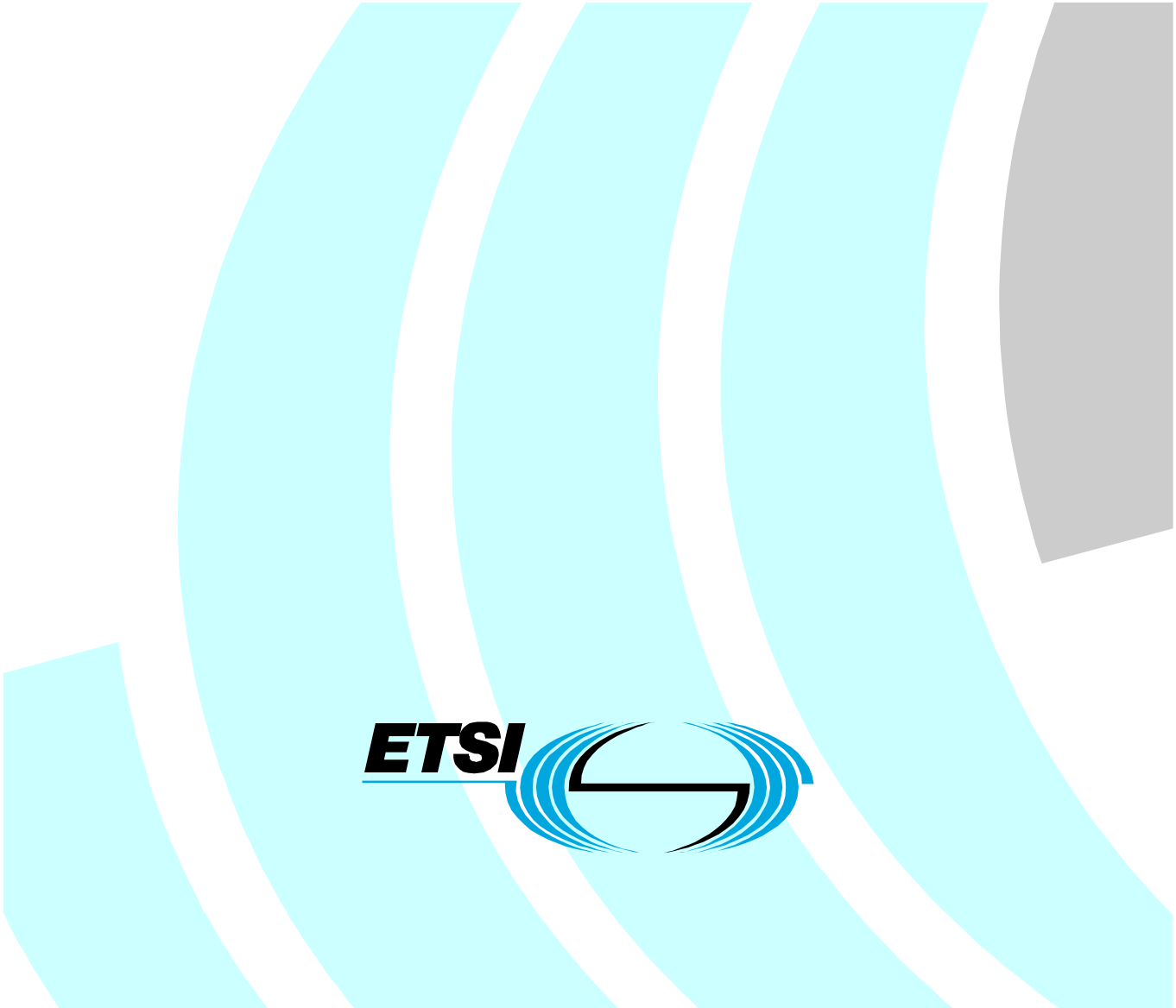
ETSI TR 102 434 V1.1.1 (2005-06)

Technical Report

Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Alternative Interference Mitigation Technologies to Listen Before Talk (LBT) for Ultra Low Power Active Medical Implants (ULP-AMI) operating from 403,5 MHz to 403,8 MHz with a duty cycle of less than or equal to 0,01%; System Reference Document



