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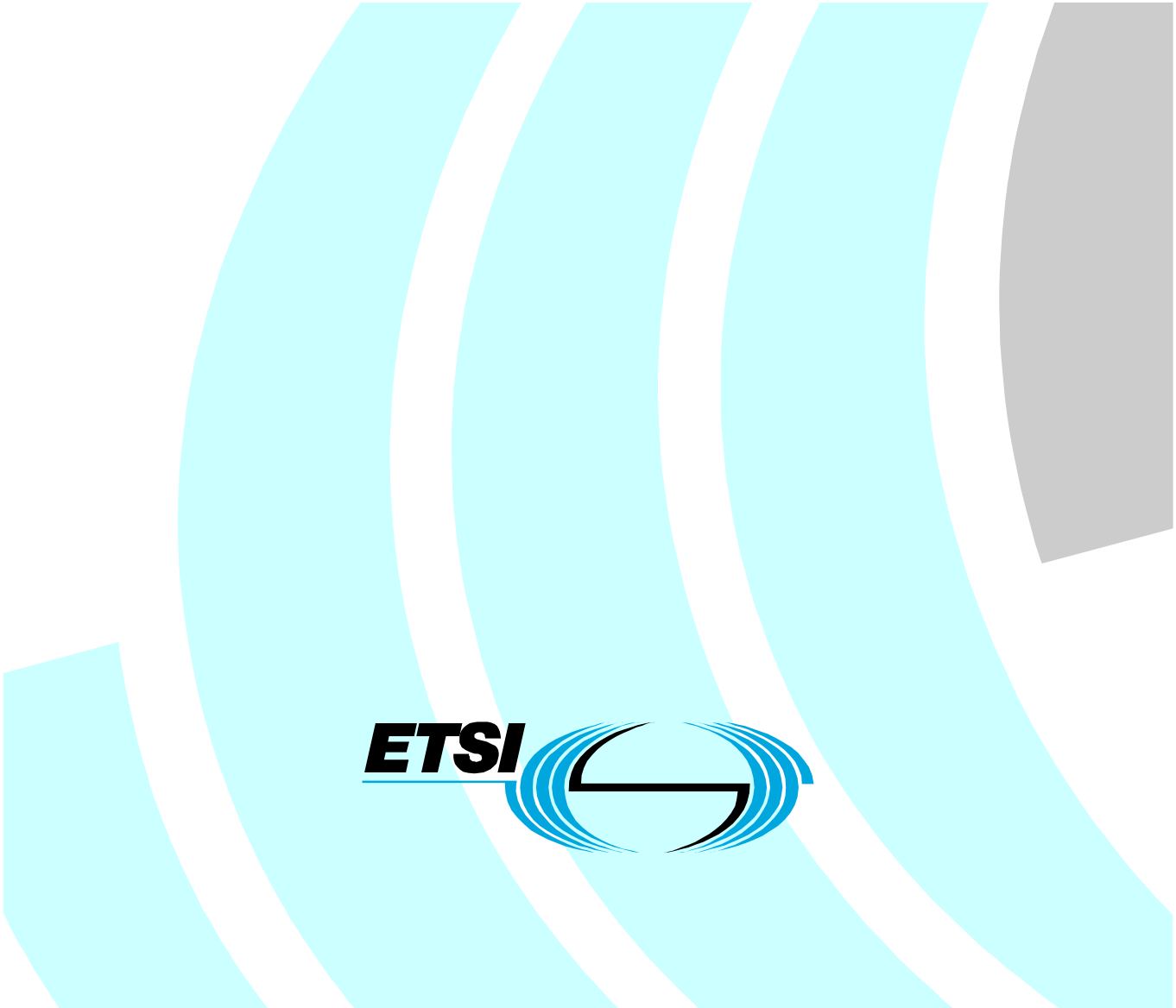
Technical Report

Electromagnetic compatibility and Radio spectrum Matters (ERM); Ultra Low Power Active Medical Implants (ULP-AMI) operating in the 401 MHz to 402 MHz and 405 MHz to 406 MHz bands; System Reference Document



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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 spectrum usage for ULP-AMI active medical implants and peripherals operating in the 401 MHz to 402 MHz and 405 MHz to 406 MHz frequency bands. It further defines the technical characteristics of these devices and proposes interference mitigation technologies to avoid interference to and from primary users (meteorological aids) and other medical wireless applications, to ensure reliable communication links.

