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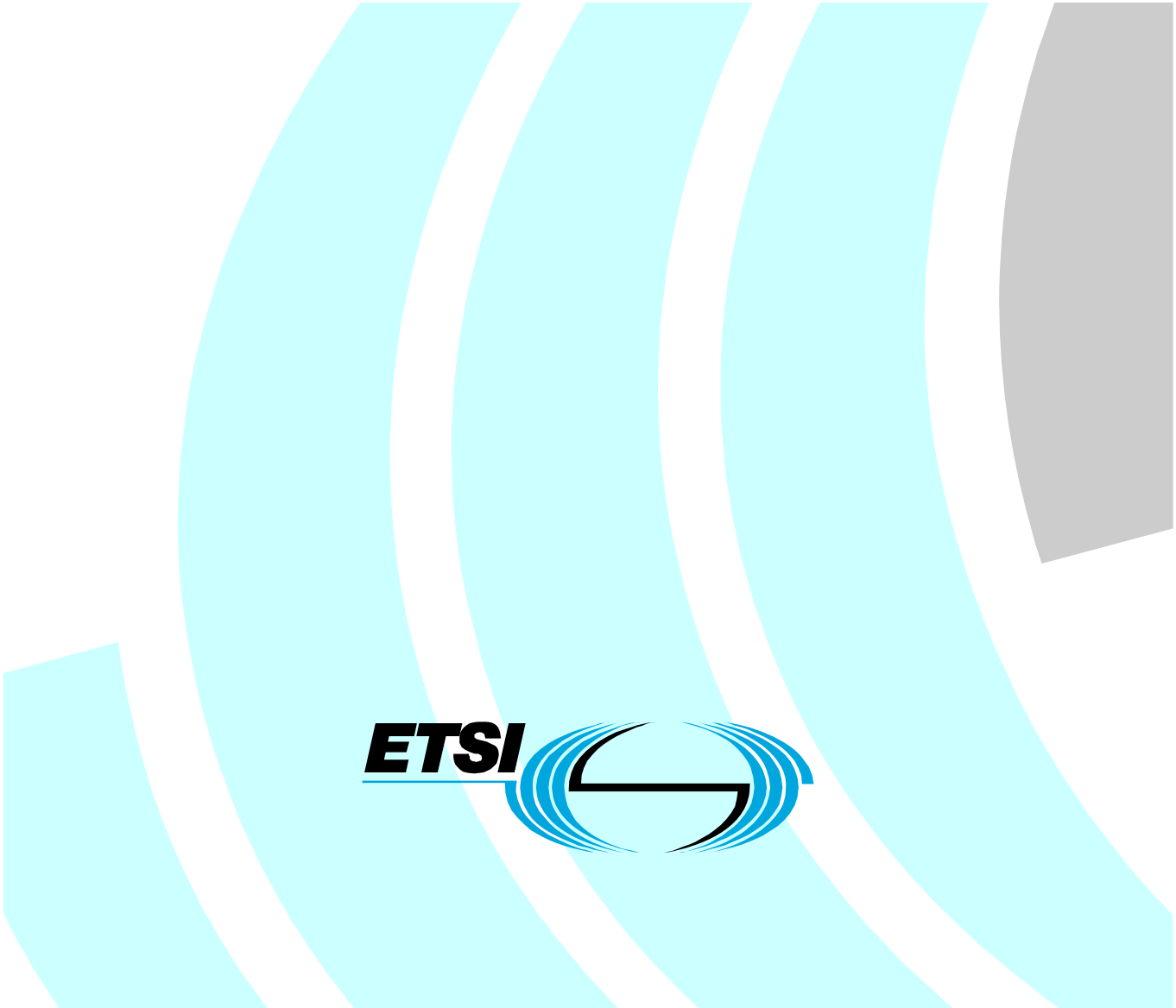
Harmonized European Standard (Telecommunications series)

Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Radio equipment in the frequency range 315 kHz to 600 kHz; Part 2: Harmonized EN covering essential requirements of article 3.2 of the R&TTE Directive



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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), 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) 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").

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 Radio Equipment in the frequency range 315 kHz to 600 kHz for Ultra Low Power Animal Implant Devices and accessory peripheral systems including devices that are intended to be outside the body but in very close proximity to it in normal operation, 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".

National transposition dates	
Date of adoption of this EN:	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 Ultra Low Power Animal Implant (ULP-AID) transmitters and receivers operating in any part or all of the band from 315 kHz to 600 kHz and any associated radio apparatus transmitting in the frequency range of 315 kHz to 600 kHz including external programmers and related telecommunication devices using digital modulation techniques such as, but not limited to, FSK or pulse position modulation.

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 will apply to equipment within the scope of the present document.

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] ETSI EN 302 536-1 (V1.1.2): "Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Radio equipment in the frequency range 315 kHz to 600 kHz; Part 1: Technical characteristics and test methods".

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

3 Definitions, symbols and abbreviations

3.1 Definitions

For the purposes of the present document, the terms and definitions given in the R&TTE Directive and EN 302 536-1 [1] apply.

3.2 Symbols

For the purposes of the present document, the symbols given in EN 302 536-1 [1] apply.

3.3 Abbreviations

For the purposes of the present document, the abbreviations given in EN 302 536-1 [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 disturbance to other equipment and services and should not be disturbed by harmful interference from other electronic devices. Transmitters and receivers may be individual or combination units.