Reference
DTR/ERM-RM-039

Keywords
radio, short range, SRDoc, UHF

ETSI

650 Route des Lucioles
F-06921 Sophia Antipolis Cedex - FRANCE

Tel.: +33 4 92 94 42 00 Fax: +33 4 93 65 47 16

Siret N° 348 623 562 00017 - NAF 742 C
Association à but non lucratif enregistrée à la
Sous-Préfecture de Grasse (06) N° 7803/88

Contents

Intellectual Property Rights

IPRs essential or potentially essential to the present document may have been declared to ETSI. The information pertaining to these essential IPRs, if any, is publicly available for **ETSI members and non-members**, and can be found in ETSI SR 000 314: *"Intellectual Property Rights (IPRs); Essential, or potentially Essential, IPRs notified to ETSI in respect of ETSI standards"*, which is available from the ETSI Secretariat. Latest updates are available on the ETSI Web server (http://webapp.etsi.org/IPR/home.asp).

Pursuant to the ETSI IPR Policy, no investigation, including IPR searches, has been carried out by ETSI. No guarantee can be given as to the existence of other IPRs not referenced in ETSI SR 000 314 (or the updates on the ETSI Web server) which are, or may be, or may become, essential to the present document.

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 single channel ULP - AMI active medical implants and peripherals operating from 403,5 MHz to 403,8 MHz (nominal centre frequency of 403,65 MHz) and having a duty cycle of less than or equal to 0,01 %. The technical characteristics of these devices along with the benefits of this access method are described.

A single channel, low duty cycle (less than or equal to 0,01 %) ULP-AMI is proposed as an alternative option to LBT and frequency agility as interference mitigation technology which ensures the assigned spectrum remains clear and available to all users of the spectrum.

This type of operation is limited only to ULP-AMI (implants) and is not permitted for ULP-AMI-P (peripheral equipment).

The proposed SRDoc prohibits external device to external device communication.

The present document 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).

It is not proposed to change the current regulations.

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 (R&TTE Directive).

[3] ITU-R Recommendation SA.1346: "Sharing between the meteorological aids service and the Medical Implant Communications 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" Lisbon January 2002 - Dublin 2003 - Turkey 2004 - Copenhagen 2004.

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

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

[9] International Telecommunications Union, ITU Radio Regulations, Article 5, 2004.

NOTE: See http://www.itu.int/dms_pub/itu-r/opb/reg/R-PN-119-04-R1-PDF-E.pdf.

[10] "The World Survey of Cardiac Pacing and Cardioverter Defibrillators: Calendar Year 2001", in Pacing and Clinical Electrophysiology (PACE), Volume 27 Issue 7 Page 955 - July 2004, Doi:10.1111/j.1540-8159.2004.00565.x.

NOTE: See http://www.blackwell-synergy.com/links/doi/10.1111/j.1540-8159.2004.00565.x/abs.

[11] ETSI TR 102 343 (V1.1.1): "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".

[12] 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".

[13] ISO 14971 (2000): "Medical devices - Application of risk management to medical devices".

3 Definitions, symbols and abbreviations

3.1 Definitions

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

Active Medical Device (AMD): 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 (AIMD): any active medical device (AMD) 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

Adaptive Frequency Agility (AFA): performance requirement for LBT specifying the usage of at least nine channels (see EN 301 839-1 [4] for more details)

Listen Before Talk (LBT): performance requirement, usually in the form of a protocol, that requires a communications system to determine if the channel it intends to communicate in is occupied by another user and select from the available spectrum a channel for communication that reduces, to the extent possible, the potential for interference to/from another user of the spectrum

Medical Device (MD): means 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.

medical implant event: occurrence or the lack of an occurrence recognized by a medical implant device or duly authorized health care professional that requires the immediate transmission of data from a medical implant transmitter in order to protect the safety of the person in whom the medical implant transmitter has been placed

NOTE: It is not permitted that this is the only mechanism a medical implant transmitter can use to access spectrum. All medical implant transmitters must have the ability and typically use this ability to transfer information to/from a medical implant programmer/control transmitter on a frequency that has been selected by the programmer/control transmitter using the LIC spectrum access protocol specified in the present document.

