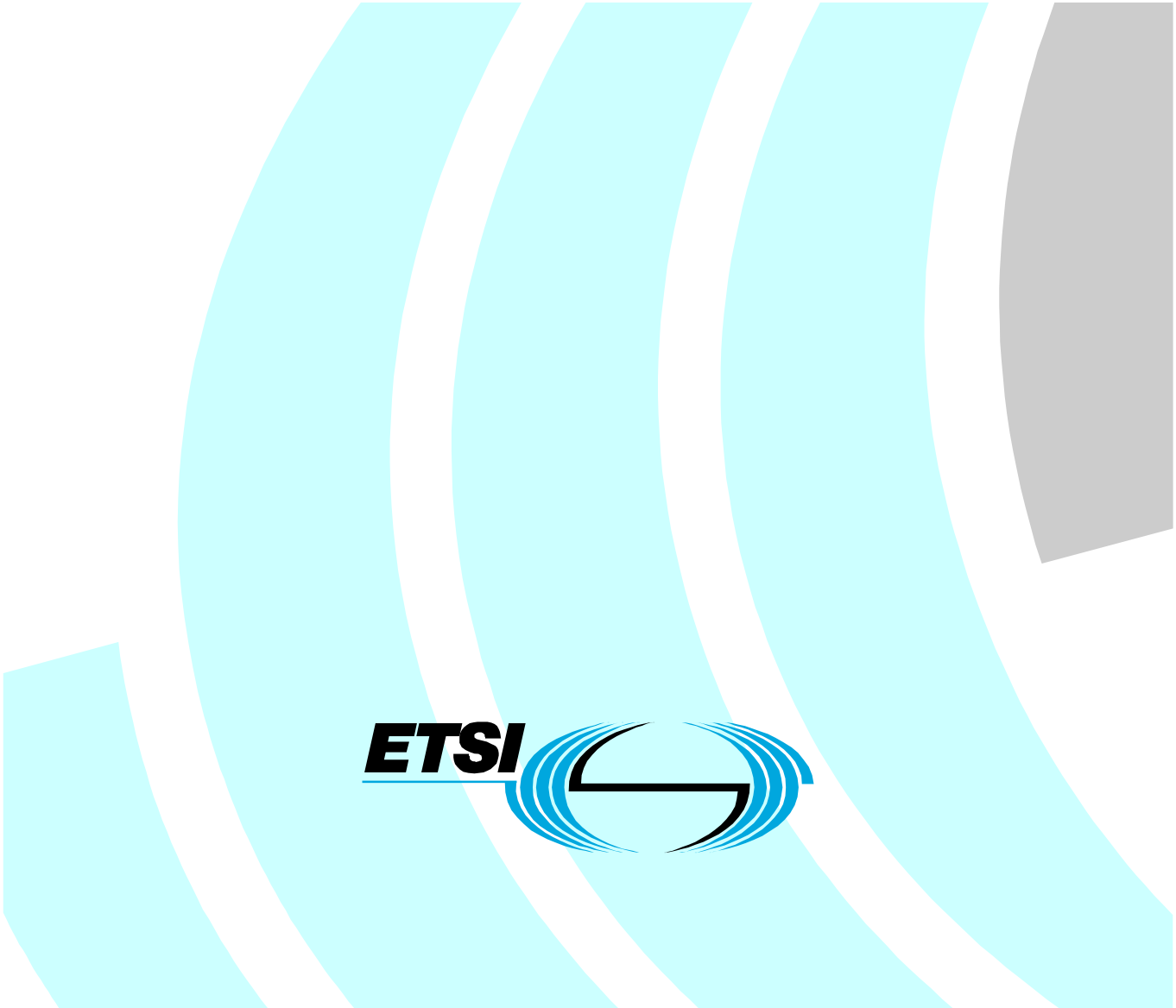
Final draft ETSI EN 301 489-31 V1.1.1 (2005-06)

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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Contents

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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.

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 only one single frequency 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 ULP-AMI or ULP-AMI-Ps

Receiver operating frequency f_o	**Receiver exclusion bands**		
	Receiver Class 1	Receiver Class 2	Receiver Class 3
9 kHz to 315 kHz	$f_o \pm 200$ kHz (see note)	$f_o \pm 315$ kHz (see note)	$f_o \pm$ 315 kHz (see note)
NOTE: Measurements shall not be carried out below 150 kHz.			

4.3.2 Exclusion band for transmitters

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. 315 kHz or less) centred on 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

The provision of 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 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 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 communications link

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

5.3 Equipment which does not provide a continuous communications link

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

5.4 Ancillary equipment

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

5.5 Equipment classification

The provisions of 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 ULP-AMI and ULP-AMI-P

The product family of Active Implantable Medical Devices (AIMD) is divided into three sub-classes 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 ULP-AMI/ULP-AMI-P may declare the classification of his devices. The test report shall note the classification of the device and whether it is based on the manufacturer's declaration or on table 2.

