SLOVENSKI STANDARD
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Elektromagnetna združljivost in zadeve v zvezi z radijskim spektrom (ERM) - Naprave kratkega dosega (SRD) - Aktivni medicinski vsadki ultra majhnih moč i (ULP-AMI) in pripadajoč e periferne naprave (ULP-AMI-P), ki delujejo v frekvenč nem območ ju od 402 MHz do 405 MHz - 2. del: Harmonizirani EN, ki zajema bistvene zahteve č lena 3.2 direktive R&TTE

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Electromagnetic compatibility and Radio spectrum Matters (ERM) - Short Range Devices (SRD) - Ultra Low Power Active Medical Implants (ULP-AMI) and Peripherals (ULP-AMI-P) operating in the frequency range 402 MHz to 405 MHz - Part 2: Harmonized EN covering essential requirements of article 3.2 of the R&TTE Directive

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Harmonized European Standard (Telecommunications series)

Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Ultra Low Power Active Medical Implants (ULP-AMI) and Peripherals (ULP-AMI-P) operating in the frequency range 402 MHz to 405 MHz; Part 2: Harmonized EN covering essential requirements of article 3.2 of the R&TTE Directive

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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).

The present document has been produced by ETSI in response to a mandate from the European Commission issued under Council Directive 98/34/EC (as amended) [5] laying down a procedure for the provision of information in the field of technical standards and regulations.

The present document is intended to become a Harmonized Standard, the reference of which will be published in the Official Journal of the European Communities referencing the Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity ("the R&TTE Directive") [1].

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Technical specifications relevant to Directive 1999/5/EC are given in annex A.

The present document is part 2 of a multi-part deliverable covering Short Range Devices (SRD); Ultra Low Power Active Medical Implants (ULP-AMI) and Peripherals (ULP-AMI-P) operating in the frequency range 402 MHz to 405 MHz, as identified below:

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Part 1: "Technical characteristics and test methods";

Part 2: "Harmonized EN covering essential requirements of article 3.2 of the R&TTE Directive".

National transposition dates	
Date of adoption of this EN:	29 June 2007
Date of latest announcement of this EN (doa):	30 September 2007
Date of latest publication of new National Standard or endorsement of this EN (dop/e):	31 March 2008
Date of withdrawal of any conflicting National Standard (dow):	31 March 2009

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1 Scope

The present document applies to the following radio equipment types:

- Ultra Low Power Active Medical Implants (ULP-AMI);
- and Peripherals (ULP-AMI-P).

These radio equipment types are capable of operating in all or any part of the frequency bands given below.

Table 1: Ultra Low Power Active Medical Implants (ULP-AMI) and Peripherals (ULP-AMI-P) service frequency bands

	Ultra Low Power Active Medical Implants (ULP-AMI) and Peripherals (ULP-AMI-P) service frequency bands
Transmit Ultra Low Power Active Medical Implants (ULP-AMI) and Peripherals (ULP-AMI-P)	402 MHz to 405 MHz
Receive Ultra Low Power Active Medical Implants (ULP-AMI) and Peripherals (ULP-AMI-P)	402 MHz to 405 MHz

The present document is intended to cover the provisions of Directive 1999/5/EC [1] (R&TTE Directive).

Article 3.2, which states that "….. radio equipment shall be so constructed that it effectively uses the spectrum allocated to terrestrial/space radio communications and orbital resources so as to avoid harmful interference".

An AIMD is regulated under the AIMD Directive 90/385/EEC [2]: radio parts contained therein (referred to herein as ULP-AMI and ULP-AMI-P for peripheral devices) are regulated under the Directive 1999/5/EC [1].

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In addition to the present document, other ENs that specify technical requirements in respect of essential requirements under other parts of Article 3 of the R&TTE Directive [1] may apply to equipment within the scope of the present document.

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NOTE: A list of such ENs is included on the web site http://www.newapproach.org.

2 References

The following documents contain provisions which, through reference in this text, constitute provisions of the present document.

- References are either specific (identified by date of publication and/or edition number or version number) or non-specific.
- For a specific reference, subsequent revisions do not apply.
- For a non-specific reference, the latest version applies.

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

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

[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).

[2] Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices.

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[3] ETSI EN 301 839-1 (V1.2.1): "Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Ultra Low Power Active Medical Implants (ULP-AMI) and Peripherals (ULP-AMI-P) operating in the frequency range 402 MHz to 405 MHz; Part 1: Technical characteristics and test methods".

[4] ETSI TR 100 028 (V1.4.1): "ElectroMagnetic Compatibility and Radio Spectrum Matters (ERM); Uncertainties in the measurement of mobile radio equipment characteristics".

[5] 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.

3 Definitions and abbreviations

3.1 Definitions

For the purposes of the present document, the terms and definitions given in EN 301 839-1 [3], clause 3.1 apply.

3.2 Abbreviations

For the purposes of the present document, the abbreviations given in EN 301 839-1 [3], clause 3.3 apply.

