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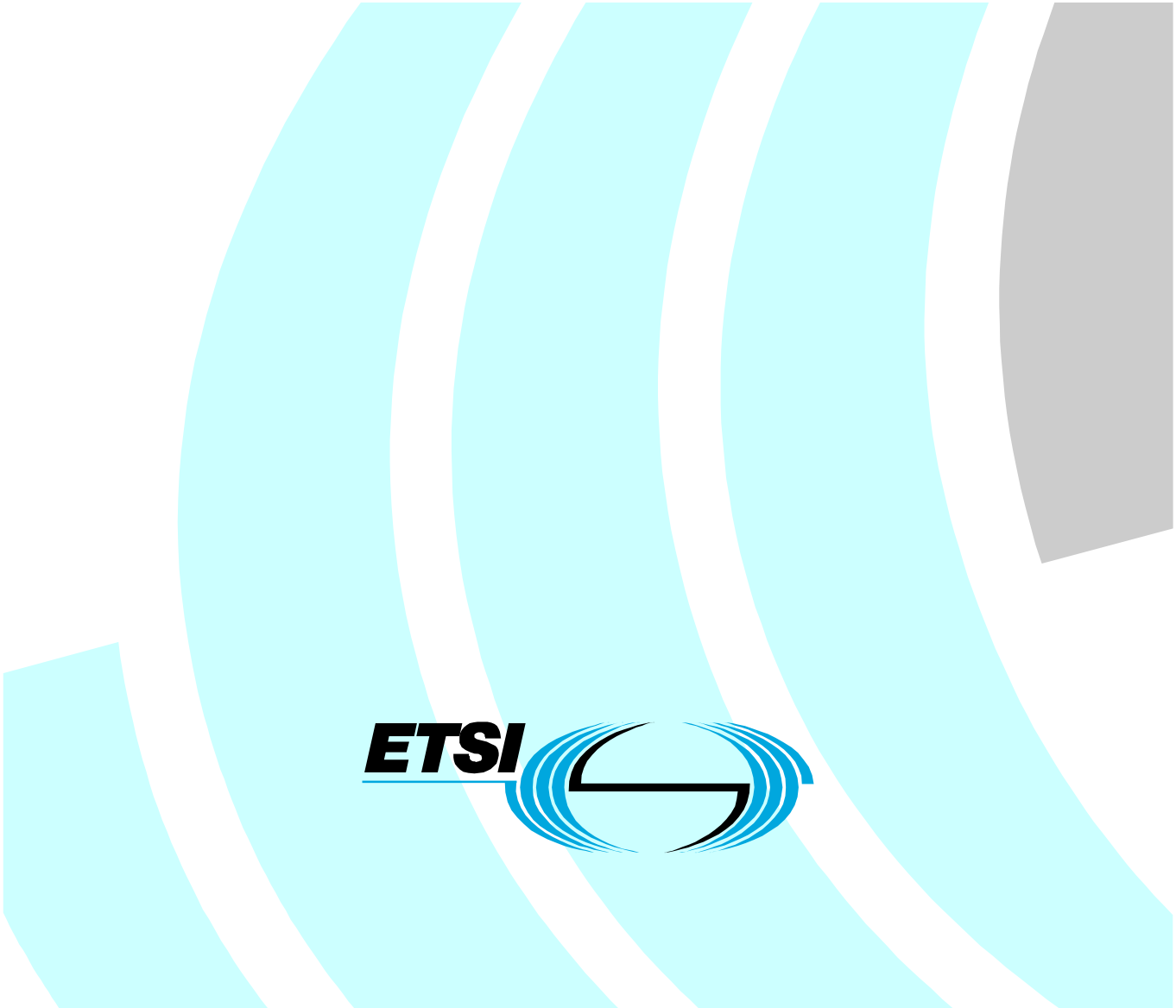
Technical Report

Electromagnetic compatibility and Radio spectrum Matters (ERM); Ultra Low Power Active Medical Implants (ULP-AMI); "Membrane Implant" devices operating in the 30 MHz to 37,5 MHz band; System Reference Document



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Contents

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Foreword

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

1 Scope

The present document defines the requirements for radio frequency usage for ULP - AMI membrane medical implants operating in the frequency range from 30 MHz to 37,5 MHz. It defines the radio-communication link between the implanted membrane device, the associated transmitter to activate and power the membrane, and to the associated receiver for registering the blood pressure data.

