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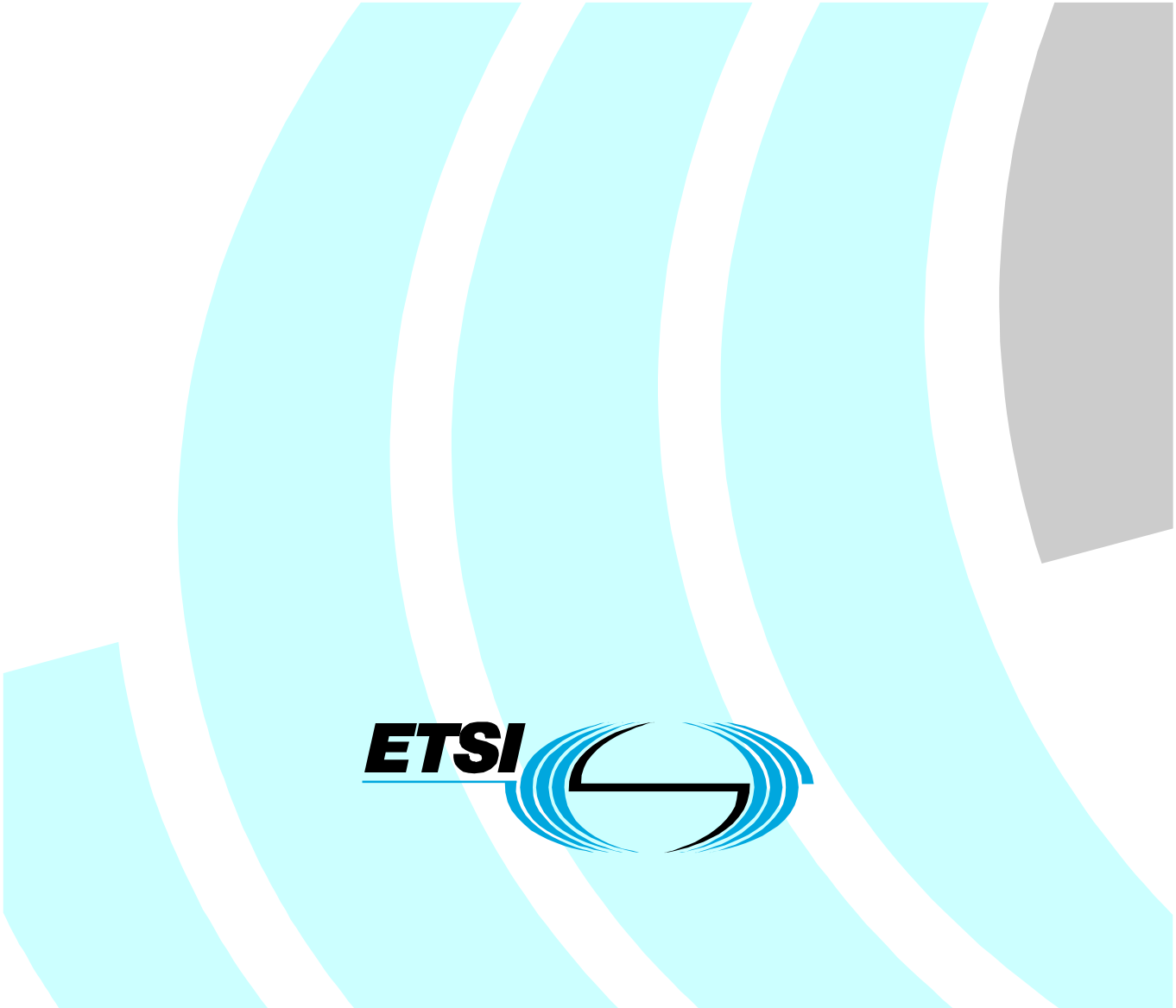
Harmonized European Standard (Telecommunications series)

Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Ultra Low Power Medical Data Service Systems operating in the frequency range 401 MHz to 402 MHz and 405 MHz to 406 MHz; 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 Public Enquiry 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 [5] (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 (R&TTE Directive) [1].

The present document is part 2 of a multi-part deliverable covering Radio equipment in the frequency range 401 MHz to 402 MHz and 405 MHz to 406 MHz for Ultra Low Power Active Medical Devices including Body Worn, Hand-Held, Data systems, etc., the medical section of which is regulated under the Medical Device Directive [6] and Active Medical Implants and Peripherals the medical section of which is regulated under the Active Implantable Medical Device Directive [2], 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 covers various individual devices which when operating together form a system operating as a Medical Data Service (MEDS) that provides medical practioners with therapeutic and/or diagnostic information used to provide improved medical treatment of a patient and/or to provide an interactive system for patient control of therapeutic devices.. MEDS is intended only for transmission of non-time critical data the loss of which will not compromise the health and/or safety of the patient.

