ETSI EN 301 489-35 V2.1.1 (2016-12)

**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;
Harmonised Standard covering the essential requirements
of article 3.1(b) of Directive 2014/53/EU**

Reference
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Contents

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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.6] 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 35 of a multi-part deliverable. Full details of the entire series can be found in ETSI EN 301 489-1 [1].

National transposition dates	
Date of adoption of this EN:	12 December 2016
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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 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 of 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 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 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 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] CENELEC EN 61000-4-5:2006: "Electromagnetic compatibility (EMC) - Part 4-5: Testing and measurement techniques - Surge immunity test".

[3] ETSI EN 301 559 (V2.1.1) (10-2016): "Short Range Devices (SRD); Low Power Active Medical Implants (LP-AMI) and associated Peripherals (LP-AMI-P) operating in the frequency range 2 483,5 MHz to 2 500 MHz; Harmonised Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU".

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.

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 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] 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.4] http://niremf.ifac.cnr.it/.

[i.5] Camelia Gabriel: "Compilation of the dielectric properties of body tissues at RF and Microwave Frequencies", (Physics Department, Kings College, London WC2R 2LS, UK.

[i.6] 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 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 301 559 [3], Directive 2014/53/EU [i.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 abbreviations given in ETSI EN 301 489-1 [1], ETSI EN 301 559 [3], Directive 2014/53/EU [i.1] and the following 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
RF	Radio Frequency
SRD	Short Range Devices

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 LP-AMI and associated Peripheral devices (LP-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.

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 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 (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 RF output of transmitters

4.2.2.0 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.

4.2.2.1 ULP-AMI transmitters

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

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

4.2.2.2 ULP-AMI-P transmitters

The provisions of the ETSI 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 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 4.2.4 shall apply with the following modification, if appropriate:

- if direct access to the receiver output of the LP-AMI and associated LP-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.

4.3 RF exclusion band of radio equipment

4.3.1 General

The emission measurement and immunity test exclusions are referred to as "exclusion bands" and are defined in the clauses 4.3.2 and 4.3.3 of the present document.

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 LP-AMIs and/or associated LP-AMI-Ps.

4.3.2 Exclusion band for receivers

The exclusion band for receivers (including receivers that are part of transceivers), defined in table 1, is determined as follows:

- for receivers capable of operating on 16 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 bands for the receiver part of LP-AMIs or LP-AMI-Ps

Receiver operating frequency f_o	Receiver exclusion bands
2 483,5 MHz to 2 500 MHz	f_o ± 20 MHz

4.3.3 Exclusion band for transmitters

For transmitters operating, or intended to operate, in a channelized arrangement in the 2 483,5 MHz to 2 500 MHz frequency band, the exclusion band is three times the maximum occupied bandwidth allowed for that service, centred around the operating frequency. For the 2 483,5 MHz to 2 500 MHz band, the maximum occupied bandwidth is 2 MHz. The actual occupied bandwidth is determined using the procedures in ETSI EN 301 559 [3] 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 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.

4.4 Narrow band responses of receivers or receivers which are part of transceivers

The provision of ETSI EN 301 489-1 [1], clause 4.4 shall apply.

4.5 Normal test modulation

The RF carrier shall be modulated with a test signal that produces specific selective messages or commands as stated by the manufacturer, representing a practical selection of usable selective messages/commands. The manufacturer shall declare the format of the modulation signal and any error detection and correction involved. Where transmitters do not have a modulation input port, the internal equipment modulation is used.

5 Performance assessment

5.1 General

The provision of ETSI EN 301 489-1 [1], clause 5.1 shall apply.

The manufacturer shall at the time of submission of the device(s) for test, supply the necessary general information as requested in ETSI EN 301 489-1 [1], clause 5.1. Additionally he shall supply the following product-related information:

- the class of the device selected by the manufacturer according to table 2 (see clause 6.1).

The performance assessment is dependent on whether the type of device is an ULP-AMI or an ULP-AMI-P.

For both types of devices the performance assessment is based on:

- the maintenance of function(s);
- the way an eventual loss of function(s) can be recovered;
- the unintentional behaviour of the EUT.

For both types of devices it shall be possible to assess the performance by monitoring the intended functions before, during and after the tests.

5.2 Equipment which can provide a continuous communication link

The provisions of ETSI EN 301 489-1 [1], clause 5.2 shall apply.

