

SLOVENSKI STANDARD
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Standard elektromagnetne združljivosti (EMC) za radijsko opremo in storitve - Harmonizirani standard, ki zajema bistvene zahteve člena 3.1(b) direktive 2014/53/EU - 27. del: Posebni pogoji za aktivne medicinske vsadke ultra majhnih moči (ULP-AMI) in pripadajoče periferne naprave (ULP-AMI-P)

ElectroMagnetic Compatibility (EMC) standard for radio equipment and services - Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU - Part 27: Specific conditions for Ultra Low Power Active Medical Implants (ULP-AMI) and related peripheral devices (ULP-AMI-P)

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**ElectroMagnetic Compatibility (EMC)
standard for radio equipment and services;
Part 27: Specific conditions for Ultra Low
Power Active Medical Implants (ULP-AMI) and
related peripheral devices (ULP-AMI-P);
Harmonised Standard covering the essential requirements
of article 3.1(b) of Directive 2014/53/EU**

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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.4] 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 27 of a multi-part deliverable. Full details of the entire series can be found in ETSI EN 301 489-1 [1].

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Date of withdrawal of any conflicting National Standard (dow):	30 September 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).

"**must**" and "**must not**" are **NOT** allowed in ETSI deliverables except when used in direct citation.

1 Scope

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

The present document covers the EMC requirements for the radio functions of ULP-AMI and ULP-AMI-P devices.

Technical specifications related to the antenna port and emissions from the enclosure port of the ULP-AMI and ULP-AMI-P devices radio system 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 ULP-AMIs and associated Peripheral devices (ULP-AMI-Ps).

Definitions of types of ULP-AMIs and ULP-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 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 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 <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 (V2.1.1) (11-2016): "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".

NOTE: Available at http://www.etsi.org/deliver/etsi_en/301400_301499/30148901/02.01.01_30/en_30148901v020101v.pdf.

- [2] ETSI EN 301 839 (V2.1.1) (04-2016): "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".
- [3] IEC EN 60601-1-2 (2007): "Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests".
- [4] IEC EN 61000-4-5 (2006): "Electromagnetic compatibility (EMC) - Part 4-5: Testing and measurement techniques - Surge immunity test".

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] Camelia Gabriel: "Compilation of the dielectric properties of body tissues at RF and Microwave Frequencies", Physics Department, King's College, London WC2R 2LS, UK. February 1996.

NOTE: Available at <http://www.dtic.mil/dtic/tr/fulltext/u2/a305826.pdf>.

- [i.4] 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.5] Italian National Research Council, Institute for Applied Physics.

NOTE: Available at <http://niremf.ifac.cnr.it/>

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3 Definitions and abbreviations

3.0 Applicability

For the purposes of the present document, definitions and abbreviations have the meanings ascribed herein in clause 3.

Where such meanings are not so ascribed the meanings in ETSI EN 301 489-1 [1], clause 3, apply.

Where such meanings are not so ascribed the meanings in ETSI EN 301 839 [2], clause 3, apply.

Where such meanings are not so ascribed the meanings in the Directive 2014/53/EU [i.1] apply.

3.1 Definitions

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

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 402 MHz to 405 MHz frequency band for the purpose of providing a two-way digital communications link

environmental profile: range of environmental conditions under which equipment within the scope of the present document is required to comply with the provisions of the present document

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

Medical Implant Communications Link (MIDL): 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 ULP-AMI and an associated ULP-AMI-P

Ultra Low Power Active Medical Implant (ULP-AMI): transmitter or receiver or transceiver forming part of an active medical implant, that is used in a medical implant communications system radio link set up by the peripheral device (ULP-AMI-P)

Ultra Low Power Active Medical Implant Peripheral device (ULP-AMI-P): radio part of equipment outside the human body, including body worn devices, used to program and/or control an ULP-AMI by means of a Medical Implant (radio) Communications Link (MICL), such as an external programmer or control transceiver

3.2 Abbreviations

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

AC	Alternating Current
AIMD	Active Implantable Medical Device
AMI	Active Medical Implant
DC	Direct Current
EMC	ElectroMagnetic Compatibility
ERP	Effective Radiated Power
EUT	Equipment Under Test
ISM	Industrial, Scientific and Medical
MICL	Medical Implant Communications Link
MICS	Medical Implant Communications System
RF	Radio Frequency
ULP-AMI	Ultra Low Power Active Medical Implant
ULP-AMI-P	Ultra Low Power Active Medical Implant Peripheral device

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4 Test conditions

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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 ULP-AMI and associated ULP-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.

ULP-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 (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

4.2.2.1 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.

4.2.2.2 ULP-AMI transmitters

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

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

4.2.2.3 ULP-AMI-P transmitters

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

- ULP-AMI-Ps are designed to be used external to a human body;
- the manufacturer shall provide a suitable receiver or alternate technique 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.