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Ultra Low Power Active Medical Implants (ULP-AMI) and associated Peripherals (ULP-AMI-P) operating in the frequency range 402 MHz to 405 MHz; Harmonised Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU

Reference

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Foreword

This draft Harmonised European Standard (EN) has been produced by ETSI Technical Committee Electromagnetic compatibility and Radio spectrum Matters (ERM), and is now submitted for the combined Public Enquiry and Vote phase of the ETSI standards EN Approval Procedure.

The present document has been prepared to provide a means of conforming to the essential requirements of Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC [i.2].

NOTE: The corresponding Commission's standardization request is expected shortly.

Once the present document is cited in the Official Journal of the European Union under that Directive, compliance with the normative clauses of the present document given in table A.1 confers, within the limits of the scope of the present document, a presumption of conformity with the corresponding essential requirements of that Directive, and associated EFTA regulations.

Proposed national transposition dates	
Date of latest announcement of this EN (doa):	3 months after ETSI publication
Date of latest publication of new National Standard or endorsement of this EN (dop/e):	6 months after doa
Date of withdrawal of any conflicting National Standard (dow):	18 months after doa

Modal verbs terminology

In the present document "**shall**", "**shall not**", "**should**", "**should not**", "**may**", "**need not**", "**will**", "**will not**", "**can**" and "**cannot**" are to be interpreted as described in clause 3.2 of the ETSI Drafting Rules (Verbal forms for the expression of provisions).

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Introduction

ULP-AMI/ULP-AMI-P equipment in the MICS service is an evolving technology, available worldwide in the medical field, that provides high speed communications capability between individuals with AIMDs and medical practitioners engaged in utilizing these AIMDs for the purposes of diagnosing and delivering therapy to individuals with various illnesses. Equipment in the MICS service consists of active medical implants that communicate to other active medical implants and/or to ULP-AMI-P as e.g. external programmer/control transmitters.

The present document includes methods of measurement for Ultra Low Power Active Medical Implants (ULP-AMI) and Peripherals (ULP-AMI-P), fitted with antenna connector and/or integral antenna. Equipment designed for use with an integral antenna may be supplied with a temporary or permanent internal connector for the purpose of testing, providing the characteristics being measured are not expected to be affected.

If equipment, which is available on the market, is required to be checked it should be tested in accordance with the methods of measurement specified in the present document.

Clauses 1 through 3 provide a general description on the types of equipment covered by the present document and the definitions, symbols and abbreviations used.

Clause 4 provides the technical requirements specifications, limits and conformance relative to transmitter, receiver and spectrum access.

Clauses 5.1 and 5.2 specify the conditions for testing of the equipment and interpretation of the measurement results with the maximum measurement uncertainty values.

Clause 5.3.7 specifies the required measurement methods. In particular clause 5.3.7.1 describes the monitoring system performance specifications that have been chosen to minimize harmful interference to other equipment or services and minimize the potential for disturbance to this equipment from ambient sources or other medical device users in the band.

Annex A (normative) provides the relationship between the present document and the essential requirements of Directive 2014/53/EU [i.2].

Annex B (normative) provides specifications concerning radiated measurements.

Annex C (normative) provides technical performance of the spectrum analyser.

Annex D (informative) bibliography; provides additional information.

1 Scope

The present document applies to the following radio equipment types:

- Ultra Low Power Active Medical Implants (ULP-AMI).
- Ultra Low Power Active Medical Implant Peripherals (ULP-AMI-P).

These radio equipment types are capable of operating in all or any part of the frequency bands in table 1.

Table 1: Ultra Low Power Active Medical Implants (ULP-AMI) and Peripherals (ULP-AMI-P) operating frequency bands

	Ultra Low Power Active Medical Implants (ULP-AMI) and Peripherals (ULP-AMI-P) operating frequency bands
Transmit Ultra Low Power Active Medical Implants (ULP-AMI) and Peripherals (ULP-AMI-P)	402 MHz to 405 MHz
Receive Ultra Low Power Active Medical Implants (ULP-AMI) and Peripherals (ULP-AMI-P)	402 MHz to 405 MHz

The present document contains the technical characteristics for ULP-AMI and ULP-AMI-P radio equipment which is also addressed by ERC/DEC (01)17 [i.1].