Devices covered by the present document are an evolving new technology to be made available world wide by the medical equipment industry that will provide high speed communications capability between devices associated with an individual patient that are part of a complete MEDS System as defined in clause 3.1. Examples of MEDS devices falling under the scope of the present document are portable body worn physiological sensors that allow ambulatory monitoring, implanted devices and external system devices used to transfer data collected by a MEDS System to medical practitioners that will use the data to diagnose and treat a patient.

These devices utilize ultra low power radio transmitters in combination with medical devices the medical portion of which is regulated by the Medical Device Directive [6] (MDD) or the Active Implantable Medical Device Directive (AIMD [2]). The radio part of medical devices regulated by the MDD is hereafter referred to as ULP-AMD, ULP-AMD-P for peripheral devices, and ULP-BWD for body worn devices. ULP-BWD are devices, such as a physiological parameter sensor or handheld devices that are intended to operate in very close proximity to the human body, including touching the body, whose radio antenna is external to the body and is used to communicate with a device that is part of a MEDS System. The radio part of medical devices regulated under the AIMD is hereafter referred to as Ultra Low Power-Active Medical Implants (ULP-AMI) and peripherals (ULP-AMI-P) used in a Medical Data Service (MEDS).

The present document contains required characteristics considered necessary for the radio sections 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 MEDS Systems operating in the band or between a MEDS System and the primary users of the band.

The present document is a specific product standard applicable to ultra low power transmitters that are part of a system used in the MEDS operating in spectrum within the frequency bands 401 MHz to 402 MHz and 405 MHz to 406 MHz. The present document contains the technical characteristics for ultra low power radio equipment and is referencing CEPT/ERC/REC 70-03 [7] and annex 12 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 ultra low power systems and accessories operating in spectrum within the bands 401 MHz to 402 MHz and 405 MHz to 406 MHz that operate in the MEDS service:

- for telecommand and telemetry between any devices that are part of a MEDS (see definition of MEDS);
- with or without an integral antenna; and/or
- with an antenna connection provided only for the purpose of connecting an external dedicated antenna.

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] 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] 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.

[3] ETSI EN 302 537-1 (V1.2.1): "Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Ultra Low Power Medical Data Service Systems operating in the frequency range 401 MHz to 402 MHz and 405 MHz to 406 MHz; Part 1: Technical characteristics and test methods".

[4] ETSI TR 100 028 (V1.3.1): "ElectroMagnetic Compatibility and Radio Spectrum Matters (ERM); Uncertainties in the measurement of mobile radio equipment characteristics Part 1".

[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.

[6] Council Directive 93/42/EEC of 14 June 1993 on the approximation of the laws of the Member States relating to medical devices (MD Directive).

[7] CEPT/ERC/REC 70-03 (2006): "Relating to the use of Short Range Devices (SRD)".

3 Definitions and abbreviations

3.1 Definitions

For the purposes of the present document, the terms and definitions given in EN 302 537 -1 [3], clause 3.1 apply.

3.2 Abbreviations

For the purposes of the present document, the abbreviations given in EN 302 537 -1 [3], 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 MEDS System 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 MEDS service 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 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 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 302 537-1 [3], clause 8.1.1.

4.2.2.2 Limits

The frequency error limits shall be as defined in EN 302 537-1 [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 302 537-1 [3], clause 8.2.1.

4.2.3.2 Limits

The emission bandwidth limits shall be as defined in EN 302 537-1 [3], 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 302 537-1 [3], clause 8.3.1.

4.2.4.2 Limits

- The e.r.p. limit shall be as defined in EN 302 537-1 [3], clause 8.3.2.1 for systems using LBT and AFA for spectrum access.
- The e.r.p. limit shall be as defined in EN 302 537-1 [3], clause 8.3.2.2 for systems using low duty cycle and low power for spectrum access.

4.2.4.3 Conformance

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

4.2.5 Spurious emissions

4.2.5.1 Definition

The spurious emissions shall be as defined in EN 302 537-1 [3], clause 8.4.1.

4.2.5.2 Limits

The spurious emissions limits shall be as defined in EN 302 537-1 [3], 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 302 537-1 [3], clause 8.5.1.

4.2.6.2 Limits

The frequency stability under low voltage conditions limits shall be as defined in EN 302 537-1 [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 302 537-1 [3], clause 9.1.1.

4.2.7.2 Limits

The spurious radiation of receivers limits shall be as defined in EN 302 537-1 [3], 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 provider declares a spectrum access method. At least one of the following methods shall be chosen. A provider may chose to implement both methods in his equipment, however, he may operate using both access methods if the total emission bandwidth does not exceed 100 kHz.

