SLOVENSKI STANDARD
SIST EN 301 559-2 V1.1.2:2012

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Elektromagnetna združljivost in zadeve v zvezi z radijskim spektrom (ERM) - Naprave kratkega dosega (SRD) - Aktivni medicinski vsadki majhnih moči (LP-AMI), ki delujejo v frekvenčnem območju od 2483,5 MHz do 2500 MHz - 2. del: Harmonizirani EN, ki zajema bistvene zahteve člena 3.2 direktive R&TTE

Electromagnetic compatibility and Radio spectrum Matters (ERM) - Short Range Devices (SRD) - Low Power Active Medical Implants (LP-AMI) operating in the frequency range 2 483,5 MHz to 2 500 MHz - Part 2: Harmonized EN covering the essential requirements of article 3.2 of the R&TTE Directive

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Electromagnetic compatibility
and Radio spectrum Matters (ERM);
Short Range Devices (SRD);
Low Power Active Medical Implants (LP-AMI)
operating in the frequency range 2 483,5 MHz to 2 500 MHz;
Part 2: Harmonized EN covering the essential requirements
of article 3.2 of the R&TTE Directive

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Foreword

This Harmonized European Standard (EN) 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 Directive 98/34/EC [i.5] as amended by Directive 98/48/EC [i.6].

The title and reference to the present document are intended to be included in the publication in the Official Journal of the European Union of titles and references of Harmonized Standard under the Directive 1999/5/EC [i.1].

See article 5.1 of Directive 1999/5/EC [i.1] for information on presumption of conformity and Harmonised Standards or parts thereof the references of which have been published in the Official Journal of the European Union.

The requirements relevant to Directive 1999/5/EC [i.1] are summarised in annex A.

For non EU countries the present document may be used for regulatory purposes.

The present document is part 2 of a multi-part deliverable covering Low Power Active Medical Implants (LP-AMI), Peripherals (LP-AMI-P) operating in the frequency range 2 483,5 MHz to 2 500 MHz as described in the systems reference document for the equipment, TR 102 655 [i.4].

Part 1: "Technical characteristics and test methods";

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

National transposition dates	
Date of adoption of this EN:	18 June 2012
Date of latest announcement of this EN (doa):	30 September 2012
Date of latest publication of new National Standard or endorsement of this EN (dop/e):	31 March 2013
Date of withdrawal of any conflicting National Standard (dow):	31 March 2014

1 Scope

The present document covers, for Low Power Active Medical Implants (LP-AMI), and associated Peripherals (LP-AMI-P) used in an Active Medical Implant Communications System (AMICS), the required characteristics considered necessary to efficiently use the available spectrum and serve the interests of patients with implanted devices. The specifications contained in the present document were developed to ensure that the health and safety of the patients that are using this equipment under the direction of medical practitioners is protected. Of particular importance is the inclusion of spectrum monitoring and access requirements designed to significantly reduce any interference potential between AMICS operating in the band or between AMICS and other primary or secondary users of the band. An AIMD is regulated under the AIMD Directive 90/385/EEC [i.3] radio parts contained therein (referred to herein as LP-AMI, and LP-AMI-P for associated peripheral devices) are regulated under the Directive 1999/5/EC [i.1] (R&TTE Directive).

It is intended that the present document applies to operation in the band 2 483,5 MHz to 2 500 MHz that devices that can also operate in spectrum outside this band also meet any applicable requirements for operation in such bands.

The present document contains the technical characteristics for LP-AMI and associated peripherals radio equipment which is also addressed by CEPT/ERC/REC 70-03 [i.2] and annex 12 band f to that document. It does not necessarily include all the characteristics, which may be required by a user, nor does it necessarily represent the optimum performance achievable.

It applies to LP-AMI and LP-AMI_P operating in the band 2 483,5 MHz to 2 500 MHz:

- for telecommand and telemetry between LP-AMI and LP-AMI-P;
- for telecommand and telemetry between LP-AMI to another LP-AMI;
- with or without an integral antenna; and/or
- with an antenna connection provided only for the purpose of connecting a dedicated antenna.

The present document contains required characteristics considered necessary for the radio devices used in AMICS to meet in order to efficiently use the available spectrum for the purpose of transferring data that is used in diagnosing and delivering therapies to individuals with various illnesses. Of particular importance is the inclusion of spectrum monitoring and access requirements (listen before talk protocol) designed to significantly reduce any interference potential between AMICS operating in the band or between an AMICS and the primary users of the band.

The present document is a specific product standard applicable to low power transmitters that are part of a system used in the AMICS operating in spectrum within the frequency band 2 483,5 MHz to 2 500 MHz.

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 [i.1] will apply to equipment within the scope of 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 specific references, only the cited version applies. For non-specific references, the latest version of the reference document (including any amendments) applies.

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

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2.1 Normative references

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

[1] ETSI EN 301 559-1 (V1.1.2): "Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Low Power Active Medical Implants (LP-AMI) operating in the frequency range 2 483,5 MHz to 2 500 MHz; Part 1: Technical characteristics and test methods".

[2] ETSI TR 100 028 (V1.4.1): "Electromagnetic compatibility and Radio spectrum Matters (ERM); Uncertainties in the measurement of mobile radio equipment characteristics".

2.2 Informative references

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 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] CEPT/ERC/REC 70-03 (2011): "Relating to the use of Short Range Devices (SRD)".

[i.3] 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 (AIMD Directive).

[i.4] ETSI TR 102 655: "Electromagnetic compatibility and Radio spectrum Matters (ERM); System reference document; Short Range Devices (SRD); Low Power Active Medical Implants (LP-AMI) operating in a 20 MHz band within 2 360 MHz to 3 400 MHz".

[i.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.

[i.6] Directive 98/48/EC of the European Parliament and of the Council of 20 July 1998 amending Directive 98/34/EC 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 301 559-1 [1], clause 3.1 apply.

3.2 Abbreviations

For the purposes of the present document, the abbreviations given in EN 301 559-1 [1], clause 3.3 apply.

4 Technical requirements and specifications

4.1 Environmental profile

The technical requirements of the present document apply under the environmental profile for operation of the equipment as described in the user's manual and declared by the provider. The equipment shall comply with all the technical requirements of the present document at all times when operating within the boundary limits of the operational environmental profile as described above. The provider shall declare that interruption of the communications link for his AMICS shall not result in compromising the health and safety of the patient.