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Harmonized European Standard (Telecommunications series)

**Electromagnetic compatibility
and Radio spectrum Matters (ERM);
ElectroMagnetic Compatibility (EMC)
standard for radio equipment operating
in the 401 MHz to 402 MHz
and 405 MHz to 406 MHz bands;
Part 29: Requirements for
Medical Data Service Devices (MEDS)**



Reference

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ETSI

650 Route des Lucioles
F-06921 Sophia Antipolis Cedex - FRANCE

Tel.: +33 4 92 94 42 00 Fax: +33 4 93 65 47 16

Siret N° 348 623 562 00017 - NAF 742 C
Association à but non lucratif enregistrée à la
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Foreword

This 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 Public Enquiry 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 [3] (as amended) laying down a procedure for the provision of information in the field of technical standards and regulation.

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 29 of a multi-part deliverable. Full details of the entire series can be found in part 1 [1].

Proposed national transposition dates	
Date of latest announcement of this EN (doa):	3 months after ETSI publication
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Date of withdrawal of any conflicting National Standard (dow):	36 months after doa

1 Scope

The present document together with EN 301 489-1 [1], covers the assessment of all radio transceivers associated with Ultra Low Power Active Medical Implants (ULP-AMIs), Ultra Low Power Active Medical Devices (ULP-AMDs), Ultra Low Power Body Worn Devices (ULP-BWDs) and associated Ultra Low Power Active Medical Implant Peripherals (ULP-AMI-Ps), Ultra Low Power Active Medical Device Peripherals (ULP-AMD-Ps) in respect of ElectroMagnetic Compatibility (EMC).

The radio link may be part of life supporting or non life supporting equipment and can be classified independently of the classification of the medical portion of the device.

The present document covers the EMC requirements for the radio functions of ultra low power implanted, body worn and associated ultra low power peripheral devices.

Technical specifications related to the antenna port and emissions from the enclosure port of these radio system 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 the following equipment, ULP-AMIs, ULP-AMDs, ULP-BWDs, and associated peripheral devices ULP-AMI-Ps and ULP-AMD-Ps.

Definitions of types of the above equipment that are covered by the present document are given in annex A.

In case of differences (for instance concerning special conditions, definitions, abbreviations) between the present document and EN 301 489-1 [1], the provisions of the present document take precedence.

The environmental classification and the emission and immunity requirements used in the present document are as stated in the EN 301 489-1 [1], except for any special conditions included in the present document.

2 References

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

- For a specific reference, subsequent revisions do not apply.
- Non-specific reference may be made only to a complete document or a part thereof and only in the following cases:
 - if it is accepted that it will be possible to use all future changes of the referenced document for the purposes of the referring document;
 - for informative references.

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NOTE: While any hyperlinks included in this clause were valid at the time of publication ETSI cannot guarantee their long term validity.

2.1 Normative references

The following referenced documents are indispensable for the application of the present document. For dated references, only the edition cited applies. For non-specific references, the latest edition of the referenced document (including any amendments) applies.

- [1] ETSI EN 301 489-1 (V1.4.1): "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] 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.
- [4] ETSI EN 302 537-1 (V1.1.2): "Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Ultra Low Power Medical Data Service Systems operating in the frequency range 401 MHz to 402 MHz and 405 MHz to 406 MHz; Part 1: Technical characteristics and test methods".
- [5] ETSI EN 302 537-2 (V1.1.2): "Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Ultra Low Power Medical Data Service Systems operating in the frequency range 401 MHz to 402 MHz and 405 MHz to 406 MHz; Part 2: Harmonized EN covering essential requirements of article 3.2 of the R&TTE Directive".
- [6] CENELEC EN 60601-1-2 (2007): " Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests ".
- [7] CEPT/ERC/REC 70-03: "Relating to the use of Short Range Devices (SRD)".
- [8] CENELEC EN 61000-4-5 (2006): "Electromagnetic compatibility (EMC) - Part 4-5: Testing and measurement techniques - Surge immunity test".