It includes necessary information to support the co-operation between ETSI and the Electronic Communications Committee (ECC) of the European Conference of Post and Telecommunications Administrations (CEPT), including:

- Detailed market information (annex A).
- Technical information (annex B).
- Expected compatibility issues (annex C).

2 References

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

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

[2] 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.

[3] 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 (AMD Directive).

[4] ETSI EN 302 195-2: "Electromagnetic compatibility and Radio spectrum Matters (ERM); Radio equipment in the frequency range 9 kHz to 315 kHz for Ultra Low Power Active Medical Implants (ULP-AMI) and accessories; Part 2: Harmonized EN covering essential requirements of article 3.2 of the R&TTE Directive".

[5] The BBI Newsletter, Vol. 26, No. 5, May 2003.

[6] ETSI EN 302 195-1: "Electromagnetic compatibility and Radio spectrum Matters (ERM); Radio equipment in the frequency range 9 kHz to 315 kHz for Ultra Low Power Active Medical Implants (ULP-AMI) and accessories; Part 1: Technical characteristics and test methods".

[7] CEPT/ERC Report 25: "The European Table of Frequency Allocations and Utilisations Covering the Frequency Range 9 kHz to 275 GHz: Lisboa January 2002 - Dublin 2003 - Turkey 2004".

[8] ITU Radio Regulations (ed. 2001).

[9] ERC/DEC/(01)17: "ERC Decision of 12 March 2001 on harmonised frequencies, technical characteristics and exemption from individual licensing of Short Range Devices used for Ultra Low Power Active Medical Implants operating in the frequency band 402 - 405 MHz".

3 Definitions, symbols and abbreviations

3.1 Definitions

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

ULP-AMI "membrane implant" transmitter: device containing resonant circuit components that is implanted in the body of a patient

NOTE 1: The resonant frequency of the circuit is expected to vary as a function of the measured parameter.

NOTE 2: Typical sizes and shapes are provided in clause B.1.2 of the present document.

ULP-AMI "membrane system": system consisting of an energy source delivering power via RF magnetic field coupling to a membrane implant that uses the energy to transmit its internally generated resonate frequency to a receiver outside the body

vascular: of or pertaining to the arterial or venous system contained within the human body

3.2 Symbols

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

f	Frequency
H	Magnetic field strength
P	Power
R	Distance
t	Time

3.3 Abbreviations

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

AIMD	Active Implantable Medical Device
CT	Computer Tomography
dB	decibel
erp	effective radiated power
ECA	European Common Allocation
IF	Intermediate Frequency
PMR	Private Mobile Radio
R&TTE	Radio and Telecommunications Terminal Equipment
RF	Radio Frequency
SRD	Short Range Device
SRD-MG	Short Range Device Maintenance Group
ULP-AMI	Ultra Low Power Active Medical Implant
ULP-AMI-P	Ultra Low Power Active Medical Implant Peripheral
WG FM	Working Group Frequency Management

4 Executive summary

4.1 Status of the System Reference Document (SRDoc)

The TC ERM, in its 22nd meeting in Sophia Antipolis, reviewed version 1.1.1_0.0.5 of the present document and provisionally approved it, under the condition that it be fully aligned with the decision of the 29th CEPT-ECC SRD-MG meeting for proposal to CEPT-ECC WG FM. Working group ERM_RM has since approved the final document at its 27th meeting in Brest for publication, on behalf of TC ERM.

