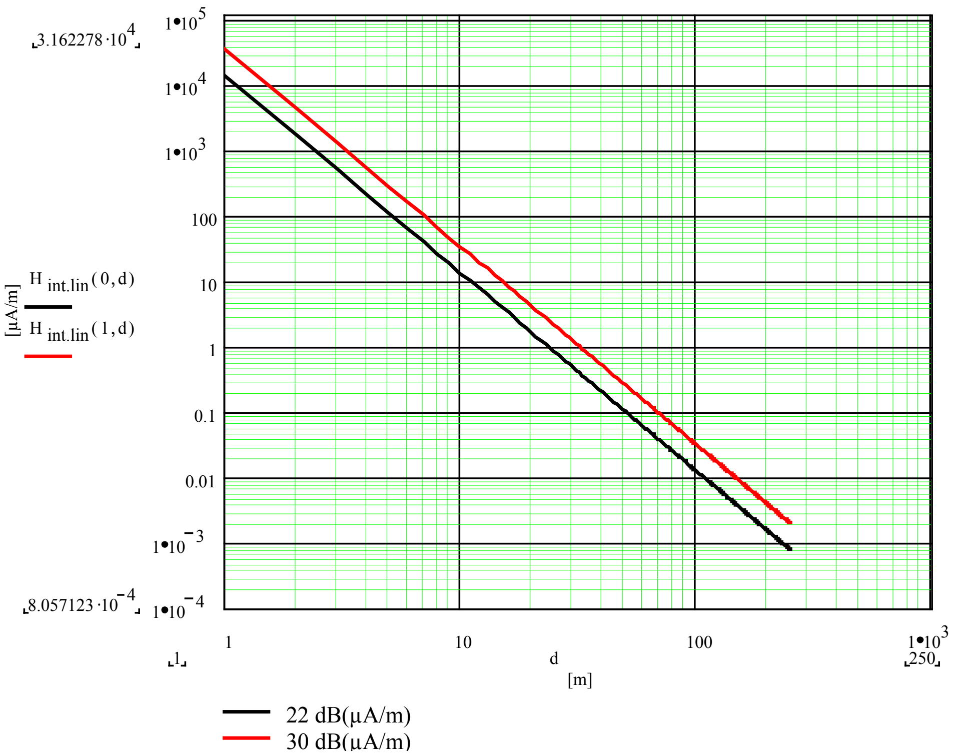

Figure 6.1

Note:
The values above 160 m within this graph are to be ignored, because from that point the far-field conditions should be used.

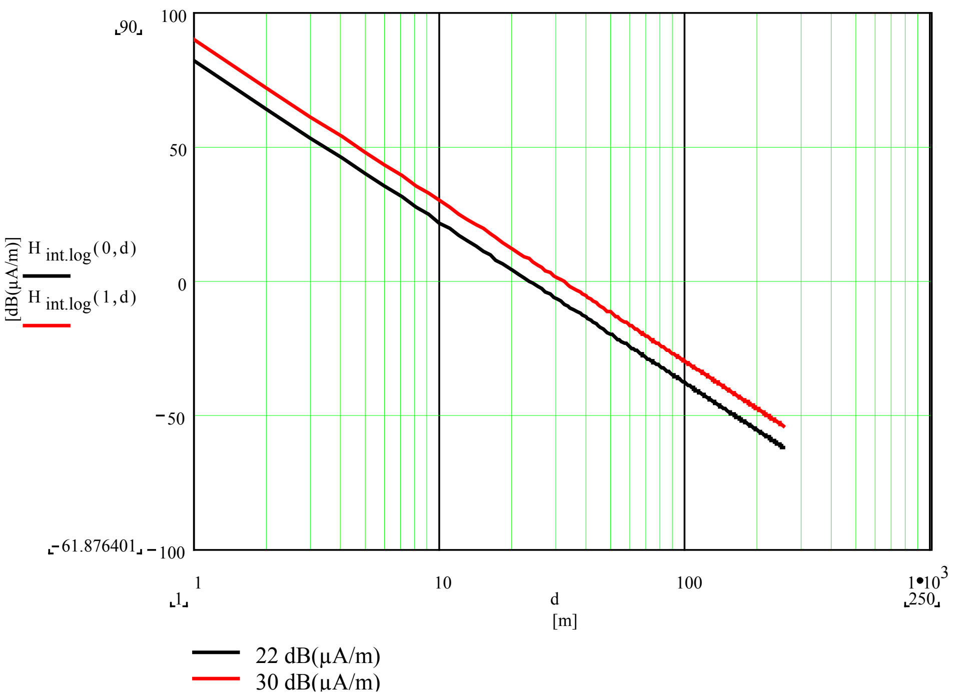

Figure 6.2

Note:
The values above 160 m within this graph are to be ignored because from that point the far-field conditions should be used.