2.2 Informative references

The following referenced documents are not essential to the use of the present document but they assist the user with regard to a particular subject area. For non-specific references, the latest version of the referenced document (including any amendments) applies.

- [9] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.
- [10] 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).

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:

ancillary equipment: See definition in EN 301 489-1 [1].

environmental profile: range of environmental conditions under which equipment within the scope of EN 301 489-XX is required to comply with the provisions of EN 301 489-1 [1]

life supporting equipment: equipment whose continued normal operation is required in order to sustain life

Medical Data Service (MEDS): service that uses a system specifically for the purpose of providing non-voice digital communications between active medical implants and/or body worn devices and other devices external to the human body engaged in transferring non-time critical individual patient related physiological information

Medical Data Service (MEDS) System Communication Link (MEDSCL): collection of transmissions that may or may not be continuous, between MEDS system devices including at least one active medical implant or body worn device together with other devices external to the body engaged in transferring non-time critical patient related physiological information collected by a single MEDS system

Medical Data Service (MEDS) communication session: collection of transmissions that may or may not be continuous, between co-operating ULP-AMI, ULP-AMI-P, ULP-BWD, ULP-AMD and ULP-AMD-P

Medical Data Service (MEDS) System: a collection of medical devices having RF transmitting capability, that are associated with a specific patient that have the ability to communicate with each other using frequencies in the 401 MHz to 402 MHz and/or 405 MHz to 406 MHz bands

Medical Data Service (MEDS) System Communication Channel: any continuous segment of spectrum that is equal to the emission bandwidth of the device with the largest bandwidth that is to participate in a MEDS session

NOTE: As stated in CEPT/ERC/REC 70-03 Annex 12 Bands a1) and a2), it is permitted to aggregate 25 kHz segments up to a maximum of 100 kHz for each channel bandwidth.

Medical Data Service (MEDS) System Device: Any ultra low power medical device transmitting in the 401 MHz to 402 MHz and/or 405 MHz to 406 MHz band. Only two types of MEDS system devices are permitted under the present document:

- Frequency agile devices that are designed to access a minimum of 18 channels evenly distributed across the 401 MHz to 402 MHz and 405 MHz to 406 MHz bands with a minimum of 9 channels defined for each 1 MHz segment (i.e. 401 MHz to 402 MHz and 405 MHz to 406 MHz).
- Devices capable of operation only on a single channel using low duty cycle and low power for spectrum access in the 401 MHz to 402 MHz and 405 MHz to 406 MHz bands, see clause 8.6 and subclauses.

Ultra Low Power Active Medical Implant (ULP-AMI): the radio part of an AIMD

Ultra Low Power Active Medical Implant Peripheral (ULP-AMI-P) device: the radio part of medical equipment outside the human body that communicates with an ULP-AMI to establish a medical implant communications link

Ultra Low Power Active Medical Device (ULP-AMD): the radio part of a medical device that is also regulated under 93/42/EEC [9]

Ultra Low Power Active Medical Device Peripheral (ULP-AMD-P): the radio part of medical equipment outside the human body that communicates with an ULP-AMD, ULP-BWD or other ULP-AMD-P that is part of a MEDS communication system

Ultra Low Power Body Worn Device (ULP-BWD): the radio part of a medical device, such as a physiological parameter sensor or handheld device, that is intended to operate in very close proximity to the human body, including touching the body, which has its radio antenna external to the body

3.2 Abbreviations

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

EMC	ElectroMagnetic Compatibility
EUT	Equipment Under Test
MEDSCL	Medical Data Service System Communications Link
MEDS	Medical Data Service
R&TTE	Radio and Telecommunications Terminal Equipment
RF	Radio Frequency
ULP-AMI	Ultra Low Power Active Medical Implant
ULP-AMI-P	Ultra Low Power Active Medical Implant Peripheral device
ULP-BWD	Ultra Low Power Body Worn Device
ULP-AMD	Ultra Low Power Active Medical Device
ULP-AMD-P	Ultra Low Power Active Medical Device Peripheral

4 Test conditions

For the purposes of the present document, the test conditions of the EN 301 489-1 [1], clause 4, shall apply as appropriate. Further product related test conditions for ULP-AMI, ULP-AMI-P, ULP-BWD, ULP-AMD and ULP-AMD-P are specified in the present document.