4.2.1.2 Antennas

Equipment operating in the ULP-AID band shall have an integral antenna, an external dedicated antenna or both. If 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 manufacturer.

4.2.1.3 Controls

Those controls that, if maladjusted, might increase the disturbing 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 Permitted frequency range of the modulation bandwidth

4.2.2.1 Definition

The modulation bandwidth shall be as defined in EN 302 536-1 [1], clause 8.3.1.

4.2.2.2 Limits

The modulation bandwidth limits shall be as defined in EN 302 536-1 [1], clause 8.3.3.

4.2.2.3 Conformance

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

4.2.3 Effective radiated field strength of the fundamental emission

4.2.3.1 H-field

4.2.3.1.1 Definition

The effective radiated H-field shall be as defined in EN 302 536-1 [1], clause 8.2.1.1.

4.2.3.1.2 Limit

The effective radiated H-field limit shall be as defined in EN 302 536-1 [1], clause 8.2.1.3.

4.2.3.1.3 Conformance

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

4.2.3.2 E-field

4.2.3.2.1 Definition

The effective radiated E-field shall be as defined in EN 302 536-1 [1], clause 8.2.2.1.

4.2.3.2.2 Limit

The effective radiated E-field limit shall be as defined in EN 302 536-1 [1], clause 8.2.2.3.

4.2.3.2.3 Conformance

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

4.2.4 Spurious emissions

4.2.4.1 Definition

The spurious emissions shall be as defined in EN 302 536-1 [1], clause 8.4.1.

4.2.4.2 Limits

The spurious emissions limits shall be as defined in EN 302 536-1 [1], clause 8.4.2.2.

4.2.4.3 Conformance

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

4.2.5 Spurious radiation of receivers

4.2.5.1 Definition

The spurious radiation of receivers shall be as defined in EN 302 536-1 [1], clause 9.1.1.

4.2.5.2 Limits

The spurious radiation of receivers limits shall be as defined in EN 302 536-1 [1], clause 9.1.3.

4.2.5.3 Conformance

Conformance tests as defined in clause 5.3.4 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 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: Maximum measurement uncertainty

Radio frequency	$\pm 1 \times 10^{-7}$
RF power, conducted	±0,75 dB
RF power, radiated	±6 dB
Temperature	±1°C
Humidity	±5 %
Voltage	±1 %

5.3 Essential radio test suites

5.3.1 Permitted frequency range of the modulation bandwidth

The test for bandwidth specified in EN 302 536-1 [1], clause 8.3.2 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 Effective radiated field strength of the fundamental emission

The test for radiated magnetic field strength of the fundamental emission specified in EN 302 536-1 [1], clause 8.2.1.2 and for radiated electric field strength specified in EN 302 536-1 [1], clause 8.2.2.2, appropriate to the EUT shall be carried out. The results obtained shall be compared to the H-field limit in clause 4.2.3.1.2 and the E-field limit in clause 4.2.3.2.2 in order to assess compliance with the requirement.

5.3.3 Spurious emissions

The test for spurious emissions specified in EN 302 536-1 [1], clause 8.4.2.1 appropriate to the EUT shall be carried out. The results obtained shall be compared to the limits in clause 4.2.4.3 in order to assess compliance with the requirement.

5.3.4 Spurious radiation of receivers

The test for spurious radiation of receivers specified in EN 302 536-1 [1], clause 9.1.2 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 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 302 536-1 [1], clauses 5.3 and 5.4.

5.3.6 Test power source

The test power source shall meet the requirements of EN 302 536-1 [1], clause 5.2 as applicable.

5.3.7 Choice of samples for test suites

Measurement shall be performed, according to the present document, on samples of equipment defined in EN 302 536-1 [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 essential 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 302 536-2 The following essential requirements and test specifications are relevant to the presumption of conformity under Article 3.2 of the R&TTE Directive						
Essential 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	Modulation bandwidth	4.2.2	U		E	5.3.1
3	Radiated H-field magnetic field strength	4.2.3.1	U		E	5.3.2
4	Radiated E-field electric field strength	4.2.3.2	U		E	5.3.2
5	Spurious emissions (of transmitters)	4.2.4	U		E	5.3.3
6	Spurious radiation of receivers	4.2.5	U		E	5.3.4

Key to columns:

Essential 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 essential 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

Language	EN title
Bulgarian	
Czech	
Danish	
Dutch	
English	Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Radio equipment in the frequency range 315 kHz to 600 kHz; Part 2: Harmonized EN covering essential requirements of article 3.2 of the R&TTE Directive
Estonian	
Finnish	
French	
German	
Greek	
Hungarian	
Icelandic	
Italian	
Latvian	
Lithuanian	
Maltese	
Norwegian	
Polish	
Portuguese	
Romanian	
Slovak	
Slovenian	
Spanish	
Swedish	Elektromagnetisk kompatibilitet och radiospektrumfrågor (ERM); Kortdistansutrustning (SRD); Radioutrustning i frekvensområdet 315 kHz till 600 kHz; Del 2: Harmoniserad EN omfattande väsentliga krav enligt artikel 3.2 i R&TTE-direktivet

Annex C (informative): Bibliography

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 (AMD Directive).

ECC Report 12 (2002): "Ultra Low Power Active Medical Implant Systems (ULP-AMI)".

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

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.

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).

History

Document history				
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