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

safety: freedom from unacceptable risk

Ultra Low Power Active Medical Implant (ULP-AMI): the radio part of an AIMD

Ultra Low Power Active Medical Implant Peripheral (ULP-AMI-P): the radio part of equipment outside the human body that is designed to communicate with an ULP-AMI

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:

AFA	Adaptive Frequency Agility
AIMD	Active Implantable Medical Device
AMD	Active Medical Device
CEPT	European Conference of Post and Telecommunications Administrations
dB	deciBel
dBi	deciBel relative to an isotropic radiator
DBS	Deep Brain Stimulation
e.r.p.	effective radiated power
ECA	European Common Allocation
ECC	Electronic Communications Committee
EMC	ElectroMagnetic Compatibility
LBT	Listen Before Talk
LDC	Low Duty Cycle
LIC	Least Interfered Channel
MD	Medical Device
MICS	Medical Implant Communications System
R&TTE	Radio and Telecommunications Terminal Equipment
RF	Radio Frequency
Rx	Receiver
SRD	Short Range Device
Tx	Transmitter
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

An earlier version of the present document was presented to the ERM-RM working group, in its 28th meeting in Montegrotto.

It was discussed during the 6th TG 30, TG 30 Ad Hoc #1 and 7th TG30 meeting and approved by TG 30#7 subject to further comments to be placed in clause 4.1 by April 4th, 2005 (cf. TG 30#7 meeting minutes). The comments have been included in clause 4.1.1.

ERM RM#30 (3-6 May 2005) approved the present document. It will be forwarded to CEPT for consideration and to ERM#26 (13-17 June 2005) for approval for publication.

4.1.1 Statement from Medtronic

QUOTE

Medtronic operates a substantial European manufacturing facility in Tolochenaz, Switzerland as well as research and development facilities in the Netherlands. Medtronic Bakken Research Center BV objects to the proposal in the present document based on the following facts:

1) This mode of operation (one-way, low duty cycle (LDC)) was previously proposed and adopted in TR 102 343 [11] for ULP-AMI applications in the 401 MHz to 402 and 405 MHz to 406 MHz bands. The bands 401 MHz to 402 and 405 MHz to 406 MHz are currently being considered in SE24.

2) The SRDoc proposes modification of an existing MICS standard (EN 301 839-2 [5]) to accommodate one European medical device manufacturer whose existing product's centre frequency lies within the proposed band of 403,5 MHz to 403,8 MHz.

3) CEPT/ERC Recommendation 70-03 [1], annex 12 sub-band (a) does not impose any restriction on duty cycle with a 25 microwatt power limit. Therefore, the request raises the issue of whether the regulations must be changed before an ETSI standard can restrict the operation of a device that otherwise complies with the parameters specified in the legislation.

4) ERC/DEC (01)17 [12], paragraph p), states "that ITU-R Recommendation SA.1346 [3], specifies the feasibility of sharing in the band 401 MHz to 406 MHz between the Meteorological Aids Service and Medical Implant Communication Systems (MICS) that are in compliance with the technical and operational characteristics described in the Recommendation".

5) ERC/DEC (01)17 [12], paragraph q), states "that interference mitigation techniques used by MICS equipment, as described in Annex 1 to ITU-R Recommendation SA.1346 [3] provide a high level of protection to their operation from possible interference by the Meteorological Aids systems". The interference mitigation techniques described in ITU-R Recommendation SA.1346 [3] are Listen Before Talk (LBT) and Adaptive Frequency Agility (AFA).

6) Paragraphs p) and q) in the considerations section of ERC/DEC (01)17 [12] clearly require the interference mitigation techniques described in ITU-R Recommendation SA.1346 [3]. ITU-R Recommendation SA.1346 [3], paragraph f), states "that interference mitigation techniques used by the Medical Implant Communication System equipment, as described in Annex 1, provides a high level of protection to their operation from possible interference by Meteorological Aids systems".

7) Rejection of the proposal will preserve the use of LBT and AFA for the 402 MHz to 405 MHz band so that the band can support applications requiring the transmission of time-critical data in order to avoid compromising the health and/or safety of the patient. Systems conforming to EN 301 839-1 [4] and EN 301 839-2 [5] provide the technological capability for the communication of time-critical data. These systems fulfill the essential requirement expressed in article 3.1 of the R&TTE directive [2] to protect the health and the safety of the user and any other person.

8) The existing LBT and AFA protocol described in EN 301 839-1 [4] and subsequently referenced in EN 301 839-2 [5] should remain unchanged as both LBT and AFA provide for spectrum management using smart radio techniques. Allowing transmit-only operation (i.e. non-LBT and non-AFA) in the band will degrade communications between devices supporting life-critical, time-sensitive operations.