4.1 General

For emission and immunity tests the normal test modulation, test arrangements, etc., as specified in the present document, clauses 4.1 to 4.5 shall apply.

Whenever the Equipment Under Test (EUT) is provided with a detachable antenna, the EUT shall be tested with the antenna fitted in a manner typical of normal intended use, unless otherwise specified. If the EUT can be used with several types of antenna the test shall be repeated for each type of antenna.

ULP-AMI devices (active medical implants) and ULP-BWD (body worn devices) are designed to be implanted within or worn in very close proximity to a human body. Implant radio systems are isolated from disturbances by the surrounding body tissue and body worn devices are subject to field distortions due to the proximity of the body. In order to adequately assess the EMC characteristics of ULP-AMI and ULP-BWD devices, the use of a simulated man is necessary. See annex B for additional details. The provisions of annex B are intended to provide an operational environment that simulates, to the extent possible, actual usage conditions for these devices. It is necessary to use this special fixture as described in Annex B when making radiated emission measurements and immunity tests with radiated RF fields.

4.2 Arrangements for test signals

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

4.2.1 Arrangements for test signals at the input of the transmitter

The provisions of the EN 301 489-1 [1], clause 4.2.1 shall apply with the following modifications:

- The transmitter shall be modulated with normal test modulation as specified for that type of equipment (see clause 4.5). Where transmitters do not have a modulation input port, the internal equipment modulation shall be used.

4.2.2 Arrangements for test signals at the output of the transmitter

The provisions of the EN 301 489-1 [1], clause 4.2.2 shall apply with the following modification:

- The provider may provide a suitable companion receiver or other equipment that can be used to set up a communications link and/or to receive messages.

4.2.2.1 ULP- AMI and ULP-BWD transmitters

For ULP-AMI and ULP-BWD transmitters the test fixture described in annex B shall be used:

- The provider shall provide a suitable receiver or other equipment that can be used to monitor the medical device communications link.

4.2.2.2 ULP-AMI-P, ULP-AMD and ULP-AMD-P transmitters

The provisions of EN 301 489-1 [1], clause 4.2.2 shall apply with the following modifications:

- ULP-AMI-P, ULP-AMD and ULP-AMD-P devices are designed to be used external to a human body;
- the provider shall provide a suitable receiver or other equipment that can be used to monitor the medical system communications link.

4.2.3 Arrangements for test signals at the input of the receiver

The provisions of EN 301 489-1 [1], clause 4.2.3 shall apply with the following modifications:

- the wanted RF input signal, coupled to the receiver, shall be modulated with normal test modulation as specified for that type of equipment (clause 4.5);
- the level of the wanted RF input signal shall be 20 dB above the threshold sensitivity level of the receiver, but in all cases it shall be below the overload characteristics of the receiver;
- the provider 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 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 devices covered by the present document is not possible, then the provider shall provide the method by which the receiver's functionality can be monitored during the immunity tests.

4.2.5 Arrangements for testing individual transmitters and receivers that are intended to operate together in a MEDS system

The provisions of EN 301 489-1 [1], clause 4.2.5 shall apply with the following modification:

- the transmitter and the receiver of each device intended to operate in a MEDS system may be tested together, if appropriate and agreed to by the provider and the test laboratory.

In this case all 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 4.3.2 of the present document.

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

The frequencies on which the transmitter part of the EUT(s) is(are) 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 the equipment covered by the present document.

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 the lower frequency of the exclusion band is the lower frequency of the used frequency channel minus the extension value given in table 2, and the upper frequency of the exclusion band is the upper frequency of the used frequency channel plus the extension value given in table 2. The calculated extension value shall be based on the operating frequency.
- For receivers capable of operating on 9 or more channels within the frequency band specified in table 1 and not having an alignment range, the lower frequency of the exclusion band is the lower frequency of the used frequency channel minus the extension value given in table 1, and the upper frequency of the exclusion band is the upper frequency of the used frequency channel plus the extension value given in table 1. The calculated extension value shall be based on the operating frequency.

