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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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Contents

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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.

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 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.

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 disturbance to other equipment and services. It should not be disturbed by harmful interference from other electronic devices and users of the band. Transmitters and receivers may be individual or combination units.

4.2.1.2 Antennas

Equipment operating in the AMICS shall have an integral antenna or a dedicated external antenna or both Where provision for an external antenna connection is made, the connector shall be a unique type to prevent use of an antenna other than a dedicated antenna supplied by the provider.

4.2.1.3 Controls

Those controls which, if maladjusted, might increase the interfering potentialities of the equipment, shall not be accessible to the user.

4.2.1.4 Automatic 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, if possible, 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 301 559-1 [1], clause 8.1.

4.2.2.2 Limits

The frequency error limits shall be as defined in EN 301 559-1 [1], clause 8.1.

4.2.2.3 Conformance

Conformance tests as defined in clause 5.3 shall be carried out.

4.2.3 Emission bandwidth

4.2.3.1 Definition

The emission bandwidth shall be as defined in EN 301 559-1 [1], clause 8.2.

4.2.3.2 Limits

The emission bandwidth limits shall be as defined in EN 301 559-1 [1], clause 8.2.

4.2.3.3 Conformance

Conformance tests as defined in EN 301 559-1 [1], clause 5.3 shall be carried out.

4.2.4 Effective isotropic radiated power of the fundamental emission

4.2.4.1 Definition

The effective isotropic radiated power shall be as defined in EN 301 559-1 [1], clause 8.3.

4.2.4.2 Limits

The e.i.r.p. limit shall be as defined in EN 301 559-1 [1], clause 8.3.2.

4.2.4.3 Conformance

Conformance tests as defined in EN 301 559-1 [1], clause 5.3 shall be carried out.

4.2.5 Transmitter unwanted s emissions

4.2.5.1 Out-of-band emissions

4.2.5.1.1 Definition

The out-of-band emissions of transmitters shall be as defined in EN 301 559-1 [1], clause 8.5.

4.2.5.1.2 Limits

The out-of-band emissions limits shall be as defined in EN 301 559-1 [1], clause 8.5.

4.2.5.2 Spurious emissions

4.2.5.2.1 Definition

The transmitters spurious emissions shall be as defined in EN 301 559-1 [1], clause 8.4.

4.2.5.2.2 Limits

The transmitters spurious emissions limits shall be as defined in EN 301 559-1 [1], clause 8.4.

4.2.5.3 Conformance

Conformance tests as defined in EN 301 559-1 [1] shall be carried out as defined in clause 5.3.

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 301 559-1 [1], clause 8.6.

4.2.6.2 Limits

The frequency stability under low voltage conditions limits shall be as defined in EN 301 559-1 [1], clause 8.6.

4.2.6.3 Conformance

Conformance tests as defined in EN 301 559-1 [1], clause 5.3 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 301 559-1 [1], clause 9.1.

4.2.7.2 Limits

The spurious radiation of receivers limits shall be as defined in EN 301 559-1 [1], clause 9.1.

4.2.7.3 Conformance

Conformance tests as defined in EN 301 559-1 [1], clause 5.3 shall be carried out.

4.2.8 Spectrum access

The spectrum access shall be as defined in EN 301 559-1 [1], clause 10.

4.2.8.1 Spectrum access

4.2.8.1.1 Definition

Under this method, spectrum access for AMICS is based on the system frequency of operation being under the control of a system device meeting the technical requirements of EN 301 559-1 [1], clause 10. A monitoring system is the circuitry in an AMICS device that assures conformity with the technical requirement for use of the spectrum access protocol specified EN 301 559-1 [1], clause 10.

4.2.8.1.2 Limits

The AMICS requirements are as specified in EN 301 559-1 [1], clause 10 and applicable subsequent clauses.

4.2.8.1.3 Conformance

Conformance tests as defined in EN 301 559-1 [1], clause 5.3 shall be carried out.

5 Testing for compliance with technical requirements

5.1 Environmental conditions for testing

Tests defined in the present document shall be carried out at representative points within the boundary limits of the operational environmental profile as declared in clause 4.1.

Where technical performance varies subject to environmental conditions, tests shall be carried out under a sufficient variety of environmental conditions (within the boundary limits of the operational environmental profile) to give confidence of compliance for the affected technical requirements.

5.2 Interpretation of the measurement results

The interpretation of the results recorded in a test report for the measurements described in the present document shall be as follows:

- the measured value related to the corresponding limit shall be used to decide whether an equipment meets the requirements of the present document;

- the value of the measurement uncertainty for the measurement of each parameter shall be included in the test report;
- the recorded value of the measurement uncertainty shall be, for each measurement, equal to or lower than the figures in table 1.

