SLOVENSKI STANDARD
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Elektromagnetna združljivost in zadeve v zvezi z radijskim spektrom (ERM) - Naprave kratkega dosega (SRD) - Aktivni medicinski vsadki majhnih moči (LP-AMI), ki delujejo v frekvenčnem območju od 2483,5 MHz do 2500 MHz - 1. del: Tehnične karakteristike in preskusne metode

Electromagnetic compatibility and Radio spectrum Matters (ERM) - Short Range Devices (SRD) - Low Power Active Medical Implants (LP-AMI) operating in the frequency range 2 483,5 MHz to 2 500 MHz - Part 1: Technical characteristics and test methods

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Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Low Power Active Medical Implants (LP-AMI) operating in the frequency range 2 483,5 MHz to 2 500 MHz; Part 1: Technical characteristics and test methods

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Foreword

This European Standard (EN) has been produced by ETSI Technical Committee Electromagnetic compatibility and Radio spectrum Matters (ERM).

For non EU countries the present document may be used for regulatory purposes.

The present document is part 1 of a multi-part deliverable covering Low Power Active Medical Implants (LP-AMI), Peripherals (LP-AMI-P) operating in the frequency range 2 483,5 MHz to 2 500 MHz as described in the systems reference document for the equipment, TR 102 655 [i.8].

Part 1: "Technical characteristics and test methods";

Part 2: "Harmonized EN covering the essential requirements of article 3.2 of the R&TTE Directive".

National transposition dates	
Date of adoption of this EN:	18 June 2012
Date of latest announcement of this EN (doa):	30 September 2012
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Introduction

LP-AMI/LP-AMI-P equipment in the AMICS is a unique new technology, that will provide for example 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 AMICS consists of LP-AMI and/or LP-AMI-P that provide human therapeutic and diagnostic data storage and analysis capability.

The present document includes methods of measurement for Low Power Active Medical Implants (LP-AMI), and Peripherals (LP-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 a guide to requirements, the number of samples required in order that tests may be carried out and any markings on the equipment that the provider has to supply.

Clauses 5 and 6 provide general test conditions to be used.

Clause 7 gives the maximum measurement uncertainty values.

Clauses 8, 9 and 10 specify spectrum utilization parameters and the measurement methods that are required for the protection of the spectrum and patient. Clause 10 describes channel access requirements and methods. In particular clause 10.1 describes the monitoring system performance specifications that have been chosen to minimize harmful interference to other equipment or services, reduce the potential for disturbance to this equipment from ambient sources or other medical device users in the band and provide a high degree of link reliability in the interest of the patient.

Annex A (normative) provides specifications concerning radiated measurements.

Annex B (informative) bibliography; provides additional information.

1 Scope

The present document covers, for Low Power Active Medical Implants (LP-AMI), and associated Peripherals (LP-AMI-P) used in an Active Medical Implant Communications System (AMICS), the required characteristics considered necessary to efficiently use the available spectrum and serve the interests of patients with implanted devices. The specifications contained in the present document were developed to ensure that the health and safety of the patients that are using this equipment under the direction of medical practitioners is protected. Of particular importance is the inclusion of spectrum monitoring and access requirements designed to significantly reduce any interference potential between AMICS operating in the band or between AMICS and other primary or secondary users of the band. Also included in the present document is the capability of Low Duty Cycle/Low Power Access in the frequency band.

An AIMD is regulated under the AIMD Directive 90/385/EEC [i.7]: radio parts contained therein (referred to herein as LP-AMI, and LP-AMI-P for associated peripheral devices) are regulated under the Directive 1999/5/EC [i.1] (R&TTE Directive).

It is intended that the present document applies to operation in the band 2 483,5 MHz to 2 500 MHz that devices that can also operate in spectrum outside this band also meet any applicable requirements for operation in such bands.

The present document contains the technical characteristics for LP-AMI and associated peripherals radio equipment which is also addressed by CEPT/ERC/REC 70-03 [i.2] and annex 12 band f to that document. It does not necessarily include all the characteristics, which may be required by a user, nor does it necessarily represent the optimum performance achievable.