- For wide band receivers, i.e. receivers operating in a non-channelized arrangement, the lower frequency of the exclusion band is the lower 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 MEDS Devices

Receiver operating frequency f_o	Receiver exclusion bands		
	Receiver class 1	Receiver class 2	Receiver class 3
401 MHz to 402 MHz	$f_o \pm 10$ MHz	$f_o \pm (5 \% \times f_o)$	$f_o \pm (5 \% \times f_o)$
405 MHz to 406 MHz	$f_o \pm 10$ MHz	$f_o \pm (5 \% \times f_o)$	$f_o \pm (5 \% \times f_o)$

4.3.2 Exclusion band for transmitters

For transmitters operating, or intended to operate, in a channelized arrangement in the 401 MHz to 402 MHz and 405 MHz to 406 MHz frequency band, the exclusion band is nine times the maximum occupied bandwidth allowed for that service, centred around the operating frequency. For the 401 MHz to 402 MHz and 405 MHz to 406 MHz frequency bands, the maximum occupied bandwidth is 100 kHz. The actual occupied bandwidth is determined using the procedures in EN 302 537-1 [4] for measuring emission bandwidth.

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 which produces specific selective messages or commands as stated by the provider, representing a practical selection of usable selective messages/commands. The provider 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 provider 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 provider according to table 2 (see clause 6.1).

The performance assessment is dependent on whether the device is an implantable, body worn or external device.

For each type of device 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 any type of device 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 provision of EN 301 489-1 [1], clause 5.4 shall apply with the following modification.

Emissions levels for ancillary equipment shall be measured according to the requirements for the specific device.

Immunity levels for ancillary equipment that is specifically used with the EUT shall be tested with it connected to the EUT in which case compliance shall be demonstrated to the appropriate clauses of the present document.

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 device/equipment and/or associated ancillary device/equipment shall be classified into one of the following types:

ULP-AMI	Ultra Low Power Active Medical Implant
ULP-AMI-P	Ultra Low Power Active Medical Implant Peripheral device
ULP-BWD	Ultra Low Power Body Worn Device
ULP-AMD	Ultra Low Power Active Medical Device
ULP-AMD-P	Ultra Low Power Active Medical Device Peripheral

- 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 Classification and Performance criteria

6.1 Class of ULP-AMI, ULP-AMI-P, ULP-BWD, ULP-AMD and ULP-AMD-P devices covered by the present document

The radio systems of a product family of Active Implantable Medical Devices (AIMD), Active Medical Devices, Body Worn Devices (BWD) and/or their associated peripheral devices forming part of or in total a Medical Data Service operating in the 401 MHz to 402 MHz and 405 MHz to 406 MHz are classified in table 2. This classification is based upon the impact on persons and/or goods in case the equipment does not operate at or above the specified minimum performance level under EMC stress. The provider of the above device(s) shall declare the classification of his device(s). The test report shall note the classification of the device based on the providers' declaration in table 2.

Table 2

Class of EUT	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).

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 classes of ULP-AMI/ULP-AMI-P/ULP-BWD ULP-AMD and ULP-AMD-P devices (see table 2) in combination with the different equipment types 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 specified time are stated in clause 7.2.2, table 4.

The device shall meet the performance criteria as specified in the following clauses, for the appropriate class of devices.

6.3 Performance criteria and table

For all device classes and types of EUTs 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 provider; or
- for devices under test that cannot be assessed using the above methods for assessment, the provider 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 provider and remain safe for the user. The tested device may exhibit a degradation of performance (deviation from provider's specifications) as detailed in table 3.