7 INTERFERENCE EVALUATION

Based on the victim receiver characteristics (see section 5):

$$H_{int} := \begin{bmatrix} -5.5 \\ -15.5 \\ -18.5 \\ -29.5 \end{bmatrix} \qquad dB\left(\frac{\mu A}{m}\right)$$

,

the minimum interference distances are given in **Figure 7.1** as a graph.

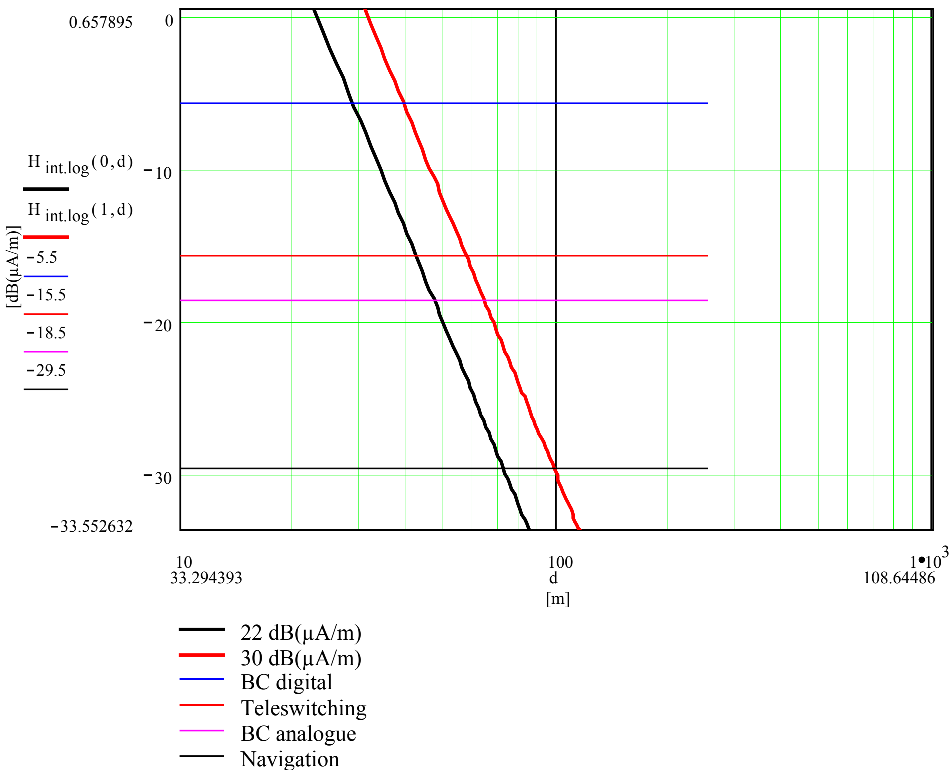

Figure 7.1

The corresponding formula for Minimum interference distance is:

$$d_{min}(i,j) := \sqrt[3]{\frac{K(i)}{2 \cdot \pi \cdot 10^{\frac{H_{int}(j)}{20}}}} \qquad m$$

where:

- $d_{min}(i,j)$ – minimum interference distance [m];
- i,j – indexes;
- K(i) – constants, see section 6, [μAm^2];
- $H_{int}(j)$ – maximum interference level [dB(µA/m)].

The calculated minimum interference distances are shown in **Table 7.1**

Service	**Max. interference level [dB(µA/m)]**	**Min. interference distance [m] vs. interferer output level [dB(µA/m)]**	
		22	**30**
BC digital	-5.5	29	39
Teleswitching	-15.5	42	57
Navigation	-18.5	47	64
BC analogue	-29.5	72	98

Table 7.1

The results of this calculation should be interpreted in a way that outside the areas of the minimum calculated interference distances no harmful interference will occur.

It can be assumed that within a minimum distance of less than 200 m normally neither maritime nor aeronautical navigation equipment will be used. Therefore only the impact on the receiver of Teleswitching and BC analogue services was studied further.

For the probability of interference, the interference calculation described in section 7 "Interference Calculation" of the ECC Report 1 [6] is used (including the values for N_{pop} and d):

$$p_{int} := \sum_{x} \frac{N_{int} \cdot ms \cdot dc \cdot fr^{\frac{2}{3}} \cdot \pi \cdot R^2 \cdot N_{user}}{\frac{N_{pop}}{d}}$$

where:

p_{int}	–	probability of interference;
x	–	number of different kinds of application of the interferer;
N_{int}	–	number of interferer of each kind of application;
ms	–	market share factor of the application;
dc	–	duty cycle of the interferer;
fr	–	reduced field strength of the application;
R	–	minimum interference distance (equal to d_{min});
N_{user}	–	number of victims in use;
N_{pop}	–	number of inhabitants within the CEPT countries;
d	–	population density factor.