4.2 Technical Issues

AIMDs based on ULP-AMI membrane technology will provide significant benefits for patients who have undergone vascular surgery due to arterial diseases. Typically, such surgery requires periodic monitoring of vascular blood pressure. Such monitoring gives early warning that postoperative physician intervention is required to protect the health and safety of the patient. Membrane technology is a new technology that is capable of providing real time, highly accurate, vascular diastolic and systolic blood pressure levels that cannot be obtained by any other non-invasive technique at this time. This technology will allow physicians to quickly and easily monitor postoperative patients to determine if emergency intervention is required after surgery to repair damaged vascular structures within the human body. The present document covers implanted membrane communication technology operating in the range from 30 MHz to 37,5 MHz.

4.2.1 System description

The system consists of three functionally independent devices:

a) an external inductive activator (ULP-AMI-P) whose only function is to activate and power the membrane implant via coupling of RF energy (ULP-AMI-P);

b) a separate internal transmitting device (membrane implant, ULP-AMI) that has been implanted in a patient that communicates to c); and

c) an external receiver (ULP-AMI-P) that decodes the signal from the "membrane implant".

4.2.2 Applications

Membrane technology is specifically targeted for providing a non-invasive technique for pressure monitoring. Specifically, the initial application is in the field of vascular surgery where blood pressure levels must be closely monitored with a highly accurate readout of systolic and diastolic pressures.

4.2.3 Short market information

The current market for this application in Europe is about 8 000 activators. Expected growth rate is about 30 % each year for 6 years.

4.2.4 Spectrum requirement and justifications

This technology has several factors that influence the decision as to what constitutes a **suitable frequency band**. Membrane implants for blood pressure measurement are intended to be installed in the blood vessel of the patient at the time surgery to repair the vessel is performed. This drastically limits the size of the sensor since the method of delivery is by catheter through vessels to prevent the need for surgical insertion of the implant. Tissue absorption must be minimized due to the very low electromagnetic field radiated by the implant. Power must be supplied via magnetic coupling to the membrane implant from an external source. The system design requirement is to provide accurate pressure measurements over a range of 200 mm of mercury accounting for a maximum frequency variation of over 2 MHz due to blood pressure variation.

Taking into account the above factors, the band 30 MHz to 37,5 MHz was selected as the **best compromise.** Radiated power from the external transmitter (ULP-AMI-P) measured with the appropriate test set-up for simulating the real use conditions is of the order of 1 mWatts. Radiated power from the membrane implant transmitter (ULP-AMI) is of the order of 600 picoWatts or less. Typical bandwidth of the signal during a measurement sequence is of the order of 550 kHz representing a frequency variation associated with a systolic diastolic pressure difference of 50 mm. Measurement time is of the order of 30 seconds. Maximum duty cycle is less than 10 % with a typical duty cycle of less than 1 %.

4.2.5 Current regulations

For spectrum conformity testing the radio will comply with revised harmonized standards EN 302 195-1 [6] and EN 302 195-2 [4]. This work will be undertaken by ERM-TG30 that has responsibility for standardization of ULP-AMI systems.

4.2.6 Proposed regulation

It is proposed that CEPT adopt provisions in annex 12 of ERC Recommendation 70-03 [1] for ULP-AMI equipment to permit operation of active implantable devices using membrane technology, as described, in the frequency band **d** listed in the table below. Incorporation of the additional frequency band **d** in annex 12, specifically for ULP-AMI "membrane implant" equipment, will provide that other SRDs will not proliferate in this frequency band. The proposed maximum power limit of 1 mWatt e.r.p. (for the complete system "Implanted membrane + External activator") is an order of magnitude below those provided for other SRD devices that operate in portions of this band and consequently cannot reasonably be expected to cause interference to the existing users of the band.

Frequency band		Power	Duty cycle	Channel spacing	ERC Decision	Notes
a	402 MHZ to 405 MHz	25 uW e.r.p.	No Restriction	25 kHz	ERC DEC (01)17	Individual transmitters may combine adjacent channels for increased bandwidth up to 300 kHz
b	9 KHz to 315 kHz	30 dBuA/m at 10 m	<10 %	No spacing		
d	30 MHz to 37,5 MHz	1 mWatt e.r.p.	<10 %	No spacing		The Application is for ULP-AMI "Membrane implants" for blood pressure measurement

4.2.7 Compatibility issues

The ITU allocation for the frequency band 30 MHz to 37,5 MHz is given in clause C.2. The relevant clause of the European Common Allocation (ECA) table is given in clause C.3.