Table 3

Class 1, All devices covered by the present document		
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, All devices covered by the present document		
Criteria	During test	After test
A	Operate as intended No loss of function below providers specification No unintentional responses	Operate as intended The communication link shall be maintained or recover No loss of function below providers 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 providers specifications No degradation of performance No loss of stored data or user programmable functions
Class 3, All devices covered by the present document		
Criteria	During test	After test
A and B	May be loss of function (one or more) No unintentional responses	Operate as specified by the provider, 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 provider

The following degradations or failures are not allowed during any phase of testing of devices covered by the present document:

- 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.

6.4 Performance criteria for continuous phenomena applied to transmitters

For transmitters, the performance criteria A of the applicable class as given in clause 6.3 shall apply.

For the transmitter part of 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 provider.

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 transmitters, 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 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 provider.

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 the performance criteria A of the applicable class as given in clause 6.3 shall apply.

For the receiver part of 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 provider.

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 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 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 provider.

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

7 Applicability overview

7.1 Emission

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 and/or external to the body devices such as a pacemakers, defibrillators, nerve stimulators, drug pumps, programmer/controllers, monitors 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) of the device 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. Accordingly, the performance levels specified for equipment covered by the present document reflect the expected environmental disturbances associated with medical facilities.

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

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

The emission measurements applicable to the antenna or enclosure port of MEDS service devices are specified in the harmonized product standard EN 302 537-2 [5].

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 and body worn 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 provider and recorded in the subsequent test documentation. An analysis supporting the use of the alternate specialized test fixture shall be included in the report.

It is intended that the performance criteria and immunity requirements in the present document and in EN 60601-1-2 [6] be essentially equivalent. For ULP-AMI devices as well as the other types of equipment covered by the present document, 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.

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

Reference to clauses in EN 301 489-1 [1]	Special product-related conditions, additional to or modifying the test configuration in EN 301 489-1 [1], clause 9									
9.2.2 Test method; Radio frequency electromagnetic field	<p>The following conditions apply:</p> <ul style="list-style-type: none"> - 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 measure or control a physiological parameter, the operating frequency restrictions specified below shall apply. <table border="1" data-bbox="646 685 1437 994"> <thead> <tr> <th data-bbox="646 685 903 853">Intended use</th> <th data-bbox="903 685 1166 853">Modulation frequency</th> <th data-bbox="1166 685 1437 853">Physiological simulation frequency and Operating frequency of the simulation circuit</th> </tr> </thead> <tbody> <tr> <td data-bbox="646 853 903 965">To control, monitor or measure a physiological parameter</td> <td data-bbox="903 853 1166 965">2 Hz</td> <td data-bbox="1166 853 1437 965">Less than 1 Hz or greater than 3 Hz</td> </tr> <tr> <td data-bbox="646 965 903 994">All other</td> <td data-bbox="903 965 1166 994">1 kHz</td> <td data-bbox="1166 965 1437 994">Not applicable</td> </tr> </tbody> </table> <p>The test shall be performed over the frequency range 80 MHz to 2 500 MHz. The appropriate exclusion band as defined in clause 4.3 and sequence may be excluded from this requirement.</p>	Intended use	Modulation frequency	Physiological simulation frequency and Operating frequency of the simulation circuit	To control, monitor or measure a physiological parameter	2 Hz	Less than 1 Hz or greater than 3 Hz	All other	1 kHz	Not applicable
Intended use	Modulation frequency	Physiological simulation frequency and Operating frequency of the simulation circuit								
To control, monitor or measure a physiological parameter	2 Hz	Less than 1 Hz or greater than 3 Hz								
All other	1 kHz	Not applicable								
9.3.2 Test method; Electrostatic discharge	<p>The test severity level for contact discharge shall be ± 6 kV and for air discharge ± 8 kV. This test is not applicable to ULP-AMI devices.</p>									
9.4.2 Test method; Fast transient, Common mode	<p>The following conditions apply:</p> <ul style="list-style-type: none"> - 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. 									
9.5 Radio frequency, Common mode	<p>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 an implanted device RF link 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 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 RF link must be tested for radio frequency common mode ambient levels, the provider may specify an alternate technique for determining compliance. The alternate technique must be agreed to by the test laboratory. One example of an alternate technique would be direct coupling of a signal adjusted in level to account for tissue attenuation that would occur under normal operating conditions.</p>									