Table 2

ULP-AMI or ULP-AMI-P Receiver classification	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).
NOTE: Receiver classes defined in this table are identical to those defined in table 1.	

6.2 General performance criteria

The performance criteria for the different sub-classes of ULP-AMI/ULP-AMI-P (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 sub-class of ULP-AMI/ULP-AMI-P.

6.3 Performance criteria and table

For both types of devices 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

Class 1 ULP-AMI/ULP-AMI-P		
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
Class 2 ULP-AMI/ULP-AMI-P		
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
Class 3 ULP-AMI/ULP-AMI-P		
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 the user No degradation of performance Lost functions shall be self-recoverable or recoverable as specified by the manufacturer

6.4 Performance criteria for continuous phenomena applied to transmitters

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

For the transmitter part of ULP-AMIs and ULP-AMI-Ps that 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 ULP-AMI and ULP-AMI-P the performance criteria B of the applicable class 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 ULP-AMIs and ULP-AMI-Ps that 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 ULP-AMI and ULP-AMI-P, the performance criteria A of the applicable class as given in clause 6.3 shall apply.

For the receiver part of ULP-AMIs and ULP-AMI-Ps that 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

Fort he receiver part of ULP-AMI and ULP-AMI-P, the performance criteria B of the applicable class 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 the receiver part of ULP-AMIs and ULP-AMI-Ps that 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 Emission

7.1.1 General

EN 301 489-1 [1], table 2 contains the applicability of EMC emission measurements to the relevant ports of radio and/or associated ancillary equipment.

7.1.2 Special conditions

No special conditions applicable.

7.2 Immunity

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 B.

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.

It is intended that the performance criteria and immunity requirements in the present document and in EN 60601-1-2 [7] be essentially equivalent. For ULP-AMI and ULP-AMI-P, guidance is given as to applicability of the test in table 4.

7.2.1 General

EN 301 489-1 [1], table 3 contains the applicability of EMC immunity tests to the relevant ports of radio and/or associated ancillary equipment.

When testing individual units or a combination of unit see recommendation in annex C.

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 EN 301 489-1 [1], clause 9.

Table 4: Special conditions for EMC immunity tests

<table>
<tr><th>Reference to clauses in EN 301 489-1 [1]</th><th>Special product-related conditions, additional to or modifying the test configuration in EN 301 489-1 [1], clause 9</th></tr>
<tr><td>9.2.2 Test method; Radio frequency electromagnetic field</td><td>The following conditions apply:
- for non-life supporting communications link, the test level shall be 3 V/m (measured unmodulated);
- for life supporting communications link, 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 2 500 MHz. For some type of equipment the appropriate exclusion band as defined in clauses 4.3, 4.3.1 and 4.3.2 may be excluded from this requirement as declared by the manufacturer; this shall be recorded in the test report.</td></tr>
<tr><td>9.3.2 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 ULP-AMI-P devices. If the equipment or system is labelled with the IEC 60417-5134 [3] symbol or equivalent text, adjacent to a connector, that connector is exempt from this testing.</td></tr>
<tr><td>9.4.2 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>
</table>

<table>
<tr><th>Reference to clauses in EN 301 489-1 [1]</th><th>Special product-related conditions, additional to or modifying the test configuration in EN 301 489-1 [1], clause 9</th></tr>
<tr><td>9.5 Radio frequency, Common mode</td><td>This test is applicable to devices having a combined length or dimension of 2,5 meters 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 2,5 meters. In the case of implanted equipment which must 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 absorption (see torso simulator annex B) 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 .
The manufacturer may specify the RF coupling technique for determining compliance. The alternative technique must be agreed by the test laboratory e.g. direct coupling of a signal adjusted in level to account for tissue attenuation that would occur under normal operating conditions.
This choice shall be recorded in the test report.</td></tr>
<tr><td>9.5.2 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. For some type of equipment the appropriate exclusion band as defined in clauses 4.3, 4.3.1 and 4.3.2 may be excluded from this requirement as declared by the manufacturer; this shall be recorded in the test report.</td></tr>
</table>