9) Both LBT and AFA have been widely recognized by ETSI as effective techniques for enabling successful spectrum sharing and avoiding interference. The proposed SRDoc contains technical provisions (i.e. low duty cycle, low transmit power, single channel operation) that, collectively, only reduce interference to other users of the MICS band from LDC transmitters.

10) In effect, the proposed SRDoc decreases the number of 300 kHz channels from ten to nine and thus reduces the effectiveness of LBT and AFA for MICS users. Taken further (e.g. additional LDC channels), the effectiveness of LBT and AFA within the MICS band would be completely compromised.

Medtronic has participated in technical discussions of this SRDoc during recent TG30 meetings and has submitted two input documents, 06_07 (TG30 #6) and 07_11 (TG30 #7), that provide comments on specific paragraphs. While the rapporteur has incorporated some additional text into the SRDoc in response to these input documents, the SRDoc is still deficient or inaccurate in several areas, each described below.

- Paragraph 4.2.4 states: "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 as the most suitable for implant technology by the ITU-R Recommendation SA.1346 [3]". The 401 MHz to 402 MHz and 405 MHz to 406 MHz band (TR 102 343 [11]) also provides these advantages, as a subset of the 401 MHz to 406 MHz band. The justification for a new and incompatible type of operation within the 402 MHz to 405 MHz band is not fully elaborated. This is particularly important because the proposed operation of LDC devices is specifically not permitted based on the considerations and analysis provided by the ITU-R Recommendation SA.1346 [3].

- Paragraph 4.2.8: If CEPT allows for this type of operation (LDC) via regulation or liaison statement, then a separate ETSI standard should be developed based upon the low duty cycle, low transmit power, and single channel technical parameters contained in the SRDoc. This standard would be in addition to the modifications proposed for EN 301 839-2 [5], in clause 4.2.8.

UNQUOTE

4.1.2 Statement from Secrétariat d'Etat à l'Industrie and Bundesministerium für Wirtschaft und Arbeit

QUOTE

Secrétariat d'Etat à l'Industrie, as well as BMWI (RegTP), express their serious concerns about the comments provided by Medtronic in clause 4.1.1 since several statements are considered not adequate:

- reaction to point 6 of clause 4.1.1: ERC/DEC (01)17 [12] does **not** require the interference mitigation techniques (i.e. Listen Before Talk (LBT) and adaptive frequency agility (AFA)) as described in ITU-R Recommendation SA.1346 [3]. ERC/DEC (01)17 [12] does only stipulate that:

  "considering:

  p) that ITU-R Recommendation SA.1346 [3], specifies the feasibility of sharing in the band 401 MHz to 406 MHz between the Meteorological Aids Service and Medical Implant Communication Systems (MICS) that are in compliance with the technical and operational characteristics described in the Recommendation;

  r) that the ITU-R, in adopting ITU-R Recommendation SA.1346 [3], considered Medical Implant Communication Systems to require a single band available worldwide, and may operate in the mobile service currently allocated on a secondary basis in the band 401 MHz to 406 MHz;"

- reaction to point 7 of clause 4.1.1: the band 402 MHz to 405 MHz is not preserved for LBT nor AFA since neither ERC/DEC(01)17 [12] nor CEPT/ERC Recommendation 70-03 [1] "decides" / "recommends" the use of such mitigation techniques;

- reaction to point 8 of clause 4.1.1: EN 301 839-1 [4] and EN 301 839-2 [5] do not require the use of LBT but only propose it as a possible option;
- reaction to point 9 of clause 4.1.1: low duty cycle has also been recognized both by ETSI and CEPT as an effective technique for enabling successful spectrum sharing and avoiding interference.

UNQUOTE

4.1.3 Position of Biotronik, St. Jude, Ela Medical, Zarlink and Bolt Consult

Biotronik, St. Jude, Ela Medical, Zarlink and Bolt Consult support this SRDoc without any reservation.

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 disorder 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 implanted devices are defibrillators, pacemakers, and various types of nerve stimulators. In current systems typically used in the patient's home ("Home Monitoring") the ULP-AMI device sends data to the ULP - AMI - P device. Patient monitoring is also possible in clinics, hospitals and managed care facilities. In addition, there will be other systems where data will also be sent from the ULP-AMI-P to the ULP-AMI (e.g. "programming"). The latter systems will typically be used in hospitals and/or doctor's office environments.

