Draft ETSI EN 301 489-29 V2.2.0 (2017-03)

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

Reference

REN/ERM-EMC-375

Keywords

EMC, harmonised standard, radio, regulation, short range

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
Sous-Préfecture de Grasse (06) N° 7803/88

Important notice

The present document can be downloaded from:
http://www.etsi.org/standards-search

The present document may be made available in electronic versions and/or in print. The content of any electronic and/or print versions of the present document shall not be modified without the prior written authorization of ETSI. In case of any existing or perceived difference in contents between such versions and/or in print, the only prevailing document is the print of the Portable Document Format (PDF) version kept on a specific network drive within ETSI Secretariat.

Users of the present document should be aware that the document may be subject to revision or change of status. Information on the current status of this and other ETSI documents is available at https://portal.etsi.org/TB/ETSIDeliverableStatus.aspx

If you find errors in the present document, please send your comment to one of the following services:
https://portal.etsi.org/People/CommiteeSupportStaff.aspx

Copyright Notification

Contents

Intellectual Property Rights

IPRs essential or potentially essential to the present document may have been declared to ETSI. The information pertaining to these essential IPRs, if any, is publicly available for **ETSI members and non-members**, and can be found in ETSI SR 000 314: *"Intellectual Property Rights (IPRs); Essential, or potentially Essential, IPRs notified to ETSI in respect of ETSI standards"*, which is available from the ETSI Secretariat. Latest updates are available on the ETSI Web server (https://ipr.etsi.org/).

Pursuant to the ETSI IPR Policy, no investigation, including IPR searches, has been carried out by ETSI. No guarantee can be given as to the existence of other IPRs not referenced in ETSI SR 000 314 (or the updates on the ETSI Web server) which are, or may be, or may become, essential to the present document.

Foreword

This draft Harmonised European Standard (EN) has been produced by ETSI Technical Committee Electromagnetic compatibility and Radio spectrum Matters (ERM), and is now submitted for the combined Public Enquiry and Vote phase of the ETSI standards EN Approval Procedure.

The present document has been prepared under the Commission's standardisation request C(2015) 5376 final [i.7] to provide one voluntary means of conforming to the essential requirements of Directive 2014/53/EU on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC [i.1].

Once the present document is cited in the Official Journal of the European Union under that Directive, compliance with the normative clauses of the present document given in table A.1 confers, within the limits of the scope of the present document, a presumption of conformity with the corresponding essential requirements of that Directive and associated EFTA regulations.

The present document is part 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):	18 months after doa

Modal verbs terminology

In the present document "**shall**", "**shall not**", "**should**", "**should not**", "**may**", "**need not**", "**will**", "**will not**", "**can**" and "**cannot**" are to be interpreted as described in clause 3.2 of the ETSI Drafting Rules (Verbal forms for the expression of provisions).

"**must**" and "**must not**" are **NOT** allowed in ETSI deliverables except when used in direct citation.

1 Scope

The present document together with ETSI EN 301 489-1 [1], covers the assessment of all radio transceivers associated with 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 applies to ULP-AMI, ULP-AMD, ULP-BWD, ULP-AMD-P and ULP-AMI-P devices with RF power levels ranging up to 25 µW 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 [i.3]. 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 standard:

- ETSI EN 302 537 [2]: "Ultra Low Power Medical Data Service (MEDS) Systems operating in the frequency range 401 MHz to 402 MHz and 405 MHz to 406 MHz; Harmonised Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU [i.1]".

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

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

The present document, together with ETSI EN 301 489-1 [1], are aimed to cover requirements to demonstrate an adequate level of electromagnetic compatibility.

2 References

2.1 Normative references

References are specific, identified by date of publication and/or edition number or version number. Only the cited version applies.

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

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

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

[1] ETSI EN 301 489-1 (V2.2.0) (03-2017): "ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and the essential requirements of article 6 of Directive 2014/30/EU".

NOTE: Available at: http://www.etsi.org/deliver/etsi_en/301400_301499/30148901/02.02.00_20/.

