ETSI EN 302 537-2 V1.1.2 (2007-12)

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

Reference
DEN/ERM-TG30-005-2

Keywords
health, regulation, SRD

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Sous-Préfecture de Grasse (06) N° 7803/88

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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).

The present document has been produced by ETSI in response to a mandate from the European Commission issued under Council Directive 98/34/EC [3] (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) [6].

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 401 MHz to 402 MHz and 405 MHz to 406 MHz for Ultra Low Power Active Medical Devices and implants. This includes Body Worn, Hand-Held, Data systems, etc., the medical section of which is regulated under the Medical Device Directive [4] and Active Medical Implants and Peripherals the medical section of which is regulated under the Active Implantable Medical Device Directive [4], 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:	14 December 2007
Date of latest announcement of this EN (doa):	31 March 2008
Date of latest publication of new National Standard or endorsement of this EN (dop/e):	30 September 2008
Date of withdrawal of any conflicting National Standard (dow):	30 September 2009

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 practitioners 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 worldwide 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 [4] (MDD) or the Active Implantable Medical Device Directive (AIMD [7]). 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 addressed by CEPT/ERC/REC 70-03 [5] 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 [6] 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 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.

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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 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".

[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

[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.

[4] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (MD Directive).

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

[6] 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).

[7] 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 Definitions and abbreviations

3.1 Definitions

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

3.2 Abbreviations

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

4.2.2.2 Limits

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

4.2.3.2 Limits

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

4.2.4.2 Limits

- The e.r.p. limit shall be as defined in EN 302 537-1 [1], 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 [1], 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 [1], clause 8.4.1.

4.2.5.2 Limits

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

4.2.6.2 Limits

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

4.2.7.2 Limits

The spurious radiation of receivers limits shall be as defined in EN 302 537-1 [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 provider declares a spectrum access method. At least one of the following methods shall be chosen. A provider 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 100 kHz.

- LBT/AFA requirements for the monitoring system are specified in EN 302 537-1 [1], 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 [1], clauses 8.3.2 and 8.6.3. Providers 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 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 [1], clause 10. A monitoring system is the circuitry in a MEDS service system device that assures conformity with the technical requirement for use of the spectrum access protocol specified EN 302 537-1 [1], 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 [1], 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.