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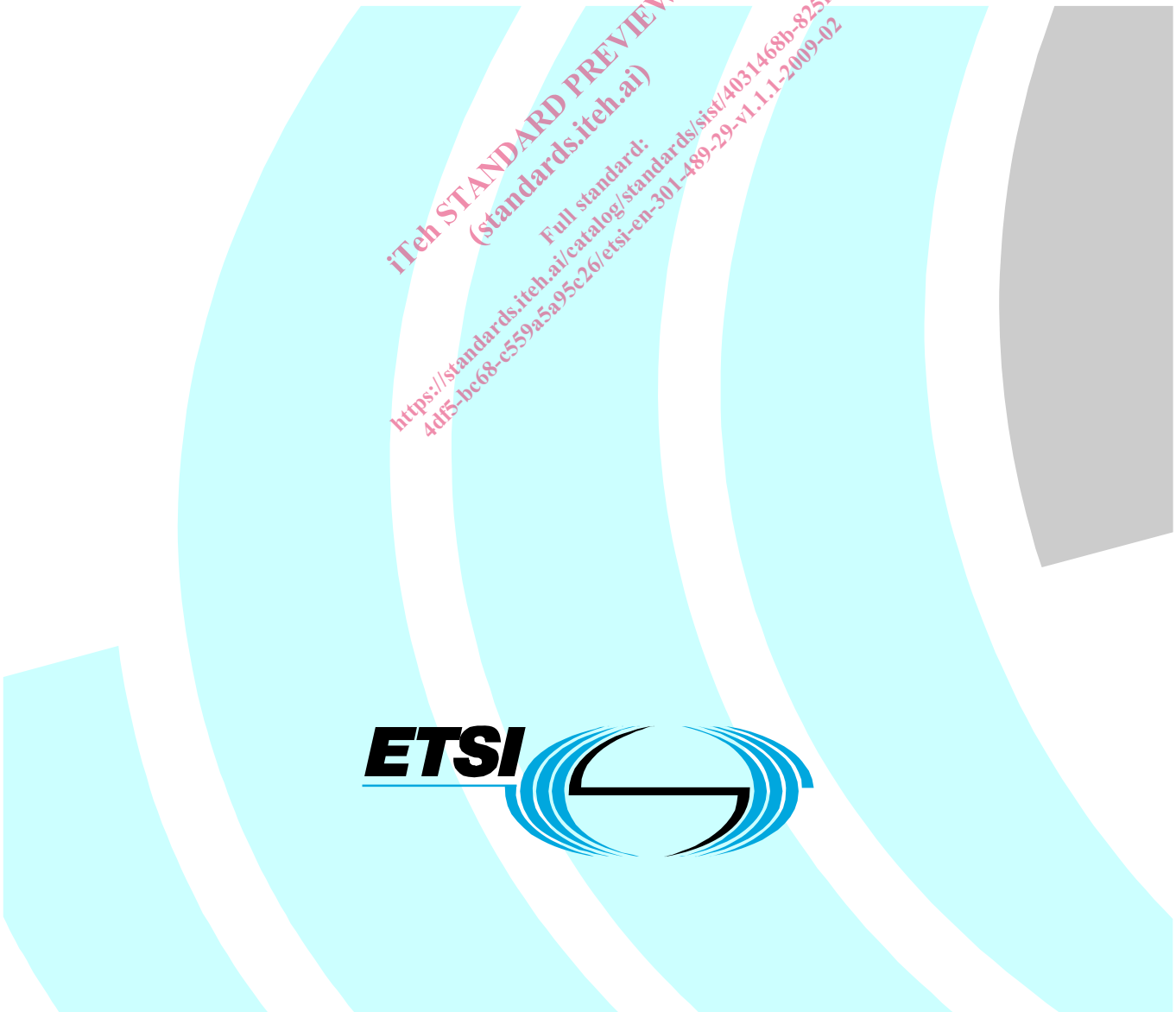
Harmonized European Standard (Telecommunications series)

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



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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 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 [i.2] (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 [i.1] 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").

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
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):	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.

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

For online referenced documents, information sufficient to identify and locate the source shall be provided. Preferably, the primary source of the referenced document should be cited, in order to ensure traceability. Furthermore, the reference should, as far as possible, remain valid for the expected life of the document. The reference shall include the method of access to the referenced document and the full network address, with the same punctuation and use of upper case and lower case letters.

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 (V1.8.1): "Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements".

[2] 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".

[3] 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".

[4] 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 ".

[5] 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.

[i.1] 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).

[i.2] Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations.

[i.3] CEPT/ERC/Recommendation 70-03: "Relating to the use of Short Range Devices (SRD)".

[i.4] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

[i.5] 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).

[i.6] ETSI EN 301 489 (all parts): "Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services".

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 each part the multi-part deliverable EN 301 489 [i.7] 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: 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 [i.3], 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

Ultra Low Power Active Medical Device (ULP-AMD): radio part of a medical device that is also regulated under 93/42/EEC [i.4]

Ultra Low Power Active Medical Device Peripheral (ULP-AMD-P): 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 Active Medical Implant (ULP-AMI): radio part of an AIMD

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

AIMD	Active Implantable Medical Devices
BWD	Body Worn Devices
EMC	ElectroMagnetic Compatibility
EUT	Equipment Under Test
MEDS	Medical Data Service

MEDSCL Medical Data Service System Communications Link
R&TTE Radio and Telecommunications Terminal Equipment
RF Radio Frequency
ULP-AMD Ultra Low Power Active Medical Device
ULP-AMD-P Ultra Low Power Active Medical Device Peripheral
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

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.