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] CEPT/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] ITU-R Recommendation SA.1346: " Sharing between the meteorological aids service and medical implant communication systems (MICS) operating in the mobile service in the frequency band 401-406 MHz".

[4] ETSI EN 301 839-1 (V1.1.1): "Electromagnetic compatibility and Radio spectrum Matters (ERM); Radio equipment in the frequency range 402 MHz to 405 MHz for Ultra Low Power Active Medical Implants and Accessories; Part 1: Technical characteristics, including electromagnetic compatibility requirements, and test methods".

[5] ETSI EN 301 839-2 (V1.1.1): "Electromagnetic compatibility and Radio spectrum Matters (ERM); Radio equipment in the frequency range 402 MHz to 405 MHz for Ultra Low Power Active Medical Implants and Accessories; Part 2: Harmonized EN covering essential requirements of article 3.2 of the R&TTE Directive".

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

[7] International Diabetes Federation: http://www.idf.org/e-atlas/home/index.cfm?node=84.

[8] ECC/SE24(96)37 (1996) "Compatibility study between SRD and Meteorological Aids at 403 MHz".

[9] CEPT/ERC Decision (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".

[10] ETSI TR 102 313: "Electromagnetic compatibility and Radio spectrum Matters (ERM); Frequency-agile Generic Short Range Devices using Listen-Before-Transmit (LBT) Technical Report".

[11] ETSI EN 300 220: "Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Radio equipment to be used in the 25 MHz to 1 000 MHz frequency range with power levels ranging up to 500 mW".

[12] DTR/ERM-RM-030: "Electromagnetic compatibility and Radio spectrum Matters (ERM); System Reference Document for TETRA Enhanced Data Service (TEDS).

[13] ETSI EN 301 489-27: "Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 27: Specific conditions for Ultra Low Power Active Medical Implants (ULP-AMI) and related peripheral devices (ULP-AMI-P)".

[14] ETSI TR 101 445: "Electromagnetic compatibility and Radio spectrum Matters (ERM); Short-Range Devices (SRD) intended for operation in the 862 MHz to 870 MHz band; System Reference Document for Radio Frequency Identification (RFID) equipment".

[15] ITU Radio Regulations (2001).

3 Definitions, symbols and abbreviations

3.1 Definitions

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

active medical device: any medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity

active implantable medical device: any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure

medical device: any instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with any accessories or software for its proper functioning, intended by the manufacturer to be used for human beings in the:

- diagnosis, prevention, monitoring, treatment or alleviation of disease or injury;
- investigation, replacement or modification of the anatomy or of a physiological process;
- control of conception,

and which does not achieve its principal intended action by pharmacological, chemical, immunological or metabolic means, but which may be assisted in its function by such means

monitoring device: ULP-AMI-P equipment used to monitor a ULP-AMI

patient activator: ULP-AMI-P equipment intended to be used by a patient

programmer/controller: ULP-AMI-P equipment used by a physician or patient

Ultra Low Power Active Medical Implant: radio part of an AIMD

Ultra Low Power Active Medical Implant Peripheral: radio part of equipment outside the human body that is designed to communicate with an AIMD

3.2 Symbols

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

f	Frequency
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
CRC	Cyclic Redundancy Check
E/S	Earth-to-space
ECA	European Common Allocation
EMC	Electro Magnetic Compatibility
FEC	Forward Error Correction
IDF	International Diabetic Foundation
LBT	Listen Before Talk
MICS	Medical Implant Communications Systems
R&TTE	Radio and Telecommunications Terminal Equipment
S/E	Space-to-Earth
SRD	Short Range Device
TEDS	TETRA Enhanced Data Service
UHF	Ultra High Frequency
ULP-AMI	Ultra Low Power Active Medical Implant
ULP-AMI-P	Ultra Low Power Active Medical Implant Peripheral

4 Executive summary

4.1 Status of the System Reference Document

The first draft document was presented to the ERM_RM working group, at its 27th meeting in Brest. At that meeting it was decided that due to urgency, the document, revised according to comments provided by ERM_RM#27, could be finalized by ERM_TG 30#5 and approved by ERM_RM on two week circulation. A revised document was generated by the ERM_TG30 secretariat. The present document has been approved by ERM_RM via approval by correspondence.