It applies to ULP-AMI devices and accessories ULP-AMP-P operating in the frequency band 402 MHz to 405 MHz:

- for telecommand and telemetry to/from an AIMD in a patient's body to an ULP-AMI-P; or
- for telecommand and telemetry to/from an AIMD to another AIMD within the human body.

The present document contains requirements to demonstrate that Ultra Low Power Active Medical Implants (ULP-AMI) and Peripherals (ULP-AMI-P) used in a Medical Implant Communications Service (MICS)" … *shall be so constructed that it both effectively uses and supports the efficient use of radio spectrum in order to avoid harmful interference*" (article 3.2 of the Directive 2014/53/EU) [i.2], it does not necessarily include all the characteristics, which may be required by a user, nor does it necessarily represent the optimum performance achievable.

2 References

2.1 Normative references

References are either specific (identified by date of publication and/or edition number or version number) or non-specific. For specific references, only the cited version applies. For non-specific references, the latest version of the referenced document (including any amendments) applies.

Referenced documents which are not found to be publicly available in the expected location might be found at http://docbox.etsi.org/Reference.

NOTE: While any hyperlinks included in this clause were valid at the time of publication, ETSI cannot guarantee their long term validity.

The following referenced documents are necessary for the application of the present document.

[1] CISPR 16-2-3 (2010): "Specification for radio disturbance and immunity measuring apparatus and methods - Part 2-3: Methods of measurement of disturbances and immunity - Radiated disturbance measurements".

2.2 Informative references

References are either specific (identified by date of publication and/or edition number or version number) or non-specific. For specific references, only the cited version applies. For non-specific references, the latest version of the referenced document (including any amendments) applies.

NOTE: While any hyperlinks included in this clause were valid at the time of publication, ETSI cannot guarantee their long term validity.

The following referenced documents are not necessary for the application of the present document but they assist the user with regard to a particular subject area.

[i.1] ECC Decision (01)17 (2011 amendment): "Harmonised frequencies, technical characteristics and exemption from individual licensing of Ultra Low Power Active Medical Implant (ULP-AMI) communication systems operating in the frequency band 401 - 406 MHz on a secondary basis".

[i.2] Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (RE-D).

[i.3] ETSI TR 100 028 (all parts) (V1.4.1): "Electromagnetic compatibility and Radio spectrum Matters (ERM); Uncertainties in the measurement of mobile radio equipment characteristics".

[i.4] Recommendation ITU-T O.153: "Basic parameters for the measurement of error performance at bit rates below the primary rate".

[i.5] Radiofrequency Radiation Dosimetry Handbook (October 1986), USAF School of Aerospace Medicine, Aerospace Medical Division (AFSC), Brooks Air Force Base, TX 78235-5301.

NOTE: See http://niremf.ifac.cnr.it/docs/HANDBOOK/home.htm.

[i.6] CEPT/ERC/REC 74-01: "Unwanted Emissions in the Spurious Domain".

[i.7] Recommendation ITU-R RS.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".

[i.8] "Simulated Biological Materials for Electromagnetic Radiation Absorption Studies", by G. Hartsgrove, A. Kraszewski, and A. Surowiec as published in Bioelectromagnetics 8:29-36 (1987).

3 Definitions, symbols and abbreviations

3.1 Definitions

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

access protocol: specification for measuring natural and man-made ambient background levels for the purpose of providing a technique for spectrum access that reduces the potential for harmful interference to/from other users of the spectrum

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): ability to determine and use an unoccupied sub-band or channel of operation in order to maximize spectrum utilization

artificial antenna: reduced-radiating dummy load equal to the nominal impedance specified by the applicant

conducted measurements: measurements that are made using a direct connection to the equipment under test

dedicated antenna: removable antenna supplied and tested with the radio equipment, designed as an indispensable part of the equipment

duty cycle: ratio, expressed as a percentage, of the maximum transmitter "on" time monitored over one hour, relative to a one hour period

NOTE: See clause 4.2.3.1.2.2.

effective radiated power: power radiated within the emission bandwidth of the EUT in the direction of the maximum level under specified conditions of measurements in the presence of modulation or without modulation as appropriate

NOTE: See clause 4.2.1.3.1.

emission bandwidth: measured as the width of the signal between the points on either side of carrier centre frequency that are 20 dB down relative to the maximum level of the modulated carrier