5.3 Equipment which does not provide a continuous communication link

The provisions of ETSI EN 301 489-1 [1], clause 5.3 shall apply.

5.4 Ancillary equipment

The provisions of ETSI EN 301 489-1 [1], clause 5.4 are not applicable.

5.5 Equipment classification

The provisions of ETSI EN 301 489-1 [1], clause 5.5 shall apply with the following modifications.

For the purpose of EMC performance assessment in the present document, the radio devices/equipment and/or associated ancillary devices/equipment shall be classified into one of the following types:

- ULP-AMI (implantable devices); or
- ULP-AMI-P (external peripheral devices used in conjunction with ULP-AMI).

Life supporting devices shall meet the criteria specified for this type of device.

Radio equipment declared as capable of being powered for intended use by the main battery of a vehicle shall additionally be considered as mobile equipment.

6 Performance criteria

6.1 Classification of LP-AMI and LP-AMI-P devices

The product family of Active Implantable Medical Devices (AIMD) is divided into three class of devices, each having its own set of minimum performance criteria. This classification is based upon the impact on persons and/or goods in case the equipment does not operate above the specified minimum performance level under EMC stress. In lieu of using these classification guidelines, the manufacturer of LP-AMI and LP-AMI-P devices may declare the classification of his devices. The test report shall note the classification of the device and whether it is based on the manufacturers' declaration or on table 2.

Table 2

Category of LP-AMI and LP-AMI-P devices	Risk assessment of receiver performance
1	Highly reliable communication media; e.g. serving human life inherent systems (may result in a physical risk to a person).
2	Medium reliable communication media; e.g. causing inconvenience to persons, which cannot simply be overcome by other means.
3	Standard reliable communication media; e.g. inconvenience to persons, which can simply be overcome by other means (e.g. manual).

6.2 General performance criteria

The performance criteria for the different categories of LP-AMI and LP-AMI-P devices (see table 2) in combination with the different equipment types (see clause 5.5) during and after immunity test are specified in this clause:

- performance criteria A for immunity tests with phenomena of a continuous nature;
- performance criteria B for immunity tests with phenomena of a transient nature;
- performance criteria for immunity tests with power interruptions exceeding a certain time are specified in clause 7.2.2, table 4.

The device shall meet the performance criteria as specified in the following clauses, for the appropriate categories of LP-AMI and LP-AMI-P devices.

6.3 Performance criteria and table

For all types of devices covered by the present document it shall be possible to assess the performance by monitoring the intended functions before, during and after the tests:

- the device under test can be assessed for performance by comparing, on an equal to or less than basis, the measured bit error rate with the bit error rate performance as specified by the manufacturer; or
- for devices under test that cannot be assessed using the above methods for assessment, the manufacturer shall specify the assessment method to be used.

Under the test conditions specified in the present document the device and/or system under test shall be able to provide the intended clinical benefit as specified by the manufacturer and remain safe for the user. The tested device may exhibit a degradation of performance (deviation from manufacturer's specifications) as detailed in table 3.

Table 3

Category 1 LP-AMI and LP-AMI-P devices		
Criteria	**During test**	**After test**
A	Operate as intended No loss of function No unintentional responses	Operate as intended The communication link shall be maintained No loss of function No degradation of performance No loss of stored data or user programmable functions
B	May be loss of function (one or more) No unintentional responses	Operate as intended The communication link shall have been maintained No loss of function(s) No degradation of performance No loss of stored data or user programmable functions
Category 2 LP-AMI and LP-AMI-P devices		
Criteria	**During test**	**After test**
A	Operate as intended No loss of function below manufacturers specification No unintentional responses	Operate as intended The communication link shall be maintained or recover No loss of function below manufacturers specifications No degradation of performance No loss of stored data or user programmable functions
B	May be loss of function (one or more) No unintentional responses	Operate as intended The communication link shall be maintained or recover No loss of function below manufacturers specifications No degradation of performance No loss of stored data or user programmable functions
Category 3 LP-AMI and LP-AMI-P devices		
Criteria	**During test**	**After test**
A and B	May be loss of function (one or more) No unintentional responses	Operate as specified by the manufacturer, the communication link may be lost, but shall be recoverable by user No degradation of performance Lost functions shall be self-recoverable or recoverable as specified by the manufacturer

The following degradations or failures are not allowed during any phase of testing of LP-AMI devices:

- component failures;
- changes in programmable parameters;
- reset to factory defaults (manufacturer's presets);
- change of intended operating mode;
- false alarms;
- cessation of any intended operation, even if accompanied by an alarm;
- initiation of any unintended operation, including unintended or uncontrolled motion, even if accompanied by an alarm;
- error of a displayed numerical value sufficiently large to affect diagnosis or treatment;
- failure of automatic diagnosis or treatment devices and/or systems to diagnose or treat, even if accompanied by an alarm.