Reference to clauses in EN 301 489-1 [1]	Special product-related conditions, additional to or modifying the test configuration in EN 301 489-1 [1], clause 9																		
9.5.2 Test Method; Radio frequency, Common mode	<p>The following conditions apply:</p> <ul style="list-style-type: none"> - 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 border="1" data-bbox="639 741 1442 1048"> <thead> <tr> <th>Intended use</th> <th>Modulation frequency</th> <th>Physiological simulation frequency and Operating frequency of the simulation circuit</th> </tr> </thead> <tbody> <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> </tbody> </table> <p>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.</p>	Intended use	Modulation frequency	Physiological simulation frequency and Operating frequency of the simulation circuit	To control, monitor or measure a physiological parameter	2 Hz	Less than 1 Hz or greater than 3 Hz	All other	1 kHz	Not applicable									
Intended use	Modulation frequency	Physiological simulation frequency and Operating frequency of the simulation circuit																	
To control, monitor or measure a physiological parameter	2 Hz	Less than 1 Hz or greater than 3 Hz																	
All other	1 kHz	Not applicable																	
9.7 Voltage dips and interruptions	This test does not apply to ULP-AMI devices.																		
9.7.2 Test method; Voltage dips and interruptions	<p>The tests levels shall be as indicated in the following tables.</p> <p style="text-align: center;">Immunity test level for voltage dips</p> <table border="1" data-bbox="639 1279 1442 1420"> <thead> <tr> <th>Voltage test level (%Ut)</th> <th>Voltage dip (%Ut)</th> <th>Duration (Periods)</th> </tr> </thead> <tbody> <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> </tbody> </table> <p>NOTE: Ut is the AC mains voltage prior to application of the test signal.</p> <p style="text-align: center;">Immunity test level for voltage interruptions</p> <table border="1" data-bbox="639 1570 1442 1653"> <thead> <tr> <th>Voltage test level (%Ut)</th> <th>Voltage dip (%Ut)</th> <th>Duration (Seconds)</th> </tr> </thead> <tbody> <tr> <td>< 5</td> <td>> 95</td> <td>5</td> </tr> </tbody> </table> <p>NOTE: Ut is the AC mains voltage prior to application of the test signal.</p>	Voltage test level (%Ut)	Voltage dip (%Ut)	Duration (Periods)	< 5	> 95	0,5	40	60	5	70	30	25	Voltage test level (%Ut)	Voltage dip (%Ut)	Duration (Seconds)	< 5	> 95	5
Voltage test level (%Ut)	Voltage dip (%Ut)	Duration (Periods)																	
< 5	> 95	0,5																	
40	60	5																	
70	30	25																	
Voltage test level (%Ut)	Voltage dip (%Ut)	Duration (Seconds)																	
< 5	> 95	5																	

Reference to clauses in EN 301 489-1 [1]	Special product-related conditions, additional to or modifying the test configuration in EN 301 489-1 [1], clause 9
9.7.3 Performance criteria	<p>For a voltage dip corresponding to a reduction of the supply voltage of 30 % for 25 periods the following performance criteria apply:</p> <ul style="list-style-type: none"> - 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 provider (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. <p>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:</p> <ul style="list-style-type: none"> - 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 provider (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.
9.8 Surges	<p>These tests do not apply to ULP-AMI devices.</p>
9.8.2 Test Methods; Surges	<p>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 [8].</p> <p>The test generator shall provide the 1,2/50 µs pulse as defined in EN 61000-4-5 [8].</p> <p>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°.</p> <p>Equipment and/or systems without any grounded interconnections are exempted from line(s) to ground testing.</p> <p>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.</p>

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

A.1 ULP-AMI, ULP-AMD, ULP-BWD, ULP-AMD-P and ULP-AMI-P devices intended for operation in the frequency range 401 MHz to 402 MHz and 405 MHz to 406 MHz