It applies to LP-AMI and associated peripherals operating in the band 2 483,5 MHz to 2 500 MHz:

- for telecommand and telemetry to/from an LP-AMI in a patient's body to LP-AMI-P or between these equipments;
- for telecommand and telemetry to/from an LP-AMI to another LP-AMI within the human body;
- with or without an integral antenna; and/or
- with an antenna connection provided only for the purpose of connecting an external dedicated antenna.

The present document covers requirements for radiated emissions above 30 MHz.

2 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 reference 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.

2.1 Normative references

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] 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".

2.2 Informative references

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] 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).

[i.2] CEPT/ERC/REC 70-03 (2011): "Relating to the use of Short Range Devices (SRD)".

[i.3] ITU-T Recommendation O.153: "Basic parameters for the measurement of error performance at bit rates below the primary rate".

[i.4] 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.5] CEPT/ERC/REC 74-01: "Unwanted Emissions in the Spurious Domain".

[i.6] Simulated Biological.

[i.7] Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (AIMD Directive).

[i.8] ETSI TR 102 655: "Electromagnetic compatibility and Radio spectrum Matters (ERM); System reference document; Short Range Devices (SRD); Low Power Active Medical Implants (LP-AMI) operating in a 20 MHz band within 2 360 MHz to 3 400 MHz".

[i.9] Hartsgrove and Kraszewski: "Composition And Electrical Properties Of A Liquid That Has The Electrical Properties Of Tissue", 1984.

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 Medical Implant Communication Channel (AMICC): any continuous segment of spectrum that is equal to the emission bandwidth of the device with the largest bandwidth that is to participate in an AMICL session

NOTE: The following type of devices for Active Medical Implant Communications Systems is covered by the present document: Frequency agile devices (i.e. having implemented LBT&AFA) designed to access a minimum one of 16 channels or 8 in the case of two channels dynamically aggregated for greater instantaneous bandwidth, that are evenly distributed across the 2 483,5 MHz to 2 500 MHz band and having Duty Cycle of less than 10 % for LP-AMI-P.

Active Medical Implant Communication Link (AMICL): collection of digitally modulated transmissions that may or may not be continuous, between LP-AMIs, and LP-AMI-Ps transferring information in a communications system

Active Medical Implant Communications System (AMICS): system specifically for the purpose of providing transmission of human therapeutic digital information between one or several LP-AMI and one or several LP-AMI-P

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

NOTE: Under normal operational circumstances the AMICS are allowed to be triggered, set-up and maintained only by an LP-AMI-P acting as a master device. LP-AMI may attempt initiating the link only in cases of emergencies, described as "medical implant event".

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 there for a long period after the procedure

Adaptive Frequency Agility (AFA): ability to determine and change to an unoccupied or least interfered sub-band or channel of operation in order to maximize spectrum utilization

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

channel aggregation: combining two or more adjacent channels for greater bandwidth up to 2 MHz

composite equipment: any combined equipment made of two or more individual products or functions

NOTE: The individual products or functions in composite equipment might be subject to different technical standards.

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 per AMICS session, relative to a one hour period

NOTE: See clause 8.7.

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

effective isotropically radiated power (e.i.r.p.): product of the power supplied to the antenna and the antenna gain in a given direction relative to an isotropic antenna

NOTE: See clause 8.3.

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

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

frequency range: range of operating frequencies over which the equipment can be adjusted

NOTE: See also clause 8.1.1.

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 8.6.1.

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 an AMICS communication session according to the next available channel

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

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

Low Power Active Medical Implant Peripheral (LP-AMI-P) device: the radio transmitting/receiving part of an equipment that communicates indoor with one or more LP-AMI to establish an AMICL

NOTE: LP-AMI-P transmissions are allowed without limitation in cases of emergencies, described as "medical implant event".

Low Power Active Medical Implant (LP-AMI): the radio transmitting/receiving part of an AIMD inside the human body

NOTE: LP-AMI transmissions are allowed without limitation in cases of emergencies, described as "medical implant event".

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

medical implant event: occurrence recognized by a medical implant system device 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 system transmitter has been placed

NOTE: An example of medical implant event is when the LP-AMI identifies the imminent critical health condition of monitored patient. Cannot be used for scheduled data transmissions.

monitoring system: circuitry in an LP-AMI and/or LP-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) or the unoccupied sub-band or channel

out-of-band emissions: emissions on a frequency or frequencies immediately outside the necessary **emission bandwidth**, which result from the modulation process, but excluding **emissions in the spurious domain**

spurious domain emissions: emissions at frequencies separated by more than 250 % of the occupied bandwidth from the centre of the AMICC

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

NOTE: See clause 9.1.1.