In addition for LP-AMI-P devices the following degradations are not allowed:

- artefact or distortion in an image in which the artefact is indistinguishable from physiologically-produced signals or the distortion interferes with interpretation of physiologically-produced signals;
- noise on a waveform in which the noise is indistinguishable from physiologically-produced signals or the noise interferes with interpretation of physiologically-produced signals.

6.4 Performance criteria for continuous phenomena applied to transmitters

For the transmitter part of LP-AMI and LP-AMI-P devices the performance criteria A of the applicable category as given in clause 6.3 shall apply.

For the transmitter part of LP-AMI and LP-AMI-P devices which require a communication link to be maintained during the test, it shall be verified that the link is maintained during each individual exposure in the test sequence, by appropriate means supplied by the manufacturer.

The test shall be repeated with the EUT in standby mode to ensure that no unintended transmission occurs as a result of transmitter operation.

6.5 Performance criteria for transient phenomena applied to transmitters

For the transmitter part of LP-AMI and LP-AMI-P devices the performance criteria B of the applicable category as given in clause 6.3 shall apply, except for power interruptions exceeding a certain time the performance criteria deviations are specified in clause 7.2.2.

For the transmitter part of LP-AMI and LP-AMI-P devices which require a communication link to be maintained during the test, it shall be verified that the link is maintained during each individual exposure in the test sequence, by appropriate means supplied by the manufacturer.

The test shall be repeated with the EUT in standby mode to ensure that no unintended transmission occurs as a result of transmitter operation.

6.6 Performance criteria for continuous phenomena applied to receivers

For the receiver part of LP-AMI and LP-AMI-P devices, the performance criteria A of the applicable category as given in clause 6.3 shall apply.

For the receiver part of LP-AMI and LP-AMI-P devices which require a communication link to be maintained during the test, it shall be verified that the communication link is maintained during each individual exposure in the test sequence, by appropriate means supplied by the manufacturer.

Where the EUT is a transceiver, under no circumstances shall the transmitter operate unintentionally during the test.

6.7 Performance criteria for transient phenomena applied to receivers

For the receiver part of LP-AMI and LP-AMI-P devices, the performance criteria B of the applicable category as given in clause 6.3 shall apply, except for power interruptions exceeding a certain time where the performance criteria are as specified in clause 7.2.2.

For both, the receiver part of LP-AMI and LP-AMI-P devices which require a communication link to be maintained during the test, it shall be verified that the communication link is maintained during each individual exposure in the test sequence, by appropriate means supplied by the manufacturer.

Where the EUT is a transceiver, under no circumstances shall the transmitter operate unintentionally during the test.

7 Applicability overview

7.1 EMC emission

7.1.1 General

Table 1 of ETSI EN 301 489-1 [1], contains the applicability of EMC emission measurements to the relevant ports of radio and/or associated ancillary equipment.

Equipment covered by the present document is intended to be used to provide diagnostic information to medical professionals and/or deliver therapeutic benefits to patients in a medical/hospital environment. This equipment typically utilizes a wireless communication link for the purpose of programming (telecommand) and retrieving data (telemetry) from various implanted devices such as pacemakers, defibrillators, nerve stimulators, drug pumps, and others. For devices of the type covered by the present document, it is reasonable that the EMC performance levels of each section (medical and communications) should correspond to the same EMC values. Studies have shown that medical environments have higher levels of disturbances that impact on the performance of this equipment than are normally associated with a non-medical environment. The performance levels specified for equipment covered by the present document reflect the expected environmental disturbances associated with medical facilities, accordingly.

7.1.2 Special conditions

The following special conditions relate to the emission test methods used in the ETSI EN 301 489-1 [1], clause 8.

The emission measurements applicable to the antenna or enclosure port of LP-AMI and LP-AMI-P devices are specified in the harmonised product standard ETSI EN 301 559 [3].

7.2 Immunity

7.2.1 General

Table 2 of ETSI EN 301 489-1 [1], contains the applicability of EMC immunity tests to the relevant ports of radio and/or associated ancillary equipment. Arrangements for test signals shall be as specified in clause 4.2 of the present document.