The present document applies to ULP-AMI, ULP-AMD, ULP-BWD, ULP-AMD-P and ULP-AMI-P devices with RF power levels ranging up to 25 μ W ERP and intended for operation in the frequency range 401 MHz to 402 MHz and 405 MHz to 406 MHz in accordance with the provisions of annex 12, band b) and band c), to CEPT/ERC/REC 70-03 [7]. Definitions of such ULP-AMI, ULP-AMD, ULP-BWD, ULP-AMD-P and ULP-AMI-P radio devices are found in the following functional radio standards:

- EN 302 537-1 (V1.1.2): "Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Ultra Low Power Medical Data Service Systems operating in the frequency range 401 MHz to 402 MHz and 405 MHz to 406 MHz; Part 1: Technical characteristics and test methods" [4].
- EN 302 537-2 (V1.1.2): "Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Ultra Low Power Medical Data Service Systems operating in the frequency range 401 MHz to 402 MHz and 405 MHz to 406 MHz; Part 2: Harmonized EN covering essential requirements of article 3.2 of the R&TTE Directive" [5].

Annex B (normative): Test fixture for Implanted (ULP-AMI) and Body Worn Devices (ULP-BWD)

B.1 Equipment in close proximity to the human body but external to it and devices intended to be implanted in the body

For equipment designed to be external to but in very close proximity to a human body the use of the torso simulator arrangements provided for in clause B.2 below shall be used with the following changes. MEDS devices in this category shall have the EUT affixed to the outside surface of the torso simulator at a height of 380 mm from the bottom of the simulator. Any leads attached to the EUT shall be tightly coiled around the EUT in a plane corresponding to the greatest length around the EUT and the entire assembly affixed to the surface of the torso simulator. Any RF leads shall be terminated in their respective design impedance. Tissue substitute material and temperature shall be as described in clause B.2.

Implanted devices shall be arranged as shown in figure B.1.

B.2 Human torso simulator for ULP-BWD and ULP-AMI

ULP-AMIs and ULP-BWEs shall be tested using the simulated man constructed as follows in order to simulate operation of the ULP-AMI under actual operation conditions as shown in figure B.1. Note the addition of a shelf for testing ULP-BWD devices.