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 may result in compromising the health and/or safety of the patient

transient power: power falling into adjacent spectrum due to switching the transmitter on and off during normal operation (e.g. cyclic keying during data transmission)

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

3.2 Symbols

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

B	bandwidth
dB	decibel

dBm	absolute power level referred to one milliwatt
E	electrical field strength
e.i.r.p.	effective isotropically radiated power
f	frequency
fc	channel centre frequency
fe	frequency under extreme conditions
G	Antenna Gain
NaCl	sodium chloride
P	power
ppm	parts per million
R	distance
PTh	maximum threshold power level (see clause 10)
T	temperature
t	time
λ	wavelength

3.3 Abbreviations

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

AC	Alternating Current
AFA	Adaptive Frequency Agility
AIMD	Active Implantable Medical Device
AMICC	Active Medical Implant Communication Channel
AMICL	Active Medical Implant Communication Link
AMICS	Active Medical Implant Communications System
CW	Continuous Wave
DC	Direct Current
DUT	Device Under Test
EUT	Equipment Under Test
ICD	Implantable Cardiac Defibrillator
LBT	Listen Before Talk
LIC	Least Interfered Channel
LP	Low Power
LP-AMI	Low Power Active Medical Implant
LP-AMI-P	Low Power Active Medical Implant Peripheral
MD	Medical Device
r.m.s.	root mean square
RF	Radio Frequency
RMS	Root Mean Square
SRD	Short Range Device
VSWR	Voltage Standing Wave Ratio

4 Technical requirements and specifications

4.1 General requirements

4.1.1 Transmitter requirements

See clause 8 for transmitter requirements.

4.1.2 Receiver requirements

See clause 9.

4.2 Presentation of equipment for testing purposes

Each equipment submitted for testing shall fulfil the requirements of the present document on all frequencies over which it is intended to operate. Compliance with this requirement should be shown by testing each unit on a frequency near 2 490 MHz according to its intended function.

The provider shall declare the range of operating conditions and power requirements, as applicable; to establish the appropriate test conditions.

Additionally, technical documentation and operating manuals, sufficient to make the test, shall be supplied for all LP-AMI-P and LP-AMI device.

An appropriate human simulator and tissue substitute material for testing LP-AMI, shall be used (see clause 6.5).

Measurements shall be performed, according to the present document, on samples of equipment defined in clause 4.2.

The physical arrangement used for the testing shall be fully documented in the test report.

4.2.1 Choice of model for testing

The provider shall supply one or more samples of each model or type of transmitter (LP-AMI and/or LP-AMI-P), as appropriate for testing. Any ancillary equipment needed for testing shall be provided as requested by the testing laboratory.

If an equipment has several optional features, considered not to affect the RF parameters, then the tests need only to be performed on the equipment configured with that combination of features considered to be the most complex or most likely to affect the RF parameters, as proposed by the provider, agreed to by the test laboratory and recorded in the test report

4.2.2 Spurious emission testing for composite equipment

A composite equipment consisting of an LP-AMI-P or LP-AMI transmitter and a specific type of host equipment such as a computer for digital data recovery or programming/controlling the LP-AMI-P or LP-AMI should be tested according to the following requirements.

For emission tests, the most appropriate EMC standard shall be applied to the non-radio part of the host equipment.

The emissions requirements in the applicable clauses of the present standard apply only to the LP-AMI and LP-AMI-P radio part of the composite equipment.

In the case where the radio device is integrated and cannot operate independently, emissions from the non-radio part shall be tested with the radio part disabled.

With the radio operating in transmit, receive and standby (if applicable) modes, the emission requirements of the present document shall be applied.

Additional requirements and limits for multi radio equipment are set out in the relevant radio product standards applicable to the other radio parts.

4.2.3 Testing of equipment with alternative power levels

Equipment designed to operate with different emitted powers shall have each transmitter parameter tested on samples of equipment defined in clause 4.2.1. See clause 8 for details on testing. Spurious emissions tests shall be performed in accordance with requirements in clause 8.4.