4.1.1 Position of Biotronik

Biotronik objects to a request for additional spectrum in the 401 MHz to 402 MHz and 405 MHz to 406 MHz bands at this time. Biotronik feels it would be more efficient to fully exploit the currently allocated 402 MHz to 405 MHz band by including additional interference mitigation techniques such as duty cycle or power limitations into the standard EN 301 839-1 [4].

4.1.2 Reaction of Medtronic to position in clause 4.1.1

Medtronic disagrees with the above position in clause 4.1.1. The 402 MHz to 405 MHz band has been designated as a Class 1 band. Any changes to the current specifications in CEPT/ERC Recommendation 70-03 [1] annex 12 band (a) would require withdrawal of the Class 1 band designation affecting the plans of the entire medical implant industry. Medtronic also is of the opinion that the 402 MHz to 405 MHz band should remain for use of life supporting systems with frequency agility based on listen before talk protocols.

4.2 Technical Issues

ULP-AMI and ULP-AMI-P devices currently provide significant life saving and quality of life benefits for medical patients afflicted with a variety of heart conditions, nerve disorders and other afflictions. The systems operating in the 402 MHz to 405 MHz band consist of devices that are implanted in the body that only communicate with an external peripheral device. Examples of these implanted devices are defibrillators, pacemakers, and various types of nerve stimulators.

Providing an additional 2 MHz of spectrum for medical systems will permit the expansion of the types of communication links supported by these systems to permit downloading of data to mass storage facilities from a peripheral device for further review and analysis. An accumulation of a large database of retrieved data over time that can be analysed by physicians to diagnose a patient's condition will improve the therapy delivered by the implant. Another type of communications that can be supported with the additional spectrum is semi-continuous data readout of physiological parameters.

Based on the ITU-R sharing analysis [3] and ambient background scans of various hospital environments, 3 MHz of spectrum is needed for devices whose transmission characteristics are typical of low duty cycle intermittent operation with communication only between a peripheral device and an implant. With the development of new medical sensor technologies there is now a need for spectrum that provides for higher duty cycles, with periodic transmissions of the order of 1 per minute or greater. Such systems will potentially collect large amounts of data that must be downloaded to mass storage media if it is to be permanently saved. The requested additional spectrum allocation will permit data download for mass storage as well as continuous transmission for those applications requiring such operation while maintaining the integrity of the current 402 MHz to 405 MHz allocation to devices typified by pacemakers and defibrillators that are life supporting. It is proposed that equipment operating in this additional spectrum will operate in accordance with the "recommends section" of ITU-R Recommendation SA.1346 [3].

4.2.1 System description

Medical systems proposed to be operated in the additional 2 MHz of spectrum consist of devices implanted within the body and external devices that support the operation of the implanted device. Implanted devices are placed in the body to deliver therapies and/or provide diagnostic data that is used by a physician to determine the condition of the implanted patient and develop appropriate therapies. External devices (peripherals) operating under the provisions of the present document support the operation of the implanted devices by providing a means for programming or altering the programming of the implanted device, retrieving medically related diagnostic data from the implant, transferring data to a mass storage system, provide real time readout of physiological parameters.

4.2.2 Applications

Currently, MICS technology in the 402 MHz to 405 MHz band is utilized in cardiac devices such as pacemakers that control the rhythm of heart contractions, defibrillators that recognize an abnormally high heart rate and deliver a high-energy pulse to restore a more natural rhythm, and combination devices that can do both of the above. The 402 MHz to 405 MHz band is used for initial programming of the ULP-AMI, transferring diagnostic information from the ULP-AMI, and monitoring in the patient's home. These types of applications formed the basis of the ITU-R deliberations [3] that resulted in a recommendation that national administrations consider providing 3 MHz of spectrum in the 401 MHz to 406 MHz band for MICS.

Other medical implant devices that deliver drugs to the patient and devices that stimulate nerves to control pain are under development and exploit new sensor technology. For example, semi-permanent glucose sensors have been developed that permit blood glucose levels to be monitored over extended periods of time and transmitted to internal and external insulin pumps to adjust insulin levels "on demand". Significant advances in neural stimulation to control otherwise uncontrollable reflex muscular reactions from diseases such as Parkinson's and other brain disorders have been developed. Still other neural implant technologies are used to control incontinence and pain by applying an electrical stimulus to the human nervous system.

