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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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Foreword

This draft Harmonised European Standard (EN) has been produced by ETSI Technical Committee Electromagnetic compatibility and Radio spectrum Matters (ERM), and is now submitted for the combined Public Enquiry and Vote phase of the ETSI standards EN Approval Procedure.

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].

Proposed national transposition dates	
Date of latest announcement of this EN (doa):	3 months after ETSI publication
Date of latest publication of new National Standard or endorsement of this EN (dop/e):	6 months after doa
Date of withdrawal of any conflicting National Standard (dow):	18 months after doa

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 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/.

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The following referenced documents are necessary for the application of the present document.

[1] ETSI EN 301 489-1 (V2.1.0) (04-2016): "ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Harmonised Standard covering the essential requirements of article 3.1(b) of the Directive 2014/53/EU and the essential requirements of article 6 of the Directive 2014/30/EU; Part 1: Common technical requirements".

NOTE: Available at http://www.etsi.org/deliver/etsi_en/301400_301499/30148901/02.01.00_20/en_30148901v020100a.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] Void.

[i.3] Camelia Gabriel: "Compilation of the dielectric properties of body tissues at RF and Microwave Frequencies", Physics Department, Kings College, London WC2R 2LS, UK.

[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/.

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 (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 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

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 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.

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.

4.3 RF exclusion band of radio equipment

4.3.0 General

The emission measurement and immunity test exclusions are referred to as "exclusion bands" and are defined in the clauses 4.3.1 and 4.3.2.

The frequencies on which the EUT is intended to operate, shall be excluded from conducted and radiated RF immunity tests.

The frequencies on which the transmitter part of the EUT is intended to operate shall be excluded from emission measurements when performed in transmit mode of operation.

During emission measurements, a frequency exclusion band does not apply for the receiver part of ULP-AMIs and/or associated ULP-AMI-Ps.

4.3.1 Exclusion bands for receivers

The exclusion band for receivers (including receivers that are part of transceivers) is determined as follows:

- for receivers capable of operating on 9 or more channels within the frequency band specified in table 1 and not having an alignment range, the lower frequency of the exclusion band is the lower frequency of the used frequency channel minus the extension value given in table 1, and the upper frequency of the exclusion band is the upper frequency of the used frequency channel plus the extension value given in table 1. The calculated extension value shall be based on the operating frequency;
- for receivers capable of operating on more than one frequency and having an alignment range, the lower frequency of the exclusion band is the lower frequency of the alignment range minus the extension value given in table 1, and the upper frequency of the exclusion band is the upper frequency of the alignment range plus the extension value given in table 1. The calculated extension values shall be based on the centre frequency of the alignment range;
- for wide band receivers, i.e. receivers operating in a non-channelized arrangement, the lower frequency of the exclusion band is the lower frequency of the intended operating band minus the extension value given in table 1 and the upper frequency of the exclusion band is the upper frequency of the intended operating band plus the extension value given in table 1, or the total exclusion band is twice the intended operating frequency band of the receiver centred around the centre frequency of the intended operating band, whichever is the greater.

Table 1: Exclusion band for the receiver part of ULP-AMI or ULP-AMI-Ps

Receiver operating frequency f_o	Receiver exclusion band
402 MHz to 405 MHz	$f_o \pm 10$ MHz

4.3.2 Exclusion band for transmitters

For transmitters operating, or intended to operate, in a channelized arrangement in the 402 MHz to 405 MHz frequency band, the exclusion band is nine times the maximum occupied bandwidth allowed for that service, centred around the operating frequency. For the 402 MHz to 405 MHz band, the maximum occupied bandwidth is 300 kHz. The actual occupied bandwidth is determined using the procedures in ETSI EN 301 839 [2] for measuring emission bandwidth.

For wide band transmitters, i.e. transmitters in a non-channelized frequency band, the exclusion band is twice the intended operating frequency band (i.e. 3 MHz or less) centred around the centre frequency of the intended operating frequency band.

In case the receiver and transmitter are tested together as a system (see clause 4.2.5) the exclusion band defined for receivers or the exclusion band defined for transmitters shall be used, whichever is greater.