SLOVENSKI STANDARD
SIST EN 301 489-31 V1.1.1:2006

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Elektromagnetna združljivost in zadeve v zvezi z radijskim spektrom (ERM) ï Standard elektromagnetne združljivosti (EMC) za radijsko opremo in storitve ï 31. del: Posebni pogoji za opremo za aktivne medicinske vsadke ultra majhnih moļ i (ULP-AMI) in pripadajoļ ih perifernih naprav (ULP-AMI-P), ki delujejo v frekvenļ nem pasu od 9 kHz do 315 kHz

Electromagnetic compatibility and Radio spectrum Matters (ERM); 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)

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Candidate Harmonized European Standard (Telecommunications series)

Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 31: Specific conditions for equipment in the 9 to 315 kHz band for Ultra Low Power Active Medical Implants (ULP-AMI) and related peripheral devices (ULP-AMI-P)

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Foreword

This Candidate Harmonized European Standard (Telecommunications series) has been produced by ETSI Technical Committee Electromagnetic compatibility and Radio spectrum Matters (ERM), and is now submitted for the Vote phase of the ETSI standards Two-step Approval Procedure.

The present document has been produced by ETSI in response to a mandate from the European Commission issued under the Council Directive 98/34/EC [4] (as amended) laying down a procedure for the provision of information in the field of technical standards and regulations.

The present document is intended to become a Harmonized Standard, the reference of which will be published in the Official Journal of the European Communities referencing the Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity ("the R&TTE Directive" [2]).

The present document is part 31 of a multi-part deliverable. Full details of the entire series can be found in 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

1 Scope

The present document together with 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 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 EN 301 489-1 [1], except for any special conditions included in the present document.

2 References

The following documents contain provisions which, through reference in this text, constitute provisions of the present document.

- References are either specific (identified by date of publication and/or edition number or version number) or non-specific.

- For a specific reference, subsequent revisions do not apply.
- For a non-specific reference, the latest version applies.

Referenced documents which are not found to be publicly available in the expected location might be found at http://docbox.etsi.org/Reference.

[1] ETSI EN 301 489-1: "Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements".

[2] Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity (R&TTE Directive).

[3] IEC 60417-DB-12M: "Graphical symbols for use on equipment - 12-month subscription to online database comprising all graphical symbols published in IEC 60417".

[4] Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations.

[5] ETSI EN 302 195-1 (V1.1.1): "Electromagnetic compatibility and Radio spectrum Matters (ERM); Radio equipment in the frequency range 9 kHz to 315 kHz for Ultra Low Power Active Medical Implants (ULP-AMI) and accessories; Part 1: Technical characteristics and test methods".

[6] ETSI EN 302 195-2 (V1.1.1): "Electromagnetic compatibility and Radio spectrum Matters (ERM); Radio equipment in the frequency range 9 kHz to 315 kHz for Ultra Low Power Active Medical Implants (ULP-AMI) and accessories; Part 2: Harmonized EN covering essential requirements of article 3.2 of the R&TTE Directive".

[7] CENELEC EN 60601-1-2: "Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests".

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

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

3 Definitions and abbreviations

3.1 Definitions

For the purposes of the present document, the terms and definitions given in EN 301 489-1 [1] and the following apply:

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 EN 301 489-31 is required to comply with the provisions of EN 301 489-31

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

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

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 Abbreviations

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

AIMD	Active Implantable Medical Device
AMI	Active Medical Implant
EMC	ElectroMagnetic Compatibility
EUT	Equipment Under Test
MICL	Medical Implant Communications Link
R&TTE	Radio and Telecommunications Terminal Equipment
ULP-AMI	Ultra Low Power-Active Medical Implant
ULP-AMI-P	Ultra Low Power-Active Medical Implant Peripheral device

4 Test conditions

For the purposes of the present document, the test conditions of 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.

4.1 General

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

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

4.2.1 Arrangements for test signals at the input of the transmitter

The provisions of the 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 output of the transmitter

The provisions of the 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 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.

4.2.2.2 ULP-AMI-P transmitters

The provisions of the 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 input of the receiver

The provisions of 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 the receiver

The provisions of 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 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 Exclusion bands

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.

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

The frequency 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.