The performance of systems compliant with EN 301 839-1 [4] (i.e. those implementing LBT and AFA) may be degraded if the 403,5 MHz to 403,8 MHz channel is selected as the Least Interfered Channel (LIC). In such a scenario, the communication link may be interrupted by a low duty cycle system that does not implement LBT and AFA. The degradation is minimized if the single channel (403,5 MHz to 403,8 MHz) is excluded from the set of operating channels for systems compliant with EN 301 839-1 [4].

Two types of devices are envisioned with the present document: the first is a single frequency transmit-only LDC system, the second is a device that uses LDC to initiate an LBT/AFA session.

Single-frequency transmit-only Low Duty Cycle (LDC) systems cannot change frequency to avoid interference from the primary user of the band (Meteorological Aids), multi-user (MICS band devices), or man-made (unintentional emitters) noise sources. Single-frequency transmit-only Low Duty Cycle (LDC) implanted devices do not offer LBT and AFA as protection from narrow-band interference sources. Instead, they may repeat transmissions within the duty cycle limitations to improve transmission reliability.

Low duty cycle ULP-AMI devices compliant with the provisions of this SRDoc may transmit for the purpose of initiating a communications session that conforms to the LBT and AFA requirements specified in EN 301 839-1 [4].

4.2.1 System description

MICS systems 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.

One example of such a device is currently being offered for the communication of diagnostic data, the loss of which would not endanger patient's safety. This system (Home Monitoring) consists of an implant and a patient device. The system is designed to operate in such a way that the implant can send data to the patient device placed at the patient's bedside or worn by the patient. This data is then sent by the patient device to a service centre, which forwards this data to the physician. Transmissions from the device occur at any time within the duty cycle constraints after activation by a health care professional.

Each transmission of this system does not exceed 280 ms. Transmissions may occur up to ten times a day resulting in a duty cycle of less than 0,005 % on a daily basis, while on an hourly basis the duty cycle does not exceed 0,01 %. Devices are typically programmed to operate during the late night or early morning hours or at other times when the patient is typically in his or her home. The output e.r.p. does not exceed 100 nW.

This proposed SRDoc also specifies a duty cycle of less than 0,01 % on an hourly basis with the number of transmissions limited to a maximum of ten in any hour. Low duty cycle operation is limited to a single defined channel from 403,5 MHz to 403,8 MHz with a nominal centre frequency of 403,65 MHz.

4.2.2 Applications

Currently, the Home Monitoring System described above 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.

In addition to Cardiac Rhythm applications the following applications may also utilize this technology:

1) Neurological stimulator implants. Deep Brain Stimulation (DBS) is an example of this type of implant, with devices having periods of relatively high duty cycle operation.

2) Data collection systems. Portable devices for recording diagnostic data sent from an implant. Heart patients such as those who have experienced recent periods of arrhythmia could wear these devices.

3) Body-worn sensor(s) communicating to an implanted device for the treatment of neurological disorders. These systems may require continuous or near continuous telemetry operation.

4) Medical systems to diagnose and treat a wide variety of medical conditions (diabetes, gastrointestinal disorders, neurological conditions) that utilize implanted sensors and peripheral devices. These systems will have a range of operating scenarios with widely varying duty cycles.

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 implantable cardiac devices. Active medical implants are the only technology capable of full time non-stop delivery of medically necessary therapy that is required to preserve and enhance the quality of life for many for this category of patients worldwide. Detailed market information about cardiac pacemakers and cardioverter defibrillators can be found in [10].

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 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 as the most suitable for implant technology by the ITU-R Recommendation SA.1346 [3]. 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. This proposal is being made for single channel operation from 403,5 MHz to 403,8 MHz (nominal centre frequency of 403,65 MHz).

Channel access via very Low Duty Cycle (less than or equal to 0,01 %) is proposed as an additional interference mitigation technique. This duty cycle is measured over any one hour time period (*i.e.* a one hour sliding window). Thus, an implant using low duty cycle is limited to 360 ms transmission during any one hour time period. After a cumulative transmission of 360 ms within a single hour, the implant cannot transmit unless:

a) enough time elapses such that any transmission will not violate the *360 ms within one hour* rule described above;

EXAMPLE: After a single 360 ms transmission, one hour must elapse before any further low duty cycle transmissions can occur;

b) a medical implant event occurs, allowing the implant to transmit; or

c) the ULP-AMI responds to a LBT / AFA session initiated by the ULP-AMI-P.