Equipment covered by the present document is intended to be used in both, medical and residential areas and will have both life supporting and non-life supporting applications. Accordingly, the immunity test levels and conditions specified in the present document are based on the levels associated with the above applications.

Further, the immunity of these systems to radiated ambient fields is subject to their usage condition and, for example, implanted equipment should be tested using an appropriate test fixture as described in annex C.

For some applications, it may be appropriate to devise other types of specialized test fixtures. Where such a specialized test fixture is used, details of the fixture shall be provided by the manufacturer and recorded in the subsequent test documentation.

For LP-AMI devices, guidance is given as to applicability of the test in table 4.

7.2.2 Special conditions

The following special conditions set out in table 4 relate to the immunity test methods and performance criteria used in ETSI EN 301 489-1 [1], clause 9.

Table 4: Special conditions for EMC immunity tests

<table>
<tr><th colspan="2">Reference to clauses in ETSI EN 301 489-1 [1]</th><th>Special product-related conditions, additional to or modifying the test configuration in ETSI EN 301 489-1 [1], clause 9</th></tr>
<tr><td>9.2.2</td><td>Test method; Radio frequency electromagnetic field</td><td>The following conditions apply:
- for non-life supporting equipment, the test level shall be 3 V/m (measured unmodulated);
- for life supporting equipment, the test level shall be 10 V/m (measured unmodulated);
- for equipment and/or systems intended to monitor or measure a physiological parameter, the physiological simulation frequency restrictions specified below shall apply. When the modulation frequency of 2 Hz is used, then it is not necessary to additionally test with a modulation frequency of 1 kHz;
- for equipment and/or system intended to control a physiological parameter, the operating frequency restrictions specified below shall apply.
<table>
<tr><th>Intended use</th><th>Modulation frequency</th><th>Physiological simulation frequency and Operating frequency of the simulation circuit</th></tr>
<tr><td>To control, monitor or measure a physiological parameter</td><td>2 Hz</td><td>Less than 1 Hz or greater than 3 Hz</td></tr>
<tr><td>All other</td><td>1 kHz</td><td>Not applicable</td></tr>
</table>
The test shall be performed over the frequency range 80 MHz to 6 000 MHz. The appropriate exclusion band as defined in clause 4.3 and sequence may be excluded from this requirement.</td></tr>
<tr><td>9.3.2</td><td>Test method; Electrostatic discharge</td><td>The test severity level for contact discharge shall be ±6 kV and for air discharge ±8 kV. This test is only applicable to LP-AMI-P devices.</td></tr>
</table>

<table>
<tr><th colspan="2">Reference to clauses in ETSI EN 301 489-1 [1]</th><th>Special product-related conditions, additional to or modifying the test configuration in ETSI EN 301 489-1 [1], clause 9</th></tr>
<tr><td>9.4.2</td><td>Test method; Fast transient, Common mode</td><td>The following conditions apply:
- the test level for signal ports, telecommunication ports, and control ports shall be ±1 kV open circuit voltage;
- signal and interconnecting cables of less than 3 m in length and patient-coupled cables are not tested;
- the test level for AC mains and DC power input ports shall be ±2 kV open circuit voltage.</td></tr>
<tr><td>9.5</td><td>Radio frequency, Common mode</td><td>This test is applicable to devices having a combined tip-to-tip lead length or dimension of 1 m or greater. In general, most implanted devices are exempt from testing according to the requirements of this clause due to their overall length falling under 1 m. In the case of implanted equipment which shall be tested, it is appropriate to reduce the immunity test levels specified in this clause by a factor, in dB, equivalent to the attenuation (in dB) of external signals due to tissue absorption for the frequency of interest under the conditions the implant is intended to be used. For these situations, the test report shall state the reduction in dB and the justification for the reduction at the measurement frequency. In the event an implanted device shall be tested for radio frequency common mode ambient levels, the manufacturer may specify an alternate technique for determining compliance. The alternate technique shall be agreed to by the test laboratory such as direct coupling of a signal adjusted in level to account for tissue attenuation that would occur under normal operating conditions.</td></tr>
<tr><td>9.5.2</td><td>Test Method; Radio frequency, Common mode</td><td>The following conditions apply:
- for non-life supporting equipment, the test level shall be 3 V rms (measured unmodulated);
- for life supporting equipment, the test level shall be 10 V rms (measured unmodulated) for all frequencies in the ISM bands, and 3 V rms in non-ISM bands;
ISM bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz;
- for equipment and/or systems intended to monitor or measure a physiological parameter, the physiological simulation frequency restrictions specified below shall apply. When the modulation frequency of 2 Hz is used, then it is not necessary to additionally test with a modulation frequency of 1 kHz;
- for equipment and/or system intended to control a physiological parameter, the operating frequency restrictions specified below shall apply.
<table><tr><th>Intended use</th><th>Modulation frequency</th><th>Physiological simulation frequency and Operating frequency of the simulation circuit</th></tr><tr><td>To control, monitor or measure a physiological parameter</td><td>2 Hz</td><td>Less than 1 Hz or greater than 3 Hz</td></tr><tr><td>All other</td><td>1 kHz</td><td>Not applicable</td></tr></table>The test shall be performed over the frequency range 150 kHz to 80 MHz. The appropriate exclusion band as defined in clause 4.3 and sequence may be excluded from this requirement.</td></tr>
<tr><td>9.7</td><td>Voltage dips and interruptions</td><td>This test only applies to LP-AMI-P devices.</td></tr>
</table>

