SLOVENSKI STANDARD
SIST EN 301 489-31 V2.2.1:2019

01-junij-2019

Standard elektromagnetne združljivosti (EMC) za radijsko opremo in storitve - 31. del: Posebni pogoji za opremo za aktivne medicinske vsadke ultra majhnih moči (ULP-AMI) in pripadajoče periferne naprave (ULP-AMI-P), ki delujejo v frekvenčnem pasu od 9 kHz do 315 kHz - Harmonizirani standard, ki zajema bistvene zahteve člena 3.1(b) direktive 2014/53/EU

ElectroMagnetic Compatibility (EMC) standard for radio equipment and services - Part 31: Specific conditions for equipment in the 9 kHz to 315 kHz band 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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ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 31: Specific conditions for equipment in the 9 kHz to 315 kHz band 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 31 of a multi-part deliverable. Full details of the entire series can be found in part 1 [1].

National transposition dates	
Date of adoption of this EN:	20 June 2017
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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 inductive Ultra Low Power Active Medical Implant (ULP-AMI) transmitters and receivers operating in the range from 9 kHz to 315 kHz and any associated external radio apparatus (ULP-AMI-Ps) transmitting in the frequency range of 9 kHz to 315 kHz including external programmers and patient related telecommunication devices in respect of ElectroMagnetic Compatibility (EMC). Non-radio parts of the above equipment may be covered by other directives and/or standards when applicable.

Technical specifications related to the antenna port and emissions from the enclosure port of the radio systems of these devices 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 assessment of the radio communications link for ULP-AMI and ULP-AMI-Ps.

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] ETSI EN 302 195 (V2.1.1) (06-2016): "Short Range Devices (SRD); Ultra Low Power Active Medical Implants (ULP-AMI) and accessories (ULP-AMI-P) operating in the frequency range 9 kHz to 315 kHz Harmonised Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU".

[3] CENELEC EN 61000-4-5 (2014): "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] Camelia Gabriel: "Compilation of the dielectric properties of body tissues at RF and Microwave Frequencies", Physics Department, Kings College, London WC2R 2LS, UK.

[i.3] Void.

[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.

3 Definitions, symbols 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 302 195 [2], Directive 2014/53/EU [i.1] and the following apply, unless otherwise ascribed herein:

emission bandwidth: bandwidth between two points that are 20 dB down on either side of the frequency with the maximum level in the modulation envelope

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

H-field test antenna: electrically screened loop or equivalent antenna, with which the magnetic component of the field can be measured

life supporting equipment: equipment or system that includes at least one function that is intended to actively keep alive or resuscitate patients and the failure of which is likely to lead to serious injury or death of a patient

non-radio part: those portions of a device not used for communication via electromagnetic waves

radio part: that portion of a device used for communication via electromagnetic waves

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

Ultra Low Power Active Medical Implant Peripheral device (ULP-AMI-P): radio part of equipment outside the human body, including body worn devices and monitors, used to program and/or control or receive data from an ULP-AMI

3.2 Symbols

For the purposes of the present document, the symbols given in ETSI EN 301 489-1 [1], ETSI EN 302 195 [2] and Directive 2014/53/EU [i.1] apply.

3.3 Abbreviations

For the purposes of the present document, the abbreviations given in ETSI EN 301 489-1 [1], ETSI EN 302 195 [2], Directive 2014/53/EU [i.1] and the following apply, unless otherwise ascribed herein:

AC	Alternating Current
AIMD	Active Implantable Medical Device
AMI	Active Medical Implant
DC	Direct Current
EMC	ElectroMagnetic Compatibility
EUT	Equipment Under Test
ISM	Industria, Scientific and Medical
RF	Radio Frequency
ULP-AMI	Ultra Low Power-Active Medical Implant
ULP-AMI-P	Ultra Low Power-Active Medical Implant Peripheral device

4 Test conditions

4.1 General

For the purposes of the present document, the test conditions of ETSI EN 301 489-1 [1], clause 4 shall apply as appropriate. Further product related test conditions for equipment covered by the scope of the present document are specified herein.

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.

Active Medical Implant inductive devices 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 as they are intended to be used, the use of a simulated man is permitted. See annex B for additional details. The provisions of annex B are intended to provide an operational environment that simulates, to the extent possible, actual usage conditions for internal implanted devices. It may be 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 B 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 sufficiently above the threshold sensitivity level to provide reliable communication 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 if needed.

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.

4.2.5 Arrangements for testing transmitter and receiver together (as a system: ULP-AMI together with an associated ULP-AMI-P)

The provisions of ETSI EN 301 489-1 [1], clause 4.2.5 shall apply with the following modification:

- The transmitter of an ULP-AMI and the receiver of an associated ULP-AMI-P or the receiver of an ULP-AMI and the transmitter of an associated ULP-AMI-P may be tested together, if appropriate and agreed by the manufacturer and the test laboratory (size of devices, etc.).

In this case both EUTs shall be located in their respective test environment and exposed simultaneously to the EMC phenomena.