For the test methods, according to the present document, the measurement uncertainty figures shall be calculated in accordance with TR 100 028 [2] and shall correspond to an expansion factor (coverage factor) k = 1,96 or k = 2 (which provide confidence levels of respectively 95 % and 95,45 % in the case where the distributions characterizing the actual measurement uncertainties are normal (Gaussian)).

Table 1 is based on such expansion factors.

Table 1: Measurement uncertainties up to 12,5 GHz for RF measurements

Parameter	Maximum Measurement Uncertainty
Radio Frequency	$\pm 1 \times 10^{-7}$
Adjacent channel power	±3 dB
RF power, conducted	±0,75 dB
Conducted emission of transmitter	±4 dB
Conducted emission of receivers	±3 dB
Radiated emission of transmitter	±6 dB
Radiated emission of receiver	±6 dB
Conducted monitoring test system	±4 dB
Radiated monitoring test system	±6 dB
Temperature	±1 °C
Humidity	±5 %
DC voltage	±1 %
AC voltage	±1 %

5.3 Essential radio test suites

5.3.1 Frequency error

The test for frequency error specified in EN 301 559-1 [1], clause 8.1 appropriate to the EUT shall be carried out. The results obtained shall be compared to the limits in clause 4.2.2.2 in order to assess compliance with the requirement.

5.3.2 Emission bandwidth

The test for emission bandwidth specified in EN 301 559-1 [1], clause 8.2 appropriate to the EUT shall be carried out. The results obtained shall be compared to the limits in clause 4.2.3.2 in order to assess compliance with the requirement.

5.3.3 Effective isotropic radiated power of the fundamental emission

The test for effective isotropic radiated power of the fundamental emission specified in EN 301 559-1 [1], clause 8.3 appropriate to the EUT shall be carried out. The results obtained shall be compared to the limits in clause 8.3 in order to assess compliance with the requirement.

5.3.4 Unwanted emissions

5.3.4.1 Out-of-band emissions

The test for LP-AMI-P Transmitter's out-of-band emissions specified in EN 301 559-1 [1], clause 8.5 appropriate to the EUT shall be carried out. The results obtained shall be compared to the limits referred to in clause 8.5.3 in order to assess compliance with the requirement.

5.3.4.2 Transmitter spurious emissions

The test for transmitter spurious emissions specified in EN 301 559-1 [1], clause 8.4 appropriate to the EUT shall be carried out. The results obtained shall be compared to the limits in clause 8.4.2 in order to assess compliance with the requirement.

5.3.5 Frequency stability under low voltage conditions

The test for frequency stability under low voltage conditions specified in EN 301 559-1 [1], clause 8.6 shall be carried out. The results obtained shall be compared to the limits in clause 8.6.2 in order to assess compliance with the requirement.

5.3.6 Receiver spurious emissions

The test for receiver spurious emissions specified in EN 301 559-1 [1], clause 9.1 appropriate to the EUT shall be carried out. The limits are in EN 301 559-1 [1], clause 9.1.2.

5.3.7 Spectrum access

The tests for spectrum access requirements specified in EN 301 559-1 [1], clause 10 and applicable subsequent clauses shall be carried out. The results obtained shall be compared to the requirements listed in clause 10.

5.3.8 Normal and extreme test-conditions

The test conditions shall be as declared by the provider. The requirements and test procedures shall be as specified in EN 301 559-1 [1], clauses 5.3 and 5.4.

5.3.9 Test power source

The test power source shall meet the requirements of EN 301 559-1 [1], clause 5.2.

5.3.10 Choice of samples for test suites

Measurement shall be performed, according to the present document, on samples of equipment defined in EN 301 559-1 [1], clause 4.2.

Annex A (normative): HS Requirements and conformance Test specifications Table (HS-RTT)

The HS Requirements and conformance Test specifications Table (HS-RTT) in table A.1 serves a number of purposes, as follows:

- it provides a statement of all the essential requirements in words and by cross reference to (a) specific clause(s) in the present document or to (a) specific clause(s) in (a) specific referenced document(s);
- it provides a statement of all the test procedures corresponding to those requirements by cross reference to (a) specific clause(s) in the present document or to (a) specific clause(s) in (a) specific referenced document(s);
- it qualifies each requirement to be either:
  - Unconditional: meaning that the requirement applies in all circumstances; or
  - Conditional: meaning that the requirement is dependent on the manufacturer having chosen to support optional functionality defined within the schedule;
- in the case of Conditional requirements, it associates the requirement with the particular optional service or functionality;
- it qualifies each test procedure to be either:
  - Essential: meaning that it is included with the Essential Radio Test Suite and therefore the requirement shall be demonstrated to be met in accordance with the referenced procedures;
  - Other: meaning that the test procedure is illustrative but other means of demonstrating compliance with the requirement are permitted.