From the ECA table, the primary co-existence issue to consider is that of interference to the mobile services in the band with utilizations by defence systems, radio microphones, model control, and PMR. Model control and radio microphones operate in the band, however, these are SRDs and shall not cause harmful interference to, and shall not claim protection from harmful interference caused by, a station operating in accordance with the provisions of the Constitution, the Convention and the Radio Regulations.

Due to the hospital environment that membrane technology will be used in and the extremely low power, it is reasonable to conclude that no interference to the PMR service will occur from these systems.

5 Main conclusions

5.1 Business importance

The ability to measure pressure within the human body will become a powerful tool for physicians who diagnose, manage and treat venous disease. One example of the utility of this concept is non-invasive pressure monitoring in patients who undergo endovascular aneurysm repair. Following their surgery, these patients are subjected to an extensive and expensive series of non-invasive and invasive studies including enhanced CT and duplex ultrasound for monitoring the durability of the repair. These tests are surrogate measurements for intra-sac pressure, which is believed to be the critical variable that determines the risk of aneurysm rupture. An implantable pressure sensor strategically located within the excluded aneurysm sac provides long term, non-invasive, real-time measurements of intra-sac pressure. The capability to perform this measurement wirelessly has been termed "the holy grail in vascular surgery" in a prominent, peer-reviewed, medical journal.

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 spectrum in the range of 30 MHz to 37,5 MHz.

Implanted patients are mobile and may require emergency medical assistance while they are travelling. 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 intra- or inter-country travels.

5.2 Expected timing for products to market

Products for use by the medical community are currently undergoing clinical trials. These trials are expected to be completed in mid 2004 at which time the products will be made available to physicians for use.

5.3 ECC and ETSI actions

ETSI requests the ECC to consider the following actions:

a) approval by CEPT-ECC WG FM of the band d in annex 12 of ERC Recommendation 70-03 [1];

b) adoption of band d in annex 12 of ERC Recommendation 70-03 [1] and;

c) adoption of a CEPT Decision for this application by the ECC.

ETSI actions:

ETSI expects to revise EN 302 195-1 [6] and EN 302 195-2 [4] at a later stage to cover the spectrum parameters and measurement requirements for ULP-AMI membrane implant devices that are the subject of the present document. They will be included as a normative annex in EN 302 195-2 [4].

Annex A:
Detailed market information

A.1 Range of applications

Blood pressure monitoring and other applications, such as cranial pressure and heart chamber monitoring, are expected to be developed.

A.2 Market size and value

It is estimated that there is a current market for 8 000 activators in Europe and that the need for them will grow at approximately 30 % per year. Since medical institutions are the only users of the energizing section (external inductive system), they are much more limited with an estimated population of less than 3 000 in Europe, according to a BBI Newsletter [5].

Governmental organizations, the medical community and consumer groups support the ULP-AMI membrane implant market and technology.

A.3 Traffic evaluation

Spectrum use and efficiency:

The emission of electromagnetic radiation and the actual frequency usage is very low.

The reasons are that:

a) Readout of blood pressure takes a very short period of time, of the order of 30 seconds typically. This process is generally limited to post operative examinations in close time frame with the actual surgery. Further the pulse nature and of the system only emanating a short very low level burst of energy within the hospital environment is not a significant source of disturbance to other systems. Duty cycles are normally less than 1 % and would never exceed 10 % under any condition considering transmit format and operational conditions.

b) The attending physician only activates transmitters on demand.