NOTE: See clause 5.3.2 for details on how to determine compliance.

frequency error: difference between the nominal frequency as measured on the devices under test and under normal test conditions and the frequency under extreme conditions

NOTE: See also clause 4.2.1.1.1.

frequency stability under low voltage condition: ability of the equipment to remain on the nominal operating frequency when the battery voltage falls below the lower extreme voltage level

NOTE: See also clause 4.2.1.5.1.

integral antenna: permanent fixed antenna, which may be built-in, designed as an indispensable part of the equipment

LBT threshold power level: ambient signal power level above which the monitoring system selects spectrum for use in a MICS communication session according to the next available channel with the lowest level of ambient signal power or least interfered channel (LIC)

Least Interfered Channel (LIC): channel, among the available channels that has the lowest potential for causing disturbance to or receiving disturbance from other users of the band

NOTE: LIC may be used for spectrum selection provided the monitoring system has sufficient sensitivity to measure ambient signals at or below the LBT threshold power level. See clause 5.3.7.1.6.

Listen Before Talk (LBT): combination of the listen mode followed by the talk mode

listen mode: action taken by an interrogator to detect an unoccupied sub-band or channel

Medical Device (MD): 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 communication channel: Any continuous segment of spectrum that is equal to the emission bandwidth of the device with the largest bandwidth that is to participate in a MICL session. Aggregation of spectrum up to a maximum of 300 kHz for a single system is permitted.

NOTE 1: As stated in ECC Decision (01)17 [i.1], it is permitted to combine adjacent channels for increased bandwidth up to 300 kHz.

NOTE 2: Two types of devices for Medical Implant Communications Systems are covered by the present document:

(i) Frequency agile devices designed to access a minimum of nine channels evenly distributed across the 402 MHz to 405 MHz band.

(ii) Single frequency devices restricted to the 403,5 MHz to 403,8 MHz centre channel.

Medical Implant Communication Link (MICL): collection of transmissions that may or may not be continuous, between ULP-AMIs and ULP-AMI-Ps, including programmer/controllers, transferring patient related information in a communications service

Medical Implant Communications System (MICS): system specifically for the purpose of providing non-voice digital communications between one or several ULP-AMI and one ULP-AMI-P or between ULP-AMI

Medical Implant Communications System (MICS) session: collection of transmissions that may or may not be continuous, between co-operating ULP-AMI and ULP-AMI-P

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.

monitoring system: circuitry in an ULP-AMI and/or ULP-AMI-P that assures conformity with the spectrum access protocol requirements based on Listen before Talk, Adaptive Frequency Agility and selection of the least interfered channel for operation (LIC)

radiated measurements: measurements, which involve the absolute measurement of a radiated field

spurious domain radiations from the receiver: components at any frequency, generated and radiated by active receiver circuitry and the antenna

NOTE: See clause 4.2.2.1.1.

talk mode: transmission of intentional radiation by a transmitter

telecommand: use of radio communication for the transmission of signals to initiate, modify or terminate functions of equipment at a distance

telemetry: use of radio communication for indicating or recording data at a distance

time-critical data: data which if not transferred immediately will result in compromising the health and/or safety of the patient

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

Ultra Low Power Active Medical Implant Peripheral (ULP-AMI-P) device: the radio part of equipment outside the human body that communicates with an ULP-AMI to establish a MICL

unwanted emissions: emissions in the spurious domain and out of band domain

NOTE: See clause 4.2.1.4.1.

3.2 Symbols

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

B	bandwidth
dB	decibel
E	electrical field strength
Eo	reference electrical field strength (see annex B)
f	frequency
f_c	channel centre frequency
f_e	frequency under extreme conditions
G	Antenna Gain
NaCl	sodium chloride
P	power
R	distance
Ro	Reference distance (see annex B)
P_{Th}	maximum threshold power level (see clause 4.2.3.1.1.2)
t	time
λ	wavelength