Because for ULP-AMI devices there are no different applications and also no different factors "ms" and "fr", the used formula is given as:

$$p_{int}(i,j) := N_{ulp} \cdot dc \cdot N_{user}(j) \cdot \frac{A_{int}(i,j)}{A_{pop}}$$

with:

$$A_{int}(i,j) := 2 \cdot \pi \cdot \left(\frac{d_{min}(i,j)}{1000}\right)^2$$ - interfered area [km^2] depending on the type of victim

N_{ulp}	–	number of ULP-AMI as interferer;
$N_{user}(j)$	–	number of victims in use (depending on the type of victim);
A_{pop}	–	N_{pop}/d.

The calculated probability of interference is shown in Table 7.2 below.

Service	N_{user}	Probability of interference vs. interferer output level and duty cycle					
		22 dB(µA/m)			30 dB(µA/m)		
		0.1%	1%	10%	0.1%	1%	10%
Teleswitching	100.000	0.008	0.084	0.84	0.015	0.155	1.55
BC analogue	500.000	0.123	1.23	12.3	0.277	2.27	22.7

Table 7.2

Note:

- *The calculated results are based on a density of $d_{average}$ = 400 hab/km^2 for an average populated area.*
- *To show the probability of interference applying to a densely populated area, e. g. with a density of d_{dense} = 10000 hab/km^2, the results should be multiplied by a correction factor d_{dense} /$d_{average}$..*

8 SUMMARY OF RESULTS

The interference evaluation assumed in each case the co-channel interference in the meaning that all interfering ULP-AMI equipment would be used at the same time with the same frequency as a considered victim receivers.

Due to the fact that the Teleswitching equipment use only one frequency (139 kHz) in the relevant frequency range, which is also covered by the ECC Report 1 [6] the probability of a co-channel interference can be ignored.

Relating to the Broadcast Services (analogue) the above calculated probability of interference is to be divided by the number of Broadcast channels available within the relevant frequency range (15 channels, each with a bandwidth of 9 kHz).

Additionally it should be taken into account that an ULP-AMI implant is active at most only four times a year each, for a period of approximately 20 minutes and that the higher power programmers typically have duty cycles in the order of 1% based on total transmission time during a one hour period. This hourly duty cycle assumes a session average of 20 minutes and that there is 3 consecutive sessions during a given hour as a worst case.

It is quite clear that whenever an ULP-AMI programmer is active the calculated probability of interference applies. On the other hand, the active transmission time will last in total, only for approximately 80 minutes a year per implant. It should be taken into account that the guaranteed supply of Broadcast Services in terms of time and locations is only 99%. In other words, assuming the duty cycle of a very limited number of programmers, any potential for interference from ULP-AMI programmers will not affect the 99% probability that broadcast services will always be available.

Further more, the calculated minimum interference distance is less than 100 m. Due to the fact that the usage area of ULP-AMI equipment is confined to hospital areas, and assuming that this hospital area is normally larger than 200 m in diameter, only Broadcast Service receivers used within that hospital area might suffer interference.

9 CONCLUSION

This study shows that, although there is a very low probability that interference may be caused by ULP-AM programmers, the risk is so slight as to be negligible and well within the bounds of acceptability.

Since the probability of interference is, considering all the described facts, extremely low, an output level of 30 dB(µA/m) measured at a distance of 10 m can be accepted for all ULP-AMI applications within the frequency range from 9 kHz to 315 kHz.

10 REFERENCES

[1] Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implant able medical devices
Official Journal L 189 , 20/07/1990 P. 0017 – 0036 , corrected by: **31990L0385R(01)**
CORRIGENDUM TO: Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implant able medical devices, *Official Journal L 007 , 11/01/1994 p. 0020*

[2] EN 300 330. 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

[3] ETSI TR 101 981. 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

[4] ERC RECOMMENDATION 70-03. RELATING TO THE USE OF SHORT RANGE DEVICES (SRD) ANNNEX 9

[5] ERC Report 69. PROPAGATION MODEL AND INTERFERENCE RANGE CALCULATION FOR INDUCTIVE SYSTEMS 10 kHz - 30 MHz

[6] ECC REPORT 1 on Compatibility between Inductive LF and HF RFID transponder and other Radio Communication Systems in the frequency ranges 135–148.5 kHz, 4.78–8.78 MHz and 11.56–15.56 MHz