[2] ETSI EN 302 537 (V2.1.1) (10-2016): "Ultra Low Power Medical Data Service (MEDS) Systems operating in the frequency range 401 MHz to 402 MHz and 405 MHz to 406 MHz; Harmonised Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU".

[3] CENELEC EN 61000-4-5 (2006): "Electromagnetic compatibility (EMC) - Part 4-5: Testing and measurement techniques - Surge immunity test".

2.2 Informative references

References are either specific (identified by date of publication and/or edition number or version number) or non-specific. For specific references, only the cited version applies. For non-specific references, the latest version of the referenced document (including any amendments) applies.

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

The following referenced documents are not necessary for the application of the present document but they assist the user with regard to a particular subject area.

[i.1] Directive 2014/53/EU of the European Parliament and of the council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC.

[i.2] Void.

[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", (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".

[i.7] Commission Implementing Decision C(2015) 5376 final of 4.8.2015 on a standardisation request to the European Committee for Electrotechnical Standardisation and to the European Telecommunications Standards Institute as regards radio equipment in support of Directive 2014/53/EU of the European Parliament and of the Council.

3 Definitions and abbreviations

3.1 Definitions

For the purposes of the present document, the terms and definitions given in ETSI EN 301 489-1 [1], ETSI EN 302 537 [2], Directive 2014/53/EU [i.1] and the following apply:

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

environmental profile: range of environmental conditions under which equipment within the scope of each part the multi-part deliverable ETSI EN 301 489 [i.6] is required to comply with the provisions of ETSI 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) 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 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) system device: any ultra low power medical device transmitting in the 401 MHz to 402 MHz and/or 405 MHz to 406 MHz band

NOTE: 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

Ultra Low Power Active Medical Device (ULP-AMD): radio part of a medical device that is also regulated under Council Directive 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 abbreviations given in ETSI EN 301 489-1 [1], ETSI EN 302 537 [2], Directive 2014/53/EU [i.1] and the following apply:

AC	Alternating Current
AIMD	Active Implantable Medical Devices
AMI	Active Medical Implant
BWD	Body Worn Devices
DC	Direct Current
EMC	ElectroMagnetic Compatibility
ERP	Effective Radiated Power
EUT	Equipment Under Test
ISM	Industrial, Scientific and Medical
MEDS	Medical Data Service
MEDSCL	Medical Data Service System Communications Link
R&TTE	Radio and Telecommunications Terminal Equipment
RF	Radio Frequency
ULP	Ultra Low Power
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

4.1 General

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

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

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

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 C for additional details. The provisions of annex C are intended to provide an operational environment that simulates, to the extent possible, actual usage conditions for 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

4.2.0 General

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

4.2.1 Arrangements for test signals at the input of transmitters

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

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

4.2.2 Arrangements for test signals at the RF output of transmitters

4.2.2.0 General

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

- The manufacturer may provide a suitable companion receiver or 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 C shall be used:

- The manufacturer 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 ETSI 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 manufacturer 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 RF input of receivers

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

- the wanted RF input signal, coupled to the receiver, shall be modulated with normal test modulation as specified for that type of equipment (clause 4.5);
- the level of the wanted RF input signal shall be 20 dB above the threshold sensitivity level of the receiver, but in all cases it shall be below the overload characteristics of the receiver;
- the manufacturer shall provide a suitable transmitter that can be used to set up the medical implant communications link.

4.2.4 Arrangements for test signals at the output of receivers

The provisions of ETSI EN 301 489-1 [1], clause 4.2.4 shall apply with the following modification, if appropriate:

- if direct access to the receiver output of the devices covered by the present document is not possible, then the manufacturer shall provide the method by which the receiver's functionality can be monitored during the immunity tests.

4.2.5 Arrangements for testing transmitter and receiver together (as a system: ULP-AMI together with an associated ULP-AMI-P)

The provisions of ETSI EN 301 489-1 [1], clause 4.2.5 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 manufacturer 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 RF exclusion band of radio equipment

4.3.1 General

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

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.