3.3 Abbreviations

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

AFA	Adaptive Frequency Agility
AIMD	Active Implantable Medical Device
CW	Continuous Wave
e.r.p.	effective radiated power
EUT	Equipment Under Test
LBT	Listen Before Talk
LDC	Low Duty Cycle
LIC	Least Interfered Channel
LP	Low Power
MD	Medical Device
MICL	Medical Implant Communication Link
MICS	Medical Implant Communications System
RF	Radio Frequency
r.m.s.	root mean square
ULP-AMI	Ultra Low Power Active Medical Implant
ULP-AMI-P	Ultra Low Power Active Medical Implant Peripheral
VSWR	Voltage Standing Wave Ratio

4 Technical requirements specifications

4.1 Environmental profile

The technical requirements of the present document apply under the environmental profile for operation of the equipment, which shall be declared by the manufacturer. The equipment shall comply with all the technical requirements of the present document at all times when operating within the boundary limits of the declared operational environmental profile.

4.2 Conformance requirements

4.2.1 Transmitter requirements

4.2.1.1 Frequency error

4.2.1.1.1 Definition

The frequency error, also known as frequency drift, is the difference between the nominal frequency as measured on the devices under test and under normal test conditions (see clause 5.1.4.3) and the frequency under extreme conditions (see clause 5.1.4.4), see also clause 3.1.

4.2.1.1.2 Limits

The frequency error for equipment operating in the 402 MHz to 405 MHz band shall not exceed ±100 ppm under normal, extreme or any intermediate set of conditions.

In addition, the transmitted emission from a device operating in the low duty cycle low power mode in the band 403,5 MHz to 403,8 MHz in any operational configuration shall be maintained in the band 403,5 MHz to 403,8 MHz at all times.

4.2.1.1.3 Conformance

Conformance tests as defined in clause 5.3.1 of the present document shall be carried out.

4.2.1.2 Emission bandwidth

4.2.1.2.1 Definition

The emission bandwidth of a ULP-AMI or ULP-AMI-P device is measured as the width of the signal between the points on either side of carrier centre frequency that are 20 dB down relative to the maximum level of the modulated emission. Compliance is determined using instrumentation employing a peak detector function and a resolution bandwidth approximately equal to 1 % of the emission bandwidth of the EUT.

4.2.1.2.2 Limits

The maximum permitted emission bandwidth shall be 300 kHz. If two or more devices that operate in a given MICS communications session operate in different portions of the 402 MHz to 405 MHz band, their combined emission bandwidths shall not exceed 300 kHz. This limits spectrum usage to a maximum of 300 kHz in any single MICS communications session. The 300 kHz limitation may be exceeded briefly due to intermittent transmissions that may occur when operating channel acquisitions or changes are required to maintain a communications session.

All emissions from each device that fall outside its emission bandwidth but do fall within the 402 MHz to 405 MHz band shall be attenuated at least 20 dB.

In addition, emissions from a device operating in the low duty cycle low power mode in the band 403,5 MHz to 403,8 MHz shall be attenuated at least 20 dB at the band edges, 403,5 MHz and 403,8 MHz.

4.2.1.2.3 Conformance

Conformance tests as defined in clause 5.3.2 of the present document shall be carried out.

4.2.1.3 Effective radiated power of the fundamental emission

4.2.1.3.1 Definition

The effective radiated power is the power radiated within the emission bandwidth of the EUT in the direction of the maximum level under specified conditions of measurements in the presence of modulation or without modulation as appropriate, see also clause 3.1.

4.2.1.3.2 Limits

4.2.1.3.2.1 LBT/AFA systems

The effective radiated power of ULP-AMI and/or ULP-AMI-P equipment that operates as part of system that incorporates a monitoring system to select the frequency of operation using LBT and AFA (as specified in clause 5.3.7.1) shall not exceed 25µW e.r.p.

4.2.1.3.2.2 LP/LDC systems

The effective radiated power of ULP-AMI transmitters operating on any frequency in the band 403,5 MHz to 403,8 MHz shall not exceed 100 nW e.r.p. unless the frequency of operation in this band has been selected by a monitoring system using LBT and AFA (as specified in clause 5.3.7.1). The duty cycle for any transmitter operating in the LDC mode is limited to 0,01 %.

4.2.1.3.3 Conformance

Conformance tests as defined in clause 5.3.3 of the present document shall be carried out.

4.2.1.4 Spurious emissions of transmitter

4.2.1.4.1 Definition

Spurious domain emissions are emissions at frequencies other than those of the carrier and sidebands associated with normal test modulation, see also clause 3.1.