Furthermore, low duty cycle access may only be used by implants (transmitted power limited to 100 nW e.r.p.) on one channel 403,5 MHz to 403,8 MHz ("signalling channel") with a specific centre frequency of 403,65 MHz.

4.2.4.1 Advantages of very low-duty cycle in relation to LBT

For some applications such as e.g. Home Monitoring this channel access method represents several advantages in relation to LBT:

- Simplified access method.
- Reduced timing synchronization requirements.
- Extended battery life.
- Allows unidirectional transmission.

Allowing the use of low duty cycle as an additional interference mitigation technique will allow medical device manufacturers to make use of these advantages.

4.2.4.1.1 Simplified Access Method

LBT requires the external patient device from a MICS system to scan the 402 MHz to 405 MHz frequency band and find the least interfered channel or a channel below threshold. It then initiates transmission on that channel; the implant responds and a telemetry session ensues. In an application such as home monitoring, where the implant has data to transmit, it would be easier for the implant to initiate transmission.

In such an implant-initiated transmission, the implant sends a short access request on the allowed access channel. The external patient device gets the access request and responds with what is essentially a LBT session; it scans channels and replies on the least interfered channel. The implant scans all channels, searching for this access response, and the telemetry session ensues.

This access method greatly simplifies implant operation (and implants are typically codespace and processor limited). The implant initiates the telemetry session. It need not search for external device-initiated session requests, and avoids the associated timing synchronization issues.

4.2.4.1.2 Reduced Timing Synchronization Requirements

The ITU sharing study (see ITU-R Recommendation SA.1346 [3]) discusses home monitoring applications and identifies the timing synchronization problem. Since the implant cannot power its receiver continuously (due to battery constraints), any periodic sessions must be scheduled. This scheduling will only be feasible if the two clocks (implant and external device) are synchronized to a certain level of accuracy. The sharing study envisions a polling process occurring approximately hourly and lasting up to one second, to prevent the clocks from drifting too far apart.

If low-duty cycle access is allowed, these synchronization requirements are reduced. The external device, when mains powered, can continuously monitor the access channel. The implant is freed from polling or poll responses.

4.2.4.1.3 Extended Battery Life

The simplified access method and reduced timing synchronization requirements discussed above directly impact battery life. For example, assuming 10 mA receiver current consumption, an hourly (1 second) receiver session consumes 240 mAs/day ($24 \times 1 \times 10$mA). This equates to 170 mAh over 7 years, equating to 15 % of a typical implant's battery. In comparison, a daily 10 ms session (not requiring synchronization) uses just
$0{,}01\ s \times 10\ mA \times 7 \times 365 / 3600 = 0{,}071$ mAh, or less than 0,01 % of a typical implant's battery.

4.2.4.1.4 Allows Unidirectional Transmission

Low-duty cycle transmissions can be used for the simplest of telemetry scenarios: unidirectional transmission. Such access extends telemetry capability to even low cost devices. Without acknowledgements, such transmissions can only be used for data the loss of which would not endanger patients' safety. Individual manufacturers would have to analyse the risk of such non-acknowledged transmissions.

4.2.5 Current regulations

Currently ULP-AMI implants and peripherals are permitted to operate in the band 402 MHz to 405 MHz as provided for in CEPT/ERC Recommendation 70-03 [1], annex 12 sub-band (a).

Table 4.2.5.1: CEPT/ERC Recommendation 70-03 [1], annex 12 sub-band (a)

Frequency band		Power	Duty cycle	Channel spacing	ERC Decision	Notes
a	402 MHz to 405 MHz	25 µW e.r.p.	No Restriction	25 kHz	ERC/DEC (01)17 [12]	Individual transmitters may combine adjacent channels for increased bandwidth up to 300 kHz.
Additional Information: Harmonized Standard: EN 301 839-2 [5].						

4.2.6 Current ETSI Standard

A harmonized emissions standard has been adopted for these devices, EN 301 839-2 [5].

4.2.7 Proposed regulation

It is not proposed to change the current regulations.

4.2.8 Proposed Modified ETSI Standard

In accordance to the proposed future regulations described above, it is proposed that in EN 301 839-1 [4] the method of accessing a single defined channel at 403,5 MHz to 403,8 MHz (nominal carrier frequency at 403,65 MHz) with a power limitation of 100 nW e.r.p. and a duty cycle limitation of less than or equal to 0,01 % is described as an alternative interference mitigation technology to the LBT method.

