
Elektromagnetna združljivost in zadeve v zvezi z radijskim spektrom (ERM) - 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

Electromagnetic compatibility and Radio spectrum Matters (ERM) - 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

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standard for radio equipment and services;
Part 35: Specific requirements for Low Power Active Medical
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Foreword

This Harmonized European Standard (EN) has been produced by ETSI Technical Committee Electromagnetic compatibility and Radio spectrum Matters (ERM).

The present document has been produced by ETSI in response to mandate 284 (M/284) [i.1] issued from the European Commission under Directive 98/34/EC [i.2] as amended by Directive 98/48/EC [i.8].

The title and reference to the present document are intended to be included in the publication in the Official Journal of the European Union of titles and references of Harmonized Standard under the Directive 1999/5/EC [i.3].

See article 5.1 of Directive 1999/5/EC [i.3] for information on presumption of conformity and Harmonised Standards or parts thereof the references of which have been published in the Official Journal of the European Union.

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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1 Scope

The present document together with 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 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 A.

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

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 <http://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.

2.1 Normative references

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

- [1] ETSI EN 301 489-1 (V1.9.2) (09-2011): "Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements".
- [2] CENELEC EN 61000-4-5:2006: "Electromagnetic compatibility (EMC) - Part 4-5: Testing and measurement techniques - Surge immunity test".
- [3] ETSI EN 301 559-1 (V1.1.2) (06-2012): "Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Low Power Active Medical Implants (LP-AMI) operating in the frequency range 2 483,5 MHz to 2 500 MHz; Part 1: Technical characteristics and test methods".
- [4] ETSI EN 301 559-2 (V1.1.2) (06-2012): "Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Low Power Active Medical Implants (LP-AMI) operating in the frequency range 2 483,5 MHz to 2 500 MHz; Part 2: Harmonized EN covering the essential requirements of article 3.2 of the R&TTE Directive".

2.2 Informative references

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] M/284: "Standardisation mandate to CEN, CENELEC and ETSI in the field of harmonised standards for the R&TTE Directive".
- [i.2] 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.
- [i.3] 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.
- [i.4] CENELEC EN 60601-1-2: "Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests".
- [i.5] CEPT/ERC/REC 70-03: "Relating to the use of Short Range Devices (SRD)".
- [i.6] 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.7] <http://niremf.ifac.cnr.it/>.
- [i.8] Directive 98/48/EC of the European Parliament and of the Council of 20 July 1998 amending Directive 98/34/EC laying down a procedure for the provision of information in the field of technical standards and regulations.

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3 Definitions and abbreviations

SIST EN 301 489-35 V1.1.2:2013

3.1 Definitions

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For the purposes of the present document, the terms and definitions given in EN 301 489-1 [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 following abbreviations 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
R&TTE	Radio and Telecommunications Terminal Equipment
RF	Radio Frequency
SRD	Short Range Devices

4 Test conditions

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

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.

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 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 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

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 (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 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 LP-AMI transmitters

For LP-AMI transmitters the test fixture described in annex B shall be used:

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

4.2.2.2 LP-AMI-P transmitters

The provisions of 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 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 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.