SLOVENSKI STANDARD
SIST EN 301 559 V2.1.1:2016

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Naprave kratkega dosega (SRD) - Aktivni medicinski vsadki majhnih moči (LP-AMI) in pripadajoče periferne naprave (LP-AMI-P), ki delujejo v frekvenčnem območju od 2483,5 MHz do 2500 MHz - Harmonizirani standard, ki zajema bistvene zahteve člena 3.2 direktive 2014/53/EU

Short Range Devices (SRD) - Low Power Active Medical Implants (LP-AMI) and associated Peripherals (LP-AMI-P) operating in the frequency range 2 483,5 MHz to 2 500 MHz - Harmonised Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU

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ETSI EN 301 559 V2.1.1 (2016-10)

Short Range Devices (SRD);
Low Power Active Medical Implants (LP-AMI)
and associated Peripherals (LP-AMI-P)
operating in the frequency range 2 483,5 MHz to 2 500 MHz;
Harmonised Standard covering the essential requirements
of article 3.2 of the Directive 2014/53/EU

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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
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Foreword

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

The present document has been prepared under the Commission's standardisation request C(2015) 5376 final [i.12] to provide one voluntary means of conforming to the essential requirements of Directive 2014/53/EU 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.1].

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.

The present document covers Low Power Active Medical Implants (LP-AMI) and associated 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, ETSI TR 102 655 [i.2].

National transposition dates	
Date of adoption of this EN:	12 September 2016
Date of latest announcement of this EN (doa):	31 December 2016
Date of latest publication of new National Standard or endorsement of this EN (dop/e):	30 June 2017
Date of withdrawal of any conflicting National Standard (dow):	30 June 2018

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

The present document is part of a set of standards developed by ETSI and is designed to fit in a modular structure to cover all radio and telecommunications terminal equipment within the scope of the Radio Equipment Directive (RE-D) [i.1]. The modular structure is shown in ETSI EG 201 399 [i.4].

LP-AMI/LP-AMI-P equipment in the AMICS is a unique technology using the frequency band 2 483,5 MHz to 2 500 MHz, 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.

The frequency usage conditions for the bands 2 483,5 MHz to 2 500 MHz are European wide harmonised for the SRD category "active medical implant devices" according to 2013/752/EU [i.13].

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.

The present document is structured as follows:

- Clauses 1 through 3 provide a general description of the types of equipment covered by the present document and the definitions of terms and symbols and abbreviations used.
- Clause 4 specifies the requirements and limits relative to transmitter, receiver, and spectrum access. The latter are primarily designed to minimize the possibility of disturbance between LP-AMI/LP-AMI-P equipment and other users of the 2 483,5 MHz to 2 500 MHz frequency range.
- Clauses 5.1 and 5.2 specify the test and general conditions for testing of the equipment.
- Clause 5.3 specifies the methods of measurement for the parameters specified in clause 4, related to transmitter, receiver, and spectrum access.
- Annex A (normative) provides an overview of the relationship between the present document and the essential requirements of the RE-D [i.1].
- Annex B (normative) gives the specifications concerning radiated measurements.
- Annex C (informative) provides the bibliography.

1 Scope

The present document covers, for Low Power Active Medical Implants (LP-AMI) using the band bands 2 483,5 MHz to 2 500 MHz, 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. An AIMD is regulated under the AIMD Directive 90/385/EEC [i.5] radio parts contained therein (referred to herein as LP-AMI and LP-AMI-P for associated peripheral devices) are regulated under the Directive 2014/53/EU [i.1].

The frequency usage conditions for the bands 2 483,5 MHz to 2 500 MHz are EU wide harmonised for the SRD category "active medical implant devices" according to Commission Implementing Decision 2013/752/EU [i.13] with the following usage restrictions:

- "This set of usage conditions is only available to active implantable medical devices. Peripheral master units are for indoor use only."

The present document contains the technical characteristics for LP-AMI and associated peripherals LP-AMI-P radio equipment which is also addressed by CEPT/ERC/REC 70-03 [i.3] annex 12 sub-band e) 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.

The present document applies to LP-AMI and LP-AMI_P operating in the band 2 483,5 MHz to 2 500 MHz:

- for telecommand and telemetry between LP-AMI and LP-AMI-P;
- for telecommand and telemetry between LP-AMI to another LP-AMI;
- with or without an integral antenna; and/or
- with an antenna connection provided only for the purpose of connecting a dedicated antenna.

The present document contains required characteristics considered necessary for the radio devices used in AMICS to meet in order to efficiently use the available spectrum for the purpose of transferring data that is used in diagnosing and delivering therapies to individuals with various illnesses. Of particular importance is the inclusion of spectrum monitoring and access requirements (listen before talk protocol) designed to significantly reduce any interference potential between AMICS operating in the band or between an AMICS and the primary users of the band.

The present document is a specific product standard applicable to low power transmitters that are part of a system used in the AMICS operating in spectrum within the frequency band 2 483,5 MHz to 2 500 MHz.

The present document contains requirements to demonstrate that Low Power Active Medical Implants (LP-AMI) "*…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.1]. The present document does not necessarily include all the requirements 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) +AMD1:2010+AMD2:2014: "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] 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] 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.3] CEPT/ERC/REC 70-03: "Relating to the use of Short Range Devices (SRD)".

[i.4] ETSI EG 201 399 (V3.1.1): "Electromagnetic compatibility and Radio spectrum Matters (ERM); A guide to the production of Harmonized Standards for application under the Radio & Telecommunication Terminal Equipment Directive 1999/5/EC (R&TTE) and a first guide on the impact of the Radio Equipment Directive 2014/53/EU (RED) on Harmonized Standards".

[i.5] 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.6] CEPT/ERC/REC 74-01: "Unwanted emissions in the spurious domain".

[i.7] Recommendation ITU-T O.153: "Basic parameters for the measurement of error performance at bit rates below the primary rate".

[i.8] ETSI TR 100 028 (all parts) (V1.4.1) (12-2001): "Electromagnetic compatibility and Radio spectrum Matters (ERM); Uncertainties in the measurement of mobile radio equipment characteristics".

[i.9] Hartsgrove G., Kraszewski A. and Surowiec A.: "Simulated Biological Materials for Electromagnetic Radiation Absorption Studies", 1987.

[i.10] Hartsgrove and Kraszewski: "Composition And Electrical Properties Of A Liquid That Has The Electrical Properties Of Tissue", 1984.

[i.11] Carl H. Durney, Ph.D., Habib Massoudi, Ph.D., Magdy F. lskander, USAFSAM-TR-85-73: "Radiofrequency Radiation Dosimetry Handbook (Fourth Edition)".

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

[i.12] Commission Implementing Decision C(2015) 5376 final of 4.8.2015 on a standardisation request to the European Committee for Electrotechnical Standardisation and to the European Telecommunications Standards Institute as regards radio equipment in support of Directive 2014/53/EU of the European Parliament and of the Council.

[i.13] Commission Implementing Decision 2013/752/EU of 11 December 2013 amending Decision 2006/771/EC on harmonisation of the radio spectrum for use by short-range devices and repealing Decision 2005/928/EC.

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 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 4.2.1.7.1.

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 4.2.1.3.1.

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

NOTE: See also clause 4.2.1.1.1.

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

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 4.2.1.6.1.

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: 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): 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 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 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
P_{Th}	maximum threshold power level (see clause 4.2.3.1)
T	temperature
t	time
λ	wavelength