<table>
<tr><th colspan="2">Reference to clauses in ETSI EN 301 489-1 [1]</th><th>Special product-related conditions, additional to or modifying the test configuration in ETSI EN 301 489-1 [1], clause 9</th></tr>
<tr><td>9.7.2</td><td>Test method; Voltage dips and interruptions</td><td>The tests levels shall be as indicated in the following tables.

Immunity test level for voltage dips

<table>
<tr><th>Voltage test level (%Ut)</th><th>Voltage dip (%Ut)</th><th>Duration (Periods)</th></tr>
<tr><td>< 5
40
70</td><td>> 95
60
30</td><td>0,5
5
25</td></tr>
<tr><td colspan="3">NOTE: Ut is the AC mains voltage prior to application of the test signal.</td></tr>
</table>

Immunity test level for voltage interruptions

<table>
<tr><th>Voltage test level (%Ut)</th><th>Voltage dip (%Ut)</th><th>Duration (Seconds)</th></tr>
<tr><td>< 5</td><td>> 95</td><td>5</td></tr>
<tr><td colspan="3">NOTE: Ut is the AC mains voltage prior to application of the test signal.</td></tr>
</table>
</td></tr>
<tr><td>9.7.3</td><td>Performance criteria</td><td>For a voltage dip corresponding to a reduction of the supply voltage of 30 % for 25 periods the following performance criteria apply:
- for transmitters the performance criteria for transient phenomena for transmitter shall apply (see clause 6);
- for receivers the performance criteria for transient phenomena for receiver shall apply (see clause 6);
- for ancillary equipment the pass/failure criteria supplied by the manufacturer (see clause 6.4) shall apply, unless the ancillary equipment is tested in connection with a receiver or transmitter in which case the corresponding performance criteria for transmitters/receivers above shall apply.
For a voltage dip corresponding to a reduction of the supply voltage of 60 % for 5 periods, or a 95 % reduction for a 0,5 period and/or a voltage interruption corresponding to a reduction of the supply voltage of greater than 95 % for 5 000 ms the following performance criteria apply:
- in the case where the equipment is fitted with or connected to a battery back-up, the performance criteria for transient phenomena for transmitters or for receivers shall apply (see clause 6);
- in the case where the equipment is powered solely from the AC mains supply (without the use of a parallel battery back-up) volatile user data may have been lost and if applicable the communication link need not to be maintained and lost functions should be recoverable by user or operator;
- no unintentional responses shall occur at the end of the test;
- the equipment shall be safe in all cases for its intended application and use;
- in the event of loss of function(s) or in the event of loss of user stored data, this fact shall be recorded in the test report;
- for ancillary equipment the pass/failure criteria supplied by the manufacturer (see clause 6.4) shall apply, unless the ancillary equipment is tested in connection with a receiver or transmitter in which case the corresponding performance criteria above shall apply.</td></tr>
<tr><td>9.8</td><td>Surges</td><td>These tests only apply to LP-AMI-P devices.</td></tr>
</table>

