

Final draft **ETSI EN 301 839-2** V1.3.1 (2009-07)

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**



Reference

REN/ERM-TG30-263-2

Keywords

radio, regulation, SRD, testing

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

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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 Harmonized European Standard (Telecommunications series) has been produced by ETSI Technical Committee Electromagnetic compatibility and Radio spectrum Matters (ERM), and is now submitted for the Vote phase of the ETSI standards Two-step Approval Procedure.

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) [i.3] 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 [i.1] 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") [i.1].

Technical specifications relevant to Directive 1999/5/EC [i.1] 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:

Part 1: "Technical characteristics and test methods";

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

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

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 in table 1.

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 [i.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 [i.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 [i.1].

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] may apply to equipment within the scope of the present document.

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

2 References

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.
- Non-specific reference may be made only to a complete document or a part thereof and only in the following cases:
 - if it is accepted that it will be possible to use all future changes of the referenced document for the purposes of the referring document;
 - for informative references.

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 indispensable for the application of the present document. For dated references, only the edition cited applies. For non-specific references, the latest edition of the referenced document (including any amendments) applies.

- [1] ETSI EN 301 839-1 (V1.3.1): "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".
- [2] ETSI TR 100 028 (all parts) (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 essential to the use of the present document but they assist the user with regard to a particular subject area. For non-specific references, the latest version of the referenced document (including any amendments) applies.

- [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] 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.
- [i.3] 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 [1] apply.

3.2 Abbreviations

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

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 [1], clause 8.1.1.

4.2.2.2 Limits

The frequency error limits shall be as defined in EN 301 839-1 [1], 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 [1], clause 8.2.1.

4.2.3.2 Limits

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

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 [1], clause 8.3.1.

4.2.4.2 Limits

The effective radiated power limits shall be as defined in EN 301 839-1 [1], 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 [1], clause 8.4.1.

4.2.5.2 Limits

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

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 [1], 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 [1], 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 [1], clause 9.1.1.

4.2.7.2 Limits

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

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 [1], 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 [1], 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 [1], 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 [1], clause 10 by use of LBT and AFA.

4.2.8.1.2 Limits

The ULP-AMI-P/ULP-AMI requirements are specified in EN 301 839-1 [1], clause 10 and applicable subsequent clauses.

4.2.8.2 LP/LDC spectrum access

4.2.8.2.1 Definition

This requirement only applies to ULP-AMI accessing the 403,5 MHz to 403,8 MHz band as described in EN 301 839-1 [1], clause 8.6.

4.2.8.2.2 Limits

The maximum power for low duty cycle operations as defined in EN 301 839-1 [1], clause 8.3.1 shall not exceed the limit in EN 301 839-1 [1], clause 8.3.2.

The maximum duty cycle, as defined in EN 301 839-1 [1], clause 8.6.1, shall not exceed the limits in EN 301 839-1 [1], clause 8.6.3.

4.2.8.3 Conformance

Conformance tests as defined in clause 5.3.7 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 declared operational environmental profile.

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 declared 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 will 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 2.

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 2 is based on such expansion factors.

Table 2: Maximum measurement uncertainty

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

5.3 Essential radio test suites

5.3.1 Frequency error

The test for frequency error specified in EN 301 839-1 [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 301 839-1 [1], clause 8.2.1.1 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 radiated power of the fundamental emission

The test for effective radiated power of the fundamental emission specified in EN 301 839-1 [1], clause 8.3.1.1 appropriate to the EUT shall be carried out. The results obtained shall be compared to the limits in clause 4.2.4.2 in order to assess compliance with the requirement.

5.3.4 Spurious emissions of transmitter

The test for spurious emissions specified in EN 301 839-1 [1], clause 8.4.1.1 appropriate to the EUT shall be carried out. The results obtained shall be compared to the limits in clause 4.2.5.2 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 301 839-1 [1], clause 8.5.1.1 shall be carried out. The results obtained shall be compared to the limits in clause 4.2.6.2 in order to assess compliance with the requirement.

5.3.6 Spurious radiation of receivers

The test for spurious radiation of receivers specified in EN 301 839-1 [1], clause 9.1.1.1 appropriate to the EUT shall be carried out. The results obtained shall be compared to the limits in clause 4.2.7.2 in order to assess compliance with the requirement.

5.3.7 Spectrum Access

5.3.7.1 LBT/AFA spectrum access

The tests for monitoring system requirements specified in EN 301 839-1 [1], clause 10 and applicable subsequent clauses shall be carried out. The results obtained shall be compared to the requirements listed in clause 4.2.8.1.2.

5.3.7.2 LP/LDC spectrum access

The tests for LP/LDC requirements specified in EN 301 839-1 [1], clauses 8.3.1 and 8.6.1 and applicable subsequent clauses shall be carried out. The results obtained shall be compared to the requirements listed in clause 4.2.8.2.2.

5.3.8 Normal and extreme test-conditions

The test conditions shall be as declared by the manufacturer.

The requirements and test procedures shall be as specified in EN 301 839-1 [1], clauses 5.3 and 5.4.

5.3.9 Test power source

The test power source shall meet the requirements of EN 301 839-1 [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 301 839-1 [1], clauses 4.2.1, 4.2.2 and 4.2.3.

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 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 dependant 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 301 839-2						
The following requirements and test specifications are relevant to the presumption of conformity under the article 3.2 of the R&TTE Directive						
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 radiated power of the fundamental emission	4.2.4	U		E	5.3.3
5	Spurious emissions (of transmitters)	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	Spurious radiation of receivers	4.2.7	U		E	5.3.6
8	Spectrum Access	4.2.8	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): The EN title in the official languages

The enlargement of the European Union (EU) resulted in a requirement from the EU for a larger number of languages for the translation of the titles of Harmonized Standards and mandated ENs that are to be listed in the Official Journal to support the implementation of this legislation.

For this reason the title translation concerning the present document can be consulted via the [e-approval](#) application.

Annex C (informative): Bibliography

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

Radiofrequency Radiation Dosimetry Handbook (October 1986), USAF School of Aerospace Medicine, Aerospace Medical Division (AFSC), Brooks Air Force Base, TX 78235-5301.

Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility (EMC Directive).

Council Directive 73/23/EEC of 19 February 1973 on the harmonization 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

Document history		
V1.1.1	June 2002	Publication
V1.2.1	July 2007	Publication
V1.3.1	January 2009	Public Enquiry PE 20090506: 2009-01-06 to 2009-05-06
V1.3.1	July 2009	Vote V 20090927: 2009-07-29 to 2009-09-28