4.2.3 Short market information

Heart failure affects about 7 million Europeans, with about 600 000 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 and/or treating various bodily functions and diseases 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 these types of medically necessary therapy that are required to preserve and enhance the quality of life for many in this group of patients.

There are currently 32 million Europeans with diabetes according to the International Diabetic Foundation (IDF) [7]. Of these 1,6 million have Type 1 diabetes and could greatly benefit from the glucose monitoring and insulin delivery system described above. Of the remaining 30,4 million Type 2 diabetics, there are potentially additional millions that would benefit from above technology that mimics the human pancreas by essentially delivering insulin "on demand". Data on afflicted patients with neurological impairments are not available, but needless to say, the numbers are quite large.

4.2.4 Spectrum requirement and justifications

The advent of technology permitting implanted devices to communicate with external devices at distances of a few meters over extended periods of time has opened up a new era in medical treatment. Considerations of tissue loss, battery life, existing users, and ambient signal levels in the selected spectrum resulted in the selection of the 401 MHz to 406 MHz band by the ITU-R [3] as the most suitable for implant technology.

In accordance with that recommendation, annex 12 band (a) of CEPT/ERC Recommendation 70-03 [1] was adopted to provide 3 MHz of spectrum for ULP-AMI and peripheral devices. In its deliberations, the ITU-R [3] used several studies of ambient RF fields in European hospitals to determine that 3 MHz of spectrum was sufficient to ensure the availability of at least one 300 kHz wide channel for use by medical systems irrespective of the geographical location within Europe.

That study was done in 1998, when cardiac type devices were the primary use of implanted technology with other types of implants still in the development stage. Today, medical device manufacturers have developed applications for implant technology that will place much greater demands on the available spectrum due to increased proliferation of devices and a need for much greater transmission duration. Additional spectrum is required to handle the increased demand. Further, some types of operations such as transmission from one external device to another external device are not permitted under the existing standards that apply to CEPT/ERC Recommendation 70-03 annex 12 band (a) [1] devices.

4.2.5 Current regulations

Currently ULP-AMI implants and peripherals are permitted to operate in the 9 kHz to 315 kHz and 402 MHz to 405 MHz bands as provided for in CEPT/ERC Recommendation 70-03, annex 12 band (a) and band (b) [1]. Harmonized emissions standards for the 402 MHz to 405 MHz band have been adopted for these devices, EN 301 839-1 [4] and EN 301 839-2 [5]. A final draft for a product specific EMC standard for the 402 MHz to 405 MHz band [13] has been published by ETSI but is not yet cited in the OJEU.

4.2.6 Proposed regulation

It is proposed that the ECC adopt the 401 MHz to 402 MHz and 405 MHz to 406 MHz bands, bands (e) and (f), in separate listings in annex 12 of CEPT/ERC Recommendation 70-03 [1] in lieu of including them in the current band (a) allocation. Incorporation in the current band (a) would affect the current Class 1 status recognition of the 402 MHz to 405 MHz band that is the subject of a current ERC decision [9].

Further, recognizing separate bands in this manner will permit modes of operation to be addressed that were not contemplated for devices in 402 MHz to 405 MHz band. Some examples of operational modes not previously contemplated are external peripheral to external peripheral communications, continuous transmission over periods of a few minutes (limited to a few minutes by duty cycle based on operation over a one hour time frame).

Moreover it is proposed that a two tiered approach to power level related to the use of interference avoidance techniques is adopted for the ULP-AMI bands (e) and (f) (i.e. 401 MHz to 402 MHz and 405 MHz to 406 MHz). The two tiered approach would be based on a technique previously described by ETSI [14] for devices operating in the 868 MHz band where higher power devices must "listen before talk" while very low power devices are permitted to transmit at will.

Also an alternative interference mitigation technique may be introduced in bands (e) and (f) permitting transmissions with a duty cycle restriction of 0,1% or less (potentially coupled with a lower transmit power level for equipment without LBT). This is suggested in the TR 102 313 [10] for SRDs with LBT in the 868 MHz UHF-band. In that technical report it is postulated that both kinds of equipment - with or without LBT - should co-exist in the new EN 300 220 [11]. For equipment without LBT, the duty cycle restriction is to be applied. i.e. either duty cycle or frequency-agility (with LBT) is mandatory.