Annex B:
Technical information

B.1 Detailed technical description

The system consists of three functionally independent systems:

a) an inductive system whose only function is to power and activate the membrane implant via inductive coupling of RF energy (ULP-AMI-P); and

b) a totally separate transmitting device (membrane implant transmitter), that has been implanted in a patient (ULP-AMI) and communicates to c); and

c) a receiver (ULP-AMI-P)located outside the body of the patient.

B.1.1 Inductive system operation

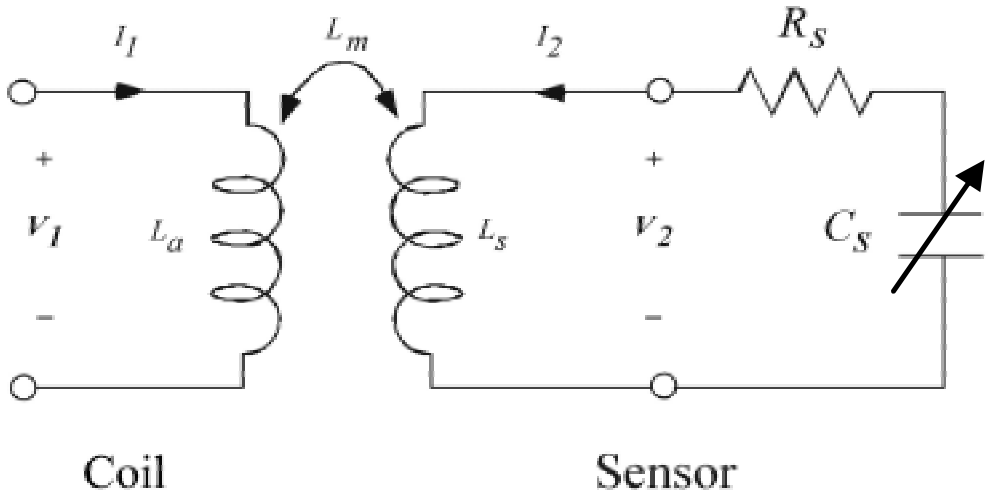
The inductive system used to power the implanted sensor via magnetic coupling operates over a frequency range from 30 MHz to 37,5 MHz in discrete steps. The magnetic coupling between this external powering coil and the implanted sensor, depicted in part (a) of figure B.1.2.1, follows the Biot-Savart relationship of magnetically coupled loops and is quite similar to a very loosely coupled transformer. Frequency stepping is necessary in order to match the resonant frequency of the implanted membrane device since the initial frequency of each implanted device is unique. This operation is somewhat similar to the use of inductive energy to couple power to a device for battery charging with the primary difference being the power is stored in a resonant circuit in lieu of a battery.

The equipment employed uses a loop antenna to magnetically couple a low-duty-cycle, gated pulse of RF energy at a single frequency with constant amplitude to the sensor. Pulse duration is approximately 2 µsec with an off period of 8 µsec. This frequency is then incrementally stepped and the process repeated across the range from 30 MHz to 37,5 MHz. Maximum on time for a measurement is typically of the order of 30 seconds. Coil diameter is approximately 20 cm and must be placed on the implanted patient as close as possible to the location of the implanted sensor. The inductive system described above generates and uses locally, radio-frequency energy for a medical purpose, i.e., to supply energy to a resonate circuit. The radiated power, measured with the adequate test set-up, simulating the real use of the device, is of the order of 1 mWatt e.r.p. (peak).