Table A.1: HS Requirements and conformance Test specifications Table (HS-RTT)

Harmonized Standard EN 301 559-2 The following requirements and test specifications are relevant to the presumption of conformity under the article 3.2 of the R&TTE Directive [i.1]						
Requirement			**Requirement Conditionality**		**Test Specification**	
No	**Description**	**Reference: clause No**	**U/C**	**Condition**	**E/O**	**Reference: clause No**
1	Mechanical and electrical design	4.2.1	U		X	
2	Frequency error	4.2.2	U		E	5.3.1
3	Emission bandwidth	4.2.3	U		E	5.3.2
4	Effective isotropic radiated power of the fundamental emission	4.2.4	U		E	5.3.3
5	Transmitter spurious emissions	4.2.5	U		E	5.3.4
6	Frequency stability under low voltage conditions	4.2.6	C	Only applies to all battery operated equipment	E	5.3.5
7	Receiver spurious emissions	4.2.7	U		E	5.3.6
8	Spectrum Access duty cycle LBT + AFA and < 10 % duty cycle	4.2.8.1	U		E	5.3.7

Key to columns:

Requirement:

No A unique identifier for one row of the table which may be used to identify a requirement or its test specification.

Description A textual reference to the requirement.

Clause Number Identification of clause(s) defining the requirement in the present document unless another document is referenced explicitly.

Requirement Conditionality:

U/C Indicates whether the requirement is to be *unconditionally* applicable (U) or is *conditional* upon the manufacturers claimed functionality of the equipment (C).

Condition Explains the conditions when the requirement shall or shall not be applicable for a technical requirement which is classified "conditional".

Test Specification:

E/O Indicates whether the test specification forms part of the Essential Radio Test Suite (E) or whether it is one of the Other Test Suite (O).

NOTE: All tests whether "E" or "O" are relevant to the requirements. Rows designated "E" collectively make up the Essential Radio Test Suite; those designated "O" make up the Other Test Suite; for those designated "X" there is no test specified corresponding to the requirement. The completion of all tests classified "E" as specified with satisfactory outcomes is a necessary condition for a presumption of conformity. Compliance with requirements associated with tests classified "O" or "X" is a necessary condition for presumption of conformity, although conformance with the requirement may be claimed by an equivalent test or by manufacturer's assertion supported by appropriate entries in the technical construction file.

Clause Number Identification of clause(s) defining the test specification in the present document unless another document is referenced explicitly. Where no test is specified (that is, where the previous field is "X") this field remains blank.

Annex B (informative): Void

Annex C (informative): Bibliography

- CISPR 16-2-3 (2010): "Specification for radio disturbance and immunity measuring apparatus and methods - Part 2-3: Methods of measurement of disturbances and immunity - Radiated disturbance measurements".
- ITU-T Recommendation O.153: "Basic parameters for the measurement of error performance at bit rates below the primary rate".
- ECC Report 149: "Analysis on compatibility of Low Power-Active Medical Implant (LP-AMI) applications within the frequency range 2360-3400 MHz, in particular for the band 2483.5-2500 MHz, with incumbent services".
- Radiofrequency Radiation Dosimetry Handbook (October 1986), USAF School of Aerospace Medicine, Aerospace Medical Division (AFSC), Brooks Air Force Base, TX 78235-5301.

NOTE: See http://niremf.ifac.cnr.it/docs/HANDBOOK/home.htm.

- CEPT/ERC/REC 74-01: "Unwanted Emissions in the Spurious Domain".
- "Simulated Biological Materials for Electromagnetic Radiation Absorption Studies", by G. Hartsgrove, A. Kraszewski, and A. Surowiec as published in Bioelectromagnetics 8:29-36 (1987).
- Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC (EMC Directive).
- Directive 2006/95/EC of the European Parliament and of the Council of 12 December 2006 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits (LV Directive).
- ETSI EG 201 399: "Electromagnetic compatibility and Radio spectrum Matters (ERM); A guide to the production of candidate Harmonized Standards for application under the R&TTE Directive".

History

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