In view of the additional operational modes it is likely that consideration for a specific transmit mask for external devices may be needed. The system specifics (power, bandwidth, etc.) related to a two-tier approach will be addressed during the ETSI standard development process.

The above proposal has a great advantage in that it will permit alternate modes of establishing medical implant communications links between an internal implant transmitter and an external device or devices without the potential of causing interference to the MICS communications links established by implants and peripherals using the 402 MHz to 405 MHz band in life supporting applications.

The maximum operational technical parameters specified for the additional band are those currently provided for in the 402 MHz to 405 MHz that are based on ITU-R Recommendation SA.1346 [3] which covered the entire 401 MHz to 406 MHz band. This will allow the previous sharing analysis by the ITU-R [3] and ECC spectrum engineering project team SE24 [8] to be applicable to the these proposed bands.

A summary of the proposed regulation is in table 4.2.6.1.

Table 4.2.6.1: Proposal for revision of annex 12 of CEPT/ERC Recommendation 70-03 [1]

Frequency Band		Power	Duty cycle	Channel spacing	ERC Decision	Notes
e	401 MHz to 402 MHz	25 µW e.r.p. (see note 1)	No Restriction for devices with LBT, otherwise < 0,1%	25 kHz		Individual transmitters may combine adjacent 25 kHz channels for increased bandwidth up to 100 kHz (see note 2)
f	405 MHz to 406 MHz	25 µW e.r.p. (see note 1)	No Restriction for devices with LBT, otherwise < 0,1%	25 kHz		Individual transmitters may combine adjacent 25 kHz channels for increased bandwidth up to 100 kHz (see note 2)
NOTE 1: Initially it is proposed that systems not providing frequency agility based on ambient RF field sensing, be limited to a lesser maximum permitted power.						
NOTE 2: Due to the limited available spectrum of 1 MHz, a maximum bandwidth of 100 kHz is proposed for these bands to ensure that several users could access the band concurrently.						

4.2.7 Compatibility issues

From the ECA table [6] (see also clause C.3), the primary services in these bands are Earth-exploration satellite (Earth-to-space), meteorological aids, and meteorological-satellite (Earth-to-space). The primary co-existence issue to consider is that of interference to the meteorological aids service.

Sharing between the meteorological aids service and MICS systems has been analysed by the ITU-R [3] and ECC spectrum engineering project team SE-24 [8]. Both organizations concluded that sharing was possible between the meteorological aids service and MICS provided the MICS equipment operated in accordance with the provisions set forth in their respective documents. On the basis of the ITU-R analysis, ETSI is of the opinion that no sharing study is necessary at CEPT level.

5 Main conclusions

5.1 Business importance

ULP-AMI devices provide a medical capability that cannot be provided to the public by any other means. This equipment can deliver therapy, detect impending severe cardiac conditions that are life threatening and take corrective action, reliably transmit that data to a physician via public telecommunications networks, collect physiological data, measure in situ physiological parameters such as blood glucose in real time and deliver medication in the correct dosage as needed, control pain and other nervous system disorders such as Parkinson's disease, and others. Millions of patients will ultimately make use of this technology thus extending and enhancing their quality of their life. Telemedicine will make use of this technology to provide in home monitoring with the ability to reprogram and/or otherwise modify the therapy delivered to the patient without the necessity of visitations to the doctor's office, i.e., effectively bringing back the "home" visit by the physician.

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 401 MHz to 402 MHz and 405 MHz to 406 MHz bands.

Further, implanted patients are mobile and may require emergency medical assistance while they are travelling. This capability demands that a common worldwide allocation be made available for these devices. 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 using this technology in order to cover emergency medical situations that may occur during patient intra or inter country travels.

5.2 Expected timing for products to market

Products (as referenced in clause 4.2.3) for use by the medical community are available and others are currently undergoing clinical trials that will greatly expand the use of the ULP-AMI bands by implanted devices.