Reference to clauses in ETSI EN 301 489-1 [1]	Special product-related conditions, additional to or modifying the test configuration in ETSI EN 301 489-1 [1], clause 9
9.8.2 Test Methods; Surges	The test level for AC mains power input ports shall be 2 kV line to ground and 1 kV line to line, with the output impedance of the surge generator as given in CENELEC EN 61000-4-5 [2]. The test generator shall provide the 1,2/50 µs pulse as defined in CENELEC EN 61000-4-5 [2]. Five surges at each voltage level and polarity shall be applied to each power line at each of the following AC voltage waveform angles: 0° and/or 180°, 90°, and 270°. Equipment and/or systems without any grounded interconnections are exempted from line(s) to ground testing. For equipment and/or systems that have, for power input, multiple voltage settings or auto-ranging voltage capability, the test shall be performed at the minimum and maximum rated input voltages.

Annex A (normative): Relationship between the present document and the essential requirements of Directive 2014/53/EU

The present document has been prepared under the Commission's standardisation request C(2015) 5376 final [i.6] 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.

Table A.1: Relationship between the present document and the essential requirements of Directive 2014/53/EU

Harmonised Standard ETSI EN 301 489-35				
Requirement			Requirement Conditionality	
No	**Description**	**Reference: Clause No**	**U/C**	**Condition**
1	Enclosure of ancillary equipment measured on a stand alone basis	8.2 of ETSI EN 301 489-1 [1]	U	
2	DC power input/output ports	8.3 of ETSI EN 301 489-1 [1]	C	Only where equipment has DC power input and/or output ports with a cable length greater than 3 m or from a vehicle power supply
3	AC mains power input/output ports	8.4 of ETSI EN 301 489-1 [1]	C	Only where equipment has AC mains power input and/or output ports
4	Harmonic current emission (AC mains input port)	8.5 of ETSI EN 301 489-1 [1]	C	Only where equipment has AC mains power input ports
5	Voltage fluctuations and flicker (AC mains input ports)	8.6 of ETSI EN 301 489-1 [1]	C	Only where equipment has AC mains power input ports
6	Wired network ports	8.7 of ETSI EN 301 489-1 [1]	C	Only where equipment has wired network ports
7	Radio frequency electromagnetic field (80 MHz to 6 000 MHz)	7.2.2	U	
8	Electrostatic discharge	7.2.2	C	Only LP-AMI-P equipment
9	Fast transients common mode	7.2.2	U	
10	Radio frequency common mode	7.2.2	C	Only devices having a combined tip-to-tip lead length or dimension of 1 m or greater
11	Transients and surges in the vehicular environment	9.6 of ETSI EN 301 489-1 [1]	C	Only where equipment is connected to vehicle power supply
12	Voltage dips and interruptions	7.2.2	C	Only LP-AMI-P equipment
13	Surges, line to line and line to ground	7.2.2	C	Only LP-AMI-P equipment

Key to columns:

Requirement:

No A unique identifier for one row of the table which may be used to identify a requirement.

Description A textual reference to the requirement.

Clause Number Identification of clause(s) defining the requirement in the present document unless another document is referenced explicitly.

Requirement Conditionality:

U/C Indicates whether the requirement shall be unconditionally applicable (U) or is conditional upon the manufacturer's claimed functionality of the equipment (C).

Condition Explains the conditions when the requirement shall or shall not be applicable for a requirement which is classified "conditional".

Presumption of conformity stays valid only as long as a reference to the present document is maintained in the list published in the Official Journal of the European Union. Users of the present document should consult frequently the latest list published in the Official Journal of the European Union.

Other Union legislation may be applicable to the product(s) falling within the scope of the present document.

Annex B (normative): Definitions of types of LP-AMI and LP-AMI-P devices in the scope of the present document

B.1 LP-AMI and LP-AMI-P devices intended for operation in the frequency range 2 483,5 MHz to 2 500 MHz

The present document applies to LP-AMI and LP-AMI-P devices with RF power levels ranging up to 10 dBm e.i.r.p. and intended for operation in the frequency range 2 483,5 MHz to 2 500 MHz in accordance with the provisions Commission Decision 2006/771/EC on harmonisation of the radio spectrum for use by short-range devices [i.3], as amended by subsequent Commission Decision consistent with annex 12, band (a), to CEPT/ERC/REC 70-03 [i.2]. Definitions of such LP-AMI and LP-AMI-P radio equipment are found in the following functional radio standards:

- ETSI EN 301 559 [3].