<table>
<tr><th>Reference to clauses in EN 301 489-1 [1]</th><th>Special product-related conditions, additional to or modifying the test configuration in EN 301 489-1 [1], clause 9</th></tr>
<tr><td>9.7 Voltage dips and interruptions</td><td>This test only applies to ULP-AMI-P.</td></tr>
<tr><td>9.7.2 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 colspan="3">Voltage test level</th></tr>
<tr><th>%Ut
In periods</th><th>Duration</th><th>%Ut Voltage dip</th></tr>
<tr><td>< 5</td><td>> 95</td><td>0,5</td></tr>
<tr><td>40</td><td>60</td><td>5</td></tr>
<tr><td>70</td><td>30</td><td>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 colspan="3">Voltage test level</th></tr>
<tr><th>%Ut
In seconds</th><th>Duration</th><th>%Ut Voltage dip</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 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 must 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 Surges</td><td>These tests only apply to ULP-AMI-P.</td></tr>
<tr><td>9.8.2 Test Methods; Surges</td><td>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 EN 61000-4-5 [9].
The test generator shall provide the 1,2/50 µs pulse as defined in EN 61000-4-5 [9].
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.</td></tr>
</table>

Annex A (normative): Definitions of types of ULP-AMI and ULP-AMI-P in the scope of the present document

A.1 ULP-AMI and ULP-AMI-P intended for operation in the frequency range 9 kHz to 315 kHz

The present document applies to ULP-AMI and ULP-AMI-P with field strength levels ranging up to 30 dBµA/m at 10 meters and intended for operation in the frequency range 9 kHz to 315 kHz in accordance with the provisions of annex 12, band (b), to ERC/REC 70-03 [8]. Applications include but are not limited to pacemakers, defibrillators, nerve stimulators, insulin pumps, etc. Definitions pertaining to this radio equipment are found in the following functional radio standards:

- ETSI EN 302 195-1 [5] (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 and Accessories; Part 1: Technical characteristics and test methods".

- ETSI EN 302 195-2 [6] (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 and Accessories; Part 2: Harmonized EN covering essential requirements of article 3.2 of the R&TTE Directive".

Annex B (informative): Test fixture for ULP-AMI (Simulated man)

Equipment intended to be implanted in a human body for purposes of the present document should be tested in a simulated man constructed as follows in order to simulate operation of the implant under actual operating conditions as shown in figure B.1.

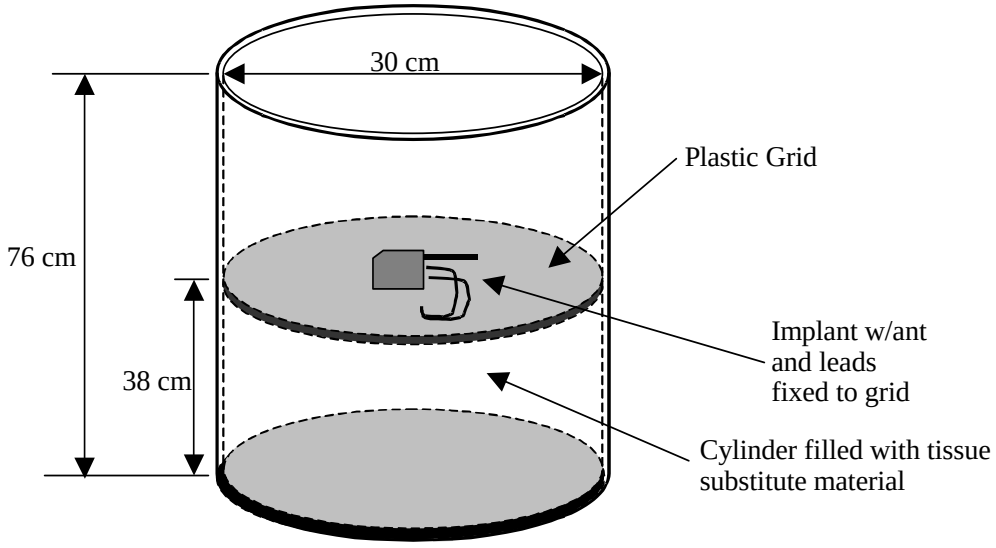

Figure B.1

A torso 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 should match the dielectric and conductivity properties of human muscle tissue at the centre frequency of operation or, if desired, at the measurement frequency. The saline solution specified below may be used for this purpose; however, it typically will not match these properties.

All radiated EMC measurements will be made using the above torso simulator with the tissue substitute material at a nominal temperature between 22°C and 38°C.

NOTE 1: This temperature will facilitate testing because it is representative of ambient conditions at many test sites.

A mounting fixture 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 fixture 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.

NOTE 2: In this frequency range, implant antennas are normally enclosed with the case of the implant.

For testing purposes the side of the implant case that is in closest proximity to the internal antenna shall be mounted in a vertical plane no further than 6 cm ± 0,5 cm from the sidewall of the container and centred vertically within the container. When switching from vertical to horizontal positioning, the implant case shall be mounted as above except the side of the case shall be mounted in a horizontal plane. In this case it may be necessary to reposition the implant (see note 3) to maintain a separation as above no greater than 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.

NOTE 3: "Clarified that antenna in this case is the implant antenna."

The above fixture shall be placed on a turntable such that the implant transmitter is located at a nominal 1,5-m above ground and at a 3-m or 10-m distance from the measurement antenna.