5.3 ECC and ETSI actions

ETSI requests the ECC to consider the following actions:

- Accept the completed compatibility studies between the meteorological aids service and MICS systems previously performed by the ITU-R [3] and ECC spectrum engineering project team SE24 [8] that concluded sharing of this spectrum is possible.
- Adoption of band (e) and band (f) in annex 12 of ERC/Recommendation 70-03 [1], as summarized in table 4.2.6.1.
- Adoption of an ECC Decision for this application.

ETSI actions:

ETSI intends to develop a standard via ETSI ERM_TG30 to cover the technical operational specifications and measurement requirements for medical implant system devices that are the subject of the present document.

Annex A:
Detailed market information

A.1 Range of applications

Current applications for this technology range from cardiac devices such as defibrillators, pacemakers, combination pacemakers and defibrillators, insulin delivery systems, physiological parameters measurements devices such as hemodynamic monitors and glucose measurement sensors, nerve stimulators and pain control devices. As medical technology evolves it is certain that new devices requiring medical telemetry will utilize these bands.

A.2 Market size and value

It is estimated that ultimately there will be more than 10 million European patients with some form of active medical implant in their body that makes use of this medical technology. If use of insulin delivery systems for Type 2 diabetes becomes the norm, then the above figure will likely be doubled or even tripled. At an average implantation cost of 5 000 to 8 000 Euros, the dollar value of this market will be of the order of 50 to 80 billion Euros or more.

This emerging technology has widespread support from governmental organizations, the medical community and consumer groups due to its benefit to the public and its potential for reducing medical costs.

A.3 Traffic evaluation

Spectrum use and efficiency:

Medical equipment covered in the present document is expected to emit electromagnetic radiation at a maximum power level of 25 microwatts e.r.p. Transmission times will vary from brief intervals for some devices to almost continuous transmission by some active medical implants and an associated peripheral or peripherals. Use of the spectrum is highly efficient for these environmentally aware systems due to the very low power and/or interference mitigation techniques as recommended in the sharing studies performed by the ITU-R [3] and ECC spectrum engineering project team SE24 [8].

The reasons for all of the above are:

a) Power and transmission time frames are product application specific. Cardiac systems tend to be accessed by a physician only occasionally during office visits, however, home monitoring of these devices will increase the access of these systems to physicians and thus their transmission times and spectrum usage. Typically implanted cardiac devices operate at lower power levels with wider bandwidths while the external programmers/controllers operate at or near the maximum permitted power level with lower bandwidths.

   In addition many devices will use only very low duty cycles (0,1 % or less).

b) Insulin delivery systems and hemodynamic monitors will exhibit a much increased transmission time in order to provide a continuously updated physiological parameter measurement to the attendant or to a device delivering a drug such as insulin.

c) Medical systems operating in the band employ a variety of interference mitigation techniques such as CRC, FEC data integrity checks, and others.

Annex B:
Technical information

B.1 Detailed technical description

Active medical implants find application for a variety of purposes such as pacemakers, defibrillators, nerve stimulators, and pumps with the list growing every day. They all have two very unique characteristics in common; (a) a part of the system or a system device is implanted within a human body and (b) the function they perform in providing medical treatment to individuals cannot reasonably be provided for by any other means. Patient quality of life and mobility require these devices to be self-contained, be as small as possible in size, have a very long operational life, and be exceptionally reliable over their lifetime.

At a minimum ULP-AMI devices must communicate with an associated external device containing a radio system that is a peripheral (ULP-AMI-P) to the implanted device. This allows the transfer of data from one device to the other that can be either stored data or telecommand or telemetry in content. Other than the unique technological requirements that are attendant to the implanted radio systems (size limits, power consumption and impedance considerations), they can be considered as typical data telemetry and telecommand devices using conventional modulation formats with proprietary telemetry protocols.

B.2 Technical justifications for spectrum

B.2.1 Power

As previously stated an implanted active medical radio system must consume very little power and be extremely small in size. The implant itself must contain a medically therapeutic section as well as an interface circuit to a radio system and the radio system itself. Based on the sharing analysis and the usage conditions envisioned for these devices, a power level of a maximum of 25 microwatts e.r.p. was determined as adequate for medical systems. This power level permits a highly reliable communications link at a distance of 2 meters to 3 meters.

