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Standard elektromagnetne združljivosti (EMC) za radijsko opremo in storitve - 35. del: Posebne zahteve za aktivne medicinske vsadke z majhno močjo (LP-AMI), ki delujejo v frekvenčnem pasu od 2483,5 MHz do 2500 MHz - Harmonizirani standard, ki zajema bistvene zahteve člena 3.1(b) direktive 2014/53/EU

ElectroMagnetic Compatibility (EMC) standard for radio equipment and services - Part 35: Specific requirements for Low Power Active Medical Implants (LP-AMI) operating in the 2 483,5 MHz to 2 500 MHz bands - Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU

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ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 35: Specific requirements for Low Power Active Medical Implants (LP-AMI) operating in the 2 483,5 MHz to 2 500 MHz bands; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU

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Contents

Intellectual Property Rights 5
Foreword 5
Modal verbs terminology 5
1 Scope 6
2 References 6
2.1 Normative references 6
2.2 Informative references 6
3 Definitions and abbreviations 7
3.1 Definitions 7
3.2 Abbreviations 8
4 Test conditions 8
4.1 General 8
4.2 Arrangements for test signals 9
4.2.0 General 9
4.2.1 Arrangements for test signals at the input of transmitters 9
4.2.2 Arrangements for test signals at the RF output of transmitters 9
4.2.2.0 General 9
4.2.2.1 ULP-AMI transmitters 9
4.2.2.2 ULP-AMI-P transmitters 9
4.2.3 Arrangements for test signals at the RF input of receivers 9
4.2.4 Arrangements for test signals at the output of receivers 9
4.2.5 Arrangements for testing transmitter and receiver together (as a system: ULP-AMI together with an associated ULP-AMI-P) 10
4.3 RF exclusion band of radio equipment 10
4.3.1 General 10
4.3.2 Exclusion band for receivers 10
4.3.3 Exclusion band for transmitters 11
4.4 Narrow band responses of receivers or receivers which are part of transceivers 11
4.5 Normal test modulation 11
5 Performance assessment 11
5.1 General 11
5.2 Equipment which can provide a continuous communication link 11
5.3 Equipment which does not provide a continuous communication link 12
5.4 Ancillary equipment 12
5.5 Equipment classification 12
6 Performance criteria 12
6.1 Classification of LP-AMI and LP-AMI-P devices 12
6.2 General performance criteria 12
6.3 Performance criteria and table 13
6.4 Performance criteria for continuous phenomena applied to transmitters 14
6.5 Performance criteria for transient phenomena applied to transmitters 14
6.6 Performance criteria for continuous phenomena applied to receivers 14
6.7 Performance criteria for transient phenomena applied to receivers 15
7 Applicability overview 15
7.1 EMC emission 15
7.1.1 General 15
7.1.2 Special conditions 15
7.2 Immunity 15
7.2.1 General 15
7.2.2 Special conditions 16

Annex A (informative): Relationship between the present document and the essential requirements of Directive 2014/53/EU 20

Annex B (normative): Definitions of types of LP-AMI and LP-AMI-P devices in the scope of the present document 22

B.1 LP-AMI and LP-AMI-P devices intended for operation in the frequency range 2 483,5 MHz to 2 500 MHz 22

Annex C (normative): Test fixture for LP-AMI devices (Simulated man) 23

Annex D (informative): Change history 25

History 26

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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.6] 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 is part 35 of a multi-part deliverable. Full details of the entire series can be found in part 1 [1].

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Date of latest publication of new National Standard or endorsement of this EN (dop/e):	31 January 2020
Date of withdrawal of any conflicting National Standard (dow):	31 January 2021

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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1 Scope

The present document together with ETSI EN 301 489-1 [1], covers the assessment of all radio transceivers associated with Low Power Active Medical Implants (LP-AMIs) and associated Peripheral devices (LP-AMI-P) in respect of ElectroMagnetic Compatibility (EMC).

The present document covers the EMC requirements for the radio functions of LP-AMI and associated Peripheral devices (LP-AMI-P).

Technical specifications related to the antenna port and emissions from the enclosure port of the radio system of LP-AMI and associated Peripheral devices (LP-AMI-P) are not included in the present document. Such technical specifications are found in the relevant product standards for the effective use of the radio spectrum.

The present document specifies the applicable test conditions, performance assessment, and performance criteria for of LP-AMI and associated Peripheral devices (LP-AMI-P).

Definitions of types of LP-AMIs and P-AMI-Ps covered by present document are given in annex B.

In case of differences (for instance concerning special conditions, definitions, abbreviations) between the present document and ETSI EN 301 489-1 [1], the provisions of the present document take precedence.

The environmental classification and the emission and immunity requirements used in the present document are as stated in the ETSI EN 301 489-1 [1], except for any special conditions included in the present document.

The present document, together with ETSI EN 301 489-1 [1], contains requirements to demonstrate an adequate level of electromagnetic compatibility as set out in Directive 2014/53/EU [i.1].

2 References

2.1 Normative references

References are specific, identified by date of publication and/or edition number or version number. Only the cited version applies.

Referenced documents which are not found to be publicly available in the expected location might be found at https://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] ETSI EN 301 489-1 (V2.2.0) (03-2017): "ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and the essential requirements of article 6 of Directive 2014/30/EU".

[2] CENELEC EN 61000-4-5:2006: "Electromagnetic compatibility (EMC) - Part 4-5: Testing and measurement techniques - Surge immunity test".

[3] ETSI EN 301 559 (V2.1.1) (10-2016): "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".

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.

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

[i.3] Commission Decision 2006/771/EC of 11 November 2006 on harmonization of the radio spectrum for use by short-range devices as amended by subsequent Commission Decisions.