Radiated EMC measurements shall then be performed to ensure compliance with the applicable technical specifications. In situations where the implant case that is in closest proximity to the internal antenna is unknown, the implant position will be investigated to determine the position producing maximum emissions. Data shall be recorded for this position to determine conformance with the applicable limit.

Implants that are designed to communicate with an external device may require the presence of the external device in order to transmit. Manufacturers should note that it is desirable if possible to activate normal implant transmitter function via a technique that does not require an external accessory device such as a programmer to be used.

Tissue parameters for various frequencies may be obtained from the following website: http://niremf.ifac.cnr.it/docs/DIELECTRIC/AppendixD2.html#D08, 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 (see bibliography). A saline solution recognized by the medical industry as a tissue medium may be used if desired by the manufacturer. As guidance, a saline solution producing a 375 Ohm-cm resistivity using a standard test cell meets this requirement".

Annex C (informative): Simultaneous testing of ULP-AMI/ULP-AMI-P and parts covered by AIMD

If it is desired to conduct simultaneous testing of ULP-AMI or ULP-AMI-P and other parts of these device covered by the AIMD, the following degradations that are not allowed in equipment performance must be respected:

- 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;
- 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.

Annex D (informative): The EN title in the official languages

Language	EN title
Czech	Elektromagnetická kompatibilita a rádiové spektrum (ERM) – Norma pro elektromagnetickou kompatibilitu (EMC) rádiových zařízení a služeb – Část 31: Specifické podmínky pro zařízení v pásmu 9 kHz až 315 kHz pro aktivní lékařské implantáty velmi nízkého výkonu (ULP-AMI) a související periferní zařízení (ULP-AMI-P)
Danish	
Dutch	
English	
Estonian	Elektromagnetilise ühilduvuse ja raadiospektri küsimused (ERM); Raadioseadmete ja raadiosideteenistuste elektromagnetilise ühilduvuse (EMC) standard; Osa 31: Eritingimused raadiosagedusalas 9 kHz kuni 315 kHz töötavatele väga väikese võimsusega aktiivsetele meditsiinililistele implantaadidele (ULP-AMI) ja nende lisatarvikutele (ULP-AMI-P)
Finnish	Sähkömagneettinen yhteensopivuus ja radiospektriasiat (ERM); Sähkömagneettinen yhteensopivuusstandardi (EMC) radiolaitteille ja -järjestelmille; Osa 31: Erityisehdot 9 - 315 kHz:n taajuusalueella toimiville radiolaitteille, jotka on tarkoitettu käytettäviksi erittäin pienitehoisiin aktiivisiin lääketieteellisiin istutteisiin (ULP-AMI) ja niiden oheislaitteisiin (ULP-AMI-P)
French	
German	
Greek	
Hungarian	
Icelandic	
Italian	
Latvian	
Lithuanian	
Maltese	
Polish	Kompatybilność Elektromagnetyczna i Zagadnienia Widma Radiowego (ERM) - Norma kompatybilności elektromagnetycznej (EMC) dotycząca urządzeń i systemów radiowych - Część 31: Wymagania szczegółowe dla urządzeń aktywnych implantów medycznych o bardzo małej mocy (ULP-AMI) pracujących w zakresie od 9 kHz do 315 kHz i związanych z nimi urządzeniami peryferyjnymi
Portuguese	
Slovak	Elektromagnetická kompatibilita a záležitosti rádiového spektra (ERM). Elektromagnetická kompatibilita (EMC), norma na rádiové zariadenia a služby. Časť 31: Osobitné podmienky na zariadenia v pásme od 9 kHz do 315 kHz pre aktívne zdravotnícke implantáty s ultranízkym výkonom (ULP-AMI) a súvisiace periférne zariadenia (ULP-AMI-P)
Slovenian	Elektromagnetna združljivost (EMC) in zadeve v zvezi z radijskim spektrom (ERM) - Standard elektromagnetne združljivosti (EMC) za radijsko opremo in storitve - 31. del: Posebni pogoji za opremo za aktivne medicinske vsadke ultra majhnih moči (ULP-AMI) in pripadajočih perifernih naprav (ULP-AMI-P), ki delujejo v frekvenčnem pasu od 9 kHz do 315 kHz.
Spanish	
Swedish	

Annex E (informative): Bibliography

Camelia Gabriel: "Compilation of the dielectric properties of body tissues at RF and Microwave Frequencies", appendix B1 and B2 (Physics Department, Kings College, London WC2R 2LS, UK).

History

Document history			
V1.1.1	November 2004	Public Enquiry	PE 20050325: 2004-11-24 to 2005-03-25
V1.1.1	June 2005	Vote	V 20050826: 2005-06-27 to 2005-08-26