B.2.2 Frequency

The 401 MHz to 402 MHz and the 405 MHz to 406 MHz frequency bands were selected for these emerging medical implant technologies based on an analysis of many factors including the proximity to the existing 402 MHz to 405 MHz band for ULP-AMI and ULP-AMI-P equipment. The frequency band has a relatively low ambient noise due to its primary usage by the meteorological aids service, they are sufficiently wide to be capable of reliably supporting high data rate transmissions, miniature manufacturing components are readily available, the band lends itself to small antenna designs and most importantly, electromagnetic fields can propagate acceptably through human tissue in this frequency band. These factors are critical in developing technology that can be implanted in patients and still have a life expectancy of 5 to 10 years before requiring replacement. With this additional spectrum, other types of communication links and devices can be provided to the medical community that would not otherwise be available such as continuous transmission and relay of data to mass storage equipment.

B.2.3 Bandwidth and other radio parameters

The primary factor relative to bandwidth considerations was to ensure that high data rate transmission capability would be provided. Data storage technology has advanced to the extent that implants can now provide information that physicians have requested for many years. The technological ability to internally store multiple records of significant medical events as well as records of other physiological parameters that are sampled at high rates is currently available; however, the ability to transfer these records at a high data rate was not available until the advent of MICS technology for the 402 MHz to 405 MHz band. High data rate capability is necessary to minimize battery power drain over the life of an implant and provide for a reasonable data recovery download time frame. Battery power budget analysis has shown a power drain of 30 mWhr over the lifetime of the implant will not significantly alter an implant's life expectancy of 5 to 10 years. The development of this new medical communications system permits the deployment of technology capable of providing the data requested by physicians.

B.3 Information on current version of relevant ETSI standard

The present document is asking that CEPT/ERC Recommendation 70-03 annex 12 [1], be modified to include the additional bands of 401 MHz to 402 MHz and 405 MHz to 406 MHz as separate sub-bands. There is no current ETSI standard that covers the operational characteristics proposed for these bands. ETSI ERM_TG30 will undertake development of standards to cover the operation of these devices.

Annex C:
Expected compatibility issues

C.1 Coexistence studies (if any)

Two studies related to coexistence between the meteorological aids service and MICS have been previously performed. The ITU-R [3] and ECC spectrum engineering project team SE24 [8] have analysed the systems and concluded that sharing is possible between the meteorological aids service and MICS.

C.2 Current ITU allocations

The ITU Radio Regulations [15] show the following allocations for Region 1 in this frequency band:

Table C.2.1

401 MHz to 402 MHz	EARTH EXPLORATION-SATELLITE (E/S) METEOROLOGICAL AIDS METEOROLOGICAL-SATELLITE (E/S) SPACE OPERATION (S/E) Fixed Mobile except Aeronautical Mobile
403 MHz to 406 MHz	METEOROLOGICAL AIDS Fixed Mobile except Aeronautical Mobile

C.3 European Common Allocation (ECA) table

The European Common Allocation table [6] shows the following information:

Table C.3.1

Frequency band	European Common Allocation	Utilization	EU footnote	Note
401 MHz to 402 MHz	EARTH EXPLORATION-SATELLITE (E/S) METEOROLOGICAL AIDS METEOROLOGICAL-SATELLITE (E/S) EU2	Meteorological radio sondes Meteorological satellites, data collection platform		
403 MHz to 406 MHz	METEOROLOGICAL AIDS EU2	Medical implants SRD Meteorological radio sondes		Medical implants within 402 to 405 MHz

EU footnotes:
EU2: Civil-military sharing

C.4 Sharing issues

The ITU-R [3] and ECC spectrum engineering project team SE24 [8] have analysed the systems and concluded that sharing is possible between the meteorological aids service and Medical Implant Communications Systems. These sharing studies have shown that these medical systems pose no interference threat to the Meteorological Aids service. There may, however, be sharing issues related to interference to medical systems operating in these bands from the meteorological aids service. Interference mitigation techniques such as CRC, FEC and frequency agility and other techniques that are employed by these medical systems as appropriate will permit them to ensure patient safety by providing a highly reliable communications link. It may be noted that the TEDS SRDoc [12] is proposing use of frequencies just below 400 MHz for use by portable and mobile phones. However, SRDs are not protected from receiving interference from primary and secondary users of the spectrum. Therefore, use of spectrum by TEDS systems is not an issue.

History

Document history		
V1.1.1	July 2004	Publication