[i.4] http://niremf.ifac.cnr.it/.

[i.5] Camelia Gabriel: "Compilation of the dielectric properties of body tissues at RF and Microwave Frequencies", (Physics Department, Kings College, London WC2R 2LS, UK.

[i.6] 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.

3 Definitions and abbreviations

3.1 Definitions

For the purposes of the present document, the terms and definitions given in ETSI EN 301 489-1 [1], ETSI EN 301 559 [3], Directive 2014/53/EU [i.1] and the following apply:

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

Active Medical Device (AMD): any medical device relying for its functioning on a source of electrical energy or any source of power

Active Medical Implant (AMI): diagnostic or therapeutic device designed to be implanted in a human body containing a power source and a transceiver using the 2 483,5 MHz to 2 500 MHz frequency band for the purpose of providing a two-way digital communications link

life supporting equipment: equipment whose continued normal operation is required in order to sustain life

Low Power Active Medical Implant (LP-AMI): low power radio part of 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

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".

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 and for prolongation of life;
- 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 Communications Link (MICL): collections of transmission that may or may not be continuous, between co-operating medical implant devices and accessories, including programmer/controllers, transferring patient related information in communications service

Medical Implant Communications System (MICS): specific system providing radiocommunications between an LP-AMI and an associated LP-AMI-P

3.2 Abbreviations

For the purposes of the present document, the abbreviations given in ETSI EN 301 489-1 [1], ETSI EN 301 559 [3], Directive 2014/53/EU [i.1] and the following apply:

AC	Alternating Current
AIMD	Active Implantable Medical Device
AMD	Active Medical Device
AMI	Active Medical Implant
AMICL	Active Medical Implant Communication Link
dB	decibel
dBm	absolute power level referred to one milliwatt
DC	Direct Current
e.i.r.p.	effective isotropically radiated power
EMC	ElectroMagnetic Compatibility
EUT	Equipment Under Test
f_o	operating frequency
ISM	Industrial Scientific Medical excluding telecommunications
LP-AMI	Low Power Active Medical Implant
LP-AMI-P	Low Power Active Medical Implant Peripheral
MD	Medical Device
MICL	Medical Implant Communications Link
MICS	Medical Implant Communications System
RF	Radio Frequency
SRD	Short Range Devices

4 Test conditions

4.1 General

For the purposes of the present document, the test conditions of the ETSI EN 301 489-1 [1], clause 4, shall apply as appropriate. Further product related test conditions for LP-AMI and associated Peripheral devices (LP-AMI-P) are specified in the present document.

For emission and immunity tests the normal test modulation, test arrangements, etc., as specified in the present document, clauses 4.1 to 4.5 shall apply.

Whenever the Equipment Under Test (EUT) is provided with a detachable antenna, the EUT shall be tested with the antenna fitted in a manner typical of normal intended use, unless otherwise specified. If the EUT can be used with several types of antenna the test shall be repeated for each type of antenna.

LP-AMI devices (active medical implants) are designed to be implanted within a human body. These radio systems are isolated from disturbances by the surrounding body tissue. In order to adequately assess the EMC characteristics of active medical implants devices, the use of a simulated man is necessary. See annex C for additional details. The provisions of annex C are intended to provide an operational environment that simulates, to the extent possible, actual usage conditions for internal implanted devices. It is necessary to use this or another appropriate special fixture when making emission measurements and immunity tests with radiated RF fields.

4.2 Arrangements for test signals

4.2.0 General

The provisions of the ETSI EN 301 489-1 [1], clause 4.2 shall apply.

4.2.1 Arrangements for test signals at the input of transmitters

The provisions of the ETSI EN 301 489-1 [1], clause 4.2.1 shall apply with the following modifications:

- The transmitter shall be modulated with normal test modulation as specified for that type of equipment (see clause 4.5). Where transmitters do not have a modulation input port, the internal equipment modulation shall be used.

4.2.2 Arrangements for test signals at the RF output of transmitters

4.2.2.0 General

The provisions of the ETSI EN 301 489-1 [1], clause 4.2.2 shall apply with the following modification:

- The manufacturer may provide a suitable companion receiver or another device that can be used to set up a communications link and/or to receive messages.

4.2.2.1 ULP-AMI transmitters

For ULP-AMI transmitters the test fixture described in annex C may be used:

- The manufacturer shall provide a suitable receiver that can be used to monitor the medical implant communications link.

4.2.2.2 ULP-AMI-P transmitters

The provisions of the ETSI EN 301 489-1 [1], clause 4.2.2 shall apply with the following modifications:

- LP-AMI-P devices are designed to be used externally to a human body;
- the manufacturer shall provide a suitable receiver that can be used to monitor the medical implant communications link.

4.2.3 Arrangements for test signals at the RF input of receivers

The provisions of ETSI EN 301 489-1 [1], clause 4.2.3 shall apply with the following modifications:

- the wanted RF input signal, coupled to the receiver, shall be modulated with normal test modulation as specified for that type of equipment (clause 4.5);
- the level of the wanted RF input signal shall be 20 dB above the threshold sensitivity level of the receiver, but in all cases it shall be below the overload characteristics of the receiver;
- the manufacturer shall provide a suitable transmitter that can be used to set up the medical implant communications link.

4.2.4 Arrangements for test signals at the output of receivers

The provisions of ETSI EN 301 489-1 [1], clause 4.2.4 shall apply with the following modification, if appropriate:

- if direct access to the receiver output of the ULP-AMI and associated ULP-AMI-P is not possible, then the manufacturer shall provide the method by which the receiver's functionality can be monitored during the immunity tests.