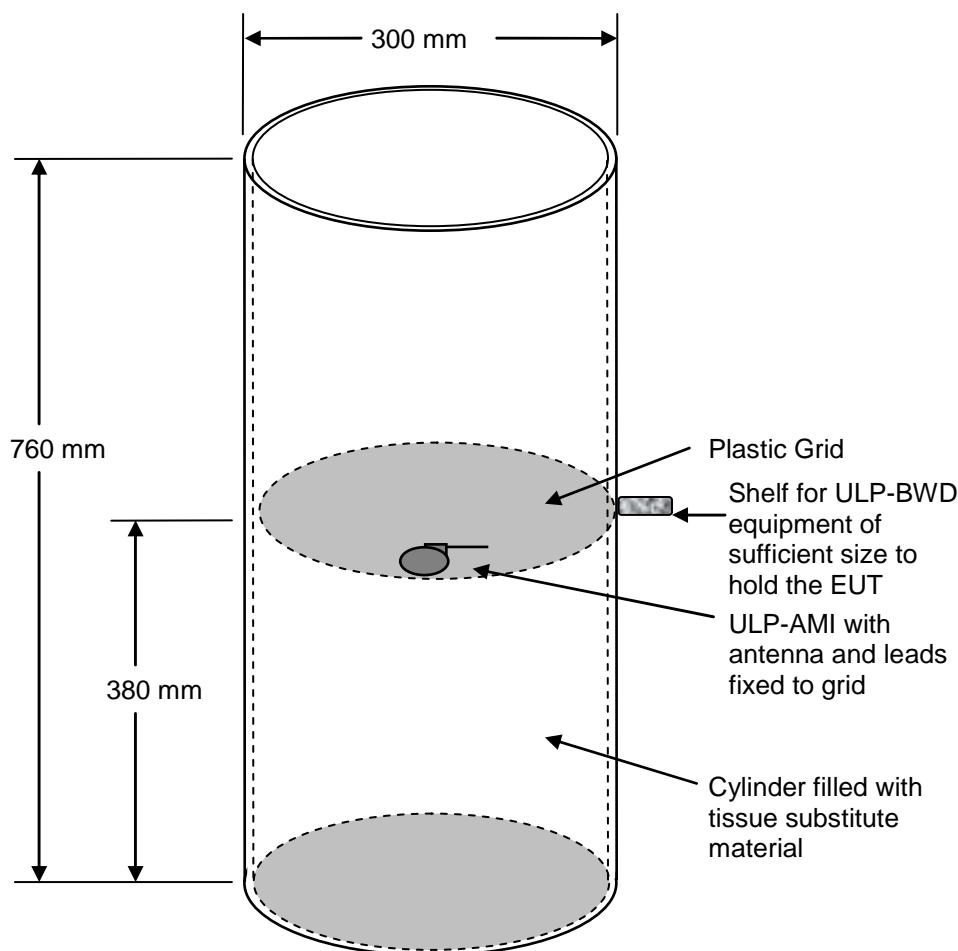


Figure B.1

An appropriate simulator for testing the above devices consists of a cylindrical acrylic container with an outside diameter of $300 \text{ mm} \pm 5 \text{ mm}$, a sidewall thickness of $6 \text{ mm} \pm 2,1 \text{ mm}$, and a fluid-filled height of $760 \text{ mm} \pm 5 \text{ mm}$. It shall be filled with a material that is sufficiently fluid that it will flow around the ULP-AMI without any voids. The dielectric and conductivity properties of this material shall match the dielectric and conductivity properties of human muscle tissue at 403,5 MHz. Simple saline solutions do not meet the dielectric and conductivity requirements for use as a substitute for human tissue. All measurements will be made using the above specification with the tissue substitute material at a nominal temperature between $22 \text{ }^\circ\text{C}$ and $38 \text{ }^\circ\text{C}$. This temperature will facilitate testing because it is typical of ambient conditions at many test sites. A mounting grid for the ULP-AMI device inside the container shall be provided that permits the radiating element or elements of the ULP-AMI to be positioned vertically and horizontally and any leads coiled around the device. The grid should also support any additional ULP-AMI device leads associated with the therapeutic function of the ULP-AMI device in a fixed repeatable manner such that they do not influence the measurement. The ULP-AMI device antenna shall be mounted $60 \text{ mm} \pm 5 \text{ mm}$ from the sidewall and centred vertically within the container. When switching from vertical to horizontal positioning, it may be necessary to reposition the antenna to maintain a separation of $60 \text{ mm} \pm 5 \text{ mm}$ from the sidewall of the test fixture along its length. ULP-AMI device leads will be coiled and placed away from the ULP-AMI device antenna while maintaining a nominal 60 mm from the sidewall. Body worn devices shall be placed next to the cylinder outer surface. The above fixture shall be placed on a table such that the ULP-AMI device 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.

A formula for a suitable tissue substitute material is defined in the paper "Simulated Biological Materials for Electromagnetic Radiation Absorption Studies" [10].

Tissue parameters for various frequencies may be obtained from the following website: <http://niremf.ifac.cnr.it/>, 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 [10]. 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.

Annex C (informative): Bibliography

Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility (EMC Directive).

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

Language	EN title
Bulgarian	
Czech	
Danish	
Dutch	
English	Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment operating in the 401 MHz to 402 MHz and 405 MHz to 406 MHz bands; Part 29: Requirements for Medical Data Service Devices (MEDS)
Estonian	
Finnish	
French	
German	
Greek	
Hungarian	
Icelandic	
Italian	
Latvian	
Lithuanian	
Maltese	
Norwegian	
Polish	
Portuguese	
Romanian	
Slovak	
Slovenian	
Spanish	
Swedish	

History

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V1.1.1	April 2008	Public Enquiry	PE 20080815: 2008-04-16 to 2008-08-15