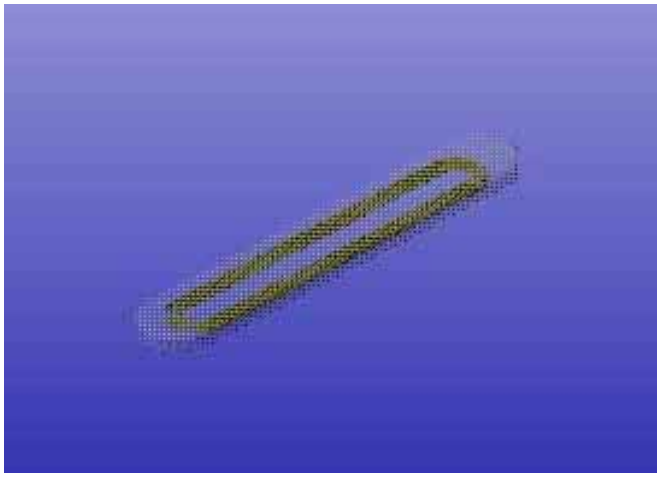
B.1.2 Membrane implant transmitter

The membrane sensor transmitter is a solid oval approximately 25,4 mm x 5 mm in width, depicted in part (b) of figure B.1.2.1, that can be implanted within the body to measure physiological parameters such as arterial pressure and potentially other biological parameters. It consists of an interconnected inductor coil and a movable-plate capacitor forming a resonant circuit, as depicted in the sensor in part (a) of figure B.1.2.1. The capacitor plates are arranged such that they face each other across a cavity, which may contain either gas or vacuum. External applied pressure will deflect the membranes closer to or further from each other, thereby altering the capacitance of the capacitor. Power to the sensor is supplied by the inductive system described above via magnetic coupling. Form factors for pressure sensors may vary somewhat from the above.

The membrane technology transmitter is placed in the patient at the time of surgery. During the immediate postoperative period, the physician may query the device on a regular basis in order to make sure blood pressure levels are not rising to the point where they may rupture the surgical incision. Later, as the patient becomes stabilized, measurement intervals are increased. Typically after 2 weeks, any querying of the patient's blood pressure using the implanted transmitter will only occur occasionally if at all. Each query session lasts approximately 30 seconds.



(a)



(b)

Figure B.1.2.1:
(a) Schematic view of the sensor illustrating inductor, capacitor, and pressure-sensitive elements;
(b) Drawing of typical sensor.

Together, the inductor and capacitor, along with any associated parasitic resistances, form a resonant circuit with a resonant frequency and quality factor. The resonant frequency can be modelled simply as:

$$f = \frac{1}{2\pi\sqrt{L_s C_s}}$$

Since, as described above, the capacitance is a function of applied pressure, this equation shows that the frequency of the resonance is also a function of the pressure. Therefore, knowledge of the resonant frequency combined with appropriate mechanical models allows determination of the applied pressure. The sensor transmits an RF pulse at the end of the inductive powering cycle. The radiated power of this signal is on the order of 600 picoWatts e.r.p.

B.1.3 Membrane implant receiver

The front end of the receiver electronics is a custom single conversion receiver. The IF is 4,725 MHz, which is phase coherent to a low phase noise master oscillator. Since the membrane sensor transmitter radiates a magnetic field at its resonant frequency, the receiver antenna uses a coil antenna. Proximity of this receiving coil is as close as possible to the implanted transmitter/sensor. Receiver tuning is achieved using two simultaneous phase-locked loops. A microprocessor relays the frequency of the excitation signal to a data acquisition routine that converts the frequency to a relative pressure change.

B.2 Technical justifications for spectrum

B.2.1 Power

The transmitter is very small consisting of a thin oval ceramic disk of the order of 25 mm by 5 mm. The disk houses an inductor and has two membranes that flex with pressure forming an oscillator tank circuit. Power for transmission is received from the external unit via a 2 µsec pulse with an off period of 8 µsec. The e.r.p. of this external transmitter is of the order of 1 mWatt . The erp of the membrane implant transmitter is of the order of <600 picoWatts.

B.2.2 Frequency

The frequency selection was based on consideration of a number of factors. Among these factors are tissue absorption, magnetic field generation and coupling for power transfer, ceramic disk size considerations, and interference due to ambient signals from systems expected to operate in a hospital environment. The band 30 MHz to 37,5 MHz was selected as the best compromise based on the above considerations.