4 Technical requirements and specifications

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4.1 Environmental profile

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The technical requirements of the present document apply under the environmental profile for operation of the equipment, which shall be declared by the manufacturer. The equipment shall comply with all the technical requirements of the present document at all times when operating within the boundary limits of the declared operational environmental profile.

4.2 Conformance requirements

4.2.1 Mechanical and electrical design

4.2.1.1 General

The equipment shall be designed, constructed and manufactured in accordance with sound engineering practice and with the aim of minimizing harmful interference to other equipment and services and should not receive harmful interference from other electronic devices. Transmitters and receivers may be individual or combination units.

4.2.1.2 Antennas

Equipment operating in the 402 MHz to 405 MHz band shall have an integral antenna, an external dedicated antenna or both. If provision for an external antenna connection is made, the manufacturer or provider shall make provision to prevent the use of an antenna other than that authorized by the manufacturer or provider.

4.2.1.3 Controls

Those controls that, if maladjusted, might increase the interference potentialities of the equipment shall not be easily accessible to the user.

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4.2.1.4 Transmitter shut-off facility

If the transmitter is equipped with an automatic transmitter shut-off facility or battery-saving feature and it interferes with testing of the device, it shall be capable of being made inoperative for the purpose of testing.

4.2.2 Frequency error

4.2.2.1 Definition

The frequency error shall be as defined in EN 301 839-1 [3], clause 8.1.1.

4.2.2.2 Limits

The frequency error limits shall be as defined in EN 301 839-1 [3], clause 8.1.2.

4.2.2.3 Conformance

Conformance tests as defined in clause 5.3.1 shall be carried out.

4.2.3 Emission bandwidth

4.2.3.1 Definition

The emission bandwidth shall be as defined in EN 301 839-1 [3], clause 8.2.1.

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4.2.3.2 Limits

The emission bandwidth limits shall be as defined in EN 301 839-1 [3], clause 8.2.2.

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4.2.3.3 Conformance

Conformance tests as defined in clause 5.3.2 shall be carried out.

4.2.4 Effective radiated power of the fundamental emission

4.2.4.1 Definition

The effective radiated power shall be as defined in EN 301 839-1 [3], clause 8.3.1.

4.2.4.2 Limits

The effective radiated power limits shall be as defined in EN 301 839-1 [3], clause 8.3.2.

4.2.4.3 Conformance

Conformance tests as defined in clause 5.3.3 shall be carried out.

4.2.5 Spurious emissions of transmitter

4.2.5.1 Definition

The spurious emissions of transmitter shall be as defined in EN 301 839-1 [3], clause 8.4.1.

4.2.5.2 Limits

The spurious emissions limits of transmitter shall be as defined in EN 301 839-1 [3], clause 8.4.2.

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4.2.5.3 Conformance

Conformance tests as defined in clause 5.3.4 shall be carried out.

4.2.6 Frequency stability under low voltage conditions

4.2.6.1 Definition

The frequency stability under low voltage conditions shall be as defined in EN 301 839-1 [3], clause 8.5.1.

4.2.6.2 Limits

The frequency stability under low voltage conditions limits shall be as defined in EN 301 839-1 [3], clause 8.5.2.

4.2.6.3 Conformance

Conformance tests as defined in clause 5.3.5 shall be carried out.

4.2.7 Spurious radiation of receivers

4.2.7.1 Definition

The spurious radiation of receivers shall be as defined in EN 301 839-1 [3], clause 9.1.1.

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4.2.7.2 Limits

The spurious radiation of receivers limits shall be as defined in EN 301 839-1 [3], clause 9.1.2.

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4.2.7.3 Conformance

Conformance tests as defined in clause 5.3.6 shall be carried out.

4.2.8 Spectrum Access

It is mandatory that the manufacturer declares a spectrum access method. At least one of the following methods shall be chosen. A manufacturer may choose to implement both methods in his equipment, however, he may operate using both access methods if the total emission bandwidth does not exceed 300 kHz.

- LBT/AFA requirements for the monitoring system are specified in EN 301 839-1 [3], clause 10. Manufacturers declaring this spectrum access method shall further conform to the requirements listed in clause 4.2.8.1 of the present document, and are not obliged to fulfil the requirements of clause 4.2.8.2 of the present document.
- LP/LDC requirements are specified in EN 301 839-1 [3], clauses 8.3.2 and 8.6.3. Manufacturers declaring this spectrum access method shall further conform to the requirements listed in clause 4.2.8.2 of the present document, and are not obliged to fulfil the requirements of clause 4.2.8.1 of the present document.

4.2.8.1 LBT/AFA spectrum access

4.2.8.1.1 Definition

Under this method, spectrum access is based on the technical requirements of EN 301 839-1 [3], clause 10. A monitoring system is the circuitry in a medical implant transmitter or an ULP-AMI-P that assures conformity with the essential requirement for use of the spectrum access protocol specified EN 301 839-1 [3], clause 10 by use of LBT and AFA.