It is further suggested that the proposed modified standard EN 301 839-2 [5] shall contain a clause 4.2.9 where this alternative interference mitigation technology is referenced (this would be in analogy to clause 4.2.8 where the LBT "Monitoring System" is referenced). Also both methods of channel access shall be referenced in the EN Requirement Table. The EN Requirement Table should state that at least one of the methods must be implemented.

Table 4.2.8.1: Proposed EN Requirement Table for modified version of EN 301 839-2 [5]

EN Reference		EN 301 839-2 [5]		Comment
No.	Reference	EN-R (see note 1)	Status	
1	4.2.1	Mechanical and electrical design	M	
2	4.2.2	Frequency error	M	Applies to all transmitters
3	4.2.3	Emission bandwidth	M	Applies to all transmitters
4	4.2.4	Effective radiated power of the fundamental emission	M	Applies to transmitters with an integral or dedicated antenna
5	4.2.5	Spurious emissions (of transmitters)	M	Applies to all transmitters
6	4.2.6	Frequency stability under low voltage conditions	M	Applies to all battery operated equipment
7	4.2.7	Spurious radiation of receivers	M	Applies to all receivers
8	4.2.8	Monitoring system	O.1	Applies to all systems accessing all channels using LBT and AFA
9	4.2.9	Power limited and Duty Cycle limited Access	O.1	This type of access is only applicable to ULP-AMI (implants) and to the channel at 403,5 MHz to 403,8 MHz (nominal centre frequency of 403,65 MHz)
10	4.2.10	Medical Implant Event	O.1	This type of access is only applicable to Medical Implant Events
NOTE 1: These EN-Rs are justified under article 3.2 of the R&TTE Directive. NOTE 2: Ad "O.1": It is mandatory to support at least one of the options grouped in "O.1" for the ULP-AMI (implant), i.e.: to access the channel the ULP-AMI (implant) must use 4.2.8 or 4.2.9 or 4.2.10. The ULP-AMI-P (peripheral equipment) however must always access the channel via the monitoring system 4.2.8.				

Key to columns:

No Table entry number;

Reference Clause reference number of conformance requirement within the present document;

EN-R Title of conformance requirement within the present document;

Status Status of the entry as follows:

M Mandatory, shall be implemented under all circumstances;

O Optional, may be provided, but if provided shall be implemented in accordance with the requirements;

O.n this status is used for mutually exclusive or selectable options among a set. The integer "n" shall refer to a unique group of options within the EN-RT. A footnote to the EN-RT shall explicitly state what the requirement is for each numbered group.

EXAMPLE: "It is mandatory to support at least one of these options", or, "It is mandatory to support exactly one of these options".

Comments To be completed as required.

The above proposal describes alternate modes of establishing medical implant communication links between an internal implant transmitter and an external device. These alternate modes account for different applications as described clause 4.2.

4.2.9 Sharing issues

From the ECA table (CEPT/ERC Report 25 [6] and 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 Recommendation SA.1346 [3]. It was concluded that sharing is possible between the meteorological aids service and MICS systems provided the MICS equipment operates in accordance with the provisions set forth in the ITU-R Recommendation SA.1346 [3].

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, 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 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.

5.2 Expected timing for products to market

Products for use by the medical community are available ECC and ETSI actions.

It is proposed that both kinds of equipment should co-exist:

- with LBT; or
- without LBT for which a duty cycle restriction and power limitation of less than 100 nW e.r.p. is to be applied.

For equipment without LBT, a maximum duty cycle of up to 0,01 % and a power limitation to less than 100 nW e.r.p. is recommended. Consequently, respective changes in EN 301 839-2 [5] are proposed to be made in order to clarify and amend the existing regulations.

A clarification by CEPT of the regulatory situation will be needed for the amendment of the respective ETSI deliverables.

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 this band in the way described above.

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 device in their body that makes use of MICS technology. At an average implantation cost of 5 000 Euros to 8 000 Euros, the value of this market will be of the order of 50 billion Euros to 80 billion Euros or more.

MICS 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.

Annex B:
Technical information

B.1 Information on current version of relevant ETSI standard

The relevant ETSI harmonized standard, EN 301 839-2 [5], covers implant equipment operating in the 402 MHz to 405 MHz band. The present document is asking that EN 301 839-2 [5] shall be modified to include an alternative interference mitigation technology as described above.