- LBT/AFA requirements for the monitoring system are specified in EN 302 537-1 [3], clause 10. Providers 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 302 537-1 [3], clauses 8.3.2 and 8.6.3. Providers declaring this spectrum access method shall further conform to the requirements listed in section 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 for a MEDS System is based on the system frequency of operation being under the control of a system device meeting the technical requirements of EN 302 537-1 [3], clause 10. A monitoring system is the circuitry in a MEDS service system device that assures conformity with the essential requirement for use of the spectrum access protocol specified EN 302 537-1 [3], clause 10 by use of LBT and AFA for a specific system.

4.2.8.1.2 Limits

The MEDS System requirements are as specified in EN 302 537-1 [3], clause 10 and applicable subsequent clauses.

4.2.8.1.3 Conformance

Conformance tests as defined in clause 5.3.7 shall be carried out.

4.2.8.2 Low Power Low Duty Cycle spectrum access

4.2.8.2.1 Definition

Using this method, spectrum access for a device operating as part of a MEDS System is based on a maximum duty cycle and repetitive transmission limit as defined in EN 302 537-1 [3], clause 8.6.1 coupled with a limit on maximum transmit e.r.p. as defined in EN 302 537-1 [3], clause 8.3.1.

4.2.8.2.2 Limits for low duty cycle low power spectrum access

The maximum duty cycle limit as defined in EN 302 537-1 [3], clause 8.6.1, shall not exceed the limit in EN 302 537-1 [3], clause 8.6.2.1.

The maximum number of repetitive transmissions within one hour as defined in EN 302 537-1 [3], clause 8.6.1 shall not exceed the limit in EN 302 537-1 [3], clause 8.6.2.2.

The maximum e.r.p. as defined in EN 302 537-1 [3], clause 8.3.1 shall not exceed the limit in EN 302 537-1 [3], clause 8.3.2.2.

4.2.8.2.3 Conformance

Conformance tests as defined in clause 5.3.8 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 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 [4] 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

RF frequency	±1 x10^{-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, 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 %
Voltage	±1 %

5.3 Essential radio test suites

5.3.1 Frequency error

The test for frequency error specified in EN 302 537-1 [3], 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 302 537-1 [3], 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 302 537-1 [3], 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

The test for spurious emissions specified in EN 302 537-1 [3], 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 302 537-1 [3], 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 302 537-1 [3], 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 for systems using LBT/AFA

The tests for spectrum access requirements specified in EN 302 537-1 [3], 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.

5.3.8 Spectrum access for devices using low power and low duty cycle

The tests for spectrum access requirements specified in EN 302 537-1 [3], clause 10 and applicable subsequent clauses (8.3.2.2, 8.6.2.1 and 8.6.2.2) shall be carried out. The results obtained shall be compared to the requirements listed in clause 4.2.8.2.2.

5.3.9 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 302 537-1 [3], clauses 5.3 and 5.4.

5.3.10 Test power source

The test power source shall meet the requirements of EN 302 537-1 [3], clause 5.2.

5.3.11 Choice of samples for test suites

Measurement shall be performed, according to the present document, on samples of equipment defined in EN 302 537-1 [3], clause 4.2 (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 essential requirements in words and by cross reference to a specific clause in the present document or to a specific clause in a specific referenced document;
- it provides a statement of all the test procedure corresponding to those essential requirements by cross reference to specific clause(s) in the present document or to a specific clause(s) in 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 supplier 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;
- when the schedule is completed in respect of particular equipment including the testing outcomes, including a completed version of table A.1 it provides a means to assert the "presumption of conformity" with the HS.

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

Harmonized Standard EN 302 537-2 The following technical 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	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 by LBT/AFA systems	4.2.8.1	U		E	5.3.7
9	Spectrum Access by LP/LDC systems	4.2.8.2	U		E	5.3.8

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 requirement in the present document unless another document is referenced explicitly.

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 essential requirements. Tests designated "E" collectively make up the Essential Radio Test Suite; those designated "O" make up the Other Test Suite. For those requirements for which no test specification applies are designated "X". All tests classified "E" shall be performed as specified with satisfactory outcomes in order to allow a presumption of conformity. Requirements associated with tests classifies "O" or "X" must be complied with although the requirement shall be complied with as demonstrated by an equivalent test or by assertion by the supplier and asserted to be complied with to allow presumption of conformity.

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
Czech	
Danish	
Dutch	
English	Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Ultra Low Power Medical Data Service Systems operating in the frequency range 401 MHz to 402 MHz and 405 MHz to 406 MHz; 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	
Slovak	
Slovenian	
Spanish	
Swedish	

Annex C (informative): Bibliography

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

History

Document history			
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