B.2.3 Bandwidth and other radio parameters

Two primary factors had to be considered relative to bandwidth considerations. These systems are expected to operate reliably over a blood pressure level of 200 mm of mercury. With a 10 kHz variation per mm of mercury, the measurement frequency range at its maximum will be 2 MHz. The other consideration is manufacture of the ceramic disk and its static frequency of operation. Current manufacturing processes have approximately a 10 % tolerance as to the frequency of operation. With the tolerance and the range of calibration, a band from 30 MHz to 37,5 MHz is needed in order to insure operation is maintained within the authorized band. Due to the extremely low power level of the fundamental, spurious emissions below the sensitivity level of the measurement systems at the specified power level.

B.3 Information on current version of relevant ETSI standard

The devices of this radio link system are ULP-AMI devices. Although the specific frequency is not provided for in the current harmonized standard EN 302 195-1 [6] & EN 302 195-2 [4] for low frequency ULP-AMI devices, the measurement techniques for the ULP-AMI, detailed in that standard, are appropriate for measurement purposes. The test set-up for measuring the output power of the External transmitter (ULP-AMI-P) to activate and power the ULP-AMI has to be added in the standard. It is planned to provide an annex to that standard to more fully cover this ULP-AMI "Membrane implant" system .

Annex C:
Expected compatibility issues

C.1 Coexistence studies (if any)

Void.

C.2 Current ITU allocations

The ITU Radio Regulations (ed. 2001) [8] show the following allocations for Region 1 in this frequency band:

29,7 MHz to 30,005 MHz	FIXED MOBILE
30,005 MHz to 30,01 MHz	SPACE OPERATION (satellite identification) FIXED MOBILE SPACE RESEARCH
30,01 MHz to 37,5 MHz	FIXED MOBILE

C.3 European Common Allocation (ECA) Table

The European Common Allocation (ECA) Table [7] shows the following information:

Frequency band	European Common Allocation	Utilization	EU footnote	Note
29,7 MHz to 30,005 MHz	MOBILE EU2	Defence systems	EU1	
		Radio microphones		Narrow band audio systems including tour guide systems on a tuning range basis.
30,005 MHz to 30,01 MHz	MOBILE EU2	Defence systems	EU1	
		Radio microphones		Narrow band audio systems including tour guide systems on a tuning range basis.
30,01 MHz to 37,5 MHz	MOBILE EU2 EU27	Defence systems	EU1	The bands 30,3 MHz to 30,5 MHz and 32,15 MHz to 32,45 MHz are harmonized military bands.
		Model control		Model control in 34,995 MHz to 35,225 MHz only for flying models.
		PMR		
		Radio microphones		Within the band 30,01 MHz to 34,90 MHz. Narrow band audio systems including tour guide systems on a tuning range basis.

EU footnotes

EU1: Within the frequency band 20-108 MHz the common military tuning range is 30-87,5 MHz, however, some equipment types use the lower (20 MHz) and upper (108 MHz) limits, regulated on a national basis. The harmonized military bands are: 30,30-30,50 MHz; 32,15-32,45 MHz; 41,00-47,00 MHz; 73,30-74,10 MHz; 79,0-79,70 MHz. When providing for additional requirements, further blocks of frequencies should be spread out over the whole common military tuning range in order to supply frequencies for frequency hopping equipment and to support a larger force (corps size, three divisions). This should be done by the national frequency management organisation(s) concerned.

EU2: Civil-military sharing

EU27: A frequency band that is in general military use in Europe and identified for major military utilisation in the ECA. Such a frequency band forms a basis for military use and planning. The band can be shared between civil and military users according to national requirements and legislation.

C.4 Sharing issues

Membrane technology implant levels are of the order of 20 dB or more below the maximum permitted levels for other SRDs operating in the same band as permitted under annexes 8 and 10 of ERC Recommendation 70-03 [1]. Under annex 8, model controls with a 100 mW power level are permitted in a portion of the band and under annex 10, radio microphones are permitted to operate throughout the band at a power level of 10 mW. Thus there is no reasonable expectation that membrane implant systems with their very limited deployment and hospital usage environment will cause disturbance to the existing primary users of the spectrum.

History

Document history		
V1.1.1	May 2004	Publication