

SLOVENSKI STANDARD

SIST EN 301 489-29 V2.1.1:2017

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Standard elektromagnetne združljivosti (EMC) za radijsko opremo in storitve - Harmonizirani standard, ki zajema bistvene zahteve člena 3.1(b) direktive 2014/53/EU - 29. del: Posebni pogoji za naprave za medicinske podatkovne storitve (MEDS), ki delujejo v frekvenčnih pasovih od 401 MHz do 402 MHz in od 405 MHz do 406 MHz

ElectroMagnetic Compatibility (EMC) standard for radio equipment and services - Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU - 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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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

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Foreword

This Harmonised European Standard (EN) has been produced by ETSI Technical Committee Electromagnetic compatibility and Radio spectrum Matters (ERM).

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

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Modal verbs terminology

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

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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 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 [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"

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

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

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

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

- [1] ETSI EN 301 489-1 (V2.1.1) (11-2016): "ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and the essential requirements of article 6 of Directive 2014/30/EU".

NOTE: Available at http://www.etsi.org/deliver/etsi_en/301400_301499/30148901/02.01.01_30/en_30148901v020101v.pdf.

- [2] 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.

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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] 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", (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) 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 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
IEC	International Electrotechnical Commission
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 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.