

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**ETSI**

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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.

Referenced documents which are not found to be publicly available in the expected location might be found at <http://docbox.etsi.org/Reference>.

For online referenced documents, information sufficient to identify and locate the source shall be provided. Preferably, the primary source of the referenced document should be cited, in order to ensure traceability. Furthermore, the reference should, as far as possible, remain valid for the expected life of the document. The reference shall include the method of access to the referenced document and the full network address, with the same punctuation and use of upper case and lower case letters.

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.

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 [1], clause 8.6.1 coupled with a limit on maximum transmit e.r.p. as defined in EN 302 537-1 [1], 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 [1], clause 8.6.1 shall not exceed the limit in EN 302 537-1 [1], clause 8.6.2.1.

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

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

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	$\pm 1^{\circ}\text{C}$
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 [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 302 537-1 [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 302 537-1 [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

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

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

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

The tests for spectrum access requirements specified in EN 302 537-1 [1], 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 [1], 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 [1], 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 [1], 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(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 302 537-2 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.

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	Електромагнитна съвместимост и въпроси на радиоспектъра (ERM); Радиосъоръжения с малък обхват на действие (SRD); Свръхмаломощни системи за предаване на медицински данни, работещи в честотния обхват от 401 MHz до 402 MHz и от 405 MHz до 406 MHz; Част 2: Хармонизиран европейски стандарт (EN), покриващ съществените изисквания на член 3.2 от Директивата за радиосъоръжения и крайни далекосъобщителни устройства (R&TTEd)
Czech	Elektromagnetická kompatibilita a rádiové spektrum (ERM) – Zařízení krátkého dosahu (SRD) – Systémy lékařské datové služby velmi nízkého výkonu pracující v kmitočtových pásmech 401 MHz až 402 MHz a 405 MHz až 406 MHz – Část 2: Harmonizovaná EN pokrývající základní požadavky článku 3.2 Směrnice R&TTE
Danish	1Elektromagnetisk kompatibilitet og radiospektrumanliggende (ERM); Apparater med kort rækkevidde (SRD); Medicinske datakommunikations systemer med ultra lav sendeeffekt som benytter frekvenser mellem 401 MHz og 402 MHz eller frekvenser mellem 405 MHz og 406 MHz — Del 2: Harmoniseret EN, som dækker de væsentlige krav i R&TTE direktivets artikel 3.2
Dutch	Elektromagnetische compatibiliteit en radiospectrumangelegenheden (ERM); Kort bereik apparatuur (SRD); Medische data service met ultra-laag vermogen in het frequentiegebied 401 MHz tot 402 MHz en 405 MHz tot 406 MHz; Deel 2: Geharmoniseerde EN welke invulling geeft aan de essentiële eisen van artikel 3.2 van de R&TTE richtlijn
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	Elektromagnetilise ühilduvuse ja raadiospektri küsimused (ERM); Lähitoimeseadmed (SRD); Raadiosagedusalades 402 MHz kuni 405 MHz ja 405 MHz kuni 406 MHz töötavad väga väikese võimsusega meditsiini andmesidesüsteemid; Osa 2: Harmoneeritud EN R&TTE direktiivi artikli 3.2 põhiolemuse alusel
Finnish	Sähkömagneettinen yhteensopivuus ja radiospektriasiat (ERM); Lyhyen kantaman laitteet (SRD); Taajuusalueella 401 - 402 MHz ja 405 - 406 MHz toimivat erittäin pienitehoiset lääketieteen datansiirtojärjestelmät; Osa 2: Yhdenmukaistettu standardi (EN), joka kattaa R&TTE-direktiivin artiklan 3.2 mukaiset olennaiset vaatimukset
French	Télécommunications - Compatibilité électromagnétique et spectre radioélectrique (ERM) - Appareils à faible portée (SRD) Systèmes à faible portée pour données médicales opérant dans la bande de fréquence de 401 MHz à 402 MHz et 405 MHz à 406 MHz. Partie 2 : EN harmonisée de l'article 3.2 de la Directive R&TTE
German	Elektromagnetische Verträglichkeit und Funkspektrumangelegenheiten (ERM) - Funkanlagen mit geringer Reichweite (SRD) - Medizinische Datendienstsysteme mit sehr kleiner Leistung, die im Frequenzbereich von 401 MHz bis 402 MHz und von 405 MHz bis 406 MHz arbeiten - Teil 2: Harmonisierte EN, die wesentliche Anforderungen nach Artikel 3.2 der R&TTE-Richtlinie enthält
Greek	Ηλεκτρομαγνητική Συμβατότητα και Θέματα Ραδιοφάσματος (ERM) – Συσκευές μικρής εμβέλειας (SRD) – Συστήματα Υπηρεσίας Ιατρικών Δεδομένων Υπερχαμηλής Ισχύος που λειτουργούν στην περιοχή συχνοτήτων 401 MHz ως 402 MHz και 405 MHz ως 406 MHz – Μέρος 2: Εναρμονισμένο EN για την κάλυψη των ουσιαστών απαιτήσεων του άρθρου 3.2 της Οδηγίας R&TTE
Hungarian	Elektromágneses összeférhetőségi és rádióspektrumügyek (ERM). Kis hatótávolságú eszközök (SRD). A 401 MHz-től 402 MHz-ig és a 405 MHz-től 406 MHz-ig terjedő frekvenciasávban működő, ultrakis teljesítményű orvosi adatátviteli rendszerek. 2. rész: Az R&TTE-irányelv 3. cikke 2. bekezdésének alapvető követelményeit tartalmazó, harmonizált európai szabvány
Icelandic	
Italian	
Latvian	Elektromagnētiskā saderība un radiofrekvenču spektra jautājumi (ERM). Maza darbības attāluma ierīces (SRD); Ļoti zemas jaudas medicīnisko datu pakalpojumu sistēmas, kas strādā frekvenču joslā no 401 MHz līdz 402 MHz un no 405 MHz līdz 406 MHz; 2.daļa: Harmonizēts Eiropas standarts (EN), kas atbilst R&TTE Direktīvas 3.2.punkta būtiskām prasībām
Lithuanian	Elektromagnetinio suderinamumo ir radijo dažnių spektro dalykai. Trumpojo nuotolio įtaisai. Ultramažos galios medicininį duomenų perdavimo paslaugų sistema, veikianti nuo 401 MHz iki 402 MHz ir nuo 405 MHz iki 406 MHz dažnių diapazone. 2 dalis. Darnusis Europos standartas, apimantis esminius 1999/5/EC direktyvos 3.2 straipsnio reikalavimus
Maltese	Kompatibilità elettromanjetika u materji relatati ma' spettru radjofoniku (ERM); Apparati ta' Medda Qasira (SRD); Sistemi ta' servizz ta' data mediċi li joperaw fil-medda ta' frekwenzi 401 MHz sa 402 u 405 MHz sa 406 u MHz; Parti 2: EN armonizzata li jkopri rekwiżiti essenzjali ta' l-artiklu 3.2 tad-Direttiva R&TTE