Annex C:
Expected compatibility issues

C.1 Coexistence studies (if any)

Two studies related to coexistence between the Meteorological Aids Service and ULP-AMI systems have been previously performed. ITU-R Recommendation SA.1346 [3] has analysed the systems and concluded that sharing is possible between the Meteorological Aids Service and Medical Implant Communications Systems.

C.2 Current ITU allocations

The ITU Radio Regulations [9] show the following allocations for Region 1 in this frequency band.

Frequency band	Service allocation	
	Primary status	**Secondary status**
402 MHz to 403 MHz	METEOROLOGICAL AIDS EARTH EXPLORATION-SATELLITE (Earth-to-space) METEOROLOGICAL-SATELLITE (Earth-to-space)	Fixed Mobile except aeronautical mobile
403 MHz to 405 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.

Frequency band	European common allocation	Utilization	Note
401 MHz to 402 MHz	EARTH EXPLORATION-SATELLITE (E/S) METEOROLOGICAL AIDS METEOROLOGICAL-SATELLITE (E/S) EU2	Meteorological radiosondes Meteorological satellites, data collection platform	
402 MHz to 403 MHz	EARTH EXPLORATION-SATELLITE (E/S) METEOROLOGICAL AIDS METEOROLOGICAL-SATELLITE (E/S) EU2	Medical implants SRD Meteorological radiosondes Meteorological satellites, data collection platform	Medical implants within 402 MHz to 405 MHz
403 MHz to 406 MHz	METEOROLOGICAL AIDS EU2	Medical implants SRD Meteorological radio sondes	Medical implants within 402 MHz to 405 MHz
EU2: Civil-military sharing.			

C.4 Sharing issues

Sharing studies have shown that MICS systems pose no interference threat to the Meteorological Aids service. There may, however, be sharing issues related to interference to MICS systems from the Meteorological Aids Service. Adaptive frequency agility, error detection and correction techniques that are employed by MICS systems will permit these systems to ensure patient safety.

In the following the meaning of "patient safety" regarding a radio link between an ULP-AMI and an ULP-AMI-P is addressed:

- The radio link is a FUNCTIONAL CONNECTION within a MEDICAL ELECTRICAL SYSTEM intended to exchange information between an AIMD and a peripheral device. The manufacturer of a MEDICAL ELECTRICAL SYSTEM shall analyze, evaluate and control risks, throughout the life-cycle of the product, according to ISO 14971 [13].

Risks associated with one way communication shall be estimated and evaluated by the manufacturer. If the residual risk is judged acceptable, then all relevant information necessary to explain the residual risk(s) shall be placed in the appropriate accompanying documents (as e.g. the users manual) supplied by the manufacturer.

C.4.1 Risks associated with the downlink

Downlink is defined as communications from an external peripheral device to an AIMD. Possible hazards related to the transmission of information on the downlink may include:

1) Erroneous data transferred:

   - the severity of harm can be significant. With error detection and error correction techniques and other mitigations (as for example in ITU-R Recommendation SA.1346 [3]) the related probability of occurrence can be reduced effectively making the risk acceptable.

2) Interruption of the link:

   - the severity of harm must be analysed by the manufacturer. The probability of occurrence can be reduced by the healthcare professional while repositioning the ULP-AMI-P to make the risk acceptable. In case of a broken link the health care professional can intervene by using other therapies. Additionally, many AIMD systems are designed such that they will continue to operate correctly until all the data in the transmission have been completed and confirmed.

C.4.2 Risks associated with the uplink

Uplink is defined as communications from an AIMD to an external peripheral device. The uplink can be used to provide, as an example, diagnostic data sent from the AIMD. The amount of data can be significant. Related hazards are:

1) Erroneous data transferred:

   - the severity of the harm is potentially less significant than in the downlink. With error detection and correction techniques the related probability of occurrence can be effectively reduced, making the risk acceptable.

2) Interruption of the link:

   - the severity of harm must be analysed by the manufacturer. For example, the severity of the related harm for diagnostic systems is low as this data is not often time critical. The probability of occurrence can be reduced by the operator by repositioning the ULP-AMI-P to re-establish the link.

The status of the radio link can often be monitored by the healthcare professional operating the AIMD system.

Radio links between peripherals and AIMDs have been used for more than twenty years. Associated hazards are well known.

History

Document history		
V1.1.1	June 2005	Publication