Annex C (normative): Test fixture for LP-AMI devices (Simulated man)

Equipment intended to be implanted in a human body shall be tested in a simulated man constructed as follows in order to simulate operation of the implant under actual operation conditions as shown in figure C.1.

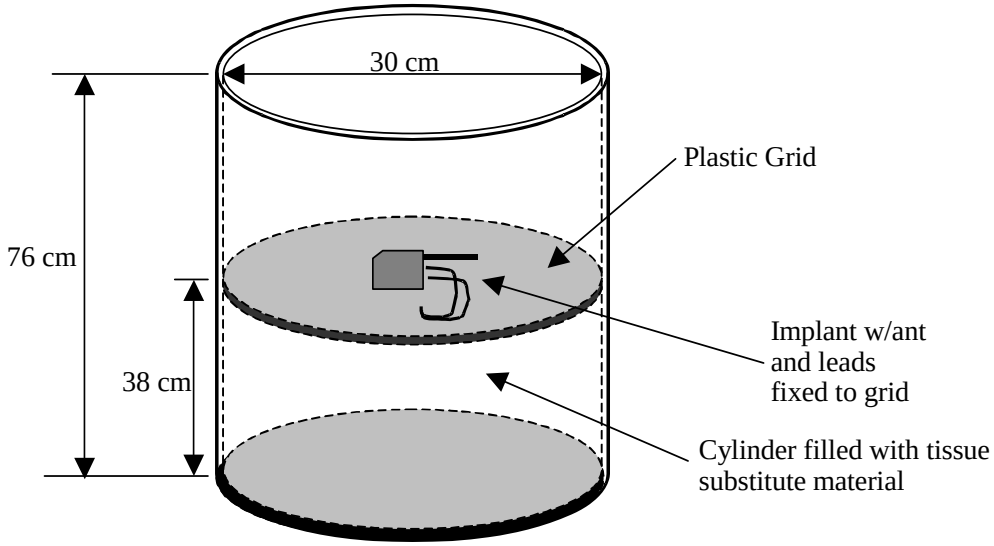

Figure C.1

An appropriate simulator for testing medical implant transmitters consists of a cylindrical Plexiglas container with a size of 30 cm ± 0,5 cm by 76 cm ± 0,5 cm with a sidewall thickness of 0,635 cm ± 0,05 cm. It shall be completely filled with a material that is sufficiently fluid that it will flow around the implant without any voids. The dielectric and conductivity properties of this material shall match the dielectric and conductivity properties of human muscle tissue at the centre frequency of operation or, if desired, at the measurement frequency.

NOTE 1: Saline solutions do not meet the dielectric and conductivity requirements for use as a substitute for human tissue.

All emissions measurements will be made using the above specification with the tissue substitute material at a nominal temperature between 22 °C and 38 °C.

NOTE 2: This temperature will facilitate testing because it is typical of ambient conditions at many test sites.

A mounting grid for the implant inside the container shall be provided that permits the radiating element or elements of the implant to be positioned vertically and horizontally. The grid should also support any additional implant leads associated with the therapeutic function of the implant in a fixed repeatable manner such that they do not influence the measurement.

The implant antenna shall be mounted no further than 6 cm ± 0,5 cm from the sidewall and centred vertically within the container. When switching from vertical to horizontal positioning, it may be necessary to reposition the implant antenna to maintain a separation of 6 cm ± 0,5 cm from the sidewall of the test fixture along its length. Implant leads shall be coiled and placed away from the implant antenna while maintaining a nominal 6 cm from the sidewall.

The above fixture shall be placed on a turntable such that the implant transmitter will be located at a nominal 1,5 m height above ground and at a 3 m distance from the measurement antenna. Radiated emissions measurements shall then be performed to insure compliance with the applicable technical specifications.

Tissue parameters for various frequencies may be obtained from the following website: http://niremf.ifac.cnr.it/ [i.4], maintained by the Italian National Research Council, Institute for Applied Physics. Other sources can be used provided they are based on the 4-Cole-Cole equations developed by Gabriel [i.5]. In most instances it may be advisable to make preliminary measurements to identify potential problem frequencies and use tissue material corresponding to human tissue characteristics at that frequency. In severe cases, tissue substitute material may be used that has conductivity and dielectric parameters that correspond to the human tissue at a problem frequency.

History

Document history		
V1.1.2	October 2013	Publication
V2.1.0	September 2016	EN Approval Procedure AP 20161212: 2016-09-13 to 2016-12-12
V2.1.1	December 2016	Publication