Language	EN title
Norwegian	Elektromagnetisk kompatibilitet og radiospektrumspørsmål (ERM); Kortholdsutstyr (SRD); Ultralavt styrket medisinsk datatjenesteutstyr system som opererer i frekvensbåndet 401 MHz til 402 MHz og 405 MHz til 406 MHz; Del 2: Harmonisert EN som dekker de grunnleggende krav i R&TTE-direktivets artikkel 3.2
Polish	Kompatybilność elektromagnetyczna i zagadnienia widma radiowego (ERM); Urządzenia bliskiego zasięgu (SRD); Systemy transmisji danych do celów medycznych o ultra niskim poziomie mocy, pracujące w zakresie częstotliwości od 401 MHz do 402 MHz i od 405 MHz do 406 MHz; Część 2: Zharmonizowana EN zapewniająca spełnienie zasadniczych wymagań artykułu 3.2 dyrektywy R&TTE
Portuguese	Assuntos de Espectro Radioelétrico e Compatibilidade Electromagnética (ERM); Equipamentos de Curto Alcance (SRD); Sistemas de Ultra Baixa Potência para Serviços de Dados Médicos operando nas faixas de frequências de 401 MHz a 402 MHz e de 405 MHz a 406 MHz; Parte 2: Norma Harmonizada cobrindo os requisitos essenciais no âmbito do artigo 3.º, n.º 2, da Directiva R&TTE
Romanian	
Slovak	Elektromagnetická kompatibilita a záležitosti rádiového spektra (ERM). Zariadenia s krátkym dosahom (SRD). Systémy zdravotníckej dátovej služby s ultranízky výkonom pracujúce vo frekvenčnom rozsahu od 401 MHz do 402 MHz a od 405 MHz do 406 MHz. Časť 2: Harmonizovaná EN vzťahujúca sa na základné požiadavky podľa článku 3.2 smernice R&TTE
Slovenian	Elektromagnetna združljivost in zadeve v zvezi z radijskim spektrom (ERM) - Naprave kratkega dosega (SRD) – Službeni sistemi ultra majhnih moči za medicinske podatke, ki delujejo v frekvenčnih območjih od 401 MHz do 402 MHz in od 405 MHz do 406 MHz - 2. del: Harmonizirani EN, ki zajema bistvene zahteve člena 3.2 direktive R&TTE
Spanish	Cuestiones de Compatibilidad Electromagnética y Espectro de Radiofrecuencia (ERM); Dispositivos de Corto Alcance (SRD); Sistemas para el Servicio de Datos Médicos de Potencia Ultra Baja operando en la gama de frecuencias de 401 MHz a 402 MHz y de 405 MHz a 406 MHz; Parte 2: Norma Europea (EN) armonizada cubriendo los requisitos esenciales según el artículo 3.2 de la Directiva R&TTE
Swedish	Elektromagnetisk kompatibilitet och radiospektrumfrågor (ERM); Kortdistansutrustning (SRD); Medicinska dataservicesystem med extrem låg effekt arbetande i frekvensområdena 401 MHz till 402 MHz och 405 MHz till 406 MHz; Del 2: Harmoniserad EN omfattande väsentliga krav enligt artikel 3.2 i R&TTE-direktivet

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			
V1.1.1	December 2006	Public Enquiry	PE 20070406: 2006-12-06 to 2007-04-06
V1.1.2	October 2007	Vote	V 20071214: 2007-10-15 to 2007-12-14
V1.1.2	December 2007	Publication	